This is **Exhibit B** referred to in the Affidavit of **Julie Donohue** affirmed before me this 22nd day of May, 2007.

A Commissioner, etc.

THE JOURNAL OF INDUSTRIAL ECONOMICS 0022-1821
Volume LII September 2004 No. 3

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

*I wish to thank Dan Ackerberg, Bill Comanor, Austun Goolsbee, V. Joseph Hotz, Tom Hubbard, Phillip Leslie, Jean-Laurent Rosenthal, the editor and an anonymous referee for helpful comments and suggestions. I am grateful for TNS Media Intelligence/Competitive Media Reporting (CMR) for generously providing the data for this study. Remaining errors are my own.

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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.

hypothesizes that 'DTCA merely motivates patients to learn more about medical conditions and treatment options and to consult their physicians, but once the dialogue is started, the physician's role is preeminent (page 381).' In sum, proponents claim that DTCA provides valuable information to consumers and increases physician visits. They argue that DTCA does not, however, affect the choice of prescription.

On the other hand, opponents of DTCA are concerned that it may affect the choice of prescription and increase the cost of services. Hollon [1999] argues that DTCA may provide information of suspect quality and, 'by creating consumer demand, undermine the protection that is a result of requiring a physician to certify a patient's need for a prescription drug.' Others also argue that DTCA may encourage people to try more expensive drugs although equally effective, but cheaper, drugs may be available (Cohen [1988]). Further, it is often reported that many physicians fear that under-informed patients will demand inappropriate therapies from doctors once they have seen DTCA. That is, opponents argue that DTCA may manipulate the choice of prescription, and this could be harmful for patients and increase medical costs as well. Clearly, the source of the controversy is the role of DTCA in this market.

While the main objective of this paper is to examine the determinants of DTCA and not to distinguish between these two claims, nonetheless, some of the results of the paper might help clarify the validity of these claims. For example, I consider whether DTCA outlays are more responsive to 'current' market size as opposed to 'potential' market size. Also, I examine whether competition with generic drugs would increase brand-name drugs' advertising outlays. If the answers are 'yes' to these questions, the results are less likely to support the proponents' claim since the 'informative' role of advertising is secondary in this situation. Now, I turn to the analytical framework to examine the determinants of DTCA.

III. DETERMINANTS OF DTCA OF PRESCRIPTION DRUGS

DTCA in the prescription drug market is unique in that the use of advertising is concentrated on a small number of products. This section discusses various classes of advertising theories that may help explain why and when firms use DTCA to promote their prescription drugs.

III(i). *Competition and DTCA*

Brand Competition: Economists have long debated the effects of competition on advertising (and vice versa).[4] Earlier literature on this issue often

[4] A large number of earlier papers examined inter-industry relationship between profitability (or concentration) and advertising intensity (e.g. Telser [1964]; Schmalensee, [1972]; Comanor and Wilson, [1974]).

found that advertising decreases as competition gets intense. For example, in their classic paper, Dorfman and Steiner [1954] showed that a monopolist's advertising intensity decreases as demand elasticity increases, other things being equal. Based on this result, it is often argued that advertising intensity should decrease with competition, since demand is more elastic in competitive markets.[5] More recently, Grossman and Shapiro [1984] examined the effects of competition on advertising in the case of differentiated product oligopoly. They show that in the case of 'informative' advertising – which informs consumers about the existence and characteristics of the product – firms reduce their advertising when there are more close substitutes in the market. This happens because, as the number of close substitute increases, consumers are likely to receive an ad from a firm located close to the consumer, whose product provides a better match between the product and patient. This in turn reduces firms' incentive to advertise.[6] Moreover, if DTCA has a market-expanding effect but not a business-stealing effect as the demand-side papers suggest, then advertising should decrease with competition since competitors may be able to free ride on rival firms' advertising.

Others argue, however, that firms increase advertising when competition becomes intense. Becker and Murphy [1993] argue that, as close substitutes increase, firms may try to differentiate themselves by using advertising, and this will lead to higher advertising expenditures. For example, they discuss that 'Perdue chicken' (and other products in a competitive market) is extensively advertised because 'Perdue ads convince consumers that a pound of its chicken is worth more than a pound of other chickens.' (pp. 954–55). Cabral [2000] also notes that as the number of competitors increases, each firm's incentive to engage in business-stealing advertising may increase. This may be the case because the return from such advertising may increase as the residual demand increases. In summary, DTCA of prescription drugs could either increase or decrease as competition gets intense: which effect dominates the other is an empirical question.

[5] Becker and Murphy [1993], however, revisit the Dorfman and Steiner model and show that the earlier discussion was sensitive to the assumption, and incentive to advertise may indeed either increase or decrease with competition.

[6] Grossman and Shapiro [1984] assume that consumer has no alternative sources of information, and is unaware of the existence of a particular brand unless she sees an advertisement describing it. In addition, consumers are assumed to remember all advertising messages transmitted to them. Under these assumptions, they show informative advertising decreases with competition. I believe these assumptions are not unreasonable in the case of prescription drugs, especially for newly discovered drugs, because it is costly for consumers to obtain information on prescription drugs. However, if we relax these assumptions, above-mentioned results may not hold. For example, if patients do not know or remember the characteristics of the drug, a monopolist may wish to (re)inform the patients about the drug's characteristics once a rival drug enters the market. In this case, informative advertising may increase with competition.

Generic Entry: It is well known that generic entry has a major impact on the market share of brand-name drugs. Typically, within a few months after patent expiration, generic entry takes place, and firms sell their generic drugs as low as 80% below the branded drug's former list price (S&P [1999]). While the price response to generic entry of branded products has been a source of controversy,[7] market share of branded drugs typically drops substantially due to drastic demand shift to generics.[8] As a result, revenue of branded drugs often drops sharply after patent expiration.

To protect their profits, incumbents may increase DTCA to differentiate the brand-name drug from generics. Again, the motivation is very similar to the 'Perdue chicken' example discussed above and thus requires no further explanation. Note, however, that advertising is likely to be wasteful in this case since generics are mostly identical to the branded drug in terms of pharmacological benefits to patients. Unlike the case of competition among brands discussed above, advertising cannot improve the matching between products and patients here.

On the other hand, firms may reduce DTCA upon generic entry due to externality of advertising. In particular, many states in the U.S. have adopted mandatory substitution laws that require pharmacists to dispense generics if they are available unless doctors say otherwise.[9] This means that even when patients request a branded drug that they saw on television and a physician actually prescribes it, the brand-name drug may not be dispensed at a pharmacy if equivalent generic drugs are available. Since the return from advertising may be lower under this situation, firms may reduce advertising expenditure upon generic entry.

III(ii). *Market-Expanding vs. Business-Stealing*

Next, I examine whether DTCA is used to expand the size of the market or shift market shares among existing brands. Advertising is viewed as market expanding when it purely increases the total size of the market. In contrast, it is referred to as business stealing when it solely shifts market share among existing brands. This distinction has long been recognized in advertising literature. Friedman [1983], for example, described the two types of advertising as 'cooperative' and 'predatory,' respectively. Roberts and Samuelson [1988] empirically examined the nature of cigarette advertising and found that it had primarily a market-expanding effect rather than a business-

[7] See Caves, Whinston, and Hurwitz [1991], Grabowski and Vernon [1992], Frank and Salkever [1997], and Wiggins and Maness [forthcoming] for the debate.

