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Direct-To-Consumer Advertising of Prescription Drugs

Editor's note: In 2007, the pharmaceutical industry spent more than \$4.9 billion on direct-to-consumer advertising (DTCA) of prescription drugs in the U.S. Controversy over DTCA has grown since the Food and Drug Administration liberalized its regulations in 1997. Proponents claim that such advertising educates consumers, promotes patient participation in clinical decisions, and improves patient adherence to medication instructions. Opponents argue that such advertising is meant to persuade, not educate, and that it promotes inappropriate use of prescription drugs, or diverts consumers from better alternatives. This Issue Brief summarizes the evidence about the effects of DTCA, and proposes guidelines for improving the utility of prescription drug advertising.

Regulation of direct-to-consumer advertising (DTCA) of prescription drugs must balance constitutional protections and public health concerns

Only the U.S. and New Zealand permit direct marketing of prescription drugs to consumers. The Food and Drug Administration (FDA) acquired jurisdiction over DTCA of prescription drugs in 1962. For the next 35 years, television advertising was limited by the requirement that ads summarize potential adverse reactions and contraindications to drugs.

- In 1997, the FDA issued guidelines that described how ads could make “adequate provision” for the full disclosure of risks and benefits by referring viewers elsewhere, to a toll-free telephone number, concurrent print ad, a web site, or a physician. As a result, the pharmaceutical industry greatly increased its spending on DTCA, and shifted the majority of its budget from print to broadcast media.
- Regulation of DTCA recognizes that prescription drugs differ from other consumer products because of the drugs’ inherent risks. Nevertheless, commercial speech is given significant protection under U.S. law, leading legal scholars to conclude that an outright ban on DTCA would not likely pass constitutional muster. The question remains about how to balance these constitutional protections with the need to protect the public’s health.
- American television viewers see as many as 16 hours of prescription drug ads per year, far exceeding the average time spent with a physician. Pharmaceutical manufacturers concentrate DTCA spending on a few brand-name drugs, mostly those used to treat chronic conditions with broad and enduring potential markets—such as high cholesterol, insomnia, or reduced bone density. In 2008, the class of drugs with the greatest DTCA spending was treatments for erectile dysfunction.

Review of evidence focuses on how DTCA affects clinical care

Frosch and colleagues reviewed studies published from 1997 to 2009. They judged the strength of the evidence for each of the competing claims about DTCA.

- Their conceptual framework centered around the consumer as an active participant in medical decision making. Exposure to prescription drug advertising can prompt prescription requests, which may be clinically appropriate or inappropriate. If the request is inappropriate, and the physician cannot or will not correct the patient's perception, DTCA may lead to unnecessary and potentially harmful prescribing. On the other hand, if the request is appropriate, DTCA may reduce under prescribing and contribute to patient adherence.
- Exposure to ads may also affect consumer perceptions of treatable illnesses even if it does not lead to a prescription request. For example, it may prompt consumers to seek medical attention for undiagnosed symptoms or remind patients about their prescriptions.

DTCA provides information that is valued by the public, but current ads may not be an effective education vehicle

DTCA proponents justify the proliferation of ads by citing their educational potential. Physicians and patients have been surveyed about their perceptions of drug ads, and the content of print and television ads have been studied.

- In surveys of the public, nearly 75% of respondents believe that ads improve their understanding of diseases and treatments, and more than 40% report using ad information when making medical decisions.
- In surveys, more than half of physicians agree that DTCA educates patients about diseases and treatments. Many physicians, however, believe that DTCA both encourages patients to make unwarranted requests for medication, and promotes unnecessary fear of side effects.
- Analyses of the content of ads find that most DTCA lacks information important to help consumers decide about the benefits and risks of prescription drugs. Benefits of drugs are often described in vague terms or through narratives that exaggerate the magnitude of benefits. In print ads, most of the content exceeds the eighth-grade reading level recommended for the general public.

Effects of DTCA on physician-patient communication are unclear, although it may reduce undertreatment and improve patient adherence in selected conditions

Studies examining the relationship between DTCA and quality of care have focused on whether patients exposed to DTCA have better discussions and relationships with their physicians.

- Surveys of physicians and patients suggest that DTCA promotes patients' participation in their medical care and gives patients more confidence to discuss health-related concerns. Patients report making better health decisions and seeking more information about current and previously diagnosed conditions.
 - Evidence concerning the relationship between DTCA and physician-patient communication is mixed. Most physicians and patients agree that DTCA can prompt important discussions; however, physicians are less likely to endorse the positive aspects of DTCA and more likely to worry that DTCA promotes longer, unnecessary visits and inappropriate medication requests.
 - Limited evidence, including some randomized trials, suggests that DTCA may ameliorate under treatment of selected conditions, such as depression.
 - DTCA may have a small beneficial effect on patient adherence. Analyses of claims data show a small but significant association between DTCA spending and duration of treatment with antidepressants and cholesterol-reducing statins.
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DTCA-prompted requests increase both appropriate and inappropriate prescribing

Critics of DTCA cite its potential to increase inappropriate prescribing, reflecting both cost and safety concerns.

