

# BYPASSING THE GATEKEEPERS:

## Selling Prescription Drugs Directly to Consumers

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## **ABSTRACT:**

Prior to 1989 prescription drug manufacturers rarely used consumer advertising, spending less than \$5 million between 1985 and 1988. The manufacturers' reluctance was largely due to physicians, which bitterly opposed their use of consumer advertising. However, by 1996, a mere seven years later, the situation had reversed itself, as drug manufacturers spent over \$790 million on the marketing, despite continued physician opposition. Over the course of those seven years physicians lost their influence vis-à-vis consumer advertising, and explaining why is the central goal of this paper. Towards that end I address four questions: (1) Why were physicians opposed to consumer advertising?; (2) Why did this opposition influence drug manufacturers prior to 1989?; (3) Why did the opposition cease to deter the drug manufacturers in the 1990's?; (4) How did drug manufacturers work to overcome physician opposition? In the end I will argue that physician influence was diminished by two factors: 1) the Managed Care revolution circumscribed physician prescribing authority, which, in turn, weakened their influence over the drug industry, and 2) drug manufacturers studied physician opposition, which enabled them to deploy the ads in a way that was less likely to provoke physicians. Moreover, this work will contribute to the market sociology literature.

## **INTRODUCTION**

While prescription drug manufacturers<sup>1</sup> have advertised to doctors since at least the 1930's, their use of consumer advertising is a recent phenomenon, for it's only in 1985 that they first used this marketing approach.<sup>2</sup> Moreover, by 1989 their use of Direct-to-Consumer (DTC) ads had grown very little, for that year drug manufacturers only spent \$10 million dollars on this type of marketing (Young & Surrusco, 2001). Today, however, drug manufacturers spend over \$3.2 billion per year on this marketing strategy (Hollon, 2005), representing a 300-fold increase since 1989.

In and of itself, such explosive advertising growth is remarkable, as it represents a complete reversal from the previous status quo. What makes it particularly remarkable is that the ads emerged despite the physicians' strenuous opposition to them, opposition that had previously deterred the manufacturers from using the ads (Lipsky & Taylor 1997, Weissman et al. 2004). Consequently, studying this marketing revolution provides a unique opportunity to identify 1) the factors that account for sudden shifts in marketing strategies, 2) the social forces that constrain industry from using those strategies, and 3) how industry manages and overcomes opposition to their new marketing strategies.

To shed greater light on these issues I analyze the relationship between doctors and pharmaceutical companies, and address four central questions: (1) Why were physicians opposed to DTC ads in the first place?; (2) Why did this opposition influence drug manufacturers prior to 1989?; (3) Why did that opposition cease to deter drug manufacturers in the 1990's?; (4) How did drug manufacturers work to overcome physician opposition? In the end I will argue that physician influence was diminished by two factors: 1) the Managed Care revolution circumscribed physician prescribing authority, which, in turn, weakened their influence over the drug industry, and 2) drug manufacturers studied physician opposition, which enabled them to deploy the ads in a way that was less likely to provoke physicians.

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1. "Prescription drugs" can be defined as drugs whose legal acquisition requires a doctor's prescription. Such drugs are to be differentiated from the Over-The-Counter (OTC) drugs (e.g. aspirin, cough medicine, etc.), which can be purchased without a doctor's prescription.

2. brand-name prescription drugs are to be differentiated from generic drugs, which are cheaper to produce and are far more affordable for consumers.

## **THE STATE OF KNOWLEDGE ABOUT DTC ADVERTISING**

The rise of DTC ads has sparked vigorous debate, both in public as well as academic forums, with much being written about the potential and realized consequences of this marketing, including how the ads might impact 1) consumer medical knowledge (Bell et al. 2000, Kaphingst et al. 2004, Young et al. 2005), 2) the physician-patient relationship (Weissman et al. 2005, Robinson et al. 2004, Berndt 2005), 3) prescription decisions (Zachry et al. 2002, Kravitz et al. 2005, Mintzes et al. 2003), 4) prescription drug spending (GAO 2002, Woloshin et al. 2001, Kaiser Family Foundation 2003), 5) patient safety (Hochhauser 2005), and 6) the cost of healthcare (Rizzo 1999).

