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Prime Time Pushers

Freed from federal restrictions, pharmaceutical companies are flooding television with ads for prescription drugs. What does it mean for our health care when serious medicine is marketed like soap?

By Lisa Belkin

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Wherever you flip on the TV dial nowadays you will find commercials for medications that you cannot actually buy. Not without the permission of your doctor (or the aid of the Internet, but we'll talk more about that later). These are serious drugs, with potentially dangerous consequences, but the mood of the ads is upbeat and cheery. Cholesterol busters battle for market share. Antidepressants come with handy checklists of symptoms. Joan Lunden hawks Claritin. Newman from "Seinfeld" pitches an influenza drug. Pfizer spokesman Bob Dole promotes cures for erectile dysfunction.

No, you are not simply getting old and noticing this more. Television ads for prescription drugs, which were all but outlawed as recently as four years ago, are now taking over your TV set. To wit: Pharmaceutical companies spent an estimated $1.7 billion on TV advertising in 2000, 50 percent more than what they spent in 1999, more than double the 1998 amount. In 1991, only one brand of prescription medication was marketed on network television by the route the industry calls "direct to consumer," or DTC. By the end of 1997, there were 12 drugs on that list, and by 2000, there were at least 50.

The rush to the airwaves was triggered by the U.S. Food and Drug Administration, which, until four years ago, had required that manufacturers include nearly all of the consumer warning label in any pitch -- something possible in a magazine advertisement, but prohibitive in a 30-second television spot. The sole exceptions were for so-called reminder and help-seeking ads -- ones that named either the product or the condition being treated, but not both. The result was some very confusing ads.

For the better part of a decade, advertising agencies, pharmaceutical companies, and the major television networks lobbied for less restrictive rules, and, in August 1997, the fda issued a "clarification" of its 30-year-old regulations. Television commercials may now name both the product and the disease, as long as viewers are given information about "major" risks of the drug

and directed to other sources of information -- Web sites, magazine ads, toll-free numbers -- for more detail. (And you thought those phone numbers were simply there to be helpful.)

Thus the United States became one of only two countries in the world (New Zealand being the other) where prescription drugs are hawked in prime time. Proponents of the FDA's policy shift say it creates a more informed patient because viewers see the ads, then have an intelligent give-and-take with a doctor. Critics say the shift creates more business for pharmaceutical companies by encouraging patients to seek out expensive, potentially dangerous drugs that they -- and too often their doctors -- know little about. "It was a sellout," says Larry D. Sasich, a pharmacist with Public Citizen's Health Research Group in Washington, D.C. "It's nothing more than a response to pressure from Madison Avenue."

Whatever the motivation, the shift has resulted in a quiet but dramatic transformation of the whole of our health care system. Gone is the time when doctors held complete power and prescription medicines were treated as a sacred and separate world. These ads mark the full dawning of an age when our very health is sold to us like soap. So turn on your TV set, relax, and take a pill. It's Prilosec time.

Before we talk about what is wrong (and unseemly and potentially dangerous about all of this), let's look at what's right. Seen through a certain lens, the explosion of DTC drug advertising is a continuation of the patients' rights movement that began in force 30 years ago. Allowing such ads, says Nancy Ostrove, a branch chief within the FDA's Division of Drug Marketing, Advertising, and Communication, is not only a recognition of the unstoppable power of television, but also the best way to inform consumers about available drugs. "There are certain real health benefits that can be achieved," she says.

Talk to any pharmaceutical company and they will tell you how thrilled they are to be educating the public. "From our point of view, one of the main purposes of direct-to-consumer advertising is education," says Emily Denney, a program manager in public affairs at AstraZeneca. Her company makes Prilosec, a drug that treats gastroesophageal reflux disease, a painful condition in which acid leaks from the stomach, causing chronic heartburn and even ulceration of the esophagus. Because of the $79.5 million the company spent on Prilosec ads in 1999, Denney says, "patients have been more easily able to diagnose symptoms that went ignored for many years. Our whole goal is just to encourage a conversation with your health care provider."

It is, to be sure, a self-interested, image-polishing argument, but the fact is that millions of us are sick and do not know it. According to the American Diabetes Association, more than 5 million diabetics in this country are unaware that they have the disease; one-third of Americans with major depression seek no treatment; and millions of Americans are ignorant of the fact that they have high blood pressure. Now consider this: In the two years since ads for Viagra first began to air, millions of men have visited their doctors specifically to get that drug -- and thousands of them were diagnosed with serious underlying conditions. The Pharmaceutical Research and Manufacturers of America estimates that for every million men who asked for the medicine, it was discovered that 30,000 had untreated diabetes, 140,000 had untreated high blood pressure, and 50,000 had untreated heart disease.

