This is "Exhibit 2" referred to
in the Affidavit of Michael Wilkes
affirmed before me at the City of Davis, California,
this _____ day of _____, 2006.

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A Report on the Effects and Issues Related to Direct to Consumer Advertising of Pharmaceuticals in the United States

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PART I – DTCA IN THE UNITED STATES

A. Introduction

Direct-to-consumer advertising of prescription drugs is a relatively new phenomenon that is affecting patients, doctors, and health care organizations in profound but not altogether predictable ways. Surveys suggest that Americans ask their doctors for information about advertised drugs, many ask for the drug itself, and many of these expect the doctor to comply and write them a prescription regardless of the doctor's professional opinion. There is no data to suggest that the public's health has improved as a result of these drugs, and lots of data to suggest that expenditures on drugs have increased and patients' expectations have changed with regard to medications. This testimony will outline what is known about the effects of direct to consumer advertising in the United States, and in particular the effects on patient behavior and doctor patient relations. I acknowledge that the pharmaceutical industry is an important contributor to modern health care, but its corporate objectives can collide with the health needs of the populace. In my opinion, on a fair reading of the evidence, the time for "trial periods" and "further study" is past; it is safe to conclude at this point that DTCA has negative effects (and no positive effects) on public health.

B. The History of Direct-to-Consumer Advertising of Prescription Medicines.

The Food, Drug and Cosmetic Act of 1938 gave the Food and Drug Administration (FDA) authority over the labeling of pharmaceuticals, but control over drug advertising remained with the Federal Trade Commission (FTC) until 1962. For years, the industry promoted drugs exclusively to physicians but in 1981 sought to target consumers as well. In 1985 the FDA announced that current regulations sufficiently protected consumers.[1] In effect, the pharmaceutical industry was allowed to advertise to the public but had to abide by existing standards, especially the "fair balance" provision mandating coverage of major risks and benefits. In 1997, the FDA issued draft guidelines on broadcast DTC advertising. For the first time manufacturers were allowed to provide both the drug's name and the medical condition in an advertisement without disclosing all of the product's side effects. However, advertisers were required to mention important risks and means for obtaining additional information.

C. FDA Oversight of DTCAs

While manufacturers are required to have the FDA oversee the launch of a new ad campaign, the agency seemed to be overwhelmed with the task and has not provided the

[1] Federal Register, 56 (September 9, 1985):36677.

guidance and protection that public expects. They have not assured the "fair balance" between risks and benefits required by law. In addition those complaints that the FDA does receive, often from manufacturers of competitive products, are handled with contempt and disregard spending months in processing and evaluation before issuing a warning letter. Even then, the companies often disregard these letters.

D. Current State Of Direct-To-Consumer Advertising in the US

Direct-to-consumer advertising of prescription drugs, defined as "any promotional effort by a pharmaceutical company to present prescription drug information to the general public in the lay media," is affecting consumers, patients, and physicians as never before.[2] Spending on direct-to-consumer advertising of prescription drugs in the United States totaled $4.65 billion in 2005.[3] DTCA has become a stable, if controversial, feature of the media landscape. Public health experts charge that DTC advertisements lead to over-prescribing of unnecessary, expensive, and potentially harmful medications, while manufacturers and advertisers counter that they can serve a useful educational function and help avert under-use of effective treatments for conditions that may be poorly recognized, highly stigmatized, or both. A thoughtful DTC advertising campaign could encourage patients to seek effective care for important conditions, however, DTC advertising could also promote prescribing of medicines to patients with minor or no symptoms in the absence of clearly defined indications. Through 2005, dozens of prescription drug brands were advertised directly to consumers. In theory, there are some advantages and disadvantages of DTCA. These are outlined in Table 1 to this report. However, the theory in respect of the advantages is weak, while the evidence of the disadvantages is very strong as previewed below and explained in detail later in this report.

PART II – VALUE IN DTCA

A. Is there a value of direct-to-consumer prescription drug advertising?

Controversies surrounding DTC advertising involve whether it informs or confuses consumers, increases or decreases health care costs, improves or undermines the clinical

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[2] Wilkes MS, Doblin BH, Shapiro MF. Pharmaceutical advertisements in leading medical journals: Experts assessments. Annals of Intern Med 1992; 116:912-919. Lexchin J. What information do physicians receive from pharmaceutical representatives? Can Fam Physician 1997; 43: 941-5

[3] Mattews A. The Science of DTC.*Medical Marketing and Media*, 2006

relationship between physician and patient, and improves or worsens patient health.[4] DTC advertisements deliver little drug education to consumers;[5] only 65% of DTC advertisements provided a fair balance of risk and benefit.[6] This result parallels the findings of studies documenting inaccurate claims in prescription drug advertisements targeted at physicians,[7] in materials distributed to physicians by drug sales representatives,[8] and in over-the-counter (OTC) advertising directed at consumers.[9] Concerns have also been raised over consumers' ability to understand and interpret DTC advertising.[10] Advocates of DTC ads argue that the messages contained in DTCA are "educational" and improve the public's health by stimulating consumers to seek additional information about drugs and conditions and may help them have better discussions with their doctors.[11]

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[4] Dr. Celebrity. Consumer Reports, May 1999, 8-9; Pinto MB. On the nature and properties of appeals used in direct-to-consumer advertising of prescription drugs. Psychological Reports 2000, 86:597-607; Kravitz RL, Bell RA, Azari R, Kelly-Reif S, Krupat E, Thom D. Patients' requests for services: prevalence, correlates, and effects on physician test ordering, referral, and prescribing. Unpublished manuscript, UC Davis, 2001; Mintzes B, Pan R, Evans R, Kravitz RL et al. Influence of direct-to-consumer advertising in Vancouver and Sacramento. Unpublished report, University of British Columbia, 2001; U.S. Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications. "Attitudinal and Behavioral Effects of Direct-to-Consumer Promotion of Prescription Drugs." http://www.fda.gov/cder/ddmac/researchka.htm.

[5] Rost K, Nutting P, Smith J, Coyne JC, Cooper-Patrick L, Rubenstein L. The role of competing demands in the treatment provided primary care patients with major depression. Arch Fam Med. 2000 Feb;9(2):150-4; Carthy P, Harvey I, Brawn R, Watkins C. A study of factors associated with cost and variation in prescribing among GPs. Family Practice 2000; 17(1): 36-41.

[6] Davis P, Gribben B, Scott A, Lay-Yee R. The "supply hypothesis" and medical practice variation in primary care: testing economic and clinical models of inter-practitilr variation. Social Science and Medicine 2000; 50: 407-18.

[7] Hart J, Salman H, Bergman M, Neuman V, Rudniki C, Gilenberg D, Matalon A, Djaldetti M. Do drug costs affect physicians' perception decisions? Journal of Internal Medicine 1997; 241: 415-20.