[8] For example, during the first week of patent expiration of Prozac, a blockbuster antidepressant drug selling $2.6 billion in 2000, eighty percent of U.S. patients switched to a generic equivalent (*The Financial Times*, 'Majority of Prozac-Users Switch to Generics,' August 21, 2001)

[9] See Hellerstein [1998] for more about the mandatory substitution law and its effects.

stealing effect. In contrast, Gasmi et al. [1992] found that advertising in the carbonated soft-drink industry is primarily characterized as business stealing. Typically, advertising has been viewed as welfare reducing unless it increases total market demand.[10]

These distinctions are also important in the current context. As discussed in Section II, one of the main arguments in favor of DTCA was that DTCA encourages patients to visit physicians' offices and seek medical help. Because many chronic diseases, such as high cholesterol and diabetes, are seriously under-diagnosed and under-treated, they argue, DTCA could potentially improve welfare by informing future patients of the existence of treatments. In other words, proponents argue that DTCA has primarily a market-expanding effect rather than a business-stealing effect. Empirically, I distinguish the two effects by examining whether DTCA is targeted to currently treated or untreated patients. Naturally, market-expanding advertising should be sensitive to the number of currently untreated patients, while business-stealing advertising should respond to the number of currently treated patients.

III(iii). *Drug Quality and DTCA*

Another issue of interest is the relationship between product quality and DTCA. Specifically, I ask whether firms spend more advertising dollars for high-quality drugs or low-quality ones. Traditionally, economists have discussed whether product quality and advertising are complements or substitutes. The most often cited theory that connects advertising to product quality is Nelson's [1974] theory of advertising as a signal of quality. He argues that the mere fact that firms spend a lot of money in advertising reveals its high quality even when ads do not contain any explicit quality information. This is possible because, for experience goods whose quality can be judged only after consumption, high-quality products are more likely to attract repeat purchases. The return from advertising that induces initial purchases is higher for high-quality products, and thus high-quality firms will spend more on advertising. Milgrom and Roberts [1986] formalized Nelson's idea by allowing both price and dissipative advertising to be used as signals of quality. They show that a separating equilibrium exists in which only high-quality firms advertise, as long as the marginal cost advantage of low-quality firms is not substantially large.[11] If otherwise, price alone can signal quality and advertising will not be used as a signal.

There are other situations, however, in which firms may advertise more when the drug is of high quality. In particular, if advertising can *directly*

[10] See Becker and Murphy [1993] (pp. 959–60) for more discussions.

[11] While I do not observe marginal costs in my data, marginal costs are typically small in the case of prescription drugs and may not increase substantially even for high-quality drugs.

inform the quality of the product to consumers and marginal costs of high-quality products are not substantially higher than that of low-quality products, then marginal return from advertising may be higher for high-quality drugs. This would also encourage high quality producers to advertise more. In fact, this is also a plausible scenario in the current case since, as discussed before, prescription drug advertising is likely to convey credible quality information. Also, marginal costs are generally small and are not likely to increase substantially even for high quality drugs. Thus, at least two views predict that high-quality drugs will advertise more.

III(iv). *Order of Entry*

Next, I examine whether order of entry in each market affects the use of DTCA. This is certainly possible if the marginal return of DTCA is different depending on the timing of entry. One can easily think of a case in which early entrants advertise more than late entrants. For example, because the cost of learning is high for physicians, physicians might form a 'habit' and keep prescribing the same drugs, most likely pioneer drugs. In fact, such persistence of doctors' prescription behavior has been shown in recent literature including Hellerstein [1998], Stern and Trajtenberg [1998], and Coscelli [2000]. Under this circumstance, return from advertising may be higher for early entrants, and this would make them advertise more than late entrants.

Whether there is an asymmetry in the effectiveness of marketing instruments is a recent research agenda in marketing literature. Bowman and Gatignon [1996], for example, examined whether order of entry affects the effectiveness of advertising. Their results from two durables and three nondurables, however, did not support an asymmetric effect of advertising. In contrast, Shankar et al. [1998] showed that, using data from 13 pharmaceutical brands in the 1970s and 1980s, noninnovative late entrants have less effective marketing spending compared to pioneers.

It should be noted that if the order of entry does indeed affect the extent of advertising, then DTCA might affect market structure and firms' R&D decisions in the long run. In particular, if early entrants enjoy the benefits of DTCA more than late entrants do, then returns for a pioneer would increase while the incentives to develop 'me-too' drugs would decrease. Thus, the race to become a pioneer may become intense and only a smaller number of firms may be able to exist in each market. DTCA may lead to a more concentrated market structure.

III(v). *Drug Age and DTCA*

Finally, I examine whether the use of DTCA varies depending on the age of the drug. Various advertising models predict different time paths. For

example, if the role of advertising were to inform consumers about the existence of products as in Grossman and Shapiro [1984], then newer drugs would be advertised more often than older drugs. Over time, as people learn about the drug through advertisement, the informative role of advertising becomes less important, and thus DTCA may decrease as the drug gets older, other things equal. Nelson's signaling model (e.g., Milgrom and Roberts [1986])—which assumes perfect learning—predicts the same time path because the return from signaling quality will diminish over time as the number of experienced consumers increases. Horstmann and MacDonald [1994], however, show that the conclusion may be reversed, i.e., advertising expenditures increase over time, if the learning of consumers is imperfect. In a separate paper (Horstmann and MacDonald [2003]), they examine compact disc players and show that advertising expenditures increase over time in this market.

IV. DATA AND VARIABLES

The data set was compiled from several sources, as described below. I have a total of 606 drug-year observations for 169 unique brand-name drugs over the period 1996–1999. These drugs belong to one of the following broad categories: central nervous system agents, respiratory agents, and renal and genitourinary agents.[12] *Drug Facts and Comparisons*, a standard medical reference, was consulted to discover drugs that belong to each of these categories. Drugs approved before 1982 were excluded from the estimation because of the lack of comparable information. However, I included these drugs when counting the number of competing drugs in each therapeutic class (see below). Definitions of variables and data sources are summarized in Table I.

DTCA Expenditure for each brand-name drug was obtained from TNS Media Intelligence/Competitive Media Reporting (CMR). CMR monitors advertising units and expenditures for several different media, including cable TV, network TV, newspapers and magazines. All ads for prescription drugs that appeared in these media are included in the CMR database. In the estimation, I use annual total DTCA expenditure as the dependent variable.

Age of Drug was calculated as the year since FDA approval. The date of FDA approval was obtained from the FDA's *Orange Book*. While the FDA approval date may not be exactly the same as the product launch date, the difference is usually not very large. Thus, I use the FDA approval date to calculate the age of the drug.

[12] I limit my samples to these categories largely due to the high cost of constructing the data set. While the estimation results may or may not extend to the remaining categories, these categories represent roughly 46% of industry sales in 1996 (S&P [1999]).

