

**DO DRUG ADS EDUCATE OR MISLEAD CONSUMERS? Series: THE
SELLING OF A NEW DRUG One in an occasional series.**

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Authors: Robert Steyer
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* Spending on direct-to-consumer advertising has jumped five-fold from 1994 to 1998. Drug makers say the ads help the public. Many physicians say they build unrealistic expectations.

Depending on who's talking, the dramatic rise in advertising of prescription drugs is producing smarter consumers -- or creating a legion of wild-spending, over-medicated hypochondriacs.

Is Joan Lunden, the former daytime television show hostess, a good source of information about allergies, based on her TV ads promoting the antihistamine Claritin?

Is Bob Dole, the former U.S. senator, the best person to advise men about erectile dysfunction in TV and print ads, financed by Pfizer Inc., the maker of Viagra?

"No," says a chorus of physicians who are infuriated not only with celebrity sales pitches but with other ads aimed directly at consumers.

"They create hysteria among patients," said Dr. Sadiq Mohyuddin of Godfrey. "The drug companies are bypassing the doctors. They build up patients' expectations."

Mohyuddin, a specialist in internal medicine and lung diseases, became so angry that he offered a resolution to the Illinois State Medical Society, demanding that companies "be encouraged to discontinue mass advertisement" of prescription drugs.

The group endorsed the resolution. It will be offered for a vote at the American Medical Association's annual convention, which starts Sunday in Chicago.

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Direct-to-consumer ads have clearly rattled the medical profession, in part because total ad spending jumped five-fold between 1994 and 1998; television spending alone went up nearly twenty-fold in that same period.

Much of this growth has come in the past two years after the Food and Drug Administration gave greater leeway to promoting prescription drugs on television.

The FDA is testing the ads' impact on public health and on doctor-patient relationships; results are expected in late summer.

"The big issue is medication by demand vs. medication by need," said Dr. Arthur Gale, an Overland internist and AMA delegate. "My personal feeling is that the more knowledge the patient gets, the better it is. On the other hand, the advertising 'de-professionalizes' the profession to some degree."

In addition to voting on the Illinois medical group's proposal, AMA delegates will vote on an amendment to the association's code of medical ethics, exhorting doctors to inform the FDA about distorted ads.

"Physicians must remain vigilant to assure that direct-to-consumer advertising does not promote false expectations," says one portion of the amendment. "Although physicians should not be biased against drugs that are advertised, physicians should resist commercially induced pressure to prescribe such drugs when not indicated."

Doctors say the pressure can be intense.

"People come in with a notion that the drug they saw advertised is the best drug," said Dr. Keith Starke, vice president of medical affairs for Unity Medical Group. "In the back of the doctor's mind, he's thinking if he doesn't give the patient this medicine, the patient will go elsewhere."

Critics say ads can oversell benefits and underplay a drug's risks.

Drug makers say the ads make patients more aware of ailments and encourage the patients to learn more from their doctors.

"While such advertising prompts more people to seek professional help, it does not dictate the outcome of the physician visit or the kind of help patients eventually receive," Alan F. Holmer said in a Jan. 27 article for the Journal of the American Medical Association. He is president of the Pharmaceutical Research and Manufacturers of America, the biggest drug industry trade group.

"We look at this as a supplement to physicians and pharmacists and health care providers," said Joseph Papa, president of U.S. operations for G.D. Searle & Co., the Monsanto Co. drug subsidiary that makes the arthritis drug Celebrex. Searle started Celebrex ads on TV last month.

"From our point of view," he added, "if we get more patients asking their doctors about new therapies, Celebrex will get its fair share."

Critics wonder how much patient empowerment -- a favorite word of drug companies and ad firms -- can come from a 30-second or 60-second TV commercial.

They also wonder whether consumers can evaluate the multisyllabic medical terms -- about side effects and interactions with other drugs -- stuffed into magazine and newspaper ads.

"I don't believe 99 out of 100 people have the ability or the understanding to read the minuscule print," said Dr. Arthur Levin, a vice president for Prudential Healthcare. "But they see these splashy ads. They don't understand the nuances."

Some consumer groups complain that ads can be misleading -- overselling benefits, underplaying risks -- despite the FDA's monitoring.

"We need firm regulations for both print and television," said Larry D. Sasich, a pharmacist at the Health Research Group, a unit of Public Citizen, a consumer organization based in Washington.

"One of the myths perpetuated by the pharmaceutical industry is that physicians act as gatekeepers to prevent inappropriate prescribing," Sasich added. "Physicians aren't adequate gatekeepers because many rely heavily on information from the same advertising agencies that market drugs to consumers."

Although direct-to-consumer ads have soared, most drug marketing is still played out in doctors' offices and hospitals. Platoons of company representatives promote the latest advances.

