NBER WORKING PAPER SERIES

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Working Paper 12001
http://www.nber.org/papers/w12001

NATIONAL BUREAU OF ECONOMIC RESEARCH
1050 Massachusetts Avenue
Cambridge, MA 02138
January 2006

This research was supported by Award # R01 CA094020-01 from the National Cancer Institute, and an unrestricted educational grant from The Merck Company Foundation, the philanthropic arm of Merck & Co. Inc. Andrew Sfekas provided excellent research assistance. We thank participants at various seminars and conferences for helpful comments; the usual disclaimers apply. The views expressed herein are those of the author(s) and do not necessarily reflect the views of the National Bureau of Economic Research.

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NBER Working Paper No. 12001
January 2006
JEL No. I1, L5

ABSTRACT

In this paper we investigate how direct-to-consumer (DTC) advertising of pharmaceutical products in affected by regulations of the Food and Drug Administration and by market conditions. We focus on a relatively under-studied segment of the pharmaceutical market -- the market for smoking cessation products. Because of their proven effectiveness, these products could be the key to meeting public health goals to reduce smoking. However, in many ways, smoking cessation products have been more heavily regulated than cigarettes. Our empirical analysis uses data on advertising expenditures and data from an archive of print advertisements. The archive includes all smoking cessation product advertisements that appeared in over 13,000 issues of 28 magazines between January 1985 and May 2002. Our study period begins shortly atfer the first nicotine replacement product was introduced, and covers the evolution of the market as new products are introduced while some of the older products move from prescription to over-the-counter (OTC) status. OTC status eases the disclosure requirements imposed on advertisements of prescription pharmaceuticals, substantially reducing the costs of a print advertisement. Our results suggest that OTC status is associated with an increase in advertising expenditures and the number and pages of magazine advertisements. A current proposal to reduce disclosure requirements on all DTC advertisements of prescription drugs could have similar effects. Our results also suggest that advertising increase with the introduction of new products and with market competition.

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I. Introduction

Cigarette industry advertisements and anti-smoking public service campaigns are familiar features of the U.S. mass media. A large body of economics research investigates cigarette advertising and the impact of regulating or even banning cigarette advertisements.[1] A similarly large body of public health research addresses the design and impact of public service anti-smoking campaigns.[2] The 1998 Master Settlement Agreement between states and the tobacco industry simultaneously imposed new restrictions on cigarette advertising and established new anti-smoking media campaigns (Bulow and Klemper 1998, Gruber 2001). In contrast to the intense focus on other smoking-related advertisements, researchers almost seem to have overlooked advertisements of pharmaceutical products for smoking cessation.[3] In this paper, we empirically investigate firms' decisions to advertise as the new market for smoking cessation products developed. We focus particularly on how Food and Drug Administration (FDA) regulations affect these advertising decisions.

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[1] For a meta-analysis, Gallet and List (2003) identify 137 estimates of the elasticity of cigarette demand with respect to advertising expenditures. Chaloupka and Warner (2000) review 13 econometric studies that examine the impact of the U.S. ban on broadcast cigarette advertising, while a smaller research literature uses pooled international data sets to study the impact of cigarette advertising bans (Saffer and Chaloupka 2000, Nelson 2003).

[2] Chapters 3 and 7 of the 2000 Surgeon General's Report review evidence on the effectiveness of counter-advertising campaigns (USDHHS 2000a). Several econometric studies compare the impact of industry advertising versus public service counter-advertisements by exploiting the fact that the U.S. ban on television advertising also resulted in the elimination of anti-smoking counter-advertisements required by the Fairness Doctrine (Lewit, Coate and Grossman 1981, Schneider, Klein and Murphy 1981).

[3] Hu *et al*. (2000) and Keeler *et al*. (2002) study the aggregate sales of smoking cessation products, while Tauras and Chaloupka (2003) use scanner data to estimate consumer demand for smoking cessation products. However, none of these studies focuses on advertising in this market.

Our study of smoking cessation product advertisements contributes to research on another increasingly familiar feature of U.S. mass media – direct-to-consumer (DTC) advertisements of pharmaceuticals. The debate on whether DTC advertising leads to better or worse consumer health care often involves analysis of the regulatory system as a whole (Mintzes 2001, 2002, Calfee 2002). However, the benefits and costs of regulating DTC advertisements are likely to vary greatly, depending on the medical condition the drug treats and the knowledge base of consumers. To improve understanding of the benefits and costs in specific contexts, recent empirical studies focus on the impact of DTC advertising on the demand for narrow classes of pharmaceutical products (Berndt *et al*. 1995, Iizuka and Jin 2002, Ling, Berndt and Kyle 2002, Calfee, Winson and Stempski 2003, Rosenthal *et al*. 2003, and Wosinska 2002, 2003). Rather than analyzing the role of DTC advertising regulations on all pharmaceuticals broadly, or estimating the impact of DTC advertising on consumer demand, in this paper we examine the impact of FDA regulations on firms' advertising choices in a specific market. In the market we look at – the market for pharmaceutical products approved as aids for smoking cessation – DTC advertising plays a particularly important role: Ma *et al.* (2003) find that in 1998 smoking cessation was the only class of drugs primarily advertised directly to consumers, rather than to physicians or to both consumers and physicians.

The market for smoking cessation products is potentially very important for public health. A public health initiative, *Healthy People 2010,* aims to cut the prevalence of smoking among adults in half, from the current rate of about 24 percent to 12 percent (USDHSS 2000b). Over the past twenty years, the pharmaceutical industry has introduced a number of products designed to help smokers quit. Because of their proven effectiveness, these products could be

the key to meeting the *Healthy People 2010* goal. For example, Hays *et al.* (1999) report that nicotine patch therapy generally doubles abstinence rates over placebo controls in both short- and long-run follow-ups. While recent policy debates have tended to focus on how to prevent youth from starting to smoke, a recent analysis concludes that the *Healthy People 2010* goal cannot be met without large increases in smoking cessation rates (Mendez and Warner 2000, 2004).

Despite the potential public health significance of smoking cessation products, current regulatory policy towards consumer information about smoking seems disjointed. FDA regulation of prescription drugs results in a peculiar regulatory asymmetry: in many ways, smoking cessation products have been much more heavily regulated than cigarettes. For example, to comply with FDA regulations the typical DTC advertisement of a prescription drug for smoking cessation includes a full extra page disclosing information on side effects, contraindications, and effectiveness. In contrast, a cigarette advertisement only needs to include a relatively small warning label. The irony is that smoking cessation product advertisements may serve some of the same public health goals as public service anti-smoking campaigns. For example, in 1996 the Great American Smokeout, sponsored by the American Cancer Society, included activities in collaboration with a manufacturer of nicotine medications (Burton *et al.* 1997) . More generally, previous research suggests that producers' health claims in advertisements are important sources of consumer information about a range of topics, including dietary fiber in breakfast cereals (Ippolito and Mathios 1990, 1991), the fat content of foods (Ippolito and Mathios 1995, Mathios 1998, 2000), and aspirin and heart attacks (Keith 1995). We contribute to this line of research by describing and analyzing the flow of producer-provided

information about smoking cessation.