TABLE I
DEFINITION OF THE VARIABLES AND DATA SOURCE

Variable	Definition	Source
DTC ads	Annual, total DTCA dollars ($1000)	CMR
HIGH_Q	Dummy = 1 if the drug provides the highest quality in the therapeutic class	*Orange Book* FDA
1st Move	Dummy = 1 if the drug is the first drug approved in the therapeutic class and 0 if otherwise	FDA
2nd Move	Dummy = 1 if the drug is the second drug approved in the therapeutic class and 0 if otherwise	FDA
AGE	Years from FDA approval	*Orange Book*
G_ENTRY	Dummy = 1 if generic alternative exists and 0 if otherwise	*Drug Facts and Comparisons*
THRP_COMP	Number of brand-name drugs in the same therapeutic class	*Drug Facts and Comparisons*
PTNT_SIZE	Estimated number of potential patients treatable by the drug	NHIS, Medical journals
CRNT_SIZE	Estimated number of current patient office visits treatable by the drug	NAMCS
ACUTE	Dummy = 1 if used for acute treatments and 0 if otherwise	*Drug Facts and Comparisons*
INJECT	Dummy = 1 if injectable drug and 0 if otherwise	*Drug Facts and Comparisons*
D_SIZE	Dummy = 1 if market size information is available and 0 if otherwise	NHIS, NAMCS
D_RESP	Dummy = 1 if Respiratory drug and 0 if otherwise	*Drug Facts and Comparisons*
D_CNS	Dummy = 1 if Central Nervous System agents and 0 if otherwise	*Drug Facts and Comparisons*

Drug Quality. I use the FDA's rating of new drugs as a quality measure. Until 1991, the FDA assigned three types of quality ratings for new drugs, depending on their potential therapeutic gains. The 'A' or 'B' code represents a drug offering significant (or moderate) therapeutic gains compared to existing drugs. The 'C' code was given to a drug offering little or no therapeutic gains. These therapeutic potential codes were replaced by 'priority' and 'standard' reviews in 1992. 'Priority' review is now given to a drug with significant improvement compared to marketed products and replaced previous 'A' and 'B' codes. The 'Standard' review is given to a drug substantially equivalent to marketed products and replaced the former 'C' code (FDA [1992]).

One potential problem in using the FDA's quality rating is that the timing of approval reflects the quality rating. That is, if there are two equivalent, innovative drugs on the market, then the one approved early may get 'P' but the second one gets 'S.' Thus, if we take the FDA code at face value, then a 'me-too' drug, which may still be a high-quality drug, will not be coded as a high-quality drug.

To avoid this misclassification, I carefully examined the order of entry and the FDA ratings of all drugs in each therapeutic class. In particular, I define as 'high quality' any drug that provides the highest quality (equivalent to 'A,'

'B,' or 'P' code) in each therapeutic class whether it is a pioneer or a 'me-too' drug. To do so, I assumed the drugs with 'C' or 'S' ratings after a breakthrough drug ('A,' 'B,' or 'P') are equivalent to the breakthrough drug in each therapeutic class.[13] In addition, since many old therapeutic classes have not seen any innovation for a long time, therapeutic classes with no therapeutic advances since 1982 are also treated as 'C' or 'S.'[14] The FDA ratings are available from FDA [1991] and from its website. A dummy variable (*HIGH_Q*) equals 1 if the drug is 'high quality' and 0 if otherwise.

While this quality measure may provide important information, criticisms exist on the use of the FDA rating as a quality index. For example, critics point out that these ratings are given at the end of the approval process and before the drug is used in practice, and thus may not reflect the true quality of the drug. Wardell et al. [1980] also show that the FDA ratings do not necessarily coincide with the ratings given by panels of experts who examined the same drugs (see Lu and Comanor [1998] for more discussions). Regardless of the criticisms, the FDA rating is probably the only comprehensive quality measure produced by a third party and available for the public. Moreover, it is attractive in the sense that the quality index is not subject to the success of the drug, and thus may be treated as exogenous. Thus, the FDA classification appears to provide reasonable information on drug quality, though it may not be a perfect system.

Potential Market Size was constructed from the *1995 National Health Interview Survey (NHIS)* and other resources. *NHIS's Series 10 Report* provides prevalence rates for selected chronic conditions based on household interviews conducted every year. This provides an estimate of the number of potential patients, including both currently treated and untreated. If the number of potential patients is not available from NHIS, then medical journals and news sources were searched using *Lexis-Nexis Academic Universe*. Once the number of potential patients was established, then these numbers were matched with each drug by looking at the primary indications of the drug.

In some cases, it is difficult to identify the potential (and current) market size for each drug. This was especially so if the drugs were used for general purposes, thus making it difficult to identify their primary disease categories. Examples of such drugs include cough suppressants, diuretics, and painkillers. Instead of dropping these observations, a dummy variable (*D_SIZE*) was created, and market size variables were interacted with the

[13] Of course, this is a simplification. However, I have looked at several therapeutic classes and, in practice, this assumption works well. Firms tend to produce derivatives of a pioneer drug, i.e., 'me-too' drugs, following the entry of the pioneer drug.

[14] This was done for two reasons. First, this prevents old drugs that saw no improvements to be categorized as 'high-quality.' Second, I do not have information on approval dates and FDA ratings for drugs approved before 1982. This makes it difficult to code quality information for the therapeutic classes where no therapeutic advances occurred after 1982.

dummy. *D_SIZE* equals 1 if estimates for both potential and current market sizes are available and 0 if otherwise.

Current Market Size for each drug was constructed from the National Ambulatory Medical Care Survey (NAMCS) micro data set for 1995–1998.[15] It provides data on a national sample of patients' office visits to office-based physicians.[16] After consulting the *International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM)*, the number of patient visits for specific disease categories was computed from the micro data based on the occurrence of the visits in the sample and its probability. Since NAMCS data do not cover patients' hospital visits, I assume that the market size computed is proportional to the actual current market size. To avoid the endogeneity problem, current market size is lagged by one year in the estimation.

Therapeutic & Generic Competition. In order to discuss the effects of competition, a relevant market has to be defined. After consulting the classification in *Drug Facts and Comparisons*, I define therapeutic class as the drugs that share similar mechanisms of actions and/or have similar chemical structures. These drugs are likely to be the closest substitutes and competitors due to their similarities. For example, the antidepressant agents Prozac and Paxil share similar chemical compounds and belong to the same therapeutic class, Selective Serotonin Reuptake Inhibitors (SSRI). Eighty therapeutic classes are included in the data set. A variable *THRP_COMP* represents the number of brand-name competitors in each therapeutic class including drugs approved before 1982. For generic competition, *Drug Facts and Comparisons* was consulted to find out whether brand-name drugs have generic alternatives on the market. A dummy variable *G_ENTRY* equals 1 if generics exist and 0 if otherwise.

Category Fixed Effects. In some models, in addition to the variables discussed above, I include category-fixed effects based on the ICD categories already discussed to control for some unobserved drug attributes that may be correlated with the variables of interest. The ICD categories are slightly larger groupings than therapeutic classes. For example, while ACE inhibitors and Calcium Channel Blockers may be treated as different therapeutic classes, they are under the same ICD category, 'hypertension.' More detailed category-fixed effects, such as therapeutic fixed effects, are difficult to include since these categories tend to 'perfectly explain' the zero advertising expenditure in the Probit specification, and I lose a number of observations. While it may not be perfect, I expect that the ICD fixed effects capture some important unobserved attributes, such as demand shocks, that

[15] The data are publicly available from The National Center for Health Statistics (NCHS).

