

Draft: Do not cite without permission

Regulating Advertisements: The Case of Smoking Cessation Products

Rosemary Avery
Cornell University

Donald Kenkel
Cornell University

Dean Lillard
Cornell University

Alan Mathios
Cornell University

December 2003

Contact Information:

Alan Mathios

Department of Policy Analysis & Management

MVR Hall

Ithaca, NY, 14850

e-mail: adm5@cornell.edu

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. Helpful comments on earlier drafts were provided by Steve Lehrer, participants at the University of Pennsylvania Leonard

Davis Institute Seminar Series, and participants at the health economics seminar at the London School of Hygiene and Tropical Medicine. The usual disclaimers apply.

ABSTRACT

In this paper we investigate how direct-to-consumer (DTC) advertising of pharmaceutical products is affected by regulations of the Food and Drug Administration (FDA) 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 a unique archive of print advertisements. The archive includes all smoking cessation product advertisements, cigarette advertisements, and public service anti-smoking advertisements that appeared in over 7,000 issues of 14 magazines between January 1985 and December 2002. Our study period begins when 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 preliminary results suggest that OTC status is associated with an increase in advertising expenditures and an increase in the number of print advertisements. A current proposal to reduce disclosure requirements on all DTC advertisements of prescription drugs could have similar effects. Our preliminary results also suggest that advertising increases with the introduction of new products and with market competition.

I. Introduction

Cigarette industry advertisements and anti-smoking public service counter-advertisements 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.

¹ In their meta-analysis of the determinants of cigarette demand, 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, especially when combined with school-based programs and community-wide efforts (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 (2001) 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 is designed to address, and the related knowledge base of consumers. To improve our 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.⁴ 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 the market for the class of pharmaceutical products approved as aids for smoking cessation.

The market for smoking cessation products is potentially very important for public health. A recent 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

⁴Calfee, Winson and Stempki (2002) and Wosinska (2002, 2003) study the impact of DTC advertising in the market for cholesterol-lowering drugs. Berndt *et al.* (1995) and Ling, Berndt and Kyle (2002) study the impact of DTC advertising in the market for H₂ antagonist drugs, which are used to treat a wide range of gastrointestinal disorders. Iizuka and Jin (2002) study the impact of DTC advertising on the choice of cholesterol-lowering drugs and non-sedating antihistamines. Rosenthal *et al.* (2003) study the impact of DTC advertising of five therapeutic classes of drugs: recent vintage antidepressants; cholesterol-lowering drugs; proton pump inhibitors; nasal sprays; and antihistamines.

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).

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) a unique archive of DTC print advertisements. The archive includes all smoking cessation product advertisements, cigarette advertisements, and public service anti-smoking advertisements that appeared in over 7,000 issues of 14 magazines between January 1985 and December 2002. In section IV we use these data to document the trends in smoking cessation product DTC advertising. Our study period begins when 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. To place the trends in smoking cessation product advertisements in context, we also document trends in cigarette industry advertising and trends in public expenditures on tobacco control. In section V we present an econometric model of the advertising decisions of profit-maximizing firms. We present results in section VI. 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 1965.⁵

Although interest in smoking cessation has been long-standing, 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 these findings.⁶ 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 bupropion, 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

⁵Estimates in this paragraph are based on USDHHS (1989, 2000) and Schoenborn, Vickerie, and Barnes (2003).

⁶For example, Schwartz (1987) 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 “ (p.47); and that “The comments regarding the methodology and evaluation of hypnosis trials...apply as well to acupuncture.” (p. 50).

products and its regulatory environment. For now we will focus mainly on the history of the products; 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 market by introducing nicotine patches, nasal spray, and inhalers. In addition, in 1997 the anti-depressant bupropion 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 one-third of smokers use a medication when they try to quit (Hughes 2000). 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. Based on clinical studies of effectiveness, they estimate the extra sales translated into almost 20,000

extra quits in 1995. Burton *et al.* (1997) estimate that the 1996 Great American Smokeout, coordinated with a manufacturer of a nicotine replacement product, led to almost 100,000 extra attempts at quitting using nicotine medications.

The Regulatory Environment

In addition to documenting the introduction of smoking cessation products, Table 1 also lists important events in the regulatory environment of this market. As shown in Table 1, during the latter half of the 1990s the FDA moved nicotine gum and nicotine patches from prescription to over-the-counter (OTC) status. This move is important for advertising because the Federal Trade Commission (FTC), not the FDA, has regulatory authority over advertising claims for OTC products. The FTC has no required disclosures and advertising is regulated under the general requirements that firms have substantiation for the claims that they make and that the advertisements are not false or misleading. Of course, in addition to the different requirements for advertisements, OTC status also eliminates the need to see a physician, reducing the full cost of using these products and thus stimulating demand.⁷

Table 1 also lists three FDA actions – in 1983, 1985, and 1987 – that more broadly altered

⁷The impact of OTC status on out-of-pocket costs is ambiguous for consumers with generous health insurance plans that cover prescription drugs. However, in 1985, only 12 percent of health plans covered treatment for nicotine addiction (National Center for Health Statistics 2001). In a 1997 survey of managed care organizations, 75 percent provide coverage for some smoking cessation interventions, but coverage for pharmaceutical products was much less common (McPhillips-Tangum 1998). Only 25 percent covered nicotine replacement therapy with enrollment in a smoking cessation program. Only 18 percent covered the prescription drug bupropion, but this was somewhat more common than coverage for the OTC products, which was provided by only 7 percent of the plans. About half of State Medicaid programs now provide coverage for smoking cessation purposes (USDHSS 2000a), but these programs often cover both prescription-only and OTC products (reference). Overall, for most smokers the switch to OTC status lowered out-of-pocket costs. The empirical evidence noted above suggests the net impact of the switch to OTC was to increase demand (Keeler *et al.* 2002).

the regulatory environment governing DTC advertising of prescription drugs. The last two of these broad regulatory changes directly affected advertisements of smoking cessation products. The first action, in 1983, occurred before pharmaceutical products for smoking cessation were even on the market. In reaction to the ever-increasing marketing of prescription drugs through DTC advertising, the FDA asked the manufacturers to comply with a voluntary moratorium.

In requesting the moratorium, the FDA wanted time to study whether or under what conditions DTC advertising might meet the statutory requirements of the Federal Food, Drug, and Cosmetic Act (the act). The Act focuses on labeling and does not specifically define “advertising.” However, under the act the definition of labeling includes all ‘written, printed, or graphic’ materials accompanying the regulated product. Moreover, the Supreme Court has upheld FDA interpretation that this definition is not limited to physical accompaniment (*Kordel. vs. United States*). Consequently, under this interpretation, the FDA has regulatory authority over the advertisements for prescription drugs. As part of this authority under this interpretation of the Act, the FDA requires that advertisements must contain “other information in brief summary relating to side effects, contraindications, and effectiveness.”⁸ In practice, this requirement is fulfilled by including the sections of the approved labeling that discusses the product’s adverse event profile, contraindications, warnings and precautions. Failure to disclose these facts would cause the product to be misbranded.

After two years, in 1985 the FDA withdrew their request for the voluntary moratorium, but simultaneously imposed significant restrictions on DTC advertising. In particular, the FDA required

⁸ 21 U.S.C. 352(n).

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.⁹ 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 would have 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 issued a notice of public hearing and request for comments on the regulation of DTC advertisements.¹⁰ Following this public hearing and the receipt of public comments the FDA, on August 12th, 1997 issued draft guidance for industry with respect to DTC advertising.¹¹ The intended purpose of this guidance was to "enable product 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

⁹ Section 202.1(e)(5)ii of the Federal Food, Drug and Cosmetic Act.

¹⁰ See Department of Health and Human Services: Docket No. 95N-0227

¹¹ 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.