The rest of the paper proceeds as follows. In section II we provide a brief history of the market for smoking cessation products and its regulatory environment. In section III, we describe the data we use. Our two primary sources of data are: (i) advertising expenditures by media type; and (ii) an archive of DTC print advertisements. The archive includes all smoking cessation product advertisements that appeared in over 13,000 issues of 28 magazines between January 1985 and May 2002. Our study period begins shortly after the first nicotine replacement product was introduced, and covers the evolution of the market as new products are introduced while some of the older products move from prescription to over-the-counter status. Section IV describes the econometric model and hypotheses to be tested and Section V presents our results. In the final section we summarize our results and discuss the implications for public policy and future research.

II. Evolution of the Market for Smoking Cessation and the Regulatory Environment

The Market for Smoking Cessation

Since the first Surgeon General's Report on the hazards of smoking was published in 1964, the prevalence of smoking among U.S. adults has dropped from 42 percent to about 24 percent. To give an idea of the importance of the role of smoking cessation in this drop, currently there are about as many former smokers (23 percent of adults) as there are current smokers. Put differently, the number of former smokers as a fraction of lifetime (current and former) smokers, sometimes called the quit ratio, is now almost 50 percent, up from 30 percent in 1965 (USDHHS 1989, 2000, Schoenborn, Vickerie, and Barnes 2003).

Interest in tobacco cessation has been long-standing; an advertisement for a "tobacco

cure" appeared in *Harper's Weekly* in 1862 (HarpWeek 2004). However, only recently have pharmaceutical innovations led to smoking cessation methods of proven effectiveness. A review of research published between 1957 to 1968 concludes that "few [methods] have shown high success rates." (Schwartz 1969). Reviews of research published between 1969-1977 (Schwartz and Rider 1977) and 1978-1985 (Schwartz 1987) identify some promising non-pharmacological methods; but they also note deficiencies in the research design and methods that cast doubt on the findings for methods such as hypnosis and acupuncture.[4] In contrast, based on a meta-analysis of evidence from clinical trials, the current *Public Health Service's Clinical Practice Guidelines* concludes that "Numerous effective pharmacotherapies for smoking cessation now exist....that reliably increase long-term smoking abstinence rates," and identifies buproprion, nicotine gum, nicotine inhaler, nicotine nasal spray, and the nicotine patch as first-line pharmacotherapies (USDHHS 2000c). The result of the meta-analysis suggest that smokers randomly assigned to use the pharmaceutical products are 1.5 to 3 times more likely to successfully quit than smokers in the placebo control groups.

Table 1 documents the rapid developments in the market for pharmaceutical smoking cessation products and its regulatory environment. For now we will focus mainly on the history of the product market; the regulatory history is discussed in more detail below. From its introduction in 1984 until 1991 nicotine gum was the only pharmaceutical product approved for use as an aid to smoking cessation. Over the 1990s, pharmaceutical companies competed in this

[4]Schwartz (1987, p. 47) concludes that "It is difficult to assess the true effect of hypnosis as a treatment for smoking since the studies reported were weak in followup methodology ;"and that "The comments regarding the methodology and evaluation of hypnosis trials...apply as well to acupuncture." (p. 50).

market by introducing nicotine patches, nasal spray, and inhalers. In addition, in 1997 the anti-depressant buproprion was approved for smoking cessation under the name Zyban. Varenicline, a nicotine agonist, is currently in phase III clinical trials. Other recent developments include new flavors of nicotine gum, a nicotine lozenge, and emerging competition from generic versions of nicotine gum and patch marketed at retail establishments like Wal-Mart.

The development of effective pharmaceutical aids for smoking cessation is changing the way many smokers quit, and may be increasing smoking cessation rates. As recently as 1987, almost 90 percent of former smokers had quit 'cold turkey,' and only 1.5 percent had used nicotine gum, the only nicotine replacement therapy available (USDHSS 1989). Currently, about twenty percent of smokers use a pharmaceutical product when they try to quit (Plassman *et al.* 2005). Two recent econometric studies examine the role of nicotine replacement therapies in reducing aggregate tobacco consumption and increasing quitting. Hu *et al.* (2000) estimate that a 10 percent increase in sales of nicotine replacement products reduces cigarette sales by 0.04 percent. They estimate that, when nicotine patches became available in 1992 (as opposed to nicotine gum), cigarette sales fell by an additional 0.076 percent. Keeler *et al.* (2002) estimate that, when the FDA allowed smoking cessation products to be sold over-the-counter (OTC), consumption of nicotine patches and gum increased 78 - 92 percent and 180 percent respectively. Under the assumption that the products were as effective in practice as found in clinical trials, they estimate the extra sales translated into almost 20,000 extra quits in 1995. Burton *et al.* (1997) study the impact of the 1996 Great American Smokeout (GASO), sponsored by the American Cancer Society in collaboration with a manufacturer of nicotine medications. Using Nielsen data they estimate that paid advertisements that mentioned the GASO reached 122

million adults. Burton *et al.* (1997) also estimate that purchases of nicotine medications increased by 11 percent around the 1996 GASO, but they can not tie that increase specifically to the impact of GASO advertising.

The Regulatory Environment

In addition to documenting the introduction of smoking cessation products, Table 1 also lists two types of other important regulatory decisions that affect their advertising. The first type is the FDA's decision of whether the product may be sold OTC. During the latter half of the 1990s, the FDA moved nicotine gum and nicotine patches from prescription to over-the-counter (OTC) status. The second type is the FDA's decision of how to regulate the advertising of products that are sold by prescription only.

FDA decisions to permit firms to sell their products OTC obviously affect the product costs faced by consumers. Less obviously, these decisions also affect the advertising costs faced by firms. Advertising costs fall because advertising of OTC products carries a lower regulatory burden than does advertising of prescription only products.

This lower regulatory burden flows from the agency with whom regulatory authority rests for each type of product. The FDA has regulatory authority over advertising of prescription drugs. That authority flows from The Food, Drug and Cosmetic Act (FDCA) of 1938 (52 Stat. 1040; 21 U.S.C. §301, et seq.) (hereafter "the Act"). Although the Act focuses on labeling and does not specifically define what constitutes advertising, the Act defines labeling to include all 'written, printed, or graphic' materials that accompanies the product. The FDA interpreted this language broadly to mean that they have the authority to regulate any material associated with a product, even if it does not physically accompany the product, as is the case for print or

broadcast advertising. In Kordel v. United States the US Supreme Court upheld the FDA's interpretation and effectively granted the FDA regulatory authority over the advertisements for prescription drugs. Under this authority the FDA requires that advertisements for prescription drugs must contain "other information in brief summary relating to side effects, contraindications, and effectiveness."[5] By contrast the Federal Trade Commission (FTC), which has regulatory authority over advertising claims for OTC products, does not require disclosures of the above sort. In regulating advertising, the FTC generally requires only that advertisements are not false or deliberately misleading and that advertisers are able to substantiate claims.

FDA regulations make it more expensive to advertise prescription products because, to meet the FDA disclosure requirements, firms must accompany each advertisement with the sections of the labeling the FDA approved that discuss the product's adverse event profile, contraindications, warnings and precautions. As seen in Figure 1, in practice the typical advertisement of a prescription product for smoking cessation includes at least a page of fine print disclosures. The disclosures are not required by the FTC.