[8] Veninga CC, Lundborg CS, Lagerlov P, Hummers-Pradier E, Denig P, Haaijer-Ruskamp FM. Treatment of uncomplicated urinary tract infections: exploring differences in adherence to guidelines between 3 European countries. Drug Education Project Group. Annals of Pharmacotherapy, 2000; 34(1): 19-26.

[9] Steffensen FH, Sorensen HT, Olesen F. Diffusion of new drugs in Danish general practice. Family Practice 1999; 16: 407-13.

[10] Gill P, Scrivener G, Lloyd D, Dowell T. The effect of patient ethnicity on prescribing rates. Health Trends 1995-96; 27(4): 111-4; Avorn J, Solomon DH. Cultural and economic factors that (mis)shape antibiotic use: the nonpharmacologic basis of therapeutics. Annals of Intern Med 2000; 133(2): 128-135; Britten N, Ukoumunne O. The influence of patients' hopes of receiving a prescription on doctors' perceptions and the decision to prescribe: a questionnaire survey. *BMJ* 1997; 315(7121):1506-10.

[11] Cockburn J, Pit S. Prescribing behaviour in clinical practice: patients' expectations and doctors' perceptions of patients' expectations–a questionnaire study. *BMJ* 1997; 315:520-523

B. Types of DTC Advertisements

Before looking at the impact of DTC advertisements on the public it is important to paint a picture of the current spectrum of advertisements. DTC advertisements fall into three categories, according to Bradley and Zito:

- *Health seeking advertisements* are promotions that educate the reader about a disease or medical condition. The specific drug is not mentioned. An example would be an advertisement by Upjohn that encouraged men who were concerned about hair loss to talk with their physicians about the matter; Rogaine, a product aimed to treat hair loss, was never mentioned.
- *Reminder advertisements* provide the name of the drug and other minimal information, but say nothing about the drug's use, effectiveness, or safety. This type of advertisement is not required to provide a brief summary.
- *Product-specific advertisements* are promotions that mention a drug therapy by name, describes its therapeutic use(s), and makes representations about safety and effectiveness. The vast majority of advertisements fall within this category. These advertisements are the focus of our review.[12]

C. Content in DTC Advertising

I was a member of a team that conducted a content analysis of product-specific DTC prescription drug advertisements in an effort to describe trends in the prevalence of such advertising. The results of this study were published[13] in the article attached as **"Annex 1"** to this report. In brief, prescription drug advertisements appearing in each of 18 diverse lay magazines were collected. Judges independently coded each advertisement based on written messages into categories pertaining to the promotion's target audience, use of inducements, and product benefits. A total of 320 distinct advertisements were identified, representing 101 brands and 14 categories of medical conditions.

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[12] Bradley LR, Zito JM. Direct-to-consumer prescription drug advertising. Medical Care 1997; 35:86-92

[13] Bell RA, Wilkes MS, Kravitz RL. The educational value of consumer-targeted prescription drug print advertising. J Fam Pract. 2000 Dec;49(12):1092-8.

New advertisement and brand introductions increased dramatically over the course of the decade, as shown in Figure 1 to the study. Two-thirds of advertisements were for oral medications. Advertisements for dermatological, HIV/AIDS, and obstetrical/gynecological drugs were most common. Almost all advertisements were targeted to the potential user of the drug, not to third-party intermediaries such as parents and spouses. Women were more likely to be targeted than men. The finding that female-directed advertisements were more common than male-targeted advertisements is consistent with anecdotal evidence that women may be more influenced by brand-based drug promotions than men.[14]

The most common appeals used were based on claims of effectiveness, symptom control, innovativeness, and convenience. For instance, two-fifths of advertisements made claims of "innovativeness." Since advertisers often use "new and improved" claims to sell consumer products, it is not surprising that this heuristic is used to market pharmaceuticals. In truth, when it comes to drugs, what is new is not necessarily better and could even be more risky. Many new drugs are "me-too" products that offer few advantages over older drugs and have less well-understood safety profiles.[15] DTC ads tend to play up the positive features of a drug and downplay the negative or unknown aspects. Note, for instance, that side effects are almost always discussed last, not first. Headings and subheadings play up benefits. Side effects discussions are typically buried in the narrative.

While the breadth of prescription treatments advertised to consumers is impressive, the vast majority of drugs in the physician's arsenal have never been promoted in this manner. Clearly, treatments for certain kinds of conditions are more likely to be advertised to consumers.[16] Well represented are drugs for unfamiliar conditions (e.g., toe nail fungus), under-treated ailments (e.g., hypertension, depression), and conditions not treatable in the past with medication (e.g., erectile dysfunction). Also advertised often are drugs for chronic conditions routinely dismissed by physicians as minor, however miserable (e.g., allergies) or distressful (e.g., dermatological conditions). In contrast, treatments for acute conditions that are unlikely to be experienced by the reader at the time of media exposure were rarely advertised (e.g., antibiotics).

D. The controversy over a "need" for DTCAs

The primary goal of the pharmaceutical industry, to maximize profits, is no different than that of other industries. "The management must generate the highest level of profitability possible

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[14] Masson A, Rubin PH. Matching prescription drugs and consumers. N Engl J Med. 1985; 313:513-515.

[15] Bell RA, Wilkes MS, Kravitz RL. Advertising-induced prescription drug requests: Patients' anticipated reactions to a physician who refuses. J Family Practice 1999; 48: 446-52

[16] Bell, R.A., Kravitz, R.L., & Wilkes, M.S. *Ten Years of direct-to-consumer prescription drug advertising in the U.S.: Conditions, Targets, Inducements and Appeals*. Paper presented at the Annual Meeting of the International Communication Association, San Francisco, May 28, 1999.

to fulfill its fiduciary duty of maximizing shareholder value."[17] Towards this end, the pharmaceutical industry (Pharma) has been enormously successful. Its profits, whether measured in total dollars, net profits or CEO compensation, consistently rank at the top among industries.[18] It provides the public with many important and life-saving medicines, pays for a great deal of pharmaceutical research and sponsors a large percent of continuing medical education. These important activities are most likely to occur when the products are profitable and of interest to patients who can afford them. There is, however, a striking difference between Pharma's philanthropic claims about "putting every disease on the path to extinction,"[19] and its actual behaviors.

In response to criticisms that it almost completely neglects diseases of the poor – with for example virtually no research or spending on the world's leading killers, like malaria – in favor of wrinkle creams, baldness treatments, or even anti-anxiety medicines for pets,[20] a defender of Pharma cites the "fiduciary responsibility" of company executives to shareholders (rather than to patients, or to the public health). He notes "pharmaceutical companies have to discriminate" (against diseases or conditions whose treatment is unlikely to yield great profits), as "the decision must be based purely on sales and costs."[21] Other equally candid expressions from industry representatives, also stand in stark contrast to the nobler sentiments expressed to physicians and to the public. An industry representative predicts the "winners in prescription drug category are not going to be ones with the best products, but those that are best marketers."[22] Profit summaries confirm this prediction; sales of the 50 most heavily advertised drugs to consumers, was responsible for nearly half (47.8%) of the $20.8 billion increase in prescription sales in 1999-2000, compared to the other approximately 9,850 drugs that made up the other 52.2%.[23]

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[17] Perkins L. Pharmaceutical companies must make decisions based on profit. *WJM* 2001;175:422-423.

