

POINT/COUNTERPOINT

An Assessment of Direct-to-Consumer Advertising of Prescription Drugs

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Advertising is widely seen by economists and regulators as beneficial to markets and consumers.¹ The prescription drug market offers exceptional opportunities^{2,3} for direct-to-consumer advertising (DTCA) to provide new-product information, improve compliance, alleviate widespread underdiagnosis and undertreatment,⁴ and motivate new-product development.⁵ DTCA can also induce excess or even dangerous prescribing, however, partly because patients are poorly informed and usually pay far less than the full cost of drugs. Empirical research can help resolve these issues.

Research on DTCA

Selected research on direct-to-consumer advertising (DTCA) has been summarized elsewhere.^{6–8} Research has come mainly in two overlapping waves. The first consisted mainly of surveys, usually of patients but sometimes of physicians. The most notable early work began in 1998 with the first of several annual DTCA consumer surveys designed by a professionally trained survey researcher at *Prevention* magazine.^{9,10} Social psychologists at the Food and Drug Administration (FDA) extended that work with a consumer survey in 1999 (ref. 11) and a larger survey in 2002 that added a sample of physicians.¹² Arguably the most important work since then has been the consumer and physician surveys described in Weissman *et al.*^{13,14} (also see Murray *et al.*^{15,16}).

These surveys have generally found that consumers like DTCA because it provides information about new treatments (86% agreement in the 1999 FDA survey) and helps them prepare to talk to their physicians (61%). Risk and benefit information are both very prominent (90% recall for both was reported in the 2002

FDA survey, in which 89% also recalled information on who should not use the advertised drug). Although patients seldom schedule a physician visit because of an advertisement (only 4% in the 2002 *Prevention* survey), most surveys find that about one-third of respondents discussed advertised drugs in visits scheduled for other reasons. Often (43% of the time in one survey) they are prescribed the drug they asked about.¹³ In the 2002 FDA survey, which focused partly on patient–physician relationships, well over 80% said their physicians welcomed their patients' questions and only 3% of them were angry or upset.

Results from physician surveys are far more mixed. In the 2002 FDA survey, only very small minorities of physicians and patients thought that DTCA-motivated exchanges were disruptive. In the most comprehensive physician survey, 75% agreed that DTCA helps educate patients about treatments and 67% agreed that it helped them have better discussions with their patients. But 79% thought it encouraged patients to seek unnecessary treatment, and 82% thought ads failed to provide balanced risk and

benefit information. Another large but less comprehensive survey produced results less favorable to DTCA.¹⁶

In addition, there have been several content analyses of DTCA in which scholars rated ad content according to various standards, typically a checklist of desirable information such as disease prevalence and available treatments, including nonpharmacological ones.¹⁷ The policy relevance of content analysis is questionable. There is no reason to expect advertising to contain all information relevant to the conditions for which patients might seek treatment, nor is it clear that more comprehensive advertising would be more beneficial. Advertising for physicians, hospitals, cancer clinics, and the like do not contain comparable information and contain little if any data about the substantial risks involved. For drug warnings, a long stream of research, reflected in the FDA's 2005 guidance for print DTCA, indicates that streamlined ads featuring the most essential information are actually more useful than relatively complete information.

The second wave of DTCA research has worked with market data rather than

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survey data. This work has been dominated by econometric analysis that controls numerous factors that could affect the relationship between DTCA and outcomes such as physician visits, patient inquiries, prescribing, and pharmaceutical sales. Advertising effects are notoriously difficult to measure, and DTCA poses particularly knotty problems. The prescription requirement, for example, prevents an immediate consumer response in the form of a purchase. Moreover, the effects of even a successful ad will play out over weeks or months in ways that vary among patients.

Early econometric work used marketwide data on advertising, prescriptions, and so on.^{18,19} Measured effects of DTCA on brand shares, and separately on entire therapeutic classes, were generally small or insignificant. Recent econometric work has used mainly managed-care prescription databases or panel data, greatly increasing the likelihood of detecting DTCA effects.⁸ Yet again, with few exceptions, effects on brand shares have been negligible, and therapeutic class effects have usually been quite small,^{20–22} although there is some evidence that DTCA can substantially increase physician visits.²³

Finally, we are fortunate to have data from a randomized clinical trial in which actors pretending to be patients presented to primary care physicians with either major depression or adjustment disorder.²⁴ For patients with major depression, DTCA-motivated questions provided substantial benefits. “Minimally acceptable initial care” (which did not necessarily include an antidepressant prescription) was offered to 98% of patients who requested an antidepressant, 90% of those who asked for a specific brand, but only 56% who did not request a drug. Patients with adjustment disorder were also more likely to receive drug therapy if they asked, but practice guidelines neither clearly endorse nor reject drug therapy.