Companies spent \$4.55 billion last year on these professional promotions and medical journal advertising, up from \$3.33 billion in 1995, say IMS Health and Competitive Media Reporting, firms that track prescriptions and advertising. The \$1.32 billion spent on direct-to-consumer ads last year accounted for 22 percent of prescription drug marketing, up from 9 percent five years ago.

"This advertising is here to stay; so, physicians have to look at them," said Dr. Steven A. Wexler, assistant clinical professor of ophthalmology at the Washington University School of Medicine. "It stimulates discussion of products in doctors' offices. I'm not offended by that."

Bib drug sales aren't always built on big advertising campaigns.

It's still difficult to make broad correlations of ads to changes in consumers' attitudes and drug-buying habits. Are higher sales caused by ads or by new drugs that are more effective and have fewer side effects, or both?

"Ads aren't going to carry the day if the drugs aren't any better than what's on the market," said Andy McCormick, a Pfizer spokesman.

According to some research, many ads don't work well. A 1998 survey by a marketing firm, CME Health in Minneapolis, found that twice as many people strongly disliked most ads as strongly liked them. Respondents who suffered from diseases for which drugs are aimed were as neutral about these drugs' ads as anyone else.

Big sales don't necessarily need big ad campaigns. The drug Lipitor is leading the pack in prescriptions for cholesterol-lowering medicine even though it is being outspent on ads by several competitors.

But there are successes such as Schering-Plough's ads for Claritin, and advertising critics say companies wouldn't be spending so much so fast if they doubted the ads' potential.

One poll of 1,200 people says 74 percent believe these ads help them be more involved in their own health care, while 67 percent say the ads teach them about drugs' risks and benefits. People who saw these ads are more likely to believe a drug was safe than people who didn't see the ads, says this 1998 poll, commissioned by the magazine Prevention.

But 61 percent say the ads cause confusion about drugs' risks and benefits, while 38 percent say the ads cause tension between patients and doctors. Of patients who talked to their doctors about

a drug that they saw advertised, 28 percent asked for a prescription. Eighty percent of the doctors complied.

"This is not an appropriate way for patients to learn about pharmaceutical agents," said Dr. Terry D. Weiss, a St. Louis County rheumatologist.

Dr. Garry Vickar, chairman of the psychiatry department at Christian Hospital-Northwest, said: "The public service component is superb, but these advertisements don't present as much balanced information as they should. If I had to make a 'yes or no' vote, then I'd vote 'no.'"

Managed care company executives fret that ads cause higher health costs, prodding consumers to demand new, expensive drugs that offer little or no improvement over generic or cheaper, older brand name drugs.

Express Scripts Inc., the St. Louis County-based pharmacy benefits management and mail-order drug company, has found significant spikes in sales among drugs backed by heavy consumer advertising.

Between 1996 and 1997, Express Scripts found a 29 percent rise in the number of antihistamines like Claritin prescribed for patients covered by its services -- more than six times the average growth rate for 25 drug categories. The average member's spending for antihistamines soared 38.5 percent -- more than double the average increase for all drugs.

"I would presume a good piece of this was due to higher direct-to-consumer advertising," said Fred Teitelbaum, an Express Scripts vice president.

This gain coincided with a promotional flood for Claritin, Zyrtec and Allegra. Express Scripts will release its 1998 survey later this month; it has estimated that antihistamine expenditures rose 28 percent, nearly double the increase it has predicted for all drugs.

Between 1996 and 1997, Express Scripts said direct-to-consumer ads helped stimulate sales for antifungal drugs, cough/cold medications, cholesterol-reducing drugs and decongestants. It predicts high ad spending will continue for these categories.

"I think you'll see a substantial increase" in prescriptions and ad expenditures for arthritis drugs, Teitelbaum added, as Searle and Merck step up their marketing of Celebrex and Vioxx, respectively.

The FDA is working on formal guidelines for drug advertising.

Searle is easing its way into direct-to-consumer advertising with a 15-second TV commercial that mentions Celebrex but doesn't tell what the drug treats. It also has a 30-second commercial telling people there are new arthritis treatments, but it doesn't mention Celebrex.

Both ads tell people to consult their doctors or pharmacists, both ads provide toll-free numbers for free information, and both ads carry logos of Searle and its marketing partner, Pfizer.

These ads are less subject to FDA restrictions than the Joan Lunden ad for Claritin, in which a drug name and disease are mentioned. These branded ads must provide a "fair balance" between benefits and risks. (The Bob Dole ad never mentions Viagra, even though everyone from Jay Leno to David Letterman knows Dole has used it.)

"We view this as a progression," said Papa of Searle. "We'll do branded TV advertising at some point." The company also will promote Celebrex in magazines and newspapers, mixing its sales pitch with small-print warnings found on drug labels.

Searle has had mixed results in the direct-to-consumer arena. Ads for another arthritis drug, Daypro, and a blood pressure drug failed to achieve goals. A disease-oriented ad on sleep disorders -- Searle markets the insomnia drug Ambien -- performed better.

