Court File No. 05-CV-303001PD2

ONTARIO
SUPERIOR COURT OF JUSTICE
(DIVISIONAL COURT)

BETWEEN:

CANWEST MEDIAWORKS INC.

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

AFFIDAVIT OF JULIE DONOHUE

I, Julie M. Donohue, of the City of Pittsburgh, in the State of Pennsylvania, in the United States of America, solemnly affirm that:

1. I am an assistant professor in the Department of Health Policy and Management, in the Graduate School of Public Health, at the University of Pittsburgh. This is a position I have held since 2004. I also have a faculty appointment in the Department of Psychiatry in the University of Pittsburgh, School of Medicine, and am affiliated with the Center for Bioethics and Health Law and the Center for Research on Health Care both at the University of Pittsburgh. I teach a course on health policy analysis for master's students in health administration and public health.

2. I received a Ph.D. in Health Policy from Harvard University and completed a post-doctoral fellowship in pharmaceutical policy research at Harvard Medical School.

discuss what is known about the determinants of spending on DTCA given its high concentration among relatively few products.

11. In the second part of my report, I will review the evidence of DTCA's impact on demand for prescription drugs from economic and marketing studies that have been conducted in several drug classes. These studies consistently show that, when DTCA has an effect, it is on increasing class sales or market size rather than shifting market share.

12. In the third part of my report, I will discuss the potential theoretical effects of DTCA on consumer welfare and public health. I will review the limited empirical and experimental evidence on the effects of DTCA on public health.

13. In the final part of my report, I will draw some conclusions on the policy implications of the evidence. My overall conclusion is that the evidence does not justify a ban on DTCA.

Introduction

14. It has been nearly 10 years since the U.S. Food and Drug Administration ("FDA") loosened the restrictions on broadcast advertising of prescription drugs. Spending on direct-to-consumer advertising of prescription drugs in the U.S. now exceeds $4 billion per year. While direct-to-consumer advertising (DTCA) represents a departure from traditional pharmaceutical marketing practices, which for decades were aimed solely at

influencing health professionals, it is consistent with recent efforts to provide consumers with more information on health care treatment and purchasing decisions.[1]

15. In spite of the dramatic increase in spending on DTCA in the U.S. it still makes up a small portion of total pharmaceutical promotional spending. Data suggests that DTCA is used for a small subset of prescription drugs that are newer, of high quality, with few therapeutic substitutes, that are used to treat undertreated conditions. Several studies have demonstrated that DTCA increases pharmaceutical sales, primarily by expanding the number of people receiving drug treatment. In some cases, evidence suggests this expanded use is appropriate and in other cases its appropriateness may be open to question. The ratio of benefit to cost resulting from DTCA is unknown and likely varies across drugs, depending on the safety of the drug and the severity of the treated condition. The goal of a regulatory regime overseeing DTCA of prescription drugs should be to maximize the potential benefits of DTCA while reducing the potential for harm.

Part 1: Spending on Direct-to-Consumer Advertising

16. Pharmaceutical manufacturers promote their products in several ways including visits from pharmaceutical sales representatives to office- and hospital-based physicians (known as "detailing" because the representative discusses the details of the drugs), distribution of free samples to physicians, educational meetings and events for physicians, advertising in medical journals, and most recently direct-to-consumer

[1] For historical perspective on the rise of direct-to-consumer advertising in the context of health care patient and consumer empowerment movements see Donohue J. A history of drug advertising: the evolving roles of consumers and consumer protection. *Milbank Quarterly* 84(4): 659-699, 2006.

advertising in television, radio, print media, and the internet. In this part of my report, I make two main points. First, as a percentage of total promotional expenditures, DTCA makes up a relatively small portion in spite of the dramatic increase in spending on this form of promotion in the late 1990s. The implication of this finding is that while the pharmaceutical industry views DTCA as an important form of promotion, it is not the primary means of promotion for most products. A second and related point is that DTCA spending is highly concentrated in a small number of brands for which it is viewed by pharmaceutical firms as effective. Evidence from recent studies that have examined the determinants of DTCA spending for prescription drugs is reviewed.

17. Real (inflation-adjusted) spending on DTCA increased from $351 million in 1994 to $4.24 billion in 2005 (Figure 1).[2] The majority of DTCA is for television advertising.[3] As a percentage of total promotional spending, however, DTCA makes up a relatively small share. Figure 2 shows the distribution of pharmaceutical promotional expenditures by type of promotion for 2004 when DTCA made up only 15 percent of total promotional spending. This proportion is identical to that reported for 2000.[4] The retail value of free samples distributed to physicians' offices made up 57 percent of total promotional expenditures and the remainder was spent on promotion to physicians via detailing and journal advertising. Valuing free samples at their retail prices likely

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[2] Berndt ER., Donohue JM. Direct-to-consumer advertising in health care: an overview of economic issues. Available on-line at http://www.oberlin.edu/cgi-bin/cgiwrap/events/calendar.pl?display=college&which=&s=99&_e=14327

[3] Kreling, D.H., D.A. Mott, and J.B. Wiederholt.. 2001. *Prescription drug trends: a chartbook update*, November. Henry J. Kaiser Family Foundation. Available on-line at http://www.kff.org/rxdrugs/upload/Prescription-Drug-Trends-A-Chartbook-Update-Chartbook.pdf, last accessed July 27, 2006.

[4] Rosenthal MB, Berndt ER, Donohue JM, Epstein AM, Frank RG. Promotion of prescription drugs to consumers. *New England Journal of Medicine* 346(7): 498-505, 2002.

overestimates the true cost of free samples which is difficult to determine. Nevertheless, even if the true cost of free samples were available professional promotion would likely still outweigh DTCA in terms of expenditures.

18. That DTCA makes up a small portion of the pharmaceutical industry's promotional spending is related to the fact that DTCA is heavily concentrated in a few brands. In 2000, the top 20 DTCA spenders made up 58.8 percent of total industry spending on this form of promotion.[5] While most brand name products are promoted via detailing, very few use DTCA.[6] Only 20.8 percent of all drug classes had any DTCA advertising between 1995 and 2000.[7] Even for those products with any DTCA investment, spending on other forms of promotion (e.g. detailing, meetings and events, free samples and journal advertising) tends to outweigh DTCA spending.[8]

Determinants of DTCA Spending

19. A classic finding from the advertising economics literature known as the Dorfman-Steiner (1954) theorem states that the profit-maximizing ratio of dollars spent on advertising to dollars of sales revenue (advertising to sales ratio) is equal to the ratio of two elasticities – the demand elasticity of sales with respect to advertising effort (a

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[5] Rosenthal MB, Berndt ER, Donohue JM, Epstein AM, Frank RG. Promotion of prescription drugs to consumers. *New England Journal of Medicine* 346(7): 498-505, 2002.
[6] Neslin SA. ROI analysis of pharmaceutical promotion, unpublished study. Hanover NH: Amos Tuck School of Business, Dartmouth. Available on-line from http://www.rxpromoroi.org/rapp
[7] Iizuka T., Jin G. 2005. The effect of prescription drug advertising on doctor visits. *Journal of Economics and Management Strategy* 14(3): 701-727.
[8] Ma J, Randall S, Stafford ? Cockburn IM, Finkelstein SN. 2003. A statisitcal analysis of the magnitude and composition of drug promotion in the United States in 1998. *Clnical Therapeutics* 25: 1502-1517.

measure of demand response to advertising), and the absolute value of the demand elasticity of unit sales with respect to price (responsiveness of demand to price).[9]

20. Several economic studies have examined the determinants of promotional spending in the pharmaceutical industry. These determinants can be viewed as factors affecting either the numerator of the Dorfman-Steiner theorem (demand response to advertising) and/or the denominator (demand response to price). Early studies focused on the level of detailing spending while more recent studies have examined factors associated with firms' use of DTCA. In terms of the level of promotional spending, patent life or "product life cycle" factors play a significant role in pharmaceutical firms' marketing decisions. Economic studies have shown that investments in promotion are typically highest in the years following FDA approval and begin to decline at least 2 years before patent expiration and generic entry.[10] Promotional spending drops markedly, often to zero, once generic entry has occurred. This is due to the fact that generic drugs capture most of the benefit from advertising by the brand name drug thereby reducing the effectiveness of advertising from the brand name firm's perspective (the numerator in the Dorfman-Steiner theorem).