Table 1 also lists FDA's decisions – in 1983, 1985, and 1997 – that have affected the advertising of products that are sold by prescription only. Over the decade of the 1970s and early 1980s pharmaceutical firms increasingly marketed prescription drugs by advertising directly to consumers. In 1983, before pharmaceutical products for smoking cessation were on the market, the FDA reacted to this trend. The FDA asked the manufacturers to voluntarily stop DTC advertising. The FDA asked for this moratorium because they wanted time to study whether or under what conditions DTC advertising might meet the statutory requirements of the

[5] 21 U.S.C. 352(n).

act.

The advertising of smoking cessation products was directly affected in 1985, when the FDA withdrew their request for the voluntary moratorium, but simultaneously imposed significant restrictions on DTC advertising. In particular, the FDA required DTC advertisements to meet the same standards as advertisements directed towards physicians. This standard required that advertisements that made safety and efficacy claims about a particular drug must include a brief summary of the product's side effects, contraindications, and effectiveness.[6] The 1985 FDA disclosure requirements applied to DTC advertisements in both print and broadcast media. Although the disclosure requirement for broadcast advertisements was shorter, it still had to meet the FDA standard of being "adequate." Moreover, broadcast advertisements would be required to make provisions for viewers to obtain the detailed FDA prescribing information. Meeting these disclosure requirements in broadcast advertisements was generally impractical.

The general regulatory environment significantly changed again in 1997, when the FDA substantially reduced the burden of disclosure for broadcast DTC advertisements of pharmaceuticals. In 1995 the FDA had issued a notice of public hearing and request for comments on the regulation of DTC advertisements.[7] Following this public hearing and the receipt of public comments, on August 12th, 1997 the FDA issued draft guidance for industry with respect to DTC advertising.[8] The intended purpose of this guidance was to "enable product

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[6] Section 202.1(e)(5)ii of the Federal Food, Drug and Cosmetic Act.

[7] See Department of Health and Human Services: Docket No. 95N-0227

[8] See Department of Health and Human Services: Docket No. 97D-0302. It is reasonably clear from the request for comments that the FDA was contemplating relaxed disclosure requirements for the adequate provision elements of the regulations.

sponsors to fulfill the requirements for consumer-directed broadcast advertisements, while providing consumers with required risk information about the advertised product." The requirements for print disclosure did not change.

While the new guidance surrounding broadcast advertising did not involve any formal regulatory action, it did create a new relatively safe harbor for manufacturers with respect to how FDA would interpret disclosure requirements. The 1997 FDA draft guidance continued to require manufacturers to include in all broadcast advertisements a major statement of the most important risks. The guidance suggested that manufactures could meet the requirement of providing detailed FDA prescribing information through toll-free telephone numbers, web sites, and references to labeling information in print advertisements appearing concurrently. The draft guidance required that broadcast advertisements should also indicate that health care professionals can provide additional information.[9]

Many observers believe the 1997 FDA regulatory change led to a sharp increase in DTC broadcast advertisements. The pharmaceutical industry's spending on DTC advertising tripled between 1996 and 2000, increasing from $791 million to almost $2.5 billion (Rosenthal *et al.* 2002). Even more dramatically, the industry's spending on television advertising increased more than seven-fold, from $220 million to about $1.6 billion. Rosenthal *et al.* (2002) note that the initial surge in DTC advertising preceded the FDA's release of draft guidelines in 1997, and suggest that these guidelines may not have been the most important reason for the overall increase. However, the FDA had announced a review of its approach in 1995 and some sort of reform was generally anticipated. Hence, it is perhaps not surprising that expenditures began to

[9]The 1997 draft guidance was amended slightly in 1999.

increase even before the more official notification in 1997 of the change in regulatory approach.

Further regulatory changes may be in the air, but it is not clear in which direction the regulatory winds are blowing. In 2003, the FDA reviewed its regulatory approach to DTC advertising. The FDA review process included a request for comments from federal agencies, corporations and lobbying groups with an interest in DTC regulatory matters. The FTC's written comments in response to this request suggested that the FDA should drop its requirement that pharmaceutical print advertisements include detailed drug side-effects listings, in favor of allowing the same kind of "brief summary" risk warnings in print advertisements that are now used in broadcast commercials. More generally, the FTC urged the FDA not to impede DTC pharmaceutical advertising. In 2004, the FDA issued draft guidance suggesting that a briefer print disclosure can be appropriate, but no final rule has been issued and it is unclear if the draft guidance provides a safe harbor for firms to use abbreviated disclosures.

III. Data

We use two main sources of data on DTC advertising of nine smoking cessation products: Nicorette Gum; Nicoderm CQ Patch; Habitrol Patch; ProStep Patch; Nicotrol Patch; Nicotrol Inhaler; Zyban (buproprion); and Commit (nicotine lozenge). First, we use data on advertising expenditures by product category, for both print and broadcast media. We use the "Media Intelligence" advertising expenditure data from Competitive Media Reporting [CMR]. The series runs from 1986 - 2002. The Consumer Price Index is used to express the expenditure data in constant 2002 dollars.

The second main source of data is an archive of pharmaceutical product DTC advertisements in the print media. The Smoking Cessation Advertisements (SCADS) Archive

includes all advertisements for smoking cessation products that appeared in any issue of 26 consumer magazines and two medical journals between January 1985 and May 2002, yielding a sample of 13,497 issues. The data measure each advertisement's brand, the length of advertisement in standardized pages, and the data of the issue of each magazine in which it appears. The SCADS Archive is discussed in more detail in the Data Appendix.

Figure 2 shows trends in total expenditures on smoking cessation product advertisements from 1986 to 2002. Advertising expenditures are fairly low from 1986 through 1991, after which advertising expenditures spiked up to about $100 million, driven by the introduction and intensive marketing of the first nicotine patches. After returning to lower levels, beginning around 1995 advertising expenditures increase again. The 1996-1999 spike roughly coincides with the relaxation of FDA regulations on DTC advertising in broadcast media; however it also coincides with the introduction of new products (nicotine nasal spray, nicotine inhaler, and buproprion), and the conversion of older products from prescription-only to OTC status. Total advertising expenditures hit about $200 million at their peak in 1999. It is also notable that after 1995 the composition of expenditures shifted dramatically towards television. In 1992, print media advertisements account for about 80 percent of total expenditures, while broadcast media account for only 20 percent. In 1999, broadcast media advertisements account for about 90 percent of total expenditures. However, advertising in both broadcast and print media initially increase after 1995. In the last few years of our study period, expenditures on both print and television advertising fall.

Figure 3 compares total advertising expenditures for the smoking cessation products with the number of pages advertisements for each product that appear in our archive. In addition to

helping document the trends, Figure 2 shows that there is a very strong relationship between total advertising expenditures and the SCADS advertising data. The first peaks in both series occur in 1992 around the introduction of the nicotine patch, with about 400 pages of archived print advertisements for smoking cessation products. As with expenditures, the number of pages increases again from 1995 - 1999, peaking at about 200 pages in 1997 and 1998. In some years during the 1980s, our archive contains print advertisements for smoking cessation products even though the CMR data show zero print media advertising expenditures. This appears to be an artifact of the CMR data, where small levels of expenditures are either missed or collapsed into a non-itemized category. At the very end of our study period, the CMR data show substantial expenditures in 2002 on print media advertisements of the newly-introduced Commit nicotine lozenge. However, the SCADS archive ends in May 2002, before the October 2002 launch of Commit. For most of the period and most of the products, the SCADS archive appears to be representative of the universe of all smoking cessation product advertisements in magazines.