However, with all the focus given to the consequences, very little has been written about the causes behind this marketing revolution, which is surprising when we consider the consternation the ads have provoked in the medical community. One of two exceptions is John Abramson's work, which attributes the rise of DTC ads to a) the 1997 easing of Food & Drug Association (FDA) regulations, and b) the Americans' migration to health plans that cover prescription drug expenditures (Abramson 2004). Although Abramson's causal explanation is an interesting one, and is worth further investigation, there are two main problems with it: 1) he provides very little support for his claim, and 2) he posits 1997 as the watershed year in this marketing revolution, whereas drug manufacturers began using DTC ads in 1989. While it is true that manufacturers only spent \$10 million on DTC ads in 1989, by 1996 that spending had mushroomed to \$791 million (Mercola 2002), thus underscoring the need to study the pre-1997 events.

The second exception has been my previous work on the issue, which demonstrated that the sudden shift to DTC ads was driven by three market altering events, each of which strengthened generic drug producers at the expense of brand-name drug manufacturers (Vallée 2002). Those events were: 1) the 1982 TEFRA Act, which encouraged the growth of the HMO industry, and led to the rationing of

brand name drugs, 2) the 1984 “Drug Price Competition and Patent Restoration” Act, which made it easier to produce generic drugs, and 3) the generic drug industry’s 1985 court victory over the FDA, which permitted generic drug manufacturers to use consumer ads for their products. In that altered environment generic drug manufacturers had a much stronger hand, which gave brand name producers a much stronger incentive to pursue consumer advertising.

Despite this contribution, however, the analysis was still incomplete, for while the economic pressures began mounting in the early 1980s, and were quite significant by 1985, the brand-name drug producers didn’t turn to DTC advertisements until 1989. Moreover, it wasn’t for a lack of interest on their part. As one 24-year advertising veteran articulated:

"we had long wanted to go to consumer advertising... for the creative and economic benefits that it promised, but always refrained from doing so, for fear of pissing off the doctors." (interview June 1997)

Apart from reflecting the industry’s interest in DTC ads, his comment suggests that physicians were strongly opposed to this form of marketing, and, importantly, the drug manufacturers knew it and respected it.<sup>3</sup> This underscores that DTC advertising didn’t emerge unopposed, and that many agents had a stake in opposing the use of this advertising. Along these lines, one could also point to regulatory agencies<sup>4</sup> and HMO bureaucrats<sup>5</sup> as other agents who opposed DTC ads. Doctors, though, are particularly important to this story, for, ever since the emergence of prescription drugs, they have been the gatekeepers between drug manufacturers and the consumer market, a fact drug manufacturers

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3. Some might argue that the FDA’s deterrence effect was just as important, citing the lack of DTC ads during the FDA’s mid-1980s moratorium on prescription drug consumer advertising. However, such an argument would be unsatisfactory for two reasons. First, prior to the moratorium, in 1983, there were no governmental regulations prohibiting the DTC ads, yet manufacturers refrained using such marketing. This suggests that manufacturer behavior was influenced by other agents with power. Second, after the moratorium was lifted, in 1985, brand-name manufacturers refrained from using the ads until 1989, thereby also suggesting that manufacturers were being deterred by another source of power. Consequently, while the FDA’s moratorium may have slowed the manufacturers’ movement towards consumer advertising, it is the physicians’ opposition that served as the primary deterrence..