21. But product life cycle effects explain very little of the variation in manufacturer decisions about investments in DTCA. The affidavit by Michael Wilkes asserts that many advertised drugs are "'me too' products that offer few advantages over older

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[9] Dorfman, Robert and Peter O. Steiner. 1954. Optimal advertising and optimal quality. *American Economic Review*. December, 44:826-836.

[10] Caves RE, Whinston MD, Hurwitz MA. Patent expiration, entry and competition in the U.S. pharmaceutical industry *Brookings Papers on Microeconomics* 1991. pp 1-66.

drugs and have less well-understood safety profiles...drugs for unfamiliar conditions, under-treated ailments, and conditions not treatable in the past with medication" (page 5). Also advertised, Wilkes asserts "are drugs for chronic conditions routinely dismissed by physicians as minor, however miserable or distressful" (page 5). As evidence for his description of the drugs for which DTCA is used, he offers content analyses of a selected sample of prescription drug advertisements as opposed to data on pharmaceutical industry spending on DTCA. However, the sample of advertisements reviewed in that particular study is unlikely to provide a representative view of the types of drugs advertised.

22. In a study of the product and market-level determinants of spending on DTCA, Iizuka (2004) examined a total of 606 drug-year observations for 169 unique brand-name drugs from three broad categories (central nervous system agents, respiratory agents, and renal and genitourinary agents) over the period 1996-1999.[11] He examined the effect of a number of factors on whether a drug had any DTCA expenditures and the level of spending conditional on any spending. This study is included as Exhibit B. Table 1 displays a summary of the results from Iizuka's analysis of factors associated with a firm's likelihood of using DTCA for a particular drug. A "+" symbol indicates that the factor is positively associated with use of DTCA while a "-" symbol indicates that the likelihood of advertising decreases as the value of the variable increases.

[11] Iizuka, Toshi. 2004. What Explains the Use of Direct-to-Consumer Advertising of Prescription Drugs? *Journal of Industrial Economics*, 52(3):349-379.

23. Iizuka finds that drugs that are of high quality are more likely to advertise to consumers. As an approximation of drug quality he uses the priority rating given the drug by the FDA during its drug approval process. Products earning a high FDA quality rating may either be more efficacious than existing treatments, more user friendly (e.g. easier dosing scheme), or safer (lower incidence of side effects).[12] Iizuka's finding is consistent with early theoretical work in economics by Nelson (1974) who argued that high quality products were more likely to advertise than low-quality products.[13] Nelson showed this was possible because, among goods whose quality could be judged only after consumption (so-called "experience" goods), high quality products are more likely to attract repeat purchases than low quality products. The return from advertising that induces the initial purchase and thus the incentive to advertise is higher for high quality products.

24. Iizuka's work also shows that pharmaceutical firms' marketing decisions are highly sensitive to a drug's competitive environment. For instance he found that drugs of high quality that are the first in their class are particularly likely to advertise. Drugs that are of high quality but are the second entrant (so-called "me too" drugs) are actually less likely to use DTCA. He also found that newer drugs and those in classes with fewer brand names were more likely to use DTCA. This is consistent with Dorfman-Steiner predictions about the relationship between the effectiveness of advertising and

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[12] While there are some challenges to using FDA priority rating as an indicator of drug quality, which Iizuka discusses in the paper, it is the only standardized, widely available marker of drug quality for use in quantitative analysis.

[13] Nelson P. 1974. Advertising as information. *Journal of Political Economy* 82(4): 729-754.

the level of advertising expenditures. In addition, drugs with FDA approved generic equivalents are much less likely to use DTCA than drugs without generic equivalents.

25. Importantly, Iizuka examines the impact of market size on pharmaceutical firms' decisions regarding DTCA. He estimates the effects of both *current* and *potential* market size on DTCA spending. Current market size is measured by the number of patient visits for specific disease categories based on the National Ambulatory Medical Care Survey (1995-1998). Potential market size was constructed using the 1995 National Health Interview Survey which provides prevalence rates for selected chronic conditions based on household interviews conducted annually. This provides an estimate of the combined number of potential treated and untreated patients. He finds that while current market size is negatively although not statistically significantly associated with use of DTCA, potential market size has a strong positive association with spending on DTCA. Taken together, these results "imply that firms spend more advertising dollars if the number of the currently *untreated* population (i.e. potential market size minus current market size) rather than *treated* population is large." (page 369, emphasis in original).[14]

26. Table 2 displays the top 20 products in terms of DTCA spending in the U.S. in 2005. These products made up 54.4 percent of total industry spending on DTCA in that year. Some of these products are used to improve the quality of life or treat symptoms associated with non-life threatening conditions. However, 10 out of the top 20 DTCA

[14] Iizuka, Toshi. 2004. What Explains the Use of Direct-to-Consumer Advertising of Prescription Drugs? *Journal of Industrial Economics*, 52(3):349-379.

spenders are used to prevent or treat the 10 conditions listed as high priority by the Agency for Healthcare Research and Quality in the U.S. Department of Health and Human Services. These priority conditions are ischemic heart disease, cancer, COPD/asthma, stroke and control of hypertension, arthritis, diabetes, dementia, pneumonia, peptic ulcer disease, and depression.

27. To summarize, DTCA makes up a small part of pharmaceutical manufacturers' marketing budgets and evidence suggests that DTCA is used for a subset of drugs that are newer, with few competitors that treat a range of conditions many of which are undertreated.

Part II: Demand effects of direct-to-consumer advertising

28. Several studies have examined the impact of DTCA on demand for prescription drugs in a range of therapeutic categories. Many of these studies examined the effects of detailing in the same analysis in order to understand how if at all the two forms of promotion interact. These studies have focused on answering two primary questions: 1) does DTCA expand the size of the market? and 2) does DTCA affect the market shares of the advertised products? This latter effect is often referred to as "business stealing" in the marketing literature. The evidence to date consistently shows that when DTCA has an effect it is to increase total market size or sales in the class as a whole. Effects on market share have been found by only a few studies and the effect sizes are quite small relative to that of detailing. Before describing the methods and results from the demand effects studies, I will provide a theoretical discussion of the implications of

market expanding vs. business stealing effects of advertising in general and in prescription drug markets in particular.