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. The 1999 draft guidance was amended slightly in 1999.

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

Further regulatory changes may be in the air. The FDA is again reviewing its regulatory approach to DTC advertising, and is expected to issue new guidelines by the end of 2003. The FDA review process includes 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 suggest that the FDA should drop its requirement that pharmaceutical print advertisements included 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.

III. Data

We use two main sources of data on DTC advertising of smoking cessation products. 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. Only quarterly data are available from 1986-1988, while monthly expenditure data are available thereafter. We use the entire series for descriptive purposes in the next section, but our econometric analysis uses monthly data from January 1989 to December 2002. The Consumer Price Index is used to express the expenditure data in constant 2002 \$.

The second main source of data is our unique archive of pharmaceutical product DTC advertisements in the print media. The Smoking Cessation Advertisements (SCADS) Archive includes digitally extracted images of advertisements for smoking cessation products, smoking products, and smoking-related public service announcements. Our analysis uses all advertisements that appeared in any issue of 12 consumer magazines and two medical journals between January 1985 and May 2002, yielding a sample of 7,339 issues. Each advertisement is coded with the brand and manufacturer name (or sponsor of a public service announcement), the length of advertisement, and other characteristics (e.g. color versus black/white). The SCADS Archive is discussed in more detail in the Data Appendix.

IV. An Overview of Smoking Cessation Product Advertising

Broad Trends in Smoking Cessation Product Advertising

Figure 1 shows trends in total expenditures on smoking cessation product advertisements from 1984 to 2002. Advertising expenditures are fairly low from 1984 through 1991, after which advertising expenditures spiked up to about \$100 million, driven by the 1992 introduction and intensive marketing of the nicotine patch. After returning to lower levels, beginning around 1995 advertising expenditures increase again. The 1995-1999 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 bupropion), and the conversion of older products from prescription-only to OTC status. Total advertising expenditures hit about \$200 million at their peak in 1999. In addition, although not shown in Figure 1, it should be noted 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 somewhat.

Figure 2 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 number of pages of archived advertisements. 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, because we only have a sample of all magazines, our archive does not contain any of these advertisement. For most of the period and most of the products, however, the SCADS archive appears to be reasonably representative of the universe of all smoking cessation product advertisements in magazines.

Cigarette Industry Advertising and Public Sector Anti-Smoking Campaigns

An advertisement for a specific smoking cessation product may appear in the same magazine not only with advertisements for its competitors' products, but with advertisements for products that are its anti-thesis – cigarettes. At the same time, public service anti-smoking campaigns may reinforce the advertising of smoking cessation products. So to place the advertising of smoking cessation products in its broader context, we turn now to a brief discussion of trends in cigarette industry advertising and public sector campaigns.

Current advertising and promotion practices of the cigarette industry are driven in part by regulations adopted long before the period we study. In the 1950s, the U.S. Federal Trade Commission began to regulate cigarette advertising by issuing cease-and-desist orders against false and misleading health claims. Industry-wide cigarette advertising guidelines were enacted in 1955;

additional regulations followed the 1964 Surgeon General's report; and eventually a ban on broadcast-media advertising became effective in 1971.

Figure 3 shows the trends in cigarette industry's expenditures on advertising from 1984 to 2001. The data are from the Federal Trade Commission (2003). Over this period, total expenditures on advertising and promotion have increased from \$2 billion to over \$11 billion, apparently dwarfing expenditures on advertisements for smoking cessation products. However, the composition of expenditures has shifted away from advertisements, towards promotional activities. By 2001, promotional allowances paid to retailers account for 40 percent of total expenditures on advertising and promotion, and retail value added promotions (e.g. 'buy one, get one free') account for another 42 percent. Cigarette industry expenditures on actual newspaper, magazine, outdoor and transit advertisements have been dropping in recent years. In 2001 cigarette industry advertising expenditures totaled a little over \$200 million in 2001, on the same order of magnitude as the pharmaceutical industry's expenditures on smoking cessation product advertisements. However, the industry spent another \$284 million on point-of-sale cigarette advertisements.

The impact of cigarette advertising and promotion on the market for smoking cessation products is very difficult to determine. There is a long-standing debate about whether advertising in general, and cigarette advertising in particular, expands the total size of the market, or instead just affects market shares. After reviewing the extensive research on cigarette industry advertising, Chaloupka and Warner (2000,p. 1593) conclude that "Clearly, there is no 'smoking gun' that proves that advertising and promotion play a significant role in expanding or maintaining the market for tobacco products, or that they do not." Thus it remains an open question whether, as Warner (1986) suggests,

cigarette advertising and promotion reduce current smokers' willingness to quit, or even induces former smokers to resume their habit.

In addition to industry advertising, smokers face significant counter-advertising anti-smoking campaigns at both the state and national level. Figure 4 shows the trend in states' expenditures on tobacco control activities from 1984 to 2002. Although negligible in the early part of our study period, state tobacco control programs have grown enormously and now may be on par with, or even exceed, the pharmaceutical industry's expenditures on smoking cessation product advertisements. In the late 1980s, states' expenditures on tobacco control totaled between \$2 to \$3 million annually. During the 1990s, however, major programs were put into place in a number of states including California, Massachusetts, Arizona, Oregon, Maine, Mississippi and Florida (CDC 2001). Total state expenditures jumped from \$2.5 million in 1989 to \$180 million in 1990. The late 1990s saw further increases, to \$472 million in 2000. The 1998 Master Settlement Agreement (MSA) with the tobacco industry provided another stimulus to state anti-smoking campaigns, in the form of the settlement payments. Gross *et al.* (2002) point out of the \$6.5 billion of funds received in 2001 by the states as part of the MSA, only 6 percent were devoted to tobacco control. However, even this small share of the settlement funds represents a large increase in state tobacco control program expenditures, which increased to \$950 million in 2001 and \$864 million in 2002.¹²

¹²Centers for Disease Control and Prevention, State Tobacco Activities Tracking and Evaluation System. Data for 2002 expenditures in Arizona and Massachusetts were unavailable as of December 11, 2003. In 2001, expenditures on tobacco control in Arizona and Massachusetts were \$37 million and \$63 million, respectively. If these levels were maintained in 2002, the total expenditures across all states would be \$964 million.

The levels of state expenditures shown in Figure 4 may be somewhat misleading, because state programs include components such as school-based prevention activities that may not be very relevant to the market for smoking cessation products. Unfortunately, systematic information on the composition of state tobacco control expenditures is not available, so it is not clear how much states spend annually on the most relevant components including mass media campaigns and smoking cessation activities. Biener, Harris and Hamilton (2000) summarize the allocation of expenditures in the Massachusetts program, which may be illustrative, especially because it tended to serve as a model for subsequent state programs. In Massachusetts, about one third of the annual expenditures were spent on the mass media anti-smoking campaign. Massachusetts also provided extensive services to help smokers quit, and these services accounted for another 40 percent of annual expenditures. The CDC (2001) emphasize nine components of comprehensive tobacco control programs; the CDC funding guidelines imply that about 20 percent of the recommended budget should be spent on counter-advertising and perhaps another 20 percent on services to help smokers quit. If actual state allocations are in the same ballpark, it suggests that by 2000 - 2002 state expenditures on tobacco control activities that contribute to smoking cessation probably exceeded the pharmaceutical industry's expenditures on smoking cessation product advertisements.

The MSA stimulated tobacco control campaigns at the national level as well as the state level. It created the American Legacy Foundation, which is spending approximately \$100 million annually on counter-advertisements known as the *truth* campaign. In addition, in the new environment cigarette manufacturers are publicly against youth smoking: Philip Morris's youth smoking prevention department has an annual budget of about \$100 million; and Lorillard has committed more than \$55

million since it launched its program in 1999.¹³ However, the American Legacy Foundation campaign and the industry campaigns are primarily aimed at youth smoking, and so are probably less relevant to the market for smoking cessation products.