An Assessment of DTCA

DTCA is a weak force in the health care market. There are compelling reasons to think that advertising is a relatively weak force in the prescription drug market just as it is in two other much-

studied markets, alcoholic beverages and tobacco.^{25,26} **Table 1** presents total DTCA expenditures and pharmaceutical sales for the years 2002–2006. Although DTCA as a percentage of sales has been increasing, it was still only 2.0% in 2006. The implication is that if DTCA generates sales far in excess of advertising costs, it does so for very few drugs and not for the market generally. In fact, DTCA has always focused on a small number of drugs. The top 25 brands accounted for 57% of spending in 2006.²⁷ Most brands are not advertised to consumers at all. DTCA’s limited effects are also borne out by econometric studies, which almost always detect small or negligible sales increases from DTCA. It is very unlikely that DTCA is a major factor in either the size or rate of growth of pharmaceutical spending (**Table 1**).

Notwithstanding these data, however, we cannot rule out the possibility that DTCA exercises substantial latent power simply by being available. Whereas the United Kingdom has seen an emotional and litigious debate over National Health Service coverage for treating early-stage breast cancer with trastuzumab (Herceptin; Genentech, South San Francisco, CA), private insurance in the United States has generally covered both approved and established off-label uses of targeted cancer therapeutics. One reason may be the ability of manufacturers to appeal directly to patients if necessary.

Patient risks from DTCA are almost certainly small. Somewhat surprisingly, there seems little reason to think that DTCA induces rapid, excessive, and possibly dangerous usage. Econometric research strongly suggests that large prescription increases from DTCA are rare. Many of the most heavily advertised drugs address undertreated conditions (such as hypercholesterolemia, depression, insomnia, and asthma)

or are extremely safe (such as proton pump inhibitors).²⁷ Several studies of statin prescribing have found that market growth has come from appropriate treatment of more patients rather than from expanded inappropriate prescribing.^{22,28} Even research on valdecoxib (Vioxx; Merck, Whitehouse Station, NJ, withdrawn 2004) has found that DTCA tended to target prescriptions more closely at patients at risk for nonsteroidal anti-inflammatory drug–induced upper gastrointestinal bleeding.^{21,29} On the whole, excessive use induced by DTCA is far more likely to be financially costly than dangerous.

The physician’s role remains dominant. The fact that econometric research usually finds that DTCA’s effects focus on entire therapeutic classes rather than individual brands strongly suggests that, at least in terms of prescription choices, DTCA leaves the physician’s role relatively undisturbed. It is quite common for patients to receive a prescription after asking about an advertised drug. However, there is considerable evidence that whether or not DTCA is involved, physicians tend to cater to patient preferences when they ask for prescriptions as long as the risks are minimal.³⁰ In the most comprehensive physician survey, 46% of physicians who wrote a prescription in response to a request thought the prescribed drug was the most effective and another 48% thought it was as effective as other drugs.¹⁴

The financial impact of DTCA is poorly understood. Research has shown that a substantial portion (perhaps one-third) of drug-spending increases between 1987 and 1996 were the result of patients’ insulation from paying the full costs of drugs.³¹ Whether this has changed after the rapid escalation of DTCA spending after 1997 is unknown. There is little reason to expect large and

Table 1 Pharmaceutical sales and DTCA expenditures: United States, 2002–2006 (US\$ billions)

	2002	2003	2004	2005	2006
Pharmaceutical sales	\$195.1	\$219.5	\$239.8	\$253.7	\$247.8
DTCA expenditures	\$2.6	\$3.3	\$4.0	\$4.8	\$5.6
DTCA as percentage of sales	1.4%	1.5%	1.7%	1.9%	2.0%

Sources: IMS Health and Nielsen Monitor-Plus as reported in DTC Perspectives.^{27,35,36}

adverse effects on spending, however. Most drugs remain unadvertised. Some of the most heavily advertised drugs are in therapeutic classes (such as statins and antidepressants) that are underprescribed and that sometimes reduce total health-care costs. There is little evidence that DTCA increases drug prices.³²

