

P E R S P E C T I V E

Direct-To-Consumer Drug Advertising: You Get What You Pay For

A proposal to address consumer protection and excessive spending while balancing the commercial right to free speech.

by **James M. Jeffords**

ABSTRACT: Between 1997 and 2001 spending on direct-to-consumer (DTC) drug advertising more than doubled. Opinions differ as to whether and to what extent DTC advertising benefits the doctor-patient relationship. Some analysts argue that the current regulatory regime is sufficient, others advocate a stricter enforcement, and still others promote an outright ban. An alternative may be to use the purchasing power of the federal government to require the inclusion of comparative quality data, thus creating a basis for more informed consumer choice. This approach could create incentives for the pharmaceutical industry to adjust spending on DTC advertising while avoiding “big government” interference with commercial free speech.

F EW HEALTH CARE ISSUES draw more attention in the U.S. Congress today than the appropriate role of the federal government with respect to the pharmaceutical industry, whether that role is as the industry's regulator or as its principal customer (in part because of the recent enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [P.L. 108-391]). It seems that each facet of this rocky relationship is steeped in its own controversy and that in some instances these two roles overlap. The practice of direct-to-consumer (DTC) drug advertising may be one of those instances.

What is the appropriate role of the federal government with respect to DTC advertising? Are there conflicts between the government's responsibility to ensure the safety and efficacy

of medicines and the constitutional protections afforded to commercial free speech? If change is needed, what might be the most effective, politically acceptable means for accomplishing it?

The pharmaceutical industry's increasing use of DTC advertising has generated considerable interest among health policy experts both within and outside of government. Research has examined the increasing level of DTC advertising supported by industry and the purported (good and bad) impact of that activity on consumers' behavior and health care spending. The research has also generated a range of opinions as to whether DTC advertising should be allowed and, if so, to what extent the federal government should regulate it.

The papers by Joel Weissman and colleagues and by Steven Woloshin and col-

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leagues are important contributions to understanding one of the most vexing issues in health policy.¹ These papers are especially relevant because they bring a greater understanding of how DTC advertising is perceived by the two most important participants in this policy debate: the physician and the patient.

The gist of this debate involves the increase in spending for DTC advertising—from \$1.1 billion in 1997 to about \$2.7 billion in 2001—and the effect of that spending on consumers' behavior, use of prescription drugs, and costs.² (The year 1997, not incidentally, coincides with the publication of draft guidance from the Food and Drug Administration, or FDA, on regulatory requirements for advertising prescription drugs to the broadcast media. Just one year earlier, there was little if any high-cost broadcast advertising done.)

Supporters of DTC advertising point to research showing its usefulness as a means of educating the patient; its contributions to the doctor-patient relationship; and the beneficial quality outcomes associated with new and, in some cases, high-priority diagnoses.³ They argue that the FDA's existing regulatory regime is sufficient to protect the public health, that the agency is doing a good job of enforcement, and that the government should not mandate unnecessary restraints on commercial free speech. Altruism aside, there seems to be little discussion among supporters about the 21.4 percent increase in prescriptions dispensed among the most heavily advertised drugs.⁴

Critics of DTC advertising argue that it leads to inappropriate patient demands on providers, overuse of prescription drugs, and, in some instances, the increased demand for expensive "me-too" medicines when less expensive and equally effective alternatives are available.⁵ Recommended solutions to these problems run the gamut from an outright ban on DTC advertising, to removing business expense tax deductions, to strengthening the FDA's oversight capacity. The most ardent critics seem to neglect the constitutional protections afforded to commercial free speech.

In addition to the accompanying papers, an October 2002 report from the U.S. General Ac-

counting Office (GAO) provides a useful summary of these points.⁶ As requesters of that report, my colleagues and I sought to better understand the role DTC advertising plays in the pharmaceutical marketplace. The GAO was asked to (1) compare spending by pharmaceutical companies on DTC advertising with spending on all promotional activities and on research and development, (2) evaluate the effect of DTC advertising on prescription drug use and spending, and (3) evaluate the extent and effectiveness of the FDA's oversight of DTC advertising since it issued its 1997 draft guidance for broadcast advertisements.