It should also be noted that many significant developments in public service anti-smoking efforts at the national level either preceded or took place very early in the period we study. A series of econometric studies suggest that health information ‘shocks’ such as the 1964 Surgeon General’s Report decreased cigarette demand (Hamilton 1972, Lewit, Coate and Grossman 1981, Schneider, Klein and Murphy 1981, Blaine and Reed 1994). However, by the mid-1980s information about the health consequences of smoking was becoming fairly widely disseminated in the U.S. (Kenkel and Shin 1999). In 1985, cigarette packages and advertisements were required to carry one of four rotating warning labels, including one that stated: “Quitting smoking now greatly reduces serious risks to your health.” This was followed in 1990 by the publication of a Surgeon General’s Report titled *The Health Benefits of Smoking Cessation*. In these ways, public sector anti-smoking efforts helped create an environment generally supportive of smoking cessation, and of course the efforts were stepped up after the 1998 MSA.

V. Econometric Model of Advertising Choices and Hypotheses to be Tested

¹³The policy statements and expenditure amounts are from the Philip Morris and Lorillard websites. Beginning in 2001, the Federal Trade Commission began requiring major cigarette manufacturers to report expenditures on advertisements to reduce youth smoking. For 2001 manufacturers reported spending a total of \$79.4 million on such advertising (Federal Trade Commission 2003). Of course, given the industry’s history and its profit incentives, it is reasonable to question the sincerity of the current youth smoking prevention policies and efforts. Farrelly *et al.* (2002) provide evidence that the American Legacy Foundation’s *truth* campaign is more effective than Philip Morris’ ‘Think. Don’t Smoke’ campaign.

Our econometric model is designed 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 advertising goodwill or brand image (Roberts and Samuelson 1988, Chintagunta and Vilcassim 1994, Lee 2002). In the case of smoking cessation products, the stock of advertising good will 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, implicitly define the firm's input demand function for advertising. The simplest version of our econometric model is 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:

$$(1) \quad \text{Advertising}_{pmt} = \alpha_0 + \alpha_1 \text{OTC Status}_{pt} + \alpha_2 \text{Post 1997}_t + \alpha_3 \text{Introductory Period}_{pt} + \alpha_4 \\ \text{Date first approved for sale}_{pt} + \alpha_5 \text{Number of Products}_t + \alpha_6 \text{Cigarette advertisements}_{pmt} + \\ \alpha_7 \text{PSAs}_{pmt} + e_{pmt}$$

In our empirical analysis we estimate three different versions of equation (1) corresponding to different measures of Advertising: (i) expenditures on advertising for product p during month t; (ii) the

number of print media advertisements for product p in magazine m during month t ; (iii) the number of pages of print media advertisements for product p in magazine m during month t .¹⁴ To estimate model (i) we “stack” observations of advertising expenditures for each product currently on the market that appear in three different media – print, broadcast, and billboard. We include on the right hand side additional dummy variables to control for media type.¹⁵ This provides a sample size of 2849 observations for the model of advertising expenditures from 1989-2002. Note that we do not have expenditures by magazine, so the m subscripts do not appear in model (i)’s version of equation (1). In models (ii) and (iii), we use observations of whether a product that is currently on the market is advertised in a specific issue of each magazine in the archive from 1985-2002. The SCADS archive of 7,339 issues therefore yields an estimation sample of 32,186 observations.

In this preliminary analysis, all models are estimated by ordinary least squares. The dependent variables for models (ii) and (iii) 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

¹⁴In models (ii) and (iii), 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.

¹⁵In principle, demand for print and broadcast media advertising could be estimated as a system of input demand equations (similar to the approach taken by Silk, Klein and Berndt, 2002). We rely on single equation methods, but as will be discussed below we include variables intended to capture both own-price and cross-price effects on the demand for advertisements.

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 rely on ordinary least squares for this preliminary analysis; future work will explore alternative count data models discussed by Mullahy (1997) and Wooldridge (2002).

Turning to the explanatory variables and hypotheses to be tested, our approach exploits variation in the costs of advertising over time and across products created by the regulatory environment.¹⁶ These are captured by two variables. The first regulatory variable, $OTC\ Status_{pt}$, indicates if product p at time t is available over-the-counter, as opposed to by prescription only. OTC advertising is less regulated and hence less costly, so this variable is hypothesized to have an own-price effect on the quantity demanded of print media advertisements. The second regulatory variable, $Post\ 1997_t$, indicates if the observed advertisement occurs after the FDA 1997 regulatory change. This change reduced the cost of DTC television advertisements, so the hypothesized own-price effect is to increase firms’ demand for broadcast media advertising. The cross-price effects of OTC status on the demand for broadcast advertising and of the 1997 regulatory change on the demand for print media

¹⁶A standard specification of an advertising demand function would include a measure of the price of advertising space or time as a key explanatory variable. This is problematic in our study for several reasons. Magazines with larger circulation (reach) can charge higher prices for advertisements. In the data, high price advertisements cost more but reach more readers, and so there is an ambiguous relationship between advertising prices and advertising demand. We are collecting detailed information on each magazine’s demographics, so in future work we will be able to more precisely measure the magazine’s reach in terms of readers who smoke. This may allow us to identify a standard price effect in the advertising demand function.

advertising are difficult to sign *a priori*. Although it might be natural to assume broadcast and print media advertisements are substitutes, in the current regulatory environment they may be complements. Advertisements of prescription products on television are required to refer the customer to a print advertisement – where the full disclosure continues to be required.

Equation (1) also includes measures of the market environment that may affect firms' demand for advertisements. Marketing research suggests that the returns to advertising vary over a product's life cycle. We include a variable that indicates each product's introductory period, defined as the three months following the first introduction of the product. We also include the date when each product was first approved for sale, which is inversely related to the product's "age" on the market. To capture the potential effect between brand competition and the returns to advertising, we include the number of smoking cessation products on the market at time t . The conventional wisdom is "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). 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 moderately concentrated industry. Accordingly, we hypothesize that the demand for advertising will increase with the number of products on the market.¹⁷ Finally, the market environment

¹⁷In 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

for smoking cessation products may be influenced by cigarette industry advertising and public service anti-smoking campaigns.

We also begin to exploit the richness of our archived data on print media advertisements to estimate an extended version of equation (1). This version shows the demand for advertising in a specific magazine as a function of attributes of the magazine's readership:

$$(2) \quad \text{Number/ Pages of Ads}_{pmt} = \alpha_0 + \alpha_1 \text{ OTC Status}_{pt} + \alpha_2 \text{ Post 1997}_t + \alpha_3 \text{ Introductory Period}_{pt} + \alpha_4 \text{ Date first approved for sale}_{pt} + \alpha_5 \text{ Number of Products}_t + \alpha_6 \text{ Cigarette advertisements}_{pmt} + \alpha_7 \text{ PSAs}_{pmt} + \alpha_8 \text{ Medical journal}_m + \alpha_9 \text{ Jet/Ebony}_m + \alpha_{10} \text{ Modern Maturity}_m + \alpha_{11} \text{ OTC Status}_{pmt} * \text{Medial journal}_m + \alpha_{12} \text{ OTC Status}_{pmt} * \text{JetEbony}_m + e_{pmt}$$

In addition to providing a richer description of advertising behavior, estimation of equation (2) allows us to test additional hypotheses (discussed below) about the impact of the regulatory environment on advertising choices.