Table 2 provides an overview of how the advertisements in the SCADS archive are distributed across the consumer and medical magazines, and across prescription versus OTC products. About three quarters of the slightly more than 1000 advertisements for smoking cessation products appear in the 26 consumer magazines, while the two medical journals account for the other quarter of all advertisements. About three quarters of the advertisements are for prescription products, with about twice as many of these advertisements appearing in the consumer magazines than in the medical journals. Even afer products are available OTC they are still advertised in the medical journals, but it is clear that the advertising effort shifts more towards the consumer magazines. It should be kept in mind that while there are more

advertisements for prescription products than for OTC products, for much of our sample period there were also more prescription products on the market.

IV. Econometric Model of Advertising and Hypotheses to be Tested

In this section we develop an econometric model to estimate the impact of the regulatory environment and other market-level forces on the advertising of smoking cessation products. The model and hypotheses to be tested are based on a profit-maximizing framework. We follow a standard approach and assume that a firm in an oligopolistic or monopolistically competitive industry advertises to invest in a stock of consumer knowledge (Roberts and Samuelson 1988, Chintagunta and Vilcassim 1994, Lee 2002, Bhattacharya and Vogt 2003). For smoking cessation products, advertising may increase consumer demand both by informing consumers about the health benefits of smoking cessation, and by informing consumers about the availability and efficacy of the advertised product. Advertising thus increases the firm's total revenues by increasing consumer demand for its product. As Berndt *et al.* (1995) note, for pharmaceutical products marginal production costs are low, so shifting out consumer demand is essentially the same as increasing profits.

The first order conditions for profit maximization, which require that the marginal revenues from advertising are set equal to the marginal costs of advertising, implicitly define the firm's input demand function for advertising. This motivates the specification of our econometric model given by equation (1), which can be thought of as a version of an input demand function, where advertising demand depends on the costs of advertising and the market environment:

(1) $\text{Advertising}_{p(m)t} = \alpha_o + \alpha_1 \text{ OTC Status}_{pt} + \alpha_2 (\text{OTC Status}_{pt}) * (\text{JAMA}) + \alpha_3 (\text{OTC}$

$$\text{Status}_{pt})^{*}\ (\text{NEJM}) + \alpha_4\ \text{Introductory Period}_{pt} + \beta\ \text{Year Dummies} + \gamma\ \text{Month Dummies}$$

$$+ \delta\ \text{Magazine Dummies} + \zeta\ \text{Product Dummies} + e_{pmt}$$

We estimate equation (1) using different measures of advertising as the dependent variable: expenditures on print media advertisements for product p in month m; expenditures on television advertisements for product p in month t; the number of print media advertisements for product p in magazine m during month t; and the number of pages of print media advertisements for product p in magazine m during month t.[10] Our approach to understand the economic determinants of smoking cessation product advertising exploits variation in the costs of advertising over time and across products created by the regulatory environment. Equation (1) also includes sets of dummy variables for year, month, and product. When the dependent variables are the number and pages of magazine advertisements, the models also include a set of magazine dummies; the dummies for the two medical journals – the *Journal of the American Medical Association* (JAMA) and the *New England Journal of Medicine* (NEJM) – are also interacted with the measure of OTC status. The various dummies are included to capture other important aspects of the market environment and the costs of advertising.[11] Table 3 provides the

[10]Our unit of observation is chosen to be the number of advertisements or pages per month because some of the magazines in our sample are monthly magazines. For those magazines that are weekly we add the value of the dependent variable across the 4 (or 5) weekly issues that have that month on the date of the publication.

[11]The year dummies capture general time trends as well as the degree of competition in the market for smoking cessation products; below, we further explore the role of competition in equation (2) by replacing the set of year dummies with a specific parameterization of the effect of time. In equation (1), the magazine dummies capture the price of advertising space as well as

means of the dependent and independent variables.

We hypothesize that the marketing status of the product (prescription versus OTC) will be an important factor in a firm's decision to advertise. In our empirical models, we capture this aspect of the regulatory environment by the variable $OTC\ Status_{pt..}$ This variable indicates if product p at time t is available over-the-counter. OTC status is hypothesized to generate a number of influences, most of which will tend to increase advertising. First, we expect an own-price effect: the removal of disclosure requirements lowers the costs of advertisements and thus increases firms' demand for advertising. Second, by eliminating the need to see a physician, OTC status lowers the full costs consumers face to obtain smoking cessation products, which can be expected to increase consumer demand, thus increasing the returns to advertising.[12] Third, OTC status may make advertising more effective: because firms are no longer required to disclose side effects so prominently, consumers may be more likely to respond to advertisements. A change to OTC status may also work in the other direction and cause certain types of advertising to decrease. A cross-price effect might tend to decrease magazine advertising: because OTC status decreases the relative cost of television advertising, firms may

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other aspects of a particular magazine such as total circulation and readership demographics.

[12]Because of health insurance, in principle the switch to OTC can have ambiguous effects on the return to advertising. Insured consumers may actually see lower out-of-pocket costs when the drug is available by prescription only. Moreover, health insurance coverage will tend to make demand more price inelastic, increasing manufacturers' expected returns on advertising (Danzon and Pauly 2002, pp. 608-609). For some drugs, therefore, a switch to OTC status may reduce demand and make demand more price elastic, thus reducing the returns to advertising. However, health insurance coverage of prescription drugs for smoking cessation was uncommon for most of the period we study (McPhillips-Tangum 1998, National Center for Health Statistics 2001), and empirical evidence suggests that the switch of these drugs to OTC status shifted the demand curve out (Keeler *et al*. 2002).

substitute away from magazine advertising into television. Finally, we expect that OTC status reduces the returns to advertising targeted at physicians, so in the models of the number and pages of magazine advertisements we include interactions with the dummy variables for the two medical journals (JAMA and NEJM).

The FDA also influences the market for smoking cessation advertising through its initial approval to allow new products on the market. Equation (1) includes a variable *Introductory Period* $_{pt}$, which is defined as the six month period following approval. This allows us to test Bhattacharya and Vogt's (2003) theoretical prediction that pharmaceutical advertising levels are set high early in the product's life cycle to build public knowledge about the product.

