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DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS: WHAT ARE THE CONSEQUENCES?

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

WASHINGTON, DC

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DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS: WHAT ARE THE CONSEQUENCES?

TUESDAY, JULY 22, 2003

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The committee met, pursuant to notice, at 10:05 a.m., in room SD–628, Dirksen Senate Office Building, Hon. Larry Craig (chairman of the committee) presiding.

Present: Senators Craig, Collins, Breaux, Stabenow, and Carper.

OPENING STATEMENT OF SENATOR LARRY CRAIG, CHAIRMAN

The CHAIRMAN. Good morning, everyone and thank you for joining us. The Senate Special Committee on Aging will be convened.

We are here today to look carefully at the issue of direct-to-consumer advertising prescription drugs and ask some important questions. The questions would go like this. Does it drive up prices? Does it drive up costs? Does it lead to inappropriate prescribing? Does it provide useful information to consumers? Ultimately, does direct-to-consumer advertising of prescription drugs benefit or harm the health care system and especially the seniors of our country?

This is an issue that we as legislators hear about quite often. In my town meetings across the State of Idaho and other places I have traveled where this issue becomes a topic of discussion, the question is why so much advertising? I know that it is increasing the cost of the pharmaceuticals that I am taking. Is that true? We thought it was important to begin to build a record to find out if, in fact, that is the case.

Too many Americans, often seniors, are not able to afford prescription drugs. We know that. We are wrestling with that here in the U.S. Senate as we speak and in the House with the modernization of Medicare and the inclusion of a prescription drug program within it.

When they see the introduction of new and expensive advertising campaigns on television, many ask why are pharmaceutical companies spending all of this money on ads instead of lowering the price of their drugs? Although direct-to-consumer advertising may not be the most expensive promotion drug companies do, it is by far the most visible. The public has noticed the dramatic increase in broadcast advertising over the last few years and many tell us that they

are concerned about it. As I look at the rising cost of prescription drugs I can certainly understand their concern.

I also have heard concerns about direct-to-consumer advertising from doctors. They have told me their patients occasionally see advertising for prescription drugs and do not understand the risks associated with taking drugs or do not recognize other treatment options that might be available. Some of those treatment options may be less expensive than the prescription drugs themselves. I have had some doctors tell me that direct-to-consumer advertisements negatively impact the doctor/patient relationship.

On the other hand, I have heard that individuals who, as a result of direct-to-consumer advertising, were prompted to visit a doctor concerning a condition they would not have otherwise have found treatment for. There are certainly individuals, including many seniors, who have treatable illnesses and are not being treated. If direct-to-consumer advertising can get them to see the doctor, this is certainly a positive aspect of this kind of advertising.

I support the idea of consumer-driven health care. If we expect consumers to be good decisionmakers, we need to assure that they have access to good information. Proponents of direct-to-consumer advertising claim that it can provide some of that information.

These questions are especially timely in light of what I have just mentioned—the effort on the part of Congress and the taxpayers of this country to respond to the needs of many of our citizens to have access to prescription drugs. So that is why, in part, we are holding the meeting today.

Now let me turn to the ranking member of this committee, who plays a key role in all of these issues and whose leadership has been dominant in this committee for a good number of years, my colleague from Louisiana, Senator John Breaux. Senator.

OPENING STATEMENT OF SENATOR JOHN BREAUX

Senator BREAUX. Thank you, Mr. Chairman. Thank you for having this hearing. It is an important hearing.

I have always taken the position that good information allows people to make good decisions. Bad information, on the other hand, causes people unfortunately to make incorrect and wrong decisions. Therefore, the question of how information is received, where does it come from, how much do people get, are vital issues that need to be discussed and debated.

Advertising for prescription drugs is not the same as advertising for deodorant or used cars. The products are much more substantial, more difficult to understand, and obviously have a much greater impact on the lives of the American people than some of the other products that we see advertised.

So I am anxious to hear from some of the experts today and some of the industry representatives as to the purpose of advertising, what they hope to get from it, and how that advertising influences people with regard to the knowledge that they need to take better control of their own health care. Hopefully some of these answers will be found today at today's hearing and I thank you for having it. Thank you.

The CHAIRMAN. Thank you very much, Senator.

Now let me recognize our colleague from the State of Michigan, Senator Stabenow. Welcome.

STATEMENT OF SENATOR DEBBIE STABENOW

Senator STABENOW. Thank you, Mr. Chairman, and welcome, Dr. Woodcock and others who will be testifying today. This is an issue that I have been extremely interested in and involved in and appreciate the opportunity to have the testimony today.

I also think it is important that we have an opportunity to analyze all kinds of information regarding this issue and would ask, Mr. Chairman, as part of the record to put out a different view than may be reflected in some of the testimony today. There is a recent book out called "The Big Fix" by Catherine Grader and Chapter 5 talks about direct-to-consumer advertising and I would appreciate your willingness to put Chapter 5 into the record.

[The information follows:]

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17/04/03

TITLE: THE BIG FIX

376 MG TAB Left: 0

TITLE: How the Pharmaceutical Industry Rips Off American Consumers

AUTHOR: DIN : 006513

Katharine Greider

one tablet(s) twice a day with meals

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For David

[chapter 5]

GETTING TO YOU

DRUGMAKERS' EFFORTS to influence doctors' behavior are ultimately aimed at influencing ours. And more than ever before, these companies are bringing their pitch straight into Americans' everyday lives, advertising on radio, in popular magazines, and especially on TV. Here the message eschews the dry language of clinical research, its end points and data sets, for the powerful emotional image: a flower opening, an old person frolicking like a colt, people of all colors linking arms. Or to strike a different mood, an apparently healthy middle-aged woman suddenly dropping from the frame.

Although magazine ads weren't uncommon in the 1980s, direct-to-consumer (DTC) drug advertising is largely a phenomenon that arose in the 1990s. A 1997 FDA rule making it more practical to advertise on television—companies could now substitute a toll-free number or web address for the "small print" details about drug side effects and contraindications—was undoubtedly an important catalyst. Then a few

bold and enormously successful campaigns convinced other big players that they couldn't afford to stay on the sidelines. Spending on consumer ads surged from a scant $266 million in 1994 to $2.6 billion in 2001. Controversial in the United States, the practice of pushing prescription medicine much the same way as soda pop is virtually unheard of elsewhere in the developed world. As Boston University's Sager says, "They're laughing at us again."

Traditionally, prescription drugmakers have emphasized as a defining feature of their industry that they did not advertise to the consumer, but only to the learned physician. Among other things, this approach facilitated the industry's close association with scientific authority. The recent promotional focus on patients reflects a sea change in medicine and in culture itself. As Mickey Smith, Ph.D., an expert in pharmaceutical marketing at the University of Mississippi, puts it, "People are much better educated—not smarter necessarily, but better educated. The ads you see right now, if they'd run in the Fifties, would have fallen on deaf ears because people wouldn't have had a clue what you were talking about." Now that you, Consumer, are trawling the Internet for health information, now that you're motivated to take care of yourself and empowered to make decisions about your own medical care, the drug industry would like a moment of your time.

The ads seem to be getting the job done, reaching the great majority of Americans, winning their trust, and, in more than a few cases, prompting people to ask for a drug by name. Nine out of ten consumers surveyed in 2000 by *Prevention Magazine* said they'd seen or heard a drug ad. When queried by the Henry J. Kaiser Family Foundation in 2001,

30 percent of consumers reported having talked with their doctor about a drug they'd seen advertised. Nearly half of those who asked for an advertised drug—13 percent of all consumers—came away with a script. In another Kaiser study, co-sponsored by *The NewsHour with Jim Lehrer*, nearly half of American consumers said they trust advertisements to provide them with accurate information. But perhaps most telling are these results of a recent NIHCM study: Between 1999 and 2000, prescriptions for the fifty most heavily advertised drugs rose at six times the rate of all other drugs. Sales of those fifty intensively promoted drugs were responsible for almost half the increase in Americans' overall drug spending that year. Makers of the new arthritis drug Vioxx spent $160 million pushing it to consumers in 2000, more advertising dollars than were dropped on Pepsi Cola, Budweiser beer, Nike shoes, or Campbell's soups. Vioxx sales shot up 360 percent.

The way industry spokespeople tell it, Americans should count themselves lucky—drug ads are educational, informing us about health conditions so we can seek appropriate treatment. "The bottom line is that direct-to-consumer advertising is good for patients and good for public health," says a PhRMA spokesman. Sometimes public-health goals do overlap with marketing goals: More people recognizing the signs of clinical depression might boost antidepressant sales and bring relief to many. But skeptics of the drug industry's ads-equal-education equation point out that plenty of important public-health messages go begging for want of profit potential. For example, several pharmaceutical companies have introduced discount programs for low-income seniors. "Have you seen one ad promoting those

discount cards?" asks Wennar, of United Health Alliance in Vermont. "Do they do anything on TV to tell people about them?"

What we're getting from DTC drug advertising is lots of exposure to a relatively small number of drugs—generally speaking, new medicines with huge markets and plenty of patent life left. The Kaiser Family Foundation reports that with thousands of drugs on the market, 60 percent of DTC spending in 2000 went to plug just twenty products. This intensive exposure creates what ad people call "brand awareness." A recent survey by market research firm Insight-Express found that, for example, 74 percent of respondents knew Claritin by name. More than half recognized Paxil, 45 percent knew the cholesterol-lowering Zocor, and nearly 80 percent were aware of the pharmaceutical phenomenon Viagra. All have been among the most heavily advertised drug products.

As for what else people take away from the ads, opinions are mixed, and consumer research is limited. One AARP survey found that one-third of the DTC audience failed to notice fine-print information on indications, side effects, and other issues included in magazine ads. Of those who did notice the information, two-thirds said they weren't in the habit of reading it. TV ads have to direct consumers to a phone number, web site, or other ad where they can get more information. But in a Kaiser Family Foundation study, nine out of ten respondents shown three televised drug ads couldn't remember where to get this additional information. Respondents who were shown the drug ads (which included mention of major side effects) judged the side effects to be more serious than those who hadn't seen the

ads, but just after viewing the ad, only about half could identify the side effects.

As in all advertising, the main event isn't the discursive information the ads deliver directly, but the suggestive fantasies buried in their music and pictures. "The Nexium ads are so phenomenal that I'd like to take the drug and I don't even have the problem," says Gerstein. "They show a variety of people, very diverse, all standing on jagged stone promontories, and they all start moving together . . . If Disney had done it, you'd say 'Wonderful!'" An ad for an oral contraceptive shows a couple grinning and nuzzling, with the tag line, "Isn't it great when you finally find the right one?" The sound track is a tune whose words—not heard in the ad—are, "This will be an everlasting love."

Other drug ads trade on the cachet of various famous people—baseball legend Cal Ripken Jr., pitching a blood-pressure drug, figure skater Dorothy Hamill praising arthritis medicine, journalist Joan Lunden flogging an allergy med. *Med Ad News* recently reported on a team-up between pharmaceutical-marketing firm Catalyst Communications and a sports-marketing company founded by a former New York Yankees VP. Catalyst's chief stated, "We chose Perello & Company because it understands the divergent worlds of pharmaceuticals and sports." So much for the square in the white coat. Indeed, the use of celebrities has facilitated the industry's bringing together any number of divergent worlds. Is it journalism or is it advertising? Is it fantasy or real life?

Naturally reporters' and editors' in-boxes are stuffed with company press releases and ready-made copy—perhaps a feature on a golf pro's arthritis and how he overcame it with

Drug X. That's par for the course. What's surprising and not a little disturbing is that some big stars have been getting air on major news outlets to chat about their conditions and urge others to seek treatment—without anyone mentioning they were being paid by a drug company. Newspeople were chagrined by a *New York Times* exposé in the summer of 2002 that depicted a veritable three-ring circus: Kathleen Turner raving to *Good Morning America*'s Diane Sawyer about "extraordinarily effective" new medications to treat her rheumatoid arthritis (thank you, Wyeth); Lauren Bacall spooking the daylights out of *Today* viewers over an eye disease that can cause blindness (thank you, Novartis); actor Noah Wyle being interviewed as if he were an expert in post-traumatic stress disorder, even as his fictional character on *ER* endured the aftermath of a violent attack (thanks, Pfizer). A week after the *Times* report, CNN did a story telling viewers that some celebrities interviewed on its own network had been paid by drug companies. It announced a new policy of asking famous people scheduled to talk about medical issues whether they have financial ties to related companies and to reveal any such ties on the air.

As long as they don't mention a drug by name, celebs stirring up interest in a particular disease don't have to adhere to the FDA's "fair balance" rule, which requires that any claim linking a specific drug to a specific action be accompanied by mention of the drug's limitations and side effects. Ads can accomplish this, too. "Reminder" ads feature the name of a drug without saying what it's for; they may have the stylized vagueness of ads for hip perfumes. Other drug ads come off as public-service announcements: Bob Dole wants to talk to you about erectile dysfunction. These "help-

seeking" ads mention a condition and may flash the company name, but won't name the drug (Viagra) you'll get when you follow the ad's exhortation to see your doctor.

Indeed, to browse the archives of FDA notices of violation to drug companies for misleading ads is to get a sense of how utterly at a loss the agency is to address the various ways expert image makers get across their "claims." Here's what the FDA had to say about an ad for the sleep aid Ambien: "The reminder advertisement presents graphics of the sun and the earth going from night to day, a flower closing and opening, and the Ambien tablet falling on a sheet or pillow, together with the verbal statement 'the rhythm of life.' Thus, the advertisement in total, with the graphics and verbal statement, makes a representation about the product." "Reminder" ads—which don't have to name side effects—aren't supposed to make claims either. But *every* ad makes a representation about a product. What else is an ad for?

Another FDA notice complained that the "totality of the images, the music, and the audio statements" in a sixty-second TV spot for arthritis med Celebrex overstated the drug's efficacy. The ad showed silver-haired arthritis sufferers rowing boats and riding scooters to the joyous sound track, "Celebrate, celebrate, do what you like to do!" (Celebrex hasn't been shown to reduce pain any more effectively than, for example, the generic ibuprofen that sells for a fraction of the cost.) The Celebrex spots have changed—most ads cited by the FDA are either modified or pulled without further regulatory action—but they communicate the same basic idea, with an attractive, well-dressed older couple dancing energetically to happy music. You could argue that the ads

associate Celebrex not only with pain relief (whether exaggerated or not is subjective) but also with energy, wealth, youth, beauty, and a happy marriage. That's how the medium works. As one professor of pharmacy puts it, "They're making it look chic to take certain drugs. You don't focus on the product or the disease, you focus on the lifestyle that the drug allows or creates. They're selling lifestyles, not drugs."

Still another FDA missive ordered the discontinuation of a consumer mailer that touted brand-name tamoxifen (Nolvadex) for prevention of breast cancer in women at high risk for the disease. The agency said the mailer overstated the drug's efficacy in this role, minimized side effects, and failed to make clear that women who score 1.7 on a breast-cancer risk assessment, though they may be considered "high risk," have only a 1.7 percent chance of getting breast cancer. But FDA enforcers didn't mention—and in fact are not empowered to address—how the brochure, titled "Are You a Helpless Female?" capitalized on women's terror, with models who stare fixedly at the reader and the tag line: "Now *predict* your chances of getting *breast cancer*. And *act* on it."

Even a drug's trade name is an advertisement, enlisting the deep and not always conscious associations of language to tout the drug's wonderful qualities wherever and whenever it's mentioned. Hardly indifferent to this fact, drugmakers put a good deal of effort into inventing brand names, sometimes hiring outside consultants to conduct market research and screen the name for unfortunate connotations in an array of languages. Sildenafil is one thing—but Viagra, with its suggestion of vitality, virility, and the

mighty flow of the Niagara, is quite another. According to one report, Lilly's new impotence drug Cialis was derived from the French word for sky, *ciel,* to give users the impression that "the sky's the limit." The alchemy of naming turns the rather awkward atorvastatin into Lipitor, which combines the word for blood fats, "lipid," with a hint of the avenging action hero. And Baycol (a cholesterol reducer withdrawn from the market for safety reasons)—can it be a coincidence that the name invokes a certain tasty (if fatty) breakfast meat?

The fact is, it's not the job of advertising (or "branding," as marketers call it) to educate, to put it all in context. In the Kaiser study, respondents who'd seen an ad for Nexium were more likely to know that heartburn and acid reflux can lead to more serious stomach problems—but did they understand that more often than not, this doesn't happen? And did the ad give them insight into whether this problem affects them personally? It's extremely rare for an ad to give information about a drug's mechanism of action, success rate, or length of treatment, much less about alternative treatments or cost. "Let's pretend that a drug ad is completely accurate," says Bodenheimer. "It doesn't mention that there's an alternative drug that costs ten times less and is just as good."

Defenders of prescription-drug advertising suggest it's all about promoting conversations between patients and their doctors, the only people empowered to write prescriptions. But often patients simply ask for a drug, and doctors see their way clear to giving it. "Believe me there's definitely pressure," says Steinman. "Some patients will be quite insistent. Also there's just a question of time. You're always run-

ning late. It's a lot easier to say, 'Sure I'm going to give you that prescription' than to go into a lengthy explanation of why you're not going to give it." One in five consumers surveyed by AARP reported having asked their doctor about a drug the doctor didn't even know about. Few physicians would send a patient off with a script that's potentially dangerous or clearly inappropriate (one doc recalls declining to prescribe a drug for male-pattern baldness to a woman). But most often the decision falls into a "gray area," says Steinman. There might be something cheaper out there, the patient might not need *this* drug—but it's not going to hurt the patient and it'll probably help. Like the availability of free drug samples, consumer ads lower the threshold for prescribing whatever the drug companies happen to be promoting this year.

And like its approach to the doctor, the industry's engagement of consumers is becoming ever more creative, at times straining the limits of good taste. In 2000, Pfizer's adorable "Zithromax zebra," the mascot for an antibiotic used to treat the ubiquitous childhood ear infection, dangled from the stethoscopes of pediatricians and "sponsored" episodes of *Sesame Street*. This drew the fire of media watchdog group Fairness and Accuracy in Reporting, upset over the commercialization of kids' public television. It also irritated some public-health experts, since the ink was hardly dry on a recommendation by the Centers for Disease Control to use a cheaper antibiotic for ear infections. Officials of the U.S. Drug Enforcement Agency (DEA) were taken aback when in 2001, the makers of stimulants to treat kids with attention deficit hyperactivity disorder (ADHD) decided to pitch their new long-acting versions straight to moms via women's

magazines and cable TV; this broke with a thirty-year-old voluntary international agreement to abstain from promoting controlled substances—drugs with addictive or abuse potential—to consumers. One DEA policy official told *USA Today* that the campaign, picturing happy kids and smiling mothers, evinced "the mentality of 'mother's little helpers' from the '60s." Likewise, breastfeeding advocates were disturbed to find the logo of a major producer of baby formula on the cover of the American Academy of Pediatrics' *New Mother's Guide to Breastfeeding*. Still others expressed doubts about the appropriateness of a new drug-ad vehicle called the Patient Channel, which would wrap the ads around educational segments about particular conditions and send them into hospital rooms, where patients lay convalescing. File this one under "Really gross, presumably rare": Warner-Lambert (now part of Pfizer) is accused in a whistle-blower lawsuit of promoting an epilepsy drug by, among other things, paying doctors to work as consultants, to participate in clinical trials—and to let drug reps watch while they examined patients, sometimes allowing the reps to make recommendations for treatment. Pfizer has denied many of the changes, which date from before it acquired Warner-Lambert.

IN WITH THE NEW

Taken together, the drug industry's promotional tools—reps dropping samples, medical "opinion leaders" working conference halls, ads every night on TV—create an extremely powerful momentum toward the use of new brand-name

drugs. With this comes the widespread assumption that the newest drug is the best drug. And sometimes it is. Other times, not.

All things being equal, some experts argue, we ought to prefer the older drug. When it comes to drugs, unlike other "hot" consumer items, there's safety to consider. We have less experience with new drugs and therefore less understanding of their risks. Premarketing clinical trials that involve a few thousand carefully selected patients can easily miss a safety problem that arises in, say, 1 in 5,000 cases. Sometimes relevant information emerges after years of general use. A 2002 study published in *JAMA* found that of all drugs with new active ingredients approved between 1975 and 1999, fully one in ten was the subject of after-the-fact warnings of serious adverse effects or was pulled from the market entirely. Half these changes took place within seven years of the drug's launch.

With these figures in mind, decisions about whether to go for the newest thing on the market should take into account whether it's truly a breakthrough with no tried-and-true alternatives and whether the condition it treats is a serious one, says the study's author, Harvard Medical School's Karen Lasser, MD. Otherwise, says Lasser, it makes sense to wait.

But public-health educators often find themselves spitting in the wind when they go up against Big Pharma's marketing juggernaut. In some cases, patients in great numbers are taking the blockbuster even while experts and best-practice guidelines recommend an older, less expensive treatment.

One might begin with the 50 million Americans who

have high blood pressure. Many will need to control this risk factor for heart disease and stroke by taking medicine every day, for years. The medical and financial stakes are high: Which medicine will they try first? On this question the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (part of the NIH) is unequivocal: The first line of treatment should be two older classes of drugs, diuretics and beta-blockers. The committee made this recommendation in 1993, and again in 1997. But the 1990s saw an increase in prescribing of another type of drug for hypertension: calcium channel-blockers (CCBs), sold under brand names like Procardia, Cardizem, and, more recently, megaseller Norvasc. Two years after the committee issued its guidelines favoring diuretics and beta-blockers, calcium channel-blockers were being prescribed about twice as often for hypertension.

As doctors debated emerging evidence on efficacy and risks of the various drugs, drugmakers wasted no time in pushing the newer and costlier brand-name CCBs. Between 1985 and 1996, ads touting CCBs in the *New England Journal of Medicine* proliferated; by 1996, they were the most heavily advertised of any medications, according to a study published in *Circulation* in 1999. Meanwhile, ads for beta-blockers declined from 12.4 percent of total ad pages in 1985 to zilch—no ads—in 1996, three years after the national committee recommended them as first-line treatment for one of the most common health conditions.

Drug-company efforts at persuasion apparently weren't confined to ad pages. When researchers at the University of Washington reported the results of a limited study showing increased rates of heart attack in patients using short-acting

CCBs versus those on diuretics and beta-blockers, the news hit the front pages, patients became alarmed, and industry people fell on the investigators like a ton of bricks. "Academic consultants to companies manufacturing calcium channel-blockers issued blistering critiques, publicly questioned the investigators' integrity, and emphasized dubious contraindications" to using the cheaper drugs, according to a report in the *New England Journal of Medicine* coauthored by the University of Washington researchers. One company issued a Freedom of Information request that demanded "all records related to study design and methodology, study protocol(s), individual data for all study results and data, data sets, statistical calculations, methodologies, and analyses" as well as meeting minutes and correspondence from researchers, staff, or oversight committees. This, from an industry that likes to keep its own minutes and data tapes to itself.

Analyzing the medical literature during a critical eighteen-month period in the controversy over CCBs, University of Toronto researchers discovered that an astounding 96 percent of commentators whose published views supported CCBs had financial ties to their manufacturers. Indeed, the industry seemed to have a hand in everywhere; over one-third of those who criticized CCBs also had ties to the companies that sold them.

Prescriptions for the specific type of CCBs that raised concerns about heart attack—short-acting versions that have to be taken more often, and in particular a drug called short-acting nifepidine—have given way to scripts for other forms of the drug, says Bodenheimer. Still, he says, "huge numbers" of people are being treated for high blood pres-

sure with a drug that's more expensive than those recommended by official guidelines. The Norvasc web site, featuring a lean middle-aged man on a diving board, calls the drug "the most prescribed cardiovascular agent in the world."

Drug companies tend not to sponsor research that pits their products directly against other drugs, especially cheaper ones. Therefore, it took the federal government mounting the most ambitious hypertension trial ever to finally bring attention to the merits of older blood-pressure drugs. Published in *JAMA* in December 2002, the study found that a diuretic—the "water pill" that's been around for half a century and costs pennies a pill—was slightly more effective than CCBs and ACE inhibitors (another relatively new and pricey drug) at preventing heart attacks and other complications of hypertension. "[T]here is no cost-quality tradeoff; the most effective therapy was also the least expensive," said a *JAMA* editorial accompanying the study. "Many of the newer drugs were approved because they reduce blood pressure and the risk of heart disease compared with a placebo. But they were not tested against each other," said National Heart, Lung and Blood Institute director Claude Lenfant, MD, in announcing the study's results. "Yet, these more costly medications were often promoted as having advantages over older drugs, which contributed to the rapid escalation of their use." Had diuretic use not dropped off precipitously following the introduction of pricier alternatives, researchers estimated, hypertension scripts during the ensuing decade would have cost $3.1 billion less. The government's study suggests the cheaper scripts would also have resulted in better health for Americans with high blood pressure.

A more recent example of fleet drug-industry promotions matched against the slow-grinding wheels of research and expert debate involves the extraordinarily rapid adoption by the American public of drugs called selective COX-2 inhibitors—Vioxx and Celebrex—to treat arthritis pain. Both have been among the drugs most intensively advertised to consumers and among the biggest contributors to increased spending for prescription drugs, with sales of each topping $2 billion in 2001. Typically, a prescription costs between $80 and $100. Far more expensive but apparently no better at reducing pain than generic ibuprofen or naproxen, the new drugs' main selling point is their lower risk profile; they're less likely to cause stomach problems like ulcers.

But as noted earlier, the main study proving this benefit from Celebrex abandoned six months' worth of data in reaching its conclusions. An editorial published in June 2002 in the influential *British Medical Journal* took the authors of the Celebrex study to task for "serious irregularities" in the research, including "post hoc changes in design, outcomes, and analysis." The editorial also noted that in spite of its flaws, the study had achieved widespread currency in the medical world: Thirty thousand copies had been ordered from the publisher, and the study had been cited 169 times in the professional literature.

As for Vioxx, the single most advertised drug in 2000, an important trial did find that it caused fewer serious gastrointestinal problems than the comparison drug, naproxen—but the study also turned up an unexplained four- to fivefold increase in heart attacks in the Vioxx group. In 2001, the FDA sent Merck & Co. a warning letter: "You have engaged in a promotional campaign for Vioxx that

minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study," the letter said. Among the promotional materials referred to in the letter is a May 2001 press release entitled "Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx." The FDA called the claim "simply incomprehensible." It may be that the comparison drug naproxen actually protects the heart and thus made Vioxx look bad. Nevertheless, although new FDA-approved labeling for Vioxx moderates warnings on stomach problems, it adds information about possible heart effects.