[18] Angell M. The pharmaceutical industry--to whom is it accountable? [editorial]. *NEJM* 2000;342:1902-1904; "Fortune 500," *Fortune Magazine*, April 2001. www.fortune.com; Families USA publication No. 01-104. Off the charts: pay, profits and spending by drug companies. 2001; www.familiesusa.org.

[19] Silverstein K. Millions for viagra, pennies for diseases of the poor. Research money goes to profitable lifestyle drugs. *The Nation* July 1999 p13-19.

[20] Ibid.

[21] Masson A, Rubin PH. Matching prescription drugs and consumers. *N Engl J Med.* 1985; 313:513-515

[22] Freeman, L. Prescription for profit: aggressive strategy helps propel Claritin to top slot. Schering ruffles feathers as it pushes limits on guidelines. *Ad Age* 3/16/98;69(11):S6-S7.

[23] NIHCM Foundation. Prescription Drugs and Mass Media Advertising, 2000. *A Research Report by the National Institute for Health Care Management.* 2001;November 2001:1-17. www.nihcm.org

E. The Educational Value Of Direct-To-Consumer Advertising

In the United States, industry representatives claim DTCA is not merely an educational tool in the fight against disease, but an essential liberty, a matter of "freedom of speech" needed to protect people "untreated and in pain" from a "government or insurance companies...(who do not)... want people to know there is a cure."[24] Industry contends that advertisements and marketing materials directed at physicians are educational, and "without distribution of information by pharmaceutical companies ...patients would be deprived of state-of-the-art care."[25] It is critical to the discussion of potential harms of DTCA to consider if Pharma has lived up to its "educational" commitment to physicians and patients.

1. The "education" of the American public

If the goal of advertising were to educate physicians, it should be possible to identify a relationship between advertising and deficiencies in medical practice. Instead, what we find is a relationship between marketing and the expense of - and thus potential profits from - the drugs in question. When ciprofloxacin was first approved it was "indicated" for only a handful of rare conditions, but was nevertheless one of the leading antibiotics in terms of number of prescriptions written and dollars spent, reflecting the intensive marketing of a new and expensive antibiotic.[26] Although no authority recommends calcium channel blockers as first line agents for hypertension, they are extremely big sellers, in a manner that closely mirrors marketing patterns.[27] Generic medicines, no matter how effective (and inexpensive), are not likely to be advertised. With the recent removal of cervistatin (Baycol©) from the market, a number of full page advertisements urged patients to see their doctors for an alternate medicine, some offering free coupons; lovastatin, the only generic in this class of drugs, was the only product not featured.[28] In most instances marketing is concentrated not on pharmaceutical advances, but rather on "non-innovative drugs in competitive therapeutic categories."[29] "Important new drugs do not need much promotion. "Me-too" drugs do because they are no better than drugs already on the market."[30]

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[24] Matthews M. Advertising and the informed patient. Pfizer forum (advertising supplement) 2001. www.pfizerforum.com

[25] Beary JF. Pharmaceutical marketing has real and proven value. Characteristics of materials distributed by drug companies: four points of view. *Gen Intern Med* 1996;11:635-636.

[26] Frieden TR, Mangi RJ. Inappropriate use of oral ciprofloxacin. *JAMA* 1990;264:1438-1440.

[27] Wang TJ, Ausiello JC, Stafford RS. Trends in antihypertensive drug advertising, 1985-1996. *Circ* 1999;99:2055-2057.

[28] Substituting For Cervastatin (Baycol). *Medical Letter* Sep 17, 2001;43:79-82.

[29] Stryer D, Bero LA. Characteristics of materials distributed by drug companies: an evaluation of appropriateness. *J Gen Intern Med* 1996; 11:575-583.

[30] Angell M. The pharmaceutical industry--to whom is it accountable? [editorial]. *NEJM* 2000;342:1902-1904.

2. *Lessons learned from the quality of direct-to-physician advertisements that provide insight to consumer issues*

Pharmaceutical advertisements often use images that appear to have nothing to do with the disease in question to evoke strong emotions and circumvent the logical evaluation of products.[31] Advertisements rarely present research data in sufficient detail for reasoned interpretation,[32] and when they contain scientific graphs or data tables they often promote numeric distortion - visual underestimation or overestimation of the results – in violation of specific FDA regulations.[33] Advertisements and materials distributed by drug companies frequently do not provide scientific support for their claims,[34] have little or no educational value,[35] and include claims that fail to comply with FDA regulations.[36]

In a content analysis we examined the educational value of DTC advertising (see **"Annex 1"**).[37] We found that few advertisements reported details about the condition's precursors or its prevalence or attempted to clarify misconceptions about the condition. Advertisements seldom provided information about the drug's mechanism of action, its success rate, treatment duration, alternative treatments, or behavioral changes that could enhance the patient's health. Thus, while informative advertisements were identified, most promotions provided only a minimal amount of information.

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[31] Ferner RE, Scott DK. Whatalotwegot – the messages in drug advertisements. *BMJ* 1994;309:1734-1736.

[32] Gutknecht DR. Evidence-based advertising? A survey of four major journals. *J Am Board Fam Pract* 2001;14:197-200.

[33] Cooper RJ, Schriger DL, Wallace RC, Mikulich VJ, Wilkes MS. Graphics in Pharmaceutical Advertisements: Are they truthful, are they adequately detailed? http://www.ama-assn.org/public/peer/prc_program2001.htm#ABSTRACTS.

[34] Stryer D, Bero LA. Characteristics of materials distributed by drug companies: an evaluation of appropriateness. *J Gen Intern Med* 1996; 11:575-583.

[35] Wilkes MS, Doblin BH, Shapiro MF. Pharmaceutical advertisements in leading medical journals: experts' assessments. *Ann Intern Med* 1992;116:912-919.

[36] Stryer D, Bero LA. Characteristics of materials distributed by drug companies: an evaluation of appropriateness. *J Gen Intern Med* 1996; 11:575-583; Wilkes MS, Doblin BH, Shapiro MF. Pharmaceutical advertisements in leading medical journals: experts' assessments. *Ann Intern Med* 1992;116:912-919; Rothermich EA Pathak DS, Smeenk DA. Health-related quality-of-life claims in prescription drug advertisements. *Am J Health-Syst Pharm* 1996;53:1565-1569.

[37] Bell RA, Wilkes MS, Kravitz RL. The educational value of consumer-targeted prescription drug print advertising. J Fam Pract. 2000 Dec;49(12):1092-8.