The GAO's analysis of the first two issues provided information that is valuable in understanding the economic factors associated with DTC advertising. It has also contributed to subsequent comparative research and continues to be cited today. The third inquiry is at the heart of the regulatory enforcement question of DTC advertising, and the GAO made specific recommendations for strengthening this aspect of the agency's mission. Since passage of the Food, Drug, and Cosmetic Act (FDCA) early in the twentieth century, Congress and the executive branch have struggled to ensure that the regulatory regime fits the needs of the public without being unnecessarily burdensome to the pharmaceutical industry. The goal continues: ensuring that the medicines available to the American public are safe and effective.

To ensure that claims made in pharmaceutical ads are truthful, the FDA has regulatory authority through the FDCA to review the accuracy of claims and requires that they (1) be neither false nor misleading, (2) present a "fair balance" of information about the risks and benefits of using the drug, (3) contain "facts" that are "material" to the product's advertised use, and (4) in general, include a "brief summary" of every risk from the product's approved labeling. These efforts are done principally through the FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC).

The GAO found, however, that this division's oversight of DTC advertising was limited

and that despite the agency's efforts, "it has not prevented some pharmaceutical companies from repeatedly disseminating new misleading advertisements for the same drug."⁷ In response, my colleagues and I wrote to the Department of Health and Human Services (HHS) urging removal of the existing impediments to enforcement. In June 2002 the FDA announced the reorganization of the DDMAC; this led to a team-based enforcement approach, which will focus on DTC advertising materials.

Also in 2002, Congress authorized more than a doubling of the budget available to the DDMAC in fiscal year 2005 (to \$5.5 million), to be used to monitor broadcast and Internet ads more vigilantly and to ensure that the messages conveyed do not mislead consumers. Unfortunately, these increased funds have not been requested by the current administration, and the DDMAC continues to be underfunded. Clearly, additional congressional oversight is called for.

What, if anything else, should be done beyond the regulatory scope of the federal government? Beyond its regulatory function, the federal government is a major purchaser of pharmaceuticals and bears two additional responsibilities. The first is its fiduciary responsibility to taxpayers to ensure that their tax dollars are not wasted; the second is to ensure that it does all it can in terms of safety and quality to leverage its purchasing power on behalf of its employees and beneficiaries.

Obtaining the "best price" will continue to be an issue with government purchases of pharmaceuticals. However, given the government's purchasing power, the likelihood is that prices it pays will be very competitive. The more significant potential is the extent to which the government requires, as part of any purchasing agreement, drug makers to disclose information about safety and comparable effectiveness as part of their DTC advertising. In addition, we should better use federally funded research and build upon tools such as the prescription drug benefit box that Woloshin and colleagues propose.

As this information becomes more widely

acknowledged and available, it will come into greater demand by other purchasers, including self-insured corporations, labor unions, and state governments. Ultimately it can provide the competitive edge to those pharmaceutical companies and pharmacy benefit managers (PBMs) that want to expand their markets.

This mechanism could bring additional information to consumers, and it should be strengthened. Although this is not the mandatory, regulatory approach some would advocate, it is an approach that makes sense from a market perspective and one less likely to be fought by stakeholders opposed to "big government" incursions on the constitutional right to commercial free speech. With hundreds of billions of dollars at stake, if the federal government insists that comparative information useful to the consumer is what it will pay for, then that is what it will get.

NOTES

1. J.S. Weissman et al., "Physicians Report on Patient Encounters Involving Direct-to-Consumer Advertising," *Health Affairs*, 28 April 2004, content.healthaffairs.org/cgi/content/abstract/hlthaff.w4.219 (28 April 2004); and S. Woloshin et al., "The Value of Benefit Data in Direct-to-Consumer Drug Ads," *Health Affairs*, 28 April 2004, content.healthaffairs.org/cgi/content/abstract/hlthaff.w4.234 (28 April 2004).
2. U.S. General Accounting Office, *Prescription Drugs: FDA Oversight of Direct to Consumer Advertising Has Limitations*, Pub. no. GAO-03-177 (Washington: GAO, October 2002).
3. D.U. Vogt, "Direct-to-Consumer Advertising of Prescription Drugs," *CRS Report for Congress*, RL31603 (Washington: Congressional Research Service, 10 October 2002).
4. *Ibid.*, 2-7.
5. *Ibid.*, 2-7.
6. GAO, *Prescription Drugs*.
7. *Ibid.*, 4