4. For instance, the FDA’s monitoring of the pharmaceutical industry has been made more difficult by the additional responsibility of having to monitor and regulate consumer advertising, a task for which they are understaffed, and underfunded.

recognized and respected.<sup>6</sup> With that said, something changed in 1989, as physician opposition ceased to be an effective deterrence against consumer advertising. Shedding light on why will be this paper's central goal.

For theoretical insight on these developments I turned to Paul Starr's *The Social Transformation of American Medicine*, which illuminated the 150 year relationship between physicians and drug manufacturers (Starr 1982). Starr showed that 19<sup>th</sup> century drug manufacturers openly competed against physicians, using consumer ads that explicitly denigrated the medical profession. As well, he specified how the medical profession got even with the drug industry in the early 1900s. More specifically, during the second half of the 19<sup>th</sup> century medical profession leaders sought to improve the profession, and over time their efforts led to greater scientific credibility, prestige, wealth, and political power. In turn, the profession's newly acquired muscle gave them the power to rein in the drug manufacturers' marketing activities, leading the drug producers to abandon their use of consumer advertising. Given this history, it stands to reason that if greater organizing enabled physicians to stamp out the original consumer ads, the loss of such organizational power would help explain why physicians ceased being a deterrence in the late 1980s. This is the main theoretical proposition that this paper will engage with, and I will return to it in the concluding chapter.

The core of this paper is divided into four sections. The first analyzes the physician opposition, and elucidates the real concerns they had with DTC ads, while the second explains why drug manufacturers previously respected physician opposition to. The third section focuses on a) the medical bureaucrats' growth in power, b) how that growth in power circumscribed the physicians' ability to prescribe, and c) how the physicians' circumscribed power diminished their leverage vis-à-vis the drug manufacturers. And the fourth section will demonstrate how drug manufacturers worked

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5 . The medical bureaucrats' opposition to DTC ads dates back to 1983, when passage of the TEFRA act gave them far greater incentive to ration medical resources, and reduce the use of expensive resources, such as brand-name prescription drugs.

6. A significant part of the advertiser's mission is shaping how physicians perceive drug manufacturers and their products, for industry research has demonstrated that while physicians like to posit themselves as making purely 'rational' decisions, the truth is far different,

to defuse and control the physicians' opposition. In the concluding section I will tease out how the implications of this case for our understanding of A) the likelihood that drug manufacturers will use DTC ads in other countries, B) the source of physician power, and C) the sociology of markets literature.

## **THE PHYSICIAN OPPOSITION TO CONSUMER ADVERTISING**

### **1) The Source of Physician Opposition**

Why were physicians opposed to consumer advertising? In order to answer that question it is essential to understand the physician concerns with consumer advertising. Moreover, we can shed light on the issue by examining the letters that medical associations sent to the FDA, during the agency's 1983-85 moratorium on consumer advertising.

The overarching concern emerging from those letters is that DTC ads would confuse patients, because they were destined to make overly general claims, and omit pertinent information about side effects and contraindications.<sup>7</sup> In addition, presuming the ads provided all the necessary information, physicians believed that patients lacked the capacity to properly understand the medical information provided in the ads (US Gov. 1984).

In turn, physicians feared that such confusion would impact healthcare in three ways. First, the ensuing confusion would frighten the patient, and delay them from seeking medical attention. Second, the ads would lead consumers to pressure doctors into prescribing advertised products when such products were inappropriate, or were an inferior treatment option (ibid.). And third, the confusion from the ads would reduce the amount of time dedicated to addressing the patient's illnesses, as doctors would have to spend time correcting the misinformation that patients absorbed from the ads. Not only

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with emotional factors playing a significant role in physician prescription decisions. Thus, the advertisers try to avoid doing things that could lead physicians to see the drug manufacturer in a negative light.

would they have to correct the misinformed patient, physicians would also be obliged to explain why advertisements were not a viable source of medical information, thus further reducing the amount of time dedicated to the patient illnesses (ibid.).