29. Economists generally consider market expanding effects of advertising to be positive for consumer welfare because it is indicative of advertising meeting consumers' need for information on the availability of a product. Business stealing effects are considered to have neutral if not negative effects on consumer welfare resulting simply in an advertising spending "arms race" race between competitors (e.g. Coke and Pepsi). However, conventional wisdom on market size vs. share effects does not necessarily extend to prescription drug markets.[15]

30. Increased sales to the therapeutic category resulting from DTCA (i.e., market expanding effects) would likely result from an increase in the number of people treated rather than from an increase in the volume of drugs used by currently treated individuals. Chronic conditions with high disease burdens such as diabetes, hypertension, hyperlipidemia, and mental disorders are frequently under-treated.[16,17,18,19,20] DTCA could help to alleviate problems with underuse by helping patients to self-identify as having the condition and making them aware of the existence

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[15] Berndt ER., Donohue JM. Direct-to-consumer advertising in health care: an overview of economic issues. Available on-line at http://www.oberlin.edu/cgi-bin/cgiwrap/events/calendar.pl?display=college&which=&s=99&_e=14327

[16] McGlynn EA, Asch SM, Adams J et al. 2003. The quality of health care delivered to adults in the U.S. *New England Journal of Medicine* 348(26): 2635-45.

[17] Abookire SA, Karson AS, Fiskio J, Bates DW. Use and monitoring of "statin" lipid-lowering drugs compared with guidelines. *Archives of Internal Medicine* 161(1): 53-8, 2001.

[18] Berlowitz DR, Ash AS, Hickey EC et al. Inadequate management of blood pressure in a hypertensive population. *New England Journal of Medicine* 339: 1957-1963, 1998.

[19] Kessler RC, Demler O, Frank RG, et al. Prevalence and treatment of mental disorders, 1990-2003. *New England Journal of Medicine* 352(24): 2515-2523, 2005.

[20] Saydah SH, Fradkin J, Cowie CC. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. *Journal of the American Medical Association* 291(3): 335-342, 2004.

of treatments. But expanding the number of individuals receiving drugs in a particular therapeutic category could also lead to overuse if the drugs offer no therapeutic advantage over less expensive treatments, or if the drugs are not indicated. Overuse could lead to unnecessary health care costs and/or unnecessary exposure to side effects of the drug. I will review the few studies that shed light on these issues in section III. Suffice it to say that the evidence suggests that DTCA can increase both appropriate and inappropriate use. Importantly, there is no direct evidence that permits an assessment of whether the benefits (from appropriately averting underuse) outweigh the costs of DTCA (from overuse) or vice versa.[21] However, other evidence on the quality of medical care delivered in the U.S. in particular indicates that underuse may be a more significant public health problem than overuse.

31. Thus, while general economic theory would suggest that market expanding effects of DTCA lead to increased patient welfare, it is possible that their impact could be mixed. However, indirect evidence suggests that the beneficial aspects of DTCA's market expanding effects address a more serious public health problem than their potential negative aspects.

32. Were DTCA to have an impact on market share (i.e. business stealing effects) it could result in inappropriate drug use (e.g. increased market share for drugs that are more expensive and/or that have a less well-established safety profile than their therapeutic alternatives). Alternatively, DTCA could increase use of drugs that have a better side effect profile, or easier dosing scheme (e.g. once daily dosing) both of which

[21] Donohue IJPM calls for cost-benefit analysis.

may improve adherence. Given that advertised drugs tend to be of higher quality this benefit is quite plausible (Iizuka 2004). Evidence suggests that patients and doctors learn a great deal about the effectiveness of medications after just one prescription.[22] DTCA may enhance this learning process and lead to better patient-drug matches.[23] Thus, while general economic theory would suggest that business stealing effects of DTCA would not contribute to increased patient welfare, in this context they could have some positive impact.

33. Below I review the evidence on the effects of DTCA on class- and product-level sales.

Class Effect

34. My colleagues and I conducted the first published study of the demand effects of DTCA on class sales and market share in five commonly used pharmacologic classes: antidepressants, antihistamines, cholesterol-lowering medicines, (statins), nasal sprays and proton pump inhibitors.[24] This study is presented as Exhibit C. These classes were chosen because they included drugs with high DTCA expenditures and because there was variation within the class on product-level spending on DTCA. In the first analysis, we examined the association between monthly spending on DTCA for each class and total aggregate sales in that class adjusting for unrelated trends in the use of those

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[22] Crawford GG, Shum M. 2005. Uncertainty and learning in pharmaceutical demand. *Econometrica* 73(4): 115-127.
[23] Masson A, Rubin P.H. Matching Prescription Drugs and Consumers: The Benefits of Direct Advertising. *New England Journal of Medicine* 313(8): 513-515, 1985.
[24] Rosenthal M, Berndt ER, Donohue JM, Epstein AM, Frank RG. 2003. Demand effects of recent changes in prescription drug promotion. *Frontiers in Health Policy Research* 6: 1-26.

medications and characteristics of the classes. We estimated a statistically significant association between class-level DTCA spending and class sales. Our estimate of the advertising elasticity was 0.10.; in other words, a 10 percent increase in total class spending on DTCA was associated with a 1 percent increase in class sales. Applying this elasticity to sales data for the 25 largest therapeutic classes, we estimated that between 13 percent and 22 percent of the increase in total prescription drug spending growth between 1999 and 2000 in the U.S. was attributable to DTCA. In other words, DTCA was an important driver but by no means the most important factor influencing prescription drug spending.

35. The class-effect has been replicated in other studies of the association between DTCA spending and aggregate sales for non-sedating antihistamines. In a study of the effect of DTCA and detailing for non-sedating antihistamines Narayanan and colleagues (2004) found that DTCA had a positive effect on total class sales while detailing had no effect.[25] In contrast, detailing spending had a large positive effective on product market share that was 5 times that of DTCA. Only one economic study found no evidence of a class-effect. Calfee and colleagues found that advertising had no statistically significant effect on the volume of prescriptions sold in the statin class.[26]

36. A similar vein of research has investigated the association between DTCA spending and doctor visits for conditions the advertised drugs are intended to treat. For

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[25] Narayanan S, Desiraju R, Chintagunta PK. 2004. Return on investment implications for pharmaceutical promotional expenditures: the role of marketing mix interactions. *Journal of Marketing* 68: 90-105.
[26] Calfee JE, Winston C, Stempski R. 2002. Direct-to-consumer advertising and the demand for cholesterol reducing drugs. *Journal of Law and Economics* 45: 673-90.

instance, Iizuka and Jin (2005) found that outpatient office visits to physicians increased following periods of high DTCA spending in several drug classes.[27] For a typical class, they find that every additional $28 spent on DTCA is associated with an additional office visit in which a drug is prescribed. Similarly, a study of celecoxib (Celebrex) and rofecoxib (Vioxx) found that advertising for both products increased the number of visits for osteoarthritis although not necessarily prescribing for the advertised drug.[28] In addition, Zachry and colleagues (2002) found a positive association between DTCA expenditures (pre 1997) for statins (cholesterol-reducing medicines) and diagnoses of hyperlipidemia as well as prescriptions for statins.[29] Neither market share nor medication choice was examined in that study. These findings are consistent with the market expanding effects documented in the aggregate sales studies reviewed above.

