A Decade of Controversy: Balancing Policy With Evidence in the Regulation of Prescription Drug Advertising

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Direct-to-consumer advertising (DTCA) of prescription drugs has remained controversial since regulations were liberalized by the Food and Drug Administration in 1997. We reviewed empirical evidence addressing the claims made in the policy debate for and against DTCA. This advertising has some benefits, but significant risks are evident as well, magnified by the prominence of DTCA in population-level health communications.

To minimize potential harm and maximize the benefits of DTCA for population health, the quality and quantity of information should be improved to enable consumers to better self-identify whether treatment is indicated, more realistically appraise the benefits, and better attend to the risks associated with prescription drugs. We propose guidelines for improving the utility of prescription drug advertising.

The role of patients in medical decision making has changed in recent decades. Patients are no longer viewed as passive recipients of medical care, but instead as active participants who play a key role in making clinical decisions with their health care providers. The expansion of DTCA stems in part from these shifts in the conceptualization of the patient's role.

As shown in Figure 1, exposure to prescription drug advertisements can prompt prescription requests. These requests, mediated or moderated by consumers' backgrounds (e.g., education and medical history), can be driven by ads that include insufficient, inaccurate, or otherwise misleading information or alternatively by ads that include sufficient, accurate, and balanced information.

CONCEPTUAL FRAMEWORK

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By prompting requests for prescriptions, DTCA can promote patient participation in clinical decisions; however, the downstream effects may vary significantly depending on the quality of the information. If a request is clinically inappropriate, but physicians are unable (because of lack of knowledge, time, or other background...
Exposure to prescription drug advertisement

Mediators/Moderators: consumer age, sex, education, medical history

Prescription request driven by high quality information

Prescription request driven by low quality information

Participatory clinical care

Adherence to prescribed regimen

Amelioration of undertreatment

Inappropriate prescribing

Medicalization

Note. Contextual factors to consider for this model include medical visit type and physician specialty (e.g., primary care, specialty care), physician marketing exposure, physician's previous patient communication training, system of care (e.g., health maintenance organization, fee-for-service), and quality-of-care indicators.

FIGURE 1—Conceptual model of the effects of prescription drug advertising.

The debate over DTCA is mired in competing claims, each of which we examined.

EDUCATIONAL VALUE OF ADVERTISEMENTS

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 has been studied. More than half of physicians agree that DTCA educates patients about health conditions and available treatments. In surveys of the public, nearly 75% of respondents agree that ads improve their understanding of diseases and treatments, and more than 40% report using ad information in their decision-making process. Many physicians, however, believe that DTCA encourages patients to make unwarranted requests, while paradoxically promoting unnecessary fear of side effects. Only a fraction of physicians (1.3%) and consumers (5.4%) feel that ads provide sufficient information about drug costs.

More objective content analyses of print and television ads find that most provide the indication for the product and describe some symptoms of the target condition. Significantly fewer ads provide information on the drug’s mechanism of action or the prevalence of, risk factors for, or causes of the condition. Fewer than one third of ads provide information about alternative treatments or behavioral changes that could substitute for or complement medication. Benefits of drugs are frequently described in vague qualitative terms or through the use of narratives that exaggerate their magnitude.

Television ads spend significantly less time on a drug’s risks than on its benefits. Although risk information is typically provided in one continuous stream, benefit information tends to be interspersed throughout the ad. Only a minority of ads acknowledge variations in product effectiveness.

The majority of ad content exceeds the eighth-grade reading level recommended for the general public, potentially exacerbating health inequities. Between 1992 and 2002 educational content in print ads declined, while promotional content increased. Companies typically send supplemental materials about products to consumers requesting them through a toll-free telephone number. These more frequently contain information about drug mechanisms of action and supportive behaviors but also often exceed the recommended eighth-grade reading level. On product Web sites, benefit information is frequently accessible on the first page, whereas risk information typically requires several clicks to access and is often incomplete.

Consistent with these findings, a study that assessed consumer learning following ad exposure found that participants recalled more benefit than risk
information. Two experimental studies suggest that providing the risk information at the end of an ad would increase recall. A study that assessed rote learning found inaccurate recall of both benefit assessed rote learning found risk information at the end of an ad studies suggest that providing the quality of medical care have implications between DTCA and the quantitative information not typical, there is insufficient evidence to conclude that ads are an effective educational vehicle. More objective content analyses consistently find that most ads emphasize benefits over risks and may be difficult for patients with average health literacy to understand. Several small studies suggest that immediate recall of information transmitted by ads in their current format is suboptimal. Rigorous experimental evidence indicates that exaggerated perceptions of benefit can be corrected with quantitative information not typically provided in current ads.