Let's face it, though, even the drug companies would agree that they are not spending all this money just to be helpful. They are spending all this money to sell their products. "We don't invest in things we don't find valuable to the business," says AstraZeneca's Denney.

Direct-to-consumer advertising has paid off handsomely for the pharmaceutical companies -- often turning solid earners into blockbuster drugs. After spending nearly $80 million on Prilosec advertising in 1999 (up from $50 million in 1998), AstraZeneca saw sales rise 27 percent, to $3.8 billion. Pfizer, in turn, upped consumer advertising for its cholesterol drug, Lipitor, by more than $45 million in 1999, and sales of the drug jumped too -- 56 percent, to $2.7 billion.

Some of the most dramatic ad-and-effect can be seen in the category of allergy drugs. Claritin maker Schering-Plough launched the televised assault against sneezing in 1998 when it spent $185 million on advertising and saw sales more than double to $2.1 billion. Following the leader, Pfizer spent $57 million to promote its drug Zyrtec in 1999 and saw a 32 percent increase in sales; that same year, Aventis spent $43 million to promote Allegra, and sales increased by 50 percent.

There is no reason to believe, however, that there was any increase in the number of allergy sufferers in the United States during this time, and no sudden outpouring of pollen either. There was just an increase in the sale of prescription allergy medications. According to Scott-Levin, a pharmaceutical consulting company in Pennsylvania, doctor visits by patients complaining of allergy symptoms were relatively stable between 1990 and 1998, at a rate of 13 to 14 million per year. In 1999, there were 18 million allergy visits. The cause of the spike, critics point out, is clearly the advertising.

The purpose of allergy ads in particular and pharmaceutical ads in general "is to drive patients into doctors' offices and ask for drugs by brand name," says Sasich, of Public Citizen. And once they are in that office, patients often get what they want. "Physicians are more interested in pleasing their patients than you might think," says Steven D. Findlay, an analyst who is director of research and policy at the National Institute for Health Care Management. "It's a subtle interchange and exchange that happens between patient and doctor."

"Patients can be difficult to dissuade," says Dr. Jack Berger, an internist and rheumatologist in private practice in White Plains, New York, and sometimes it is easier for doctors to give in. "It adds an extra source of confusion and frustration to the doctor/patient relationship when the patient starts directing the treatment based on what they learned on TV," he says.

Studies have shown that patients requesting specific drugs often get just what they ask for. A survey by the FDA of people who had recently been to their doctors, for instance, found that 72 percent had seen or heard an ad for prescription drugs in the previous three months, mostly on TV. Close to 25 percent of those respondents had also asked their doctors for the first time about a condition or illness. Of those who asked for a specific drug by name, nearly half were given a prescription for it; 21 percent were recommended a different drug.

"These ads have had a very large impact on a somewhat hypochondriacal public," says Findlay. The ads do, in fact, educate consumers, he says, but what they often teach is how to describe

your symptoms so you will be given a certain medication. "The purpose of advertising is not to inform people," Findlay continues. "It never has been and it never will be. The purpose of advertising, as we all know, is to make people buy more product so the company can make more money. It makes you desire that new product, just like that new car or that new gizmo."

Yes, doctors still hold the prescription pad, but parents have long held the credit cards and toys are advertised directly to kids. At a dinner recently, Findlay listened as two other guests "kept going on and on about Celebrex," a new arthritis drug from Pfizer/Pharmacia. "They were talking about it like you talk about PCs," he says, "and there was a pride in the fact that they both were taking Celebrex, because it's advertised, it's on TV."

Evolution in advertising favors the slick and jazzy, and so it is with DTC television spots. In the old days, when the ads could not mention both the disease and the cure, the industry argued that such rules led to confusion. In the words of the Pharmaceutical Researchers and Manufacturers of America, the restrictions "prompted companies to advertise on television in more oblique ways, which, while meeting legal requirements, may have been less helpful to consumers. Consumers were often left to guess what the medicine was for."