PART III -- THE EFFECTS OF DTCA

A. Introduction

DTCA has effects on the consumer and the physician in three ways previewed here and detailed further in the remaining report. First, the evidence strongly suggests that DTCA has a significant effect on consumers; consumer awareness of DTC advertisements is high and consumers often act upon the advertisements they see. Second, DTCA influences physician prescribing, including placing pressure on physicians to prescribe a specific product. Third, DTC advertisements may also affect the patient-physician relationship. On the one hand, DTC ads do seem to encourage clinical dialogue. On the other, such ads may foster prescription shopping and doctor switching.

B. The Effect of DTCA on Consumers

Up to one-third of American consumers have asked their doctors for information about a drug due to an advertisement, nearly a quarter have asked for a prescription, and of those, ¾ have received a prescription based on such a request.[38] DTC ads rely on the best of modern marketing appeals.[39] Indirect evidence supports the success of these appeals: growth in spending on drugs has been concentrated in 4 therapeutic categories that are among the most heavily promoted (antidepressants, antihistamines, cholesterol reducers, and anti-ulcerants).

Over the past 8 years, Drs. Bell, Kravitz and I have conducted research on DTC prescription drug advertising examining the consumer's orientation toward these promotions, the content of the advertisements, and regulatory and other policy issues. Much of this work was recently summarized in Health Affairs,[40] which is attached to this report as **"Annex 2."**

In a random phone survey of adult respondents were aware of nearly two-fifths of campaign advertisements (67% were aware of ads for Prozac). Awareness was associated with prescription drug use, media exposure, positive attitudes toward DTC advertising, poorer health, and insurance status. Consumers harbored substantial misconceptions about the regulation of DTCA. One-third of respondents reported asking their physicians for drug information on the basis of an ad and one-fifth requested a prescription.

When asked what they would do if their physician denied a request for an advertised prescription medication, 47% thought they would be disappointed, 25% anticipated resorting

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[38] Prevention/American Pharmaceutical Association. Navigating the medical marketplace: how consumers choose. Washington D.C. 1997.

[39] Dr. Celebrity. Consumer Reports, May 1999, 8-9; Pinto MB. On the nature and properties of appeals used in direct-to-consumer advertising of prescription drugs. Psychological Reports 2000, 86:597-607.

[40] Wilkes, M.S., Bell, R. and Kravitz, R. "Direct to Consumer Advertising: Trends, Impact, and Implications." Health Affairs Journal March 2000;19:110-128.

to prescription shopping by asking a different doctor for the drug, and 15% considered doctor switching a possibility. The respondents most likely to react in these ways tended to evaluate their physicians' communication abilities poorly, to like DTC advertising, and to possess unfounded faith in the government's regulation of DTCA.[41] This study, detailing these results, is attached as **"Annex 3"** to this report.

In a follow-up study, Bell et al. coded drug advertisements appearing in each of 18 diverse lay magazines into categories pertaining to the target audience, use of inducements, and product benefits. A total of 320 distinct advertisements were identified, representing 101 brands and 14 medical conditions. New advertisement and brand introductions increased dramatically over the course of the decade. Women were more likely than men to be exclusively targeted. Many ads offered a monetary incentive (e.g., a rebate or money-back guarantee) and one-third made offers of additional information in printed or audio-video form. The most common appeals used were effectiveness, symptom control, innovativeness, and convenience.

C. The Effect Of Direct-To-Consumer Advertising On Physician Prescribing

1. Influence on prescribing practices

On the basis of indirect evidence, exposure to a DTC advertisement approximately at least doubles the probability that a patient will receive a *specific* prescription medication. Supporting data are derived from three studies: 1) a 1999 survey of 909 adult patients and their physicians in Sacramento;[42] attached to this affidavit as **"Annex 4"**; 2) a 2001 survey of 1431 primary care patients in Sacramento and Vancouver (Binational), attached to this affidavit as **"Annex 5"**, in which our team collaborated with University of British Columbia colleagues,[43] and 3) a population-based survey of 1081 U.S. adults (FDA).[44] In these studies, 10-15% of patients made a request for a specific new medication during any given visit. Of patients making a drug request, 61% (95% confidence interval (CI), 35% to 87%) mentioned or referred to a specific DTC ad (FDA). Following a direct request, the likelihood of receiving a new prescription increased from 33% (95% CI, 31% to 35%) to 74% (95% CI, 68% to 80%) in the Binational study and by a factor of 2.6 (odds ratio) in the Kravitz et al. study. These estimates may be conservative, as Rost et al. recently reported that the odds of receiving an

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[41] Bell RA, Wilkes MS, Kravitz RL. Advertising-induced prescription drug requests: Patients' anticipated reactions to a physician who refuses. J Family Practice 1999; 48: 446-52.

[42] Kravitz RL, Bell RA, Azari R, Kelly-Reif S, Krupat E, Thom D. Direct Observations of Requests for Clinical Services in Office Practice. Arch Intern Med. 2003 Jul 28;163(14):1673-81.

[43] Mintzes B, Pan R, Evans R, Kravitz RL et al. Influence of direct-to-consumer advertising in Vancouver and Sacramento. Unpublished report, University of British Columbia, 2001.

[44] U.S. Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications. "Attitudinal and Behavioral Effects of Direct-to-Consumer Promotion of Prescription Drugs." http://www.fda.gov/cder/ddmac/dtcindex.htm.

antidepressant were increased by a factor of 4-5 when patients merely considered such therapy acceptable (without making a direct request).[45]

In the Binational study, participants included 1431 adults visiting primary care practitioners in Sacramento and Vancouver. When queried prior to the visit, 27% were hoping to receive a diagnostic test, 23% a specialty referral, and 18% a new prescription. Physicians rarely reported that they felt "pressured to prescribe," but the likelihood of receiving a new prescription was much higher among patients who asked directly for medication (74%) compared with those who did not ask (33%).

In the one recently completed study that we published in JAMA[46] attached as **"Annex 6"** to this report, we set out to ascertain the effects of patients' DTC-related requests on physicians' initial treatment decisions. Using standardized patients ("SPs" – actors trained to play a fixed role) we had "patients" show up primary care doctors offices with symptoms of a major depression and adjustment disorder. The doctors did not know the actors were no real patients. The SPs were randomly assigned to make 298 unannounced visits. The SPs made a brand-specific drug request, a general drug request, or no request (control condition) in approximately one third of visits. All doctor-"patient" encounters were audio-recorded. Our finding suggest that in major depression, rates of antidepressant prescribing were 53%, 76%, and 31% for SPs making brand-specific, general, and no requests, respectively (P<.001). In adjustment disorder, antidepressant prescribing rates were 55%, 39%, and 10%, respectively (P<.001). In this community-based randomized trial, antidepressants were prescribed far more often when SPs requested them. In addition, SPs portraying major depression and making either brand-specific or general requests were more likely than patients making no request to receive minimally acceptable initial depression care. These results underscore the idea that patients have substantial influence on physicians and can be active agents in the production of quality. Direct-to-consumer advertising may have competing effects on quality, potentially both averting underuse and promoting overuse.

