Direct-to-Consumer Advertising (DTC) of Pharmaceuticals

by Amy Shaw

Introduction

A popular sleep advertisement shows an unshaven insomniac at a kitchen table with Abe Lincoln and a talking beaver. "When you can't sleep, you can't dream," intones the narrator. "That's why there's Rozerem."

Source: http://www.afterthesemessages.com/obe/review/51

In the summer of 2006, Takeda Pharmaceuticals North America Inc. launched a massive advertising campaign telling insomniacs that their dreams miss them and that the sleeping pill, Rozerem, can reunite them. This advertisement joined a host of others that pitch prescription drugs directly to consumers. The first DTC television advertisement, for the British company Boots Pharmaceuticals Inc. anti-arthritis drug called Rufen, aired in the early 1980s (Donohue, 2006). Today, a typical American television viewer can expect to spend 16 hours per year watching DTC drug advertisements (Frosch et al, 2007). DTC advertising is concentrated among a small number of drugs for chronic conditions such as insomnia, depression and erectile dysfunction. Attesting to their ability to generate sales, DTC advertisements are everywhere. They are broadcast on TV and the radio; they are on Web sites and billboards; and they fill the pages of newspapers and magazines.

Consumer groups such as the U.S. Public Interest Research Group (U.S. PIRG) say that the Food and Drug Administration (FDA) needs to increase its oversight of DTC advertisements of pharmaceuticals to prevent consumers from being harmed by misleading advertising. Many physicians worry that these advertisements are a danger to the doctor-patient relationship and that they cause patients to request drugs that they do not need. The pharmaceutical industry asserts that they educate patients on treatment options, empowering them in discussions with their doctors. According to their association, the Pharmaceutical Research and Manufacturers of America (PhRMA), these DTC advertisements can increase the likelihood that patients will contact their physicians to discuss and receive appropriate care for conditions that are often under-diagnosed and under-treated (PhRMA, 2005). The National Consumers League calls these advertisements "an effective vehicle that motivates consumers to seek information" and says that it "can hardly be a bad thing" if they encourage doctor-patient dialog (Donohue, 2006).

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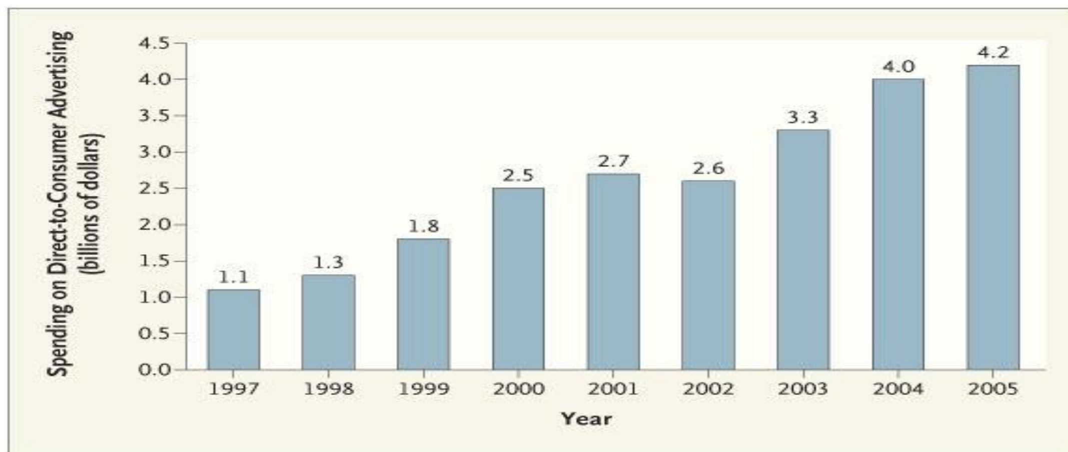
Trends in DTC Advertising Spending

An Astra-Zeneca advertisement for its cholesterol-fighting drug shows a trim woman jogging down a street. "She took medication. She ate right. And ran. Yet it wasn't enough." Her doctor advises her to switch to Crestor.

