Direct-to-Consumer Communications

Consumers benefit from information about diseases and medical treatment options received through direct-to-consumer (DTC) communications, including advertising. DTC communication raises the awareness of medical conditions, informs consumers about the benefits and risks of medicines, and motivates people to discuss prevention, diagnosis, treatment and wellness information with their health care professional.

Background

Providing information to consumers about diseases and available treatments helps patients make educated choices about their health and encourages informed conversations between patients and their physicians. DTC communication is a primary mechanism through which biopharmaceutical companies provide information to consumers about diseases and treatments. Examples of DTC communications include advertising, brochures, websites, physician office materials, and adherence programs.

Perhaps the most notable DTC communication has been advertising for prescription medicines; prescription medicine advertisements began appearing in print media in the early 1980s. In 1997, the Food and Drug Administration (FDA) adopted guidelines that facilitated television and radio broadcast advertisements. The FDA continues to study DTC communications and its impact on patient disease and product understanding. It is encouraging that FDA is evaluating evolving regulations to meet consumer information needs as mobile phone and Internet information shape medical decision-making.

Millions of Americans have seen advertisements that inform them of health conditions and treatment options. These people have sought additional information and/or have had a conversation with a health care provider that has led to critically needed treatment. In addition to traditional media, biopharmaceutical companies are providing educational material on the Internet and in other electronic media because that is where people now seek information.

In the U.S., DTC communication from biopharmaceutical companies is highly regulated. A variety of mechanisms, including regulatory oversight and voluntary industry standards, help ensure responsible DTC communications. The FDA regulates almost every aspect of the pharmaceutical business, from research and development to sales and marketing. In accordance with FDA regulations, DTC advertising and promotion must be consistent with the approved product labeling and must appropriately balance information about a product’s benefits and risks.

Failure to adhere to FDA advertising and promotion regulations can result in a requirement to run corrective advertising or “pre-clear” future promotional materials, and FDA has authority to impose civil monetary penalties for violative DTC advertisements. FDA can respond to noncompliance with a notice of violation or, in more serious situations, a warning letter, product seize, or civil and/or criminal litigation. Off-label promotion may additionally lead to prosecution by the Office of Inspector General of the Department of Health and Human Services and the Department of Justice. Many states also have laws that apply to marketing and sales practices and that are enforced by state prosecutors.

Beyond government regulation and enforcement, the pharmaceutical industry itself has standards governing DTC promotion. Specifically, Pharmaceutical Research and Manufacturers of America (PhRMA) members voluntarily adopted Guiding Principles: Direct-to-Consumer Advertisements about Prescription Medicines, which were updated in December 2008. Among other things, the Principles provide that DTC advertising should:

- Acknowledge that actors are portraying health care practitioners in advertisements or that health care practitioners are being compensated for their appearance.
- Maintain verification that a celebrity endorser used in DTC advertisements accurately reflects the opinions, findings, beliefs, or experience of that person.
- Include information about other options such as diet and lifestyle changes.
- Be targeted to audiences of approximately 90 percent adults (18 years and older) if the DTC television and print advertisements contain content that may be inappropriate for children.
- Include information for prescription access programs.
Moreover, in addition to the FDA requirement that all DTC communication be submitted to the Agency by the time of first use, the Principles also call for the submission of all new DTC television advertisements to FDA before they are released for broadcast.

Key Facts and Figures
- Research indicates that 25 percent of patients visiting their doctor as a result of DTC advertising are diagnosed with a new condition. Of these, 43 percent of diagnoses were for high priority, chronic disease conditions such as diabetes, cholesterol, and arthritis. Chronic diseases are the leading cause of death and disability in the U.S., accounting for 70 percent of all deaths and 75 percent of total health care costs.6
- A 2015 University of Pennsylvania study confirmed that DTC advertising raises awareness of health conditions and treatments and all products in a therapeutic category, including generics, benefit from one brand’s advertising. The authors question if branded advertising is discontinued, what entity would fill the void in public awareness education?7
- A survey by the National Medical Association found that 80 percent of their physicians thought that DTC advertisements made their patients aware of treatment options, and 73 percent reported that DTC ads prompted thoughtful questions from their patients.8 The same survey also found that 2 out of 3 physicians said DTC advertisements prompt patients to alert them of medical problems earlier.
- The 2012 annual DTC Advertising Survey sponsored by Prevention Magazine found that 26 percent of American adults had talked to a physician as a result of seeing a prescription medicine advertisement. Three-quarters of survey respondents strongly or somewhat agreed that advertisements tell people about new treatments; 74 percent said that advertisements alert them to symptoms related to a medical condition; and 71 percent of respondents believed that advertisements allow them to be more involved with their health care.9
- In a 2013 survey conducted by Makovsky Health, Americans spent more than 52 hours online looking for health information. Physician referral, news articles, and recommendations are the sources for referring patients to a biopharmaceutical company website.10

Pfizer’s Position
Pfizer believes that providing information to consumers about medical conditions and available treatments helps patients make educated choices about their health and encourages informed conversations between patients and their physicians. Pfizer supports the continued ability of companies to provide information to consumers about pharmaceutical products and medical conditions through ethical and responsible DTC communication that meets all regulatory requirements and industry standards. Pfizer is committed to evolving its DTC communication practices to better meet the needs of patients, physicians and the health care system in general. To that end, Pfizer believes that regulations should allow companies — who know the most about their medicines — to continue to use technology and new communication channels to provide information when and where our patients seek disease and treatment information. Legislation has been proposed to eliminate the tax deductibility of prescription medicine advertising with the intended effect of reducing or eliminating this channel of information.11 Unintended consequence may be fewer patients seeking medical care for chronic conditions that could be managed earlier and more cost-effectively. The Tax Code and its deductions should be applied with patients in mind and be applied equally to all industries.

How Patients, Health Care Professionals, and the Health Care System Benefit
DTC communication helps increase consumer awareness of diseases and potential treatment options by informing and motivating more productive conversations between patients and their physicians.12 DTC communication benefits the health care system by educating and prompting patients to visit their physicians to discuss their health concerns.

What It Means for Pfizer
DTC communication helps increase consumer awareness of potentially beneficial medicines and treatment approaches—including Pfizer products—and the diseases they treat.

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3. Unpublished results of the 2012 Direct to Consumer Advertising Survey, with permission from Pfizer Inc.
7. Unpublished results of the 2012 Direct to Consumer Advertising Survey, with permission from Pfizer Inc.

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