VI. Econometric Results

Tables 2 and 3 present estimates of the determinants of the demand for advertising by manufacturers of pharmaceutical smoking cessation products. The results suggest that FDA regulation of whether a product is available by prescription-only or OTC has a substantial influence on firms' advertising decisions. From the first column in Table 2, OTC status is associated with a large increase

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.

in advertising expenditures. The second column of Table 2 presents the results from a model that includes an interaction term between OTC status and the dummy variable indicating television expenditures. The large positive coefficient on the interaction term, and the insignificant coefficient on the main OTC effect, suggest that when a product becomes available OTC, manufacturers increase expenditures on television advertising while maintaining the level of expenditures on print advertising. This pattern tends to be confirmed in Table 3's models of the number and pages of print advertisements. OTC status is associated with an increase in the number of print advertisements, but an offsetting decrease in the pages of advertisements. It appears that when OTC status eliminates the extra page required to meet the disclosure requirement, manufacturers compensate by increasing the number of advertisements, while keeping total expenditures on print advertising roughly constant.

In addition to the own- and cross-price effects, OTC status may have additional indirect effects on firms' demand for advertising, if OTC status stimulates consumer demand for the product. This could occur because the product cost to consumers of reacting to the advertising is lower once it is OTC (the consumer does not need to see a physician). In addition, because firms are no longer required to disclose the side effects of the drug in such a prominent fashion more consumers might purchase the product in response to the advertisement.¹⁸ By increasing consumer demand, OTC status

¹⁸ Whether the disclosure discourages consumption is an interesting question. On the one hand if consumers over-react to low probability side effects the disclosures can be counter-productive. On the other hand, if the disclosures assist consumers in making informed choices the lack of disclosures could lead to over-consumption. Wosinska (2002) finds that patients who start on anti-hyperlipidemic drug therapy following high levels of category advertising are more compliant. However, advertising for a specific brand decreases compliance among patients using that brand, suggesting that patients pay attention to disclosures only for the brand they are taking.

is expected to increase the returns on all types of advertising. The results in Tables 2 and 3 are broadly consistent with this prediction.¹⁹

The results for equation (2), also reported in Table 3, further explore the role of OTC status on advertising decisions. The key results are the estimated coefficients on the interaction terms between OTC status and magazine readership (medical, African-American, or older). Not surprisingly, when a product becomes available OTC, manufacturers reduce the number and pages of advertisements for that product in medical journals. OTC status also seems to be associated with fewer advertisements in the magazines with predominantly African-American readership (Jet and Ebony), and in the magazine with an older readership (Modern Maturity). These results shed additional light on whether OTC status increases advertising through its direct effect of lowering the cost of advertising, or through indirect effects because OTC status makes it easier for consumers to respond to advertisements. The indirect effects of OTC status should be larger for African-Americans and older adults, because their lower incomes and poorer health insurance limit their access to prescription drugs. This suggests that OTC status could be expected to have a disproportionately positive impact on advertisements that reach these two groups. The estimated results contradict this implication: if anything, OTC status

¹⁹In the presence of health insurance, a switch to OTC can have more ambiguous effects on the return to advertising. As discussed above in footnote 7, because of differential insurance coverage, consumers' out-of-pocket costs may actually be lower 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, as discussed above in footnote 7, health insurance coverage of prescription drugs for smoking cessation was uncommon, and evidence suggests that the switch of these drugs to OTC status shifted the demand curve out.

reduces advertisements in Jet, Ebony, and Modern Maturity.

The results in Tables 2 and 3 do not provide consistent evidence of a strong impact of the 1997 regulatory change, when the FDA relaxed its requirements on DTC advertisements in broadcast media. Somewhat surprisingly, the results in Table 2 do not suggest this regulatory change increased advertising expenditures. The results in Table 3 tend to suggest that the number and length of print media advertisements may have fallen after 1997. However, there is some evidence of multicollinearity between some of the explanatory variables in the models, suggesting that it may be difficult to separately identify the impact of the 1997 regulatory change from the impacts of the other changes in the market for smoking cessation products.

The results in Tables 2 and 3 suggest a number of other aspects of the market environment are important determinants of advertising decisions. First, there appears to be a large introduction effect. That is, the period in which the product is introduced is accompanied by an increase in advertising expenditures and large increases in the number and pages of advertisements for the product. Second, the product's age, which is inversely related to the date it was first approved for sale, is associated with increased advertising expenditures and increases in the number and pages of advertisements. This is consistent with a first-mover effect, where the older products, with more market share, see higher returns to advertising. Third, more competition, as measured by the number of products on the market, also increases advertising expenditures and the number and pages of advertisements. Finally, the number of cigarette advertisements that appear in the same issue of the magazine are associated with more advertisements for smoking cessation products. This probably reflects the fact that both advertisers are trying to reach the same audience – smokers – even though the intended impact of the

two types of advertisements are diametrically opposed.

VII. Conclusion

Our preliminary results provide fairly consistent evidence that a switch to OTC status is associated with increased advertising on smoking cessation products. This evidence sheds new light on the FTC's recent (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 this could result in a substantial increase in DTC advertising of pharmaceuticals.

Of course, there are different views of whether a substantial increase in 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 conditions they do not suffer from. There does not seem to be much of a chance of non-smokers mis-diagnosing themselves as smokers.²⁰ 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). De-regulating their

²⁰There 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.

advertising has the potential to help make further increases in smoking cessation, improving public health. In future work, we will explore the impact of advertisement exposure on smoking cessation, which will allow us to quantify these public health benefits.

References

- Berndt, Ernst R., Linda Bui, David R. Reiley, and Glen L. Urban (1995). "Information, Marketing, and Pricing in the U.S. Antiulcer Drug Market." *American Economic Review Papers and Proceedings* 85 (2): 100 - 105.
- Biener, Lois, Jeffrey E. Harris, and William Hamilton (2000). "Impact of the Massachusetts Tobacco Control Programme: Population Based Trend Analysis." *British Medical Journal* 321 (5): 351-354.
- Blaine, Thomas W and Michael R. Reed (1994). "U.S. Cigarette Smoking and Health Warnings: New Evidence from Post World War II Data." *Journal of Agricultural and Applied Economics*, 26 (2):535-544.
- Bulow, Jeremy and Peter Klemperer (1998). "The Tobacco Deal." *Brookings Papers on Economic Activity: Microeconomics*, 323-394.
- Burton, SL, and others (1997). "Impact of Promotion of the Great American Smokeout and Availability of Over-the-Counter Nicotine Medications, 1996." *Morbidity and Mortality Weekly Report* 46 (37): 867 - 869.
- Calfee, John E. (2002). "Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs." *Journal of Public Policy and Marketing* 174-194.
- Centers for Disease Control and Prevention [CDC]. (2001). *Investment in Tobacco Control: State Highlights 2001*. U.S. Department of Health and Human Services.
- Chaloupka, Frank J. and Kenneth Warner (2000). "The Economics of Smoking." *Handbook of Health Economics*, Joseph Newhouse and Anthony Culyer, Editors. (North-Holland)

- Chintagunta, Pradeep K. and Naufel J. Vilcassim (1994). "Marketing Investment Decisions in a Dynamic Duopoly: A Model and Empirical Analysis." *International Journal of Research in Marketing* 11: 287-306.
- Danzon, Patricia M. and Mark V. Pauly (2002). "Health Insurance and the Growth in Pharmaceutical Expenditures." *Journal of Law and Economics*, XLV.
- DiClemente, C.C., et al. (1991). "The Process of Smoking Cessation: An Analysis of Precontemplation, Contemplation, and Preparation Stages of Change." *Journal of Consulting and Clinical Psychology* 59 (2): 295-304.
- Farrelly, Matthew C., and others (2002). "Getting to the Truth: Evaluation National Tobacco Countermarketing Campaigns." *American Journal of Public Health* 92 (6): 901-907.
- Federal Trade Commission (2003). *Cigarette Report for 2001*.
- Fiore, M.C., S. Smith, D. Jorenby and T. Baker (1994). "The Effectiveness of the Nicotine Patch For Smoking Cessation: A Meta-Analysis." *Journal of the American Medical Association* 271 (24):1940-1947.
- Flay, B.R. (1987). "Mass media and smoking cessation: A critical review." *American Journal of Public Health*, 77(2), 153-60.
- Gallet, Craig A., and John A. List (2003). "Cigarette Demand: A Meta-Analysis of Elasticities." *Health Economics* 12: 821-835.
- Geweke, John and Donald L. Martin (2002). "Pitfalls in Drawing Policy Conclusions from Retrospective Survey Data: The Case of Advertising and Underage Smoking." *Journal of Risk and Uncertainty* 25 (2): 111-131.