In 2004, Astra-Zeneca spent $216 million promoting Crestor, almost matching the $212 million spent on Pepsi for that year (<a href="reviewf.php#" target="_blank">Huh and Langteau, 2007). The greatest amount of advertising money spent on pharmaceuticals in 2005 was for 10 drugs in the following seven categories: 1) heartburn, 2) insomnia, 3) cholesterol, 4) asthma and allergy, 5) nail fungus, 6) blood clots and 7) erectile dysfunction (Heinrichs, 2007). According to the Government Accountability Office (GAO), DTC drugs are often among the best-selling drugs (United States 2002).

Pharmaceutical companies spend nearly twice as much on marketing in the U.S. as they do on research and development (R&D) (Gagnon and Lexchin, 2008). There has been an upward and accelerating trend in spending on DTC advertising. In 2005, $4.2 billion was spent on DTC advertising (United States, 2006), compared with $1 billion in 1997 (Huh and Langteau, 2007). Yet drug companies spend more promoting prescription drugs to physicians, according to the GAO, $3 billion more than to consumers in 2005 (2006).



Julie M. Donohue, Marisa Cevasco, Meredith B. Rosenthal. (2007). A Decade of Direct-to-Consumer Advertising of Prescription Drugs. The New England Journal of Medicine, 357(7), 673-681

Television advertising takes up the bulk of DTC pharmaceutical marketing expenditures, but drug marketers have increased their marketing efforts on the Internet (Sheehan, 2007) as searching for health-related information has become the third most common activity for online users (Choi and Lee, 2007). In 2003, the pharmaceutical industry spent $59 million on DTC promotion on the Internet (Choi and Lee, 2007). A Cegedim Dendrite Survey reveals that as pharmaceutical industries increase their presence on the Internet,

spending on traditional mass marketing advertising—such as television, radio and direct mail—will decrease (DTC, 2007).

Advertising spending positively correlates with increases in the number of prescriptions written for DTC drugs (Spake and Joseph, 2007). A study reviewed by the GAO (2006) found a median increase in sales of more than $2 for every $1 spent on advertising (United States, 2006). Another study found that each dollar spent on advertising in 2000 generated additional sales of $4.20 (The Henry J. Kaiser Family Foundation, 2003). In 2000, DTC advertising raised drug sales 12%, costing patients and insurers an additional $2.6 billion (Healy, 2007).

While the pharmaceutical industry is profiting from DTC advertising, it generates more money marketing to physicians. In 2005, compared with the $4.2 billion spent on DTC advertising, pharmaceutical companies spent $7.2 billion on promotion to physicians (United States, 2006). According to a 2001 study by Dartmouth College marketing professor Scott Neslin, every additional dollar spent on advertising in medical journals generated $5 worth of sales, and an extra dollar spent to sponsor continuing medical education and professional meetings yielded approximately $3.56 in sales (Healy, 2007). In addition, every dollar spent on physician-detailing generated sales worth approximately $1.72, except for the most aggressively marketed drugs, which generated sales of more than $10 (Healy, 2007).

DTC Regulation

The only developed countries that allow DTC advertising of prescription drugs are the United States and New Zealand (Frosch et al, 2007). In the United States, DTC advertising is unique for two reasons: the product cannot be purchased without a physician's prescription and it is regulated by the FDA (Huh and Langteau, 2007).

The FDA regulates the advertising of prescription drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA) (Rados, 2004). The Division of Drug, Marketing, Advertising, and Communications (DDMAC) within the FDA's Center for Drug Evaluation and Research (CDER) is responsible for implementing the regulations governing DTC advertising (United States, 2002). Section 502(n) of the FFDCA requires that an advertisement include "the established name, the brand name (if any), the formula showing quantitatively each ingredient, and information in brief summary which discusses side effects, contraindications, and effectiveness." ("Advertising/Labeling Definitions," 2007). This requirement is further defined in the prescription drug advertising regulations in the Code of Federal Regulations, Title 21, part 202 (21 CFR part 202). These implementing regulations specify that prescription drug advertisements must not be false or misleading, must not omit material facts, and must present a fair balance between effectiveness and risk information.