To further explore the economic determinants of advertising choices, we re-specify equation (1) by replacing the set of year dummies with a specific parameterization of the effect of time:

(2) $\text{Advertising}_{pmt} = \alpha_o + \alpha_1 \text{OTC Status}_{pt} + \alpha_2 (\text{OTC Status}_{pt}) * (\text{JAMA}) + \alpha_3 (\text{OTC Status}_{pt}) * (\text{NEJM}) + \alpha_4 \text{Introductory Period}_{pt} + \beta_1 \text{Number of products on market}_t + \beta_2 (\text{Number of products on market}_t)^2 + \beta_3 \text{Post 1997 Regulations} + \beta_4 (\text{Rx Status}_{pt}) * (\text{Post 1997 Regulations}) + \gamma \text{ Month Dummies} + \delta \text{ Magazine Dummies} + \zeta \text{ Product Dummies} + e_{pmt}$

To capture the potential impact of brand competition on the returns to advertising, equation (2) includes the number of smoking cessation products on the market at time t, and the square of this measure. This allows us to test the conventional wisdom about the relationship between competition and advertising – "the so-called inverted U hypothesis, which implies that

moderately concentrated industries engage more intensively in advertising than both atomistically competitive and highly concentrated industries." (Lee 2002, pp. 89 - 90). In other contexts, the measures of the market environment might be endogenous to advertising levels, but this does not seem likely in the market for smoking cessation products. An incumbent's advertising might discourage entry (Schmalensee 1983), reducing the number of products on the market. Scott Morton's (2000) empirical analysis suggests that brand advertising is not a barrier to entry by generic firms into the U.S. pharmaceutical market. Over most of the period we study, entry into the market for smoking cessation products did not involve generics but instead involved the introduction of new branded products. Introduction of these products was the last step of a long process of development and testing begun long before current advertising could be known. The exact timing of FDA approval is also not a choice variable of the firm. For this reasons, we believe it is appropriate to treat the measures of the market environment as exogenous to current advertising choices.

Equation (2) also introduces another regulatory variable, $Post\ 1997_t$, which indicates if the observed advertisement occurs after the FDA 1997 regulatory change for broadcast advertising. By lowering the cost of broadcast advertising, we predict own-price effects that will increase the demand for television advertising and possible cross-price effects to reduce demand for magazine advertising. Because the 1997 regulatory change applied to prescription products, $Post\ 1997_t$ is interacted with an indicator variable for whether the product is available only by prescription at time t.

To estimate our models of advertising expenditures, we use a sample of 998 observations of the advertising expenditures for each product in each month it was on the market from

January 1985 to December 2002. The models are estimated by ordinary least squares (OLS). We also estimate a two part model, where the first part is a probit model of the probability that advertising expenditures were positive, and the second part is an OLS model of the log of expenditures for the sub-sample with positive expenditures. When we estimate models of magazine advertisements, our sample consists of the number (pages) of advertisements that appear in each SCADS magazine in each month a product was on the market from January 1985 to May 2002. Our SCADS sample consists of 25,021 observations. We estimate the models of the number and pages of magazine advertisements by OLS.[13]

V. Results

Tables 4 and 5 present estimates of equations (1) and (2) for our models of advertising expenditures; Table 6 presents estimates of equations (1) and (2) for our models of the number and pages of magazine advertisements. The results suggest that a firm's decision to advertise is significantly affected by FDA regulation of whether a product is available by prescription-only or OTC. OTC status is associated with an increase in expenditures for advertising in both magazines and television. For magazine advertising, the two-part model results suggest that

[13]The dependent variables for these models are counts of the number of advertisements and the number of pages of advertisements. The Poisson model, an extension of the regression model that is appropriate when the dependent variable is a count rather than a continuous variable, relies on restrictive assumptions that are problematic for our data. For example, about 98 percent of the observations of the number of advertisements take the value of zero, while the nonzero values range from 1 to 10. This suggests there may be "excess zeros" and/or "overdispersion" (Mullahy 1997, Wooldridge 2002). Wooldridge (2002, p. 651) cautions that "In the case of overdispersion, the standard errors [on the coefficients from the standard Poisson model] ... will systematically underestimate the asymptotic standard deviations, sometimes by a large factor." We therefore adopt OLS as a more conservative approach. We have also collapsed the dependent variables to 0-1 measures of any advertisements or any pages. Probit models using these variables yield similar results to the OLS models reported; the probit results are available upon request.

most of the effect is through the probability of any expenditures rather than on the amount of expenditures conditional on positive advertising. For television advertising, OTC status is associated with an increase in both parts of the expenditures model. In Table 6, OTC status is also associated with an increase in the number of magazine advertisements and an increase in the pages of advertisements, although the latter effect is not quite statistically significant when the year dummies are replaced with the parameterized time trend. Not surprisingly, when a product becomes available OTC, manufacturers reduce the number and pages of advertisements for that product in the two medical journals (JAMA and NEJM).

Because OTC magazine advertisements no longer include the full page of disclosures, it would have been possible for manufactures to increase the number of advertisements while holding constant or even decreasing total expenditures and the pages of advertisements. The fact that total expenditures and the number of pages of advertisements instead actually increase suggest that advertising demand is quite responsive to the own-price effects and other influences created by OTC status.

To shed more light on the practical significance of the OTC effect, we can use our models to predict the amount of magazine advertising under two hypothetical policy regimes. The first, admittedly radical, simulated policy change assumes that the FDA allowed all products to be immediately sold OTC rather than by prescription only. This would result in an approximate tripling of the number of observations of OTC products in our sample. Our model predicts that this change would increase the number of advertisements for smoking cessation products by 80 percent, from 1069 to 1921 total advertisements. Our second simulation considers a much more modest change. Suppose that, for each product currently sold OTC, the

FDA approved it for OTC sale exactly one year before the actual approval date. This hypothetical policy change would increase the number of observations of OTC products by about twenty percent. According to our model, this change would increase the number of magazine advertisements by a little less than nine percent, from 1069 to 1160 advertisements.

Our results also show that the FDA's decisions to approve new products affects advertising in two ways: through initial advertising during the introductory period; and through effects on market competition. All of the models reported in Tables 4, 5 and 6 show a large introduction effect. Consistent with the prediction of Bhattacharya and Vogt (2003), advertising is much higher during the 6 month introductory period. We also find that when a product vies against more competing products, firms advertise more, but the increase in advertising associated with each additional competitor falls as more products come onto the market. This result fits the inverted-U hypothesis. During the period under study, the market for smoking cessation products evolved from a highly concentrated industry (when nicotine gum was the only approved pharmaceutical product on the market) into a less concentrated industry. The estimated coefficients from our model imply that the maximum amount of advertising occurs with about four to five products on the market, a level of competition reached around the time several different manufacturers introduced the nicotine patch in 1991 - 1992. Although the introduction effect and the competition effect are affected by FDA regulatory decisions, it is hard to develop reasonable counter-factuals for policy simulations. That is, earlier or later FDA approval would change the timing of the introduction effect and the date when advertising is maximized, but would not necessarily change the total advertising over the entire period.

Results in Table 5 show that the 1997 regulatory change increased expenditures on

television advertising of prescription smoking cessation products. Because the 1997 regulatory change made it much easier to advertise on television, this pattern is expected and is consistent with other research (Rosenthal *et al.* 2002). However, the results in Tables 4 and 6 do not provide consistent evidence of a strong impact of the 1997 regulatory change on the demand for magazine advertising. This may not be that surprising because the current regulatory environment tends to induce a complementarity between the two forms of advertising. Some types of advertisements for prescription products on television must refer the customer to a print advertisement – where the full disclosure continues to be required.