[16] For example, in 1998, it contains the data on 23,339 patient visits to the 1,226 physicians who participated in NAMCS.

may be correlated with the variables of our interest. Twenty-five ICD fixed effects are included in the estimation.

V. EMPIRICAL SPECIFICATIONS

V(i). *Censored Regression Model*

In the first specification, I use a censored regression model to explain DTCA expenditures as a function of product and market characteristics[17]:

$$(1) \qquad y_{it}^{*} = x_{it}\beta + \varepsilon_{it}$$

$$(2) \qquad y_{it} = \max\{y_{it}^{*}, 0\}$$

where y_{it}^{*} is a latent variable and not observable. Instead, we observe y_{it}, DTCA expenditure of product i at time t. x_{it} is product and market characteristics discussed in the previous sections, and ε_{it} is the error term. If we assume that the error terms are normal and independent of regressors, this yields the familiar Tobit model.

V(ii). *Two-Stage Model*

In the second specification, I estimate a firm's decision to advertise in a two-stage model. Here, a firm's participation decision, i.e. whether to advertise or not, is analyzed in the first stage. In the second stage, the level of advertising conditional on participation is examined. Amemiya [1985] calls this type of sample selection model as Type II Tobit model. Formally, the model is

[17] I use advertising expenditure as the dependent variable (instead of advertising-to-sales ratio) partly because I do not have sales data for all drugs in the sample. However, it is also reasonable to use advertising expenditure in the current context. First, theories on 'advertising as a signal of quality' (e.g. Milgrom and Roberts [1986]) analyze the relationship between advertising level (instead of advertising-to-sales ratio) and product quality. It is the level of advertising, not the advertising-to-sales ratio, which provides information to consumers. Accordingly, empirical papers often look at the level of advertising (e.g., Horstmann and MacDonald [2003]) or the rank correlation between product quality and advertising level (e.g., Caves and Greene [1996]). Similarly, in the models of informative advertising such as Grossman and Shapiro [1984], advertising-to-sales ratio does not appear in their equilibrium condition. Moreover, even if the Dorfman-Steiner condition is the right model, omitting the sales variable would not lead to a false positive conclusion on the effect of competition on advertising. To see this, first, move the sales variable to the right-hand side along with the competition variables. If we estimate a linear model with advertising levels on the left-hand side, then the coefficient for sales is likely to be positive since larger markets tend to attract more advertising. Now, if we omit the sales variable on the right hand side, then it would positively bias the coefficient for the competition variables since the market size and the extent of competition are likely to be positively correlated. Fortunately, as shown in the estimation results in Section VI, estimated coefficients for the competition variables are negative and significant, although these coefficients may be potentially biased positively. Therefore omitting the sales variable is less likely to affect the qualitative result of the paper regarding competition and advertising.

defined as follows:

$$(3) \qquad y_{1it}^{*} = x_{it}\beta_1 + \varepsilon_{1it}$$

$$(4) \qquad y_{2it}^{*} = x_{it}\beta_2 + \varepsilon_{2it}$$

where y_{1it}^{*} and y_{2it}^{*} are latent variables and not observable, β_1 (and β_2) a vector of first (and second) stage estimates, respectively. $(\varepsilon_{1it}, \varepsilon_{2it})$ are i.i.d. drawings from a bivariate normal distribution with mean zero, variances ${\sigma_1}^2$ and ${\sigma_2}^2$ and covariance σ_{12}. We observe y_{1it} and y_{2it} defined as:

$$(5) \qquad y_{1it} = 1\{y_{1it}^{*} > 0\}$$

$$(6) \qquad y_{2it} = y_{2it}^{*} \text{ if } y_{1it} = 1$$

$$(7) \qquad y_{2it} = 0 \text{ if } y_{1it} = 0$$

Here, it is assumed that in the first stage only the sign of y_{1it}^{*} is observed. In the second stage, y_{2it}^{*} is observed only if $y_{1it}^{*} > 0$. The first stage model can be estimated using the Probit model. To estimate the second stage, we need to consider the 'sample selection' bias. The expectation of the error term in the second stage is given by:

$$(8) \qquad E(\varepsilon_{2it}|x_{it}, y_{1it} = 1) = E(\varepsilon_{2it}|\varepsilon_{1it} > -x_{it}{\beta_1}') = \sigma_{12}/\sigma_1 \cdot \lambda(-x_{it}{\beta_1}'/\sigma_1)$$

where $\lambda(\cdot)$ indicates the inverse of Mill's ratio (IMR) and β_1' is the maximum likelihood Probit estimate of β_1. We can get consistent estimates in the second stage by including the IMR as a regressor and using only the observations with $y_{1it} = 1$.

The two-stage model may be useful compared to the censored regression model for at least two reasons. First, the Probit model can be used to check the robustness of the results from the censored regression model. Because DTCA is concentrated on a small number of drugs, it is possible that some outliers may be driving the estimation results of the Tobit model. I can check the robustness of the estimation results by using the Probit model, which only concerns a qualitative choice. Second, the two-stage model is flexible compared to the single equation specification. In particular, the two-stage model allows the participation decision (i.e. whether or not advertise) to be qualitatively different from how much to advertise. This may provide useful insights into the nature of advertising decisions in this market.

V(iii). *Instrumental Variable*

As noted before, some of the explanatory variables included in the analysis, such as product quality and potential market size, may be assumed as

exogenous or predetermined. However, such an assumption may not hold for other variables, particularly market structure variables such as the number of brand-name drugs. For example, DTCA may affect the number of competitors by increasing the sunk cost of entry. For this concern, first, I test whether the number of brand names is endogenous. Smith and Blundell [1986] and Rivers and Vuong [1988] provide exogenity tests for Tobit and Probit models, respectively.[18] The test result shows that the number of brand names is indeed endogenous.[19]

In order to instrument for the number of brand-name drugs, I created a variable 'time since entry of the first drug in the therapeutic class.' This variable is likely to be correlated with the number of brand names within each class since the number of 'me-too' drugs increases over time after the entry of a breakthrough drug. Since the problems caused by weak instruments have been widely discussed in the recent literature (e.g., Bound et al. [1995] and Staiger and Stock [1997]), I examined the validity of the instrument. First, the F-statistic of the excluded instrument in the first stage is 166, which is substantially higher than the minimum F-statistics standard of 10 proposed by Stainger and Stock [1997]. The partial R-squared associated with the excluded instrument is 0.15, which suggests the correlation is not weak. Thus, these test statistics indicate that the instrument is promising. Using this instrument, instrumental variables Tobit and Probit models were estimated based on Newey [1987].