From the 1950s to the early 1980s, pharmaceutical advertisements were absent in the mass media (Donohue, 2006) but were directed primarily to medical personnel. Relying on the strength of the traditional doctor-patient relationship, pharmaceutical companies targeted their marketing dollars to physicians. This changed with the airing of the earlier mentioned Rufen commercial and the advent of an advertising campaign by Merck and Dohme of its pneumonia vaccine, Pneumovax (Donohue, 2006). These pioneering advertisements were the result not of any sudden change in federal regulations. Rather they came from the pharmaceutical companies' recognition that the doctor-patient relationship had changed with the rise of consumer and patients' rights movements. According to Julie Donohue, these two drug-marketing campaigns "broke with tradition and pursued a marketing strategy that depended on consumers' taking a more active role in prescribing decisions" (2006). Following these early advertisements, concerns were raised about DTC advertisements, including their potential to mislead the public. In response, the FDA called for a voluntary moratorium on DTC advertising in 1983 so that it could create a more explicit policy.

The moratorium ended in 1985 when the FDA released guidelines that prescription drugs should adhere to the same rules that govern pharmaceutical advertising to physicians. Therefore the advertisements had to include the product generic name, side effects and contraindications, and could not be false or misleading (Bradford and Kleit, 2006).

Although it had been legal for pharmaceutical companies to engage in broadcast advertising, the big increase in this form of marketing took place in 1997 when the FDA relaxed rules that had made it difficult for companies to air effective advertisements. That year the FDA ended a prohibition on using the drug's brand name and benefits in the same advertisement, eliminating a source of confusion for consumers. Prior to this, the companies operated under rules governing advertising to physicians, which allowed "reminder" advertisements that uses the drug's name but didn't say what it was intended to treat. This policy change made it easier for drug companies to advertise on television (Donohue, 2007) because it eased the type of risk disclosure needed. Pharmaceutical companies could now tell consumers where to find additional information, such as by referring them to a Web site or an 800 number. In 2004, the FDA announced that print advertisements would no longer need to include full prescribing information (Sheehan, 2007)

The FDA describes three types of DTC advertisements:

- **Product Claim Advertisements:** The most common of the three, these typically include both the brand name and the condition the drug treats. They also describe the risks and benefits associated with taking the medication.

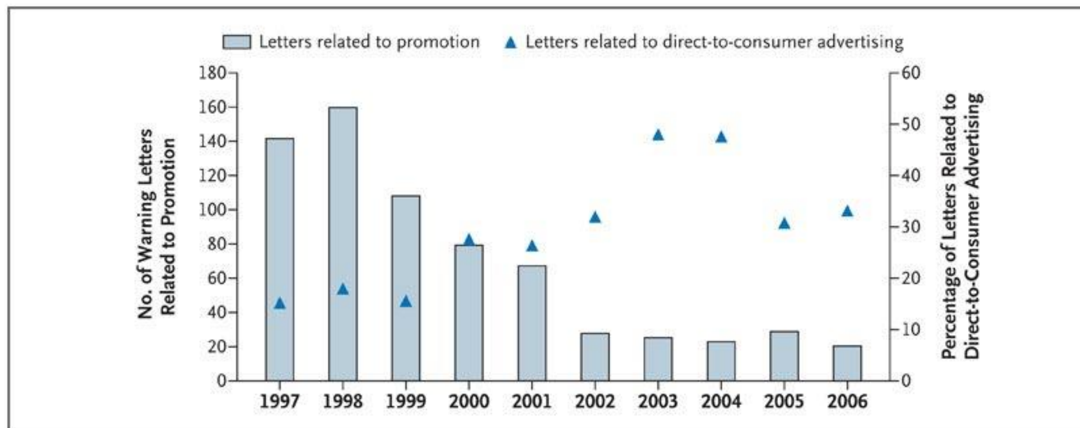
- **Help-Seeking Advertisements:** Also known as disease-awareness communications, these mention the disease or health condition but not the name of the drug that treats it. The purpose of this type of advertisement is to create an awareness of symptoms or conditions among consumers. (United States, 2002) These advertisements are not required to provide risk information and are not regulated by the FDA.