Although not reported in the Tables, we also estimated equation (1) parameter vectors β, γ, δ and ζ corresponding to the vectors of year, month, magazine, and product dummy variables. An interesting pattern from these estimates is that advertising is highest in January and November. This pattern suggest that the manufacturers of smoking cessation products may perceive greater returns to advertising in months when smokers are pre-disposed to quit because of New Year's resolutions and the Great American Smokeout. There also seems to be evidence of 'summer doldrums,' with less advertising of the products in June, July and August.

VII. Conclusion

Our results provide strong evidence that a switch to OTC status is associated with increased advertising of smoking cessation products. This evidence sheds new light on the FTC's December 2003 recommendation that the FDA should change its disclosure requirements for pharmaceutical print advertisements. If the FDA adopts this recommendation, requirements for all DTC advertisements of prescription pharmaceuticals would be similar to current requirements for advertisements of OTC products. Our results suggest the new regulatory stance

could substantially increase DTC advertising of pharmaceuticals.

Of course, there are different views of whether more DTC advertising of pharmaceuticals will improve consumer welfare. The general debate on DTC advertising is beyond the scope of this paper. However, it should be noted that standard objections to DTC advertising do not seem to carry as much weight in the context of smoking cessation products. For example, a common concern is that patients may incorrectly self-diagnose and pressure physicians for inappropriate prescriptions for non-existent conditions. Such a situation seems unlikely for smokers.[14] The wide availability of nicotine replacement products in the late 1990s has been credited with producing "the largest increase in smoking cessation since the 1964 Surgeon General's report on smoking." (Hughes 2000, p. 147). Because de-regulating the advertising of smoking cessation products is likely to help more smokers quit, such a regulatory change can also improve public health. In on-going work, we are exploring whether advertising of smoking cessation products translates into more ex-smokers. The results of our on-going research will allow us to quantify the public health benefits of changes to the FDA's DTC advertising regulations.

[14]There is some concern that non-smokers will use nicotine replacement products. Because virtually all of the adverse health consequences of smoking are due to the inhaled smoke, and not the nicotine *per se*, it is not clear that this small potential cost of advertising smoking cessation products could outweigh the benefits of increased cessation.

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TABLE 1: Events in the Development and Advertising of Smoking Cessation Products

Year	Event
1983	Food and Drug Administration (FDA) requests voluntary moratorium on direct-to-consumer (DTC) advertising of prescription drugs
1984	Nicorette© Gum (2 mg) approved for prescription sale (January)
1985	FDA lifts moratorium on DTC advertising (with significant restrictions).
1991	Nicoderm© CQ Patch approved for prescription sale (September) Habitrol© Patch approved for prescription sale (September)
1992	ProStep© Patch approved for prescription sale (January) Nicorette© Gum (4 mg) approved for prescription sale (June) Nicotrol© Patch approved for prescription sale (August)
1994	Nicorette© Gum patent expires
1995	FDA invites comments on adequate disclosure requirements (August)
1996	Nicorette© Gum (2 and 4 mg) approved for over-the-counter (OTC) sale (February) Nicotrol© Nasal Spray approved for prescription sale (March) Nicotrol© Patch approved for OTC sale (July) Nicoderm© CQ Patch approved for OTC sale (August)
1997	Nicotrol© Inhaler approved for prescription sale (May) Zyban© approved for prescription sale (May) FDA relaxes disclosure requirements governing DTC advertising of prescription drugs on television and radio
1998	Nicorette Mint© Gum (2 and 4 mg) approved for OTC sale (December)
1999	ProStep© Patch approved for OTC sale (January) Nicotrol© Gum (2 and 4 mg) approved for OTC sale (March) Habitrol© Patch approved for OTC sale (November) Combined Zyban© / Nicotine transdermal systems patch therapy approved for prescription sale
2000	Nicorette Orange© Gum (2 and 4 mg) approved for OTC sale (September)
2002	Commit Lozenge© approved for OTC sale (October)
2003	Federal Trade Commission comments on FDA regulatory approach to DTC advertisements (December)

Source: authors' compilation from Food and Drug Administration archives. Lists of drug approval dates and dates for movements to OTC status were obtained from the website http://www.fda.gov/opacom/7approvl.html and from various newspaper and journal articles. Regulatory events surrounding direct-to-consumer advertising are obtained from press releases on the FDA website and federal register documents.

TABLE 2: Smoking Cessation Product Advertisements by Magazine Type and OTC Status

	Consumer Magazines	Medical Journals	Total
Prescription Products	531	243	774
OTC Products	245	50	295
Total	776	293	1069

Source: SCADS archive. Consumer Magazines include: Ebony, National Geographic, Better Homes & Gardens, Sports Illustrated, Readers Digest, Time, Money, Modern Maturity, Family Circle, Women's Day, Cosmopolitan, YM, Rolling Stone, Good Housekeeping, Playboy, Glamour, Vibe, Seventeen, Newsweek, Jet, Business Week, TV Guide, People, U.S. News &World Report, Entertainment Weekly, McCall's/Rosie and Essence. Medical Journals include: Journal of the American Medical Association and the New England Journal of Medicine.

TABLE 3: Descriptive Statistics	
Variable	**Mean**
Expenditures on magazine advertising (million $)	271.32
Expenditures on television advertising (million $)	925.17
Number of magazine advertisements	0.043
Pages of magazine advertisements	0.081
OTC	0.357
Introductory period	0.053
Number of products on market	6.746
Post 1997	0.515
Post 1997 * Rx Product	0.203
Notes: The mean of the first two variables in the table are derived from the expenditure data with a sample size of 998. The mean of the remaining variables in the table are derived from the SCADS data with a sample size of 25,021.	

TABLE 4: Models of Magazine Advertising Expenditures

	With Year Effects			Parameterized Time Trend		
	OLS ($)	**Probit ($ > 0)**	**OLS (Log $ > 0)**	**OLS ($)**	**Probit ($ >0)**	**OLS (Log $ >0)**
OTC	344.26*** (3.63)	0.355*** (4.69)	0.327 (0.51)	206.85* (1.72)	0.326*** (4.06)	0.293 (0.77)
Introductory period	277.87*** (2.58)	-0.0335 (0.76)	0.2967 (0.75)	513.24*** (4.87)	0.066 (0.92)	0.805** (2.05)
Number of products on market	n.a.	n.a.	n.a.	106.76*** (3.29)	0.081*** (3.93)	0.228 (1.60)
Number of products on market – squared	n.a.	n.a.	n.a.	-11.54*** (5.31)	-0.009*** (6.36)	-0.017* (1.96)
Post 1997	n.a.	n.a.	n.a.	-29.61 (0.22)	-0.013 (0.15)	-0.127 (0.38)
Post 1997 * Rx Product	n.a.	n.a.	n.a.	68.74 (0.46).	-0.015 (0.13)	-1.818*** (4.01)
Month effects?	Yes	Yes	Yes	Yes	Yes	Yes
Year effects?	Yes	Yes	Yes	No	No	No
Product effects?	Yes	Yes	Yes	Yes	Yes	Yes
R-squared	0.256	0.343	0.415	0.170	0.241	0.285
Mean of dependent var.	271.32	0.251	6.365	271.32	0.251	6.365
N	998	916	250	998	916	250

Absolute values of t-ratios in parenthesis. Probit results are the marginal effects of the independent variables on the probability that expenditures > 0. In probit models, product 8 predicted failure perfectly, so it was dropped eliminating 82 observations. * (**)(***) indicates significance at 90, 95, and 99 % level respectively.