Now the rules have changed. What, then, are we to make of new ads like those for Prilosec that feature a lithe woman in a flowing purple gown against the background of a clock with the uninformative slogan "It's Prilosec Time"? Is this a cure for depression? Irregularity? The ad itself gives no clue.

The original Prilosec ads, AstraZeneca's Denney says, described gastroesophageal reflux disease, or GERD, in some detail, showing cartoons of people in obvious distress and quizzing viewers about how often they experience heartburn. But GERD "is not the most pleasing-sounding word," Denney explains, and "you can't describe it perfectly in 60 seconds"Ñwhich may be why the company shifted to these more free-form reminder ads, which play up the fact that the pill itself is purple. And it's not just on television. The woman in the purple dress also appears in print ads, on the Web, and in subway stations plastered with purple pills. "The purpleness is a form of branding," Denney says. "People know Prilosec as 'the little purple pill.'"

One can't help but wonder, however, if such branding is having a far more troubling effect -- whether occasional heartburn sufferers looking for a silver (or, in this case, purple) bullet might not be pressing their doctors for a powerful drug they don't really need. Americans tend to prefer the easy x, and the ubiquitousness of direct-to-consumer ads, which dress medicine up in the same telegenic tinsel as perfume or sports cars, make our health seem as simple as we would like it to be. "The ads send a strong signal," says a report from the National Institute for Health Care Management, "that prescription drugs are just like any consumer product -- soap, cereal, cars, snack food, etc."

Look more closely at a category of drugs known as statinsÑsold under such brand names as Lipitor, Pravachol, and Zocor -- which have proved so effective at lowering cholesterol that some doctors see advertising them as a public service. "There are countless people who would be better served if they knew these drugs were available," says Dr. Ira S. Nash, associate director of the cardiovascular institute at the Mount Sinai School of Medicine in New York City. Yet other

doctors worry about the side effect of those same ads. Statins can cause dangerous liver complications and their use needs to be carefully monitored by a doctor. In most cases, statins should be prescribed only to patients who have tried the lines of first defense -- namely, diet and exercise -- and who have failed to lower their cholesterol in spite of these lifestyle changes. If the ads make fighting cholesterol look too easy, patients may insist on skipping the hard part and going straight for the pill. "It takes time to speak to a patient about exercise, weight control, and diet. It takes less time to just write a prescription," says Dr. Berger, the private practitioner, and there is a danger that doctors will choose the easier course.

Cholesterol, at least, is a problem that can be measured. What about conditions whose symptoms are far more difficult to evaluate? Last year's ads for Paxil fall into this category. Paxil is an antidepressant approved by the FDA for the secondary purpose of treating social anxiety disorder, which GlaxoSmithKline's ads describe as "an intense, persistent fear and avoidance of social situations." In its true, clinical form, it is a real and debilitating condition, but by reducing it to an ad -- in which the subject experiences dread while giving an office presentation -- Paxil can too easily sound like a pill for shyness.

One television ad that I find particularly egregious, bordering on offensive, is for a relatively new drug called Sarafem. The chemical composition of the pill is identical to that of Prozac, but last summer manufacturer Eli Lilly and Company received FDA permission to market it simultaneously for treatment of premenstrual disphoric disorder, or PMDD. The condition differs from pms in that its symptoms are more emotional than physical and include depression, anxiety, and bursts of anger. And yet a television spot for the drug shows a frustrated woman struggling with a shopping cart in front of a supermarket, and makes Sarafem look like an easy fix for your average bad day.

"They're making everything into a disease," adds Dr. Nash, "and not only is it a disease, but it's a disease that society has a pill for."

Because more is at stake, viewers should bring a higher level of skepticism to pharmaceutical ads. Instead, there is reason to believe they are bringing less. A recent study in the *Journal of General Internal Medicine* found that nearly half of respondents believed that drug ads are prescreened and somehow sanctioned by the FDA. In fact, quite the opposite is true. The FDA's Ostrove explains that the agency is "forbidden by law from requiring preclearance." Although some pharmaceutical companies choose to submit their ads in advance, she says, they do so at their own discretion. All the FDA can require is that a copy of an ad be sent to its office when the ad begins to air.

Once the commercial arrives at the agency's Rockville, Maryland, headquarters, it is reviewed by 1 of the 14 employees who screen 30,000 pieces of promotional material each year. "We allow a certain degree of puffery," Ostrove says, "but we don't allow overstatement of effectiveness or minimization of the risks." Even with such allowances, the FDA found that for the first 37 drugs marketed directly to consumers on television, 20 ads failed to comply with federal regulations, including those requiring "fair balance" and the disclosure of side effects.