- Gross, Cary P., and others (2002). "State Expenditures for Tobacco-Control Programs and the Tobacco Settlement." *New England Journal of Medicine* 347 (14): 1080-1086.
- Gruber, Jonathan (2001). "Tobacco at the Crossroads: The Past and Future of Smoking Regulation in the United States." *Journal of Economic Perspectives* 15 (2): 193-212.
- Hamilton, J.L. (1972). "The Demand for Cigarettes: Advertising, the Health Scare, and the Cigarette Advertising Ban." *Review of Economics and Statistics* 54: 401-411.
- Hays, Taylor J., Ivana T. Croghan, Darrell R. Schroeder, Kenneth P. Offord, Richard D. Hurt, Troy D. Wolter, Mitchell A. Nides and Michael Davidson (1999). "Over-The Counter Nicotine Patch Therapy for Smoking Cessation: Results From Randomized, Double-Blind, Placebo-Controlled, and Open Label Trials." *American Journal of Public Health* 89 (11): 1701-1707.
- Hu, Teh-Wei, Hai-Yen Sung, Theodore E. Keeler and Martin Marciniak (2000). "Cigarette Consumption and Sales of Nicotine Replacement Products." *Tobacco Control* 9:60-63.
- Hughes, John R. (2000). "New Treatments for Smoking Cessation." *CA Cancer Journal for Clinicians* 50 (3): 143-151.
- Hughes, John R., S. Schiffman, P. Callas, and J. Zhang (2003). "A Meta-Analysis of the Efficacy of Over-the-Counter Nicotine Replacement," *Tobacco Control* 12: 21 - 27.
- Ippolito, Pauline M. and Alan Mathios (1990) "Information, Advertising and Health Choices: A Study of the Cereal Market." *RAND Journal of Economics* 21 (3):459-480.
- Ippolito, P., and Mathios, A., (1991) "Health Claims in Food Marketing: Evidence on Knowledge and Behavior in the Cereal Market," *Journal of Public Policy and Marketing*, 10(1):15-32,

Spring.

Ippolito, P. and Mathios, A., (1995) "Information and Advertising: The Case of Fat Consumption in the United States," *American Economic Review: Papers and Proceedings*, 85 (2) May.

Iizuka, Toshiaki and Ginger Z. Jin (2002). "The Effects of Direct-to-Consumer Advertising in the Prescription Drug Market." Working Paper.

Keeler, Theodore E., Teh-wei Hu, Allison Keith, Richard Manning, Martin Marciniak, M. Ong, and Hai-yen Sung (2002). "The Benefits of Switching Smoking Cessation Drugs to Over-the-Counter Status." *Health Economics* 11 (5): 389-402.

Keith, Alison (1995). "Regulating Information About Aspirin and the Prevention of Heart Attack." *American Economic Review Papers and Proceedings* 85 (2): 96-99.

Kenkel, Donald S. and Likwang Chen (2000). "Consumer Information and Tobacco Use". In Jha P and FJ Chaloupka, Editors. *Tobacco Control in Developing Countries*. Oxford University Press, 2000, pp. 177-214.

Lee, Chang-Yang (2002). "Advertising, Its Determinants, and Market Structure." *Review of Industrial Organization* 21: 89-101.

Lewit, Eugene, Douglas Coate and Michael Grossman (1981). "The Effects of Government Regulation on Teenage Smoking." *Journal of Law and Economics*, 24 (3): 545-69.

Ling, Davina C., Ernst R. Berndt, and Margaret K. Kyle (2002). "Deregulating Direct-to-Consumer Marketing of Prescription Drugs: Effects on Prescription and Over-the-Counter Product Sales." *Journal of Law and Economics*, XLV.

Mathios, Alan, (1996) "Socioeconomic Factors, Nutrition, and Food Choices: An Analysis of the

- Salad Dressing Market,"*Journal of Public Policy and Marketing*, 15 (1).
- Mathios, Alan, (1998) "The Importance of Nutrition Labeling and Health Claim Regulations on Product Choice: An Analysis of the Cooking Oil Market," *Agricultural and Resource Economics Review*.
- Mathios, Alan, (2000) "The Impact of Mandatory Disclosure Laws on Product Choices: An Analysis of the Salad Dressing Market," *Journal of Law and Economics*, 43 (2), October.
- McPhillips-Tangrum, C. (1998). Results from the first annual survey on addressing tobacco in managed care. *Tobacco Control* 7:S11-S13, 1998.
- Mendez, David and Kenneth E. Warner (2000). "Smoking Prevalence in 2010: Why the Healthy People Goal is Unattainable." *American Journal of Public Health* 90: 401-403.
- Mintzes, Barbara (2001). *An Assessment of the Health System Impacts of Direct-to-Consumer Advertising of Prescription Medicines*. Health Policy Research Unit, Centre for Health Services & Policy Research, University of British Columbia.
- Mintzes, Barbara (2002). *Journal of Public Policy and Marketing*
- Mullahy, John (1997). "Heterogeneity, Excess Zeros, and the Structure of Count Data Models." *Journal of Applied Econometrics* 12: 337-350.
- National Center for Health Statistics (2001). *Healthy People 2000 Final Review*. Hyattsville, Maryland: Public Health Service.
- Nelson, Jon P. (2003). "Cigarette Demand, Structural Change, and Advertising Bans: International Evidence, 1970-1995", *Contributions to Economic Analysis & Policy* Vol. 2: No. 1, Article 10.

- Pierce, J.P., Won S. Choi, Elizabeth Gilpin, Arthur Farkas, and Charles Berry (1998). "Tobacco Industry Promotion of Cigarettes and Adolescent Smoking," *JAMA* 279: 511-515.
- Prochaska J O and C C DiClemente (1983). "Stages and Process of Self-change of Smoking: Toward an Integrative Model of Change." *Journal of Consulting and Clinical Psychology* 51 (3): 390-395.
- Roberts, Mark J. and Larry Samuelson (1988). "An Empirical Analysis of Dynamic, Nonprice Competition in an Oligopolistic Industry." *RAND Journal of Economics* 19 (2): 200 - 220.
- Rosenthal, Meredith B., Ernst R. Berndt, Julie M. Donohue, Richard G. Frank, and Arnold M. Epstein (2002). "Promotion of Prescription Drugs to Consumers," *New England Journal of Medicine* 346 (7): 498 - 505.
- Rosenthal, Meredith B., Ernst R. Berndt, Julie M. Donohue, Arnold M. Epstein, and Richard G. Frank (2003). "Demand Effects of Recent Changes in Prescription Drug Promotion." In *Frontiers in Health Policy Research*, Vol. 6, edited by Alan M. Garber and David M. Cutler. Cambridge, Mass.: MIT Press (for National Bureau of Economic Research).
- Saffer, Henry and Frank Chaloupka (2000). "The Effects of Tobacco Advertising Bans on Tobacco Consumption." *Journal of Health Economics* 19 (6): 1117- 1137.
- Schmalensee, R. (1983). "Advertising and Entry Deterrence: An Exploratory Model." *Journal of Political Economy* 91: 636-653.
- Schoenborn, Charlotte A, Jackline L. Vickerie, and Patricia M Barnes (2003). "Cigarette Smoking Behavior of Adults: United States 1997-98," *Advance Data from Vital and Health Statistics* Number 331, February 7.