Market Share Effects

37. In the study of DTCA demand effects in five classes described earlier, we examined the association between DTCA for individual drugs and demand for those drugs measured by market share of dollar and quantity sales. Importantly, we adjusted for the fact that firms are more likely to advertise drugs with high sales and therefore advertising expenditures cannot be assumed to be an independent determinant of sales. We also adjusted for detailing expenditures, the order in which the drug entered the class, characteristics of the medication class, and time trend variables to adjust for

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[27] Iizuka T., Jin G.Z. 2005. The effect of prescription drug advertising on doctor visits. *Journal of Economics and Management Strategy* 14(3): 701-727.

[28] Bradford WD, Kleit AN, Nietert PJ, Steyer T, McIlwain T, Ornstein S. 2006. How direct-to-consumer television advertising for osteoarthritis drugs affects physicians' prescribing behavior. *Health Affairs* 25(5): 1371-1377.

[29] Zachry WM, Sheperd MD, Hinich MJ, Wilson JP, Brown CM, Lawson KA. 2002. Relationship between direct-to-consumer advertising and physician diagnosing and prescribing. *Am J Health-Syst Pharm* 59: 42-50.

unrelated trends in the use of these medications. We did not find a statistically significant relationship between DTCA and dollar or quantity market share for the products we studied.

38. Other papers have examined the association between DTCA and medication choice in the antidepressant[30], antihyperlipidemic[31], and antihistamine markets.[32] These papers found either no association between DTCA advertising expenditures and prescription choice within the class, or very small effects relative to those of detailing.

39. The fact that pharmaceutical industry investments in DTCA have continued (see figure 1) in spite of the fact that studies have documented little impact on market share may be viewed as paradoxical. Most of the studies cited above were conducted using data from the late 1990s shortly after the FDA policy change, a period of experimentation by the industry with a new form of promotion. Contemporary DTCA campaigns may be more effective at increasing the share of sales for the advertised drug. Assuming, however, that DTCA increases the total number of people treated but not the market shares of a particular drug, this strategy could be valuable from the pharmaceutical firm's perspective if used in combination with other forms of promotion

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[30] Donohue JM, Berndt ER. 2005. Direct-to-consumer advertising and choice of antidepressant. *Journal of Public Policy and Marketing* 23(2): 115-127.

[31] Wosinska M. Just what the patient ordered? Direct to consumer advertising and the demand for pharmaceutical products. HBS Marketing Research paper No. 02-04. Available on-line at http://ssrn.com/abstract=347005

[32] Iizuka, Toshiaki and Jin, Ginger Zhe, "Direct to Consumer Advertising and Prescription Choice" . Available at SSRN: http://ssrn.com/abstract=700921

difficult to change.[39] This not only explains the predominance of class effects of DTCA, but also tends to rebut the suggestion that DTCA is harmful because prescribing physicians will be easily overwhelmed by insistent patients.

42. These findings are consistent with the finding presented earlier that pharmaceutical industry relies primarily on labor-intensive face-to-face detailing to influence prescriber decisions. And, interventions that have proven most effective at improving the quality of physician prescribing decisions have adopted the same model (i.e. academic detailing).[40,41,42] It is not surprising that DTCA expenditures are concentrated in medication classes that are new or for under-treated conditions where the focus is on getting patients to self-identify as having the condition and request drug treatment.

Part III: Public health effects of Direct-to-Consumer Advertising

43. It is useful to examine the empirical evidence on the demand effects of DTCA within the context of problems with prescription drug use. This section briefly reviews the literature on suboptimal prescribing practices and considers the role that DTCA may play in either exacerbating or alleviating these problems. I then review the empirical evidence on the relationship between DTCA and public health.

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[38] Hellerstein J. The importance of the physician in the generic versus trade name prescription decision. *RAND Journal of Economics* 29: 108-137, 1998.
[39] Majumdar SR, Soumerai SB. Why most interventions to improve physician prescribing do not seem to work. *Canadian Medical Association Journal* 169(1): 30-31, 2003.
[40] Soumerai SB, Majumdar SR, Lipton HL. Evaluating and improving physician prescribing. In (Strom B (ed) *Pharmacoepidemiology* 3rd edition. Toronto: John Wiley and Sons, 2000, pp.483-503.
[41] Grimshaw JM, Shirran L, Thomas R, MOwatt G, Fraser C, Bero L et al. Changing provider behavior: an overview of systematic reviews of interventions *Medical Care* 39(8 suppl 2): 483-503.
[42] Hanlon JT, Schmader KE, Ruby CM, Weinberger M. Suboptimal prescribing in older inpatients and outpatients. *Journal of the American Geriatric Society* 200-209, 2001.

Suboptimal prescribing practices

44. Problems with the quality of prescribing generally fall under one of two categories: overuse of inappropriate medications or underuse of appropriate medications.[43,44,45,46] Medication use is considered inappropriate if it is not indicated or if the drug has more potential risk than benefit. Inappropriate medication use can include prescriptions written for an inappropriate duration; at too high or low a dose; a drug that is contraindicated; or a drug that could cause drug-drug interactions. Some medication appropriateness measures identify drugs for which more effective and less costly alternatives are available as inappropriate,[47] although most quality indicators focus more on clinical risks than economic costs associated with medication use. Underuse is simply defined as the omission of drug therapy that is indicated.

45. Studies of the quality of pharmacologic care suggest that underuse is more of widespread problem than is overuse. For example, Shrank et al (2006) examined the quality of pharmacologic care for adults in the U.S. and found that performance was

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[43] Montamat SC, Cusack B. 1992. Overcoming problems with polypharmcacy and drug misuse. *Clin Geriatr Med* 8: 143-58.
[44] Gurwitz JH. 1994. Suboptimal medication use in the elderly: the tip of the iceberg. *JAMA* 272: 316-17.
[45] Schmader K, Hanlon JT, Weinberger M et al. 1994. Appropriateness of medication prescribing in ambulatory elderly patients. *J Am Geriatr Soc* 42: 1241-17.
[46] Beers MH, Ouslander JG, Rollingher I et al. 1991. Explicit criteria for determining inappropriate medication use in nursing home residents. *Arch Int Medicine* 151: 1825-32.
[47] Fitzgerald LS, Hanlon JT, Shelton PS, Landsman PB, Schmader KE, Pulliam CC, et al. *Annals of Pharmacotherapy* 31: 542-8, 1997.

much lower on indicators of underuse of appropriate medications (62.6%) than for avoiding inappropriate medications (83.5%).[48]

46. DTCA has been praised for alleviating underuse and criticized for leading to overuse and/or use of a drug for which more effective and less costly alternatives are available. However, given that the studies cited above found either no or very little impact of DTCA on product market share, it is unlikely that DTCA has been the main driver of the trend toward substitution of newer more expensive medications for older drugs. Evidence on the association between DTCA and overuse and underuse will be reviewed in this section.