A similar concern exists for the entry of generics. Specifically, generic entry may also be endogenous since incumbents may try to deter generic entry by changing the level of DTCA.[20] One potential remedy is to instrument for generic entry by creating a variable such as 'time from patent expiry.' Unfortunately, it turns out to be difficult to find out patent expiry dates for all drugs in the data set. As an alternative, I looked at the relationship between DTCA and generic entry by dropping observations whose patent expired after 1997.[21] Interestingly, after dropping those drugs, there were no brand names using DTCA when generics are on the market. Since the market structure may be viewed as predetermined for the remaining drugs, this provides some evidence that

[18] They propose the following procedure: (1) run an OLS regression of number of brand names on exogenous variables, including excluded instruments, and save the residuals, (2) estimate the Tobit (or Probit) model with all right-hand side variables, including the residuals saved in the first step. They show that if the coefficient for the residuals is significantly different from zero, this provides the evidence for the endogeneity problem.

[19] The coefficient for the residuals is significant at the one-percent confidence level.

[20] See Ellison and Ellison [2000] for how pharmaceutical incumbents change detailing promotion to deter entry prior to patent expiration.

[21] Most of the generic entry took place before 1997 in my sample, and only a handful of brand-name drugs went off patent thereafter.

TABLE II
SUMMARY STATISTICS

Variable	Mean	Std. Dev.	Min.	Max.	Obs.	w/ DTC Ads (n = 92)	w/o DTC Ads (n = 514)	Mean Diff.
(Dep. Var.)								
DTC ads ($1000)	3,496	13,391	0	170,651	606	23,023	–	***
(Product Chars.)								
AGE	7.15	5.19	0.02	18	606	4.15	7.69	***
HIGH_Q	0.42	0.49	0	1	606	0.55	0.39	***
HIGH_Q*1st Move	0.21	0.41	0	1	606	0.33	0.19	***
HIGH_Q*2nd Move	0.06	0.24	0	1	606	0.10	0.06	
ACUTE	0.24	0.43	0	1	606	0.05	0.28	***
INJECT	0.18	0.38	0	1	606	0.03	0.20	***
D_RESP	0.14	0.34	0	1	606	0.10	0.14	
D_CNS	0.60	0.49	0	1	606	0.49	0.62	**
(Mkt. Size)								
D_SIZE	0.69	0.46	0	1	606	0.95	0.64	***
D_SIZE*CRNT	4.08	4.98	0	14	606	5.86	3.76	***
D_SIZE*PTNT	11.05	12.14	0	60	606	20.88	9.29	***
(Competition)								
G_ENTRY	0.23	0.42	0	1	606	0.01	0.27	***
THRP_COMP	6.51	5.47	1	19	606	4.11	6.94	***
(Time Trend)								
Y97	0.25	0.43	0	1	606	0.27	0.24	
Y98	0.26	0.44	0	1	606	0.25	0.26	
Y99	0.27	0.44	0	1	606	0.28	0.27	

*Significant at 10%; **Significant at 5%; ***Significant at 1%

firms are less likely to use DTCA when generic alternatives are available on the market.

VI. RESULTS

VI (i). *First Look at the Data*

Table II presents summary statistics. The first five columns show the summary statistics for all observations. The next two columns split the sample into two groups, i.e. with and without DTCA, and show the mean of each variable for each group. The last column tests whether the mean differences are statistically significant. DTCA was observed in 92 cases out of the 606 observations.

The last three columns in the table indicate that the drugs with DTC ads are systematically different from non-advertised drugs. In particular, advertised drugs are younger than non-advertised drugs (see *AGE*) and advertised drugs exhibit higher quality compared to non-advertised ones (see *HIGH_Q*). These differences are statistically significant at the one percent confidence level. In addition, drugs for acute treatments (*ACUTE*) and injectable drugs (*INJECT*) are less likely to be advertised. The degree of competition also differs between the two groups of drugs. First, it is clear that, almost always, advertised drugs do not have generic competitors (see *G_ENTRY*). Second, similarly, advertised drugs face less competition

(*THRP_COMP*) than those not advertised. These differences are also statistically significant at the one-percent level. Finally, both current and potential market sizes (*CRNT_SIZE* and *PTNT_SIZE*, respectively) are larger for advertised drugs compared to non-advertised drugs. In addition, market size information (*D_SIZE*) is more often available for advertised products.

The Appendix lists all therapeutic categories used in the analysis, including the number of competing drugs in each class, the number of drugs advertised in each class, along with the corresponding ICD categories. The Appendix also supports the above discussion: those drugs that face many competitors appear to use DTCA less frequently. Moreover, in a therapeutic class with many competitors, only a few drugs use DTCA. These facts appear to indicate that competition tends negatively to affect the use of DTCA.

VI(ii). *Censored Regression Model*

Table III shows the results for the censored regression model. The first model estimates the standard Tobit model. The ICD category-fixed effects are added in Model 2. The next two models repeat the same by instrumenting for the number of brand names (*THRP_COMP*). Since estimation results change little across models, I mainly discuss the results from the standard Tobit model and only touch upon the differences across models when appropriate. Relatively small differences in the results between the models with and without the category effects suggest that, after controlling for the explanatory variables in Model 1, few unobserved product attributes remain in the error term that are common to the category and correlated with the explanatory variables.

Drug Quality, Order of Entry, Age of Drug. Let us look at the first group of independent variables, including product quality, order of entry, and age of the drug. The coefficient for *HIGH_Q* is positive and significant in all models, indicating that drugs with high therapeutic potential are more intensively advertised than low quality drugs. This implies that DTCA is complimentary to the quality of the drug. Previous surveys on DTCA showed that patients who saw DTCA frequently mention the name of the drug, request it from their physicians, and often get what they asked for (see, for example, *Prevention* [1998]). Estimation results suggest that, even if patients do not understand or examine the quality of information in DTCA, *on average*, they are more likely to be exposed to the advertisement of high quality drugs.

In the next two rows, I examine whether a firm's decision to use DTCA varies depending on the order of entry among high-quality drugs. The coefficient for the first mover interacted with high-quality dummy (*HIGH_Q*1ST*) is significantly positive in all models, suggesting that

TABLE III
CENSORED REGRESSION MODEL

	(1) Tobit	(2) Tobit w/ category fixed effects	(3) iv Tobit	(4) iv Tobit w/ category fixed effects
HIGH_Q	14,572**	15,157**	18,552**	16,848**
	(7,140)	(7,154)	(7,512)	(7,262)
HIGH_Q*1ST	33,330***	38,676***	22,180**	31,500***
	(8,425)	(8,941)	(9,432)	(9,712)
HIGH_Q*2nd	7,602	8,133	2,350	5,369
	(9,220)	(9,007)	(9,722)	(9,182)
AGE	−1,969***	−2,168***	−1,692**	−2,092***
	(658)	(758)	(668)	(758)
THRP_COMP	−3,702***	−4,024***	−5,265***	−4,971***
	(827)	(925)	(1,068)	(1,095)
G_ENTRY	−62,335***	−69,803***	−49,603***	−65,079***
	(18,329)	(19,184)	(18,726)	(19,448)
D_SIZE	−8,973	45,545	−18,280*	41,762
	(9,994)	(31,269)	(10,826)	(29,243)
D*CRNT_SIZE	−651	−1,289	236	−1,664
	(780)	(2,875)	(899)	(2,896)
D*PTNT_SIZE	2,226***	2,357***	2,129***	2,472***
	(278)	(591)	(285)	(595)
ACUTE	−13,669	48,493*	−4,912	55,013**
	(10,533)	(28,364)	(11,368)	(26,426)
INJECT	−26,984*	−27,312*	−29,887**	−29,881**
	(15,012)	(14,738)	(15,054)	(14,800)
D_RESP	−43,066***	−51,130	−48,812***	−53,707
	(10,314)	(35,055)	(11,026)	(35,226)
D_CNS	−39,279***	−31,496	−45,956***	−32,833
	(6,167)	(27,010)	(7,014)	(27,181)
Y97	10,994*	11,968*	10,824	11,762*
	(6,470)	(6,227)	(6,619)	(6,235)
Y98	12,840**	12,557**	11,797*	12,358*
	(6,515)	(6,390)	(6,663)	(6,404)
Y99	17,478***	17,556**	15,615**	17,620**
	(6,464)	(7,132)	(6,629)	(7,137)
Constant	−18,414	−71,913*	−580	−63,041*
	(13,265)	(37,742)	(15,027)	(36,452)
Observations	606	606	606	606