While the FDA letters communicated the medical profession's concern for their patients, they fail to divulge the physicians' vested interests vis-à-vis DTC advertising. For instance, the letters fail to communicate that disseminating information to consumers would erode the physician monopoly over medical-knowledge, which would weaken both their "cultural authority"<sup>8</sup>, and their control over the physician-patient relationship. This is not an idle point, for Paul Starr found that the power of American physicians was founded on the profession's ability to monopolize medical knowledge in the 1910s & 1920s, which, ironically enough, was achieved by compelling drug manufacturers to restrain from advertising directly to consumers (Starr, 1982).

Moreover, the FDA letters also failed to disclose the physician concern that such a loss of authority could drive a wedge between themselves and some of their clients, thereby impacting their livelihood. More specifically, many physicians feared that consumer advertising would lead patients to arrive at the clinical encounter with expectations of getting a specific medication, and predisposed to taking their business elsewhere if the physician didn't comply. Such concerns are exemplified with the following:

"one morning this month, Dr. Michael Buenaflor, a family practitioner in Northampton, PA., took a call from a patient who wanted a prescription. And not just any prescription. The caller insisted on Nicorette, a drug intended to help people stop smoking. How did he find out about it? From an advertisement. When Buenaflor suggested that the drug might not be appropriate for prolonged use, since the patient had a heart condition and an ulcer, the man hung up and took his 'business' elsewhere. Concludes Buenaflor: 'The pressure to use these drugs is incredible.'" (Purvis 1990)

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7. "Contraindications" refers to conditions under which the patient should not be taking a particular drug. These can include having a certain illness, or be undergoing another medical therapy, such as other pharmaceutical medications.

8. In *The Social Transformation of American Medicine* Paul Starr argued that the physicians' success at monopolizing medical knowledge is what enabled them to accrue their "cultural authority" that physicians were able to consolidate their "cultural authority" because they successfully monopolized medical knowledge, which was partially accomplished by diminishing the amount of information that drug manufacturers disseminated to consumers (p. 128-133).

Similar episodes emerged during physician interviews, with one physician relating how he lost a client due to his unwillingness to prescribe Sporanox, a medication designed to eliminate toe-nail fungus.

"a few months ago one of my long-time patients called me, asking me to prescribe Sporanox. However, I refused because that drug was contraindicated with the pharmaceuticals he was already taking. Unfortunately, he wasn't ready to take 'no' for an answer, and spent the next 15 minutes trying to change my mind... Having failed to do so, he hung up in a huff and I haven't heard from him since." (Interview Nov. 1997)

Such episodes suggest that physicians were justified in being concerned about the ads, both for their impact on physician interests, as well as patient well-being. What I now turn to is addressing how the physician opposition manifested itself over time, as well as why such opposition deterred the drug manufacturers from using DTC advertising.

## **2) The Source of Physician Power**

Why was physician opposition previously a deterrence to DTC ads? In order to answer that question we need to historicize the relationship between drug manufacturers and physicians, for the struggle over consumer advertising stretches back to the mid 19<sup>th</sup> century, and tracing that struggle will illuminate why the balance of power changed at the end of the 20<sup>th</sup> century.

Ever since its inception, in 1844, the American Medical Association (AMA) opposed consumer ads for pharmaceutical products, because drug manufacturers were competing directly with physicians, and their ads explicitly denigrated the medical profession. The medical profession's first organized response to the ads occurred in 1849, when the AMA attempted, unsuccessfully, to establish a council dedicated to regulating the drug industry (Starr 1982). In the ensuing decades the AMA pursued several other efforts to rein in drug advertising, but the AMA always lacked the financial resources necessary for success.