Alleviating underuse

47. To examine the impact of DTCA on under treatment of chronic conditions, my colleagues and I chose to study depression. Our study is included as Exhibit D. Depression is a highly prevalent condition that results in substantial morbidity and mortality.[49] The societal costs of depression in the U.S. alone are estimated to be $83 billion (2000 dollars) due to increased health care costs, premature death due to suicide, and reduced worker productivity.[50] A variety of pharmacologic and non-pharmacologic (e.g. psychotherapy) interventions have been found effective at treating depression. Yet, depression is substantially under-treated. Roughly half of individuals

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[48] Shrank WH, Asch SM, Adams J, Setodji C, Kerr EA, Keesey J, Malik S, McGlynn EA. The quality of pharmacologic care for adults in the United States. *Medical Care* 44(10): 936-945, 2006.
[49] Spitzer RL, Kroenke K, Linzer M et al. 1995. Health-related quality of life in primary care patients with mental disorders: results from the PRIME-MD 1000 study. *JAMA* 274: 1511-1517.
[50] Greenberg PE, Kessler RC, Birnbaum HG et al. 2003. The economic burden of depression in the United States: how did it change between 1990 and 2000? 64(12): 1465-73.

with depression receive no treatment and those who are treated seldom receive the proper duration of treatment.[51,52] Depression is a good condition in which to study the effects of DTCA because antidepressants are among the most heavily advertised drugs in the U.S. According to IMS Health, Selective Serotonin Reuptake Inhibitors (SSRIs) and selective norepinephrine reuptake inhibitors (SNRIs) together had the highest total promotional spending of any drug category in 2004 ($509 billion). DTCA could lead to increased rates of treatment for depression by making patients aware of symptoms and treatments, and reducing stigma.[53]

48. To study the connection between DTCA and treatment of depression we obtained data on spending on DTCA and physician detailing on antidepressants between 1997 and 2000.[54] The level of antidepressant DTCA spending varied over time for individual products and for the class as a whole. In our study we assessed the association between variation in monthly spending on DTCA for antidepressants and patterns in the treatment of individuals with depression using a large health insurance claims dataset. Periods of high DTCA spending were treated as the "treatment group" and periods of low DTCA spending the "control group." We examined the impact of consumer- and physician-directed marketing of antidepressants on (1) the likelihood that someone diagnosed with a new episode of depression received antidepressant

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[51] Kessler RC, Berglund P, Demler O et al. 2003. The epidemiology of major depressive disorder: results from the National Comorbidity Survey Replication. *JAMA* 289: 3095-3105.
[52] Young AS, Klap R, Sherbourne CD et al. 2001. The quality of care for depressive and anxiety disorders in the United States. *Arch Gen Psychiatry* 55-61.
[53] The stigma surrounding mental illnesses has remained remarkably stable over time in spite of advances in diagnosis and treatment. See Phelan JC, Link BG, Stueve A, Pescosolido BA. 2000. Public conceptions of mental illness in 1950 and 1996: what is mental illness and is it to be feared? *Journal of Health and Social Behavior* 41: 188-207.
[54] Donohue JM, Berndt ER, Rosenthal MB, Epstein AM, Frank RG. 2004. Effects of pharmaceutical promotion on adherence to the treatment guidelines for depression. *Medical Care* 42(12): 1176-1185.

medication, and (2) whether they received antidepressant medication for the appropriate duration.

49. We found that individuals diagnosed with depression following periods of high antidepressant DTCA spending were 6 percentage points more likely to receive medication treatment than individuals who were diagnosed during periods of low DTCA spending (See Table 3 in this report). This finding is consistent with the view that DTCA expands treatment of undertreated conditions. Unfortunately, because our study used administrative data to establish treatment patterns for depression we were not able to assess the appropriateness of prescribing. However, an experimental study reviewed below sheds light on this issue.

50. We also found an association between DTCA spending and the duration of treatment for depression. Advertising for the drug taken by the individual was not associated with the duration of treatment. However, advertising for other drugs in the class was positively associated with the duration of treatment. Individuals diagnosed following periods of high DTCA spending in the class were 5 percentage points more likely to receive at least 4 months of antidepressant treatment compared to individuals who began treatment following a period of low DTCA spending (see Table 2). A Harvard Business School study found a similar effect of DTCA on adherence in the statin class.[55]

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[55] Wosinska M. 2005. Direct-to-consumer advertising and drug therapy compliance. *Journal of Marketing Research* XLII: 323-32.

and leads to substantial morbidity and mortality.[70] As discussed earlier, studies of the quality of pharmacologic care suggest that underuse is more of widespread problem than is overuse. One cannot conclude from a fair reading of the evidence that DTC has no public health benefit and results only in harm. On the contrary, the studies reviewed in this report suggest that DTCA could lead to substantial benefits in terms alleviating underuse of appropriate medications. To date, much of the criticism of DTCA has centered on the economic costs of expanded drug use and these critiques have not assessed the true value of increased spending on prescription drugs.

70. The cost to benefit ratio of DTCA is largely contingent on the regulatory system put into place. The challenge is to develop a regulatory framework that maximizes the benefits associated with prescription drug advertising and minimizes the potential harms. I conclude from a review of the empirical evidence on the effects of DTCA on consumer and provider behavior that a regulatory system that permits DTCA of prescription drugs and carefully regulates the content of the advertisements is preferable to a total ban on DTCA. Drug advertisements should be carefully monitored to ensure that they do not contain misleading information, and adequately disclose the risks of prescription drugs, but not prohibited.

71. My conclusion is based upon the following. First and foremost, in an era of increased consumer empowerment and involvement in health care decisions, the presumption should be against limiting the flow of information unless there is strong

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[70] McGlynn EA, Asch SM, Adams J et al. 2003. The quality of health care delivered to adults in the U.S. *New England Journal of Medicine* 348(26): 2635-45.

empirical evidence to justify it. That evidence is lacking. Second, there is evidence that underuse of prescription medications is a more significant public health problem than overuse, which provides indirect evidence that DTCA's benefits outweigh its costs. Third, the nature of the harm arising from underuse is that it is difficult to address by means other than DTCA, while costs arising from overuse may be mitigated by other means.

72. For problems of underuse (i.e. patients with untreated or undertreated conditions that could be alleviated by prescription drugs), the public health challenge is to get them into doctors' offices and to get them to initiate conversations that lead to appropriate diagnosis and treatment. In theory this could be addressed by public health campaigns, but practical experience is that public authorities have neither the incentives nor the resources to undertake such campaigns on a scale comparable to DTCA[71].

73. For problems of overuse, there are regulatory mechanisms that may temper the potential for harm. Drugs may only be marketed once they have been approved by the FDA as safe and effective for a particular use, following a lengthy approval process. Advertisements are required to disclose known risks. In addition, the FDA can require special labeling for some drugs it considers to carry higher risks (e.g. black box warnings). While I do not suggest that these mechanisms are infallible, they may limit the risks of clinically inappropriate prescriptions. For the potential economic costs of unnecessarily expensive prescriptions that offer no advantages over less expensive

[71] Donohue JM, Berndt ER, Rosenthal MB, Epstein AM, Frank RG. 2004. Effects of pharmaceutical promotion on adherence to the treatment guidelines for depression. *Medical Care* 42(12): 1176-1185.

therapies, public and private plans may use their power to either exclude those drugs from their formularies or require consumers to pay a larger share of the costs out-of-pocket.[72] These mechanisms may provide strategies for limiting the potential costs of DTCA.

74. These considerations lead me to conclude that it is better public policy to allow DTCA in appropriately regulated form, rather than prohibiting it.