ADVERTISEMENTS AND THE QUALITY OF CLINICAL CARE

Studies examining the relationship between DTCA and the quality of medical care have queried 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, although it is unclear whether these subjective perceptions result from physician–patient discussions about advertised drugs. Patients report making better health decisions, seeking more information about current medical conditions, and having medication-related discussions with their physicians prompted by DTCA. In addition, most patients and physicians in nationally representative surveys agree that DTCA viewing gives patients more confidence to discuss health-related concerns with their physicians. However, a recent study found that medication requests were significantly less common among patients with low socioeconomic status, and ads promoting drugs for cardiovascular disease prevention were less likely to include ethnic minority characters or to appear in magazines read by African Americans, potentially contributing to health inequalities.

Evidence concerning the relationship between DTCA and the quality of physician–patient communication is mixed. The majority of physicians (67%) and patients (54%) report that DTCA positively affects physician–patient discussions and interactions, and most agree that DTCA can prompt important discussions. However, I study failed to show better or more medication-related discussions following print ad exposure, and another indicated that few patients discover previously undiagnosed conditions as a result of DTCA viewing.

The evidence is also conflicted about how DTCA affects satisfaction with the physician–patient relationship. In nationally representative surveys, 39% of physicians and 30% of patients felt that DTCA interferes with the physician–patient relationship. An industry-funded survey of physicians found that most (82%) do not believe DTCA causes problems with their relationships with patients; however, in another survey 89% of family physicians did not feel that DTCA enhanced their relationships. Physicians reported more annoyance when presented with a hypothetical medication request motivated by DTCA than they are when the query arises from a more traditional medical reference such as the Physicians’ Desk Reference. Overall, physicians are less likely than patients to endorse the positive aspects of DTCA and more likely to worry that DTCA promotes longer, unnecessary visits and inappropriate medication requests. Patients may react negatively if their physician refuses a medication request.

EFFECTS OF ADVERTISEMENTS ON PATIENT ADHERENCE

Patient nonadherence costs approximately $100 billion annually in lost productivity and added health care expenditures. Propos-
In a representative survey, 72% of physicians agreed that ads promote patients’ adherence to instructions. However, a majority of physicians (54%) in a pharmaceutical industry-funded survey disagreed that they increase adherence. A nationally representative survey of the public found that 82% of respondents believed ads promote adherence to physicians’ instructions, but among patients recruited from physicians’ waiting rooms 23% indicated they would be more likely to take an advertised drug.

Some research has analyzed claims data for an association between DTCA spending and persistence of prescribed medication regimens. Brand-specific ads for antidepressants had no effect on treatment duration; however, total ad spending for all antidepressants showed a small but significant association with receiving treatment for at least 4 months. Similar small but significant prescription persistence effects have been found for cholesterol-reducing statins. High levels of DTCA for statins were also associated with patients reaching the least-restrictive low-density lipoprotein goal recommended by clinical guidelines.

There is insufficient evidence to draw clear conclusions about the effects of DTCA on adherence to prescribed regimens. However, the available evidence suggests that DTCA may have small, beneficial effects on drug adherence.

**PROMOTION OF QUESTIONABLE PRESCRIBING PRACTICES**

A chief concern of critics is the potential of DTCA to increase inappropriate prescribing, reflecting both cost and safety concerns. Physician surveys find that DTCA increases prescription volume and that some of these prescriptions are clinically inappropriate. Eighty-one percent of physicians believe that DTCA prompts medication requests, and one quarter report resulting changes in their prescribing habits. A survey of physicians and their patients found that 7% of patients made a prescription request and that DTCA exposure increased such requests. Although 78% of the requests were fulfilled, the prescribing physician judged half of these prescriptions as possible or unlikely choices for a similar patient with the same condition. In another survey, physicians judged half of DTCA-prompted requests to be clinically inappropriate. However, 69% of these requests were at least partially fulfilled, with a small but significant percentage of these requests (6%) judged as potentially harmful choices. Physicians often said they fulfilled such requests to accommodate patients.