Like many drug companies, Searle checks with the FDA before starting a new ad campaign, discussing its sales pitch. "The FDA gives us guidance rather than word-for-word approval," Papa said.

The FDA, which doesn't regulate ads for over-the-counter drugs or nutritional supplements, has been in charge of prescription drug advertising since 1962. Early ads were aimed at health care professionals; companies began experimenting with consumer-oriented ads about 15 years ago.

Companies had been reluctant to use television, especially for the branded ads like the Joan Lunden commercial. The FDA's rules on balancing risks and benefits had been too cumbersome for commercial TV. Some companies ran ads on cable TV shows targeted to doctors; the fine print from drug labels was scrolled on the screen like final credits for a movie.

But nearly two years ago, the FDA offered a "guidance" to drug marketers, saying broadcast ads could list only the major risks instead of all the fine print. The ads must mention where consumers can get more information. Such sources include toll-free numbers, Internet sites, medical professionals or print ads.

Meanwhile, the FDA continues to work on more formal advertising regulations, although a completion date hasn't been set.

"We do our best to educate manufacturers," said Nancy M. Ostrove, chief of the 14-member FDA unit that monitors thousands of ads and other promotional items each year.

"We do more advance work on television advertisements because they reach so many people and on new product launches," Ostrove said. "Even if we don't give comments in advance, we watch all TV ads."

Competitors aren't shy about telling the FDA about allegedly distorted ads, and the agency has issued 18 letters in two years to companies about improper TV advertising. If a company resists, the FDA could seize its products, but the FDA has never had to take such action.

Although some critics say the FDA lacks the clout to contain the damage caused by biased ads, Ostrove says her agency can do only what Congress permits. "No law allows us to ban advertisements," she said. "We have to recognize the free speech issue."

PHOTO, GRAPHIC; Caption: (1) Color Photo - G.D.Serle promotes Celebrex in TV commercial. (2) Color Photo - Cal Ripken pitches the hypertension drug Prinivil. (3) Color Photo headshot - Former Sen. Bob Dole is spokesman for Viagra. (4) Graphic / Chart - Biggest expenditures for direct-to-consumer ads - (U.S. prescription drugs 1998) DRUG WHAT IT TREATS AD EXPENDITURE Claritin allergies \$185.1 million Propecia baldness 92.0 million Zyrtec allergies 75.6 million Zyban smoking 64.4 million Pravachol high cholesterol 59.7 million Allegra allergies 52.5 million Prilosec ulcers 49.7 million Zocor high cholesterol 44.5 million Evista osteoporosis 42.3 million Prozac depression 41.1 million Source: IMS Health/Competitive Media Reporting (5) Post-Dispatch Color Graphic Charts - A growing role for direct-to-consumer advertising - U.S. prescription drug promotion and advertising expenditures 1994 : Direct-to-consumer ads - Television, radio, magazines, newspapers, billboards - 9% Professional promotions - Doctor's offices, hospitals, medical journal ads - 91% 1998: Direct-to-consumer ads - 22% Professional promotions - 78% Television takes the lead in direct-to-consumer ads 1994: Television 13% Other - 1% Print - 86% 1998: Television 50% Other 2% Print 48% Changing trends in U.S. prescription drug advertising Professional promotions - Doctors' offices, hospitals, professional journals In billions '94 - \$3.67 '95 - \$3.33 '96 - \$3.47 '97 - \$3.87 '98 - \$4.55 Direct-to-consumer advertising - Television, radio, billboards, magazines, newspapers In billions '94 - \$0.27 '95 - \$0.38 '96 - \$0.79 '97 - \$1.07 '98 - \$1.32 Source: IMS Health Competitive Media Reporting (6) Graphic / Chart - How consumers view drug ads 74% say ads help people become more involved in health care. 67% say ads educate people about risks and benefits of drugs. 61% say ads confuse people about drugs' risks and benefits. 59% say ads help people make their own decisions about drugs. 55% believe ads make drugs seem harmless. 38% believe ads cause tension between doctors and patients. 66% say ads are very clear or somewhat clear. (down from 71% in 1997) 30% say TV ads do an excellent or good job of informing about drugs' risks and benefits. 29% say TV ads do a poor job of informing about drugs' risks and benefits. 36% say magazine ads do an excellent or good job in discussing drugs' risks and benefits. 18% say magazine ads do a poor job in discussing drugs' risks and benefits. 28% asked doctors to prescribe a specific drug after having seen the drug advertised and having discussed the drug with a doctor. 80% of those polled got prescriptions after asking their doctor for drugs they had seen advertised. 85% of those polled, having seen direct-to-consumer ads, say that prescription drugs are very safe or somewhat safe. 64% of those polled, not having seen direct-to-consumer ads, say that prescription drugs are very safe or somewhat safe. Source: Telephone survey of 1,200 adults in March/April 1998 by Princeton Survey Research Associates for Prevention Magazine. Sample error is plus or minus 3 percentage points.

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