Use of newer, powerful antibiotics to treat simple infections may also be influenced by advertising. "Antibiotics are promoted pretty heavily to doctors through magazine ads and exhibits at conferences," says Elbert Huang, MD, of the University of Chicago. "It's very evident nobody promotes generics." This troubles public-health specialists not only because the new drugs tend to cost more but also because using the big guns when they're not required could promote the development of antibiotic-resistant organisms. For these reasons, the Infectious Disease Society of America recommends treating ordinary urinary tract infections (UTIs) with an older antibiotic, trimethoprim-sulphamethoxazole (trade names Bactrim, Septra, also available as a generic). But according to a recent study by Huang published in the *Archives of Internal Medicine,* use of the recommended antibiotic for urinary tract infections has declined over the last decade from 48 percent in 1989–1990 to only 24 percent in 1997–1998. Meanwhile, UTI scripts for another class of antibiotics, fluoroquinolones such as Cipro, rose from 19 percent to 29 percent. Bayer recently applied to the FDA for

approval of a special dosage form of Cipro—Cipro UTI—which, the company says, "can be used to effectively treat uncomplicated urinary tract infections in only three days." Except in areas where there are high rates of pathogen resistance to it, the older and far less expensive drug is likely to do just as well. "In the garden-variety UTI, Bactrim works in the same three-day period that Cipro works," says Huang.

IN WITH THE NEW—FASTER!

When weighing whether to approve a new drug for marketing, the FDA must strive for efficiency—so that patients don't wait too long for breakthrough medicines—but also, of course, for safety.

The Prescription Drug User Fee Act (PDUFA), first implemented in 1992, was meant to speed up a regulatory-review procedure that had delayed the introduction of important drugs for AIDS and other scourges. In the process, it created a new relationship between the drug industry and the agency that regulates it: Under PDUFA, the FDA collects fees from drug companies to pay the salaries of the very people who approve or reject their products for marketing. In exchange for the fees, the FDA is required to meet strict deadlines for review of all drugs, even those not anxiously awaited by patients.

The measure has succeeded in accelerating review and is hailed by the drug industry and FDA alike as a success. "The fees have enabled the FDA to pay the salaries of more than 1,000 highly-qualified reviewers and to cut the review time for new drugs almost in half since 1991, from 30.3 months at

that time to 16.4 months in 2001," PhRMA said in a June 2002 press release. Because patents are typically obtained well before FDA review even begins, a quicker review lengthens a drug's effective patent life, that is, the time it can be *sold* under patent.

The FDA has handled more applications since PDUFA took force and has approved a higher percentage of those applications, about 80 percent at the end of the 1990s, versus less than 60 percent in the years before PDUFA. Whereas in the early 1990s a new drug was rarely introduced first in the United States, now more than half launch here.

None of these facts means more dangerous drugs are clearing FDA review. The rate of drug withdrawals has remained steady at 2.7 percent, the agency says. This is rather disconcerting, though: Of fifty-three FDA reviewers who responded to a Public Citizen survey in late 1998 (172 were contacted), nineteen identified a total of twenty-seven newly approved drugs they had worked on that, in their opinion, should not have been approved.

With PDUFA set to expire in the fall, PhRMA and the FDA privately hammered out an agreement for an expanded version in the spring of 2002, which Congress passed in June, overwhelmingly and with little debate. The reauthorization spared the FDA from having to lay off reviewers that summer. It also increased drug-company fees, adding 500 new reviewers to the FDA payroll. The new PDUFA for the first time allows FDA to use drug-company fees to help monitor the safety of drugs *after* market launch as well as before.

Whatever one makes of this balance between speed and caution in the introduction and uptake of new drugs, it

seems a particularly American trait to greet the "new and improved" fruits of science and industry with enthusiastic approval. We like the idea of smarter and more powerful medicines, much the same way we like the idea of more horses under the hood or a handier way to mop the kitchen floor. And we're often right to appreciate innovation; after all, the water pills that continue to impress researchers with their anti-hypertensive properties were once the newest wonder drug. We also have a lot of faith in ourselves as individuals, believing that each of us can, in consultation with a physician, simply try a drug and decide its merits for ourselves. And surely this sense of independence serves us well in many instances. But like the physicians who believed their colleagues were influenced by pharmaceutical-industry pitches while they themselves were immune, American consumers sometimes underestimate the extent to which we are all susceptible to the vagaries of human psychology, to the assumptions of our culture, and to the insistent tide of economic incentives that are built into our health-care system.

The CHAIRMAN. Certainly. That will become a part of our record as part of the testimony today.

Senator STABENOW. When we analyze this issue of direct-to-consumer advertising I think it is important to look at the total impacts. There is no question that we all want to be informed consumers—no question about that—and that we make better decisions when we have good information. I think, though, that as we look at the rising cost of prescription drugs, the spending on prescription drugs, we should be asking questions about whether or not it is in the consumer's interest. I will just pick one drug. That Vioxx spends more to advertise than Pepsi or Budweiser beer, is that necessary for us as consumers or does that just add to utilization and add to the overall cost and price of prescription drugs?

I think common sense would tell us we do not really need to debate the increase in advertising. All we have to do is turn on the television set, Mr. Chairman. I was thinking as I was watching this morning, watching the news, that if not every commercial, every other commercial is for some kind of prescription drug. So common sense tells us that there has been a dramatic increase in advertising. Is that meaning a dramatic increase in consumer awareness and education or simply a dramatic increase in pricing, a dramatic increase in utilization?

I am caught by the fact that the GAO in 2002 reported that most of the spending increase for heavily advertised drugs is the result of increased utilization. For example, between 1999 and 2000 the number of prescription drugs dispensed for the most heavily advertised drugs rose 25 percent but increased only 4 percent for the drugs that were not heavily advertised. So I think, Mr. Chairman, that is significant.

I would just say in conclusion that we constantly, I think, struggle between more dollars for research, which we all have a great stake in, and dollars for advertising, marketing, other parts of the industry, and as a state that does a tremendous amount of that great research—Pfizer has facilities in Michigan and we are very proud of that research—I want very much to see and I think we have a stake in continuing policies that provide billions of dollars of taxpayer money through the National Institute of Health, tax credits and deductions for research, patents that protect companies to recover their costs.

But the deal at the end of the chain for the American consumer is that we will be able to afford that product because, as our ranking member indicated, this is not buying a car, although coming from Michigan, I think we should buy new cars every year and they should be American-made, but if I have cancer I need my medication and I may have to forego that new car.

I am very concerned that when we look at these issues we hear that two to three times more is spent on advertising and marketing than research. The industry, of course, disputes that. What I find interesting, Mr. Chairman, is that I put in legislation last year that simply said that the taxpayers of our country will subsidize through tax credits and deductions as much advertising and marketing as we do in research. There are two line items on tax forms, one for research, one for advertising, marketing, administration. The SEC reports show that the second line item is, on the average,

2½ times more than research. We are told no, there is more spent on research, so I simply said they should be the same, that we would only allow a subsidy in the advertising and marketing line item equal to research. I could only say that after the strong opposition of the industry, the overwhelming and tenacious opposition of the industry, it is hard for me to believe, based on that and the fact that this bill would not have affected them if, in fact, there was more being spent on research, I have to assume that, in fact, there is not.

So I will stop there, Mr. Chairman, and welcome the testimony and think that this is a very important topic for all of us.

The CHAIRMAN. Thank you very much, Senator, and thank you for your interest and involvement in this issue.

Now let me turn to our colleague from Maine, Senator Susan Collins. Welcome.

STATEMENT OF SENATOR SUSAN COLLINS

Senator COLLINS. Thank you very much, Mr. Chairman. I want to thank you for calling this morning's hearing to examine the effect that direct-to-consumer advertising has had on the pricing and utilization of prescription drugs. This issue has long been of interest to me and I appreciate having the opportunity to examine it in more detail.

Prescription drug spending increased at an annual rate of about 18 percent from 1997 through 2001 and we know that it is the fastest growing component of health care spending in the United States. With the increase in the cost of prescription drugs and in the amount of prescription drugs purchased has come the increase in direct-to-consumer advertising. Direct-to-consumer advertising of prescription drugs has tripled from $791 million in 1997 to $2.7 billion in 2001. That raises what I think is a very legitimate question: Has DTC advertising contributed to the spiraling cost of drugs in the United States?

Now we know what both sides say about this. Critics say that the advertising gives consumers incomplete information, that it promotes false expectations, that it puts pressure on physicians to write unnecessary or inappropriate prescriptions. They say that the ads prompt patients to ask their physicians to prescribe new drugs that are more expensive but not necessarily more effective than older drugs.

Proponents of the advertising, however, contend that it improves public health, that it encourages patients to seek help for untreated conditions, and has opened up discussion of once-forbidden topics. They say that the increases in the prices of prescription drugs are not due to advertising but rather, to appropriate increases in utilization and the high cost of research and development.

We do know that the high cost of prescription drugs is putting pressures on states' Medicaid programs and on insurance costs that the private sector is bearing. Rising drug costs are also important to us as we are drafting the new Medicare prescription drug plan.

All of this prompted me to join a tripartisan group of senators—Senator Jeffords and Senator Mikulski and I—in asking the General Accounting Office last year to review the effect of such advertising on the use and the cost of prescription drugs. We found

through this report that while the pharmaceutical industry did spend significantly more on R&D than on promotional activities such as direct-to-consumer advertising, the drug companies have increased spending on advertising more rapidly than they have increased spending on R&D.

The report also found that DTC advertising appears to increase utilization and spending and, perhaps not surprisingly, that the drugs that are most heavily advertised are often among the best selling drugs. In the year 2000, 22 of the 50 drugs with the highest direct-to-consumer spending were among the top 50 in sales. Moreover, the sales of drugs with the highest advertising spending have risen more quickly than the sales of other drugs.

More troubling and an issue that I want to raise with our witness today was the fact that the report indicated that the Food and Drug Administration has been unable to keep pace with those pharmaceutical companies that were bent on bad faith advertising while seeming to comply with the rules. This is an issue that we have been pursuing with the FDA.

So again I would ask that my full statement be placed in the record but thank you for holding this important hearing.

The CHAIRMAN. Senator, thank you for that statement and thank you for the work that you have done and the prompting that you did with the development of that audit. I think that is an important template from which we work in this effort and understanding it better.

Now let me turn to our panels today. We have two. Our first panel is panelist Janet Woodcock, M.D. from the FDA, Director, Center for Drug Evaluation and Research here in Washington. Janet, we thank you for your time before the committee. We also thank you for your willingness to stay on and, as my staff has said, participate with the second panel and respond to questions or interaction as we build this record. We think that is very important. We appreciate that courtesy. Please proceed.

STATEMENT OF JANET WOODCOCK, M.D., DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, FDA, WASHINGTON, DC

Dr. WOODCOCK. Thank you. Good morning, Mr. Chairman and distinguished members of the committee. I am Janet Woodcock, Director of the Center for Drug Evaluation and Research at the FDA. The Division of Drug Marketing, Advertising and Communications, which is the group in FDA that regulates prescription drug promotion, is located within the Center for Drugs.

Thank you for the invitation to discuss FDA's oversight of what we refer to as DTC advertising, the promotion of prescription drugs directly to consumers. Depending on how it is done, DTC advertising has the potential for doing good or harm. On one hand, there is real potential value in patients recognizing undertreated conditions and consulting with their doctors. As you know, undertreated chronic diseases result in a tremendous burden of illness in our country and some of this burden is preventable. Ads may help by raising awareness of symptoms and potential treatments, as well as encouraging people to be more involved in their own health maintenance.

On the other hand, there is potential for increasing inappropriate use of medicines for consumers who do not need them, for substituting the use of more costly medicines for older effective treatments, or for misinforming consumers about a drug's safety and use. Consumers may become confused and physicians frustrated when valuable time must be spent correcting misconceptions.

The purpose of FDA regulation of DTC ads is to keep the balance on the positive side for the public. The debate about where this balance lies has been particularly pointed over the past 5 years. Research data, rather than opinion, can best inform us all about the real-world impact of DTC ads, and some of the data will be discussed today.

Now there are three important things to understand about FDA's authority in this area. First, the statute and the regulations focus on the content, not the existence, of prescription drug promotion. Second, the law does not make a distinction between target audiences. The law has never prohibited advertising prescription drugs to consumers. However, until the early 1980's this just was not done. Third, the act specifically forbids requiring preclearance of ads by the FDA, except under extraordinary circumstances.

The modern era of DTC advertising really began in 1985 when FDA announced that the regulations for overseeing promotion to doctors provided sufficient safeguards to protect consumers, as well. After this, increasing numbers of DTC print advertisements appeared.

Beginning in about 1995, spending on DTC ads began to rise sharply and this trend has continued ever since. The on-going debate, though, over DTC intensified in 1997 when FDA issued a draft guidance that addressed broadcast ads.

DTC advertising of prescription drugs, including radio and TV ads, had always been legal. However, there was a feasible mechanism to make sure that consumers could get the required risk information. But by the mid–1990's, many changes had occurred, both in the marketplace and in technology. Given these changes, it was apparent to FDA that sponsors could provide a convenient way for consumers to get the additional product information.

So in 1997 we issued a draft guidance, made final in 1999, that gave advice on how sponsors could meet the adequate provision requirement for broadcast ads by giving reference to multiple sources of product information in the ad. At the time we issued the final guidance we stated our intent to assess the impact of broadcast ads, as well as the impact of DTC promotion in general on the public.

Monitoring direct-to-consumer promotion and especially broadcast ads is a top priority of our program. We want to ensure that consumers can understand the claims and the product risks. We also want to ensure that consumers get truthful and not misleading information. We are very interested in better ways to communicate risk information to consumers. We have issued a draft guidance on the brief summary in 2001 and we are working on a revision of this guidance.

Most sponsors voluntarily submit proposed broadcast ads to us for review and comment. We believe that as a result, we comment on proposals for most product claim broadcast ads before they are

aired. FTC gives DTC enforcement letters top priority to clear and to issue.

We also conduct research on DTC and keep on top of the literature. The available research shows both positive and negative effects from DTC. FDA is not aware of evidence that DTC promotion is increasing inappropriate prescribing. Our research shows that DTC promotion may encourage consumers to obtain additional information about the products and to talk to their health care providers about health issues they had not raised before.

However, our research also shows that many physicians believe that DTC ads lead patients to overestimate benefits. In addition, some physicians do feel pressured to prescribe a specific brand name product.

In summary, at this time we are not aware of evidence that DTC promotion is harming the public health. We also acknowledge that in some cases DTC promotion may expand the recognition and treatment of serious untreated conditions. However, potential for harmful consequences calls for on-going vigilance on our part. We intend to continue closely scrutinizing DTC promotion, working with industry to ensure that broadcast ads comply with regulatory requirements and taking enforcement action when appropriate.

Thank you and I will be happy to answer any questions.

[The prepared statement of Dr. Woodcock follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administratio
Rockville MD 20857

STATEMENT BY

JANET WOODCOCK, M.D.

DIRECTOR, CENTER FOR DRUG EVALUATION
AND RESEARCH

U.S. FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SENATE SPECIAL COMMITTEE ON AGING

JULY 22, 2003

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA or the Agency).

Thank you for the opportunity to discuss how FDA regulates prescription drug promotion. I will present a brief background including how regulation in this area has evolved, the Agency's statutory and regulatory authority over promotional materials developed by manufacturers (sponsors) of products, how the Agency carries out these functions, various issues concerned with bringing such promotional materials before the public, recent FDA surveys conducted to assist us in evaluating the impact of prescription drug promotion to the public, and ongoing and future plans of the Agency with respect to these functions.

Helping all Americans make better informed health decisions is a top priority of the Agency. Previous research by FDA and other entities has documented that accurate consumer-directed or direct-to-consumer (DTC) prescription drug promotion can lead to significant increases in the detection of under-treated conditions like high blood pressure, diabetes, and depression, with consequent health benefits for Americans. FDA surveys in 1999 and 2002 showed that DTC advertising encouraged substantial numbers of patients to ask a doctor about a medical condition or illness of their own that they had not talked to a doctor about before. The surveys also showed that DTC advertising encouraged patients to obtain more health information from a physician or pharmacist. On balance, if this is happening as a result of DTC advertisements, this is very promising. I welcome the opportunity today to outline the approach FDA is taking in this area.

The Division of Drug Marketing, Advertising, and Communications (DDMAC), within CDER is responsible for regulating prescription drug promotion at FDA. DDMAC's mission is to protect the public health by helping to ensure that prescription drug information is truthful, balanced, and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement and education program, and by fostering optimal communication of labeling and promotional information to both health care professionals and consumers.

KINDS OF MATERIALS REGULATED

FDA regulates advertisements and other promotional material, called "promotional labeling," disseminated by or on behalf of the advertised product's manufacturer, packer or distributor. Mostly, this means materials that the product's sponsor issues or places for publication, which are directed to consumers and patients, such as ads printed in magazines, journals and newspapers; ads broadcast over television, radio and telephone; brochures, letters and flyers sent through the mail; and videotapes, pharmacy counter displays, billboards, and patient compliance program materials. According to the October 2002 GAO report entitled, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations,* "Promotion to physicians accounted for more than 80 percent of all promotional spending by pharmaceutical companies in 2001." Therefore, the bulk of the Agency's time spent reviewing promotional material, is spent reviewing materials produced for promotion to health care professionals, such as detail aids used by manufacturer representatives, convention displays, file cards, booklets, and videotapes, which is distinct from advertising directed toward consumers.

TYPES OF ADVERTISEMENTS

Of the three different types of ads that product sponsors use to communicate with consumers, FDA regulates two of them; "product-claim" and "reminder" ads. The third type, "help-seeking" ads are not regulated by FDA.

"Product-claim" ads are regulated by FDA and are those ads which generally include both the name of a product and its use, or make a claim or representation about a prescription drug. Claims of drug benefits, such as safety and effectiveness, must be balanced with relevant disclosures of risks and limitations of efficacy. This balanced presentation of drug therapy is commonly referred to as "fair balance." In addition, when used in print ads, sponsors must provide a brief summary of risk information included in the product's FDA-approved labeling or, for broadcast "product-claim" ads, provide convenient access to the approved labeling. In our regulations, the phrase "adequate provision" is used to identify the convenient access option.

"Reminder" ads are regulated by FDA and are ads that may disclose the name of the product and certain specific descriptive information such as dosage form (i.e., tablet, capsule, or syrup) or price information, but they are not allowed to give the product's indication (use) or to make any claims or representations about the product. They specifically are not allowed for products with serious warnings (called "black box" warnings) in their labeling. The regulations specifically exempt "reminder" ads from the risk disclosure requirements because they were historically designed generally to remind health care professionals of a product's availability. Health care professionals presumably know both the name of a product and its use.

"Help-seeking" ads discuss a disease or condition and advise the audience to "see your doctor" for possible treatments. They need not include any risk information. Because no drug product is mentioned or implied, this type of ad is not considered to be a drug ad and is not regulated by FDA.

STATUTORY AND REGULATORY AUTHORITY

FDA regulates the manufacture, sale, and distribution of drugs in the United States under authority of the Federal Food, Drug, and Cosmetic (FD&C) Act (or the Act), which includes approval of prescription drug labeling that provides information about the use of a drug. Section 502(n) of the Act provides the Agency with authority to regulate prescription drug advertisements and the implementing regulations (Title 21, Code of Federal Regulations [CFR] section 202.1) which provide specifics about the content of such advertisements. Nothing in the law or regulations prohibits DTC promotion in any advertising medium even if the drug being advertised is a controlled substance. Also, the advertising provisions of the Act do not address the issues of pharmaceutical coverage by insurance companies or drug product price.

The regulations specify, among other things, that prescription drug advertisements cannot be false or misleading, cannot omit material facts, and must present a "fair balance" between benefit and risk information. Further, for print advertisements, the regulations specify that every risk addressed in the product's approved labeling also must be disclosed in the brief summary. For broadcast advertisements, however, the regulations require ads to disclose the most significant risks that appear in the labeling. The regulations further require that

broadcast advertisements either contain a brief summary of "all necessary information related to side effects and contraindications" or make adequate provision for dissemination of the product's FDA-approved labeling (and the risk information it contains) in connection with the ad.

FDA generally cannot require that prescription drug advertisements be reviewed and approved prior to their use. Prior FDA review of advertisements occurs only in very narrow circumstances, primarily for products receiving accelerated approvals. In other words, FDA's review of promotional materials is intended to occur *post hoc* – once the materials have appeared in public. Enforcement actions for advertising violations are generally intended to be taken *post hoc* as well. Most of FDA's enforcement actions request that sponsors stop using the violative materials. In some cases, FDA asks sponsors to run corrective advertisements or issue corrective letters to correct product misimpressions created by false, misleading, or unbalanced materials. To avoid this, the majority of sponsors voluntarily seek prior comment from FDA on draft broadcast ads for their products thereby reducing the likelihood that sponsors may face an enforcement action.

DEVELOPMENT OF REGULATION FOR CONSUMER-DIRECTED ADS

Prior to the early 1980s, prescription products were not promoted directly to consumers and patients. At that time, FDA's regulation of promotional drug material was limited to that which manufacturers prepared to present to physicians and other health care professionals. In the early 1980s, a few companies began advertising products directly to patient audiences (specifically, older people concerned about pneumonia and people taking prescription ibuprofen to treat arthritis pain). As questions and concerns directed to the Agency about

such DTC promotion began to grow, FDA issued a policy statement on September 2, 1983, requesting a voluntary moratorium on DTC ads. The Agency needed time to study whether the current regulations developed in the 1960s for prescription drug advertising directed toward health care professionals provided sufficient safeguards to protect consumers when applied to DTC promotion. In addition, the Agency wanted to allow time for a dialogue among consumers, health professionals, and industry, and for interested parties to conduct research on aspects of consumer-oriented advertising. The industry complied with the request. 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.

In a September 9, 1985, *Federal Register* (FR) Notice (50 FR 36677), FDA concluded that the "current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers," which lifted the voluntary moratorium.

During the early 1990s, sponsors increasingly used consumer print material (magazines, etc.) to advertise their products. The 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 using medical jargon, is not very consumer friendly.

In the 1990s, product sponsors also started using television advertisements in a limited fashion. Television advertisements were limited because of the extensive disclosure needed to fulfill the brief summary requirement, and FDA and industry did not believe that it was feasible to disseminate the product's approved labeling in connection with the ad. Therefore,

it was believed that the brief summary was required. For example, one way to satisfy the brief summary requirement would be to scroll the brief summary on the screen, which would take a minute or more at a barely readable scrolling rate. By the mid-1990s, sponsors were placing "reminder" ads on television because these ads are not required to include a brief summary. Some of these ads were confusing to consumers who were not knowledgeable about the name and use for these products.

In response to increasing consumer demand for information and clarity, FDA issued an FR Notice on August 16, 1995, announcing a public hearing to discuss several aspects of DTC advertising and a Notice for further comment on May 14, 1996, to clarify additional issues, including the brief summary requirement. Further, in light of changes in consumers' ability to get additional product information, FDA began to consider whether broadcast ads could be constructed to ensure access to product labeling information, the only alternative to including the brief summary requirement. 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" ad.

In August 1997, FDA issued a draft guidance entitled, "Guidance for Industry: Consumer-Directed Broadcast Advertisements" (see Attachment A) 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 has convenient access to the advertised product's approved labeling. The proposed approach consisted of reference in the broadcast ad to four sources the consumer could use to obtain more detailed 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 April 2001, FDA issued draft guidance for industry entitled, "Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements." The draft guidance describes how FDA did not intend to object to the use of certain FDA-approved patient labeling to fulfill the brief summary requirement for prescription drug and biological product print advertisements directed toward consumers. FDA said it would not object to the use of FDA-approved patient labeling if such labeling were reprinted in full and comprehensively discussed in consumer-friendly language the product's most serious and most common risks. FDA believed that this labeling contained the information patients would likely find helpful in deciding whether to discuss with their health care provider the possible usefulness of the product for their own health care.

CDER's DDMAC OPERATIONS

Since 1997, DDMAC has been staffed with about 28-30 staff members. This has recently been increased to 40 staff members. Of the 40 staff members, 20 are primary reviewers and 5 are secondary reviewers (team leaders). The review staff currently has six review groups. Four are Professional Review Groups, each with two review teams, who review materials prepared for health care professionals. In addition, there is one Direct-to-Consumer Review Group consisting of two review teams and one research team; one Evidence Review Group; and a Policy and Enforcement Team. All report to the Division Director.

With the transfer of the therapeutic products from the Center for Biologics Evaluation and Research, (CBER), CDER has created a seventh review group within DDMAC to be officially transferred October 1, although the staff currently is at DDMAC in detail status. The Biologic Review Group, which consists of a team leader and three reviewers, will review the promotional materials for the products that are being transferred from CBER.

Under the post-marketing submission requirement, DDMAC received approximately 31,600 pieces of all categories of promotional material in 1999; 32,100 in 2000; 34,200 in 2001 and 36,700 in 2002. Although DDMAC is unable to thoroughly review every piece, certain materials are flagged for expedited review. These include materials that introduce newly approved products or products with new indications, which we identify as launch. These go to the Professional Review Groups and to the Direct-to-Consumer Review Group if consumer materials are part of the "launch" campaign. Also flagged for expedited review are TV and radio advertisements, which go to the Direct-to-Consumer Review Group. In addition to promotional materials that are submitted at the time of initial use, DDMAC reviews complaints about promotion from competitors, health care professionals, and consumers; promotional activities in the commercial exhibit halls of scientific meetings; promotional meetings; and evolving technology..

The total number of DTC broadcast advertisements (TV and radio) submitted to DDMAC in recent years was: 1999 – 293; 2000 – 443; 2001 - 376 and 2002 – 486. This includes both those advertisements that were proposed but not aired and those that were aired. Since January 1997, sponsors of 93 prescription drugs (see Attachment B) have aired "product-claim" and/or "reminder" advertisements on television or radio. A small number of prescription biological products also have been aired. It is important to note that DDMAC

does not know how many different variations of the original advertisements have aired in broadcast media for these 93 drugs. Many of the products have been the subjects of multiple campaigns and many of the campaigns include different length "product-claim" commercials – variations of the initial commercial submitted to the Agency. It would be impossible for DDMAC to try to track the number of different broadcast advertisements that are aired. In addition, because "help-seeking" ads, if properly done, are not considered to be drug ads, most product sponsors do not send them to DDMAC. Thus, we have no measure of how many of them have been in the public domain.