Of the estimated 200 television drug spots aired since the 1997 FDA rule change, the agency has cited 32 for noncompliance and has asked the companies to change all or part of the ads. The FDA told Pfizer/Pharmacia, for instance, that an advertisement for the arthritis drug Celebrex was misleading because "various multiple physical activities portrayed by arthritis patients (such as rowing a boat and riding a scooter)," along with "the audio statement 'Powerful 24-hour relief from osteoarthritis pain and stiffness,' collectively suggest that Celebrex is more effective than has been demonstrated by substantial evidence." In other words, the product does not work as advertised. Judith Glova, a spokeswoman for the company, says the ad was pulled and modified slightly -- a statement was added, for example, noting that "individual results may vary" -- and put back on television.

Similarly, Eli Lilly and Company was told that an ad for the osteoporosis drug Evista was misleading because "it mischaracterizes the nature of osteoporosis, resulting in an overstatement of Evista's benefits." Specifically, the agency said, the ad's description of osteoporosis as "a disease of thin, weak bones that can fracture and take away your independence" exaggerated both the risk and the consequence of a fracture. Eli Lilly spokesman David Marbaugh says the ad has been "suspended" while the company works with the FDA to revise the ad.

Most recently, I was pleased to learn, the FDA sent a letter to Eli Lilly about the ads for Sarafem -- the very spots showing a woman struggling with a shopping cart. The ad does not define the condition it is designed to treat, the agency said, and as a result "trivializes the seriousness of PMDD." The company was asked to "immediately cease using this broadcast advertisement."

Eli Lilly decided to honor the agency's request, but, legally, the company could have kept running the ads indefinitely. As Findlay, the health care analyst, notes, "Everybody thinks the agency [the FDA] is this big 900-pound gorilla, but their actual power is limited." Essentially, all the agency can do is request compliance. If a company refuses, the FDA cannot impose fines or other punishments but must instead go through the courts for an injunction. "As a matter of course, most companies do change their ads," Findlay says, "but that is because they are concerned about the public relations implications. The heaviest hammer the FDA has in this department is embarrassing manufacturers."

The guiding rule of medicine is, "first, do no harm." What, then, is the harm of pharmaceutical ads? Yes, they may be misleading, but it can be argued that most consumer ads are misleading. Why should we care? Who is this hurting? The most measurable harm is economic. "There is very strong circumstantial evidence," says Public Citizen's Sasich, "that some patients are getting drugs that may be stronger than they need. A less expensive, more easily obtained drug may be more appropriate."

Celebrex, says Findlay, is one example of potential pharmaceutical overkill. With first-year sales of $1.3 billion in 1999, it was the most successful drug launch in history. Celebrex and similar new arthritis drugs, such as Vioxx, represent an advance because they do not cause the level of gastrointestinal distress that alternative treatments, such as over-the-counter ibuprofen tablets, can. However, Findlay says that "the proportion of people with arthritis at high risk for that side effect is between 10 and 20 percent." But if you extrapolate from the number of prescriptions written for the drug, he says, then Celebrex and similar medications are "being taken by

potentially 40 percent of arthritis patients. These medicines are going to people who have no clinically defined need."

A one-year dosage of Celebrex costs $900, says William Pierce, a spokesman for the Blue Cross and Blue Shield Association (bcbsa), while a one-year dosage of generic ibuprofen costs $24. Numbers like these are the major reason why BCBSA expects prescription drug costs to rise at least 15 percent each year through 2004.

"In some plans we are spending more on prescription drugs than on in-patient hospitalization, and one of the major reasons is direct-to-consumer advertising," says Christine Simmon, also of BCBSA, who notes that another reason is the aging of the population. Last year alone, BCBSA saw an estimated "25 percent increase in the cost of prescription drugs compared with 6 to 8 percent for physician and hospital services," she says.

In an effort to curb demand for expensive prescriptions, BCBSA has gone so far as to launch a new corporation, called RxIntelligence, which will attempt to inform the public about why they may not need the newest, flashiest drugs on the market. RxIntelligence, says Simmon, will study such things as the "cost benefit and risk of the drug and whether the existing treatment is just as good" -- the sort of information that does not appear in pharmaceutical ads.