Standard errors in parentheses: *Significant at 10%; **Significant at 5%; ***Significant at 1%

pioneer drugs have a stronger incentive to invest in DTCA than other high quality drugs. In contrast, the coefficient associated with the second mover (*HIGH_Q*2ND*) is not statistically significant, though positive. Thus, an asymmetry appears to exist in advertising behavior even among high-quality drugs due to the order of entry. This may be because doctors may form a habit in prescribing drugs.

The coefficient for *AGE* is negative and statistically significant, suggesting that younger drugs are more likely to be advertised than are older drugs. Presumably, one of the intentions of the FDA clarification was to reduce patients' acquisition cost of prescription drug information. Advocates of DTCA argued that DTCA can inform the existence of new drugs, and this may help improving the welfare of patients. The result suggests that DTCA

tends to transmit information on newer prescription drugs rather than older ones, although the welfare consequence is far-reaching.

Therapeutic & Generic Competition. The second group of variables examines the effects of competition on DTCA. First, the number of brand names in each therapeutic class (*THRP_COMP*) has a negative and significant effect on advertising outlays. That is, on average, firms reduce DTCA as the number of brand-name competitor increases within each therapeutic class. The results change little regardless of the instrument and the category fixed effects used in Models 2–4. Standard errors for *THRP_COMP* are slightly larger when I use instruments, but the coefficient is still statistically significant at the one-percent level. The result that advertising decreases with competition is, for example, consistent with the prediction of informative advertising by Grossman and Shapiro [1984].

The coefficient for generic entry (*G_ENTRY*) is also negative and statistically significant, indicating that firms cut back DTCA when generic alternatives are available on the market. This is an interesting contrast to the OTC drug market, where branded drugs such as Advil and Tylenol appear to use DTCA frequently in order to differentiate themselves from store-brand drugs. The difference may be explained, for example, by the mandatory substitution laws, which are only applicable to prescription drugs.

Market-Size Variables. The third group of independent variables examines the effects of potential (*PTNT_SIZE*) and current (*CRNT_SIZE*) market size on DTCA. These two variables are interacted with a dummy variable (*D_SIZE*), which equals 1 if the market size information is available and 0 if otherwise. The estimated coefficient for potential market size is positive and significant for all models in Table III, indicating that firms spend more advertising dollars if the market potential is large. Interestingly, however, the coefficient for current visits (*CRNT_SIZE*) is not statistically different from zero, suggesting that DTCA of prescription drugs is not responsive to the number of the currently treated population. Combined, these results imply that firms spend more advertising dollars if the number of the currently *untreated* population (i.e. potential market size minus current market size) rather than *treated* population is large. Thus the result is consistent with the demand-side evidence that DTCA is market expanding rather than business stealing. Estimates also provide some support for the proponents of DTCA who argue that DTCA of prescription drugs is used to bring currently untreated patients to doctors' offices.

VI(iii). *Two-Stage Model*

This section presents the results from the two-stage model. First, I estimate firms' participation decisions, i.e., 'whether or not to advertise,' using the Probit model. Then, I analyze the level of advertising, i.e., 'how much to advertise,' conditional on positive advertising.

TABLE IV
TWO-STAGE MODEL (1ST STAGE-PROBIT MODEL: 'PARTICIPATION DECISION')

	(1) Probit	(2) Probit w/ category fixed effects	(3) iv Probit	(4) iv Probit w/ category fixed effects
HIGH_Q	0.094	0.183	0.265	0.257
	(0.280)	(0.304)	(0.303)	(0.314)
HIGH_Q*1ST	1.294***	1.415***	0.874**	1.085***
	(0.327)	(0.380)	(0.371)	(0.416)
HIGH_Q*2nd	0.290	0.190	0.085	0.076
	(0.361)	(0.389)	(0.394)	(0.404)
AGE	−0.059**	−0.069**	−0.050**	−0.064**
	(0.024)	(0.029)	(0.025)	(0.030)
THRP_COMP	−0.134***	−0.130***	−0.214***	−0.184***
	(0.032)	(0.035)	(0.044)	(0.044)
G_ENTRY	−2.081***	−2.356***	−1.625***	−2.098***
	(0.588)	(0.711)	(0.611)	(0.741)
D_SIZE	−0.370	−3.487***	−0.809**	−4.686***
	(0.361)	(1.304)	(0.411)	(0.741)
D*CRNT_SIZE	−0.046	−0.022	−0.004	−0.028
	(0.033)	(0.123)	(0.038)	(0.125)
D*PTNT_SIZE	0.096***	0.080***	0.097***	0.092***
	(0.014)	(0.024)	(0.015)	(0.025)
ACUTE	−0.117	−2.961**	0.292	−3.580***
	(0.369)	(1.315)	(0.419)	(0.157)
INJECT	−0.706	−1.108*	−0.865	−1.218**
	(0.511)	(0.579)	(0.536)	(0.590)
D_RESP	−1.205***	−8.354***	−1.501***	−9.705***
	(0.389)	(1.601)	(0.436)	(0.476)
D_CNS	−1.036***	−1.139	−1.362***	−1.784
	(0.242)	(1.265)	(0.284)	(1.330)
Y97	0.358	0.389	0.379	0.396
	(0.238)	(0.259)	(0.253)	(0.265)
Y98	0.288	0.213	0.268	0.217
	(0.246)	(0.272)	(0.260)	(0.278)
Y99	0.456*	0.375	0.415	0.400
	(0.247)	(0.308)	(0.261)	(0.314)
Constant	−0.714	2.781	0.022	4.703***
	(0.469)	(0.000)	(0.559)	(1.514)
Observations	606	473	606	473

Standard errors in parentheses: *Significant at 10%; **Significant at 5%; ***Significant at 1%
133 observations had to be dropped in Model 2 and 4 because the category fixed effects 'perfectly explain' the outcome for these observations.