DDMAC does not track the number of DTC print ads. Last year, however, DDMAC estimated the consumer pieces to be about one-sixth of the total, or about 6,000. It should be noted that these are not all DTC print and broadcast ads, but also consumer promotional pieces distributed by drug companies directly to consumers or through health care providers.

An Example of How the DTC Review Group Functions

DDMAC uses a group meeting to discuss proposed promotional pieces and decide on our response to the company. A typical meeting to review a new proposal for a drug that already has been advertised in a broadcast medium includes a DTC review team and group leader, someone from one of the professional review groups, a social scientist, and a regulatory counsel, also from DDMAC's staff. Drugs that are new products, have new indications, are first in a class to have broadcast advertisements, or are being advertised in a broadcast medium for the first time have more extensive reviews.

Almost all companies send new proposed DTC broadcast concepts to DDMAC for comments in advance of use, although companies are under no obligation to follow DDMAC's advice.

Consequently, DDMAC generally does not see the final broadcast ad before the company submits it as part of its post-marketing requirements at the time the ad is first aired on TV or radio. DDMAC instituted the group review process for proposals in an effort to help ensure that DDMAC provide consistent advice to companies across product classes, and over time.

Current Regulatory Tools

As stated previously, unless sponsors voluntarily submit their draft materials for comment before use, DDMAC sees the materials at the same time as the public. DDMAC's options to address promotional materials that are false or misleading are:

- Untitled letters –notices of violations issued to sponsors directing that they discontinue use of the violative false or misleading advertising materials
- Warning Letters – issued to sponsors for more serious violations, such as those possibly posing serious health risks to the public
- Injunctions and consent decrees
- Referrals for criminal investigation or prosecution
- Seizures

FDA has moved toward a risk-based enforcement strategy designed to achieve effective deterrence through use of Warning Letters and untitled letters that are more clearly designed to serve as a basis for further enforcement action. Under a directive issued to FDA by the Department of Health and Human Services in November 2001, all Warning Letters and untitled letters that originate within FDA, including DDMAC letters, must be reviewed and cleared by the Agency's Office of the Chief Counsel (OCC) before issuance. OCC review focuses on ensuing that the correct legal violation has been cited, that the violation is substantiated by the facts, and that enforcement action is legally sustainable if the violation continues. Under this system, a firm that receives a DDMAC letter is on notice that OCC has

already determined that enforcement action based on the cited violation stands a relatively high likelihood of succeeding in court. Put another way, FDA now uses Warning Letters to presage enforcement action, not substitute for it. Moreover, firms that commit repeated violations face a much stronger basis for further enforcement action. The Agency acknowledges that in some instances, this may result in longer review times, however, OCC and DDMAC work together to minimize delays and have agreed to expedite the review of certain letters by setting a goal of 15 working days for completing such reviews.

Criteria Used When Issuing an Untitled or Warning Letter

Untitled letters are used for less serious violations than Warning Letters. Such violations may include overstating the effectiveness of the advertised drug product, suggesting a broader range of conditions than the drug was approved for, or making misleading claims because of inadequate context or lack of balancing risk information. Warning Letters address more serious violations including serious safety or health risks and/or repetitive violative conduct which, if not promptly and adequately corrected, could lead to additional enforcement actions without further notice from FDA. Warning Letters generally result in the company disseminating a remedial message to correct the violative ad.

Educational Programs for Industry

DDMAC aims to increase voluntary compliance by industry through educational programs. These programs include outreach, website postings, guidances, and advisory comments.

Outreach Programs: FDA staff participates in many panel discussions and presentations for groups including industry, law firms, consultants to industry, and marketing and advertising

agencies. These programs are intended to increase these groups' understanding of the regulations relating to promotion of prescription drugs so that industry can better comply.

Website Postings: CDER posts on its website all Warning Letters and Untitled Letters and the cited promotional materials. Industry has noted that these letters serve as useful examples of violations that FDA has acted against and helps them understand what type of promotion is unacceptable.

Guidances: FDA publishes guidances in areas for which industry seeks clarification. An example is the guidance on broadcast advertisement published in August 1999, following on the draft guidance published in August 1997. Guidances help industry understand FDA's current thinking and how to comply with the regulations.

Advisory Comments: Although there is no requirement, for most drugs, that companies submit proposed promotional materials BEFORE their initial use, companies often request DDMAC's review and comments on proposed materials. We provide this service so that companies can ensure that their materials are in compliance with the regulations.

ENFORCEMENT RELATED TO DTC PROMOTION

Since August 1997, for broadcast advertisements, FDA has issued:

- 45 untitled (or "Notice of Violation") letters on "product-claim" broadcast ads. Such letters request that the violative promotion be stopped immediately. Product sponsors virtually always comply immediately with this request.

- 3 Warning Letters on broadcast ads. This is a higher-level enforcement action, and requests that a remedial campaign be conducted by the company to correct the misimpressions left by the ad.
- 13 untitled letters on purported reminder broadcast ads.
- 3 untitled letters on purported "help-seeking" broadcast ads.

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 August 1997, for print advertisements, the Agency has issued:

- 54 untitled letters that addressed DTC print ads or other promotional materials, including purported "reminder" and "help-seeking" materials.
- 2 Warning Letters: one for a specific DTC print ad and one that included a DTC print ad as part of an overall misleading campaign.

Generally, the violations for "product-claim" print 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 benefits and risks. "Help-seeking" ad violations were due to a particular product being suggested in the message. 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.

FDA'S DTC PROMOTION RESEARCH

A number of groups, including FDA, have been conducting research on DTC promotion to learn about its effects on consumers and physicians. As part of its commitment to examine the effect of DTC promotion on public health, FDA has conducted three national telephone surveys of U.S. adults to ask their views on DTC promotion of prescription drugs and its effects on the patient-physician relationship. One consumer survey was conducted in the spring of 1999 and again in the spring of 2002. FDA has only released the preliminary results of the 2002 consumer and physician surveys and is currently working on the final report which is expected to be released some time in the fall of 2003. FDA is planning a public meeting to present this information and to give other organizations and individuals an opportunity to present their research to FDA. Specifics about this meeting will be announced in the *Federal Register* at a later date.

TWO FDA CONSUMER SURVEYS ON DTC PROMOTION

In the two consumer surveys, FDA gave special attention to surveying adults who had recently visited a physician (within the last three months). Participants were asked questions measuring the influence of DTC advertising on attitudes toward prescription drugs, health-related behavior, and on aspects of the doctor-patient relationship. The preliminary results from these two consumer studies show:

- Among respondents who had seen a doctor with the past three months and remembered seeing an ad for a prescription drug, approximately half in 1999 and approximately 40 percent in 2002 said that an advertisement for a prescription drug had caused them to seek more information, for example, about the drug and their health.

- Among those respondents who indicated that a DTC ad had caused them to search for more information in 2002, 61 percent reported they were searching for information about side effects.
- More than a quarter (27 percent) of survey respondents in 1999 and 18 percent in 2002 who had seen a doctor in the last three months said that an ad for a prescription drug had caused them to ask a doctor about a medical condition or illness that they had not talked to a doctor about before.
- In both 1999 and 2002, the most frequently reported reasons for visiting a doctor are the presence of a previous condition, the need for a checkup, or that the respondent had not been feeling well. Less than 7 percent of respondents report that they visited their doctor because of something they read or saw, or because of an ad for a prescription drug.
- Forty-two percent of respondents in 2002 agreed strongly or somewhat agree that DTC ads make it seem as though the drug will work for everyone.

The results of the two consumer surveys need additional analysis but indicate that DTC may serve as stimulus for consumers to seek more information about their health and the drug product including the risks associated with the use of the drug.

PRELIMINARY RESULTS OF FDA's 2002 SURVEY OF PHYSICIANS

Highlights of the preliminary results of FDA's survey of 500 physicians in the U.S. about DTC promotion include:

- Many physicians believe that DTC advertising can play a positive role in their interactions with their patients. For example, most agreed that because their patients saw a DTC ad, he or she asked more thoughtful questions.

- Some physicians thought the ads made their patients more aware of possible treatments.
- Many physicians thought that DTC ads made their patients more involved in their health care.
- Physicians felt they had to provide additional information to patients beyond what the patients retained from the DTC ad. About 75 percent believed that DTC ads cause patients to think the drug works better than it did, and many physicians felt some pressure to prescribe something when patients mentioned DTC ads.
- Forty percent of physicians believe that patients understood well the possible risks and negative effects of an advertised drug from the DTC ad alone.
- Eight percent of physicians felt very pressured and 20 percent felt somewhat pressured to prescribe the specific brand name drug when the patient asked the physician to do so. Most physicians suggested alternative courses of action.

The physician survey is an important tool to consider when doing the evaluation of the impact of DTC advertising on public health because of the role of the physician as the "learned intermediary." The patient does not select the drug for self-use but the decision is made by the physician in consultation with the patient. The results of the physician survey are preliminary but indicate that DTC advertising, when done correctly, can serve positive public health functions such as increasing patient awareness of diseases that can be treated, and prompting thoughtful discussions with physicians that result in needed treatments being prescribed. Often, the treatment that was prescribed was not the drug the patient saw advertised. Physicians in this survey indicate that they appeared comfortable in not necessarily prescribing the advertised drug for reasons including: that a different drug was more appropriate, the drug was not right for the patient, the drug has side effects of which the

patient was not aware, and/or a less expensive drug was available. Two concerns that physicians expressed are that DTC advertising causes patients to think that the drug works better than it did and that patients did not understand very well the possible risks of the advertised drug.

FUTURE AGENCY ACTIVITIES CONCERNING DTC ADVERTISING

FDA is committed to ensuring that its DTC advertising policies promote truthful and non-misleading advertising that helps to better inform consumers about their health and health care choices and prevents potential misconceptions about benefits and risks of the advertised treatment. Two concerns expressed by some physicians in FDA's survey, relate to overstatement of the product's efficacy and inadequate conveyance of risk information, and are two of the most common violations cited in the letters that FDA issues to pharmaceutical companies about DTC ads. FDA will continue to review DTC ads closely to ensure that essential information is communicated as clearly as possible, as outlined in our current policies. In addition, FDA will continue its comprehensive evaluation of DTC advertising and its impact on public health and FDA's policies and guidances.

In sum, prescription drug advertising can provide consumers with important information about new prescriptions and new indications for existing prescription drugs, as well as information about symptoms of treatable illnesses and other conditions. Done properly, prescription drug advertising can assist consumers in taking a pro-active role in improving their health. However, to be of value, these advertisements must not be false and misleading. As a result, FDA continues to closely monitor DTC advertising to help ensure that this promotional activity is accurate and balanced. FDA will complete evaluation of its own

research and that of other groups to help ensure that FDA's policies in regulating DTC advertising are optimal. To this end, the Agency is planning a public meeting in the fall for a full discussion of the known research.

This concludes my remarks, Mr. Chairman. I will be glad to answer any questions you may have.

The CHAIRMAN. Dr. Woodcock, thank you very much for that testimony. A couple of questions from me before I turn to the rest of my colleagues here.

I appreciate the scenario you gave of the different events that occurred that brought us to broadcast advertising and the guidance changes in 1997 and the rationale behind it. Was there on the part of the pharmaceutical companies a substantial amount of, if you will, lobbying or urging that a review of this particular regulation come about or was it a normal process of review on the part of FDA that brought you to a conclusion that has really spawned the kind of acceleration of broadcast advertising that we have seen?

Dr. WOODCOCK. It was a confluence of factors. No. 1, companies were running what are called reminder ads on television. These simply had the name of the drug. They were originally conceived of for physicians, who would have been aware of what the drug was. This was very confusing for the consumers.

Second, it is true that some sponsors were considering running ads; these broadcast ads were perfectly legal. We felt it would be best for us to set the parameters whereby adequate provision could be given for getting the consumer information, rather than letting this happen and then having to repair it afterward.

So we issued a guidance on how companies could comply, since it was apparent it was now feasible, with 1–800 numbers, with the Internet, with all the print ads that had begun to occur, it was now feasible for companies to make this information widely available.

The CHAIRMAN. The problem with that print ad is that while I have just turned 58 and I have bifocals, I get out the magnifying glass to read it.

By your testimony, it is evident to me that a letter from FDA on a given advertisement, permission to, if you will, or recommendations of are not necessary prior to the ad being aired. They are purely advisory in their character, your activity?

Dr. WOODCOCK. They are notification that we would consider that ad, if aired, violative, for example, if we sent it to the company before they air the ad. So companies follow our advise and modify their ads.

The law states that the companies need to submit the information at the time they air ads, not before, and they are not required to seek permission or clearance from the FDA to air an ad. But many companies, especially for broadcast ads, the vast majority of ads are sent to the FDA beforehand, probably they are so expensive that pulling them and correcting them would be a very expensive proposition.

The CHAIRMAN. Have ads aired that you then followed prior to a letter going to them in which you made recommendations for change and the ad was pulled and those changes made, or vice versa, the ad continued to air against your recommendations or in opposition to your recommendations?

Dr. WOODCOCK. That does not really happen.

The CHAIRMAN. OK, that does not happen?

Dr. WOODCOCK. No. We have additional sanctions we can take beyond these letters. They are just the initial notification.

The CHAIRMAN. Thank you very much. Let me turn to my colleague, Senator Breaux. John?

Senator BREAUX. Thank you very much, Mr. Chairman.

Thank you, Dr. Woodcock, for your presentation. Is it a policy that the FDA has to review the ad on a pharmaceutical before it is shown or does the FDA see it at the same time the public would see it for the first time? Tell me what the requirements are and what happens in actual practice.

Dr. WOODCOCK. The requirements are that firms have to submit the ad at the time it is aired. They do not have to seek any clearance from the FDA. They do not have to send it in and have us look at it. They simply have to send it to us at the time it is made public.

In practice for broadcast advertising, the vast majority of ads are sent to the FDA and FDA is consulted before the ad is aired.

Senator BREAUX. You make suggestions at that time or would you give them a warning that this ad is really not in compliance?

Dr. WOODCOCK. Yes, we send advisory letters to them. We send quite a few of these letters out.

Senator BREAUX. Before the ad is shown?

Dr. WOODCOCK. Yes. Then those ads are modified according to our advice.

Senator BREAUX. What percentage of the ads that are shown, for instance on television, do you think you all have a chance to review before they are shown? Fifty percent, more than that?

Dr. WOODCOCK. We have estimated around 90 percent but we cannot give you an exact figure.

Senator BREAUX. Of the ones that are not previewed, what percentage of them get letters of violation or whatever that letter is called saying you are not in keeping with what the standards should be?

Dr. WOODCOCK. We do not have data cut that way. The average I think is about 5 percent of all——

Senator BREAUX. The total?

Dr. WOODCOCK. Mm-hmm.

Senator BREAUX. How rapid do the companies respond to a letter that would be sent by the FDA? What happens if they get—what do you call the letter? I am sorry.

Dr. WOODCOCK. A notice of violation.

Senator BREAUX. A notice of violation letter. What is the respondent rate from the companies? Do they fight you on that? Do they comply? Tell me what happens after they get a letter.

Dr. WOODCOCK. Almost uniformly the companies comply immediately.

Senator BREAUX. What would that consist of?

Dr. WOODCOCK. Pulling the ad.

Senator BREAUX. Do they make changes in the ad and rerun it?

Dr. WOODCOCK. They may but it would have to conform to our requirements.

Senator BREAUX. One of the witnesses to follow will talk about the policy of the American Medical Association. They have instituted a policy on direct-to-consumer advertising and they have a policy that has, in fact, been published and contains a number of guidelines.

I understand that the FDA has not accepted those guidelines. Why would that be? Do you think you are already doing that or you disagree with them, or what?

Dr. WOODCOCK. The legal requirements are different than recommendations, say, that ads be educational. Those might be very desirable characteristics and it is not that we would disagree with those aims, but the legal requirements, the regulatory requirements for advertising are different and we are enforcing the regulatory requirements, as outlined in the statute and regulations.

Senator BREAUX. So you would interpret the AMA recommendation on guidelines as being other than what you do already?

Dr. WOODCOCK. Well, there are some additional—as I understand them, there are additional goals that the AMA is looking for, that ads, for example, help educate patients about disease, and so forth. That is very desirable but it is not a legal requirement of an advertisement.

Senator BREAUX. So what would establish what the legal requirements are? There is not an act of Congress that we passed and I did not notice it?

Dr. WOODCOCK. Yes.

Senator BREAUX. There is?

Dr. WOODCOCK. It is in the Food, Drug and Cosmetic Act and the implementing regulations.

Senator BREAUX. That was what your regs in 1997 were pursuant to?

Dr. WOODCOCK. We did not issue regs in 1997. Our guidance that we issued in 1997 was referring to our long-ago regulations, which I believe are from the 1960's, implementing the advertising provisions in the statute.

Senator BREAUX. When is the last time Congress has acted on the rules are regarding to advertising of pharmaceuticals?

Dr. WOODCOCK. 1962.

Senator BREAUX. But we were not advertising with the media and we were not doing direct-to-consumer advertising in those days, were we?

Dr. WOODCOCK. That is correct. It was a very different environment at that time. In fact, if you recall, from a medical standpoint we were coming out of an era where it was felt to be desirable not to inform the patient very much.

Senator BREAUX. Sometimes that is still true.

Let me ask you, then, if the act that Congress last enacted dealing with advertising was back in the 1960's, has FDA further advanced what those requirements are or are you still just basically implementing the 1960 act, although you said the situation is entirely different?

Dr. WOODCOCK. Right. We have continued, as our guidance shows, to clarify how we are currently interpreting the statute and regulations but we cannot obviously extend our power beyond the powers that are delineated, the limits that are delineated in the statute.

Senator BREAUX. Do you think there is anything that you would recommend to the Congress that should be changed in light of the 1960 act?

Dr. WOODCOCK. I think it is a very complicated issue. We feel that we are doing an effective job in regulating direct-to-consumer advertising. We feel that the ads meet the requirements in the statute, except when we send them letters. So we feel the program in general is quite effective but we are continuing to evaluate it.

Senator BREAUX. Final question. Is there anything that you feel that is lacking that the FDA ought to be doing in this area?

Dr. WOODCOCK. We could do more surveillance and other activities which were mentioned by GAO if we had additional resources to do these activities.

Senator BREAUX. But statutorily it does not seem to be a problem? It is a question of manpower, people power?

Dr. WOODCOCK. I think statutorily we have our limits. That is what we are following.

Senator BREAUX. But is that a problem for you or it is not?

Dr. WOODCOCK. No, I do not think that is a problem.

Senator BREAUX. Thank you.

The CHAIRMAN. Thank you very much, Senator. We will go with time of arrival of our colleagues, so let me turn to you, Senator Stabenow.

Senator STABENOW. Thank you, Mr. Chairman. Thank you again.

I wonder if you might respond, in light of your answer to Senator Breaux, about a section in the GAO report where they indicated that a recent change in the Department of Health and Human Services policy for reviewing regulatory letters has sharply reduced FDA's effectiveness in issuing untitled or warning letters in a timely manner. They have indicated this change has increased the time between FDA's identification of a misleading advertisement and FDA's request to remove it from dissemination, with the result that some regulatory letters may not be issued until after the advertising campaign has run its course.

Would you agree with that assessment by the GAO? If you might speak to that.

Dr. WOODCOCK. The change was put into place to ensure legal review of the letters, a thorough legal review before they went out, but there is no doubt they had impacted on the timeliness of the letters. We agree with that, based on our data.

We have recently instituted a program in the last several months reforming our process of getting review through chief counsel and our response to those reviews and I am happy to announce that we have issued quite a few letters in the past month. We expect to issue several more warning letters this month and we expect that this will get our rate of output of letters back up to our goal.

We recognize there is a balance between timeliness and legal sufficiency and quality but we feel that the legal review has improved the quality of the letters.

Senator STABENOW. So are you indicating that you supported the change that was made in the procedures that has created this situation for you?

Dr. WOODCOCK. We feel that it has improved the quality but we are going to have to do something about the timeliness.

Senator STABENOW. So you have better quality but at this point, in fact, you would agree with their statement that regulatory letters, in fact, may be coming out after the ads have already run?

Dr. WOODCOCK. They were taking too much time to get done and we have modified our procedures and we are seeing an effect of improved timeliness over the last 45 days.

Senator STABENOW. Is that an issue also—you mentioned funding—is that an issue of staff resources, and so on, as well?

Dr. WOODCOCK. We will have to see. We will implement these changed procedures and see how well we can keep up with the timeliness.

Senator STABENOW. I wonder if you might also talk a little bit more about the findings in your research. You indicated that the direct-to-consumer advertising is not causing harm to public health. However, I wonder if you have examined if the DTC is causing patients to request a more expensive, newer drug when an older or less expensive one or generic drug might, in fact, do just as well for their health condition.

Dr. WOODCOCK. Well, in our physician survey that we did, a little over half of the physicians who recalled a patient who came in and had seen an ad, that patient actually did ask for a specific brand name drug. In about half of the cases the physician actually prescribed that particular brand name drug. In other cases a physician did not prescribe it and one of the reasons given was that drug was too expensive, otherwise it was not right for the patient, and many other appropriate medical reasons for not prescribing the drug.

Our survey was not really capable of determining whether or not more expensive drugs are being prescribed in individual cases. We did find that some physicians feel pressured during an encounter. Whether the patient has seen an ad or not, they feel pressure to prescribe a drug and that pressure was increased if the patient had seen an ad.

Senator STABENOW. I certainly have had those same conversations with my own physician, who indicated she could see 15 to 20 drug company representatives in her office every week promoting their newest, best, most expensive drugs if she were to allow that to happen. So there is a whole series of things I think that relate, as well as DTC.

Is it fair to say that DTC gives consumers the impression that newer drugs are better drugs? Is that a reasonable statement, you think?

Dr. WOODCOCK. Well, the drugs that are advertised are newer drugs and the physicians in our survey said that the patients had a better impression of the effectiveness of the drugs than how effective the physicians felt the drugs were. In other words, they felt the patients developed an exaggerated idea of the effectiveness of the drug as a result of the ad.

The fact is that older drugs are not advertised. Older, effective drugs may not be advertised because they are off-patent or whatever.

Senator STABENOW. So this really does relate and I would suggest it very definitely relates to the cost of health care in terms of utilization going up of the higher-priced prescription drugs going up and not only older drugs possibly not being asked for by consumers, even though they might be just as effective, but generic drugs or unadvertised drugs, basically those drugs that come about

as a result of companies using information once a patent has expired—that also does not get adequately in the mix.

I would just say as an aside, Mr. Chairman, I think one of the really positive things that we did in the Senate in passing as part of the prescription drug bill was the portion dealing with closing loopholes regarding unadvertised brands or generic drugs going on the market. I think that was a very positive bipartisan effort of the Senate and I hope it will become law. It is now in the conference committee.

I would just also say that as you looked at your study, as you looked at the situation, you did not analyze those other issues. That really was not within the scope of your study in terms of cost, and so on, because when we talk about public health effect, I think people in Michigan would say that the inability to purchase the medications that they desperately need as a result of the price is as much of a public health threat to them as anything else. But I am assuming from what you said that those issues were not a part of the scope of your study; is that correct?

Dr. WOODCOCK. Right. Our studies were not economic studies. They looked at the attitudes and responses of physicians and consumers to direct-to-consumer advertising. So we came from that end.

Senator STABENOW. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator, thank you.

Now let us turn to our colleague from Maine, Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Dr. Woodcock, in your survey of physicians you found that 75 percent believed that direct-to-consumer ads caused patients to think that a drug works better than it did and a majority of the physicians surveyed also felt that patients who had seen these ads did not understand very well the possible risks of the advertised drug.

Don't those facts suggest the need for better scrutiny of the ads or for additional consumer disclaimers? If 75 percent of the physicians felt that higher expectations than justified have been raised by these ads, then does that not suggest a problem?

Dr. WOODCOCK. I think that advertising in general, it probably would be very difficult to provide a balanced medical perspective on a drug. That is why there is a learned intermediary for prescription drugs, which is that a patient must go to a prescriber and seek better information.

We also found that patients have an appropriately skeptical attitude toward these ads and they do not think that all information is being presented. Often their response is to go to their physician, their pharmacist, the Internet or other sources of information to seek more information about the drug. So they do not see it as the be-all-and-end-all of their drug information.

Senator COLLINS. Nevertheless, your survey showed that 75 percent of the physicians felt that their patients were coming in with unrealistic expectations.

Dr. WOODCOCK. That is right, and they also reported they felt it was somewhat of a problem because they had to spend time correcting those impressions.

If I may say so, we feel that one of the problems that we still have and we are working very hard on is in the print ads, the information that runs alongside of those ads, which I am sure you all have seen, is basically incomprehensible to the consumer and that information is supposed to relay the risks very clearly and lay out some of the problems and down sides of the drug.

We are working very hard. In 2001 we issued a guidance saying that if there was improved patient label, that could be run instead, and that is in consumer-friendly language. So more people are doing that. We would like to go further with that and develop some kind of standard format or something for that information so that consumers—because when they see a broadcast ad, they are really supposed to go to one of these other sources of information. That was the whole idea, but they are not very good right now.

Senator COLLINS. I guess I would question how effective that litany of possible side effects in a broadcast ad is, either. It seems like it is the same list for every drug. I am not sure that really registers with consumers and I think your survey would suggest that it does not. Perhaps that is something for you to look at, as well.

Some of the opponents of direct-to-consumer advertising say that the decisions on the use of prescription drugs should rest with doctors to make sure that they are based on the best scientific knowledge. They say that it confuses the issues for consumers to get involved. I do not agree with that, but to what degree do you think that marketing directed to physicians affects utilization? After all, every physician has the sales reps coming to his or her office, has seminars offered and other free samples and enticements to use particular drugs.

Dr. WOODCOCK. I am glad you asked that question because as a physician, I feel that is a much more powerful mechanism and it is the primary way of trying to move, I think, new products into doctors' offices and being prescribed and there is quite a bit more money, of course, spent on physician detailing and sampling than there is on direct-to-consumer advertising. We also, DDMAC also regulates that aspect of drug promotion.

Senator COLLINS. Finally, since you mentioned DDMAC, I did receive a response just this morning from the FDA to the letter that we sent last fall.

Dr. WOODCOCK. Yes.

Senator COLLINS. On the issue of the change in procedure delaying the FDA's ability to respond quickly to a misleading ad.

Dr. WOODCOCK. Yes.