By 1900, however, the situation began to change. The medical profession, thanks to the AMA's efforts, had finally achieved a high degree of professional unity, which enabled the AMA to accrue tremendous financial resources. With such resources in hand, the AMA took another stab at regulating the advertising, asking medical journals to reject all advertisements that were either A) marketed to the public, or B) whose ingredients weren't disclosed to the public. Although that request fell on deaf ears, they tried again in 1905 and succeeded, as the profession's leading medical journal (e.g. The Journal of the AMA (JAMA)) took the editorial decision to reject all ad submissions for products that were also advertised to consumers. Other medical journals quickly followed JAMA's lead, and effectively forced drug manufacturers to choose between marketing their products to consumers or to physicians. Given physicians' growing medical authority, the drug manufacturers were left with little real choice in the matter. Furthermore, in 1924 the medical profession strengthened its assault against consumer advertising, as JAMA extended its advertising policy to exclude all drug companies who used consumer advertising for any product (Starr 1982). From this point onwards, drug manufacturers had to decide to either dedicate themselves entirely to the consumer market or to the medical profession, with the majority choosing the latter. The self-imposed ban on consumer ads even persisted during the 1950s, the Golden age of pharmaceuticals, when drug manufacturers made one discovery after another, and had millions to spend on advertising.

However, in the early 1980s something changed, as manufacturers openly expressed their interest in consumer ads, which, in turn, prompted physicians to re-manifest their opposition to the marketing. In particular, the opposition manifested itself during the FDA public discussions on DTC advertising<sup>9</sup>, held between 1983-85, where numerous medical associations (including the American Medical Association, the American Society of Internal Medicine, The American Academy of Family Physicians, and the American Academy of Ophthalmology) voiced their explicit opposition to all

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<sup>9</sup>. The FDA organized these discussions in conjunction with their 1983-85 moratorium on consumer advertising, and their main purpose was to identify the consequences that might follow the legalization of DTC ads, as well as predict their potential impact on healthcare.

prescription drug consumer advertising (US Gov. 1984). A decade later physician opposition was still alive and well, as as 80% of surveyed physicians believed the ads were a bad idea, citing that such ads lead to increased costs and promote "misleading, and biased views" of prescription drugs (Lipsky et al., 1998). As well, such opposition manifested itself in the physician interviews I conducted, as the physicians complained that the ads a) undermined their authority, b) strained their relations with patients, and c) led consumers to pursue treatments that were either inappropriate, or dangerous for their given condition (interview April 1997).

Thus, we see that physicians were explicitly opposed to DTC ads, and that the opposition maintained itself right through the 1990s. However, despite the unyielding opposition, drug manufacturers pursued consumer advertising, which suggests that physicians lost their power to deter. Accounting for why that happened is what we now turn to.

### **3) The Managed Care Revolution and the Physician Loss of Power**

The Managed Care revolution had a profound effect on the physicians' power, for the revolution gave medical bureaucrats a growing incentive to cut medical costs, thereby encouraging them to play a larger role in prescription decisions. As this pertains to prescription drugs, the bureaucrats sought to limit prescriptions via four different tactics. First, bureaucrats prohibited hospital pharmacies from carrying the costliest drugs, which left physicians with little choice but to either prescribe generic equivalents, or prescribe the cheaper brand-name drugs that had similar therapeutic effects. A second tactic was to institute "generic substitution" practices, whereby HMO and hospital pharmacists were required to fill prescriptions with the generic version of a drug, even when physicians had specifically prescribed the more expensive brand-name version (American College Physicians, 1990). Third, bureaucrats instituted "therapeutic substitution" practices, whereby prescriptions for expensive brand-name drugs are automatically filled with drugs that differ in chemical composition, but are cheaper, and are believed to have the same therapeutic effect (ibid.). Although this tactic faced strong

opposition from medical associations (Meyer 1987), by 1990 therapeutic substitution was occurring in "more than 52% of the nation's acute care hospitals and more than 30% of health maintenance organizations" (American College Physicians, 1990).