More rigorous evidence measuring DTCA-prompted inappropriate prescribing comes from studies of claims data. Patients in a California health maintenance organization who reported exposure to ads for cyclo-oxygenase-2 (COX-2) inhibitors were more likely to receive a prescription for a COX-2 inhibitor than for a nonsteroidal anti-inflammatory drug. This study used multiple measures of appropriateness and found that ad exposure significantly increased both appropriate and inappropriate COX-2 prescribing. A study of a large cohort of private health plan patients found higher rates of switching to an advertised brand of proton pump inhibitor among patients living in television markets with high DTCA volume for these drugs. The therapeutic equivalence among members of this class of drugs raises questions about the appropriateness of these switches, because the advertised brands are more expensive and therefore increase treatment costs. The most rigorous evidence regarding DTCA-prompted prescribing comes from a randomized experiment. Unannounced standardized patients (actors) making brand requests were the most likely to receive unwarranted prescriptions for adjustment disorder. However, these requests also increased the likelihood of obtaining appropriate prescriptions for major depression.

The limited body of evidence suggests that DTCA-prompted prescription requests increase both appropriate and inappropriate prescribing. Which effect is greater remains unclear.

**PROMOTION OF OVERDIAGNOSIS AND MEDICALIZATION**

Critics of DTCA are concerned that it leads to medicalization, the process by which nonmedical problems come to be defined as treatable illnesses, thereby potentially increasing unwarranted diagnoses. Critics argue that medicalization occurs as a result of mass marketing that widens the boundaries of illness in order to expand markets rather than improving population health. DTCA proponents argue that advertising helps address pervasive undertreatment.

Case studies of various marketing campaigns have examined the process and consequences of medicalization. For example, Paxil marketing campaigns for various anxiety disorders were found to advertise medicalized feelings of social discomfort with slogans such as “imagine being allergic to people.” Antidepressant print ads have been found to contain incomplete syllogisms, leading readers to conclude that their emotional symptoms are treatable with medications.

A content analysis of advertisements found that DTCA often focuses on conditions that may not be recognized by consumers as pathological or treatable. The only randomized experiment that examined medicalization found that adjustment disorder symptoms are more likely to be treated with medication when prompted by a DTCA-specific request.

Although it is clear that DTCA appears to medicalize symptoms previously not defined as illness, the question of whether a net social benefit exists is a complicated cultural and political question not easily answered through scientific studies.

**BALANCING EVIDENCE AND REGULATORY POLICY**

Table 1 provides a summary of the evidence supporting the claims made in the DTCA debate and identifies where further research is necessary. Although DTCA carries some benefits, significant risks are evident as well, magnified by the prominence of DTCA. Several changes in the content of ads could...
TABLE 1—Summary of Evidence for Claims Made by Supporters and Opponents of Prescription Drug Advertising to Consumers

<table>
<thead>
<tr>
<th>Claim</th>
<th>Summary of Evidence</th>
<th>Strength of Evidence and Future Research Directions</th>
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<tbody>
<tr>
<td>Prescription drug advertisements are educational</td>
<td>More than half of physicians and the public surveyed agreed that DTCA educates the public about diseases and treatments. Content analysis studies found that most DTCA lacks important information to help consumers make truly informed decisions about the benefits and risks of prescription drugs. Ad information often requires a high level of literacy for comprehension. Experimental studies found that consumer recall of information in ads is suboptimal.</td>
<td>Physicin and patient survey findings reflect subjective perceptions of the educational value of DTCA, rather than objective assessments that DTCA increases knowledge about prescription drugs. Content analysis studies provide more objective assessments of the educational potential of DTCA, but do not reflect what consumers actually learn. Few studies have longitudinally or experimentally assessed learning after exposure to DTCA.</td>
</tr>
<tr>
<td>Prescription drug advertisements improve the quality of clinical care</td>
<td>In some surveys, physicians and patients agreed that DTCA promotes patient involvement, increases patients’ participation in their health care, and positively affects physician-patient discussions. One study suggested that prescription requests are less likely among patients from economically disadvantaged groups. Limited rigorous experimental evidence suggests that DTCA-prompted requests can enhance diagnostic sensitivity and treatment provision.</td>
<td>The majority of studies examining the effect of DTCA on the quality of care were cross-sectional surveys assessing subjective perceptions of physicians and patients. Few studies used rigorous objective measures to assess the effects on quality of care. Nothing is known about the effects of DTCA on health outcomes.</td>
</tr>
<tr>
<td>Prescription drug advertisements promote patient adherence to prescribed regimens</td>
<td>In some surveys, but not in others, the majority of physicians and patients agreed that DTCA promotes adherence. Studies of claims data found small positive ecological (or area level) associations between DTCA spending and prescription persistence for antidepressants and lipid-lowering agents. Survey studies of the effect of DTCA on patient adherence relied on subjective perceptions of physicians and patients. No studies directly link individuals’ ad exposure to improved adherence.</td>
<td>Rigorous evidence concerning questionable prescribing in response to DTCA-prompted requests is limited to a small number of therapeutic areas.</td>
</tr>
<tr>
<td>Prescription drug advertisements promote questionable prescribing practices</td>
<td>In some surveys, physicians indicated that they fulfilled questionable DTCA-prompted patient requests for prescriptions. Studies of claims data found evidence for inappropriate prescribing of COX-2 inhibitors and proton pump inhibitors associated with DTCA exposure. Experimental evidence suggests that DTCA-prompted requests increase clinically questionable prescribing of antidepressants for adjustment disorder.</td>
<td>Proving medicalization is challenging for researchers. The effects of expanding diagnostic boundaries on population health outcomes remain unknown.</td>
</tr>
<tr>
<td>Prescription drug advertisements promote overdiagnosis and medicalization</td>
<td>Case studies of marketing campaigns and content analyses illustrate how ads expand the diagnostic boundaries of illnesses. Limited experimental evidence supports DTCA-prompted medicalization in the context of a mild psychiatric condition.</td>
<td></td>
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Note: COX = cyclo-oxygenase; DTCA = drug advertising to consumers.