- Schneider, Lynne, Benjamin Klein, and Kevin M. Murphy (1981). "Governmental Regulation of Cigarette Health Information." *Journal of Law and Economics* 24 (3):575-612.
- Schwartz, Jerome L. (1987). *Review and Evaluation of Smoking Cessation Methods: The United States and Canada, 1978-1985*. Published by Division of Cancer Prevention and Control, National Cancer Institute, U.S. Department of Health and Human Services. NIH Publication No. 87-2940.
- Scott Morton, Fiona M. (2000). "Barriers to Entry, Brand Advertising, and Generic Entry in the US Pharmaceutical Industry." *International Journal of Industrial Organization* 18: 1085-1104.
- Shiffman, Saul, Joe Gitchell, John M. Pinney, Steven L. Burton, Katherine E. Kemper, and Eduardo A. Lara (1997). "Public Health Benefit of Over-the-Counter Nicotine Medications." *Tobacco Control* 6: 306-310.
- Silk, Alvin J., Lisa R. Klein, and Ernst R. Berndt (2002). "Intermedia Substitutability and Market Demand by National Advertisers." *Review of Industrial Organization* 20: 323-348.
- Sloan, Frank A., V. Kerry Smith, and Donald H. Taylor, Jr. (2002). "Information, Addiction, and 'Bad Choices': Lessons from a Century of Cigarettes," *Economics Letters* 77: 147-155.
- Tauras, John A., and Frank Chaloupka (2001). "The Demand for Nicotine Replacement Therapies," NBER Working Paper 8332.
- U.S. Department of Health and Human Services [USDHHS]. 1989. *Reducing the Health Consequences of Smoking. 25 Years of Progress. A Report of the Surgeon General. 1989*. U.S. Department of Health and Human Service, Public Health Service, Centers for Disease Control, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and

Health.

U.S. Department of Health and Human Services [USDHHS] (2000a). *Reducing Tobacco Use: A Report of the Surgeon General*. . Atlanta, Georgia: U.S. Department of Health and Human Service, Public Health Service, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

U.S. Department of Health and Human Services [USDHHS] (2000b). *Healthy People 2010*. 2nd Edition. With Understanding and Improving Health and Objectives for Improving Health. 2 vols. Washington, DC: U.S. Government Printing Office.

U.S. Department of Health and Human Services [USDHHS] (2000c). *Clinical Practice Guideline: Treating Tobacco Use and Dependence*.

Warner, Kenneth E. (1986). *Selling Smoke: Cigarette Advertising and Public Health*. (American Public Health Association, Washington).

Wooldridge, Jeffrey M. (2002). *Econometric Analysis of Cross Section and Panel Data*. Cambridge, Massachusetts: The MIT Press.

Wosinska, Marta (2002). "Direct-to-Consumer Advertising and Therapy Compliance." Harvard Business School Working Paper.

Wosinska, Marta (2003). "Just What the Patient Ordered? Direct-to-Consumer Advertising and the Demand for Pharmaceutical Products." Harvard Business School Working Paper No. 03-058.

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 various newspaper and journal articles.

TABLE 2
OLS Models of DTC Advertising Expenditures

	-1	-2
OTC	483.24*** (6.89)	-79.58 (1.06)
OTC * TV	n.a.	1688.46*** (16.4)
Post 1997 Regulations	-26.96 (0.21)	-26.96 (0.22)
Introductory period	225.31* (1.83)	225.31* (1.92)
Number of products on market	396.56*** (4.42)	396.56*** (4.6)
(Number of products on market) ^2	-18.46** (2.10)	-18.46** (2.20)
Date first approved for sale	-34.482*** (4.57)	-34.482*** (4.78)
Time trend	-102.66*** (3.62)	-102.66*** (3.78)
Cigarette print advertisements	0.0003 (0.13)	0.0003 (0.13)
Cigarette billboard advertisements	0.01341*** (2.75)	0.01341*** (2.88)
Cigarette broadcast advertisements	0.07732** (2.11)	0.07732** (2.21)
Other print advertisements	1.937 (1.32)	1.937 (1.38)
Other billboard advertisements	2.352 (0.21)	2.352 (0.22)
Other broadcast advertisements	0.478* (1.92)	0.478* (2.00)
TV	645.102*** (10.62)	-17.838 (0.25)
Billboard	-353.914*** (5.83)	-353.914*** (6.10)
Dependent mean	451.08	451.08
R-squared	0.1396	0.2154

t-ratios in parenthesis

TABLE 3
OLS Models of DTC Advertisements in Print Media

	Number of Advertisements		Pages of Advertisements	
	-1	-2	-1	-2
OTC	0.00286 (0.59)	0.01261* (2.25)	-0.04587*** (4.27)	-0.03082* (2.48)
Post 1997 Regulations	-0.01936*** (3.87)	-0.02072*** (4.15)	-0.02094 (1.88)	-0.02511* (2.26)
Introductory period	0.188*** (18.55)	0.1883*** (18.63)	0.52505*** (23.28)	0.52608*** (23.41)
Number of products on market	3.79982*** (3.79)	3.82081*** (3.82)	3.90417 (1.75)	3.96848 (1.79)
Date first approved for sale	-1.887*** (3.75)	-1.89756*** (3.78)	-1.91155 (1.71)	-1.94380 (1.74)
Time trend	0.24705 (0.49)	0.55871 (1.11)	-0.97997 (0.87)	-0.02391 (0.02)
Cigarette advertisements	0.0006* (2.43)	0.00129*** (4.72)	-0.0003 (0.5)	
PSAs	-0.0029 (0.29)	-0.00233 (0.23)	-0.00957 (0.42)	
Medical journal		0.04905*** (10.61)		0.14118*** (13.74)
Medical journal * OTC		-0.02706* (2.41)		-0.08721*** (3.49)
Magazine w/ Af- American readership		-0.02602 (1.04)		-0.0211* (2.12)
A-A readership * OTC		-0.02602* (2.32)		-0.01165 (0.47)
Magazine with older readership		-0.0138* (2.25)		-0.02739* (2.01)
Older readership * OTC		-0.03251* (2.15)		-0.01973 (0.59)
Dependent mean	0.2691	0.2691	0.04881	0.04881
R-squared	0.0213	0.0258	0.0271	0.0342