TABLE 5: Models of Television Advertising Expenditures

	With Year Effects			Parameterized Time Trend		
	OLS ($)	**Probit ($ > 0)**	**OLS (Log $ > 0)**	**OLS ($)**	**Probit ($ >0)**	**OLS (Log $ >0)**
OTC	2567.84*** (10.98)	0.750*** (5.86)	10.748*** (7.13)	4517.76*** (16.60)	0.850*** (7.80)	4.231*** (5.26)
Introductory period	-560.82** (2.12)	-0.132* (1.97)	-1.043 (1.32)	-39.13 (0.16)	-0.022 (0.26)	-0.303 (0.36)
Number of products on market	n.a.	n.a.	n.a.	446.42*** (6.07)	0.048** (2.00)	0.089 (0.34)
Number of products on market – squared	n.a.	n.a.	n.a.	-40.03*** (8.12)	-0.006*** (3.65)	-0.016 (0.99)
Post 1997	n.a.	n.a.	n.a.	-2426.32*** (8.12)	-0.389*** (2.94)	-0.361 (0.65)
Post 1997 * Rx Product	n.a.	n.a.	n.a.	3072.16*** (9.13)	0.540*** (2.87)	3.518*** (4.26)
Month effects?	Yes	Yes	Yes	Yes	Yes	Yes
Year effects?	Yes	Yes	Yes	No	No	No
Product effects?	Yes	Yes	Yes	Yes	Yes	Yes
R-squared	0.444	0.430	0.514	0.472	0.374	0.334
Mean of dependent var.	925.17	0.310	6.740	925.17	0.310	6.740
N	998	916	309	998	916	309

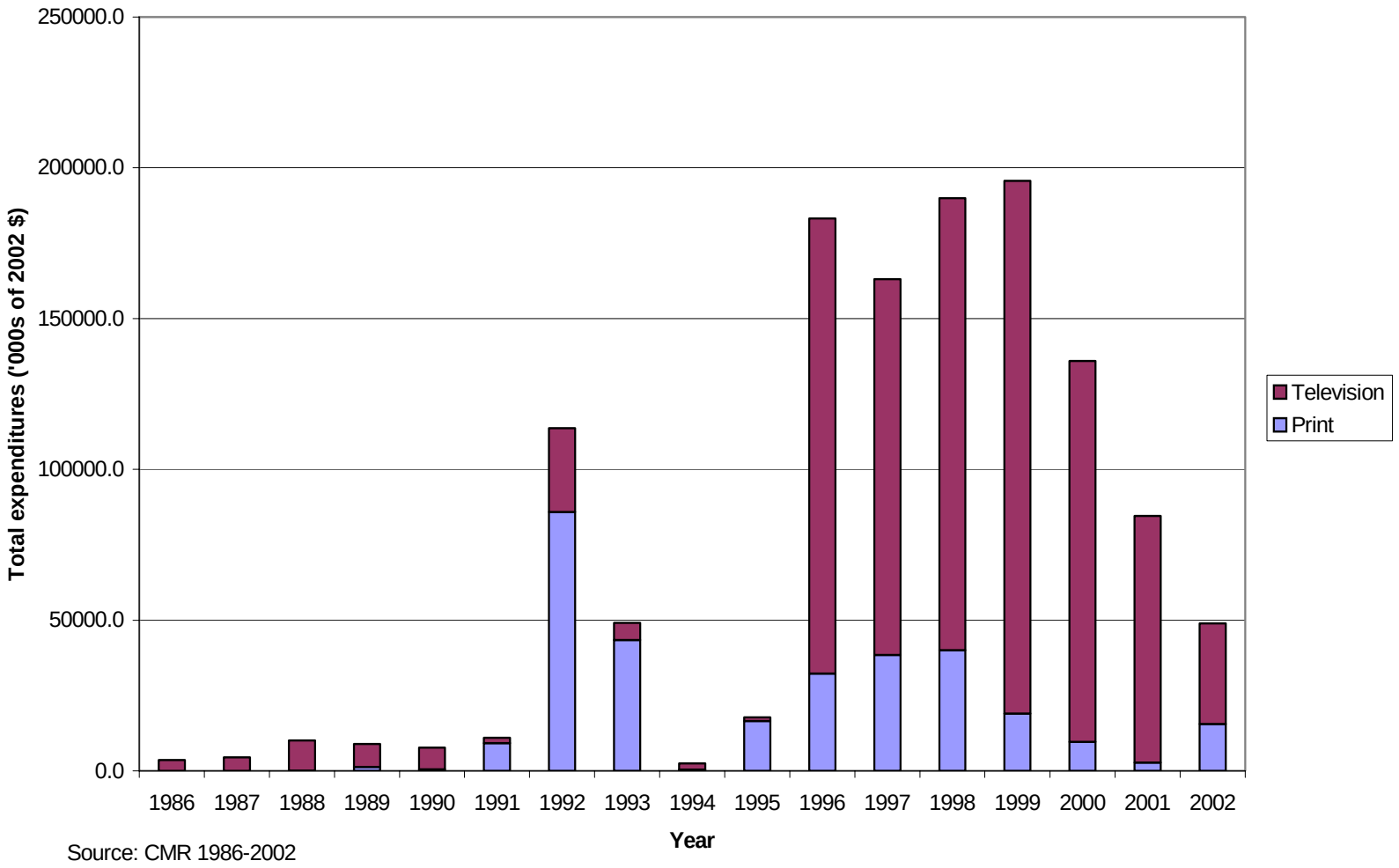
Notes: t-ratios in parenthesis. Probit results are the marginal effects of the independent variable on the probability that expenditures > 0. In probit models, product 8 predicted failure perfectly, so it was dropped eliminating 82 observations. * (**)(***) indicates significance at 90, 95, and 99% level respectively.

TABLE 6: Models of the Number and Pages of Magazine Advertisements				
	Number of Advertisements		**Pages of Advertisements**	
	1	**2**	**3**	**4**
OTC	0.062*** (7.14)	0.049*** (4.77)	0.058*** (2.92)	0.033 (1.43)
OTC * JAMA	-0.124*** (5.98)	-0.124*** (5.96)	-0.366*** (7.70)	-0.366*** (7.66)
OTC * NEJM	-0.131*** (6.30)	-0.131*** (6.27)	-0.455*** (9.58)	-0.456*** (9.53)
Introductory period	0.095*** (9.95)	0.136*** (15.49)	0.290*** (13.31)	0.379*** (18.77)
Number of products on market	n.a.	0.017*** (6.39)	n.a.	0.026*** (4.23)
Number of products on market – squared	n.a.	-0.002*** (9.69)	n.a.	-.003*** (6.60)
Post 1997	n.a.	-0.019* (1.69)	n.a.	-0.008 (0.30)
Post 1997 * Rx product	n.a.	0.023* (1.80)		0.033 (1.10)
Month effects?	Yes	Yes	Yes	Yes
Year effects?	Yes	No	Yes	No
Magazine effects?	Yes	Yes	Yes	Yes
Product effects?	Yes	Yes	Yes	Yes
R-squared	0.0727	0.0621	0.0879	0.0625
Mean of dependent var.	0.0427		0.0809	
N	25,021			
Notes: : t-ratios in parenthesis. * (**)(***) indicates significance at 90, 95, and 99 % level respectively.				