A simple model of DTC advertising holds that (1) advertisement exposure raises consumer awareness of conditions and treatments; (2) increases awareness motivates patients to seek medical care and request drug therapy; and (3) patients' requests lead, ceteris paribus, to increased prescribing. Drug manufacturers endorse this model to the tune of $3.2 billion per year, but empirical evidence has been limited. Survey research suggests that advertisements raise consumer awareness and motivate patients to request prescriptions in up to 7% of primary care encounters. Although it does not address the impact of DTC advertising on consumer awareness or care seeking, our study supplies direct experimental evidence that

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[45] Rost K, Nutting P, Smith J, Coyne JC, Cooper-Patrick L, Rubenstein L. The role of competing demands in the treatment provided primary care patients with major depression. Arch Fam Med. 2000 Feb;9(2):150-4.

[46] Kravitz R, Epstein R, Feldman M. Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants. *JAMA*. 2005;293:1995-2002.

DTC advertisement–driven requests (along with general requests) dramatically boost prescribing.

Because brand-specific requests had a differentially greater effect in adjustment disorder compared with major depression, we believe that DTC advertising may stimulate prescribing more for questionable than for clear indications. This is of concern in that most products advertised are for conditions for which the net therapeutic effect is small and possibly negative. Harms are most likely to emerge when the target condition is trivial and the treatment is relatively perilous, ineffective, or costly. From a different perspective, these data pose a possible challenge to the "learned intermediary rule." If patients can sway physicians to prescribe drugs they would otherwise not consider, physicians may not be the stalwart intermediary that the law assumes.

2. *The influence on prescribing by non-clinical factors*

Substantial variations in primary care physicians' prescribing practices have been identified.[47] Physicians' prescribing is affected by cost considerations,[48] geography,[49] attitudes toward drug therapy,[50] patient demographic characteristics[51] and other social factors.[52] Most relevant to DTC advertising is the consistent finding that physicians are very sensitive to patients' demands for drugs.[53] Expectations have the strongest impact in situations in which the appropriate course of clinical action is unclear.[54] Anxious patients may be especially likely to

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[47] Carthy P, Harvey I, Brawn R, Watkins C. A study of factors associated with cost and variation in prescribing among GPs. Family Practice 2000; 17(1): 36-41; Davis P, Gribben B, Scott A, Lay-Yee R. The "supply hypothesis" and medical practice variation in primary care: testing economic and clinical models of inter-practitilr variation. Social Science and Medicine 2000; 50: 407-18.

[48] Hart J, Salman H, Bergman M, Neuman V, Rudniki C, Gilenberg D, Matalon A, Djaldetti M. Do drug costs affect physicians' perception decisions? Journal of Internal Medicine 1997; 241: 415-20..

[49] Veninga CC, Lundborg CS, Lagerlov P, Hummers-Pradier E, Denig P, Haaijer-Ruskamp FM. Treatment of uncomplicated urinary tract infections: exploring differences in adherence to guidelines between 3 European countries. Drug Education Project Group. Annals of Pharmacotherapy, 2000; 34(1): 19-26.

[50] Steffensen FH, Sorensen HT, Olesen F. Diffusion of new drugs in Danish general practice. Family Practice 1999; 16: 407-13.

[51] Gill P, Scrivener G, Lloyd D, Dowell T. The effect of patient ethnicity on prescribing rates. Health Trends 1995-96; 27(4): 111-4.

[52] Avorn J, Solomon DH. Cultural and economic factors that (mis)shape antibiotic use: the nonpharmacologic basis of therapeutics. Annals of Intern Med 2000; 133(2): 128-135.

[53] Britten N, Ukoumunne O. The influence of patients' hopes of receiving a prescription on doctors' perceptions and the decision to prescribe: a questionnaire survey. BMJ 1997; 315(7121):1506-10; Cockburn J, Pit S. Prescribing behaviour in clinical practice: patients' expectations and doctors' perceptions of patients' expectations–a questionnaire study. BMJ 1997; 315:520-523; Webb S, Lloyd M. Prescribing and referral in general practice: a study of patients' expectations and doctors' actions. British Journal of General Practice 1994; 44:165-169.

[54] Bradley CP. Uncomfortable prescribing decisions: a critical study. BMJ 1992; 304: 294-6.

receive a prescription. Physicians may feel pressured by patients' expectations out of a concern for preserving the doctor-patient relationship, appearing compassionate and responsive to the patient's suffering, and giving patients a sense of control over their health.[55]

D. The Effect of DTCA on the Patient-Provider Relationship

1. A conceptual model

A guiding model of the prescribing process as is depicted in Figure 1, following. The model specifies that physicians' prescribing decisions are influenced by the characteristics of the patient and physician, the dynamics of the medical encounter, and the environmental context in which the physician-patient negotiation occurs. The decision to prescribe, in combination with other aspects of the clinical process of care, affects patient outcomes.

In this model, the clinical process of care begins with the clinical characteristics of the ***patient.*** Important characteristics include the clinical presentation (e.g., symptoms, comorbid conditions, previous response to treatment), demographic factors (age, gender, social class, education, ethnicity, attitudes toward prescribing, and expectations for care.[56] An independent predictive factor may be patient's exposure to media (radio, print and television).

Prescribing is also affected by ***physician characteristics***, including the physician's knowledge about particular conditions and their treatment,[57] general attitudes toward drug therapy,[58] innovativeness (i.e., willingness to be an early adopter of new treatments),[59] beliefs

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[55] Bradley CP. Factors which influence the decision whether or not to prescribe: the dilemma facing general practitioners. British Journal of General Practice 1992; 42:454-458.

[56] Gill P, Scrivener G, Lloyd D, Dowell T. The effect of patient ethnicity on prescribing rates. Health Trends 1995-96; 27(4): 111-4; Gillam SJ. Sociocultural differences in patients' expectations at consultations for upper respiratory tract infection. J R Coll Gen Pract 1987; 37:205-6; Bradley CP. Factors which influence the decision whether or not to prescribe: the dilemma facing general practitilrs. British Journal of General Practice 1992; 42:454-458; Unutzer J, Klap R, Sturm R, Young AS, Marmon T, Shatkin J, Wells KB. Mental disorders and the use of alternative medicine: results from a national survey. Am J Psychiatry. 2000 Nov;157(11):1851-7; Virji A, Britten N. A study of the relationship between patients' attitudes and doctors' prescribing. Family Practice 1991; 8; Cockburn J, Pit S. Prescribing behaviour in clinical practice: patients' expectations and doctors' perceptions of patients' expectations–a questionnaire study. BMJ 1997; 315:520-523; Elinson L, Cohen MM. Implementation of practice guidelines: case study of horml replacement therapy. Abstract Book/Association for Health Services Research 1997; 14:104.