Table IV provides the first stage estimates by the Probit model. The dependent variable corresponds to 1 if advertising expenditure is positive and 0 if otherwise. Again, the first two modes are estimated without the instrument. In Models 3 and 4, I instrument for the number of brand-name drugs. Qualitative results in Table IV are similar to the ones in the censored regression model (Table III). In particular, estimates indicate that firms are more likely to advertise when drugs are new, high quality, and when the number of the untreated population is large. In addition, competitive environment appears to matter: firms are more likely to advertise when they are the first movers among high quality drugs and face a smaller number of competitors within a therapeutic class. The results are robust across models

TABLE V
TWO-STAGE MODEL (2ND STAGE: 'HOW MUCH TO ADVERTISE?' *with* IMR)

	(1) OLS	(2) 2SLS
HIGH_Q	17,916**	18,080**
	(7,887)	(8,119)
HIGH_Q*1ST	27,782**	22,692**
	(11,843)	(10,593)
HIGH_Q*2nd	5,735	3,828
	(9,887)	(9,808)
AGE	−1,889**	−1,722*
	(918)	(890)
THRP_COMP	−2,730**	−2,721
	(1,251)	(2,048)
G_ENTRY	−55,103*	−43,348
	(28,239)	(26,803)
D_SIZE	11,455	3,583
	(12,639)	(14,105)
D*CRNT_SIZE	−1,131	−971
	(933)	(1,016)
D*PTNT_SIZE	1,491***	1,358**
	(520)	(581)
INJECT	−37,529**	−38,687**
	(16,387)	(16,828)
D_RESP	−44,191***	−43,511***
	(14,035)	(15,180)
D_CNS	−43,243***	−43,291***
	(8,844)	(11,027)
Y97	10,189	9,359
	(7,210)	(7,279)
Y98	15,208**	14,490*
	(7,551)	(7,445)
Y99	19,767**	18,946**
	(7,519)	(7,308)
Constant	−11,443	2,821
	(23,802)	(18,047)
IMR	15,067	11,514
	(11,617)	(12,877)
Observations	92	92
R-squared	0.49	0.49

Standard errors in parentheses: *Significant at 10%; **Significant at 5%; ***Significant at 1%
ACUTE is not included in the second stage because it is perfectly collinear with D_SIZE.

with or without the instrument and the category fixed effects. Overall, the Probit models add confidence to the Tobit models estimated previously.[22]

Table V shows the second stage estimates. Here the dependent variable is DTCA expenditure. In order to control for potential 'sample selection' bias, I include the inverse of Mill's ratio (IMR) as a regressor. Here, the t-statistics

[22] Estimation results from the Probit model is also interesting from the viewpoint of information disclosure literature. Theories in information disclosure predict that high-quality firms disclose credible information more often than low-quality firms given fixed disclosure costs (Jovanovic [1982]). Empirical evidence is scarce, however, partly because it is generally difficult to observe the quality level of non-disclosing firms. The results above appear to be consistent with the disclosure theory.

associated with the IMR is positive but not statistically different from zero, providing no evidence for selection bias. I only report the results without the category-fixed effects since it becomes difficult to estimate the model with much precision with the category-fixed effects due to multicollinearity.[23]

Overall, the second stage estimates provide results similar to the previous Tobit models (Table III) and Probit models (Table IV). As before, high-quality drugs appear to advertise more than low-quality ones. In addition, order of entry interacted with the quality variable shows that incentive to advertise is higher for first movers. The coefficient for *AGE* is negative and statistically different from zero as before. The coefficients for competition related variables, i.e., *THRP_COMP* and *G_ENTRY*, are also negative as before but not statistically significant in the instrumental variable estimation, although the point estimates between the two models are similar. Thus, the negative association between DTCA and competition is less clear in the second stage, while there is no strong evidence for competitive rivalry among the firms who chose to advertise. The coefficients for market size variables follow the same pattern as the previous models: DTCA expenditures respond positively to potential market size, but not to current market size. Finally, one notable difference between the first and the second stage result is that time trend is significant only in the second stage estimates. This suggests that the FDA clarification affected the level of advertising but not the participation decision. This may be due to the presence of the fixed costs of advertising, which might not be affected by the FDA clarification in 1997.[24]

VII. DISCUSSION

One remaining concern of this paper is that estimation results may be generated due to spurious correlation between the explanatory variables and other types of promotion, particularly detailing, which I do not observe in my data. Suppose the levels of DTCA and detailing promotion are jointly determined and the explanatory variables included in this paper affect detailing. Then, if I do not control for detailing, the same results may be generated by the spurious correlation. Unfortunately, I do not have detailing data to examine the relationship empirically, and thus cannot eliminate the concern completely.[25] However, available information suggests that the potential problem may not be too large.

[23] I use the same explanatory variables in the first and second stages. The correlation between the IMR and explanatory variables become more severe when I include category specific effects.

[24] Melenberg and Van Soest [1996] discuss similar differences between the first and second stage estimates in the context of vacation expenditure.

[25] Detailing expenditure data are available from pharmaceutical research firms such as IMS Health. However, due to the large sample size, detailing data corresponding to my data set are extremely expensive.

First, estimation results are consistent with the demand-side evidence on the effect of DTCA but not of detailing. As noted before, demand-side research shows that DTCA has a market-expanding effect but little or no business-stealing effect, and detailing has a business-stealing effect. If I'm solely picking up the effect of detailing, it is less likely to have the current results that potential market size determines advertising outlays but not current market size.

Second, the correlation between DTCA and detailing may not be strong for the entire sample, especially in the Probit specification. This is so because, while detailing is commonly used across drugs, pharmaceutical firms use DTCA only for a small number of drugs. Thus, it is more likely that the estimation results reflect the determinants of DTCA rather than detailing.

Additionally, industry information indicates that DTCA budgets have been allocated relatively independently from other promotional budgets. For example, IMS Health, a pharmaceutical information company, noted in 1999 that 'Audited and primary research show that the bulk of DTC (direct-to-consumer) investment growth was truly incremental to the promotion budgets of major DTC-promoted brands. In other words, DTC growth was not fueled by funds being diverted from other efforts, such as physician sales force activities, public relations efforts, patient education programs, or managed care promotion (page 76).'[26] While analyzing the relationship empirically is certainly an interesting future research agenda, available information indicates that examining DTCA separately from detailing promotion may not be unreasonable, at least for the time period I examine.

VIII. CONCLUSIONS

This paper analyzed pharmaceutical firms' incentive to use DTCA to promote prescription drugs. I find that firms advertise more when drugs are new, high quality, and when the untreated population is large. In addition, competition among rivals reduces advertising expenditure, and first movers advertise more than late entrants do. While some of these results indicate that DTCA may have potentially welfare-improving impacts, welfare analysis of DTCA is beyond the scope of this paper and left for future research.

The findings of the paper complement the demand-side evidence of DTCA, and, when combined, help advance our understanding of DTCA of prescription drugs. Demand-side research has shown that DTCA of prescription drugs is primarily characterized as market expanding rather than business stealing, and this has two supply-side implications. First, if DTCA were to exhibit strong externality, pharmaceutical firms would advertise less when they face higher competition. Second, if DTCA would

[26] *Medical Marketing and Media*, 'IMS Health Business Watch: 1998 in Review,' May 1999, p. 76.

increase market size but not affect market shares, firms would use DTCA in the markets where the potential market size, rather than the current market size, is large. In fact, both of these implications are confirmed in the current supply-side analysis. Further, the proponents' claim that the primary role of DTCA is to inform the existence of the treatment rather than to affect prescription choice is consistent with the results of the paper.