Figure 1
A Typical Advertisement for a Prescription Smoking Cessation Product

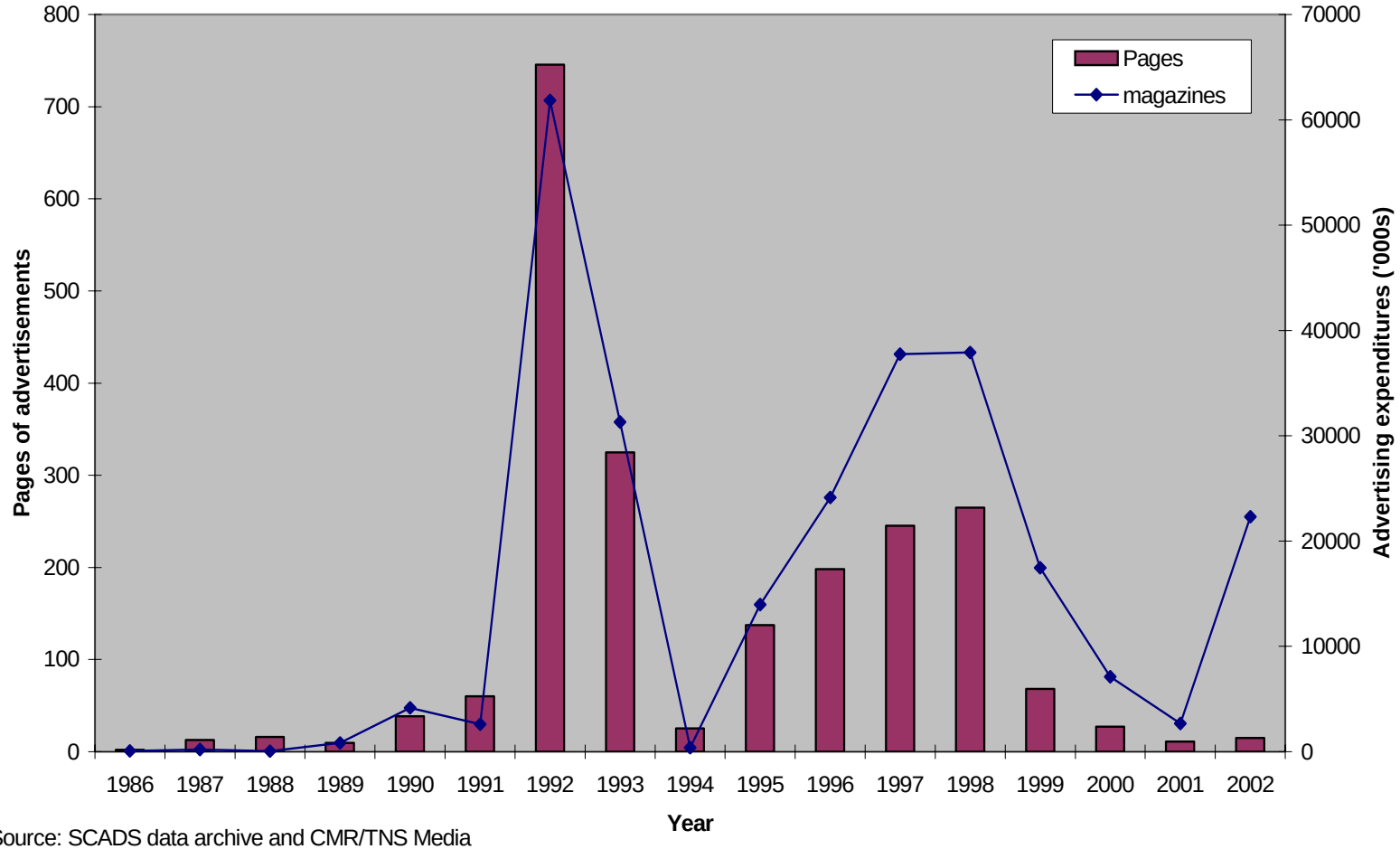
(Not available in this draft)

Figure 2
Advertising expenditures on Smoking Cessation Products and Programs 1986-2002



Source: CMR 1986-2002

Figure 3
SCADS advertisements versus CMR magazine advertising expenditures



Source: SCADS data archive and CMR/TNS Media

DATA APPENDIX: The SCADS Archive

In constructing the sample of magazines in SCADS, we faced a tradeoff between the benefits of wider coverage and the costs of data collection. To select the sample of magazines we used data from the 1998 National Consumer Survey of the Simmons Survey of Media and Markets: Choices II (NCS). These data contain self-reported information on readership of 172 magazines for approximately 20,000 consumers. Using these data, we defined groups based on demographic characteristics (race, education, income, age, gender, smoking status). We then chose the ten magazines most frequently read by members of each group. Because of substantial overlap in the set of magazines most frequently read by different groups, our final sample of magazines includes 26 consumer magazines. In the three cases in which we could not locate copies of all magazines in our sample period (1985-2002) we substituted the magazine that was the next most widely read magazine for the group in question. Based on the NCS data, we calculate that readership of the SCADS sample of 26 magazines accounts for 57.5 percent of the readership of the NCS total sample of 172 magazines. From a source independent of the NCS, we also obtained data on the circulation of 148 of those magazines. The circulation of the 26 magazines in the SCADS sample accounts for 60.7 percent of the total circulation of the 148 magazines. While there are some magazines not included in either the NCS sample or the circulation data, the missing magazines are not widely read; for example, only 0.001 of the NCS respondents read the 172nd ranked magazine in that sample. Thus, two independent calculations suggest that the SCADS sample accounts for almost sixty percent of all U.S. magazines by readership or circulation.

The advertising data archive includes digitally extracted images of all advertisements for smoking products, smoking cessation products, pharmaceutical products, and health-related public service announcements in 28 of the top read magazines in the U.S. for the period January 1985 through May 2002 (17 years and 5 months). Twenty-six of these magazines cover the consumer market and two publications focus primarily on physicians.

> Consumer magazines: Ebony, National Geographic, Better Homes & Gardens, Sports Illustrated, Readers Digest, Time, Money, Modern Maturity, Family Circle, Women's Day, Cosmopolitan, YM, Rolling Stone, Good Housekeeping, Playboy, Glamour, Vibe, Seventeen, Newsweek, Jet, Business Week, TV Guide, People, U.S. News &World Report, Entertainment Weekly, McCall's/Rosie, Essence.
>
> Physician journals: Journal of the American Medical Association, New England Journal of Medicine.

The archive contains advertisements from approximately 13,497 issues of these magazines. Each advertisement in the data base is coded with the brand name, manufacturer name, length of advertisement, position within the magazine, and for public service announcements, who sponsored the announcement.