[57] Avorn J, Solomon DH. Cultural and economic factors that (mis)shape antibiotic use: the nonpharmacologic basis of therapeutics. Annals of Internal Medicine 2000; 133(2): 128-135.

[58] Steffensen FH, Schonheyder HC, Sorensen HT. High prescribers of antibiotics among general practitilrs–relation to prescribing habits of other drugs and use of microbiological diagnostics. Scandinavian Journal of Infectious Diseases 1997; 29: 409-13.

[59] Steffensen FH, Sorensen HT, Olesen F. Diffusion of new drugs in Danish general practice. Family Practice 1999; 16: 407-13.

about and confidence in the effectiveness of available treatments,[60] and familiarity with the patient.[61] Primary care physicians are known to vary considerably in their level of comfort in diagnosing and managing patients with a variety of common conditions.[62] There is also enormous variability in physician's susceptibility to outside influence and preferred learning styles.

The ***medical encounter*** consists of a set of interactions between patient and physician. It is more than the sum of the characteristics of its principal protagonists. Prescribing is influenced not only by clinical logic but also the social interaction.[63] Patients report their complaints and physicians interpret findings with varying degrees of certainty. Patients make their expectations known to the physician through requests that range from indirect hints to overt demands for action.[64] Physicians attempt to discern patients' prescription expectations and may feel pressured to "do something" even when inaction is the best course.[65] In short, patients and physicians negotiate treatments.[66] Patients come to their visits with explanatory models,[67] agendas for the encounter, and expectations for physician behavior. They employ various strategies for acquiring desired drugs, and physicians sometimes resist with their own strategies when such treatments are believed to be inappropriate.

Beyond the clinical negotiation, the medical encounter encompasses a set of physician behaviors that together constitute the ***clinical process of care***. These behaviors include both technical and interpersonal elements and largely determine quality of care (see **Figure 1**).

This whole process is affected by the cultural, economics, practice organization as well as by the information *environment*. For example, a clinician's decision to prescribe a

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[60] Hemminki E, Topo P. Prescribing of horml therapy in menopause and postmenopause. Journal of Psychosomatic Obstetrics and Gynecology 1997; 18(2): 145-57

[61] Bradley CP. Factors which influence the decision whether or not to prescribe: the dilemma facing general practitilrs. British Journal of General Practice 1992; 42:454-458.

[62] Callahan CM, Nienaber NA, Hendrie HC, Tierney WM. Depression of elderly outpatients: primary care physicians' attitudes and practice patterns. J Gen Intern Med. 1992 Jan-Feb;7(1):26-31.

[63] Kravitz RL. Direct-to-Consumer Advertising of Prescription Drugs: Implications for the Patient-Physician Relationship. *JAMA*, November 1, 2000; Vol 284, No 17.

[64] Kravitz RL, Bell RA, Franz C. (1999). A taxonomy of requests by patients (TORP): A new system for understanding the clinical negotiation in office practice. J Family Practice, 48, 872-878; Kravitz RL, Bell RA, Franz CE, Elliott M, Amsterdam EA, Willis C, Silverio L. (In press.) Characterizing Patient Requests and Physician Responses in Office Practice. HSR: Health Services Research.

[65] Webb S, Lloyd M. Prescribing and referral in general practice: a study of patients' expectations and doctors' actions. British Journal of General Practice 1994; 44:165-169.

[66] Lazare AS, Eisenthal L, Wasserman. The customer approach to patienthood: attending to patient requests in a walk-in clinic. Arch Gen Psychiatry 1975; 32:553-558.

[67] Kleinman A. Anthropology and psychiatry. The role of culture in cross-cultural research on illness. Br J Psychiatry. 1987 Oct;151:447-54; Weiss MG, Doongaji DR, Siddhartha S, Wypij D, Pathare S, Bhatawdekar M, Bhave A, Sheth A, Fernandes R. The Explanatory Model Interview Catalogue (EMIC). Contribution to cross-cultural research methods from a study of leprosy and mental health. Br J Psychiatry. 1992;160:819-30.

drug such as an antidepressant or anti-anxiety medications may be influenced by the availability of nonpharmacological alternatives such as on-site counselors or other easily accessible specialized mental health care. Broader forces are also at play. The drug industry promoted the belief that there is "a pill for every ill."[68] Economic constraints and incentives also affect physicians' prescribing decisions.[69] Incentive structures may encourage physicians to prescribe or not prescribe specific drugs, to limit health referrals, and to code physical conditions in certain ways e.g., ("fatigue") as opposed to mental health conditions ("depression"). Choice of medication may also be limited by formulary restrictions. Apart from economics, the prescribing process is also affected by the consumer movement, traditional news and entertainment media, and the Internet.[70]

Prescribing decisions stemming from the clinical negotiation influence ***patient outcomes***. In the near term, patients whose expectations for care are met will be more satisfied (and therefore more likely to adhere to therapy and maintain an ongoing care relationship). In the long run, more effective prescribing for depression will produce better control of depressive symptoms, improved functioning, and less psychosocial distress.

DTC advertising motivates some patients to talk to their health care providers about these ads and even make explicit requests based upon them. The effects of such requests on the clinical relationship are determined in large part by the physician's skill in fielding them.[71] If the physician uses such requests as a springboard for open discussions about significant health issues, the duly activated patients may achieve better health outcomes.[72] However, if the physician views such requests as a challenge to authority or a nuisance behavior, the physician-patient relationship could suffer. Even when physicians respond to an ad-motivated request without defensiveness, the clinical quality of the encounter could suffer if the physician becomes distracted by focusing on the drug requested rather than the nature of the clinical concern.

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[68] Bradley LR, Zito JM. Direct-to-consumer prescription drug advertising. Medical Care 1997; 35:86-92; Nikelly AG. Drug advertisements and the medicalization of unipolar depression in women. Health Care for Women International 1995; 16:229-242; Lober CW. Ethics in pharmaceutical advertising. Dermatologic Clinics 1993; 11:285-88.

[69] Hart J, Salman H, Bergman M, Neuman V, Rudniki C, Gilenberg D, Matalon A, Djaldetti M. Do drug costs affect physicians' perception decisions? Journal of Internal Medicine 1997; 241:: 415-20.

[70] Berland GK, Elliott MN, Morales LS, Algazy JI, Kravitz RL, Broder MS, Kanouse DE, Munoz JA, Puyol JA, Lara M, Watkins KE, Yang H, McGlynn EA. Health information on the Internet: accessibility, quality, and readability in English and Spanish. *JAMA*. 2001 May 23-30;285(20):2612-21.

[71] Kravitz RL. Patients' expectations for medical care: an expanded formulation based on review of the literature. Med Care Res Rev. 1996 Mar;53(1):3-27.; Bell RA, Wilkes MS, Kravitz RL. Advertising-induced prescription drug requests: Patients' anticipated reactions to a physician who refuses. J Family Practice 1999; 48: 446-52.

