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DIRECT-TO-CONSUMER ADVERTISING AND THE DEMAND FOR CHOLESTEROL-REDUCING DRUGS*

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Abstract

In August 1997, the Food and Drug Administration (FDA) reinterpreted its advertising regulations to ease limits on the use of broadcast media when advertising prescription drugs directly to consumers. We estimate the effect of direct-to-consumer advertising on demand, using 1995–2000 data from the market for the statin class of cholesterol-reducing drugs. We find no statistically significant effect from any form of advertising and promotion on new statin prescriptions or renewals and no evidence of adverse market effects from advertising or the FDA policy change. We did find evidence, however, that television advertising increased the proportion of cholesterol patients who had been successfully treated, which suggests that advertising reinforces compliance with drug therapy.

I. Introduction

The subject of advertising is marked by diverse and conflicting perspectives. Popular writers and social critics, for example, often portray advertising as wasteful and manipulative, while some academic economists argue that advertising can provide useful information for consumers and lower prices.[1]

* The authors gratefully acknowledge IMS Health and Scott-Levin for providing the data described in this paper.

[1] A publication by the Media Foundation, *Adbusters,* seeks to identify the manipulative aspects of advertising. Studies by economists that found that restrictions on advertising raised prices include Lee Benham, The Effect of Advertising on the Price of Eyeglasses, 15 J. Law & Econ. 337 (1972); and John E. Kwoka, Jr., Advertising and Price and Quality of Optometric Services, 74 Am. Econ. Rev. 211 (1984). Pauline M. Ippolito & Alan D. Mathios, Information, Advertising and Health Choices: A Study of the Cereal Market, 21 Rand J. Econ. 459 (1990), and Pauline M. Ippolito & Alan D. Mathios, Information, Policy, and the Sources of Fat and Cholesterol in the U.S. Diet, 13 J. Pub. Pol'y & Marketing 200 (1994), found that the consumption of high-fiber cereals increased and the consumption of fat and saturated fat decreased when manufacturers were allowed to advertise the health content of their products. An overview of the academic and popular debate over advertising is contained in John E. Calfee & James K. Glassman, Fear of Persuasion: A New Perspective on Advertising and Regulation (1997).

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As the nation's health care costs continue to rise, it is not surprising that the pharmaceutical industry's multibillion-dollar direct-to-consumer (DTC) advertising expenditures are attracting their share of critics and defenders.

Some physicians, such as Matthew Holland, complain that DTC advertising encourages patients to ask physicians to write inappropriate prescriptions.[2] Health care providers, such as managed care organizations, and health care payers, such as employers, charge that advertising is increasing health care costs. In fact, according to Reuters, several state legislatures are considering curbs on DTC advertising.[3]

The nation's guardian against false or deceptive advertising, the Federal Trade Commission, has taken issue with the critics, arguing in 1996 and 2002 comments to the FDA that DTC advertising can be valuable for consumers. In 2002, the National Health Council, an organization of health associations (including the American Medical Association) and businesses, issued a consensus statement that concluded that "DTC advertising is an effective tool for educating consumers and patients about health conditions and possible treatments."[4]

Recent changes in federal policy toward prescription drug advertising have intensified the debate. In 1997, the Food and Drug Administration (FDA) sharply reduced restrictions on drug advertising originally imposed in 1985. The original DTC advertising regulations required print ads to include a detailed "brief summary" of risk and other information and required broadcast ads to include a "major statement" of risks, while also making "adequate provision" for viewers to obtain full FDA-approved prescribing information. Although it was not feasible for broadcast ads to meet these requirements, the FDA allowed ads of two kinds. The first could discuss an illness or condition, suggesting that consumers see a physician for treatment without mentioning a brand. The second could emphasize a pharmaceutical brand without stating what condition the drug could treat.

For some years, FDA staff and others had expressed dissatisfaction with the disclosure requirements, partly because their research had strongly suggested that the requirements were of little benefit to patients.[5] The FDA had also accelerated the pace of switching prescription drugs to over-the-counter (OTC) status, recognizing the greater role that consumers were taking in

[2] Matthew F. Hollan, Direct-to-Consumer Marketing of Prescription Drugs: Creating Consumer Demand, 281 JAMA 382 (1999).

[3] Karen Pallarito, States Target Direct-to-Consumer Drug Ads, Reuters Health, June 28, 2001.

[4] National Health Council, Direct-to-Consumer Prescription Drug Advertising (January 2002) (http://www.nationalhealthcouncil.org/advocacy/dtc.htm, accessed September 29, 2002); and National Health Council, Direct-to-Consumer Prescription Drug Advertising: Overview and Recommendations (January 2002) (http://www.nationalhealthcouncil.org/advocacy/DTC_paper.pdf, accessed June 30, 2002).

