

Direct-to-Consumer Pharmaceutical Advertising

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The American Medical Association (AMA) recently adopted a new policy supporting a ban on direct-to-consumer pharmaceutical advertising (DTCPA) of prescription drugs and medical devices in an effort to make prescription drugs more affordable.¹ Dr. Patrice A. Harris, MD, MA, chair-elect of the AMA Board of Trustees, stated that the vote “reflects concerns among physicians about the negative impact of commercially-driven promotions, and the role that marketing costs play in fueling escalating drug prices.” She added, “[it] also inflates demand for new and more expensive drugs, even when these drugs may not be appropriate.”¹

The United States and New Zealand are the only 2 countries that allow DTCPA that includes product claims.¹ There are 3 basic types of DTCPA, all of which are regulated by the US Food and Drug Administration (FDA): (1) help-seeking advertisements, which provide information about a disease but do not recommend specific drugs or devices; (2) reminder advertisements, which mention specific drugs and provide some information (eg, strength, dosage form, price) but do not mention the indication or make efficacy claims; and (3) product claim advertisements, which are the most common type and mention drug names, indications, and efficacy and/or safety data.²

The FDA’s Division of Drug Marketing, Advertising, and Communications is responsible for regulating DTCPA. The FDA has had authority to approve pharmaceutical products in the United

States since 1938 and has regulated labeling and advertising of these products since 1962. In 1969, the FDA issued regulations stipulating that drug advertisements should not be false or misleading and should provide information about risks and benefits, facts about the uses of the drug, and a list of all risks in the product’s labeling. At that time, drug advertisements were directed at health care providers—not the general public—and were mainly found in medical journals and other print sources aimed directly at physicians.

When a number of pharmaceutical manufacturers ran direct-to-consumer advertisements in print and broadcast media, the FDA had to consider how to regulate a new area of advertising. In 1985, the FDA issued a notice claiming regulatory jurisdiction over DTCPA. Believing that DTCPA was beneficial to the general health of consumers, the FDA gradually eased its regulations in recognition of the prohibitive time and expense that the older rules required. Advertisers now only had to list major risks rather than all risks and direct consumers to sources of further information.

In 1980, total spending on DTCPA by industry was \$12 million; this figure reached \$1.2 billion by 1998, topped out at \$5 billion in 2006 and 2007, and dropped to \$4.5 billion in 2009.² Today, most DTCPA spending goes toward television commercials, with the average American viewer watching as many as 9 drug advertisements per day; however, spending on Internet advertising is increasing since the return on investment in that medium is greater.

Is DTCPA beneficial or detrimental to the health of US consumers and, specifically, to patients with skin disease? Unfortunately, there are no quick answers. In a review by Ventola,² data showed that DTCPA informs, educates, and empowers patients and encourages them to seek medical care as well as to make appointments with their doctors to discuss conditions they had not previously discussed. Data also showed that DTCPA strengthens patients’ relationships with health care providers and improves

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patient compliance with treatments. Importantly, DTCPA has been shown to reduce underdiagnosis and undertreatment of medical conditions and removes the stigma associated with certain diseases. Finally, DTCPA also has been shown to encourage product competition and lower drug prices.²

In contrast, data also have shown that DTCPA can lead to patient misinformation and may damage the patient-physician relationship.² Many advertisements may overemphasize a drug's benefits while downplaying associated risks, while others may promote an unnecessary fear of side effects. These advertisements have been criticized for causing beliefs about diseases in patients that lead to overutilization of drugs and inappropriate prescribing. Some fear DTCPA may promote new drugs before their safety profiles are fully known, which may be particularly true for first-in-class drugs. Finally, DTCPA may increase the cost of drugs in general, not only because of the amount spent on the advertisements themselves, but also because DTCPAs promote copycat drugs that do not offer any increased benefit over older and cheaper medications.

How does all of this relate to dermatology? In the last few years, we have seen the development of drugs (eg, psoriasis treatments) that offer real improvement for patients who only had access to minimally effective therapies in the past. The research pipeline is full of agents for other diseases for which we lack adequate treatments, such as atopic eczema and certain forms of skin cancer. Additionally, for patients with diseases like psoriasis and eczema who may have given up on dermatologists to provide adequate

treatments, DTCPAs may give them hope and renewed interest in seeking our help.

It comes as no surprise to dermatologists and their patients that the costs for drugs used to treat dermatologic diseases have skyrocketed. Rosenberg and Rosenberg³ recently evaluated the cost of 19 dermatologic drugs from 2009 to 2015 and noted increases ranging from 60% to 1698%, the majority of which may be passed on directly to our patients.

Ultimately, there are no easy answers. Hopefully, studies evaluating the pros and cons of DTCPAs—specifically for dermatology patients—that can help dermatologists make rational decisions about how to best serve our patients in a cost-efficient manner will be forthcoming. For the time being, it is unlikely that DTCPA will be banned in the United States, as such action would surely lead to claims of unconstitutional infringement on free speech. Nevertheless, increased oversight and more stringent regulations might improve the acceptability of such advertising to those that oppose DTCPA.

REFERENCES

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