The fourth bureaucratic tactic was to formalize the physicians' decision-making process, by implementing "step-care protocols." These protocols require physicians to prescribe less expensive drugs for initial office visits, and to only prescribe costlier drugs if the patient returns with the same ailments. For example, the first time a patient complains to his doctor about abdominal pains, the doctor is to prescribe an inexpensive Over-The-Counter (OTC) pain-killer (such as Tylenol, Ibuprofen or Advil). If the patient returns with the same symptoms, the doctor is authorized to prescribe a generic prescription drug. If the patient returns for a third visit, the doctor can prescribe an inexpensive brand-name prescription medicine, such as Rodixin. If the patient comes back for a fourth visit, then, and only then, is the doctor authorized to prescribe the strongest, and costliest, drug Naprosyn (interview May 1997). Even if the doctor knows from the beginning that Naprosyn is needed, their hands are tied until they can prove, to medical bureaucrats, that the less expensive medicines have been tried and failed.

Consequently, the step-care protocol reduced the flow of expensive drugs in four ways. First, consuming over-the-counter pain-killers was sufficient to heal some patients (whether due to organic reasons or the placebo effect), who otherwise would have received Naprosyn. Second, prescribing an inexpensive prescription drug, in the second visit, also led to healing efficacy in some patients, thereby also reducing Naprosyn sales. Third, even if the first two drugs were not efficacious, the patient might not present him/herself for a third visit, due to either frustration and/or the loss of faith in drugs, their doctor, and/or the medical system. Fourth, because the Managed Care prescribing process imposes a greater delay between the initial symptoms and a potential Naprosyn prescription, it is possible that the patient's body will have healed itself before Naprosyn ever gets prescribed. Each of these scenarios

plays a role in diminishing the number of patients who will purchase Naprosyn, thus diverting money from its manufacturer (e.g. Syntex).

By implementing their four tactics medical bureaucrats effectively circumscribed the physicians' prescribing authority, and achieved their goal of reducing prescription drug expenditures. Importantly, this weakened the drug manufacturers' ability to drive drug demand through physicians, and gave them a much greater incentive to drive demand through consumers. At the same time, however, manufacturers didn't rush out to use consumer ads, and that's because they knew that physicians still had to sign off on every prescription. If they were to use DTC advertising, they had to do so very carefully, deploying the ads in a way that was unlikely to antagonize physicians. Towards that end manufacturers began studying the physician opposition to consumer advertising, which is what I now turn to.

#### **4) Managing Physician Opposition to DTC ads**

When it became clear that physicians were opposed to DTC ads, drug manufacturers turned to studying that opposition, in order to better understand it, and defuse it. Towards that end, their researchers studies four aspects of the opposition, including 1) the variance in opposition from one physician to the next, 2) the general concerns physicians had vis-à-vis consumer advertising, 3) how physicians were likely to react to specific ad campaigns, and 4) how specific DTC ad campaigns impacted prescribing behavior. In what follows I will elucidate each of these four discoveries, and show how the knowledge helped manufacturers to deploy consumer advertising in a way that was less likely to provoke the medical profession.

##### **4.1) The First Set of Findings – Varying Levels of Physician Opposition**

Although the medical profession often presents a united front to the public, physicians actually differ significantly on a whole host of issues. This is amply demonstrated in the JAMA's "Letters to the

Editor" section, where diverging opinions are voiced on a variety of topics. Importantly, drug company researchers are well aware of this variance, and accounting for it has become an important strategy in devising effective physician-targeted advertising campaigns.

Unsurprisingly, the physician opposition to DTC ads wasn't as complete as it first appeared, and that variance was one of the first things drug company researchers tried to study. Although most advertising research is proprietary and therefore inaccessible by the public, one exception is the work carried out by Petrosius and colleagues. In the early 1990s these marketing researchers studied the relationship between physician characteristics (such as medical specialty, age, number of years in practice, etc..) and physician attitudes towards consumer ads (1995). In particular, they had drug company representatives hand-deliver questionnaire surveys to the physicians, with the surveys probing the doctors about their personal characteristics, as well as their attitudes towards consumer advertising. In turn, their research identified significant fault lines within the profession, with physician opposition being weaker among physicians who a) had fewer years of experience, b) were younger, c) practiced a specialty other than internal medicine, d) practiced in urban settings (as opposed to rural ones), and e) practiced in group practices (as opposed to private practice).