- **Reminder Advertisements:** This type of advertisement, which is exempt from risk disclosure requirements, names the drug and dosage form or cost information. It does not mention the condition it treats or make claims or representations about the product.

Drug companies are required to submit final prescription drug advertising materials to the FDA when they are first shown to the public. While they are generally not required to show these materials prior to dissemination, some drug companies voluntarily submit draft DTC advertising materials to the FDA (United States, 2006). One problem with not requiring advertising companies to show these advertisements to the FDA prior to dissemination is that a misleading commercial that is not submitted could complete its run on television by the time the DDMAC issues a letter (Jaramillo, 2007).

The FDA provides safeguards against abuse. If the FDA identifies a violation of laws or regulations in a DTC advertisement, the agency may issue a regulatory letter asking the drug company to take specific actions. This may be either an untitled letter or a warning letter (United States, 2002). Untitled letters address violations, such as overstating the effectiveness of the drug. Warning letters target pharmaceutical companies that engage in continued violations of the act or address companies engaged in serious violations that affect consumer safety or health. In a warning letter, the FDA may tell a drug company that it will take further action, including judicial remediation. Both types of letters cite the violation and request that the company respond in writing to the FDA within 14 days, and require the company to take specific actions (United States, 2006).

In 2006, in response to a request from U.S. senators concerned about the effects of pharmaceutical advertising, the GAO issued a report criticizing the time the FDA takes to issue regulatory letters (United States, 2006). From 1997 to 2001 the FDA took an average of two weeks to issue a regulatory letter; however from 2002 to 2005, that had risen to an average of four months. The number of regulatory letters also dropped from 142 in 1997 to 21 in 2006 (Donohue et al, 2007), largely due to a 2002 decision by the FDA to have all such letters undergo review by its Office of Chief Counsel.



Miriam Shuchman (2007). Drug Risks and Free Speech -- Can Congress Ban Consumer Drug Ads? The New England Journal of Medicine, 356(22), 2236-2239.

A second reason for the decline in regulatory letters issued is the small number of staff members who review advertisements while advertising grows substantially (Donohue et al, 2007). In June 2002, there were only five DDMAC staff members who reviewed 248 DTC broadcast advertisements and an unknown number of DTC print advertisements. These were DTC advertisements that were submitted to DDMAC at the time of their dissemination in 2001 (United States, 2002). By September 2006, there were still fewer than a half a dozen staff members reviewing more than 15,000 DTC advertisements and brochures (United States, 2006).

With concerns growing about these advertisements, in 2007, Senators Ted Kennedy and Mike Enzi introduced S. 1082, the Food and Drug Administration Revitalization Act, in an attempt to require mandatory moratoriums on advertising new prescription drugs, preclearance of DTC advertisements, and a mandate that certain language be included in these advertisements. House Commerce Chairman John Dingell introduced H.R. 2900, the Food and Drug Administration Amendments Act (FDAAA) of 2007, which contained advertising provisions similar to S. 1082, as it was originally introduced. After pressure from the American Advertising Federation (AAF) and the advertising community, these restrictions were removed from the bill. The AAF contends that mandatory moratoriums on pharmaceutical advertising would violate the First Amendment protection for commercial speech (American Advertising Federation, 2007).

When the FDAAA of 2007 was signed into law by President George W. Bush on September 27, 2007, this Act, among other things, reauthorized and expanded the Prescription Drug User Fee Act (PDUFA) for 2008 to 2012. PDUFA, enacted in 1992 and revised in 1997 and 2002, authorizes the FDA to collect fees from pharmaceutical and biotechnology companies to fund the new drug approval process. In this program, industries provide user fees in exchange for an FDA agreement to meet drug-review performance goals, which emphasize timeliness to bring the drugs to market more quickly. While the agency can only recommend changes, the FDAAA enables the FDA to levy fines of