Senator COLLINS. We currently have a proliferation of cable stations. From what I think you said to Senator Breaux, the companies do not have to submit ads in advance, which is troubling in some ways because you may be missing a whole lot of misleading ads.

But you are still taking 15 working days or more to work out internally the legal issues before such a letter can be issued. I think that is a problem because in some cases these ads will have run their course. It may be a 2-week media buy and if it is taking 15 working days, that is 3 weeks before your letter comes out.

Dr. WOODCOCK. Well, let me explain again. The companies do need to submit the information when it is aired, so we are re-

quired—now it may be that someone will violate that requirement and not submit it, but companies are required to submit the broadcast when it is aired.

Senator COLLINS. But not prior to its being aired.

Dr. WOODCOCK. That is right. Timeliness is an important factor. As we said earlier, that is something we are looking at. We are going to do everything possible and we can prioritize. If we see an ad that we really feel is detrimental to the public health, is giving a very bad misimpression or unbalanced message, we can act much more quickly.

Senator COLLINS. I would just note in closing that the GAO came up with two specific examples where the ad campaign for a popular selling drug had been run, and terminated before the FDA was able to issue its order.

Dr. WOODCOCK. Yes.

Senator COLLINS. I think we need to have a system that prevents that from happening and it seems to me one step would be to have submission prior to airing, not when the ad airs.

Dr. WOODCOCK. Well, that would likely require statutory change.

Senator COLLINS. Thank you, Mr. Chairman.

The CHAIRMAN. Susan, thank you and Dr. Woodcock, thank you very much. We appreciate you staying on. There may be additional questions of you following our next panel. Thank you.

Now let me ask our next panel to come forward and let me introduce them as they come. Marjorie Powell, Senior Assistant General Counsel at the Pharmaceutical Research and Manufacturers of America. Dr. Nancy Nielsen, Speaker of the House of Delegates of the American Medical Association and Senior Associate Dean of Medical Education at the University of Buffalo School of Medicine and Biomedical Science is with us. Also testifying will be Dr. Meredith Rosenthal from Harvard School of Public Health, who recently published a study on DTC advertising. Also—gee, Harvard gets double take today here—also from Harvard is Dr. Arnold Relman. Dr. Relman is a Distinguished Scholar and former Editor of the New England Journal of Medicine.

We thank you all for your patience and your presence here today and we will start with Marjorie Powell, Senior Assistant General Counsel, the Pharmaceutical Research and Manufacturers of America. Marjorie, welcome before the committee.

STATEMENT OF MARJORIE POWELL, SENIOR ASSISTANT GENERAL COUNSEL, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Ms. POWELL. Thank you, Mr. Chairman, members of the committee. It is a pleasure to be here. As the chairman said, my name is Marjorie Powell. I am the Senior Assistant General Counsel at the Pharmaceutical Research and Manufacturers of America or PhRMA for short, although those of us from New England occasionally are heard to say PhRMA.

The CHAIRMAN. Before you start your testimony let me say this. All of your full statements become a part of the record. We will ask you to adhere to a 5-minute rule. Thank you.

Ms. POWELL. Thank you. I would actually like to make three major points because all of my supporting information is in the record.

First, we think that direct-to-consumer advertising encourages patients to talk with their doctors about their symptoms, about health conditions, about their current treatments. The National Health Council, for example, which is an organization that includes the 50 leading patient organizations in the country, has said that they think the more information that patients have, the more effective they can be in working with their doctor to make decisions about their health care.

The FDA's study, which has been described, documents that patients think that information in direct-to-consumer advertising is helpful. A study by Prevention Magazine in 2002 reports that 61 million Americans talked with their doctors about an advertised medicine and 25 million of those patients were diagnosed as having a condition that had not been previously diagnosed. There are a number of other studies that support this same finding, although the exact figures or percentages vary from study to study.

The information that is presented in direct-to-consumer advertising informs patients about available treatments. In many cases it informs patients about treatments for diseases that were not treatable in the past, therefore encouraging them to talk with their doctors. It may inform them about a disease that is associated with a symptom that they have but they did not associate that with a disease or did not think it was a serious symptom.

They also inform patients about the existence of treatments for their diseases, treatments that in some instances doctors may not have talked with them about before. For example, a recent Health Affairs report of research indicates that approximately a third of physicians indicate they do not discuss treatments with their patients if they think the treatments are not covered by their patient's insurance. We think it is important for patients to have information about all available treatments, including ones that may not be covered. In many instances when the recommended treatment is a medicine, particularly a branded medicine, if the patient does not have insurance and cannot cover the cost of that medicine, all of the PhRMA member companies have patient assistance programs that will provide that medicine at no cost and many of the companies now have discount card programs as an interim until the conference committee resolves differences and both houses will pass a Medicare drug benefit; by the way let me congratulate you on moving as far as the effort has so far.

We also think that direct-to-consumer advertising encourages patients to take medicines once they have been prescribed. There are a number of reports that patients who see direct-to-consumer advertising for a drug that they are taking continue to take their medicine. In some cases it reminds them that they need to take it when they have stopped taking their medicine. Given the vast expense within the health care system that is caused by patients who receive prescriptions but then stop taking their medications, particularly prescriptions for chronic conditions where the symptoms are not so severe that the patient has a direct incentive to remem-

ber to take their medication, that it is really important to encourage patient compliance.

A number of the patient advocacy organizations also say that when a new medicine is advertised for the condition for which they are advocating, they receive an increase in the number of phone calls to their 800 line from people asking for information about that disease, either for themselves or for other people.

So the direct-to-consumer advertising has a benefit in educating patients and the general public about diseases and conditions and treatments that are available.

It is also true that when a patient talks with a physician about a drug that they have seen as the subject of direct-to-consumer advertising, the physician does not automatically write a prescription for that medication. In fact, in a large number of cases—in fact, I think the FDA figure is 22 percent—the physician directs the patient to change their lifestyle, either improve their diet or stop smoking or exercise or some other event.

We think that—and let me just conclude by saying that in this debate it is important to ask some additional questions and those would be, how would patients benefit if they were less likely to know about new treatment options, if they were less likely to report to their physician symptoms that are now untreated? What is both the human and the economic costs of untreated diseases within our health care system? How is it that people who oppose direct-to-consumer advertising propose to end the amount of undertreatment of serious conditions?

We think it is important that patients have information about treatments available and that direct-to-consumer advertising is one mechanism. Let me stop and I will be pleased to answer questions when the panel is finished.

[The prepared statement of Ms. Powell follows:]

The CHAIRMAN. Ms. Powell, thank you very much.

MARJORIE E. POWELL
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BEFORE THE

SENATE SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

July 22, 2003

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I am pleased to appear at this hearing today on direct-to-consumer (DTC) advertising. I am Marjorie Powell, Senior Assistant General Counsel at PhRMA.

The first print advertising of prescription medicines designed to reach consumers started in the early 1980's. From the 1980's until the mid-1990's, most pharmaceutical advertising was confined to print – newspapers and magazines. In 1997, the Food and Drug Administration (FDA) issued a draft guidance that made possible electronic or broadcast advertising of prescription medicines. This draft guidance was finalized in 1999.[1]

DTC advertising refers to information provided by pharmaceutical manufacturers to consumers, with the content of such information subject to regulation by the FDA. DTC advertising's purpose is to inform and educate consumers about treatable conditions, the symptoms that may help them identify the diseases, and available therapies. Research demonstrates that DTC advertising helps educate patients about medical conditions and treatment options, encourages dialogue between patients and physicians, prompts large numbers of Americans to discuss illnesses with their physicians for the first time, and promotes improved compliance with physician-prescribed treatments.

In light of the documented, pervasive patterns of undertreatment of serious medical conditions, such as asthma, depression, high cholesterol, diabetes, and many others, such outreach to patients is desperately needed. The failure to treat many patients—including those who are well insured for prescription drug costs—early in the course of disease leads to much avoidable suffering, higher health care costs, avoidable hospitalizations, and lost productivity for workers and employers. Notably, the critics of DTC advertising, such as some payers, discuss the human and economic costs of undertreatment addressed by DTC advertising.

DTC advertising also helps counterbalance other aspects of our health care system. Critics of DTC advertising, such as Blue Cross Blue Shield managed care companies, complain about the information provided to patients through DTC advertising, but do not highlight the fact that they routinely use a

wide array of powerful tools to affect which medicines patients will receive. The power of these tools is illustrated by new research in the journal *Health Affairs,* which reports that nearly one-third of physicians do not discuss treatment options with patients when those options would not be covered by the patient's insurer.[2] DTC advertising is thus a vital source of information about treatment options that balances the enormous power that corporations hold over patients' health care and the information patients receive about their treatment options.

Despite claims by some critics, there is no evidence that DTC advertising encourages inappropriate prescribing of prescription medicines. Utilization of pharmaceuticals is increasing for several reasons, including changing standards of medical care (evidenced, for example, by treatment guidelines) that emphasize greater use of medicines, the development of new and improved medicines, and treatment of previously untreated or undertreated patients. Notably, these trends are reflected in the growing use of disease management, which is perhaps the leading health care quality improvement and cost containment strategy in today's health system. While disease management programs often produce substantially increased spending on prescription medicines, they also lead to overall health care savings through avoidance of hospitalizations and other costly services and to better health outcomes.

There is no evidence to suggest that DTC advertising affects the price of medicine. To the contrary, studies that have examined this have found that there is no direct relationship between the amount of money spent on DTC advertising and price increases for a prescription drug.

In light of the extensive findings about the benefits of DTC advertising for patients, we believe the time has come to shift the burden in this debate to those who favor policies that would suppress the provision of FDA-regulated information to patients. The data support asking a new set of questions about DTC: How would patients be harmed if they were less likely to report untreated conditions to their physicians? How would patients be harmed if they were less likely to know about new treatment options? How would patients be harmed if they knew less about the risks and side effects of taking medicine? And what is the payers' and other critics' plan for ending the pervasive patterns of undertreatment that cause so much avoidable suffering and cost for patients?

It also is time to recognize that the debate about DTC advertising has been framed by false assumptions. While DTC advertising is pointed to by some critics as driving spending on prescription medicines to unaffordable levels, the fact is that prescription medicines account for just ten cents out of the health care dollar. According to data reported to the National Committee for Quality Assurance (NCQA) by managed care companies themselves, in 2001, HMOs spent an average of just $32.45 per member per month on prescription medicines (in the commercial sector)—including the combined cost of brand name and generic drugs, and prescription benefit manager and pharmacy services.[3] Moreover, this figure includes both what the HMO spent directly and the patient's own out-of-pocket spending on medicines. In light of this modest cost and the fact that underuse of medicines is itself generating large, avoidable

costs, we hope that the Committee will reject the erroneous claims and focus on how we can best get patients information they need to obtain the best possible medical care.

DTC Advertising and the Physician-Patient Relationship

DTC advertising strengthens the patient-physician relationship, by prompting patients to tell their physician about previously undisclosed conditions—communication that is an essential foundation for a good physician-patient relationship—and also by educating patients about the risks as well as benefits of treatment options.

Physicians should and do remain in control of prescribing medicines. Survey data consistently show that when patients ask a physician to prescribe a DTC-advertised medicine, many receive a different medicine or a non-pharmaceutical alternative. Results from the 2002 FDA survey of consumers found that, among the minority of respondents who said advertisements had caused them to talk with a physician and ask for a drug, less than half said their doctor gave them the prescription drug they asked about.[4]

According to *Prevention Magazine's* 2002 survey, 32 percent of consumers, or an estimated 61.1 million people, have talked with their doctor about an advertised prescription medicine. Of those consumers, 29 percent asked their doctors to give them a prescription for the medicine they saw advertised. Sixty percent of consumers who ask about advertised medicines say their doctors have recommended non-drug therapies in response to their questions.[5]

DTC advertising's purpose is to encourage patients to talk to their physicians about their medical conditions and treatment options. In fact, every television advertisement for a prescription must include a message that viewers should ask their physician or pharmacist about the product. Such discussions are beneficial – for the patient in gaining an understanding of the physician's treatment recommendation, and for the physician in gaining a better understanding of the patient's needs. Notably, results from the 2002 FDA consumer survey found that most patients prompted by DTC advertising to discuss a drug with their doctor stated that their doctor welcomed the question (93%), discussed the drug with the patient (86%), and reacted as if the question were an ordinary part of the visit (83%).

The physician-patient relationship is strengthened, not weakened, when, as surveys show, DTC advertising prompts a patient to talk with a physician for the first time about a previously undiscussed condition, improves patient compliance with physician-prescribed treatment regimens, or adds to patient information of medicines' risks and side effects and who should not take a drug. The 2002 *Prevention Magazine* survey found that 24.8 million Americans spoke with their doctor about a medical condition for the first time as a result of seeing a DTC advertisement.

Another survey found that the majority of physician respondents believe that patients' awareness of DTC advertisements had a beneficial effect on office visits. Additional benefits of DTC advertising noted in the survey included:

- 85 percent of physicians treating high cholesterol conditions and 83 percent of physicians treating mood/anxiety disorders report that the drug discussed were appropriate for the patient.
- 54 percent of physicians treating high cholesterol conditions and 55 percent of physicians treating mood/anxiety disorders agree that the advertisement was influential in getting the patient to discuss their condition with a medical professional.
- For both high cholesterol and mood/anxiety disorders, 80 percent or more of physicians were satisfied with the outcome of office visits where advertisements were mentioned.[6]

A survey by the National Medical Association (NMA), the nation's oldest and largest African-American medical association, representing more than 25,000 African-American physicians, found that DTC advertisements raise disease awareness and bolster doctor-patient ties. According to NMA President, Dr. Lucille Perez:

> Doctors are finding that these ads are helping our patients talk to us about medical conditions they're at risk for. When you consider that the majority of drugs advertised can treat the diseases that disproportionately affect the African-American community, there is incredible potential. These ads can increase disease awareness that may be a beneficial tool to decrease the rampant disparities in the health of the community. The NMA will advocate for increasing the awareness of the disease states in such advertisements. Further, we must view them as one of several tools that are potentially beneficial to the physician-patient dyad.[7]

DTC Advertising and its Value to Patients

Informing Patients

In addition to encouraging discussion between patients and physicians, surveys indicate that DTC advertising makes consumers aware of new drugs and their benefits, as well as risks and side effects with the drugs advertised. The results from the FDA's 2002 consumer survey indicate:

- 90 percent of consumers surveyed recalled seeing television advertisements that contained information about the "benefits of the drug"
- 90 percent recalled information about "risks or side effects," and

- 89 percent recalled information about "who should not take the drug," and
- 86 percent recalled "how to get more information."

A survey by Kaiser Family Foundation confirmed the FDA survey results. The Kaiser survey found that a large majority of those who viewed a DTC advertisement said that the advertisement did an excellent or good job telling them about the condition the medicine is designed to treat (84%), the potential benefits of the medicine (72%), and who should take the drug (66%).[8]

As a *New England Journal of Medicine*[9] article points out, DTC advertising is concentrated among a few therapeutic categories. These are therapeutic categories in which consumers can recognize their own symptoms, such as arthritis, seasonal allergies, and obesity; or for pharmaceuticals that treat chronic diseases with many undiagnosed sufferers, such as high cholesterol, osteoporosis, and depression; and for pharmaceuticals that enhance quality of life, such as those for skin conditions and hair loss. These advertisements help consumers recognize symptoms and seek appropriate care.

Empowering Patients

DTC advertising empowers consumers and enhances public health. The FDA 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."[10] A 1999 survey by *Prevention Magazine* found that consumers give high marks to pharmaceutical advertising. Of those surveyed, 76 percent felt DTC advertisements allowed them to become more involved in their own health care. The survey established that, "the benefits of DTC [direct-to-consumer] advertising could go far beyond simply selling prescription medicines: these advertisements play a very real role in enhancing the public health."[11]

A study released by the National Health Council, whose constituency includes nearly 50 of the country's leading patient organizations representing nearly 100 million Americans with chronic diseases and/or disabilities, notes the positive impact DTC advertising can have, "The more information patients have, the more effective they can be in working with their doctor to make decisions about their health care....The Council recognizes that DTC advertising provides important information to consumers and patients, which is beneficial to their health."[12]

The benefits of advertising have been recognized by other elements of the health care sector who also advertise, including hospitals, doctors and insurers. Pharmaceutical manufacturers are not the only participants in the health care sector who advertises.

Underdiagnosis and Undertreatment of Disease

DTC advertising appears to help address some of the problems related to undertreatment and underdiagnosis of disease. DTC advertising brings patients

into doctors' offices and allows physicians to treat people who might otherwise go undiagnosed or untreated. As stated previously, the 2002 *Prevention Magazine* survey found that 61.1 million Americans since 1997 were prompted by a DTC advertisement to talk to a doctor about a medical condition they previously had not discussed.[13] According to *DTC Monitor* findings, 28 percent of those who contacted a doctor because of DTC advertising report that it was the first time they talked to their doctor about a condition. In addition, 22 percent reported that the advertising prompted them to talk to a doctor earlier than they would have otherwise.[14]

Surveys of DTC advertisements for genital herpes provide compelling results. The Centers for Disease Control (CDC) estimate that 45 million Americans over age 12 carry the virus that causes genital herpes. Yet, only about 4.5 million Americans, or just one in ten, are being treated. Surveys indicate that DTC advertisements have helped increase the number of patients aware of the disease and have increased the number of newly diagnosed patients. For example, 34 percent of physicians surveyed by Scott-Levin stated that they had seen a significant increase in the number of newly diagnosed patients after advertisements for medicines to treat genital herpes began to air.[15] In another survey, 67 percent of consumers who were aware of a genital herpes advertisement felt that the advertisements provided a valuable service in educating the public.[16]

According to a new Harvard/Harris survey, DTC adverting led to the diagnosis of a large number of "high priority" conditions. The survey found that, one-quarter of adult patients who visited their physician after seeing a DTC ad received a new diagnosis of a condition. Some of the most common new diagnoses that were discovered as a result of these visits --high cholesterol, hypertension, diabetes, and depression -- are often underdiagnosed and undertreated in the general population. Furthermore, the survey found that approximately 43 percent of new diagnoses and 51 percent of existing diagnoses were for "high priority" conditions according to the Agency for Healthcare Research and Quality (AHRQ) and Institute of Medicine (IOM) criteria.

On June 26, 2003, *The New England Journal of Medicine* published, "The Quality of Health Care Delivered to Adults in the United States." The study, which was conducted by RAND Health, the nation's largest independent health-policy research organization, and funded by The Robert Wood Johnson Foundation, found that nearly half of all adults in the United States fail to receive recommended health care.

According to researchers on the RAND study, "the deficiencies in care...pose serious threats to the health of the American public that could contribute to thousands of preventable deaths in the United States each year." More specifically, the study found that only 45 percent of patients with diabetes received the care they need; only 68 percent of patients with coronary artery disease received recommended care; only 45 percent of heart attack patients received medications that could reduce their risk of death; only 54 percent of

patients with colorectal cancer received recommended care, and less than 65 percent of patients with high blood pressure received recommended care. According to lead study author Elizabeth A. McGlynn, Ph.D., Associate Director of RAND Health, "Even people who had health insurance and access to health care services failed to receive some elements of good care. This suggests that just being able to get in the door to see a doctor is no guarantee that you'll receive the care you need."

For nine of the fifteen conditions that were selected and classified by RAND to determine underuse or overuse of health care services, medicines are the recommended treatment option. Of those nine conditions, underuse of medicines occurred in seven of them. These conditions include: asthma, cerebrovascular disease, congestive heart failure, diabetes, hip fracture, hyperlipidemia, and hypertension. According to the data set used in the RAND study, 83 of the 103 measures of quality for medication treatment or immunization showed undertreatment.

The Rand Study, as well as other recent studies published in *The Journal of American Medicine*[17] (JAMA) and *Health Affairs*,[18] highlight the underuse of needed medications and other healthcare services in the U.S.

- According to a nationally representative study of 9,090 people aged 18 and up published in JAMA, about 43 percent of participants with recent major depression are getting inadequate therapy.

- According to the article in *Health Affairs,* "During the course of a year, 31 percent [of physicians] reported having sometimes not offered their patients useful services because of perceived coverage restrictions. Among these, 35 percent reported doing so more often in the most recent year than they did five years ago."

- In addition, according to data from the NCQA's *Quality Compass®* 2002, there is significant undertreatment of asthma and depression of patients in managed care plans. Data reported in NCQA for people with asthma shows that, for each of three age groups examined, approximately two-thirds of the commercial population with asthma met the standard for use of appropriate medications. These scores are several points higher than observed in earlier years, but the remaining gap (one-third of patients) suggests that initiatives to increase appropriate use of medicines to treat asthma would be highly beneficial.

- In addition, in 2001 NCQA reported that relatively low percentages of the commercial population with depression received care meeting quality standards for antidepressant medication management. In particular, only 40.1 percent of patients with depression "received effective continuation phase treatment by remaining on antidepressant medication continuously in the six months after the initial diagnosis and treatment."

Reasons for underuse cited in the RAND study include availability of information on health care performance at all levels, non-adherence to practice guidelines, and an outdated health information system. The authors of the RAND study recommend "a major overhaul" of the "current health information system, with a focus on automating the entry and retrieval of key data for clinical decision making and for the measurement and reporting of quality" and "establishing a national base line" for performance to "asses the effect of policy changes and to evaluate large-scale national, regional, and state efforts to improve quality."

De-Stigmatizing Disease

DTC advertising also encourages patients to discuss medical problems that otherwise may not have been discussed because the disease was either thought to be too personal or that there was a stigma attached to it. For example, a *Health Affairs* article examined the value of innovation and noted that depression medications, known as selective serotonin reuptake inhibitors (SSRIs) have led to significant treatment expansion. Pharmaceutical manufacturers of SSRIs have advertised them to consumers. Prior to the 1990's, it was estimated that about half of the persons who met a clinical definition of depression were not appropriately diagnosed, and many of those who were diagnosed did not receive clinically appropriate treatment. However, in the 1990's with the advent of SSRIs, treatment has been expanded. According to the article, "Manufacturers of SSRIs encouraged doctors to watch for depression and the reduced stigma afforded by the new medications induced patients to seek help." As a result, diagnosis and treatment for depression doubled over the 1990's.[19]

Encouraging Compliance

Another benefit of DTC advertising is its ability to encourage compliance with physician-prescribed treatment regimens. Lack of compliance is a critical problem in achieving effective medical care. According to the 2002 *Prevention Magazine* survey, 17 percent of consumers said DTC advertising made it more likely (versus 2 percent less likely) they would take their medicine regularly and 12 percent of respondents reported that DTC advertisements made them more likely to refill prescriptions.[20]

This is particularly important given the estimated costs of non-compliance. According to an article in the *Journal of Research Pharmaceutical Economics*, 5.5 percent of all hospital admissions are due to non-compliance, which results in $8.5 billion annually in unnecessary hospital expenditures, plus another $17-$25 billion in estimated indirect costs.[21]

A June 2001 study by Pfizer and RxRemedy found that the percentage of diabetes, depression, elevated cholesterol, arthritis and allergy patients who remained on therapy after six months was significantly higher when the patient asked for a medicine with prompting from DTC advertising than when the patient was prescribed a medicine without such prompting.[22] This suggests the

advantages of consumers being involved with their health care and DTC advertising's role in encouraging such involvement.

What Accounts for Growth of DTC Advertising and Why it Plays a Valuable Role in the Health Care System

Patients are increasingly turning to the growing volume of accessible health care information and thus, are moving us towards a more patient-focused health care system. Given this trend, DTC advertising is widely employed throughout our health care system—managed care organizations, hospitals and doctors all advertise to consumers. Unlike much other health care information, DTC advertising for prescription medicine is subject to intense scrutiny for accuracy and balance by FDA regulators. Every DTC advertisement – in print or electronic form – must:

- Be accurate and comply with the drug's FDA-approved labeling; and
- Contain "fair balance" – that is, an explanation of the risks and effectiveness of the drug.

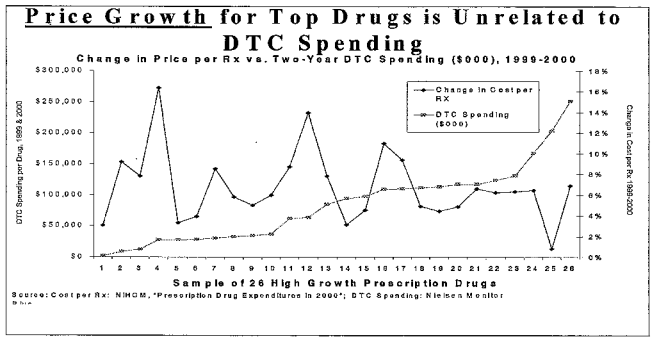
Every print advertisement must include a detailed description of the risks. Every electronic advertisement must include a statement on the major risks and provide additional ways for consumers to obtain more information. Strict FDA requirements help make DTC advertising of prescription drugs reliable and accurate.

Another environmental change that increases the value of DTC advertising of medicines is its ability to balance efforts by other health system participants, such as managed care plans, to influence the delivery of medical care. The strongest tools used by third parties to influence which medications patients receive may include: provider payment incentives that are linked to provider prescribing and dispensing patterns; formularies, which typically are structured in part based on the managed care plan's financial considerations; variable patient cost-sharing arrangements, again based in part on financial considerations; therapeutic interchange; and prior authorization. In light of these strategies designed to influence the medicines that patients receive, patients' ability to obtain information about their treatment options through DTC advertising is a healthy development that helps add balance to the system. With so many parties, including those critical of DTC advertising, using such care-limiting incentives yet encouraging patients to assume increased responsibility for their medical care, it is surprising that conveying FDA-regulated information to consumers has engendered controversy.

Increased Pharmaceutical Utilization and the Role of DTC Advertising

Payers' have questioned the effect of DTC advertising on prescription drug prices. However, the evidence shows there is no direct relationship between DTC advertising and the price growth of drugs.[23] For example, one

popular osteoarthritis drug had the highest DTC advertising spend of any brand-name medicine in 2000. Yet, the price increase from 1999 to 2000 was 3.9%, less than half a percent above the consumer price index (CPI). A common mood and anxiety disorder drug had no DTC advertising spending in 2000, but the price increase was roughly equal (3.1%) to the price increase for the most heavily advertised osteoarthritis drug. Neither price increase was out of line with CPI.[24]



It is also important to remember that spending on pharmaceuticals remains a small portion of the health care dollar. Of every health care dollar spent in the U.S., only about 10 cents is spent on prescription medicines. While drug spending continues to grown, it remains a very small share of national spending.