Identifying that variation served the pharmaceutical manufacturers in two inter-related ways. First, it allowed the manufacturers to identify the physicians who had the weakest opposition to consumer ads. Such data has parallels with army reconnaissance reports, as it enabled manufacturers to identify the weaknesses in physician opposition, and to deploy the ads precisely where opposition was weakest. At the beginning, physician opposition was weakest among dermatologists, and, not surprisingly, the first extensive use of the ads was for Rogaine, the anti-balding medication that was mostly prescribed by dermatologists.

Second, the research findings enabled manufacturers to identify the physicians who had the strongest opposition to consumer advertising. This allowed them to avoid using the advertising for drugs that those physicians were most likely to prescribe. For instance, early on it was the internists who had the

strongest opposition to DTC ads, and such ads were not initially used for the drugs prescribed by those specialists (such as drugs for heart attacks, high cholesterol, etc.). In fact, manufactures did not use DTC ads for those products until August 1994, which was after the marketing tactic had been successfully deployed for anti-balding medication, anti-allergy medications, and anti-smoking medications.

#### **4.2) The 2nd Set of Findings – The Physicians’ General Concerns with DTC Ads**

The second insight manufacturers gained was a better understanding about the physicians’ general concerns with consumer advertising. More specifically, they found that physicians were concerned with two overarching issues: 1) the impact of the ads on physician relationships with patients, and 2) their impact on patient well-being. Knowing these concerns informed manufacturers about how their use of the ads might exacerbate physician ire, thereby enabling them to craft consumer ads that respected the physicians' concerns, and, thus, reduced the chances of triggering a physician reaction.

Regarding the patient/physician relationship, physicians had two concerns, with one being that the proliferation of the ads would prompt patients to ask more questions in the medical encounter. Although physicians did not necessarily perceive this as a threat to their medical authority, many perceived that the question-answering would be a nuisance, which would burn valuable clinical time and reduce the number of patients that they could see in a day (Oct. & Nov. interviews 1997, Purvis 1990).

A second, and more important, physician concern was that consumer advertising would lead patients to self-diagnose their own symptoms, thereby fostering expectations to get the advertised product from their doctor. Physicians believed that such expectations would increase patient assertiveness in the clinical encounter, thereby undermining the physician's medical authority. In turn, the ensuing confrontation would obligate the physician to spend valuable time explaining why the advertised product was not suitable for that patient's case, while also explaining why advertisements were not a

reliable source of medical information. An even more dire possibility was that the patient's increased assertiveness would threaten the patient-physician relationship, leading patients to lose faith in their physician, and to seek one who was more amenable to prescribing the desired drug product, as was described in section 1.

However, knowing this physician concern enabled manufacturers to craft consumer ads that minimized the threat to physician authority. In the beginning (eg 1985 to 1988) this meant restricting themselves to 'public service' ads, an advertising strategy that ostensibly 'educated' consumers about a specific disease, without referring to any drug product.<sup>10</sup> An example of such ads is the 'anti-balding' advertisement found on the next page. As is demonstrated in that example, while "Upjohn" is clearly identified as the ad sponsor, no mention is made of any 'anti-balding' medication, even though Upjohn was the manufacturer of Rogaine, the leading anti-balding medication of the era. As well, the ad doesn't even mention that pharmaceutical medicines are a potential treatment for 'hair-loss'. Instead, the emphasis is on informing consumers that A) hair loss can be treated, and that B) they should consult their physicians about such treatments. With this marketing strategy manufacturers were able to stimulate consumer interest for hair-loss treatments<sup>11</sup> without providing information that could undermine the physicians' medical authority, or antagonize them.