The Pharmaceutical Researchers and Manufacturers of America (PHRMA) argues that the increase in prescription drug use "reflects the extraordinary value that medicines provide, to patients and the health care system. Increased utilization of medicines is a good thing -- it helps many patients get well quicker." But Findlay reminds us that what we allocate to one slice of the health care pie must be taken from another. "Is this how we want to be spending our money?" he asks. "Do we want to be spending 25 percent of health care dollars on medication at the expense of home care or PET scans?"

A second harm of rampant pharmaceutical advertising, a harm that is harder to quantify but far more frightening, is to our health. The entire system of direct-to-consumer advertising relies on the assumption that there is an intermediary between the patient and the potentially harmful drug. "While DTC ads prompt patients to consult their doctors about available medicines," says a recent PHRMA report, "the doctor still holds the prescribing pen. Patients cannot get prescription medicines unless their physicians find that the medicines are necessary and appropriate."

But the world is changing in ways that make this statement untrue. Patients are increasingly hearing about new drugs before their doctors do. A recent poll by the American Association of Retired Persons found that 21 percent of consumers had asked their doctors for prescription drugs that the doctors knew little or nothing about. Dr. Berger tells me he knows of doctors who began to prescribe Celebrex before the clinical trials were even published, because patients were asking for it and because initial reports in the press indicated it was effective. Indeed, sales of Celebrex reached $1 billion before the final clinical-trial results were published in a peer-reviewed journal. Many doctors apparently didn't read Celebrex's package insert either. The drug contains sulfa, which can cause an allergic reaction in some patients. "People came in itching with hives," says Berger.

Even when all the known facts about a drug are published, there is no guarantee that new facts might not emerge, especially when the drug is new. One example is the ongoing controversy over the GlaxoSK drug Relenza. Approved in 1999, Relenza is an inhalable powder designed to treat common flu symptoms, reducing the illness's length by about a day. It was introduced with a cheeky television campaign featuring the character Newman from "Seinfeld." The campaign received awards within the advertising industry, but the FDA was not amused. It described the ads as "misleading because theyÉsuggest that Relenza is more effective" than has been "demonstrated by substantial evidence."

Soon after Relenza hit the market in October 1999, seven patients using it died. In part because Relenza had been so heavily promoted, the FDA then issued a "public health advisory" saying that while the exact involvement of the drug was unclear, there had been "several reports of deterioration of respiratory function following inhalation of Relenza" in patients with underlying breathing problems. By June 2000, use of Relenza had been linked to 22 deaths; in July, GlaxoSK announced a strengthened warning label for the drug. The FDA has since reaffirmed the safety of Relenza, when it is used as directed, and attributes many of the deaths to its use by patients to whom it should never have been prescribed. Relenza remains on the market, says GlaxoSK spokeswoman Laura Sutton, but the ads are no longer on the air.

It is still possible to buy Relenza over the Internet, however, which adds another variable to consumer access to prescription drugs. In March 1999, 52-year-old Robert McCutcheon, of Lisle, Illinois, died of a heart attack that may have been triggered by Viagra, although there is no definitive way to know. Despite a family history of heart problems, which would have meant he was a poor candidate for the drug, McCutcheon had ordered Viagra online, at one of the growing number of Web sites that sell prescription medications without a doctor visit.

Viagra is hardly the only drug being sold this way. As part of my research for this article, I spent less than five minutes online and purchased a month's supply of Xenical, the Hoffmann-La Roche product for weight loss. It is intended only for patients who are clinically obese, but since no doctor ever saw me, I lied and said I weighed 300 pounds. The site even provided a handy chart telling me the exact weight cutoff for any given height in order to qualify. The pills arrived, as promised, within five business days, charged to my credit card.

Pharmaceutical companies, it should be said, are distressed by this phenomenon. Pfizer, which manufactures Viagra, recently reminded physicians that it is "improper" (though not actually illegal) to prescribe the drug without first examining the patient. And Ostrove calls the availability of drugs online "a separate but serious issue." When the FDA announced in 1997 that it was "clarifying" its regulations to favor television ads, it also announced that it would review the new approach this coming summer. "If we have reason to believe that our policies are creating a public health problem," Ostrove says, "we will reevaluate."

In the meantime, I have this bottle of Xenical sitting on my desk. While I'm not obese, there are those "few extra pounds" I put on over the holidays. What could be the harm? After all, the ads say that this stuff really works.