DTC advertising may affect utilization, by prompting treatment of more patients for previously untreated conditions and improved compliance. If so, this is a positive development. Proper use of pharmaceuticals is often the most effective and least expensive form of health care. Notably, the FDA testified in July 2001 that "there is no evidence that [DTC advertising] is increasing inappropriate prescribing."[25]

According to a 2002 study on cholesterol-lowering statins, which are DTC-advertised, there is "no statistically significant effect from any form of advertising and promotion on new statin prescriptions or renewals and no evidence of adverse market effects from advertising..."[26] These finding are supported by another recent study that looked at whether pharmaceutical marketing has led to an increase in use of medications by patients with marginal indications. The study found that high-risk individuals were receiving lipid-lowering treatment "consistent with evidence-based practice guidelines" despite the fact that "a substantial portion of patients continue to remain untreated and undertreated..."[27] The study concluded that "greater overall use did not appear to be associated with a shift towards patients with less CV [cardiovascular] risk." As Jack Calfee,

American Enterprise Institute, has observed, "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...."[28]

There are a multitude of reasons why pharmaceutical utilization is increasing other than DTC advertising. In fact, according to a June 2003 study of DTC advertising commissioned by the Kaiser Family Foundation and conducted by researchers at the Harvard School of Public Health, Massachusetts Institute of Technology, and Harvard Medical School, "[O]ur estimates indicate that DTCA is important, but not the primary driver of recent growth [in prescription drug spending]."[29] Other reasons pharmaceutical utilization is increasing, include:

- Development of Improved Medicines
- New Standards of Medical Practice Encouraging Greater Use of Pharmaceuticals
- Treatment of Previously Untreated Conditions
- Greater Attention to Preventing and Managing Disease
- Structural Shift to Prescription Drugs
- Aging of Population

1. **Improved Medicines**. The development of new and improved medicines accounts for much of the increase in prescription drug spending. For example, new medicines for serious mental illnesses are revolutionizing treatment. According to a study prepared for the Department of Health and Human Services, "[n]ew medications are not simply more costly than older ones. They may be more effective or have fewer side effects; some may treat conditions for which no treatment was available."[30]

2. **New Standards of Medical Practice Encouraging Greater Use of Pharmaceuticals**. According to guidelines set forth by an advisory group to the National Heart, Lung and Blood Institute in May 2001, 36 million Americans should be taking cholesterol-reducing drugs.[31] However, because high cholesterol does not cause obvious symptoms and detection requires a blood test, as few as 42 percent of those affected by it have been diagnosed.[32] According to the Institute's Director, if the recommendations were followed, heart disease would no longer be the leading cause of death.[33] In another example, medical standards for diagnosing, treating, and monitoring diabetes have changed significantly. In the late 1990s, the level of fasting blood glucose used for diagnosing diabetes was lowered from 140 mg/dl to 126 mg/dl because studies showed that patients with the higher fasting blood sugar levels were already developing the complications of diabetes when they were diagnosed.[34] Diagnosing patients earlier and providing them with

appropriate medications can help regulate blood sugar levels and prevent or delay these complications.

3. **Treatment of Previously Untreated Patients**. The number of Americans treated for depression has grown from 1.7 million to 6.3 million over the last decade. A primary reason was the broadening of pharmaceutical options available to treat depression, including a new class of antidepressants that tend to have fewer side effects.[35] These new medications have lowered the total cost of treating depression at the same time they have made treatment more effective – accounting for much of the decline in health insurers' spending on mental health. While pharmaceutical treatments have advanced, the price of treating acute major depression fell by 25 percent over 1991-95.[36] This reflects, among other things, increasing the pharmaceutical component and reducing the intensity of psychotherapy.

4. **Greater Attention to Preventing and Managing Disease**. Increased emphasis on diagnostic and screening programs, which increase the odds of identifying conditions that might otherwise go undiagnosed until an illness becomes acute, often means greater drug use. For example, the number of Americans diagnosed with diabetes jumped 49% from 1990 to 2000.[37] Likewise, disease-management – a strategy embraced by many health plans – often involves greater use of medicines. In a year-long disease-management program for about 1,100 patients with congestive heart failure run by Humana Hospitals, pharmacy costs increased by 60 percent, but a 78 percent drop in hospital costs produced $9.3 million in net savings.[38]

5. **Structural Shift to Prescription Drugs**. In a *Health Affairs* article, J.D. Kleinke explained that a shift from traditional medical services to consumption of medical products is taking place. Kleinke noted that the clearest example of this is a decade-long reduction in hospital admissions and lengths of stay.[39]

6. **The Aging of America**. The aging of America translates into greater reliance on pharmaceuticals to restore and/or maintain health. For example, congestive heart failure affects an estimated 2 percent of Americans age 40 to 59, more than 5 percent of those aged 60 to 69, and 10 percent of those 70 or more.[40]

Economic Value of DTC Advertising

Increased spending on pharmaceuticals often leads to lower spending on other forms of more costly health care. New drugs are the most heavily advertised drugs, a point critics often emphasize. However, the use of newer drugs tends to lower all types of non-drug medical spending, resulting in a net

reduction in the total cost of treating a condition. For example, on average replacing an older drug with a drug 15 years newer increases spending on drugs by $18, but reduces overall costs by $111.[41]

The Tufts Center for the Study of Drug Development reports that disease management organizations surveyed believe that increased spending on prescription drugs reduces hospital inpatient costs. "Since prescription drugs account for less than 10 percent of total current U.S. health care spending, while inpatient care accounts for 32 percent, the increased use of appropriate pharmaceutical therapies may help moderate or reduce growth in the costliest component of the U.S. health care system," according to Tufts Center Director Kenneth I. Kaitin.[42]

How Much Does DTC Advertising Cost

Opponents of DTC advertising often try to compare the amount of money spent by drug companies on marketing and advertising to the amount they spend on research and development of new drugs.

IMS Health reports that $21 billion was spent in 2002 on all pharmaceutical promotion for all pharmaceutical manufacturers, including non-PhRMA members.[43] (This is data that is publicly available.) This includes $12 billion in free samples and $2.6 billion on DTC advertising. In comparison, PhRMA members spent an estimated $32 billion in R&D in 2002.[44] ***In fact, IMS is the data source the General Accounting Office (GAO)[45] used in its recent report in which it reported that pharmaceutical manufacturers spend significantly more on R&D than on all promotional activities combined.***

DTC Advertising and Commercial Free Speech

DTC advertising, like all speech that "propose[s] a commercial transaction," is commercial speech.[46] Since DTC advertising is a form of commercial free speech it is constitutionally protected by the First Amendment.[47] The U.S. Supreme Court has defined commercial free speech as "expression related solely to the interests of the speaker and its audience."[48] Accordingly, the government is only allowed to challenge such acts or practices that are deceptive, lack proper substantiation, or are unfair.[49] The term "deceptive" means information that is misleading or omitted for purposes of changing the consumer's perception.[50]

The FDA's Division of Drug Marketing and Communication (DDMAC) is in charge of drug advertising oversight to ensure that DTC advertisements for prescription drugs are in compliance with FDA's rules and regulations determining "fair balance" and "adequate provision" of information about benefits and risks and sources to obtain additional risk and benefit information. Because DTC advertisements are highly regulated, and because companies have an interest in ensuring their ads are accurate and provide fair balance, pharmaceutical companies routinely subject all DTC advertisements and other

promotional material to rigorous medical, regulatory and legal review before they are ever disseminated. Although pharmaceutical manufacturers are not required by law to submit their broadcast advertisements to DDMAC for prior review, a majority of sponsors do voluntarily submit them for DDMAC's review and comment at some point before the materials are finalized.[51] If an advertisement is in violation of FDA rules or regulations, FDA does have remedies. For example, FDA can require that the violative promotion be stopped immediately. It can also require that the manufacturer conduct a remedial campaign to correct any misimpressions left by the advertisement.[52]

Most surveys of patients and physicians have demonstrated that DTC advertisements are an effective tool to educate and inform consumers about their health and health care choices. Government cannot impose restrictions on commercial free speech, including DTC advertising, unless warranted by some essential governmental interest. The current FDA regulatory system helps ensure that advertisements abide by the necessary requirements and that they provide reliable and accurate information to consumers.

Conclusion

DTC advertising provides tremendous value to patients by making them aware of risks and benefits of new drugs; it empowers patients and enhances the public health; it plays a vital role in addressing a major problem in this country of undertreatment and underdiagnosis of disease; DTC advertising encourages patients to discuss medical problems with their health care provider that may otherwise not be discussed due to a stigma attached to the disease; and it encourages patient compliance with physician-directed treatment regimens.

Although drug expenditures in recent years have continued to rise, prescription drugs still remain a very small share of total health care spending, constituting only 10 cents out of every health care dollar. To the extent that drug spending is increasing, increased utilization of pharmaceuticals is driving that increase, not price increases. Although DTC advertising may affect utilization, by prompting treatment of more patients for previously untreated conditions and improving patient compliance with physician directed treatment, this is a positive development. Proper use of pharmaceuticals is often the most effective and least expensive form of health care.

DTC advertising clearly is here to stay, and will best realize its potential as physicians "develop strategies for helping their patients evaluate this information and make appropriate and informed treatment choices."[53] With such a diversity of treatment options available for acute and chronic diseases, patients need the guidance that only a trusted health professional can provide. The health care system is stronger as a consequence. DTC advertising does not replace that relationship; rather, its purpose is to encourage an informed discussion between patient and physician.

This concludes my written testimony. I would be happy to answer any questions or to supply any additional materials by Members or Committee Staff on this or any other issue.

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Now let us turn to Dr. Nancy Nielsen, speaker of the House of Delegates, the American Medical Association.

STATEMENT OF NANCY NIELSEN, M.D., PH.D., SPEAKER OF THE HOUSE OF DELEGATES OF THE AMERICAN MEDICAL ASSOCIATION, WASHINGTON, DC

Dr. NIELSEN. Thank you, Mr. Chairman, and thank you to the members of the committee. It is a pleasure to be here.

I am Nancy Nielsen. I am an internist from Buffalo, NY and I am speaker of the House of Delegates of the American Medical Association. On behalf of our physician members and our medical student members, we are pleased to offer you our perspective on this important issue.

I brought with me some examples but you have already referred to them, about the multiplicity of magazine ads. You have already heard from both the chair and other members of the committee about TV ads. Nobody can help but notice there has been a dramatic increase in these numbers.

Patients see those ads. They then go to their physician and they ask for a prescription for a specific drug, even before a diagnosis is made. Back in 1998 the AMA developed an ethical opinion to help physicians deal responsibly with those kinds of ads. We also developed policy to help define what, to us, are acceptable direct-to-consumer ads. You have heard that mentioned by Dr. Woodcock and by the chair. Our written testimony contains the details of our written policy and I will not comment further unless there are questions.

This kind of advertising is legal, it is widespread, and it is probably here to stay. That being said, it remains controversial and we have some concerns. First, most physicians believe that these ads are marketing, not education. The AMA absolutely supports patients' access to information about drugs but the real question is whether drug advertising designed to sell a product provides the type of objective and accurate information that patients need.

What about fair balance and explanation of risks? The print ads have to provide the full disclosure but as you, Mr. Chairman, mentioned, it is real tough to read. When you go to broadcast ads, that is very different. Only the major risks have to be mentioned. Remember the girl prancing through the field of flowers and ragweed? Do any of you recall the risks that were described when that ad was running?

A 1999 study found that fully one-half of patients incorrectly believed that the ads were preapproved by the FDA and 43 percent incorrectly believed that only risk-free drugs were advertised. These misconceptions may give consumers a false sense of security that prescription drugs are risk-free.

What about the impact on the doctor-patient relationship? Consumer surveys suggest that these ads do increase the number of visits to physicians, some of which do lead to new diagnoses and to a more informed discussion. That is the good news. However, these ads also increase demand for specific drugs.

Last weekend CNN aired a story on a treatment for attention deficit disorder in adults. I do not know if any of you saw it. There is only one approved drug for this condition. TV and radio ads for

this drug center around some screening questions for consumers. Now hold on and see how you would answer these questions. Here are a few of them.

How often do you feel restless and fidgety? When you have a task that requires a lot of thought, how often do you avoid or delay getting started? If you answer even sometimes to these questions, the ads suggest you have symptoms consistent with ADD and a visit to the doctor is recommended. Education or advertising? You decide. We have a hotline in the back if anybody wants to set up a visit to their physician right away.

You have heard about some reports in Health Affairs. Let me talk about another one that I have not heard mentioned. There was a study reported in Health Affairs in which half of patients said they would be disappointed if their physician did not write the prescription they requested. A quarter said they would try to change their physician's mind. A quarter thought they might go to another doctor to get the drug and 15 percent thought they would change doctors.

You have heard about the GAO report. The question is the increased utilization and spending appropriate? Were these drugs underutilized before or is this wasteful spending and would less expensive alternatives or no drug at all work just as well.

In conclusion, we have three recommendations for the committee. First, there is room to improve the educational value of these ads and we urge the pharmaceutical industry to follow the AMA's guidelines. Second, more independent research on these ads is needed to determine their impact on the patient-physical relationship. Third, the FDA must be adequately funded by Congress to carry out its oversight role and to use enforcement when necessary.

Thank you for the opportunity to speak before you.

[The prepared statement of Dr. Nielsen follows:]

American Medical Association
Physicians dedicated to the health of America

1101 Vermont Avenue, NW
Washington, DC 20005

Statement

to the

Special Committee on Aging
United States Senate

RE: Direct to Consumer Advertising of Prescription Drugs: Exploring the Consequences

Presented by: Nancy H. Nielsen, MD, PhD

July 22, 2003

Division of Legislative Counsel
202 789-7426

STATEMENT

of the

American Medical Association

to the
Special Committee on Aging
United States Senate

Presented by Nancy H. Nielsen, MD, PhD
Speaker, House of Delegates
American Medical Association

RE: DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS: EXPLORING THE CONSEQUENCES

July 22, 2003

Mr. Chairman and members of the Committee, good morning. My name is Dr. Nancy H. Nielsen. I am an internist from Buffalo, New York, and the Speaker of the American Medical Association (AMA) House of Delegates. On behalf of the physician and medical student members of the AMA, I am honored to have been invited to discuss with the Committee the AMA's perspective on the role of direct-to-consumer advertising (DTCA) in health care, including its impact on the physician-patient relationship, its role as a source of information for patients, and its other potential benefits and disadvantages.

Introduction

Direct-to-consumer advertising has become widespread in recent years and is well known to most American households. Anyone who watches a commercial television program or reads

newspapers or magazines cannot help but notice the dramatic increase in the number of prescription drug ads. According to a recent report by the Kaiser Family Foundation, consumer surveys indicate that the percentage of people who report they have seen an advertisement for a prescription drug on television or heard one on the radio more than doubled between 1993 and 2000, hitting 81% by 2002.[1] Many physicians report that their patients have asked them about drugs as a direct consequence of DTCA, and some estimates indicate that as many as 25% of Americans have asked their physicians about a drug as a result of seeing an advertisement.[2]

The growth in spending on DTCA between 1989 and 2001 has been truly phenomenal: in 1989, the pharmaceutical industry spent only $12 million on DTCA, compared to $2.7 billion in 2001.[3] Since 1994, total spending on DTCA has grown nearly tenfold.[4] Pharmaceutical companies have increased spending on DTCA faster than they have increased spending on research and development. Between 1997 and 2001, spending on DTCA increased 145 percent, while research and development spending increased only 59 percent.[5] Over 70% of DTCA in 2001 was spent on TV ads.[6]

While common and legal, product-specific advertising of prescription drugs directly to consumers remains controversial in the health care arena generally and among AMA's member physicians specifically. Proponents argue that DTCA provides another mechanism to educate consumers about health conditions and possible treatments, which makes them more informed consumers and enables them to take a more active role in their health care. They also believe that after viewing or reading an advertisement for a prescription drug,

patients will seek out their physicians and have a more knowledgeable discussion about their health condition, and if applicable, possible treatment options.

Opponents of DTCA, including many physicians, argue that DTC advertisements are simply promotional marketing and lack educational value, and may mislead consumers into believing that they need the advertised medication. This, in turn, may adversely affect the physician-patient relationship, lead to inappropriate prescribing, increase utilization and health care costs and potentially, result in adverse health outcomes.

The AMA has been, and continues to be, concerned about the possible negative impact of DTCA on the physician-patient relationship and its impact on the already spiraling increase in prescription drug costs. The latter concern is particularly relevant now, as Congressional negotiators are debating the details of adding a prescription drug benefit to the Medicare program. The AMA is also concerned about the need to adequately fund the Food and Drug Administration (FDA) so that it can carry out its enforcement role over DTCA, as well as provide funding for quality, independent research on the impact of DTCA. These concerns are discussed in more detail later in this testimony.

History of DTCA and AMA Policy

Prescription drug advertising in the United States historically was focused mainly on physicians, who were the sole decision-makers in terms of choosing prescription drugs. In the early 1980s, as patients became more involved in their treatment, the pharmaceutical industry began marketing prescription drugs directly to consumers. Many, including the AMA, were

vigorously opposed to this, primarily on the grounds that these products were complex, not without risk, and required a prescription in order to be dispensed.

The FDA imposed a moratorium on DTCA in 1983, then lifted it in 1985, after concluding that it lacked the legal grounds to prevent this form of advertising. FDA mandated that DTC advertisements must meet the same requirements as prescription drug advertising for health professionals. Thus, DTC ads must not be false or misleading, must present a fair balance between effectiveness and risk information, and must reveal material facts, i.e., list all risk concepts in the form of a so-called "brief summary."

Until 1992, the AMA remained opposed to product-specific DTCA. However, as such advertising gradually became more common in print media, primarily magazines, the AMA reassessed its position. In 1992, the AMA's House of Delegates (our policy-making body) adopted a new position that allowed the AMA, on a case-by-case basis, to accept disease-specific, health education consumer advertisements, which may include mention of brand-name prescription drugs. In 1993, with input from the FDA, the AMA developed guidelines for an acceptable DTC advertisement.

Perhaps the most significant event in recent years regarding DTCA was the FDA's publication of a "draft" Guidance in 1997 which proposed to relax the requirement for presenting all of the risk information, i.e., the brief summary, in all broadcast advertisements – the primary focus being on television ads. The FDA stated that the so-called "adequate provision" could be met if the advertisement listed major risk information and provided four

referrals for full prescribing information – (1) see your doctor or pharmacist; (2) a 1-800 number for the pharmaceutical company; (3) an Internet address for the company; and (4) a reference to a print advertisement for the product. As a result, both the extent and frequency of advertisements for prescription drugs significantly increased in both print and broadcast media.

In 1997, the AMA sent a letter to the FDA expressing its concerns about the potential adverse impact that expanded DTCA might have on the physician-patient relationship and the potential for negative public health and economic outcomes. The AMA asked the FDA to survey physicians on the impact of DTCA on their practices and to do an economic analysis of the impact of widespread DTCA. The FDA, however, published a final guidance on DTCA in broadcast media in 1999 that was essentially the same as the draft guidance, without doing a physician survey or economic analysis.

While the AMA continued to be concerned about DTCA, our House of Delegates decided that a proactive approach needed to be taken. In 1998, the AMA's Council on Ethical and Judicial Affairs (CEJA) developed an ethical opinion (E-5.015) to help our profession and individual physicians deal responsibly with DTCA for the best interests of their patients. Then, in 1999 the AMA House of Delegates adopted as policy a series of recommendations from an AMA Board of Trustees report on DTCA. The AMA's intent was both to help define what are satisfactory DTC advertisements and to advocate for the necessary research to assess the impact of DTCA on the patient-physician relationship as well as on health and economic outcomes. This policy (H-105.988) was modified slightly in December of 1999, reaffirmed in

June 2000, and again slightly modified in December of 2000 and June of 2001. The policy continues to be revisited and modified as circumstances warrant.

Current AMA Policy on DTCA

Under AMA policy, only those product-specific DTC advertisements that follow the guidelines that were developed by the AMA, in consultation with the FDA in 1993, are acceptable. AMA policy includes the following guidelines:

a) The advertisement should be disease-specific and enhance consumer education;
b) The ad should convey a clear, accurate and responsible health education message (i.e., information on the prevention or treatment of a disease, disorder, or condition);
c) In all cases, the ad should refer patients to their physicians for more information;
d) The ad should not encourage self-diagnosis and self-treatment, but should identify the consumer population at risk;
e) Discussion of the use of the drug product for the disease, disorder, or condition should exhibit fair balance;
f) Warnings, precautions, and potential adverse reactions associated with the drug product should be clearly explained so as to facilitate communication between physician and patient;
g) No comparative claims can be made for the product. In the interest of fair balance, alternative non-drug management options for the disease, disorder, or condition can be included;

h) The brief summary information should be presented in language that can be understood by the consumer;

i) The advertisement must comply with applicable FDA rules, regulations, policies and guidelines as provided by their Division of Drug Marketing, Advertising and Communications; and

j) The ad should be part of a manufacturer's education program that would include collateral materials to educate both physician and consumer.

AMA policy has seven other points:

1. Our AMA opposes product-specific DTC advertisements, regardless of medium, that do not follow the above AMA guidelines.
2. Our AMA encourages the FDA, other appropriate federal agencies, and the pharmaceutical industry to conduct or fund research on the effect of DTCA, focusing on its impact on the patient-physician relationship as well as overall health outcomes and cost benefit analyses; research results should be available to the public.
3. Our AMA supports the concept that when companies engage in DTCA, they assume an increased responsibility for the informational content, an increased duty to warn consumers, and they may lose an element of protection normally accorded under the learned intermediary doctrine.
4. Our AMA encourages physicians to be familiar with the above AMA guidelines for product-specific DTCA and with the Council on Ethical and Judicial Affairs (CEJA) Ethical Opinion E-5.015 and to adhere to the ethical guidance provided in that Opinion.

5. Our AMA continues to monitor DTCA, including new research findings, and work with the FDA and the pharmaceutical industry to make policy changes regarding DTCA, as necessary.
6. Our AMA advocates that DTC drug advertisements contain a disclaimer "Your physician may recommend other, appropriate treatments."
7. Our AMA supports an appropriate level of funding for the FDA to more closely review DTCA of prescription drugs through television, radio, print, and other new forms of media, such as the Internet.

AMA's current policy recognizes that DTCA is legal and widespread, and most likely, here to stay. While the AMA's guidelines for an acceptable DTC ad generally have been well-received by both the FDA and the Pharmaceutical Research and Manufacturers of America (PhRMA), regrettably neither entity has endorsed them.

Key AMA Concerns about DTCA

As noted earlier, the debate over DTCA continues within the broader health care community generally and within the AMA specifically. Continuing concerns about DTCA within the physician community, include: 1) whether DTC ads provide educational value, are fairly balanced, and adequately disclose risks to consumers; 2) what is the impact of such ads on physician-patient relationships; and 3) what is the impact of such ads on health care utilization

and costs. Each of these concerns is addressed below.

1. Is DTCA Educational and Balanced?

One of the main tenets of the AMA guidelines is that DTCA should be educational, and not misleading. Do most product-specific ads meet the AMA's standard for educational value? This is difficult to answer, since what is educational to one individual may not be to another. While good data is hard to find on this issue, the majority of physicians most likely would not agree that the ads are educational. In one study that was published in the December 2000 issue of the *Journal of Family Practice*, the researchers reviewed over 300 print ads for 101 prescription drug products in 18 popular magazines over the previous decade. They found that while the advertisements were informative, they lacked important educational information about both the condition and the treatment for which the drug was being promoted.[7]

Although increased access by patients to accurate, objective information about tests to diagnose and drugs to treat illnesses is certainly important, there is the risk of confusion when commercially-driven promotional information is presented as educational. The issue is not whether consumers should obtain more information about treatment options – the real question is whether drug advertising, with its aim of selling a product, can provide the type of information consumers need or should have. Advertising has been described by one economist as "the science of arresting the human intelligence long enough to get money from it."[8] One executive of an advertising agency that focuses on DTCA has noted that "consumers react emotionally, so you want to know how they feel about your message and

what emotional triggers will get them to act…We want to identify the emotions that we can tap into to get that customer to take the desired course of action."[9]

In addition to assessing the educational value of DTCA, the AMA is concerned that consumers may not always get a balanced view of the benefits and risks of a product based on advertising. The FDA has made efforts to guide manufacturers to provide consumers with summary information, based on the drug's labeling, that is more useful and easily understood. For the most part, the AMA would concur that fair balance and adequate disclosure of risks appear in print advertisements, which require the "brief summary" (fine print) to be included. For television advertisements, however, it is more difficult to measure fair balance. Some of the ads are very effective at using pleasing, not to mention distracting, visuals as the major risk information is being discussed in audio only. Showing the major risks on screen as they are being discussed might improve fair balance.

Studies also have shown that patients have potentially dangerous misperceptions about DTCA. One research study suggested that one-half of consumers incorrectly believed that DTC advertisements are pre-approved by the FDA, and 43% incorrectly believed that only completely safe drugs can be advertised directly.[10] Another study found that consumers rated the safety and appeal of drugs described with an incomplete statement of risks more positively than similar drugs described with a more complete statement of risks.[11] These perceptions raise the question of whether widespread DTCA is giving consumers a false sense of security that prescription drugs are risk-free.

2. Impact of DTCA on Physician-patient Relationship

The AMA remains concerned about the impact of DTCA on the physician-patient relationship and the paucity of quality, independent peer-reviewed research to measure this impact. The consumer surveys that have been conducted, such as those by the FDA, *Time*, the AARP, the National Consumers League and *Prevention* magazine, suggest that DTCA increases: (1) physician office visits; (2) new diagnoses; (3) informed discussion between physician and patient about conditions and treatments; and, (4) unfortunately in some cases, demand for a specific advertised drug product. In a 2002 report by the General Accounting Office (GAO), the authors examined a number of consumer surveys and concluded that the percentage of consumers who, in response to a DTC ad, requested and received a prescription from their physician for a drug they were not currently taking was generally about 5 percent. The GAO estimated that this meant that about 8.5 million consumers in 2000 received a prescription drug after viewing a DTC ad and asking their physician for the drug.[12]

Although DTCA might have the positive effect of increasing physician office visits, resulting in the diagnosis of previously undiagnosed conditions and in better communication between physician and patient, many physicians complain that patients, armed with the latest DTC advertisements, come into their offices demanding the physician prescribe the advertised drug for them. We live in a society that prefers instant gratification and, taking a pill can often seem much easier than changing one's lifestyle. There is a danger that DTCA may cultivate a belief among the public that there is a pill for every ill and lead to an overmedicated society. If a medication is not necessary or appropriate, the physician is put in the uncomfortable and awkward position of defending why this is the case. Less time is available to diagnose and

treat the patient if the patient has a fixation on a particular drug as a result of a commercial. This can add strain and potentially distrust to a relationship that should be completely open.

