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WHAT EXPLAINS THE USE OF DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS?*

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Following the clarification of advertising regulation in 1997, direct-to-consumer advertising (DTCA) of prescription drugs has skyrocketed in the U.S., creating a controversy over the role of DTCA. Little is known, however, regarding what affects firms' advertising decisions and which drugs have been advertised to consumers. Using brand-level advertising data, I examine the determinants of DTCA of prescription drugs. I find that drugs that are new, of high quality, and for under-treated diseases are more frequently advertised. Furthermore, advertising outlays decrease with competition. These results complement the demand-side evidence that DTCA has a market-expanding effect but little business-stealing effect.

I. INTRODUCTION

Direct-to-consumer advertising (DTCA) of prescription drugs had been viewed as taboo for a long time. Traditionally, pharmaceutical firms have promoted their prescription drugs through detailing—the face-to-face selling by medical representatives directly to physicians. The clarification of advertising regulations in 1997, however, changed this tradition drastically. Now, firms can use product-specific television commercials—which mention both the name and the use of the drug—to promote their prescription drugs to consumers without fully disclosing the risks of the drugs. As a result, within only five years after the clarification of regulations, prescription drug advertising expenditures skyrocketed from $800 million in 1996 to $2.7 billion in 2001.

The dramatic increase of DTCA has created a new controversy over the role of advertising in the prescription drug market. The main argument in favor of the new policy is that consumers can gain valuable information through DTCA. It is argued, for example, that advertising can inform patients about new medications for diseases that were believed to be

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untreatable by medicines. On the other hand, critics are concerned, for example, that DTCA may affect the choice of treatments by providing information of suspect quality and encourage people to try more expensive drugs though equally effective, but cheaper, drugs may be available. Responding to these concerns, the Food and Drug Administration (FDA) has recently announced that it will review its policy on DTCA.[1]

Despite the surge of DTCA, its potential effects on consumer health, and the intensive policy debates, economics research on DTCA of prescription drugs is scarce. In particular, little is known about what affects pharmaceutical firms' advertising decisions and which drugs have been advertised to consumers. The main objective of this paper is to fill this gap by analyzing the determinants of DTCA. A striking feature of DTCA is that, unlike detailing promotion, it is concentrated on a small number of drugs in some specific therapeutic categories. Using a unique panel data set that contains more than 600 drug-year observations over 1996–1999, I examine when and why firms advertise. To this end, a censored regression model, which takes into account zero advertising expenditure by many firms, and a two-stage model, which allows for a qualitative difference between 'whether to advertise' and 'how much to advertise' are estimated. I make reference to various classes of advertising theories to guide the empirical analysis.

To be sure, the main reason for the lack of research is that DTCA of prescription drugs is only a recent phenomenon. On the demand side, however, a few recent papers have started exploring the effects of DTCA. Rosenthal et al. [2003] examine the effects of DTCA on the sales of six therapeutic classes and find that DTCA has a significant effect on aggregate demand but does not affect market shares within each class. Similarly, Iizuka and Jin [2003] find that DTCA leads to a large increase in outpatient visits, but has no effect on doctors' specific choices among prescription drugs within a therapeutic class. Wosinska [2002] focuses on cholesterol-reducing drugs and finds that DTCA affects the demand for an individual brand positively, but the impact is substantially smaller than that of detailing promotion. All of these papers suggest that DTCA may have a large market-expanding effect but little or no business-stealing effect.

On the supply side, as noted before, little research exists on DTCA of prescription drugs. Previous papers have examined, instead, various aspects of detailing promotion. Leffler [1981] observed a cross-section of 35 therapeutic categories (not individual drugs) and examined the differences in detailing intensity across the categories. He found that empirical results are consistent with both 'informative' and 'persuasive' views of advertising. Hurwitz and Caves [1988] looked at a cross-section of 56 off-patent drugs

[1] *The Wall Street Journal*, 'FDA to Review Policy Allowing Drug Ads on TV,' March 28, 2001.

and analyzed the determinants of detailing intensity. They found that, among other findings, branded products' detailing intensity decreases as the number of generic competitors increases.

Several empirical results are worth noting. First, I find that firms are more likely to advertise newer and higher-quality drugs rather than older and lower quality ones, other things being equal. The latter indicates that DTCA and product quality complement each other in this market. Second, firms advertise more when the number of potential patients, rather than currently treated patients, is large. This complements the demand-side evidence that DTCA has a market-expanding effect but little or no business-stealing effect. This result is also consistent with the claim of proponents that DTCA targets under-diagnosed therapeutic classes and, thus, could be welfare improving. Third, I find that firms advertise less when therapeutic and generic competition gets intense. This suggests that DTCA does not have a strong effect to shift market shares among alternative drugs, which is also consistent with the demand-side finding discussed above. Lastly, I find early entrants are more likely to advertise than late entrants. This suggests that the return from DTCA is higher for early entrants, i.e., 'first mover advantages' in DTCA appear to exist in this market.

The remainder of the paper is organized as follows: Section II briefly reviews regulations and controversies on DTCA. Section III discusses the potential determinants of DTCA. After describing the data and variables in the next section, Section V discusses estimation and identification issues. Section VI presents results, and Section VII discusses alternative explanations. Section VIII concludes the paper.