t-ratios in parenthesis

FIGURE 1

Total Annual Advertising Expenditures on Smoking Cessation Products, 1986-2002

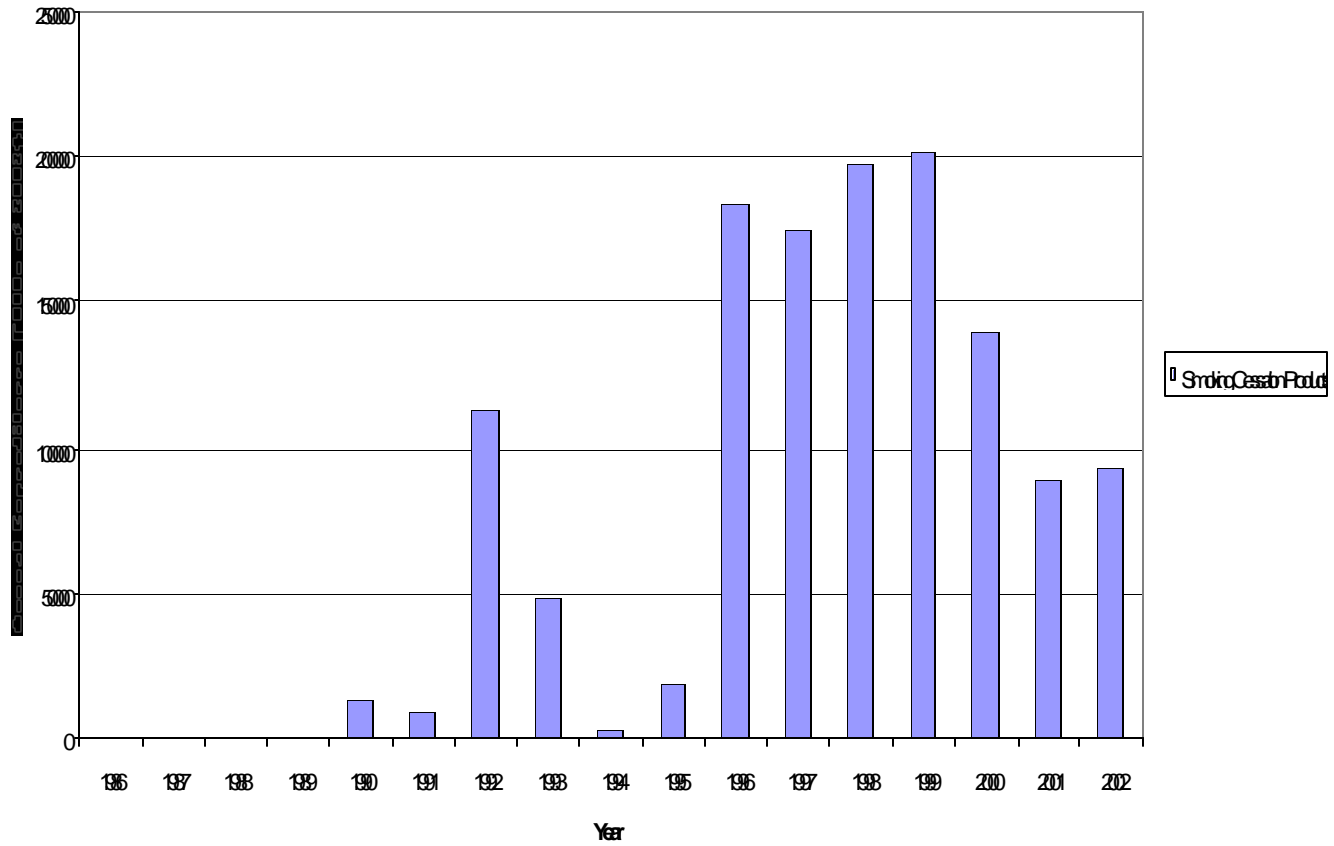
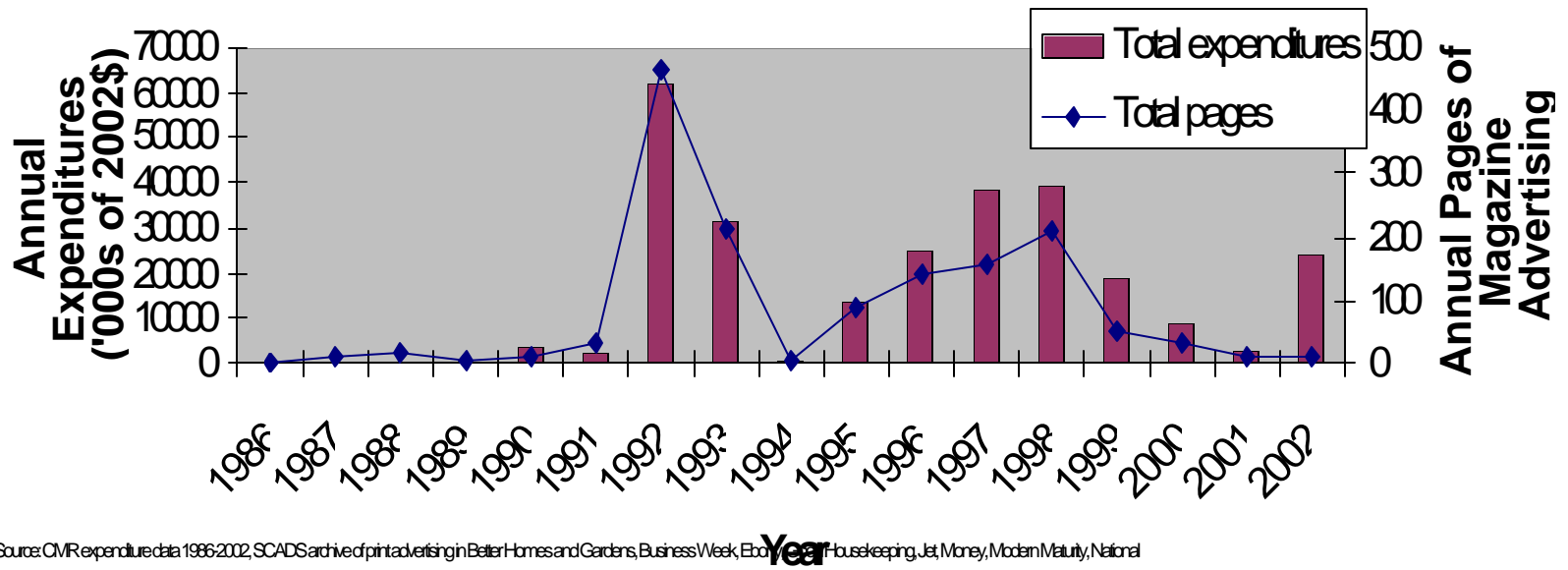


FIGURE 2

Annual Expenditures and Annual Pages of Print Advertising in 12 Selected Magazines in SCADS



Source: CMR expenditure data 1986-2002, SCADS archive of print advertising in Better Homes and Gardens, Business Week, Ebony, Esquire, Housekeeping, Jet, Money, Modern Maturity, National Geographic, Sports Illustrated, Time, TV Guide

