Direct-to-Consumer Marketing: 20 Years Later

Direct-to-consumer ("DTC") advertising of prescription drugs and devices by pharmaceutical companies has been in effect for almost 20 years. In addition to the billions spent in marketing directly to physicians, pharmaceutical companies spend billions of dollars per year (5 billion in 2015), to tell patients and potential patients why they should take certain drugs.

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In 2015, one quarter of the money spent was to advertise only five drugs. (I'm sure you can name them). Not surprisingly, the most advertised drugs are heavily prescribed and reap the biggest profits.

DTC advertising of drugs became legal in the United States in 1985. However, until 1997, the U.S. Food and Drug Administration (FDA) required that advertisements provide a detailed list of potential side effects to consumers.

DTC advertising most commonly appears on television, internet websites, radio, and print – magazines, brochures, billboards, newspapers. Ads generally fall into three categories:

- "Product-claim" – specific name and claim – i.e., Viagra, Humira.
- "Help-seeking" – do not recommend a specific drug, but discuss disease or condition, such as allergies, diabetes, asthma, osteoporosis, and high cholesterol. The ad usually includes the name of the company, and encourages the consumer to talk to their doctor.
- "Reminders" – give the name of the drug, and assumes the audience – physicians and consumers – are already aware of the drug's use.

Over the years, the debate about DTC advertising has largely focused on whether it provides useful information to consumers, resulting in better health outcomes due to disease awareness, or if it encourages expensive overuse of the costliest drugs.

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At one end of the spectrum, physician's organizations, such as the American College of Physicians (APA), believe that DTC advertising is inappropriate and undermines the physician – patient relationship leaving patients confused and misinformed about drugs.[1]

Recognizing that DTC is here to stay, the APA and the American Medical Association (AMA) encourage physicians to take an active and critical role in ensuring that DTC ads improve the communication of health information and contain accurate information on risks, benefits, and costs.[2]

FDA Regulation

The FDA has the authority to regulate "product claim" ads. Such ads must present a drug's benefits and risks in a balanced fashion, and should not be false or misleading. Print ads must also include a "brief summary" about the drug that includes the risks listed in the prescribing information.

Broadcast ads, however, must only address the drug's most important risk ("major statement") and either provide all the risks listed in the prescribing information or a variety of sources for viewers to find the prescribing information for the drug. Such sources may include a doctor, website, toll-free number, or magazine print ad.

Help-seeking ads are not generally regulated, as they are not considered drug ads. However, the FDA does regulate them if they suggest

or recommend a specific drug. Similarly, reminder ads are not regulated, unless they offer drugs with serious risks, such as those with a boxed warning, or if the ad provides or suggests information about the drug's risks and benefits.

State Regulation and Sunshine Act

The FDA regulates national advertising. Because of the FDA, there is little legislative space for states to address DTC. A few states, however, have laws that address DTC advertising, marketing, and doctor detailing. Such state laws typically contain disclosure and reporting requirements. However, with the passage of the "Sunshine Rule" or "Open Payments" rule, pharmaceutical companies now must report payments or other transfers of value to physicians for drugs and devices covered by Medicare and Medicaid.

Impact on Patient Care

Surveys of physicians cited by the FDA[3] indicate that patients who saw DTC ads asked thoughtful questions, were more involved in their healthcare, and had better discussions with their doctors.

Physicians, however, did not believe that such ads conveyed information about risks and benefits equally well. Nevertheless, according to the FDA, only eight percent of physicians felt "very pressured" to prescribe a specific brand-name drug when asked. However, in other surveys, physicians have reported that advertising induced demand made them more likely to prescribe the brand-name drug requested.[4]

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Physician Obligations

The AMA Ethics Opinion states that:

- Physicians must maintain professional standards of care when prescribing;
- Physicians should engage in a dialogue to assess the patient's understanding of the treatment;
- Physicians should not be biased against advertised drugs;
- Physicians should resist commercially induced pressure to prescribe drugs that may not be indicated;
- Physicians should deny requests for inappropriate prescriptions, and should educate patients as to why, and the different treatment options;
- Physicians should be vigilant to ensure that DTC does not promote false expectations, and to consider reporting such DTCs that do not follow the applicable FDA regulations.

Summary

DTC of drugs are now as common as beer and car commercials. However, in contrast to beer and cars, a prescription from my physician is required to obtain a DTC product.

DTC advertising is without question both successful and profitable. This means that pharmaceutical companies will continue to increase DTC to both stimulate demand and profits for their drugs.

Physicians, however, are ethically required to remain objective patient advocates. Accordingly, physicians should be educated and prepared to discuss the pros and cons of specific drugs, particularly those that are powerfully advertised. This may include being prepared to discuss evidenced-based studies on the benefits and risks of such drugs.

Physicians must, however, always remain vigilant to only prescribe drugs that are medically indicated for a patient regardless of the pressure brought to bear on their medical judgment by patients and advertisements. **AM**

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1 *See, Direct-to-consumer prescription drug advertising, American College of Physicians, a position paper (2006).*

2 *Id. AMA opinion 5.015 – Direct-to-Consumer Advertisements of Prescription Drugs, AMA Code of Ethics (1998).*

3 *See, FDA. The Impact of Direct-to-Consumer Advertising, Information for Consumers, UCM 143562, Oct. 23, 2015. http://www.fda.gov/Drugs/Resources-ForYou/Consumers/ucm143562.htm*

4 *See, Gellad & Lyles, The Impact of Direct-to-Consumer Advertising of Pharmaceuticals, Am. J. Med. 2007, Jun; 120(6), 475-480.*