Spillover benefits of DTCA may prove to be important. The fact that DTCA tends to increase demand for entire therapeutic classes rather than just the advertised brand exemplifies DTCA's spillover effects. These effects seem to work mainly to the benefit of patients. Prominent risk information in ads reinforces the perception that all drugs have side effects that should be considered. Brands with weaker safety profiles may suffer from competitive advertising.²¹ Advertisements that encourage patients to talk to physicians about previously undiagnosed or untreated conditions often trigger advice for lifestyle changes rather than a prescription, especially if the ad is for a statin, antidepressant, or diabetes treatments. Ads about one condition such as erectile dysfunction can lead to diagnoses of different, more serious conditions such as cardiovascular heart disease, for which erectile dysfunction has recently been revealed as a precursor.³³ Finally, advertising is a natural tool for improving drug compliance because consumers tend to pay attention to ads for products they actually use. This effect, like other spillovers, is difficult to measure, but limited evidence suggests at least a modest role for DTCA in improving compliance for statins^{18,21} and antidepressants.²⁰

What about the First Amendment?

In its decision providing First Amendment protection for commercial speech, the Supreme Court has paid close attention to the practical benefits of advertising and the ease with which useful advertising is suppressed in the absence of such protection. There is every reason to believe that DTCA fits comfortably within this line of reasoning.³⁴ Indeed, some DTCA is arguably more valuable than most advertising, because it supplies information (about new treatments, for example) that consumers are unlikely to obtain promptly from other sources.

Conclusions

The effects of DTCA are subtle, often indirect, and yet to be measured with confidence. Overt effects are narrowly focused on a few therapeutic drug classes, with small, almost negligible direct impact in the overall health-care market. Growing evidence shows DTCA brings important spillover benefits: new patient-physician discussions about undiagnosed, untreated, or undertreated conditions; physician recommendations for nonpharmaceutical therapies; greater patient receptivity to necessary drug therapy; and improved adherence to prescribed therapies. Physician complaints notwithstanding, the dominant role of physicians in drug prescribing is essentially unimpaired when genuine risk-benefit trade-offs are involved.

CONFLICT OF INTEREST

The author declared no conflict of interest.

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Direct-to-Consumer Advertising of Prescription Drugs: Balancing Benefits and Risks, and a Way Forward

RL Kravitz¹ and RA Bell²

As annual spending on direct-to-consumer advertising (DTCA) of prescription drugs surges toward \$5 billion, the dispute between proponents and critics of DTCA remains heated. The long-running debate may say as much about the beliefs, values, and interests of the stakeholders as it does about the evidence and issues. One question that is now beyond debate is the matter of whether DTCA is effective. There is little doubt that consumers take notice of these advertisements, request promoted drugs and—upon making a request—more often than not leave their physician's office with a prescription in hand.¹

Defenders of DTCA tend to emphasize its potential to educate consumers and encourage productive dialogue between patients and physicians. DTCA does supply information and increase consumers' awareness of medical conditions and treatments, often in memorable and vivid ways. In addition, DTCA may facilitate diagnosis and treatment of previously unrecognized problems.² In general, DTCA's advocates value open markets,

free enterprise and unrestrained exchange of information. Placing considerable faith in consumers as decision makers and in physicians as learned intermediaries, they tend not to worry about DTCA's potential to oversell. And in the event that the verbal or visual messages are just a wee bit misleading,³ well, *caveat emptor*.

Critics, on the other hand, are dismissive of DTCA's potential benefits and alarmed by the alleged risks, which include overdiagnosis, overtreatment, patient anxiety, excessive costs, wasteful use of physicians' time, disruption of the patient–physician relationship, and the medicalization of everyday experiences. There is nothing wrong with health education, these skeptics say, if only education were the focus. Unfortunately, the limited empirical evidence suggests that the educational value of drug advertisements is variable and limited.^{3,4} Ideology rears its head on this side of the debate too: some DTCA bashers seem never to have met a corporation they didn't hate or a government regulation they didn't love. Others are more circumspect but,

on weighing the evidence, still favor an outright ban.⁵ They are in good company internationally: among developed countries, only the United States and New Zealand have yet to impose a ban on consumer-targeted prescription drug advertising.

A feeling of *déjà vu* is inevitable for those of us who have investigated DTCA over the past decade. With a few exceptions, the arguments on both sides of the debate have become stale, and progress on the controversy has stalled. Is there a way forward? We believe there is, provided the parties on each side do a little reality-testing. Despite the appeal (and undeniable international popularity) of DTCA, an outright ban on it in the United States is unlikely, given First Amendment protections on commercial speech. A blanket prohibition on these ads runs a high risk of being declared unconstitutional,⁶ especially given the conservative inclinations of the current Supreme Court. Debating the matter is academically titillating but unproductive. The second reality is that DTCA is not intrinsically good or bad.⁷

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