[72] Greenfield S, Kaplan S, Ware JE Jr. Expanding patient involvement in care. Effects on patient outcomes. Ann Intern Med 1985 Apr;102(4):520-8.

2. The effects of DTCA

Our project team has considerable experience in the study of the patient-physician relationship. Kravitz (1996) suggested that requests are the mechanism by which patients' expectancies and values influence events occurring during the visit.[73] These actual events (the objective "content" of the encounter) influence patients' perceptions of events, which are major determinants of patient satisfaction. The characteristics, needs and attitudes of patients and physicians, as well as the interpersonal and organizational context, influence the clinical negotiation. The clinical negotiation has consequences for patient well-being and for patient and physician satisfaction.

Direct to consumer advertising influences physician prescribing. In a telephone poll of 199 primary care physicians in Ohio and Pennsylvania, respondents indicated that on average 5 patients per week asked them to prescribe a specific product; 30% of the time they complied. 47% reported feeling "a little" pressure to prescribe when patients asked, and 6% felt "a lot" of pressure.[74]

Our conclusions concerning the negative effects of DTCA on the physician-patient relationship are also based on my own research,[75] (see **"Annex 3"**.) So far, my colleagues and I are the only ones to conduct a study, recently published in JAMA, (see **"Annex 6"**), that directly observed how physicians behave when confronted with a patient making an advertisement-motivated request for a prescription.[76] Primary care physicians tend to hold negative attitudes toward DTC advertising.[77] Physicians' concerns about such advertising may reflect a fear of losing professional control, as well as a learned distrust of pharmaceutical promotions.

E. Actual Harms That Come From DTC Advertising

1. Cost of health care

Aside from the adverse effects generated by medicalization of various aspects of normal life (promoted so strongly by DTCA) and by unnecessary use of medications,

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[73] Kravitz RL. Patients' expectations for medical care: an expanded formulation based on review of the literature. Med Care Res Rev. 1996 Mar;53(1):3-27.

[74] Spurgeon D. Doctors feel pressurised by direct to consumer advertising. BMJ 1999;319:1321.

[75] Bell RA, Wilkes MS, Kravitz RL. Advertising-induced prescription drug requests: Patients' anticipated reactions to a physician who refuses. J Family Practice 1999; 48: 446-52.

[76] Kravitz R, Epstein R, Feldman M. Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants. *JAMA*.2005;293:1995-2002.

[77] Gill P, Scrivener G, Lloyd D, Dowell T. The effect of patient ethnicity on prescribing rates. Health Trends 1995-96; 27(4): 111-4; Avorn J, Solomon DH. Cultural and economic factors that (mis)shape antibiotic use: the nonpharmacologic basis of therapeutics. Annals of Intern Med 2000; 133(2): 128-135.

increased costs lead to medical harm, particularly for the poorest among us, in a world where healthcare budgets are at their limits, because of what else we will be forced to give up.

DTCA does not promote inexpensive, therapeutically efficacious generic medications, or preventative health services; it far more typically pushes lifestyle medicines, and new, expensive, me-too drugs. The consequences of this for the public health can perhaps be better understood by looking at the companion topic of cost-effectiveness analysis, which is becoming increasingly popular in the medical literature. It has been pointed out that a great many such "cost-effectiveness analyses" consist mostly of data manipulation by marketing departments of proprietary companies, designed to prove that a terribly expensive new drug is "really very cheap," because it only costs "a little more," while it buys so much purported benefit.[78] Cost-effectiveness, from an economist's point of view, actually has to do with getting just as much benefit for less, or (in the tough cases), getting a little less benefit while saving substantial resources; it is not about spending more to get more. That is because whenever we spend even a "little" more, for whatever purported benefit, we inevitably pay the opportunity cost for whatever else we are forced to sacrifice. From the medical and public health perspectives, we always have to give something up, because there are not unlimited resources. The sacrifices may well be worth it in some cases, but it is impossible to know without at the very least considering what it is we will give up.

The pharmaceutical industry is not interested in addressing the issue of limited resources – and why should it be, when it can create consumer demand by selling sickness to the public. In the US, money spent on DTCA has continued to increase dramatically, as has per capita spending on healthcare, without any demonstrable increase in health, and the industry enjoys continued lucrative profits. Demand for a particular drug, say the antidepressant Zoloft, seem to benefit all members in the class of antidepressants – a so called "class effect".

In the same vein, budget cuts in health care, and the public health consequences to which they will surely lead, are also inextricably linked to the skyrocketing cost of prescription medications, which is in turn due in part to DTCA. If DTCA does not produce medical benefit (as Toop et al show it does not)[79] then it is not simply medically neutral because it will inevitably lead to the loss of critical services – typically those that are actually the most cost-effective, such as childhood immunizations, or access to primary care, or the availability of inexpensive but tremendously effective medications, which are always vulnerable in the absence of powerful lobbies to champion them.

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[78] Hoffman JR, Wilkes M. Direct to consumer advertising of prescription drugs: An idea whose time should not come. BMJ 1999; 318:1301-2; Kravitz RL. Direct-to-consumer advertising of prescription drugs. Western Journal of Medicine, October 2000; 173.

[79] Toop L, Richard D, Dowell T, Tiltyard M, Fraser T, Arroll B. Direct to Consumer Advertising of Prescription Drugs: For Health of For Profit? www.chmeds.ac.nz/report.pdf

2. DTCA does not improve health by increasing clinically necessary care

DTC advertising clearly increases the volume of prescribed drugs, but little research has addressed whether these additional prescriptions are clinically appropriate. Proponents claim that DTC ads avert under-use of effective medicines without significantly increasing inappropriate use. However, substantial inaccuracies have been documented in the industry's promotional materials.[80] In addition, DTC advertising may encourage patients to pressure their physicians to switch them from well-studied treatments to new drugs, for which knowledge about benefits and risks is more limited.[81] For example, the drug citalopram (Celexa), a treatment for depression, may or may not have clinical advantages but has rapidly gained market share owing to an especially aggressive campaign by Forest Laboratories and its partner, Warner-Lambert.[82]

The bottom line is that there is much controversy, but little evidence to suggest a health benefit of DTC advertising. Long-term, the net public health gain or loss must be determined by (1) the current prevalence of under-treatment (i.e., the number of patients not receiving drug therapy who should be), (2) the amount of inappropriate (i.e., harmful) prescribing that has been stimulated by DTC advertising, and (3) the degree of harm accruing to under-treated vs. over-treated patients (including economic harm). In addition, there are issues related to lost opportunity costs and the prices of drugs which need to cover the high cost of promotional marketing of DTCA.