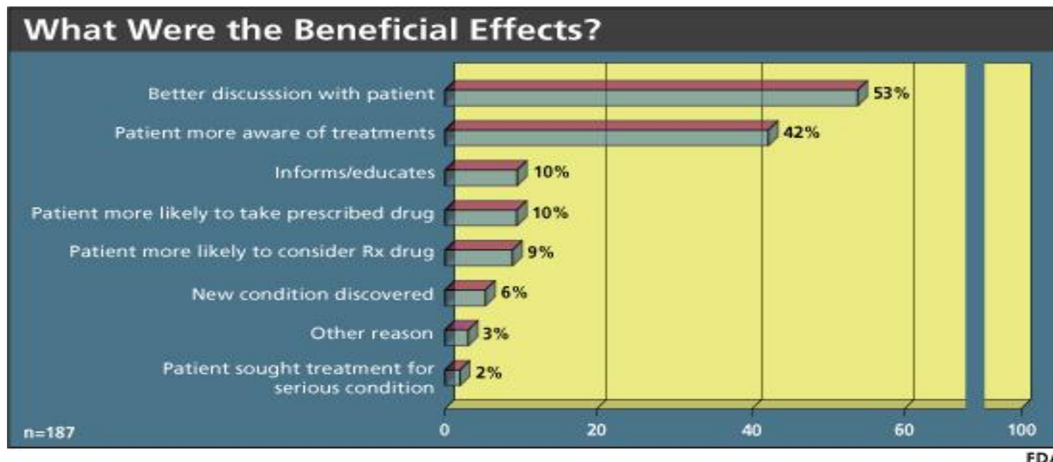
$250,000 for the first violation using false and misleading advertisements, not to exceed $500,000 for subsequent violations ("H.R. 3580," 2007). However, on January 15, 2008, the FDA announced that the DTC user fee program for advisory review of DTC television advertisements in the FDAAA will not commence due to inadequate funding by Congress. This user fee program would have paid for increased FDA staff (Kritz, 2008), which would have helped rein in misleading drug advertisements; currently, only 35% of the DTC advertisements that make it on the air are viewed by DDMAC staff members (Kritz, 2008).

On February 4, 2008, the Bush administration proposed a 5.7% increase in the FDA's budget for fiscal 2009. If approved by Congress, this funding increase would, among other things, include the user fee program. The CDER would also get an additional 283 employees (U.S. Food and Drug Administration, 2008).

In addition to FDA regulations, the pharmaceutical industry attempts to self-regulate through a 15-point code of conduct issued by its trade association, PhRMA (PhRMA, 2005). They state, for example, that all such advertising should be "accurate and not misleading, should make claims only when supported by substantial evidence, should reflect balance between risks and benefits, and should be consistent with FDA-approved labeling." Under these vague and voluntary guidelines (Frosch et al, 2007), the pharmaceutical companies promise to hold off on consumer advertising of a new medicine until they spend an "appropriate" amount of time educating health care professionals about the medicine.

The DTC Advertising Debate

PhRMA argues that DTC advertisements educate consumers about health and available treatments, empowering them to become more active participants in their own care. For example, thanks to an advertisement from Pfizer, many people who had been experiencing persistent thirst may have learned that thirst is a symptom of diabetes (Bradford, 2006). PhRMA also asserts that these advertisements foster "important doctor-patient conversations about health that might otherwise not have happened" (PhRMA, 2005). Silvia Bonaccorso and Jeffrey Sturchio of the pharmaceutical company Merck argue that while these advertisements might shift the balance of control in a doctor-patient consultation, they will "not diminish the role of the doctor." Rather, the knowledge the patient obtains from a DTC advertisement will enhance the consultation (2002).



Rados, Carol. (July-August 2004). Rx Drug Ads Come of Age. FDA Consumer Truth in Advertising.
Source: http://www.fda.gov/fdac/graphics/2004graphics/beneficial.jpg

Although many doctors are skeptical of the value of these advertisements, recent research on physicians' attitudes toward DTC advertising has become mixed or more positive (Huh and Langteau, 2007). For example, Robinson (2004) reported that a majority of physicians believe that DTC advertising has motivated patients to seek medical care. A 2006 survey of members of the National Medical Association (NMA), the nation's oldest association of physicians of color, reveals that their perceptions of the positive benefits of these advertisements far outweigh negative perceptions (Morris et al, 2007). Three FDA surveys conducted in 1999 and 2002 show mixed results, revealing that 53% of physicians found these advertisements resulted in better discussions with patients and 42% of physicians believed that patients were more aware of available treatments (Rados, 2004).