A survey of physicians by the FDA, strongly supported by the AMA and released in January 2003, concluded that most physicians view DTCA as one of many factors that affect their practice and their interactions with patients, both positively and in some respects, negatively. The FDA survey also found that physicians felt they had to provide additional information to patients beyond what patients retained from the DTC advertisement. About 75 percent of physicians believed that DTCA causes patients to think the drug works better than it did, and many physicians felt some pressure to prescribe something when patients mentioned DTC ads. The FDA survey also found that about eight percent of physicians felt very pressured to prescribe the specific brand name drug when asked about it.[13] Various surveys have shown that some physicians prescribe the requested drug. One would like to believe that objective treatment decisions were made in every case. However, the question needs to be raised as to whether clinical judgment is being compromised in some cases to preserve a positive relationship with the patient.

3. Impact of DTCA on Health Care Costs and Utilization

The AMA also is concerned about the impact of DTCA on health care costs and utilization. DTCA is targeted at an audience that often is not responsible for paying for the product because most prescriptions (at least non-Medicare, for now) are paid for, at least in part, by private or public insurance. Articles in the lay press suggest that third-party payers are seeing disproportionate increases in drug budgets for classes of heavily advertised drugs. The key

question is whether these increased costs for advertised drugs are reducing costs in other health care areas so that the net effect is more cost-effective health care. This also places the physician in a difficult situation. On the one hand, the payer expects the physician to be cost-conscious and not prescribe the most expensive drug, if not medically indicated. On the other hand, payers also grade physicians based on patient satisfaction. The physician faces pressure from the patient requesting an expensive advertised drug and pressure from the payer to prescribe comparable but less expensive alternatives.

Some recent studies have concluded that DTCA does, in fact, lead to increased spending on drugs. A new study by researchers at the Harvard School of Public Health, Massachusetts Institute of Technology, and Harvard Medical School for the Kaiser Family Foundation, released in June 2003, found that increases in DTCA have a significant impact on drug spending growth. The authors estimated that in 2000, 12 percent of drug spending growth was related to increased spending on DTCA, with each additional dollar spent on DTCA yielding an additional $4.20 in drug sales in that year.[14] The GAO report also concluded that DTCA appeared to increase prescription drug spending and utilization. The GAO found that drugs promoted directly to consumers often are among the best-selling drugs, and sales for DTC-advertised drugs have increased faster than sales for drugs that are not heavily advertised to consumers. Moreover, the GAO found that most of the spending increase for heavily advertised drugs is the result of increased utilization rather than price increases.[15]

These studies may reflect an appropriate increase in spending on drug treatments that were previously underutilized. Alternatively, this also could reflect wasteful spending on

expensive advertised drugs for which less expensive alternatives, or no drug at all, will work just as well. A clear answer to this important question is definitely needed.

Recommendations

The AMA offers the following conclusions and recommendations to the Committee as it examines the consequences of DTCA:

1. The AMA believes there is room for improvement in the educational value of DTC ads without compromising a pharmaceutical company's desire to promote their product. In this regard, the AMA urges the pharmaceutical industry to use the AMA's guidelines for DTCA. Responsible DTCA that is accurate and educational to consumers, that balances benefits and risks, and that promotes good health outcomes can have a positive impact on health care.
2. The AMA believes that consumers must be better educated to understand the limitations of DTC advertisements. The AMA stands ready to work with the FDA and consumer groups in such an educational endeavor.
3. The AMA would like to see more independent research on DTCA and, particularly, on its impact on the patient-physician relationship and on health outcomes and costs. The results of this research must be published in reputable, peer-reviewed journals and be available in the public domain. The AMA believes that both the industry that runs the advertisements and the government have an obligation to fund this research.
4. The AMA supports the concept that when companies engage in DTCA, they should assume increased responsibility for the informational content, an increased duty to

warn consumers, and possible loss of protection under the learned intermediary doctrine. In effect, the AMA's House of Delegates has given its implicit support for the decision of the New Jersey Supreme Court in Perez v. Wyeth Laboratories. Companies should not be able to use the learned intermediary doctrine as a defense in the courts to completely escape liability if they are advertising their drugs directly to consumers.

5. The FDA must be adequately funded by the Congress to carry out its oversight function of DTCA and to use its enforcement authority when necessary.
6. For its part, the AMA will continue to educate physicians on their role in identifying and reporting inappropriate DTC advertisements, in cooperating with research studies to better understand and evaluate the impact of DTCA, and to assure they are meeting their ethical duties to their patients in recommending appropriate treatments.

Endnotes

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[3]Palumbo, FB, Mullins, CD. *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation,* 57 Food & Drug L.J. 423 (2002)
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[5]United States General Accounting Office, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations.* GAO-03-177 (October 2002).
[6]Palumbo and Mullins.
[7]Bell RA, Kravitz RL, Wilkes MS. *The educational value of consumer-targeted prescription drug print advertising*. J Fam Pract 2000; 49:1092-1098.
[8]Stephen Leacock, "The garden of folly." New York: Dodd Mead, 1924: 122-31, quoted in N Engl J Med editorial by S. Wolfe, Vol. 346: 524-526, no. 7 (February 14, 2002), *"Direct to Consumer Advertising – Education or Emotion Promotion?"*
[9]*Why Rubin-Ehrenthal sticks exclusively to DTC accounts.* Medical Marketing and Media. September 1999:136-46, quoted in N Eng J Med editorial, 2/14/02.
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[11]Davis JJ. *Riskier than we think? The relationship between risk statement completeness and perceptions of direct to consumer advertised prescription drugs.* J Health Commun 2000; 5:349-369, quoted in N Eng J Med editorial, 2/14/02.
[12]*FDA Oversight of Direct-to-Consumer Advertising Has Limitations*, GAO-03-177, General Accounting Office, October 2002
[13]*Direct-to-Consumer Advertising of Prescription Drugs: Physician Survey.* Food and Drug Administration, January 13, 2003. www.fda.gov/bbs/topics/ANSWERS/2003/ANS01189.html.
[14]Rosenthal et al, June 2003, Kaiser Family Foundation report.
[15]GAO report, Oct. 2002.

The CHAIRMAN. Dr. Nielsen, thank you very much.

Now let us turn to Dr. Meredith Rosenthal from Harvard's School of Public Health, who recently published a study on DTC advertising.

STATEMENT OF MEREDITH B. ROSENTHAL, PH.D., DEPARTMENT OF HEALTH POLICY AND MANAGEMENT, HARVARD SCHOOL OF PUBLIC HEALTH, BOSTON, MA

Ms. ROSENTHAL. Thank you, Chairman Craig, Senator Breaux, distinguished committee members. Thank you for inviting me to discuss the consequences of direct-to-consumer advertising of prescription drugs. I have been asked to summarize the scientific literature in this area and highlight key findings for policy. I would also like to make note of some important missing findings, questions that are not yet answered by empirical research.

At the risk of confusing the record, I am going to use the acronym DTCA to keep my comments to a few shorter syllables.

My review will highlight three main points supported by research. First, while DTCA expenditures have increased rapidly in recent years, the share of consumers that report asking their doctor for an advertised drug and receiving that drug has remained quite stable over the same period.

Second, DTCA clearly increases spending on prescription drugs but it is not the primary driver of prescription drug spending growth.

Third, because most of the increase in spending caused by DTCA appears to be due to additional use of prescription drugs in the advertised class rather than price inflation per se or consumers switching to higher-cost brands within a class, the most crucial outstanding policy question that I see is what is the magnitude of the incremental health benefit obtained by patients who seek and obtain treatment as a result of DTCA? When I say incremental I think it is important that we should keep in mind that the comparison should be what the patient would have gotten either in the absence of DTCA if we are talking about banning it or under some other model of DTCA. That would not necessarily be a generic drug, an older drug. It might be nothing. It might be a different brand.

Among the earliest studies of DTCA are those that rely on consumer surveys; you have heard these cited already. Surveys conducted by Prevention and Men's Health Magazines, as well as the FDA and a number of others have shown that approximately 80 percent of Americans can recall seeing advertisements for prescription drugs. One-quarter to one-third of consumers report that they spoke with their physician about the specific advertised drug. Roughly 5 percent of consumers surveyed say they actually received the drug that they asked for. These figure are remarkably similar across surveys and over time.

The impact of DTCA on use and spending is the subject of several recent studies that rely on actual insurance claims or sales data, so these data actually reflect the behavior of consumers and physicians. A number of studies have found that DTCA increases prescription drug spending. Our study, a summary of which is included in your packet, funded by the Henry J. Kaiser Family Foun-

dation, suggests that DTCA accounted for roughly 12 percent of total prescription drug spending growth in 2000.

DTCA by a particular brand name drug increases the size of the market for the entire therapeutic class. Moreover, there is no evidence that DTCA increases the market share of the advertised brand. That is, brands benefit from DTCA by any drug within their class in proportion to their existing market share.

In combination, these findings are very important from an economist's point of view. We look at this as some evidence that it is not a foregone conclusion that DTCA has a negative effect on consumer welfare. Because of the fact that there is increased use of drugs and we think there may be some positive health benefit to that use, it is worth looking further. If we saw this was just about shifting market share from drug A to drug B that are roughly substitutes, we could sort of close the book there.

In most other markets we would be done and we would say that advertising is beneficial here. In health care, clearly because of imperfect information and the presence of insurance, we need to go further.

As well, there is no current evidence to suggest that DTCA increases prices, although this is admittedly very difficult to study. If indeed DTCA has no effect on prices and price competition in particular, it stands in contrast to the published literature on physician promotion, which has been found to reduce competition and increase prices. This fact should be heeded, given that DTCA and promotion to physicians are substitutes and any constraints on DTCA is likely to give rise to increases in promotion to physicians.

So in summary, I would just like to reiterate that to no one's surprise, DTCA increases spending on prescription drugs. It does not appear to be the main driver, however. DTCA appears to increase spending through increases in utilization for all drugs in a therapeutic class, not necessarily by inducing consumers to switch from one brand to another. This means that DTCA motivates consumers to seek treatment but those decisions about what treatment they will actually get when they seek that treatment are influenced by other factors, such as physician information and health insurance benefit structure.

Finally, I would like to note again I think the important outstanding question that everyone seeks to be pointing to is that we need to understand better the magnitude of the health effects for people who are using drugs as a result of DTCA. There are clearly cases where it is inappropriate and clearly cases where this is very needed treatment for chronic illness, for deceases in particular that are undertreated, such as depression, but the relative magnitude of those two phenomena is what is really important here. Thank you.

[The prepared statement of Ms. Rosenthal follows:]

Testimony of Meredith B. Rosenthal, Ph.D.

Chairman Craig, Senator Breaux, distinguished Committee members, thank you for inviting me to discuss the consequences of direct to consumer advertising (DTCA) of prescription drugs. I have been asked to summarize the scientific research in this area, highlight key findings for policy, and make note of important questions not yet answered by empirical studies.

My review will highlight three main points supported by research on the consequences of DTCA of prescription drugs. First, while consumers take notice of and sometimes act upon prescription drug advertisements, the rapid growth of DTCA has not been associated with a commensurate explosion in the rate at which consumers report that they demand and receive advertised products. Second, DTCA clearly increases spending on prescription drugs but is not the primary driver of prescription drug spending growth. Third, because most of the increase in spending caused by DTCA appears to be due to new utilization, the most crucial outstanding question for policy is: what is the magnitude of the incremental health benefit (relative to the treatment they would have received absent DTCA) obtained by these patients? Without the answer to this question we cannot know whether DTCA's effects on consumer welfare are, on net, positive or negative.

I would like to begin by noting that much of the evidence on this topic is summarized in a recent Government Accounting Office (GAO) report. In its report,[1] the GAO reviewed the evidence on the growth of DTCA, its scale relative to investment in research and development, and its impact on prescription drug use and spending. In terms of impact, the GAO concluded that the weight of the evidence supported the notion that DTCA increases utilization of and spending on prescription drugs. The GAO report did not address the impact of DTCA on appropriateness of

treatment or public health.

Impact of DTCA on Spending and Patterns of Use

Because DTCA is a relatively recent phenomenon and a difficult one to study for a number of reasons, there are only a handful of studies that directly examine the impact of this form of promotion on behavior and none so far on health outcomes. There is, however, a large literature on promotion of prescription drugs to physicians, including detailing, sampling, and journal advertising. Because the findings appear to contrast with the early evidence on DTCA, I will note a few results from selected studies. Early economic studies of physician-oriented marketing of prescription drugs by Bond and Lean, Hurwitz and Caves, Leffler, and Vernon[2-5] considered evidence that this marketing was more "persuasive" than "informative". This distinction reflects a more general literature that viewed advertising alternatively as changing consumers' preferences,[6] creating or exaggerating product differences and thereby increasing barriers to entry,[7] or as providing information about a product's characteristics and its price.[8] A common finding from the empirical literature was that professional promotion of prescription drugs made it more difficult for new brands to enter a therapeutic class and decreased price competition by increasing perceived product differences.

More recent research by King [9] on anti-ulcer medications finds that marketing by an individual brand reduces the price responsiveness of demand for that drug, but that total industry marketing reduces the extent of product differentiation (and thus increases price competition). Rizzo[10] reports that for antihypertensive drugs, both current and cumulative detailing expenditures decrease the price responsiveness of demand through the development of greater brand loyalty.

Overall, promotion of prescription drugs to physicians has been found to decrease price competition and result in changes in market shares among competitors without increasing the overall size of the market for a therapeutic class. Unlike physician-oriented promotions, to the extent that DTCA raises awareness among previously untreated consumers of the existence of potentially effective treatments, DTCA could bring more patients into physician offices.

Looking at pre-1997 DTCA, in which products could only be marketed if either the name of the product or the indication for which it was intended were omitted, Berndt[11] examined DTCA data for branded antiulcer (H_2-antagonist) prescription drugs through May 1994, along with detailing and medical journal advertising data. For the entire H_2 therapeutic class, detailing, medical journal advertising, and DTCA led to increased sales although detailing and journal advertising were much more effective than DTCA. Although detailing and medical journal advertising stocks positively affected market shares, DTCA had no significant impact on market share.

Two recent studies of DTCA by Wosinska[12] and Ling, Berndt and Kyle[13] incorporate data after the FDA's 1997 clarification of DTCA guidelines. Wosinska uses 1996-1999 prescription drug claims data for 4,728 patients who filled a total of 11,529 new prescriptions for cholesterol reducing drugs in the Blue Shield of California medical plans, along with national data on physician detailing, samples and DTCA. She finds that DTCA positively impacts total therapeutic class sales, but only impacts an individual brand positively if that brand has a preferred status on the third party payer's formulary.

Once again looking at the H_2-antagonist class, Ling, Berndt and Kyle studied promotion of both prescription and over-the-counter (OTC) forms of the same brands. Within the prescription market, detailing and medical journal advertising efforts have positive and long-lived impacts on prescription market share, while DTCA of the prescription brand has no significant impact on market share. DTCA efforts for prescription brands also have no significant impact on same-brand OTC shares.

Using monthly data for five therapeutic classes on the major types of drug promotion and sales from 1996 to 1999, my coauthors and I examined the impact of DTCA on the sales of these drugs.[14] These five classes (antidepressants, anti-cholesterol drugs, proton pump inhibitors, antihistamines, and nasal sprays) accounted for roughly 30% of DTCA spending over this period. After accounting for the fact that products with higher sales are more likely to be advertised and promoted to physicians, we found that increases in total DTCA for a therapeutic class are associated with significant growth in sales for that class. Promotion to physicians (detailing) similarly increased total sales for a therapeutic class, but to a lesser degree. No evidence was found to support the notion that DTCA was a factor in determining the market share of individual products within a class. Extrapolating the results to all drugs that advertise, these estimates imply that DTCA may account for roughly 12% of the overall growth in prescription drug spending in 2000.

Finally, in related work my coauthors and I have examined the impact of DTCA on medication use for the treatment of depression.[15,16] The first study looked at the impact of direct-to-consumer advertising and promotion to physicians on the likelihood that 1) medication treatment

was initiated for an individual diagnosed with depression, and 2) the duration of medication treatment was consistent with national guidelines. Our results suggest that advertising antidepressants to consumers may increase the likelihood that an individual with depression initiates medication therapy. Free samples of antidepressants, on the other hand, had no effect on medication use. We found no evidence that pharmaceutical promotion to consumers or physicians has an important impact on the likelihood that antidepressant therapy would be continued in a way that meets existing treatment guidelines. The second study again supports the notion that product-specific spending on detailing to physicians had a significant impact on drug choice while spending on direct-to-consumer advertising had no effect on the selection of antidepressant medication. Both of these studies provide further support for the notion that the primary effect of DTCA is on expanding use of a drug to previously untreated consumers.

Consumer and physician surveys

Prevention and *Men's Health* magazines, with technical assistance from the FDA, have been conducting consumer surveys about perceptions and effects of direct to consumer advertising of prescription drugs since 1997. In addition, the FDA and a number of other private entities have conducted similar surveys. The results of these surveys, across different samples and instruments as well as over time are remarkably consistent. More than 80% of Americans can recall seeing an ad for a prescription drug; roughly a third of people talked with their physician as a result of seeing an ad; and about 5% of consumers report that they received the advertised drug as a result of such discussions prompted by DTCA. While the share of Americans that is aware of prescription drug advertising has steadily increased since 1997, neither the percentage

of consumers that reports discussing an advertised drug or receiving an advertised drug as a result of such discussions has increased over time.[17]

Consumer surveys have also been used to gauge consumer understanding of the health conditions described in the ad, risks and benefits of the advertised product, and perceptions about the nature and value of advertising itself.[18-20] Findings from these studies suggest that DTCA is not an important source of detailed public health information: even immediately after seeing advertisements consumers often do not recall information presented on disease risk factors, drug benefits or risks. In addition, consumers appear to misunderstand the extent to which advertising is regulated by the FDA. For example, one study reported that 22% of consumers agreed that advertising of drugs with serious side effects had been banned.[19] Finally, consumers generally view DTCA positively and value it as a source of information.

Physician surveys about DTCA have generally revealed discomfort with the idea of advertising directly to consumers, particularly among primary care physicians.[21,22] Perhaps of greater concern, physicians report that DTCA leads them to write prescriptions that they feel are equivocal or at least atypical.[21,23]

Summary and Conclusions

Although DTCA of prescription drugs has increased rapidly since 1997, it currently accounts for only 14% of total promotional spending by the pharmaceutical industry. Meanwhile, prescription drug spending has more than doubled since 1997. Despite the fact that it is also true that spending on advertised drugs has grown roughly twice as fast as spending on unadvertised

drugs, these statistics do not really help us to quantify the impact of DTCA on prescription drug spending. The evidence we do have regarding the causal effect of DTCA on spending suggests that DTCA is a significant driver but explains only a small share of total spending growth. This conclusion is also supported by consumer surveys conducted from 1997 to the present, in which a small but unchanging share of consumers report that they received an advertised product as a result of seeing an ad and talking to their doctor about it.

To date there is no evidence that DTCA leads to higher prices (in contrast to physician promotion), although this is admittedly hard to study. Nor is there evidence that DTCA encourages people who are already being treated with a drug in the same therapeutic class to switch brands. These last two points are important because they suggest that DTCA might have a net beneficial effect if, on average, the incremental gains from this new treatment exceed the incremental cost of providing it. It would be naïve to suggest that all of the utilization that results from DTCA is appropriate, much less cost-effective (the widespread availability of insurance coverage for prescription drugs makes this unlikely), but it would be equally unrealistic to suggest that there is no health benefit from all these prescriptions. So the critical puzzle for research and policy is to attempt to quantify, directly or indirectly, the incremental health benefits from the prescribing that results from DTCA for a broad spectrum of drugs and conditions.

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The CHAIRMAN. Doctor, thank you very much.

Now let us turn to Dr. Arnold Relman, distinguished scholar and former editor of the New England Journal of Medicine. Doctor, welcome before the committee.

STATEMENT OF ARNOLD RELMAN, M.D., PROFESSOR EMERITUS OF MEDICINE AND SOCIAL MEDICINE, HARVARD MEDICAL SCHOOL, BOSTON, MA

Dr. RELMAN. Thank you. Mr. Chairman and members of the Special Committee, thank you for the invitation to be here. You have a copy of a longer version of what I have to say so what I am going to do is simply touch on the highlights.

The total spent on direct-to-consumer ads is now probably over $3 billion but that is only a small fraction of the total industry expenditure on marketing, advertising and sales promotion. You have already heard Dr. Rosenthal cite the evidence that these consumer ads nevertheless have an effect on patient demand and on prescription drug spending. The exact extent I think is open to interpretation of uncertain methodology but it clearly has some effect. That is not surprising, of course, because common sense dictates that industry executives would not be spending so much on direct-to-consumer advertising were they not convinced that it increased their sales.

I might add parenthetically that Dr. Rosenthal's conclusion that it does not necessarily increase the sale of the drug being promoted, rather, the class of drugs, I suspect would come as a surprise and a disappointment to all those executives who spend billions and billions of dollars believing that it does.

The industry argues that DTC ads serve more than purely commercial purposes. They say such ads educate the public about illnesses and the new medicines available to treat them and thus encourage patients to consult physicians for earlier diagnosis and treatment, but that is simply the claim of business people whose sales are increased by these ads, they think, and who therefore hardly can be unbiased.

I do not know of any hard scientific evidence that would pass critical peer review that the information that is disseminated in these ads really helps the health care system. I really do not and I would challenge the statement that there is clear evidence that health care is improved by these ads. There is no solid scientific evidence to support that contention.

There are some medical opinions in agreement with the industry's contention but they also lack data and unfortunately are often tainted by financial support from the pharmaceutical industry. I am glad to hear that my colleagues in the AMA clearly are skeptical, as they should be, about the medical value of these ads.

When one considers that the majority of direct-to-consumer drug ads are now on television and that this means a hasty 30- or 60-second spot, it is hard to imagine how useful educational information could ever be conveyed in this manner, even if these ads were not biased toward a particular product. There simply is not time to provide any information about side effects or complications, let alone to compare the cost and effectiveness of the advertised brand with other available drugs or other methods of treatment, which is

what good medical information would do. That is how we academics in medicine define useful education about drugs. You evaluate what is available, the pros and the cons, what is worth the money, what is safe, what is effective, as compared to everything else that you might do. There is none of that in these ads.

Clearly these ads are intended simply to fix a brand name in a patient's mind, with the hope that the patient will then ask the doctor about it at the next visit and will influence the doctor to write a prescription for it. Actually how often that occurs I do not think is important, but that is what the advertisers think.

Given all the above, what can we conclude about direct-to-consumer advertising? I find little to recommend it and much that argues against it, particularly in these times when rapidly rising expenditures on prescription drugs are straining the budgets of all purchasers.

In my judgment as a teacher of medicine for over 50 years, with a very large experience in medical education and in medical consulting, there are lots and lots of patients in the United States who are now being overmedicated, dangerously so, and take too many medications. I believe that these ads must, in part, be responsible. These ads promote only the newest and most expensive drugs, many of which are no better than or possibly not even as good as older, less expensive generic drugs or as effective as simpler, nonpharmaceutical treatments.

As a physician, I believe that decisions about the use of prescription drugs should rest with doctors based on the best available scientific knowledge. The education of patients should be the responsibility of doctors and of governmental, public health and professional organizations.

I do not see any basis for the industry's assumption that they have the responsibility for educating patients or, for that matter, for educating doctors. They have no such responsibility. They are businessmen. Their job is to sell honest products and advertise them honestly. They are not educators and they should not pretend that they are.

I therefore would favor a total ban on direct-to-consumer ads. If the law were to prevent such legislation then I would advocate at least a return to something like the pre-1997 FDA regulatory policy and would require that all DTC ads include approved consumer-friendly information. I would also strengthen the FDA's capacity to eliminate the delays in reviewing ads, which you have heard about.

I conclude. Prescription drugs simply are not like ordinary commercial goods and it is not in the public interest to advertise them to consumers as if they were. We need more, not less, regulation of consumer ads. Thank you for your attention.

[The prepared statement of Dr. Relman follows:

U.S. Senate Special Committee on Aging Hearing on

"Direct to Consumer Advertising: What are the Consequences?"

Tuesday, July 22, 2003 Rm 628 Dirksen Senate Office Building

Testimony by Arnold S. Relman, M.D

Professor Emeritus of Medicine and of Social Medicine
Harvard Medical School, Boston MA
Editor-in-Chief Emeritus, New England Journal of Medicine

Mr. Chairman and members of the Special Committee on Aging: Thank you for the invitation to present my views on the "direct-to-consumer" (DTC) advertising of prescription drugs. These views reflect my lifetime of experience as a practicing physician, a clinical scientist, a medical teacher and the editor of a world-class medical journal. I have also been a particularly close observer of the pharmaceutical industry for many years. A summary of what I have learned from this experience about prescription drugs, the pharmaceutical industry and its DTC ads can be found in an article Dr. Marcia Angell and I published in the New Republic magazine of December 16, 2002. I have made a few hard copies available to members of the Committee, but inasmuch as it won the George Polk Award for magazine journalism this year, our article can be downloaded from the Polk Award web site:

(www.brooklyn.liu.edu/cwis/bklyn/polk/press/tnrdrugpiece.pdf).

The total spent on DTC ads is now probably over $3 billion, but is only a small fraction of the total industry expenditure on marketing, advertising and sales promotion. You have already heard Dr. Rosenthal cite the evidence that these ads nevertheless have a significant effect on patient demand and on prescription drug spending. That should

not be surprising, because common sense would dictate that industry executives would not be spending so much on DTC advertising were they not convinced that it produced results.