- Physician surveys find that 81% of respondents believe that DTCA promotes medication requests, and one-quarter report resulting changes in their prescribing habits. In one survey, physicians judged half of DTCA-prompted requests to be clinically inappropriate, although 69% of these requests were at least partially fulfilled to accommodate patients.
- More rigorous evidence measuring DTCA-prompted prescribing comes from claims data and from a randomized experiment using standardized patients (actors). The evidence suggests that DTCA-prompted prescription requests lead to both appropriate and inappropriate prescribing. Which effect is greater remains unclear.

DTCA should better identify candidates for treatment and provide better information on drug risks and benefits

Given the evidence of the risks and benefits of DTCA, Frosch and colleagues developed guidelines to maximize the utility of the ads while minimizing their clinical risks. In developing guidelines, Frosch and colleagues proposed three goals that should guide the content of DTCA.

- Ads should help identify appropriate candidates for treatment. The majority of ads produced to date provide little information that would allow consumers to clearly identify whether the advertised product is indicated for them.
- Ads should provide accurate and specific information about the potential benefits of the advertised drug instead of the current qualitative and emotion-laden portrayals that often suggest misleadingly dramatic effects.
- Ads should provide specific quantitative information about the potential risks associated with the drug. Current ads contain a mismatch between visual imagery and verbal messages when risk information is presented.

Proposed content guidelines address evidence-based concerns

The proposed guidelines distinguish between three target audiences for DTCA: those with undiagnosed, asymptomatic conditions (such as hypercholesterolemia); those with undiagnosed symptomatic conditions (such as major depression), and those with previously diagnosed conditions (such as anemia).

- Previously diagnosed patients can judge whether they are candidates for the drug by the name of the condition alone, but those with undiagnosed conditions need more information. Ads targeting undiagnosed, asymptomatic patients should also present information on the condition's prevalence, potential clinical consequences, risk factors, and recommended screening tests; those targeting undiagnosed patients with symptoms should include information on the condition's prevalence, potential clinical consequences, symptoms, and any valid self-administered screening test available.
 - The guidelines call for precise information about absolute risk or symptom reduction expected from drug treatment, compared to placebo, lifestyle changes, and alternative drugs. The availability of generic alternatives should be noted.
 - The guidelines call for risk information to be provided in a final separate block of the ad that is narratively and visually distinct from the rest of the ad, without background music (to reduce distraction). The pace and density of information should be similar to the rest of the ad. The magnitude and frequency of risk should be compared to placebo.
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POLICY IMPLICATIONS

In effect, DTCA amounts to an uncontrolled experiment affecting population health. This review suggests that DTCA has some benefits, but significant risks are evident as well. Regulators and industry representatives alike should consider the proposed guidelines for their potential to maximize the utility of DTCA.

- The proposed guidelines will likely encounter resistance. Some may argue that existing ads are too short to provide all the suggested information. However, longer drug ads have been produced and run. Others may argue that such information should be communicated by the physician, not the ad. This response ignores the time constraints of the typical physician visit, which leave little time to address misperceptions induced by DTCA.
- To assess the proposed guidelines' effect on clinical care and population health, they should be tested in a trial period followed by careful evaluation of the changes in ad content.
- Significant gaps remain in the evaluation of the effects of current DTCA on drug expenditures and population health. Such research would be aided by making the actual air dates and times in different media markets publicly available.

This Issue Brief is based on the following articles: D.L. Frosch, D. Grande, D.M. Tam, R.L. Kravitz. A decade of controversy: balancing policy with evidence in the regulation of prescription drug advertising. American Journal of Public Health, January 2010, vol. 100, pp.24-32. See also: D.L. Frosch, P.M. Krueger, R.C. Hornik, P.F. Cronholm, F.K. Barg. Creating demand for prescription drugs: a content analysis of television direct-to-consumer advertising. Annals of Family Medicine, January/February 2007, vol. 5, pp. 6-13.

*Published by the Leonard Davis Institute of Health Economics, University of Pennsylvania, 3641 Locust Walk, Philadelphia, PA 19104.
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Published by the
Leonard Davis Institute
of Health Economics
University of Pennsylvania

Issue Brief



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