Aside from individual doctor-patient visits, the advertisements can improve the public's knowledge of health (Sheehan, 2007). The 2006 survey of NMA physicians revealed that they believed this form of advertising provides "notable educational benefits" (Morris et al, 2006). Prescription drugs often have Web sites directed to consumers, offering extensive information on particular medical conditions. DTC Web sites, such as the one for Chantix, a prescription medicine to help smokers quit (Pfizer, 2005), can give consumers a high degree of control and could improve their decision-making.

Among patients who visited doctors and asked for a prescription drug by brand name because of an advertisement, 88% actually had the condition the drug treats (Rados, 2004). And if a patient sees a physician earlier as a result of an advertisement, the physician may be in a better position to provide treatment (Finlayson, 2005). DTC advertisements can also make a condition seem less embarrassing (Rados, 2004), which advocates say can make people more likely to get help and speak openly with their doctors. And from an economic perspective, supporters assert that these advertisements lead to increased competition and lower prescription drug prices (Huh and Langteau, 2007).

DTC opponents, such as the American College of Physicians, contend that such advertising undermines the doctor-patient relationship (Spake and Joseph, 2007) while others argue that it creates a demand for prescription drugs that may not be appropriate (Huh and Langteau, 2007). According to Ed Mierzwinski, consumer program director for U.S. PIRG, DTC advertisement caused the "overprescription of drugs for conditions people weren't even aware of…[and] has resulted in massive profits for the industry by preying on consumers' emotions" (Lazarus, 2008). Most physicians indicate that DTC advertisements rarely provide enough information about the cost, alternative treatments, or adverse effects, according to a study by Robinson et al (2004). A cross-sectional survey of a nationally representative sample of U.S. physicians found that more than half had a negative response to the increase in advertising prescription drugs directly to consumers (Murray et al, 2003).

During medical visits, critics say, physicians are forced to take time away from important aspects of patient care to explain why a treatment the patient saw on TV is not appropriate. Even so, in at least 40% of visits in which discussion about a DTC-advertised drug takes place, the physician prescribes the advertised drug. And in more than half of these cases, physicians claim to have prescribed drugs to accommodate the patient's request (Metzl, 2007).

Patient advocacy groups such as Care to Live are spurring the FDA to speed the release of new drugs into the market to increase treatment options (Roan, 2007). Typically, DTC drugs are new to the market, so they lack a proven safety record (Finlayson and Mullner, 2005), as was the case with Merck's anti-inflammatory drug Vioxx, which earned the title of blockbuster drug after its sales began exceeding $1 billion per year. DTC advertisements, particularly those for new drugs, faced increasing criticism after Vioxx was linked to a significant increase in heart attacks and strokes and withdrawn from the market (Donohue et al, 2007). The Institute of Medicine issued a report in 2006 strongly advocating a moratorium on DTC advertising to address safety concerns regarding new prescription drugs (Morris et al, 2007). While PhRMA has produced voluntary guidelines for pharmaceutical companies to address this issue, critics such as the AIDS Healthcare Foundation argue that this self-regulation is not working as many drug companies continue to begin advertising campaigns for the most heavily promoted drugs within a year after FDA approval (AIDS Healthcare Foundation, 2007).

In addition to safety concerns, these newer drugs tend to be more expensive than generic drugs or older versions of a given medication. The much-promoted medications Avandia and Actos used to treat type 2 diabetes were found to be no more effective--or safe--than older drugs, yet they are much more expensive ("CR Report," 2007). And a study that examined the economic implications of antipsychotic drug prescribing practices in America found that compared with newer drugs such as Zyprexa, Seroquel, and Risperdal, older medication used to treat schizophrenia was found to be equally effective and as much as $600 a month cheaper (Vedantam, 2006).