II. PRESCRIPTION DRUG ADVERTISING: REGULATION AND CONTROVERSY

II(i). *An Overview of Advertising Regulation*

Promoting prescription drugs directly to consumers is a recent phenomenon. Traditionally, prescription drugs have been marketed exclusively to physicians either by detailing promotion, or, to a lesser extent, by advertising in medical journals. Pharmaceutical firms assumed that doctors would never accept a program that bypassed them, and DTCA was conceived as suicidal (Pines [1999]).

In the early 1980s, however, a few firms started advertising their products directly to consumers. The FDA took this seriously and asked the industry for a voluntary prohibition period during which the FDA would study the impact of DTCA on public health. In 1985, the FDA announced that current regulations, the Kefauver-Harris drug amendments of 1962, were sufficient to protect consumers. This meant that, as long as manufacturers provided a 'brief summary' of contraindications, side effects, and effectiveness and maintained 'fair balance' among them, DTCA would be permissible. The

FDA appeared to move in this new direction because, for one reason, it recognized that consumers increasingly wanted to obtain more information about prescription drugs (Pines [1999]).

Not surprisingly, DTCA increased thereafter but was mostly limited to newspapers and magazines because of the 'brief summary' requirement. Providing the 'brief summary' is costly for firms since it commonly occupies a full page or more of magazine space even though firms use very tiny fonts to describe them. The FDA essentially required TV advertising to abide by the same rule, and thus DTCA was prohibitively expensive for TV media. Accordingly, firms did not often use TV commercials to promote prescription drugs.

There were two conditions, however, under which firms could avoid the 'brief summary' in TV advertising. One was the so-called 'help-seeking' ad in which only disease symptoms were mentioned but not the specific name of the drug. The other was when the firm mentioned only the name of the drug without saying what it was for. The use of these types of ads continuously increased during the mid 1990s. The rapid growth of Health Maintenance Organizations (HMOs) and the increase of break-through drugs might have encouraged firms to use this new channel of communication.

It was not until 1997, however, that a breakthrough occurred when the FDA further relaxed its regulation of ethical drug advertising on TV. For the first time, the FDA permitted product-specific DTCA on TV, which mentioned both the drug's name and the condition for which it was to be used, without disclosing the 'brief summary.' Now firms needed only to include 'major statements' of the risks and benefits of the drug, which required substantially less information and airtime. Thus, by reducing the cost of advertising, the policy change contributed to the surge of DTCA after 1997. Pines [1999] explains that the FDA made this change because it recognized that ads that mentioned a drug's name but not its use were non-communicative and even confusing to consumers. Wilikes et al. [2000] also point out that 'the political and regulatory climate was moving toward allowing consumers more choice and empowering them to share in medical decision making.'

An interesting feature of DTCA is that the FDA assumes jurisdiction over it because the FDA views DTCA as a 'label,' a package insert describing the characteristics of the drug. Accordingly, the FDA monitors and enforces information contents of DTCA quite vigorously.[2] In fact, pharmaceutical firms often ask the FDA to review their advertising commercials before they launch an advertising campaign. Because of these interactions, as well as the

[2] The FDA has threatened violating firms with legal actions, including seizure and injunction. Pines [1999] discusses the history of the FDA's enforcement activities in detail.

'major statements' and 'fair balance' requirements, prescription drug advertising is likely to convey credible information on drug attributes.

II(ii). *The Effects of the Relaxation of Advertising Regulation*

Following the FDA clarification in 1997, DTCA of ethical drugs increased dramatically. Within five years of the clarification, DTCA surged from $800 million in 1996 to $2.7 billion in 2001. The surge of DTCA, however, was not observed equally across drugs and therapeutic classes. On the contrary, firms have been very selective in the use of DTCA. In 1999, approximately 41% of total DTCA ($1.8 billion) was spent for the top ten advertised drugs, while their sales share was only 9%.[3] Why do firms sometimes use DTCA to promote their drugs but not always? I will discuss some potential determinants of DTCA in this market in the next section.

Anecdotal evidence shows that DTCA has indeed encouraged potential patients to seek medical help. Based on a national survey conducted in 1998, *Prevention magazine* found that DTCA encouraged a projected 21.2 million consumers to talk with their doctors about a medical condition or illness they had not previously talked with their doctor about before seeing an advertisement. Furthermore, the magazine estimates that 12.1 million people received a prescribed drug as a direct result of seeing a DTC advertisement. A *Time* survey conducted in 1998 also shows that one-fourth of consumers who saw an advertisement on television or in a magazine and spoke with their physicians about it received a prescription.

II(iii). *Controversies*

The tremendous increase in DTCA and prescriptions in recent years has created a major controversy over the effects of such advertising on pharmaceutical demand. In particular, two distinct views exist on the effects of DTCA. Proponents of DTCA argue that the match between patient and drug could be improved if consumers were informed about prescription drugs through direct consumer advertising (Masson and Rubin [1985]). They also argue that direct advertising plays an important role in informing the public of the existence of treatments of diseases, some previously not believed to be treatable by medicines (Masson and Rubin [1985]; Holmer [1999]). It is known that a number of leading diseases, including diabetes, high-cholesterol, and high-blood pressure, are under-diagnosed or under-treated. Thus, they argue, DTCA could help improve the health of people with these conditions. Holmer [1999] further

[3] DTCA figures are from IMS Health's press release, 'IMS Health Reports U.S. Pharmaceutical Promotion Spending Reached Record $13.9 billion in 1999,' on April 20, 2000. Sales figures are also from IMS Health reported in *Pharmacy Times*, 'The Top 200 Drugs of 1999,' http://www.pharmacytimes.com/ top200.html.

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