FIGURE 3

Total Annual Advertising Expenditures on Tobacco Products, 1986-2002

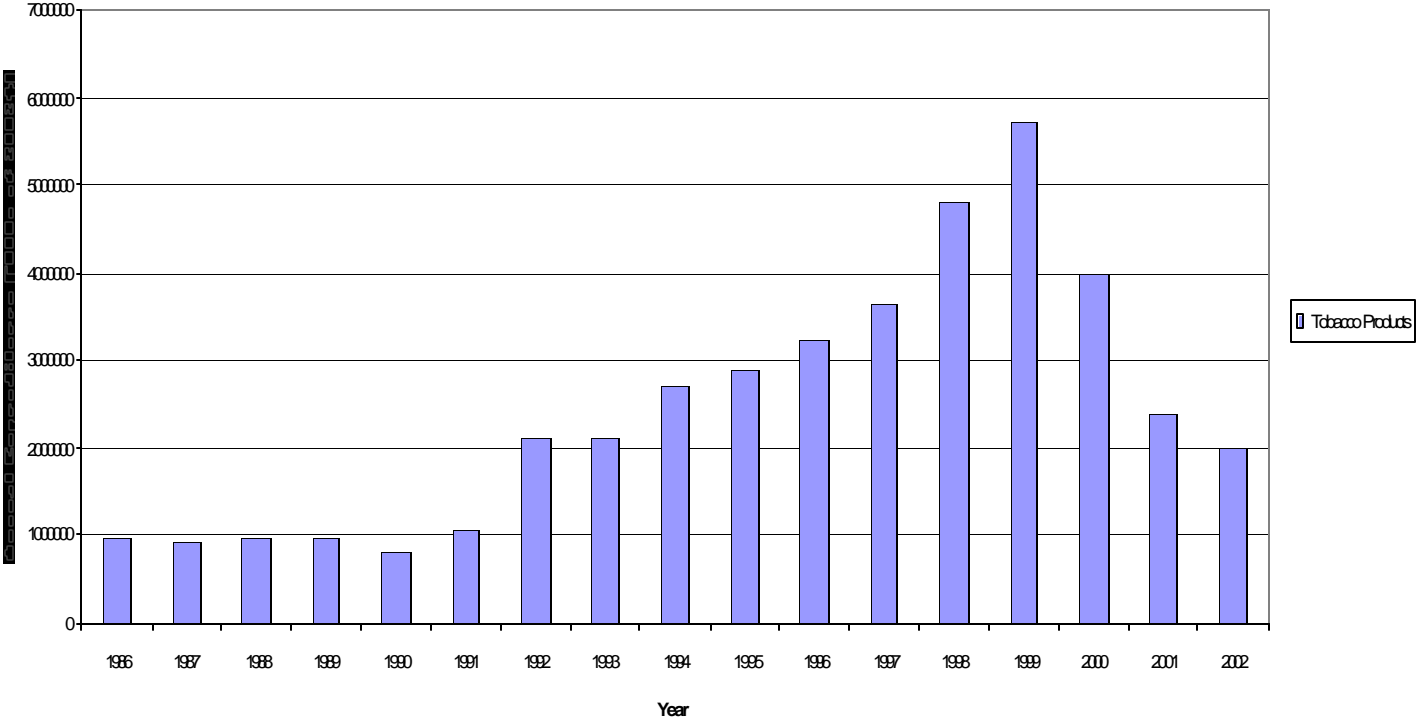
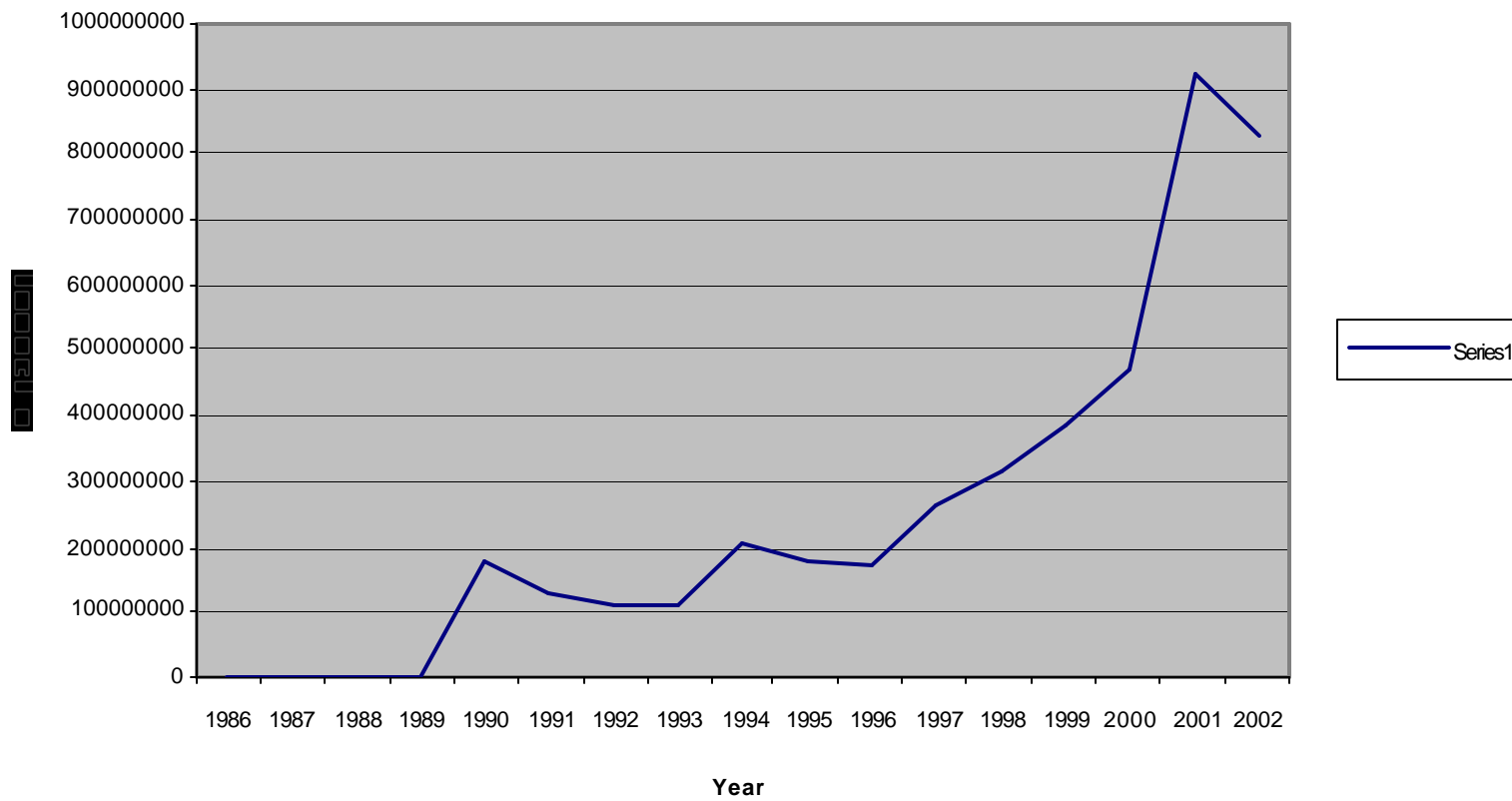


FIGURE 4

State Tobacco Control Expenditures, 1984 - 2002



DATA APPENDIX: The SCADS Archive

The original selection of magazine titles was based on whether the magazine was, in 1999, one of the top ten read magazines by any of the demographic groups of interest.²¹ The 1999 readership numbers are computed from the *National Consumer Survey of the Simmons Survey of Media and Markets: Choices III* (NCS). These data contain self reported information on which magazines each of approximately 20,000 consumers read. There are 182 magazines included in the sample. For each magazine respondents are asked whether they have read four of the last four issues (READ4), three of the last four issues (READ3), two of the last 4 issues (READ2), one of the last 4 issues (READ1) and less than one of the last 4 issues (READ0). We compute a readership for each respondent for each of the 182 magazines based on computing $READ4 + .75*READ3 + .5*READ2 + .25*READ1 + .125*READ0$. We then rank average readership scores for a variety of demographic groups and include in our content analysis the top 10 read magazines for each group. We chose the top 10 because of collection effort costs. Each magazine included in the sample adds, if it is a weekly over 600 issues to be coded. Moreover, because we are archiving all pharmaceutical advertisements (not only smoking cessation products) each magazine contributes potentially thousands of advertisements which must be identified, scanned and digitized and coded. At this point in the data collection effort we have completed enough of the magazines so that we span the magazines most often read by key demographic groups of interest.

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 29 of the top read magazines in the U.S. for the period January 1985 through May 2002 (17 years and 5 months). Twenty-seven 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.

At the time of writing this paper, 14 of the 29 magazines had been processed in the data base and are used in the analysis, 12 of these are consumer magazines and 2 are physician journals: Ebony, National

²¹ The *National Consumer Survey of the Simmons Survey of Media and Markets: Choices III* (NCS) employs a single-stage stratified probability sample, using random digit dialing methods to select households for participation.

Geographic, Better Homes & Gardens, Sports Illustrated, Readers Digest, Time, Money, Modern Maturity, Good Housekeeping, Jet, Business Week, and TV Guide, Journal of the American Medical Association, New England Journal of Medicine.

At the time of completion of the data collection effort the database will contain advertisements from approximately 13,497 issues of these magazines. The 14 magazines used in this analysis cover approximately 7,339 issues and include 565 advertisements for smoking cessation products. 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.