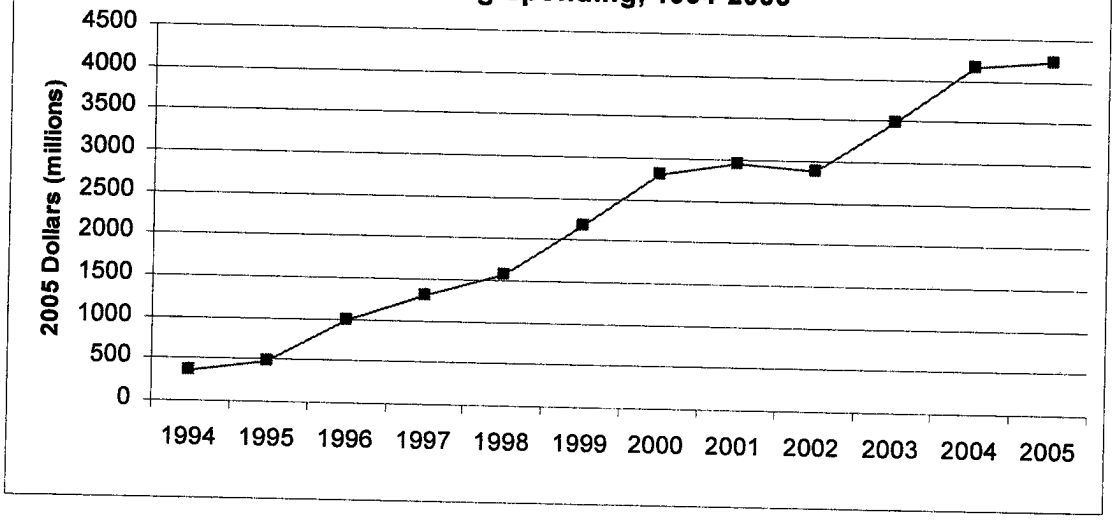
AFFIRMED BEFORE ME, in the City of Pittsburgh, in the Commonwealth of Pennsylvania this 22nd day of May, 2007

A Commissioner etc.

Julie Donohue

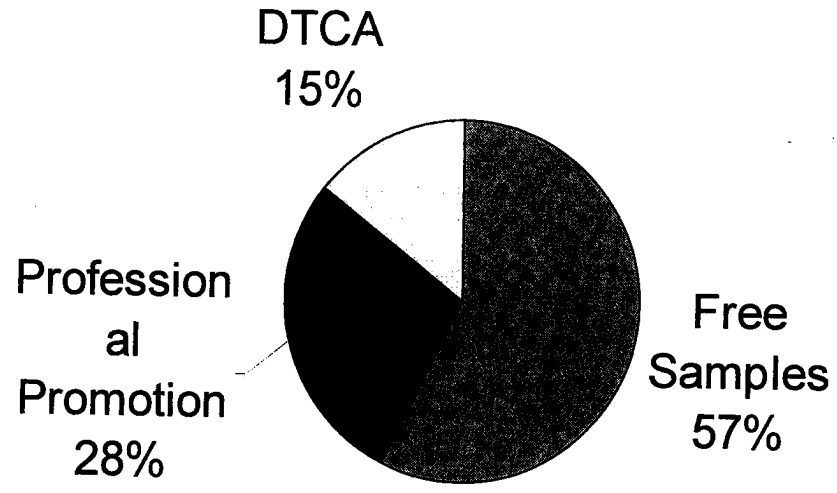
[72] Rosenthal, M.B., and Donohue, J.D. "Direct-to-Consumer Advertising: A Policy Dilemma" in Michael Santoro and Tom Gorrie (Eds.) *Ethics and the Pharmaceutical Industry in the 21st Century.* New York, NY: Cambridge University Press, 2005.

Figure 1: U.S. Pharmaceutical Industry Direct-to-Consumer Advertising Spending, 1994-2005



Source: Competitive Media Reporting unpublished data, 1994-2000; IMS Health Top-Line Industry Data 2001-2005. Available on-line at http://www.imshealth.com/ims/portal/front/indexC/0,2773,6599_5264_0,00.html

Figure 2: Distribution of Pharmaceutical Promotional Expenditures by Spending Type, 2004



Source: IMS Health Top-Line Industry Data 2001-2005. Available on-line at http://www.imshealth.com/ims/portal/front/indexC/0,2773,6599_5264_0,00.html

Table 1: Summary of Results from Iizuka (2004) on determinants of DTCA spending

High quality	+
High quality * First entrant	+
High quality * second entrant	+
Age of the drug	-
Number of therapeutic competitors	-
Generic equivalent available	-
Number of patients currently treated	-
Potential market size (number of untreated patients)	+

Shaded variables are statistically significant at $p<0.05$ level

Table 2: Top 20 Pharmaceutical Products in Terms of DTCA Spending, 2005

Drug	Company	Therapeutic Category	Used to treat or prevent AHRQ priority conditions
Nexium	AstraZeneca	GERD	*
Lunesta	Sepracor	insomnia	
Vytorin	Merck/Schering-Plough	cholesterol	*
Crestor	AstraZeneca	cholesterol	*
Advair	GlaxoSmithKline	asthma	*
Nasonex	Schering-Plough	allergy	
Flonase	GlaxoSmithKline	allergy	
Lamisil	Novartis	fungal	
Plavix	Bristol-Myers/Sanofi	stroke	*
Cialis	Lilly/ICOS	ED	
Wellbutrin XL	GlaxoSmithKline	depression	*
Singulaire	Merck	asthma	*
Lipitor	Pfizer	cholesterol	*
Ambien	Sanofi-Aventis	insomnia	
Humira	Abbott	RA; monoclonal AB	*
Imitrex	GlaxoSmithKline	migraine	
Viagra	Pfizer	ED	
Neulasta	Amgen	wbc; febrile neutropenia	*
Valtrex	GlaxoSmithKline	herpes	
Prevacid	TAP	GERD	*

* Medical Marketing and Media

Table 3: Summary of key results from Donohue et al (2004) on impact of DTCA on depression treatment

Probability of receiving drug treatment for depression by different levels of class-level DTCA spending

Class-level DTCA spending	**Percentage Point Difference**
less than $2.6 million (reference category)	(reference category)
$2.6 to $11.2 million	4.0***
$11.2 to $18.5 million	3.0**
Over $18.5 million	6.0***

Probability of receiving appropriate duration of drug treatment for depression

DTCA spending for the product taken by individual	**Percentage Point Difference**
less than $78,000	(reference category)
$78,000 to $3.4 million	1
$3.4 to $20.2 million	-2.0
Over $20.2 million	5

DTCA spending for other drugs in the class	**Percentage Point Difference**
less than $271,000	(reference category)
$271,000 to $7.2 million	0.5
$7.2 to $21.8 million	1.0
Over $21.8 million	6.0*

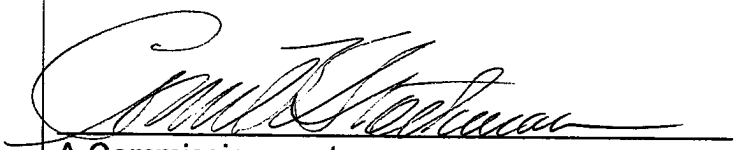
*p-value <0.05, **p-value <0.01, ***p-value <0.001

Table 4: Results from Kravitz et al (2005). Physician prescribing as a function of standardized patient request behavior

	No. of encounters	Received antidepressant	Received Paroxetine (Paxil)
Major depressive disorder	51	52.9%	27.4%
brand specific request	50	76.0%	2.0%
general request	48	31.2%	4.2%
no request			
Adjustment disorder			
brand specific request	49	55.1%	36.7%
general request	49	38.8%	10.2%
no request	51	9.8%	0.0%

Reproduced from Kravitz et al (2005)
Differences are statistically significant at $p<0.001$ for all comparisons among request types

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



A Commissioner, etc.