3. The cost of DTCA of prescription drugs in the US

Per capita spending on prescription drugs in the United States exceeds $300 annually. The nation's annual drug budget grew at double-digit rates over most of the past decade and the rate of increase is accelerating. Four-fifths of prescriptions are paid for, at least in part, through private or public insurance.[83] DTC advertising invariably promotes branded medications, subverting efforts to increase reliance upon less costly generic drugs. Furthermore, advertised drugs are often new, expensive drugs that may offer few advantages over older drugs and have less well-understood safety profiles. As an example of strategies

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[80] Wilkes MS, Doblin BH, Shapiro MF. Pharmaceutical advertisements in leading medical journals: Experts assessments. Annals of Intern Med 1992; 116:912-919; Lexchin J. What information do physicians receive from pharmaceutical representatives? Can Fam Physician 1997; 43: 941-5; Sansgiry S, Sharp WT, Sansgiry SS. Accuracy of information on printed over-the-counter drug advertisements. Health Marketing Quarterly 1999, 17(2):7-18.

[81] Committee on Drugs for the American Academy of Pediatrics. Prescription drug advertising direct to the consumer. Pediatrics 1991; 88:174-5.

[82] Business Week Online, November 11, 1999. Will Forest Labs End Its Celexa Deal with Warner-Lambert? Their co-marketing of the antidepressant Celexa

[83] Prevention/American Pharmaceutical Association. Navigating the medical marketplace: how consumers choose. Washington D.C. 1997.

drug manufacturers may employ in the future, Eli Lilly has recently re-introduced Prozac®, which is about to go off patent, as Sarafem®, remarketed for treatment of premenstrual disorder. Other drugs whose patents expired were also re-introduced with slight modifications (eOmprazole) but no clinical differences. DTC advertising has played a major role in this agent's re-introduction.

The main policy questions are whether the ad-induced requests are fulfilled selectively or indiscriminately and whether such prescriptions are cost-effective. Of course, even very expensive pharmaceuticals can be cost effective relative to their alternatives (e.g., hospitalization, electroconvulsive therapy, marked functional decline, or suicide). However, if ad-induced prescriptions are written mainly for low risk individuals with mild symptoms, such prescriptions could have unfavorable cost-effectiveness ratios.

CONCLUSION

In the United States, skilled marketing contributes greatly to Pharma's profits even when it is unbalanced or inaccurate, and even though it raises health-care costs and leads to non-evidence-based prescribing. As such it would be foolhardy to expect the industry to change its approach. When we examine advertising of prescription drugs by pharmaceutical companies in the United States, it is clear that issues of corporate profits the have taken precedence over public health[84] Although regulations do exist to define and limit what can and cannot be claimed in drug promotions, these are frequently violated in actual advertisements, and at best inconsistently enforced.[85]

The case against DTCA is evidence-based and centered around the public's health. Americans ask their doctors for information about advertised drugs, many ask for the drug itself, and many of these expect the doctor to comply and write them a prescription regardless of the doctor's professional opinion. There is no data to suggest that the public's health has improved as a result of these drugs, and lots of data to suggest that expenditures on drugs have increased and patients' expectations have changed with regard to medications in ways that may be harmful to them.

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[84] Wilkes MS, Doblin BH, Shapiro MF. Pharmaceutical advertisements in leading medical journals: Experts assessments. Annals of Intern Med 1992; 116:912-919.

[85] Pinto MB. On the nature and properties of appeals used in direct-to-consumer advertising of prescription drugs. Psychological Reports 2000, 86:597-607; Wilkes, M.S., Bell, R., and Kravitz, R. "Direct to Consumer Advertising: Trends, Impact, and Implications" Health Affairs Journal March 2000;19:110-128; Kravitz RL, Bell RA, Azari R, Kelly-Reif S, Krupat E, Thom D. Patients' requests for services: prevalence, correlates, and effects on physician test ordering, referral, and prescribing. Unpublished manuscript, UC Davis, 2001.

Table 1	
Advantages[86]	***Disadvantages***[87]
• Speeds the dissemination and adoption process for new treatments from manufacturer to endpoint user.	• Promotes the use of new treatments before their safety profile is fully understood. Encourages the false belief that new drugs are necessarily better drugs.
• Encourages consumers to visit medical providers for conditions that may have been untreated.	• Create unnecessary visits to health care providers.
• Brings more patients under treatment for serious conditions.	• Encourages unnecessary use of medications. In particular, "medicalizes" natural processes such as balding and wrinkling skin. (The term "medicalizes" is used here to refer to the process by which a condition comes to be thought of as one requiring medical intervention, including drug therapy.
• Meets consumer demand for information about symptoms, diseases, and treatments. (cont'd)	• Misinforms the public by providing information that is incomplete, misleading, and inaccurate. (cont'd)

[86] Masson A, Rubin PH. Matching prescription drugs and consumers. *N Engl J Med.* 1985; 313:513-515; Hunt, M. *Direct to Consumer advertising of prescription drugs.* National Health Policy Forum April 1998 (unpublished); Ingram RA. Some comments on direct-to-consumer advertising. *Journal of Pharmaceutical Marketing and Management.* 1992;7:5-22; Holmer AF. Direct-to-consumer prescription drug advertising builds bridges between patients and physicians. *JAMA.* 1999; 281: 380-382; Reynolds WJ. Trends in advertising pharmaceuticals: a publisher's perspective. *Journal of Pharmaceutical Marketing and Management.* 1992;7:67-74; Pines WL. Trends in health care consumer communications. *J Phar Mark and Management* 1997; 7; Keith A. The benefits of pharmaceutical promotion: An economic and health perspective. *Journal of Pharmaceutical Marketing and Management* 1992; 7:121-133.

[87] Hoffman JR, Wilkes M. Direct to consumer advertising of prescription drugs: An idea whose time should not come. *BMJ* 1999; 318:1301-2; Wilkes, M.S., Bell, R. and Kravitz, R. "Direct to Consumer Advertising: Trends, Impact, and Implications" Health Affairs Journal March 2000;19:110-128; Woloshin S, Schwartz LM, Tremmel J, Welch HG. Direct-to-consumer advertisements for prescription drugs: what are Americans being sold? Lancet 2001;358(9288):1141-6; Nikelly AG. Drug advertisements and the medicalization of unipolar depression in women. *Health Care for Women International* 1995; 16:229-242.

Table 1

Advantages[86]	*Disadvantages*[87]
• Reduces the cost of medicines by encouraging competition between products.	• By promoting unnecessary prescribing and discouraging use of generics, drives up health care costs to both managed care and health consumers.
• Helps consumers choose the best treatment with the most acceptable side effects.	• Puts pressure on physicians to prescribe inappropriately for conditions that are treated best with other drugs or not at all.
• Empowers consumers and facilitates doctor-patient communication.	• Confuses consumers by focusing attention on treatments rather than the patient's health.
• Encourages patients to take full advantage of medicines that may improve quality of life.	• Leads to adverse drug events and resistant infections, which reduces the quality of life for all of us.
• Improves the public's health, overall.	• Damages the public's health by taking the physician's time away from important health education topics and requiring "re-education" about drug products.

Figure 1 – A conceptual model of the physician-patient relationship