*Additional claims that remain relatively underexplored in the empiric literature include the effect of DTCA spending on resource allocation by pharmaceutical companies (i.e., research versus promotion), the influence of DTCA on the substitution of generic for brand name drugs, and the interactions of DTCA with direct-to-physician marketing.*
maximize their beneficial potential while minimizing their risks. Although high-quality information about prescription drugs is itself not sufficient to ensure appropriate prescribing decisions, it is a necessary ingredient to improve DTCA-prompted prescribing. The box on this page lists guidelines we propose to improve the utility of DTCA in reducing inappropriate and increasing appropriate prescribing. Pharmaceutical companies could use data from advertisement pretests to demonstrate to the FDA that these issues have been addressed before an ad is aired to the public.

Because pharmacological treatments are directed at different medical conditions, and these conditions vary in the education and information required to inform high-quality decisions about their treatment, our proposed guidelines distinguish between 3 categories: previously undiagnosed, asymptomatic conditions (e.g., hypercholesterolemia), previously undiagnosed symptomatic conditions (e.g., major depression), and previously diagnosed conditions (e.g., anemia). For some conditions, more than 1 of these categories may be applicable in improving the advertisements’ educational potential.

We discern 3 primary goals for DTCA. First, ads should facilitate the identification of appropriate patient 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.18 Including the proposed information in ads could reduce inappropriate and increase appropriate prescribing. Second, ads should provide

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**Proposed Content Guidelines for Prescription Drug Advertisements**

**Am I an Appropriate Candidate for this Prescription Drug?**

For products targeted at patients with previously undiagnosed, asymptomatic conditions (e.g., hypercholesterolemia, hypertension):

- Name of condition
- Prevalence in quantitative terms
- Potential clinical consequences of condition
- Risk factors or precursors of the condition
  - Biological (e.g., race/ethnicity)
  - Clinical (e.g., comorbidities)
  - Family history
  - Lifestyle and behavioral (e.g., sedentary)
- Recommended diagnostic or screening tests

For products targeted at patients with previously undiagnosed, symptomatic conditions (e.g., major depression, overactive bladder):

- Name of condition
- Prevalence in quantitative terms
- Identification of condition-specific symptoms, including frequency and magnitude of symptoms associated with diagnosis
- Validated self-administered diagnostic screener, if available
- Potential clinical consequences of condition

For products targeted at patients with previously diagnosed conditions (e.g., anemia of chronic kidney disease, postherpetic neuralgia):

- Name of condition

**What Are the Health Benefits of This Prescription Drug?**

For all products:

- Precise information about absolute risk or symptom reduction to be expected from drug (as appropriate for drug advertised), including duration of therapy observed in clinical trials, drawn from published studies:
  - Compared to placebo
  - Symptom or absolute risk reduction associated with lifestyle change, including description of magnitude of change necessary
  - Where possible, including results from comparative (head-to-head) clinical trials
- Availability of generic alternatives