Last updated 3/07

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EDUCATION

Harvard University
Ph.D. in Health Policy, awarded March 2004
Dissertation: "Pharmaceutical Promotion in an Age of Consumerism" (Accepted with Distinction, November 2003)

University of Colorado
Bachelor of Arts in Political Science, Graduated with Distinction, May 1995

CURRENT POSITIONS

Assistant Professor — 2004-present
Department of Health Policy and Management
Graduate School of Public Health
University of Pittsburgh

Assistant Professor — 2004-present
Department of Psychiatry
University of Pittsburgh Medical School

Core Faculty Member — 2004-present
Center for Research on Health Care

Faculty Affiliate
Center for Bioethics and Health Law — 2005-present

PAST POSITIONS

Pharmaceutical Policy Research Post-Doctoral Fellow Department of Ambulatory Care and Prevention Harvard Medical School	2003-2004
Research Assistant Department of Health Care Policy Harvard Medical School	1998-2003
Consultant Commonwealth Fund Bipartisan Congressional Health Policy Conference Kennedy School of Government, Harvard University	1999, 2001
Public Policy Director Mental Health Association of Colorado	1997-1998

PROFESSIONAL ACTIVITIES

Gerontological Society of America, Public Policy Committee Member	2006-present
Academy Health, Behavioral Health Abstract Review Committee	2007

TEACHING

Health Policy Analysis University of Pittsburgh, Graduate School of Public Health	2006, 2007
Master's Thesis Advisor University of Pittsburgh, Graduate School of Public Health	2004-present
Senior Thesis Advisor Harvard College, Government Department	2003-2004
Teaching Fellow Graduate Readings Seminar in Health Policy and Politics Graduate School of Arts and Sciences Harvard University	2002
Head Teaching Fellow Introduction to Health Care Policy Harvard College	2000

Teaching Fellow 2000
Political Analysis and Strategy for U.S. Health Policy
Kennedy School of Government
Harvard University

Teaching Fellow 1998
Introduction to Health Policy
Kennedy School of Government
Harvard University

ONGOING RESEARCH SUPPORT

KL2 RR024154-01 Kapoor (PI) 7/06-6/2010
NIH
Medicare beneficiaries and high cost pharmaceuticals: prescribing patterns, treatment adherence, and patient perceptions of quality
The major goal of this project is to reduce cost-related underuse of prescription drugs among elders with chronic medical conditions.
Role: Scholar

Massachusetts General Hospital 4/05-4/07
Subcontract to University of Pittsburgh, prime: Consumers Union
Consumers Union Consumer Reports Best Buy Drugs Program
The major goal of this project is to evaluate the impact of the Consumer Reports Best Buy Drugs Program on consumer and provider knowledge, attitudes and behavior related to prescription drug use.
Role: PI of Sub-contract

Pew Charitable Trusts Lave (PI) 3/06-03/08
Medicaid Policy Center
The major goal of this Center grant is to increase the general understanding of the Medicaid program and its role in the Pennsylvania healthcare system and economy and to improve the policy making process regarding Medicaid.
Role: Faculty Policy Analyst

COMPLETED RESEARCH SUPPORT

5P30 MH0309 15 28 Kupfer (PI) 11/04-11/05
Mental Health Intervention Research Center Small Grants Program
The impact of Medicaid prior authorization policies for antidepressants on medication choice
The major goal of this project is to examine the impact of Medicaid prior authorization policies on treatment patterns for new antidepressant users.
Role: PI of Seed Project (sub-project)

Harvard Medical School Frank (PI) 7/05-12/05
Subcontract to University of Pittsburgh, prime: NIMH
Effects of the Medicare Drug Benefit on Medicare Beneficiaries with Mental Disorders
The major goal of this project is to examine the potential impact of the Medicare drug benefit on pattern of care and economic burden for people with mental disorders.
Role: PI of Sub-contract

PUBLICATIONS (Refereed Journals)

Huskamp, H.A, Stevenson, D.G., Donohue, J.M., Newhouse, J.P., Keating, N.L. "Coverage and prior authorization of psychotropic drugs under Medicare Part D." *Psychiatric Services* In press, 2007.

Aspinall S., Sevick M.A., Donohue J., Maher R., Hanlon J.T. Medication errors in older adults: a review of recent publications. *American Journal of Geriatric Pharmacotherapy* 5(1): 75-84, 2007.

Donohue, J.M., Pincus H.A. "Reducing the Societal Burden of Depression: A review of economic costs, quality of care and effects of treatment on costs of depression." *Pharmacoeconomics* 25(1): 7-24, 2007.

Donohue, J.M. "Implications of the New Medicare Drug Benefit for Mental Health Treatment." *Psychiatrist Administrator* 6(2): 29-35, 2006.

Donohue, J.M. "A history of drug advertising: the evolving roles of consumers and consumer protection." *Milbank Quarterly* 84(4): 659-699, 2006.

Donohue, J.M. "Direct-to-Consumer Advertising of Prescription Drugs: Adding to overuse and inappropriate use or alleviating underuse?" *International Journal of Pharmaceutical Medicine* 20(1): 17-24, 2006.

Donohue, J.M. "Mental Health in the Medicare Drug Benefit: A New Regulatory Model?" *Health Affairs* 25(3): 707-719, 2006.

Donohue J.M., Hanlon J.T. "Helping Medicare patients benefit from the new Medicare drug benefit: an overview with practice tips." *American Journal of Geriatric Cardiology* 14(6): 291-297, 2006.

Donohue J.M. "The Economics of the New Medicare Drug Benefit: Implications for People with Mental Illnesses" *Psychiatric Services* 56(6): 645-647, June 2005.

Donohue, J.M., and Berndt, E.R. "Direct-to-Consumer Advertising and Choice of Antidepressant." *Journal of Public Policy and Marketing,* 23(2): 115-127, 2004.

Donohue, J.M., Berndt, E.R., Epstein, A.M., Rosenthal, M.B., Frank, R.G. "Effects of Pharmaceutical Promotion on Adherence to Guideline Treatment of Depression." *Medical Care* 42(12): 1176-1185, 2004.

Rosenthal, M.B., Berndt, E.R., Donohue, J.M., Epstein, A.M., Frank, R.G. "Demand Effects of Recent Changes in Prescription Drug Promotion." *Frontiers in Health Policy Research* 6, 2003.

Rosenthal, M.B., Berndt, E.R., Donohue, J.M., Epstein, A.M., Frank, R.G. "Promotion of Prescription Drugs to Consumers." *New England Journal of Medicine* 346(7), 2002.

Donohue, J.M., and Frank, R.G. "Medicaid Behavioral Health Carve-Outs: A New Generation of Privatization Decisions." *Harvard Review of Psychiatry* 8, 2000.

Barry, C.L., and Donohue, J.M. "The Uninsured in the U.S.: An Issue Brief." *Harvard Health Policy Review*, 1(1), Fall 2000.

BOOK CHAPTERS

Rosenthal, M.B., and Donohue, J.D. "Direct-to-Consumer Advertising: A Policy Dilemma" in Michael Santoro and Tom Gorrie (Eds.) *Ethics and the Pharmaceutical Industry in the 21st Century.* New York, NY: Cambridge University Press, 2005.