In the long run, DTCA may affect the market structure of the industry. For one thing, higher sunk costs due to DTCA may lead to a more concentrated market structure, as Sutton's [1990] seminal work would predict. For another thing, first mover advantages in DTCA may also discourage the entry of 'me-too' drugs and change firms' R&D decisions by increasing the return to become a pioneer. This may be an exciting research agenda waiting to be explored.

APPENDIX
MARKET STRUCTURE AND INTENSITY OF DTCA

Therapeutic class	No. of drugs in therapeutic class in 1999	Total no. of drugs in the data set	Total no. of drugs used DTC ads	Corresponding Major ICD categories
Renal & Genitourinary Agents				
Pentosan Polysulfate Sodium	1	1	0	Cystitis
Cellulose Sodium Phosphate	1	1	0	Calculus of kidney and ureter
Alprostadil	3	3	2	Impotents
Sildenafil Citrate	1	1	1	Impotents
Acetohydroxamic Acid	1	1	0	(Market size not identified)
Citric Acid, Glucono-Delta-Lactone	1	1	0	(Specific ICD not identified)
Cysteamine Bitartrate	1	1	0	Calculus of kidney and ureter
Tiopronin	1	1	0	Calculus of kidney and ureter
Potassium Citrate	1	1	0	(Specific ICD not identified)
Oxybutynin	1	1	1	Incontinence, Frequency of urination
Tolterotine Tartrate	1	1	1	Incontinence, Frequency of urination
Sevelamer HCL	1	1	0	(Market size not identified)
Vaginal Antifungal Agents	2	2	0	Candidiasis of vulva and vagina
Clindamycin Phosphate	1	1	0	(Market size not identified)
Metronidazole	1	1	0	(Market size not identified)
Thaizaides	18	3	0	(Specific ICD not identified)
Loop Diuretics	4	2	0	(Specific ICD not identified)
Potassium-Sparing Diuretics	3	1	0	(Specific ICD not identified)

APPENDIX (Contd.)

Therapeutic class	No. of drugs in therapeutic class in 1999	Total no. of drugs in the data set	Total no. of drugs used DTC ads	Corresponding Major ICD categories
Respiratory Agents				
Sympathomimetics	15	8	4	Bronchitis
Xanthine Derivatives	16	9	0	Bronchitis
Anticholinergics	1	1	1	Bronchitis
Mast Cell Stabilizers	2	1	0	Bronchitis
Leukotriente Receptor Antagonists	2	2	2	Asthma
Leukotriente Formation Inhibitors	1	1	0	Asthma
Corticosteroids	6	5	1	Asthma
Intranasal Steroids	7	7	5	Allergic Rhinitis
Mucolytics	2	1	0	Emphysema
Lung Surfactants	3	3	0	RDS in newborn
Antihistamine, other	10	1	0	Allergic Rhinitis
Piperazines, peripherally selective	3	5	5	Allergic Rhinitis
Central Nervous System Agents				
Analeptics	2	1	0	(Specific ICD not identified)
Amphetamines	1	1	0	ADD of childhood
Anorexiants	10	3	2	Obesity
Narcotic Agonist Analgesics	19	9	0	(Specific ICD not identified)
Narcotic Agonist-Antagonist Analgesics	5	1	0	(Specific ICD not identified)
Central Analgesics	3	2	0	(Specific ICD not identified)
Salicylates	7	1	0	(Specific ICD not identified)
Nonsteroidal Anti-inflammatory Agents 1	8	6	1	Arthritis
Nonsteroidal Anti-inflammatory Agents 2	8	6	2	Arthritis
Nonsteroidal Anti-inflammatory Agents 3	1	1	0	Arthritis
Nonsteroidal Anti-inflammatory Agents 4	2	2	2	Arthritis
Agents for Migraine	4	4	2	Migraine
5-HT3 Receptor Antagonists	3	3	1	(Specific ICD not identified)
Antiemetic/ Antivertigo Agents, Other	1	1	1	(Specific ICD not identified)
Benzodiazepines	8	1	0	Anxiety states
Anxiety Agents, Other	1	1	1	Anxiety states
Tricyclic Compounds	11	1	0	Neurotic depression
Tetracyclic Compounds	2	1	1	Neurotic depression
Bupropion HCL	1	1	0	Neurotic depression
Venlafaxine	1	2	2	Neurotic depression
Nefazodone	1	1	1	Neurotic depression
SSRI	5	6	3	Neurotic depression
Phnylbutylpiperadine Derivatives	2	1	0	(Market size not identified)
Dibenzapine Derivatives	4	3	0	(Market size not identified)
Benzisoxazole Derivatives	1	1	0	(Market size not identified)

APPENDIX (Contd.)

Therapeutic class	No. of drugs in therapeutic class in 1999	Total no. of drugs in the data set	Total no. of drugs used DTC ads	Corresponding Major ICD categories
Lithium	2	1	0	(Market size not identified)
Tacrine HCL	1	1	0	Alzheimer's Disease
Donepezil HCL	1	1	1	Alzheimer's Disease
Imidazopyridines	1	1	1	Sleep disturbances
Benzodiazepines	5	3	0	Sleep disturbances
Etomidate	1	1	0	(Specific ICD not identified)
Midazolam	1	1	0	(Specific ICD not identified)
Propofol	1	1	0	(Specific ICD not identified)
Amide Local Anesthetics	6	2	0	(Specific ICD not identified)
Hydantonins	5	1	0	Epilepsy
Benzodiazepines	4	1	0	Epilepsy
Carbamazepines	2	2	0	Epilepsy
Magnesium Sulfate	1	1	0	Epilepsy
Adjuvant Anticonvulsants	7	6	0	Epilepsy
Nondepolarizing Neuromuscular Blockers	10	7	0	(Specific ICD not identified)
Depolarizing Neuromuscular Blockers	10	1	0	(Specific ICD not identified)
Pergolide Mesylate	1	1	0	Parkinson's Disease
Selegiline HCL	1	1	0	Parkinson's Disease
Tolcapone	1	1	0	Parkinson's Disease
Dopaminergics	2	2	1	Parkinson's Disease
Adenosin Phosphate	1	1	0	(Market size not identified)
Cholinergic Muscle Stimulants	5	1	0	Myasthenia Gravis
Bupropin HCL	1	1	1	Tobacco use disorder
Riluzole	1	1	0	Amyotrophic lateral sclerosis

Notes:

- The ICD category is not identified when a drug is used for general or multiple purposes. These drugs are coded as 'Specific ICD not identified.' Also, it is sometimes difficult to identify the market size. In these cases, I categorized them as 'Market size not identified.'
- The number of drugs approved before 1982 are included in counting the extent of therapeutic competition, but not in the estimation due to the lack of comparable information. Thus, 'No. of drugs in therapeutic class in 1999' is often bigger than 'Total No. of drugs in the data set.'
- In rare instances, 'No. of drugs in therapeutic class in 1999' is smaller than 'Total no. of drugs in the data set.' This happens when a drug was withdrawn from the market and/or disappears from *Drug Facts and Comparison*.

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