The industry argues that DTC ads serve more than purely commercial purposes. They say such ads "educate" the public about illnesses and the new medicines available to treat them, and thus encourage people to consult physicians for earlier diagnosis and treatment. But that is simply the opinion of business people whose sales are increased by these ads and who are not likely to be unbiased or objective. There is certainly no scientific evidence to support their contention. The best, and almost the only, study of the effects of DTC ads on health care (as determined by a telephone survey of consumers) was reported by a team at the Harvard Medical School in the February 26 issue of the journal Health Affairs. The study could not come to any definite conclusion beyond that most consumers reported no obvious adverse consequences from these ads. However, the authors could not comment on whether the ads caused the patients to receive drugs that were more expensive than necessary or whether the ads were misleading. Furthermore, they could not say whether DTC ads increase the cost of health care or, if they do, whether their benefits justify the costs. And finally, the authors acknowledged that their study could not determine whether other sources of public information could achieve the educational benefits of DTC ads at less cost and with fewer undesirable consequences. These are critical questions but there are no controlled studies to answer them and I doubt there ever will be.

So, it seems to me that the arguments in favor of DTC ads as public policy have

no scientific support. In opposition to DTC ads are the opinions of the majority of practicing physicians, as exemplified by the recent FDA survey, which showed that 59% of physicians found no overall beneficial effects from DTC ads, and many reported negative effects such as creating pressure to prescribe inappropriate drugs, and causing patients to have unrealistic therapeutic expectations.

Indeed, when one considers that the majority of DTC drug ads are now on television, and that this means a hasty 30 or 60-second spot, it is hard to imagine that much more than the name and the claimed therapeutic indication could ever be conveyed. There simply isn't time to provide any useful information about side effects or complications. To call this "education" strains the meaning of the word. Clearly, such TV spots are intended simply to fix a brand name in a patient's mind, with the hope that the patient will then ask the doctor about it at the next visit and will influence the doctor to write a prescription for it.

And when one looks at the drugs most commonly advertised to the public, it is immediately apparent that the industry is promoting only its newest and most expensive patented brands. Many of these are simply minor variations of older medications that often are off-patent, less expensive, and at least as effective.

Given all the above, what can we conclude about DTC advertising? I can find little to recommend it and much that argues against it, particularly in these times when rapidly rising expenditures on prescription drugs are straining the budgets of all purchasers. Patients are being overmedicated, and DTC ads are in part responsible.

As a physician, I believe decisions about the use of prescription drugs should rest

with doctors, based on the best available scientific knowledge. The doctors' advice to patients should be unbiased and objective and therefore should not be derived from the industry that sells the drugs. The same applies to patients' information about drugs. Patients should be educated as much as possible about their drugs and they should participate with their physician--insofar as possible--in the decisions on which drugs they should take, but the pharmaceutical industry is not the appropriate source of education for doctors, or patients. The institutions of the medical profession should be responsible for the education of doctors, and governmental and professional organizations, should be responsible for the education of patients.

If the law allows, I would favor a total ban on DTC ads. Otherwise I would advocate at the least a return to something like the pre-1997 FDA regulatory policy, and would require all DTC ads to include approved, consumer-friendly information about side effects, complications and contraindications. This would largely preclude the commercial TV and radio spots that now masquerade as public education.

I would also strengthen the FDA's capacity to eliminate the delays in reviewing ads, which the GAO described in its recent report. Prescription drugs are not like ordinary commercial goods, and it is not in the public interest to advertise them to consumers as if they were. We need more, not less, regulation of consumer ads.

Thank you for your attention. I would be pleased to answer your questions or explain any of the points I have made.

The CHAIRMAN. Doctor, thank you very much for that very provocative statement. We appreciate it.

Now let me turn to our panelists for questions. Ms. Powell, let me start with you. The question that I would like at least your response to because my guess is you have had some opportunity to analyze it prior to this hearing—what is PhRMA's position regarding AMA's guidelines for DTC advertising?

Ms. POWELL. We have looked at the AMA's guidelines on DTC advertising and we think that many of them are, in fact, consistent with the FDA's guidance on direct-to-consumer advertising and many of them represent important public policy. We have, however, not actually adopted any kind of formal position on what we think our members should include in their advertising. We do, of course, encourage our members to provide educational information in their advertising and as Ms. Woodcock from the FDA said, the vast majority of our members do, in fact, submit advertising to FDA for review before that advertising goes on the air.

We do think it is very important, of course, that all the ads comply with the FDA requirements and one of those requirements—I think I am correct—is that the advertisement has to indicate that this is a prescription drug and that the patient should seek additional information from their physician or other health care provider about both risks and benefits because the decision does remain with the physician about what treatment a patient should receive.

The CHAIRMAN. Is there any consideration by PhRMA for developing or adopting principles, standards or guidelines not unlike what AMA is proposing?

Ms. POWELL. The AMA has actually talked with members of the PhRMA board of directors about that issue. It is something that comes up periodically. I do have to tell you realistically that right at the moment, PhRMA is focused on some other issues that have already been mentioned here and this would not be an immediate high priority but I certainly would be willing to go back to our executive officers and remind them of that request from the AMA.

The CHAIRMAN. Well, I will only tell you that I think many of us in Congress look at the whole and not the pieces as it relates to prescription drugs and as government enters in and becomes much more the participant, cost factors, cost of total program is going to be an increasing focus of this Congress, I would guess, and future Congresses to come. I think that is a reasonable observation.

Dr. Nielsen, what is the impact of this country's third-party payor system on doctors' prescribing habits?

Dr. NIELSEN. It is enormous. It has been alluded to actually in the study that just came out a week ago cited by Ms. Powell where physicians do not dangle in front of their patients therapeutic options that are unavailable to them. In this country, for better or for worse, and Congress is right on the front line on this one, for most of us unless we are independently wealthy, if something is not covered as a covered benefit by our health insurance, we cannot afford it and we cannot get it. So that is an issue. Third-party payers have had a tremendous impact.

Part of the impact may relate to what Dr. Rosenthal mentioned, as well. Patients come in seeking a specific drug because of an ad

that they have seen. They may not be able to get that drug because it is not on the formulary of their third-party payor. So I would say that that is indeed a big issue.

The CHAIRMAN. Do you believe the fact that someone else is paying for a patient's drug influences the behavior of either the patient or the physician in choosing the drug to be used?

Dr. NIELSEN. Yes. Yes to both.

The CHAIRMAN. Thank you.

This will be my last question in this round. Dr. Relman, in your testimony you stated "There is no scientific evidence to support the contention that DTC advertising encourages people to consult physicians for earlier diagnoses or treatment." How do you respond to the surveys by FDA and Prevention Magazine that indicate that as many as 20 million people visited with their doctor about a condition for the first time as a result of DTC advertising?

Dr. RELMAN. Senator, one of the basic rules of all good epidemiologic research is that there be adequate controls. There are simply no controls for all such studies. We do not know in any systematic, quantitative way what the behavior would be of patients who never heard about these ads for the simple reason that there is hardly anybody who is conscious in America these days who has not heard about these ads.

If you look at the data which says well, these ads are responsible for the behavior, it will not pass muster. It would not have been accepted for the New England Journal of Medicine or any other really rigorously peer-reviewed journal.

The CHAIRMAN. Well, Dr. Woodcock, how do you respond to that?

Dr. WOODCOCK. It would be a challenge in today's environment, as Dr. Relman just alluded to, to design such a study. It would be difficult to take a segment of our population and refuse to allow them access to prescription drug ads so that we could determine what their behavior is. There are methodologic difficulties in getting to the level of scientific proof that Dr. Relman is looking for.

The CHAIRMAN. Thank you.

Let me turn to my colleague, Senator Breaux.

Senator BREAUX. Thank you, and thank all the panel members for excellent testimony.

Dr. Woodcock, since you are back, does the FDA regulate advertising to doctors of pharmaceuticals?

Dr. WOODCOCK. Yes.

Senator BREAUX. In what way?

Dr. WOODCOCK. We have standards for all the information that goes to physicians. As I said in my testimony, it is the same standards and regulations that apply to consumers. The companies must submit their written information and other information, even the pens and all the promotional materials that they use, to the FDA at the time they are circulated to physicians.

It is more difficult for us to regulate and really have effective oversight of the verbal exchanges that go on between the detailers and the physicians.

Senator BREAUX. Dr. Nielsen, would AMA support a prohibition on pharmaceuticals advertising to doctors?

Dr. NIELSEN. No, but any doctor who gets all their information about a drug from a drug salesman is a fool.

Senator BREAUX. The division of the expenditures on promotional spending shows that the spending that is labeled doctor's office detailing, can anybody tell me what that includes? What is doctor's office detailing? It is over $4 billion back in 2000.

Dr. NIELSEN. Well, you heard Senator Stabenow address it. She said she spoke with her physician. Let me tell you what happened in my office. Let me immediately say this is not about doctors versus the pharmaceutical companies. I mean we need these products. They are life-improving; they are life-saving. So it is really not about——

Senator BREAUX. I understand. But what is doctor's office detailing?

Dr. NIELSEN. What really happens is the drug reps come to the doctor's office and they want face time with the doctor. That is what it is—sitting down, explaining what the newest drug is, what the side effect profile is, and usually offering free samples for the physician to try with their patients. That is what it means.

Senator BREAUX. Dr. Woodcock, you had a problem?

Dr. WOODCOCK. Yes, I was going to add to that or elaborate. The sampling, providing the samples, which is costed out at the market value of the samples, is actually the largest segment of drug promotion. It is the largest proportion of drug promotion and this may affect what Dr. Rosenthal was talking about. A patient may come in requesting one drug and if the doctor has samples of another, free samples of another drug, the patient will start on that other drug.

So that is also a very powerful mechanism by which patients can be initiated on a certain therapy, which they often might stay on, and that is a very high expenditure in the promotion realm.

Senator BREAUX. It seems to me that no consumer can write their own prescription. Unless they are a doctor, none of them can legally write their own prescription. So a consumer who sees an ad for a particular pharmaceutical and may not clearly understand the potential side effects of that drug, whether that particular drug is suitable for their particular condition, that individual consumer still has to go to the doctor. The doctor is the gatekeeper. Only the doctor can write a prescription that is suitable for that individual patient.

So I have less of a concern about the advertising, detailing, all the medical consequences of a drug that is advertised because I know that behind that advertisement and before the consumer can ever get the drug he has to go through the gatekeeper. The doctor looks at that patient. If the doctor has a patient that says I would like this the doctor makes a medical decision whether or not that drug is suitable for you.

Is that not the protection that consumers have? No consumer can write a prescription.

Dr. NIELSEN. That is correct. That is absolutely correct. Doctors do do that, but remember the study that said one-quarter of patients whose doctors did not give them the drug would go to another doctor to try to get it and 15 percent of them would totally change doctors.

Senator BREAUX. That is important but Dr. Rosenthal also points out that about 80 percent of consumers remember a drug ad and

of the 80 percent that even remember a drug ad, somewhere between a fourth or a third ever request their doctor to give them that particular pharmaceutical. Then the doctor responds positively to that request only 5 percent of the time. I would be concerned that if my advertising was only getting my product requested 5 percent of the time, I would say gee, I had better get a new advertising agency.

So it does not seem to me from what Dr. Rosenthal said that you have a real problem if only 80 percent remember the ads and only a third to a fourth of them ever make a request and then only about 5 percent of those that make the request ever get what they requested. That means 95 percent are either turned down by their doctor or presumably would be turned down by another doctor who would make the same medical decision that this was not the appropriate prescription for that particular person's condition.

So I do not know that you have a problem with direct-to-consumer advertising in an overrequest of a particular drug that has been advertised with a connected compliance with that request by physicians. Is that your compilation of the studies you have looked at? Am I correct in reading it like that?

Ms. ROSENTHAL. You are correct. I think in the overall picture that you have painted, that is the impression I tried to leave. I just want to correct perhaps your impression of those consumer survey numbers. The 80, a quarter to a third and 5 are all off the same denominator, so talking about all surveyed consumers. So those numbers could be translated, but it is 5 percent of all surveyed consumers say they followed through the whole chain. They saw the ad, they went to their doctor, asked about the drug, and received the drug.

But I think that you make a very important point, that many other factors intervene before a consumer actually gets to a decisionmaking process where they can purchase a prescription.

Senator BREAUX. I have one other question, if I may.

Ms. Powell, the argument is that if the drug companies are spending $2.5–3 billion annually on advertising that somehow if you were not doing that that somehow drugs would be $2.5–3 billion annually less expensive. Now I do not know that that would be correct. Can you comment on that? This is maybe not your area but it would seem to me that to a large extent if we eliminated direct-to-consumer advertising and you saved $3 billion, I doubt whether the companies would automatically reduce the price of drugs by $3 billion. You would probably look at different forms of advertising. You may hire more people to do research and development. You may do a lot of things with that other than reduce the price of the retail pharmaceuticals. I do not know if this is your area or not but can you comment on that?

Ms. POWELL. Well, the information that we have, which is collected by IMS Health, on the allocation of——

Senator BREAUX. IMS Health, just for the record?

Ms. POWELL. IMS Health is a third-party independent organization which collects information and then there are a number of other groups that look at drug spending information. We do not, as a trade association, actually collect drug marketing information but the information that we have is that the majority of the money

that is now spent on broadcast advertising or print advertising to consumers is money that had been spent on either marketing to physicians by sending sales people to their offices or money that was spent on advertising in professional journals.

So the money has not come from other research and development or has not come from price increases but has been pulled from other marketing activities. I would have to presume that companies, if they were prohibited from advertising directly to consumers, would go back to advertising not only to physicians, but also let me point out that everybody else within the physician's office may be giving information to patients about how to use their medications and they need information about what the contraindications or the risks would be, as well.

Senator BREAUX. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Breaux, thank you.

Senator Stabenow.

Senator STABENOW. Thank you, Mr. Chairman, and thank you to all the panelists. I have many questions, as all who are listening to this will have.

I will just start by saying I think it is unfortunate if we, in fact, eliminate advertising and prices would not go down. That is a very unfortunate thing because I think that the biggest risk to American consumers today is the fact that we are paying such high prices and Americans, in fact, pay the highest prices in the world, even though we greatly invest in research and development and support of the industry, which I support.

According to a July 2003 Families USA report, the prices of the 50 most prescribed drugs to seniors rose, on average, nearly three and one-half times the rate of inflation last year. I believe that is an incremental cause of concern to people's health, their ability to be able to have access to medicine.

Regarding advertising, I believe in public information, consumer information in many, many ways and support many efforts for people to be well informed, for all of us to be well informed as consumers, but I wondered if any of the panelists might want to speak from not just a statistical standpoint but from common sense, common sense. This is something that the average person does not need a study to look at; they just need to turn on their television set. It is very clear what is happening.

What I think is important to reemphasize is that we are not seeing ads on television with words from a physician explaining the pros and cons of various kinds of ailments and what people should think about in going to the physician's office and what questions to ask. We are seeing the woman in the field, the lilies. When we look at all of the possible things we would educate people on, certainly Viagra is educating us over and over again about a series of things through pretty pictures.

Again I do not mean to pick on Vioxx but since they have huge advertising, we are seeing just all kinds of pretty pictures. We are not seeing objective information explaining to people the differences in products and that is for a good sound business reason—folks who advertise want to make sure their brand name is out there and they are trying to have us all buy their product, and that is the American way and I think we should not pretend that there is

anything else going on here other than the attempt to advertise in order to increase their share of the market.

The question I have though, relates to a supposition that we are educating people when, in fact, the majority of drugs that are being advertised are for things that millions of people have because you want larger market share; you want more people buying your product, as opposed to advertising regarding orphan drugs or rare diseases, where that person sitting at home may, in fact—they know they have a headache; they may know they are a little tired; they may know that they are not feeling well but may not be aware of a rare disease, may not be aware of something that involves an orphan drug. Yet that is not what we are seeing on telephone. We are not seeing advertisements or educational promotions for those things that people may not know about. We are seeing it for the most common, the painkiller, even though on Peter Jennings they indicated on a show last year that—again unfortunately to pick on Vioxx—Vioxx has not been proven to be any more effective at treating pain than tried and true over-the-counter drugs, such as Alleve and Advil, but yet that is what we are seeing on television.

So I wonder if any of you might speak to if you were going to put together an advertising campaign that encourage consumers and is helpful in terms of health education, what would you do and what about the fact that some of the most important rare diseases that we as consumers should learn about are not advertised because it is not, I assume, beneficial from a profit standpoint to advertise that? Dr. Nielsen and then Dr. Relman?

Dr. NIELSEN. I will take a stab at it. I think it is unrealistic to expect a pharmaceutical manufacturer to be altruistic primarily and I think that is just an unrealistic expectation. On the other hand, we wish they did more of that, obviously. The orphan drugs are a problem because they are very high cost and the manufacturers are not going to reap a profit from them. So you understand why they do not choose to advertise those.

But let me go back to a little bit different aspect of what you are getting at because I think you have hit on something really important. We as physicians do appreciate when there is an educational part of the ads, and the way you go about that is make the ad disease-specific. Give screening questions for depression. If someone has not sought treatment for depression perhaps they will indeed seek such treatment. We like those ads and, in fact, that is the very first of our principles in our policy, to keep it disease specific when possible and to be educational.

But I have to say that while I would love to believe that we would encourage them or maybe even mandate them to spend a little bit of their money on this altruistic sort of maneuvering, I doubt that it fits into the big scheme of what their advertising is going to be.

Senator STABENOW. I appreciate that. Obviously I understand that and agree with that. It is a business. I think we should just recognize that in the context of all of our discussions, that it is a business decision and I very much appreciate that. Unfortunately, it is a business decision based on a product that may be life or death to someone, so I think it is a different product than other products that people can choose to purchase or not purchase.

Yes, Dr. Relman.

Dr. RELMAN. Senator Stabenow, I would like to add to what my colleague Dr. Nielsen said. Of course the pharmaceutical manufacturers are business people and they are not expected to be philanthropists. They are expected to want to sell their products and that is what they do. In response to Senator Breaux's question, it is more than $3 billion now. It passed $3 billion and that $3 billion is paid for by the patients who buy the drugs.

Now the way he framed the question, would they go out and lower their prices by $3 billion? No, they will not do that but clearly in order for them to maintain their expected level of profits, which are enormous, they have to price accordingly and part of their expense, which reduces their profit, is the $3 billion plus for direct-to-consumer ads.

But the point I want to make here is that Senator Breaux is absolutely right. The main responsibility for the proper prescribing of drugs and for the proper use of drugs and the evaluation of drugs rests with our profession. Doctors are the only ones really qualified to know what is worth the money and what is not, what works in a particular case or in general, as compared with all the other choices that are available. Doctors should advise patients about that.

Unfortunately, however, they do not do it enough. The reason is quite simple. The pharmaceutical industry spends so much money "educating doctors" as to what they ought to think about the newest drugs, and on being nice to doctors. There are many different ways in which the pharmaceutical industry influences the doctor's professional judgment. It is too bad; it is a disgrace. I feel embarrassed for our profession that we allow it to happen.

The pharmaceutical industry that says well, they spend more on R&D than on advertising and marketing and promotion than they do on R&D is simply not telling the truth. Look at the SEC filings. They say that on the average, 35 percent of their income is sales promotion and administration. They do not want to separate out what they call administration but one major pharmaceutical company does; that is Novartis. They list their administrative costs separately and that is 5 percent, and common sense tells you that is about the right kind of number.

So what we are seeing is that the pharmaceutical industry, which now is selling about $200 billion worth of drugs this year, is spending roughly 30 percent, or $60 billion, on marketing. That is much more than they admit to, but it includes the enormous amount of money they spend on an estimated 314,000 "educational" occasions when the pharmaceutical industry sponsors meetings and seminars and conferences and symposia. They spend a huge amount of money and most of that goes to influencing the opinion of doctors.

Unfortunately, there are very few professors of medicine who are teaching the students not to pay attention to that. It is very hard when people are so nice to you and want to give you all these goodies free and give you free samples for your needy patients, and so on; it is very hard not to pay attention to the pharmaceutical industry. But that is the secret and that is the dirty secret of our profession, that they are kept by the pharmaceutical industry and

that dulls their willingness to be critical about what is really worth the money and what is not.

Senator STABENOW. Mr. Chairman, thank you. I would just ask that we consider holding a hearing on the broader marketing issues. I think it is a worthy discussion to have. I would urge that we consider that and understand again from my own physician, who is a person of great integrity who talks about the daily and weekly pressures on her and the opportunities for computers and gifts and all kinds of things that constantly come that have a component related to that as it relates to marketing for the industry. I think that the biggest concern I have had is the increased pressure or requests that doctors receive to have the drug rep in the examining rooms, which I find extremely concerning.

Dr. NIELSEN. Senator Stabenow, you anticipated just what I was going to say. We just passed a resolution about that at our last meeting in June. I will say the AMA not only has ethical guidelines for how to evaluate direct-to-consumer ads but we also have ethical guidelines for our own members for how they intersect with the pharmaceutical industry and we sincerely hope that they will follow those.

Senator STABENOW. Thank you. Thank you, Mr. Chairman.

Dr. RELMAN. Unfortunately, those guidelines are voluntary.

The CHAIRMAN. Let me turn to our colleague from Delaware, Senator Tom Carper, who has joined us.

Senator CARPER. Twice.

The CHAIRMAN. Twice you have and are you here to stay now?

Senator CARPER. Not for long, no.

The CHAIRMAN. Not for long, all right. Do you have any questions for our panelists?

Senator CARPER. Actually, I do.

I want to thank you all for being here today and for your testimony. Most of my colleagues have a lot going on today; you probably do, too. You are nice to spend your morning with us.

What would probably be most helpful to me in the short time that I have is to ask you a question or some questions. There are some things that you agree on with respect to direct-to-consumer advertising and there are probably some things you do not agree on. Where do you agree? Where are the common points of agreement that you have stumbled across during the course of this discussion this morning? I do not care who goes first.

Dr. NIELSEN. Let me start. I think we agree that education of the public is a good thing and educating them about possible conditions that they might not know about is a good thing, so I think there is not anybody around the table that would disagree about that one.

I can speak for myself. I believe and the AMA believes that the FDA is doing a good job. They need more resources. I will let Dr. Woodcock expand on that, but we do believe that they have worked hard to try to make sure that there are not excesses in some of the broadcast media and certainly the print media.

So let me start with that and ask the other colleagues around the table what we agree on. I could give you a long list of what we do not agree on.

Dr. RELMAN. I think everybody agrees that education is a good thing. Nobody can argue that consumers should not have as much information as they can usefully use. The question is not whether education is a good thing for consumers. The question is who should have that responsibility for giving them the kind of education they need.

Now as a professional educator, my idea of education has not the remotest resemblance to the kind of drivel that is put out in the ads. It is not education. It is marketing. So the question is who should do that? Then we would differ. The industry thinks we should do it—we, the industry, should do it. They say that. If we do not educate doctors in continuing medical education, who is going to educate the doctors? That is absurd. That is clearly a professional educational responsibility.

I believe that doctors and their professional organizations, as well as public health organizations, and government organizations, that have the facts and would be dispassionate and unbiased in serving the public interest should be the educators of our patients. The pharmaceutical industry simply doesn't belong there.

That is why I am so mad at our profession for allowing the pharmaceutical industry to pretend that they are our educators, and our patients too. They are not. They are our seducers.

Senator CARPER. Well, that is not a word we hear every day here in hearings, not lately.

Ms. Powell.

Ms. POWELL. Senator, if I could respond, I think that all of the PhRMA members would agree that education is important and that FDA regulation of direct-to-consumer advertising and physician advertising or education or marketing is appropriate. We have always supported funding for FDA that is at least equal to and in many instances greater than the administration has asked for or Members of Congress have been willing to fund. We think it is a vital agency and one that is fully worthy of support.

We think that the FDA regulations are appropriate in providing balance between the statement of risk and the statement of benefits in both direct-to-consumer advertising and in print advertising, although personally I would have to agree that some of the print advertising statements require not only the bifocals but also more of a medical education than I have, but many of our companies are moving to make that much more informative to the nonmedical consumer.

We also think that it is really important that members of the public become aware of diseases that are underdiagnosed and there are a great many of them, some of which are the subject of direct-to-consumer advertising. For example, there are many, many people with high blood pressure. I think the estimate is 30 million people with high blood pressure who are not diagnosed. There are people with high cholesterol, people with diabetes who are not diagnosed, and we think that direct-to-consumer advertising is helpful in getting those people in to see a physician.

We also think that physicians or other prescribers if a state allows, for example, a nurse-practitioner to prescribe some subset of drugs, are the appropriate people to be making the decision about whether a patient needs and should have this drug, another drug,

or any drug at all, and that is why we note that many physicians first say, have you tried diet and exercise? In fact, in many instances FDA requires the advertisements to include that information.

Senator CARPER. Thank you.

Ms. Rosenthal, Dr. Woodcock.

Ms. ROSENTHAL. Senator Carper, may I just add? I was actually struck by just how much common information we all drew upon in our written testimonies and how we all took different interpretations of the same numbers, all the same studies.

Senator CARPER. We sometimes do that, too.

Ms. ROSENTHAL. I would say for those of us who are able to express the opinion, I think we all agree that marketing is not education. I think we all agree on the general direction of the impact of DTCA, that it is increasing spending, increasing use, and that we probably do not need too much more information to understand that that is an important effect.

I think where we disagree is whether the evidence is really all in for us to make a decision on whether the benefits exceed the costs or vice versa and I would suggest that the evidence is not in and that further research is needed to understand where the health benefits may be real and where they may result in waste in the system.

Senator CARPER. Thanks.

Dr. Woodcock, you can give the benediction if you want.

Dr. WOODCOCK. I think the classic, I believe, is true, what Dr. Rosenthal just said. We do not believe the evidence is all in. There needs to be more independent research carried on in this area on these specific questions that you have. What is the public health impact? What is the economic impact to consumers and to the health care system, and so forth? I do not think we have enough information. It has not been that long and it is in a changing environment where other things have changed, as well, such as the advent of managed care, at the same time. I think even with such expert researchers as Dr. Rosenthal, it is very difficult to sort out a lot of these factors.

Senator CARPER. Thank you all.

Mr. Chairman, I do not know that it is going to answer the question of what our course should be but that is pretty good input here and I want to commend you and our staffs for putting this together. Real timely discussion on a real important issue.

I say that as a son of a mom who turns 81 years old next month and who has Alzheimer's disease, congestive health failure, and all kinds of maladies. The kind of education that my mom would glean, even in the years before we had to put her in a health facility, her ability to sit in front of a TV or read a print advertisement and to be able to really take away from that what she needs to know was limited and has been for some time.