WORKING PAPERS

Donohue, J.M., Fischer M., Weissman J. "Savings associated with increased use of Consumer Reports Best Buy Drugs."

Donohue, J.M., Epstein A.M., Frank, R.G. "Medication Access for Dual Eligibles with Mental Disorders Under Medicare Part D."

Huskamp, H.A, J.M. Donohue, C. Koss, E.R. Berndt, R.G. Frank, Ph.D. "Manufacturer promotional strategies for antidepressants."

REPORTS

Frank, R.G., Berndt, E.R., Donohue, J.M., Epstein, A.M., Rosenthal, M.B. "Trends in Direct-to-Consumer Advertising of Prescription Drugs" February 2002. A Henry J. Kaiser Family Foundation publication.

Frank, R.G., Berndt, E.R., Donohue, J.M., Rosenthal, M.B. "Determinants and Effects of Direct to Consumer Advertising of Prescription Drugs: A Research Agenda." A background report

prepared for the Department of Health and Human Services conference, *Assessing the Impact of Direct-to-Consumer Advertising on Health Care Use, Costs and Outcomes*, April 2001.

Donohue, J.D. "E-Health: Providers, Patients and the Web." Policy Brief for Harvard University, Kennedy School of Government/Commonwealth Fund Bipartisan Congressional Health Policy Conference, January 2001.

Donohue, J.D. "Medical Safety: Putting into Practice What We Know." Policy Brief for Harvard University, Kennedy School of Government/Commonwealth Fund Bipartisan Congressional Health Policy Conference, January 2001.

Donohue, J.D. "Health Insurance: Are Employers the Solution?" Policy Brief for Harvard University, Kennedy School of Government/Commonwealth Fund Bipartisan Congressional Health Policy Conference, January 2001.

Donohue, J.D. "Rural Health Care: Dilemmas, Access, and Providers." Policy Brief for Harvard University, Kennedy School of Government/Commonwealth Fund Bipartisan Congressional Health Policy Conference, January 2001.

Donohue, J.D., Hanson, K.W., Huskamp, H.A. "Persons with Disabilities and Medicaid Managed Care: Issues in Programmatic Design, Enrollment, Procurement, and Contracting." Report prepared for the Center for Health Care Strategies, Inc., and the Robert Wood Johnson Foundation. November 1999.

AWARDS/HONORS/ACTIVITIES

- Scholar, National Institute of Health, Multidisciplinary Clinical Research Scholars Program, 2006
- Nominated for Academy Health Dissertation Award, 2004
- National Institute of Mental Health Training Grant, 1998 – 2001
- Derek Bok Teaching Award, 2000
- Member, Colorado Mental Health Planning Council/Capitation Program Advisory Committee, March 1997 to May 1998
- *Phi Beta Kappa* University of Colorado at Boulder, 1995
- Graduated with Distinction, University of Colorado at Boulder, 1995

EDITORIAL ACTIVITIES

Reviewer, *American Journal of Managed Care*
Reviewer, *Journal of Aging and Social Policy*
Reviewer, *Journal of Behavioral Health Services Research*
Reviewer, *Journal of Clinical Psychiatry*
Reviewer, *Journal of General Internal Medicine*

Reviewer, *Journal of Health Care for the Poor and Underserved*
Reviewer, *Journal of Health Economics*
Reviewer, *Journal of the American Medical Association*
Reviewer, *Health Affairs*
Reviewer, *Health Economics*
Reviewer, *Inquiry*
Reviewer, *Medical Care*
Reviewer, *Milbank Quarterly*
Reviewer, *Pharmacoeconomics*
Reviewer, *Psychiatric Services*
Reviewer, *Psychological Medicine*
Reviewer, *Social Science and Medicine*
Reviewer, *Value in Health*

INVITED PRESENTATIONS AND LECTURES

"Medication access for dually eligible beneficiaries with mental disorders under Medicare Part D," Biennial National Institute of Mental Health Conference on Mental Health Economics, Bethesda, MD, September 2006

"Economics of Direct-to-consumer advertising of prescription drugs" Incentives and Choice in Health Care Conference at Oberlin College, in Oberlin, OH, September 2006.

"Savings associated with increased use of Consumer Reports Best Buy Drugs" Society of General Internal Medicine, April 27, 2006, Los Angeles, CA.

"If we increased use of Consumer Reports Best Buy Drugs how much would we save?" Consumer Reports Best Buy Drugs Program Symposium, March 2-3, 2006, Washington D.C.

"Pharmacy Benefit Management and Mental Health: Medicare Part D and Beyond" Robert Wood Johnson Foundation Program on Depression and Primary Care, Annual Meeting February 17, 2006, Amelia Island, FL.

"Direct-to-Consumer Advertising and Medical Consumerism" Center for Bioethics and Health Law Grand Rounds, University of Pittsburgh, December 2005.

"Transitioning Dually Eligible Individuals with Mental Disorders to Medicare Part D: Estimating the Effects on Access to Care" National Institute of Mental Health Research Coordination Workshop on the Medicare Modernization Act, Bethesda MD, December 2005.

"Formulary Design in the New Medicare Drug Benefit," National Institute of Mental Health Pharmacoeonomics Workshop, Bethesda MD, May 2005.

"Effects of Direct-to-Consumer Advertising on Medication Choice: the Case of Antidepressants" Marketing Brown Bag Seminar Series, Katz Graduate School of Business, University of Pittsburgh, April 2005.

"The New Medicare Drug Benefit: Implications for Depression Treatment," *Depression in Primary Care: Linking Clinical and Systems Strategies,* Annual Program Meeting, November 2004.

"Direct-to-Consumer Advertising and the Treatment of Depression," *Health Services Research Seminar* Sponsored by the Center for Research on Health Care, University of Pittsburgh, October 2004.

"Demand Effects of Direct-to-Consumer Advertising," *Achieving DTC Success* conference sponsored by DTC Perspectives, Princeton, NJ, October 15-16, 2003.

"Effects of Direct-to-Consumer Advertising of Prescription Drugs on the Treatment of Depression," U.S. Food and Drug Administration, Center for Drug Evaluation and Research, public meeting on *Research on Consumer Directed Advertising,* Washington, D.C., September 22-23, 2003.

"A Political History of Health Reform Efforts," lecture with Colleen Barry in *Core Seminar in Health Policy* taught by Professors Joseph Newhouse, David Cutler, and Richard Frank, Fall 2001, 2002, 2003.

"Direct-to-Consumer Advertising of Pharmaceuticals," lecture in *Introduction to Business and Management in Health Care,* taught by Professors Peter Slavin and Stan Finkelstein, Harvard Medical School, Spring 2002.

"Developing a Political Strategy for Health Policy," lecture in *Political Analysis and Strategy for U.S. Health Policy* taught by Professor Robert Blendon, John F. Kennedy School of Government, Spring 2001, 2002, 2003.

"Political Institutions and Health Policy," lecture in *Political Analysis and Strategy for U.S. Health Policy* taught by Professor Robert Blendon, John F. Kennedy School of Government, Spring 2001.

"Voters, Interest Groups and Health Policy," lecture in *Introduction to Health Care Policy* taught by Professor Richard Frank, Harvard University, Fall 2000, 2001, 2003.