DTC advertisements can also prompt consumer requests for products that are unneeded. Helen Darling, president of the National Business Group on Health, asserts that "'[E]veryone, including the company, agreed that not everybody ought to be getting Vioxx…[b]ut the ads implied that there was a widespread need for it'" (Freudenheim, 2007).

Despite their complaints about the television advertisements, doctors are also influenced by marketing from pharmaceutical companies. Targeted through a marketing technique called detailing, physicians receive visits from representatives of pharmaceutical companies to give them details of their products and encourage prescribing. Generally, these visitors bring free samples. Cooperative physicians also receive other perks from these companies, such as free food, reimbursement for the cost of conferences, or money for giving speeches to convince other doctors to use companies' drugs (Miller, 2007). Some researchers wonder whether DTC is any worse than the distortion brought about by detailing (Bradford, 2006).

Aside from potentially undermining the doctor-patient relationship, these advertisements can convey misleading information about the drugs, exaggerating the benefits and understating the risks. One such advertisement, called "Videogame," was for Strattera, a psychotropic drug approved for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). The television advertisement by Eli Lilly and Company received a regulatory letter from the FDA for minimizing the serious risks of the drug and failing to communicate the Attention Deficit Disorder (ADD) indication for it (U.S. Food and Drug Administration, 2005). This is not the only commercial accused of understating the risks. A 2007 study in the *Journal of Health Communication* found that the average DTC commercial devotes less time to side effects than to benefits (Kritz, 2008), thus ignoring the fair balance requirement.

On a broader level, some critics say these advertisements contribute to the medicalization of what was previously considered part of the normal range of human experience (Frosch et al, 2007). Normal variation in sexual performance among men is now the target of the lifestyle drug Viagra (Conrad and Leiter, 2004). Lifestyle drugs are medications used to treat non-life-threatening conditions such as hair loss, obesity, and wrinkles. By focusing on selling lifestyle drugs like Viagra, which provide higher profit margins, drug companies leave fewer resources for developing drugs that are more medically necessary (Cunningham and Iyer, 2005). The pharmaceutical industry's output of such lifestyle drugs contrasts sharply with the shortage of drugs in development for chronic and emerging diseases (Croghan and Pittman, 2004).

By promoting a drug as the solution to a health problem, these advertisements can lead viewers to believe that adopting healthy behaviors, such as good diet and exercise, would be ineffective or unnecessary. Advertisements might suggest that health improvement comes from medication, perhaps in combination with healthy activities, but never from behavior modification alone (Frosch et al, 2007). However, in response to these concerns,

PhRMA's guidelines recommend that these advertisements include information about "other options such as diet and lifestyle changes where appropriate for the advertised condition." (PhRMA, 2005)

Opponents also call for more stringent oversight to protect consumers from detrimental and socially undesirable effects of DTC advertisements (Huh and Langteau, 2007). For example, the GAO has questioned the FDA's effectiveness in limiting false and misleading consumer exposure to DTC advertising (United States 2006).

Conclusion

DTC advertising has become a major marketing phenomenon in the American health care system. It has been a contentious subject among consumers, those in the medical community, and the pharmaceutical industry. The pharmaceutical companies assert that DTC advertising can help consumers become more informed about diseases and prescription drug choices. They also argue that these advertisements may make patients more likely to seek help and discuss their conditions with their doctors, thus getting the treatments they need. Furthermore, physician attitudes toward DTC advertising are changing, with more expressing positive views than in the past.

Patient advocacy groups have put a great deal of pressure on the FDA to speed the release of new drugs, some of which are found to not perform any better than older versions. The marketing of these new drugs has led to recalls of heavily advertised drugs, such as Vioxx, that were found to carry dangerous risks. PhRMA and some pharmaceutical companies, such as Bristol-Myers Squib, have reacted by announcing a voluntary moratorium on DTC advertising for new drugs.

In addition to issues regarding the advertising of new DTC drugs, critics argue that drug companies should more clearly indicate who may be at risk of the disease being treated (Frosch et al, 2007) and show fair balance in stating a drug's risks and benefits of a drug. They furthermore assert that drug companies should advise the consumers that other treatment options may be available.

The debate continues while DTC advertising grows as a marketing phenomenon in the American health care system.

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