**What Are the Health Risks of This Prescription Drug?**

For all products:

- Risk information, provided in a final separate block of the advertisement that is narratively and visually distinct from the remainder of the ad
- No background music, to reduce distraction from the information
- Fact density and pace of information provision not significantly different from the remainder of the ad
- Magnitude and frequency of major risks in comparison to placebo

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1Number needed to treat statistics are a potential alternative method for presenting information about drug benefits; however, some studies suggest that such statistics may be difficult to comprehend for consumers.65,66
accurate and specific information about the potential benefits of advertised drugs instead of the current qualitative and emotion-driven portrayals that often suggest misleadingly dramatic effects. The inclusion of quantitative benefit data from clinical trials has been shown to lead to more realistic consumer appraisals of effectiveness, even among those with fewer years of formal education.32,33 Third, ads should provide specific quantitative information about the potential risks associated with drugs.64 Current ads often contain a mismatch between visual imagery and verbal messages when risk information is presented. Research has shown that when visual and verbal messages are discordant, visual messages tend to dominate information processing, which could lead to inadequate processing of verbal risk information.67

All proposed information, including product risk information, should be provided at an eighth-grade literacy level, to ensure comprehension by a larger segment of the population than is being reached now.28 Consumers could also benefit from drug cost information; however, no accurate way of comparing prices of different drugs has been developed yet.69 Until such data become available, ads could at minimum note, where applicable, that generic alternatives are cheaper.

RESISTANCE TO CHANGE

We anticipate certain responses to our proposals. Some will argue that advertisements are too short (typically 1 minute) to include the information we propose. However, Pfizer has recently been running ads for Celebrex (celexo-cib; Pfizer, Inc., New York, NY) that are 2.5 minutes long.69 Although it is unclear whether television viewers pay attention to longer ads, following our proposed guidelines may not require ads that are as long as the recent Pfizer ad. It is also important to note that our proposals are concerned with the quality as well as the quantity of information.

Some will likely argue that the comparative benefit data we propose including in ads are often unavailable. Although there are few direct comparative trials of different treatment options, both pharmacological and nonpharmacological real-world decisions are also made in the absence of comparative trial data. Ads could communicate relevant data from trials that do not compare the options directly but do provide some measure of what is known about the effectiveness of alternative treatment options. Data should be presented in a manner that increases accurate interpretation of the results by consumers.32,33,70

Finally, critics of our proposals may contend that physicians are the learned intermediaries who should provide consumers with information about prescription drug indications, benefits, and alternatives.71 This argument ignores well-documented realities of the American health care system. Recent data suggest that the average visit with a physician lasts between 16 and 21 minutes.72,73 If prescription requests are made by patients during consultations for other issues, little time is left for the physician to address misconceptions induced by DTCA. Moreover, the reliance of the physician payment structure on satisfaction surveys introduces significant risks from denying patient requests. The negative effect of denying requests on the therapeutic relationship is well-documented—patient satisfaction declines and physician switching increases46—although it may be possible to mitigate such effects by involving patients in the decision-making process.74

It is unclear how the courts might rule on our proposed guidelines if they were to be contested on First Amendment grounds.6 However, we believe these changes would be positive for both consumers and industry, perhaps reducing the likelihood that they would be challenged.

DTCA amounts to a large and expensive uncontrolled experiment in population health, which to date shows decidedly mixed effects. The evaluation of the effects of this experiment would be aided if the industry made the times when ads were aired in different media markets publicly available. Researchers could use these data to evaluate the effects of DTCA on drug expenditures and health outcomes with much greater precision, potentially benefiting both industry and regulators. Similarly, our proposed guidelines should also be subject to a trial period followed by careful evaluation, to ensure that changes in ad content have the intended beneficial effects on population health.

Following the market withdrawal of Vioxx, several pharmaceutical manufacturers announced a voluntary time-limited moratorium on advertising new products, although it is unclear if this has been implemented as promised.75 The industry should be given the opportunity to implement our proposed changes voluntarily. If these changes are not forthcoming, legislators should consider changing existing FDA regulations to ensure that DTCA achieves its full potential for maximizing population health. ■

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**Human Participant Protection**

No protocol approval was required because no human participants were involved in the study.

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