On the other hand, there are other people who at that age are doing just fine and they can really glean the educational information they need from a variety of disparate sources. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Let me thank all of you for your time with us today and your testimony and your involvement in this issue. I might suggest that at least it is my observation that this is an issue that will not go away and it will not go away for a very important reason—your taxpayers have just become involved in it. As agents of America's taxpayers, we will have a fiduciary responsibility and that will be, as we have in the past with Medicare, to begin to micromanage that portion of the pharmaceutical market that we affect by the programs that we are now developing. That micromanagement will come with, I would trust, reasonable and effective oversight that will ultimately determine different subsets of policy that Congress will prescribe to this program and to this public benefit.

I have watched in the past. It is not that we are good at it; it is just that we do it because we are the board of directors. Certainly that was true of Medicare when, in fact, costs kept going up as to the given practice we were leveraging down those costs because we capped a certain amount of money on an annualized basis and tried to fit America's Medicare population into it.

That could well happen here and as a result of that, while I know that many in the pharmaceutical industry have applauded our entry into this health care arena, my suggestion to that industry is that the magnifying glass has just come out. We will read the fine print to attempt to understand why these costs, are rising. Recognizing at the same time the tremendous benefit that the American consumer from a health care standpoint gets from today's modern medicine and pharmaceuticals being at the cutting edge of that modernness, if you will, and to the health care of our country.

Dr. Relman, you are before us today at 80 years of age?

Dr. RELMAN. Yes, sir. Yes, I am.

The CHAIRMAN. I think that is not only remarkable; it is now becoming normal.

Dr. RELMAN. I hope so.

The CHAIRMAN. I just turned 58 Sunday and I am trusting that at 80 years of age I will not be here—I do not want to be here at 80 years of age—but that I will still remain active and involved, as many of our aging Americans are. I noticed that—or I should not say I noticed it; Senator Breaux noticed that in your resume and we were both commenting that you are a very youthful, involved 80-year-old, in part probably because of your genes but also it could well be because of modern health care and your understanding of it.

We thank you all very much. The committee will stand adjourned.

[Whereupon, 1 p.m., the committee was adjourned.]

APPENDIX

Impact of Direct-to-Consumer Advertising on Prescription Drug Spending

June 2003

The Kaiser Family Foundation is an independent, national health philanthropy dedicated to providing information and analysis on health issues to policymakers, the media, and the general public. The Foundation is not associated with Kaiser Permanente or Kaiser Industries.

With spending on prescription drugs rising faster than the costs of most other health care services, there is intense interest in the reasons why. Many in health policy circles suggest that the growth in direct-to-consumer (DTC) advertising by pharmaceutical manufacturers is a major contributor to higher prescription drug costs. A new study, commissioned by the Kaiser Family Foundation and conducted by researchers at the Harvard School of Public Health (M.B. Rosenthal and A.M. Epstein), Massachusetts Institute of Technology (E.R. Berndt), and Harvard Medical School (J.M. Donohue and R.G. Frank), provides important new information on this issue.

More than five years after the Food and Drug Administration issued new rules governing broadcast DTC advertising -- which allow television and radio ads to promote specific drugs with less detailed information in the ad itself about side effects and precautions than is required of print ads -- the marketing of prescription medications directly to consumers remains the focus of considerable debate. Proponents argue that DTC advertising informs consumers about important, treatable health conditions and encourage doctor-patient communication, while critics say that this type of advertising contributes to rising drug costs and lead people to demand unnecessary or inappropriate medications.

The new study examined changes in direct-to-consumer (DTC) advertising and physician promotion activities from 1996 to 1999 and their effects on drug sales within five therapeutic drug classes, chosen based on prevalence of DTC advertising within the classes and variation in advertising patterns and product lifecycles of drugs within the classes.[1] Impacts of the changes in DTC advertising and physician promotion on the market share of individual drugs within each class and on sales for the entire class were calculated. After accounting for the fact that drugs with higher sales are more likely to be advertised to consumers and have higher levels of promotion to physicians, the study found that increases in DTC advertising were associated with significant growth in sales for the classes of drugs studied: for every 10% increase in DTC advertising, drug sales within the classes studied increased on average by 1%. No evidence was found that changes in DTC advertising affected the market share of individual drugs within the classes.

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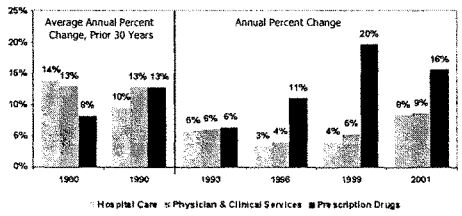
[1] Therapeutic drug classes were developed by pharmaceutical data companies to group drugs according to the type of illness they treat and their mechanism of action.

To simulate the overall impact of changes in DTC advertising on drug spending growth, these results were applied to changes in spending from 1999 to 2000 for the 25 drug classes with the highest retail sales. Drugs in these classes accounted for about 60% of the DTC advertising and about 75% of retail sales over that period. The study concludes that changes in DTC advertising during that period accounted for 12% ($2.6 billion) of the total growth in drug spending in 2000. This means that each additional dollar spent on DTC advertising in 2000 yielded $4.20 in additional pharmaceutical sales in that year.

Growth in Prescription Drug Spending

U.S. spending for prescription drugs was $140.6 billion in 2001, more than tripling since 1990. Although prescription drug spending remains a relatively small proportion (11%) of personal health care spending, it is one of its fastest growing components, increasing at double-digit rates in each of the past 7 years. National prescription spending increased 16% from 2000 to 2001, compared to a 9% increase for physician and clinical services and an 8% increase for hospital care (Figure 1).[a]

Figure 1: Change in Selected National Health Expenditures, 1980-2001



Source: Data from Centers for Medicare and Medicaid Services at www.cms.hhs.gov/statistics/nhe/default.asp.

There are several components to this rapid rise in spending: more prescriptions are being written, prices of existing drugs are rising, and higher-priced new drugs are replacing existing drugs. Between 1997 and 2001, drug spending increased 86%, with almost one-

half of the growth attributable to more prescriptions and about one-quarter of the growth attributable to price increases for existing drugs and to changes in drug mix. [b]

Actuaries at the Department of Health and Human Services project that prescription drug spending will continue to grow at between 9% and 12% annually through most of the next decade.[c] Concerned about the impact that this cost growth is having on the availability and affordability of prescription drugs, policymakers, public and private health plan managers, and others have begun to look at the factors contributing to these rapid increases, including the potential role of DTC advertising.

Promotion of Prescription Drugs

Promotional spending by pharmaceutical manufacturers has risen steadily in recent years, more than doubling from $9.2 billion in 1996 to $19.1 billion in 2001, an average annual increase of 16%. While most promotional spending (86%) remains directed at physicians, a growing proportion is directed at consumers, especially through television ads.[d]

Pharmaceutical manufacturers use several types of promotion, each of which has been growing in recent years (Figure 2):[2]

- *Detailing* (29% of spending) is the sales activities of drug representatives directed toward physicians. Most detailing is directed at office-based physicians ($4.8 billion), the rest at hospital-based physicians ($700 million).

- *Sampling* (55% of spending) is the free drug samples that pharmaceutical representatives provide to office-based physicians. Sampling, valued at retail pharmacy prices, totaled $10.5 billion in 2001.[3] Recently, samples are also being

[2] Although not included in these promotion totals, pharmaceutical companies also conduct educational meetings and events for physicians, estimated at a cost of $2.1 billion in 2001 (Scott-Levin data from "Spending Hits a Wall" in *Pharmaceutical Executive*, Sept. 2002).

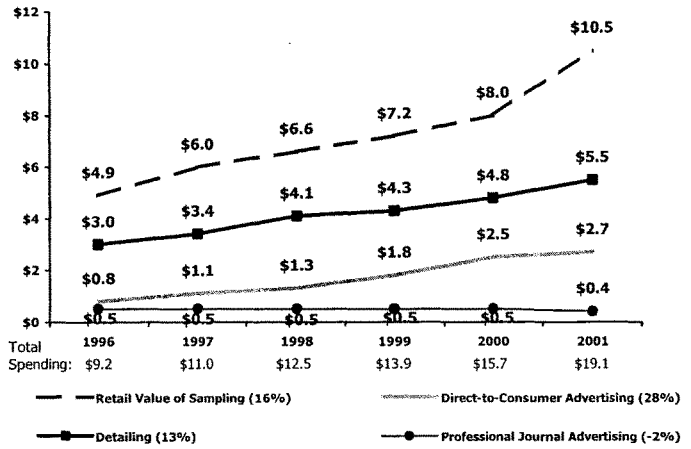
[3] The retail value of samples is used to approximate the economic cost to the pharmaceutical companies of giving away free samples. Because samples presumably crowd out at least some sales, using production costs would understate the cost of samples to the manufacturers. Using the retail price to value all free samples, however, probably overstates the opportunity cost to the manufacturer, so this approach may well overvalue the cost of sampling to manufacturers.

made available through DTC advertising venues like TV, newspapers, and the Internet.

- *Direct-to-consumer (DTC) advertising* (14% of spending) includes advertisements targeted toward consumers through magazines, newspapers, television, radio, and outdoor advertising.

- *Medical journal advertising* (2% of spending) is the value of professional journal advertisements.

Figure 2: Trends in Promotional Spending for Prescription Drugs, 1996-2001 ($ in Billions)



Note: May not add to totals due to rounding. Percents in parentheses are average annual increases from 1996-2001. Excludes promotion spending for professional meetings and events.

Source: Kaiser Family Foundation and Sonderegger Research Center, *Prescription Drug Trends, A Chartbook Update*, November 2001, using data from IMS Health, Inc. , *Integrated Promotional Service*, and Competitive Media Reporting, 1996-2000; 2001 data from IMS Health at www.imshealth.com.

While DTC advertising remains a relatively small part of overall industry promotion, its rapid spending growth in recent years (increasing an average of 28% annually from 1996-2001), frequent presence on television and in magazines, and extensive use in promoting newer, more expensive medications, have attracted the attention of critics who worry that it encourages patients to demand high-cost prescriptions for ailments that could be treated effectively with lower cost options.

The public has certainly become more aware of DTC advertising in recent years – the percent saying they had seen or heard an ad for a prescription medication grew from 63% in 1997 to 85% in 2002.[e] And the ads are resulting in consumer interest in prescriptions -- nearly a third (30%) of adults say they have talked to their doctor about a drug they saw advertised, and 44% of those who talked to their doctor received a prescription for the medication they asked about. This means that 13% of Americans have received a specific prescription in response to seeing a drug ad.[f]

Spending for DTC advertising is concentrated in a relatively small number of drugs -- the top 10 drugs with DTC advertising accounted for about a third (36%) of all DTC advertising spending in 2001. Six of the top 10 drugs advertised through DTC were also among the top 10 drugs promoted to physicians through detailing and medical journals. The drugs most heavily promoted to both consumers and physicians are typically drugs that treat chronic conditions -- in 2001, the top 3 drugs with the most promotion spending were anti-inflammatories and an anti-ulcerant.[g] Prescription drugs with the highest promotion spending tend to be newer drugs, many of which are more expensive than the drugs they are intended to replace.

Drugs that are heavily advertised to consumers typically rank high in sales -- 6 of the top 10 drugs advertised through DTC were among the top 20 drugs in dollar sales and in the number of prescription dispensed in 2000. Sales of the most heavily advertised drugs have increased much more rapidly than for other drugs – from 1999-2000, the dollar sales of the 50 most heavily promoted drugs increased 32%, while the sales of all other drugs increased 14%; the number of prescriptions sold increased 25% for the top 50 promoted drugs, compared to 4% for all other drugs.[h]

Analysis of the Effects of Promotion on Prescription Drug Spending

A recent study by researchers at the Harvard School of Public Health (M.B. Rosenthal and A.M. Epstein), Massachusetts Institute of Technology (E.R. Berndt), and Harvard Medical School (J.M. Donohue and R.G. Frank) finds that DTC advertising has a significant effect on prescription drug spending. The complete report of their study, *Demand Effects of*

Recent Changes in Prescription Drug Promotion, May 29, 2003, can be found at www.kff.org.[i]

The study examines changes in sales and drug promotion over a three-year period for five therapeutic classes of drugs in order to determine the effects of increases in DTC advertising and physician promotion on sales for the therapeutic classes and on changes in relative market shares of the drugs within the classes.[j] The five therapeutic classes studied were antidepressants, antihyperlipidemics (cholesterol-lowering), proton pump inhibitors, nasal sprays, and antihistamines. These five classes were selected based on having (1) at least one product with significant DTC advertising expenditures in the class; (2) variation in spending for DTC advertising within the class; and (3) variation in the remaining patent periods of drugs within the class. The five classes selected accounted for about 30% of all DTC advertising and 25% of physician promotion in 1999. The drugs within the selected classes treat a wide variety of ailments, are indicated for different populations, and are prescribed by a number of different clinical specialists.

To simulate the overall impact of changes in DTC advertising on drug spending growth, the price elasticity results from the five-class analysis were applied to the aggregate changes from 1999 to 2000 in total sales and total DTC spending for the 25 drug classes with the highest retail sales. Drugs in these classes accounted for about 60% of the DTC advertising over that period and about 75% of retail sales.

Significant findings from the study include:

- **The analysis of advertising and sales growth in the five therapeutic classes studied produces an advertising elasticity of .10, which means that on average a 10% increase in DTC advertising of drugs within a class results in a 1% percent increase in sales of drugs in the class.** The study offers the case of proton pump inhibitors (or PPIs, for treatment of ulcers) as an example. Between 1998 and 1999, DTC advertising spending for PPIs increased 60% (from $49.7 million to $80.1 million) and PPI sales increased 36% (from $4.2 billion to $5.7 billion). Applying the estimated elasticity of .1 to the results for this drug class, the study estimates that $252 million, or about 17% (or 6 percentage points), of the 36%

increase in PPI sales from 1998 to 1999 is attributable to the increase in DTC advertising.

- **Applying this elasticity to the growth in DTC advertising for the 25 largest therapeutic drug classes, the study estimates that increases in DTC advertising between 1999 and 2000 accounted for 12% of drug sales growth during that period.** Applying the 5-class analysis results to the 25 classes with the highest retail spending finds that DTC advertising growth during the year resulted in an additional $2.6 billion in drug spending in 2000.

- **DTC advertising is an important, but not the primary, driver of growth in prescription drug spending. However, DTC advertising produces a significant return for the pharmaceutical industry: every additional $1 the industry spent on DTC advertising in 2000 yielded an additional $4.20 in sales.**

- **For the therapeutic classes studied, the impact on sales of increased spending for promotion to physicians was considerably smaller than the impact of increased spending for DTC advertising.** The study found that every 10% increase in spending for promotion of drugs within a class to physicians leads to a .2%-.3% increase in sales for drugs in the class.

- **DTC advertising does not appear to affect relative market share of individual drugs within their therapeutic class.** While DTC advertising appeared to influence sales at the therapeutic class level, the study did not find evidence that changes in DTC advertising for individual drugs increased their sales relative to the other drugs within the class. A possible explanation for this finding is that DTC advertising prompts previously untreated patients to talk to their doctors about advertised treatments, but that the discussions may not lead to a prescription for the particular drug that was advertised. (A November 2001 survey by the Kaiser Family Foundation found that for Americans who said they talked to their doctor about a medicine they saw advertised, 44% said the doctor gave them the prescription they asked about, while 25% said the doctor recommended a different drug). The authors of this new study caution, however, that since the research models used in the study may not capture the complex timing of relationships between promotion efforts and sales for

individual drugs, or the experimentation of drug manufacturers with DTC advertising, the impact of promotion on individual drugs is more ambiguous and merits further research.

Conclusion

DTC advertising is an important, but not the primary, driver of growth in prescription drug spending. For pharmaceutical manufacturers, the return generated by increasing spending on DTC advertising appears to be significant. Although prescription drug spending growth has moderated somewhat in the last couple years, annual increases in the 9% to 12% range are still expected for most of the next decade. Given this continuing rapid growth, the debate over the costs and benefits of DTC advertising are likely to continue. This new study provides important information to policymakers as they evaluate the benefits and costs of DTC advertising.

Endnotes

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[b] Kaiser Family Foundation, *Prescription Drug Trends*, March 2003, at www.kff.org/content/2003/305702/3057_02_033103.pdf.
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[f] Kaiser Family Foundation, *Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising*, November 2001, at www.kff.org/content/2001/3197/DTC%20Ad%20Survey.pdf.
[g] *Medical Marketing & Media*, May 2002, IMS Health and Competitive Media Reporting data, at www.cpsnet.com/reprints/2005/05/IMS.pdf.
[h] National Institute for Health Care Management, *Prescription Drugs and Mass Media Advertising, 2002*, November 2001, at www.nihcm.org/DTCbrief2001.pdf.
[i] An earlier version of this report can be found in *Frontiers in Health Policy Research*, Vol. 6, edited by David M. Cutler and Alan M. Garber, MIT Press, June 2003.
[j] The Harvard and MIT study relied on several sources of information on advertising and prescription drug sales: sales and detailing data are from Scott-Levin, Inc.; DTC advertising data are from Competitive Media Reporting; and sampling data are from IMS Health, Inc. Spending on professional journal advertising, which represented only 2% of promotional spending in 2001, was not included in the study.

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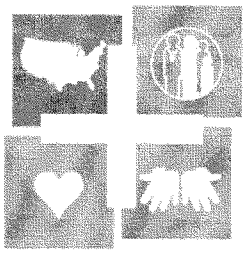

CENTER FOR
PATIENT ADVOCACY

Statement
of
The Center for Patient Advocacy

Special Committee on Aging
United States Senate

Hearing on
"Direct-to-Consumer Advertising of Prescription Drugs: What Are the Consequences?"

July 22, 2003

The Center for Patient Advocacy is pleased to submit written testimony to the Senate Special Committee on Aging as it examines direct-to-consumer advertising (DTC) of prescription drugs. We applaud the Committee for holding this hearing and welcome the opportunity to present the patient's perspective on this important issue.

Founded in 1995, the Center for Patient Advocacy is a grassroots organization representing patients nationwide and dedicated to ensuring that patients have timely access to quality health care. With a coalition of more than 100,000 members nationwide, the Center works to bring the views and concerns of patients to the attention of Congress and the Administration. We have brought the patient's perspective to a number of recent issues considered by Congress, including managed care reform, Food and Drug Administration modernization, and Medicare reform to list just a few.

In addition to advocating on behalf of patients, the Center provides assistance to them. Our toll-free hotline and e-mail helpline are available to help patients with any questions or problems they may be experiencing with their health care. Our goals in working with patients are to educate them about their health care and to encourage them to play a more proactive role not only their own health care, but also in the political process that can bring positive change to our health care system. And it is for these reasons that we are pleased to provide our views to the Committee on direct-to-consumer advertising of prescription drugs.

We understand that the Committee will hear testimony from witnesses representing the Food and Drug Administration (FDA), the pharmaceutical industry, the medical community and academia. However, we believe it is vital that you also hear the perspective of the patient community in order to gain a full understanding of the impacts of DTC advertising.

Patients Benefit From DTC Advertising

The Center for Patient Advocacy strongly believes that DTC advertising is an important health care resource patients can use to make informed decisions about their health care, leading to better outcomes and improved quality of life for patients.

Studies conducted by the FDA, the Kaiser Family Foundation and others consistently show that prescription drug advertising plays a vital role in providing patients with information regarding their health care choices. These ads educate patients about symptom recognition and available treatment options, destigmatize certain conditions, improve communication between patients and doctors and, ultimately, ensure that patients receive the best care available. Patients benefit from DTC advertising in the following ways:

- **DTC advertising educates patients about treatments**. In several recent surveys, between 71% and 86% of consumers agreed that DTC advertisements made them aware of new treatments, and 72% of physicians agreed that advertisements made their patients aware of possible treatments.

- **DTC advertising prompts patients to talk to their doctors, some of them about conditions that have not been previously discussed.** Research consistently finds that about one-third of consumers had a discussion with their doctor about a medication or condition after seeing an ad. Nearly 20% reported an ad motivated them to discuss a condition for the first time.

- **DTC advertising leads to new diagnoses, many of them for serious diseases.** One study measured the number of new diagnoses occurring after DTC-prompted discussions and found a new diagnosis after one-quarter of these discussions. Approximately 43% of these new diagnoses were for high priority conditions that are frequently under-diagnosed and under-treated in the U.S., such as high cholesterol, high blood pressure, diabetes, and depression. These are conditions that, if diagnosed early, can be effectively treated and managed, resulting in better quality of life and lower costs to the health care system overall.

- **DTC advertising prompts a variety of actions at the doctor's office.** While studies show that the advertised drug is prescribed after one-third to one-half of DTCA discussions, an alternate drug is prescribed one-fifth to one-third of the time and lifestyle changes are recommended one-third to one-half of the time. One study additionally found that specialist referrals occurred 33% of the time and lab tests were prescribed after 57% of the discussions.

- **DTC advertising leads to improved health and quality of life for patients.** In a study of the health effects of DTC advertising, about four in five patients who were prescribed a medicine (not necessarily the advertised medicine) said they had an improvement in symptoms and felt better after taking the medicine. Among the subset with lab tests, four in five had results showing a change for the better.

Clarifying the Misconceptions About DTC Ads

In addition to the benefits for patients and patient care we have noted above, we would also like to take this opportunity to clarify some of the misconceptions that exist about DTC ads.

"Patients Don't Like DTC Ads" -- In a survey by *Prevention Magazine*, patients gave high marks to direct-to-consumer advertising of pharmaceuticals. Of those surveyed, 76% felt DTC ads allowed them to become more involved in their own health care. The survey concluded "the benefits of direct-to-consumer advertising could go far beyond simply selling prescription medicines: these advertisements play a very real role in enhancing the public health."

In another survey conducted by the National Consumers League, 42% of respondents agreed that DTC ads help drug manufacturers sell their products. However, they still believe that DTC ads are useful and they should continue to have access to them.

"Patients Are Being Misled By DTC Ads" -- With today's technology, sources of information on health care are available virtually everywhere. However, DTC advertising is one of the most reliable. Unlike many other resources patients can turn to for information, DTC ads are the only source that is strictly regulated by the federal government to ensure their accuracy and truthfulness. Not only does the FDA require that ads strike a balance in the presentation of a treatment's benefits and risks, but the FDA also has the authority to prevent misleading or false ads from being seen by consumers. In fact, most prescription drug ads are reviewed by the FDA before they hit the airwaves or newsstands.

"Prescription Drug Advertising Harms the Doctor-Patient Relationship" -- A 1999 survey by Louis Harris Interactive and the Harvard University School of Public Health found growing acceptance of DTC advertising among doctors. The poll found that 49% of doctors believe DTC advertising of prescription drugs had helped "educate and inform" their patients. A 2003 survey conducted by the FDA found that the majority of patients who discussed a drug with their doctor received positive feedback from their doctor. The vast majority of patients (93%) said their doctor welcomed their questions, discussed the drug with the patient, and did not react as if the question were out the ordinary.

The FDA survey also found that 56% of physicians believe DTC ads helped patients ask better questions, 51% believe communications with their patients about health are improved by DTC ads, and 45% believe that the quality of the time they spend with patients is increased by DTC ads. Moreover, 58% of physicians believe that DTC ads can benefit their patients by encouraging them to become more involved in their health care.

"Drug Ads Lead to Inappropriate Prescriptions" -- The power to prescribe remains firmly in the hands of the doctor and these drugs are available only under a doctor's supervision.

Direct-to-consumer advertising does NOT result in patients obtaining prescriptions for drugs that may be wrong for them. While direct-to-consumer advertising clearly prompts patients to see their doctor, patients cannot get prescription medicines unless their doctor finds those drugs are necessary and appropriate for their individual situation.

According to studies by the FDA and *Prevention Magazine*, not all patients prompted to see a doctor by a DTC ad actually leave the doctor's office with a prescription for the drug they inquired about. Far from being pressured, studies even show that many doctors openly discuss alternatives, including non-drug alternatives, with their patients. Spurred by the information provided by direct-to-consumer advertising, the patient is approaching the doctor with his or her concerns and together they are making a decision about what, if any, drug may be prescribed.

The bottom line is that there is no concrete evidence that the discussions prompted by direct-to-consumer advertising or questions about specific advertised drugs lead to inappropriate prescriptions.

"Drug Manufacturers Spend More on DTC Advertising Than Research and Development" -- One of the most common misconceptions in the debate on DTC ads is that manufacturers spend more on advertising than they do on research and development. Nothing could be further from the truth. The fact is that the pharmaceutical industry spends more than tens times as much on R&D than on DTC ads. For example, in 2001 the industry spent $30.3 billion on research and development. By contrast, only $2.7 billion was spent on DTC ads. And spending on DTC ads accounted for only 2% of prescription drug sales.

"DTC Advertising is Responsible for Spiraling Health Care Costs" -- While the amount of money spent on prescription drugs has risen, drug costs still only account for 10% of overall health expenditures.

And when looking at rising drug expenditures, it is important to consider the clear benefits of prescription drugs. Drugs can help keep employees on the job and patients productive in the community; they help people avoid disability, surgery, hospitalizations, and nursing home care; and in some cases they decrease the total cost of caring for an illness.

In addition, there is evidence that advertising may actually help to reduce the price of drugs rather than increase prices. This happens, according to John E. Calfee, Ph.D., an economist at the American Enterprise Institute, primarily because advertising makes markets more competitive.

Calfee also believes that there is no evidence that recent increases in drug expenditures have been caused by the inappropriate use of prescriptions. "The evidence suggests," Calfee said in Congressional testimony on July 24, 2001, "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."

Finally, a General Accounting Office (GAO) study of DTC advertising noted that drug utilization rates are increasing around the world, including in countries that do not permit DTC ads. These countries are experiencing similar increases as those in the United States. In fact, there are a number of other causes for increased utilization and higher drug expenditures, including: an aging population; advances in medicine, which increase the number of treatments available and can lead to new treatment guidelines; increased diagnosis of disease; and changes in insurance coverage for drugs.

DTC Ads Empower Patients, Leading to More Efficient and Effective Care

The Center for Patient Advocacy strongly believes that the net effect of advertisements for prescription medicines is one of patient empowerment and better health outcomes. Advertisements are a powerful tool in helping to raise awareness among patients of conditions and treatments. And as our doctors' visits seem to get shorter and shorter, it's critical for patients to be active partners in the care and management of their conditions.

In a time when rising health care spending is a top concern for consumers, policy makers, and employers, a tool that helps patients take more control of their health should be welcomed. After all, an informed patient can lead to lower health care spending, higher quality of care and better outcomes. Aren't these the goals we all are trying to achieve?

We again would like to thank the Committee for holding this hearing.

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