[5] Louis A. Morris & Lloyd G. Millstein, Drug Advertising to Consumers: Effects of Formats for Magazine and Television Advertisements, 39 Food Drug & Cosmetic L. J. 497 (1984).

their health care decisions.[6] In August 1997, 6 months after the departure of FDA Commissioner David Kessler, an opponent of DTC advertising, the FDA greatly eased the burden for broadcast ads, allowing them to achieve "adequate balance" by including a concise summary of risks and related information (often via voiceover), specifying sources for more complete information (for example, a toll-free number, an Internet Web site address, and either concurrent print ads or specified locations such as pharmacies), and stating that information is available from all physicians and pharmacists.[7] According to studies by Wayne Pines and Chris Adams, DTC advertising, especially on television, accelerated rapidly from $579 million in 1996 to $2.6 billion in 2000.[8]

The FDA's 1997 action that eased limits on the most powerful form of consumer advertising might be expected to increase the effect of DTC advertising (and more generally promotion) on prescription drug demand, all else equal. We investigate this fundamental hypothesis as a step toward assessing the welfare effects of DTC advertising. We use market data to assess the effect of industry promotional activity, including DTC advertising, on the demand for an important class of drugs, the so-called statin drugs for reducing serum cholesterol. Surprisingly, we are unable to find any evidence that advertising has affected demand in the short run. Consumer behavior in this market appears to be influenced primarily by patients' interactions with their doctors, the sequence of visits that must be made before a prescription is filled, and the growing dissemination of objective evidence that prescription drugs are effective in reducing cholesterol and preventing heart attacks. We do provide preliminary evidence that advertising reinforces these factors, while strengthening patient compliance with statin drug therapy. It is also possible that advertising may affect demand in the long run, but we have not been able to capture that phenomenon.

II. The Statin Class of Cholesterol-Reducing Drugs

Epidemiological evidence, such as data from the Framingham Heart Study, led researchers in the 1950s to hypothesize that higher levels of serum cholesterol increased the risk of coronary heart disease. Influential segments of the public health community, including the U.S. Department of Agriculture and some agencies of the U.S. Department of Health and Human Services,

[6] Food and Drug Administration, Center for Drug Evaluation and Research: From Test Tube to Patient: Improving Health through Human Drugs (1999).

[7] In August 1999, the FDA issued a final guidance for DTC advertising (Food and Drug Administration, Center for Drug Evaluation and Research, Guidance for Industry: Consumer-Directed Broadcast Advertisements (August 1999), 64 Fed. Reg. 43197 (1999), leaving requirements essentially unchanged from the August 1997 version.

[8] Wayne Pines, A History and Perspective on Direct-to-Consumer Promotion, 54 Food & Drug L. J. 495 (1999); and Chris Adams, FDA Plans to Review Policy Allowing Direct-to-Consumer Drug Ads for TV, Wall St. J., March 28, 2001, at B1.

reached a consensus during the 1970s that reducing cholesterol, primarily through dietary changes, could substantially reduce the risk of heart disease. This limited consensus formed the basis for a number of federal policies, culminating in the 1985 National Cholesterol Education Program that urged physicians to counsel their patients to reduce dietary cholesterol or use cholesterol-reducing drugs to reduce the risk of heart disease.[9]

As with many public health claims, the hypothesized link between cholesterol and heart disease had its detractors. Many observers such as Gary Taubes noted the lack of evidence from controlled clinical trials that dietary changes could substantially affect serum cholesterol or that changes in serum cholesterol would change the risk of heart attacks or death from coronary heart disease.[10] And although several drugs were available by the 1970s to reduce serum cholesterol, all had serious side effects, and none had an established ability to reduce the risk of heart disease.[11]

With the introduction of Mevacor in 1987, a new statin class of cholesterol drugs that were largely free of serious side-effects transformed the treatment of high cholesterol.[12] Competing brands began to appear in 1991. By 1997, five manufacturers were producing six brands of statin drugs. Substantial clinical testing, required of all new drugs to win FDA approval but often continued thereafter, has found that statin drugs typically reduce the incidence of fatal and nonfatal heart attacks by 20–30 percent.[13] Research continues on these drugs, on new statin drugs still under development, and on heart disease and its treatment.

[9] James Cleeman & Claude Lenfant, The National Cholesterol Education Program: Progress and Prospects, 280 JAMA 2099 (1998); and Gary Taubes, The Soft Science of Dietary Fat, 291 Science 2536 (2001).

[10] Taubes, *supra* note 9.

[11] Martijn Katan, Review of D. John Betteridge, ed., Lipids: Current Perspectives, 336 New Eng. J. Med. 1394 (1997).

[12] Technically, the statin drugs are 3-hydroxy-3-methylglutarul coenzyme A (HMG-CoA) reductase inhibitors (*id.*). Cholesterol-reducing drugs are often referred to as lipid-lowering drugs. The most important side-effects are liver abnormalities and muscle disease. Elevated liver enzymes occur in approximately 1–2 percent of patients but return to normal following discontinuation of therapy (Richard S. Safeer & Cynthia L. LaCivita, Choosing Drug Therapy for Patients with Hyperlipidemia, 61 Am. Fam. Physician 3371 (2000)). Myopathy occurs in approximately .01 percent of patients (William C. Roberts, Twenty Questions on Atherosclerosis, 13 Baylor U. Med. Ctr. Proc. 139 (2000)). In August 2001, Baycol (introduced in 1997) was withdrawn because of an abnormal number of deaths from rhabdomyolysis, a rare muscle disease that is sometimes fatal.

[13] Susan D. Ross *et al.,* Clinical Outcomes in Statin Treatment Trials, 159 Archives Internal Med. 11793 (1999). Statin drugs have also been found effective in treating heart attacks (Gergg C. Fonarow *et al.,* Use of Lipid-Lowering Medications at Discharge in Patients with Acute Myocardial Infarction: Data from the National Registry of Myocardial Infarction, 103 Circulation 38 (2001)). In addition, a small but growing body of research has found that cholesterol reduction lowers the risk of strokes (Harvey D. White *et al.,* 2000 Pravastatin Therapy and the Risk of Stroke, 343 New Eng. J. Med. 317 (2000)) and, possibly, the risk of neurological diseases such as Alzheimer's (Susan J. Landers, Beyond Cholesterol: New Uses for Statins, Am. Med. News, June 18, 2001).

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