Dangers and Opportunities of Direct-to-Consumer Advertising

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The average television viewer in the United States (US) watches as many as nine drug advertisements per day and about 16 hours per year, far exceeding the time an average individual spends with his/her primary care physician.[1] Since 2012, spending on drug commercials has increased by 62%, and $5 billion were spent on drug commercials last year.[2] Given their ubiquity, the article by Klara, et al. in this issue of *JGIM* offers one more piece of evidence to indicate that this medium is not operating as intended, and to force us to consider alternatives to the status quo.[3]

First, it is important to consider the history and original purpose of direct-to-consumer (DTC) advertising. In the 1960s, Congress granted the Food and Drug Administration (FDA) regulating authority of prescription drug labeling and advertising. This authority included ensuring that ads (1) were not false or misleading, (2) presented a "fair balance" of both drug risks and benefits, (3) included facts that are "material" to a drug's advertised uses, and (4) included a "brief summary" that notes every risk described in the drug's labeling.[1] While the first DTC advertisement was a Merck print advertisement for the Pneumovax® vaccine in 1981, DTC advertising exploded in the late 1990s after the FDA eased up on regulations for required risk information by stipulating that ads must include only the "major risks" and provide resources that consumers can be directed to for full risk information.[1]

As the regulating body of DTC advertising, the FDA is responsible for ensuring that advertising "is truthful, balanced, and accurately communicated" through regulation, surveillance, and education.[4] In this capacity, the FDA has won substantial law suits and enforced penalties against pharmaceutical companies. For example, in 2012, Glaxo Smith Kline paid $3 billion and Abbott paid $1.6 billion in penalties for miscommunicating information in DTC advertising, while Eli Lilly paid $1.4 billion and Pfizer paid $2.3 billion in 2009.[5]

Proponents of DTC advertising report that drug ads can serve many important roles for consumers. First, they may empower and engage patients to participate in their own health care through informing patients about disease, treatment options, safety risks, and public health warnings.[1, 6] Second, they may avert underuse of effective disease treatments, and potentially increase medication adherence.[1, 6, 7] Finally, they may strengthen patients' relationships with their physicians.[1, 4] Surveys conducted by the FDA in 2004 found that most surveyed physicians felt that DTC advertising made their patients more aware of treatments and feel more engaged in their own health care. Moreover, 27% of consumers were prompted to make an appointment with their physician to discuss a condition they had not previously discussed due to DTC advertising.[4]

In contrast, critics have noted disproportionate risks and hazards related to DTC advertising. DTC ads have been shown to misinform patients by over-emphasizing treatment benefits, under-emphasizing treatment risks, and promoting drugs over healthy lifestyle choices.[1, 6] DTC advertising may also lead to overutilization and inappropriate prescribing.[6] In a study published in 2005 by Kravitz et al., standardized patients were randomly assigned to make brand name, general, and no drug requests for DTC-advertised antidepressants to 152 physicians. Patients who requested drugs received them significantly more often than those who did not, suggesting patient requests have a dramatic effect on physician prescribing.[7] Furthermore, critics argue that DTC advertising can impose strains on the patient-physician relationship and limit already limited appointment time with patients.[1, 6]

Perhaps the most significant critique of DTC advertising is its effects on rising drug costs due to over-prescribing of both inappropriate and brand name drugs (especially when cheaper generics are available). According to the Department of Health and Human Services, prescription drug spending in the US was about $457 billion in 2015.[8] Much of these costs are absorbed by the government since Medicare and Medicaid are the single largest payers for prescription drugs. As such, the existing regulatory environment influences federal and state budgets, insurance premiums, and patient out-of-pocket costs.

In the thoughtful study by Klara, et al., we see evidence of defects in the information provided by DTC advertising.[3] The authors systematically assessed adherence of DTC advertisements to FDA guidelines for ads airing in the US between January 2015 and July 2016, with specific emphases on balanced presentation of risks and benefits, quality of data presented, and off-label promotion. The authors found that among 97 advertisements reviewed by authors, the quality of data presented was low—26% provided quantitative information

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for efficacy and benefit, 0% provided quantitative information on risks, and 13% promoted off-label use of medications (which is banned by the FDA). This study demonstrates that DTC-televised advertisements are not fulfilling their original intended purpose.

The optimal role for the FDA as the regulating body of DTC ads is also commonly questioned. Many researchers (including the study authors) suggest that FDA guidelines are not prescriptive enough in terms of the extent and format by which quantitative benefits and risks should be presented. For example, Klara, et al. found a minority of DTC ads provided quantitative information about treatment benefit, and no ads provided quantitative information about risks.[3] One could argue that it is not surprising they lack this information since these ads are not explicitly required to so. Additionally, FDA enforcement of rules for DTC advertising has been weakened by increased bureaucratic procedures. An example has been the reduced number of warnings issued after the Department of Health and Human Services began requiring all regulatory warnings to be reviewed by the Office of Chief Counsel. This has also led to delays that have caused regulatory warnings to be sent long after advertising campaigns have ended.[1] Compounding these problems, significant staff shortages have resulted in a minority of DTC broadcasts actually being reviewed by FDA staff.[1]

How can we optimize the benefits of DTC advertising in empowering and engaging patients while minimizing the attendant risks of poor-quality DTC advertising? One option supported by the American Medical Association is banning DTC advertising.[9] It is notable that, outside of the US, DTC advertising is banned in all other countries except New Zealand. However, prior attempts at terminating DTC advertisements in the US have failed due to constitutional arguments that banning DTC advertisements would limit commercial freedom of speech.[1] Others (including the authors of the accompanying article) propose boosting FDA resources to provide more prescriptive regulations on the content of information presented in DTC advertising and enforcement of such regulations. Another suggested solution is the use of an unbiased entity, either to review all DTC advertisements for regulation compliance or to actually develop and disseminate DTC information to consumers independent of pharmaceutical manufacturers. Some countries' governments have served as this unbiased entity, primarily in countries where the prescription drug system is nationalized. For example, in an effort to increase generic drug use in Portugal, the government launched a television and print advertising campaign in the 2000s promoting the prescription of generic drugs through sharing effectiveness data and economic advantages with the public. Over the course of 7 years, generic drug prescribing increased by ~ 20%.[10]

DTC advertising is not satisfying its goals of providing accurate and balanced information to patients, and is most certainly leading to increased costs for the system and for patients. In our era of rising health care costs and questionable sustainability of entitlements, one would expect the government to be more invested in delivery of high-value information to patients and providers and should consider altering its role to ensure that DTC advertising better serves its purpose. Moreover, as is evident by the issues with DTC advertising raised by the authors, the current problems with DTC advertising have resulted from a combined drift from its intended purpose and regulatory and resource limitations. Although virtually all stakeholders (including patients, providers, pharmaceutical manufacturers, and private and public payers) are differentially affected by DTC advertising, they share a common goal of maximizing the value of drugs by delivering the right drug to the right patient at the right time. There seems to be a unique opportunity for a collective group with diverse members from the health care ecosystem to work together to devise solutions that optimize the benefits and minimize the risks of DTC advertising.

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