The second phase of consumer advertising began in 1989, when the manufacturers started deploying ads that not only mentioned specific drug products, but made bold medical claims about those products. Such advertising was much more likely to raise the physicians ire. However, such a risk was tempered by the fact that prior to using claim-making ads, manufacturers invariably used less

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10 . Though it's worth mentioning that the only manufacturers who used these ads were the ones who had drugs on the market, and could thus benefit from increasing consumer awareness about the condition. This was particularly true of those who had the top selling products.

11. It bears mentioning that since Rogaine was the top selling product of its class, Upjohn stood to gain the most from informing consumers that that hair-loss could be treated.

provocative ad formats, which included 'public service' ads, “Brand Awareness ads”<sup>12</sup>, or “Brand-Comparison” ads<sup>13</sup>. As TABLE 1 demonstrates, out of the 20 product types<sup>14</sup> advertised, 15 of them were first advertised via one of the more palatable advertising forms. Moreover, it wasn't until November of 1993 that any product began to be advertised with claim-making ads. Thus, the data indicates that manufacturers deployed the advertising conservatively and incrementally.

**TABLE 1 - The Gradual Progression Towards Claim-Making Ads \***

		1st Use of Public Service Ads	1st use of Brand Awareness Ads	1st use of Brand Comparison Ads	1st use of Claim-Making Ads
1	Allergy	1985 **			(Apr. 1990)
2	Dermatology ***	1987			(Jan 1989)
3	Tobacco Addiction	-	(Apr. 1989)		(Apr. 1990)
4	High Blood Pressure	(May 1992)	(July 1990)	(Apr. 1992)	(May 1995)
5	High Cholesterol	(May 1992)			(Aug. 1994)
6	Osteoporosis	(Mar. 1992)			(July 1995)
7	Depression	(June 1992)	-		(Nov. 1995)
8	Prostate Enlargement	(Nov. 1992)			(Oct. 1993)
9	Asthma	(Aug. 1993)			(Sept. 1996)
10	Heartburn	(Dec. 1993)	(May 1994)		(Mar. 1995)
	Ulcer	(Aug. 1993)			-
11	Migraine	(Feb. 1994)			(Oct. 1995)
12	Impotence	(Nov. 1995)			(Dec. 1996)
13	Hepatitis	(Nov. 1995)			(July 1996)
14	Prostate Cancer	(June 1996)			(June 1996)
15	Genital Herpes			(Sept. 1996)	(Aug. 1997)
16	Contraceptives				(Nov. 1993)
17	Epilepsy				(Feb. 1994)
18	Arthritis				(Aug. 1994)
19	Yeast Infection				(Nov. 1995)

12. “Brand-Awareness” ads are advertisements that promote a product, and make implicit suggestions about what the drug’s use may be, without making any explicit claims about the drug. Because the ads weren’t making specific claims about the drugs, physicians were less likely to feel that manufacturers were encroaching on their turf. An additional benefit is that the lack of product claims meant the ads didn’t require FDA approval. An example of this ad genre would be the ads produced for Nicorette gum (e.g. the smoking-cessation product), which made no medical claims, but whose function was implied by the product’s name.

13. Product-comparison ads compare the promoted product to another product, but without providing medical information on either product, thereby also preserving the physician's monopoly over medical information, while also escaping the FDA scalpel.

14. This only includes the drugs that were the first in their class to be advertised via consumer advertising, for once a drug had been advertised successfully to the consumers, the ice was broken for all the products in its class. For example, after Seldane’s (eg an allergy-relief medicine) manufacturer was able to successfully use consumer advertising, consumer ads were used for the other allergy relief medications, including Flonase, Allegra, Claritin, Hismanal.

\* : Based on a survey of all TIME Magazines from Jan. 1989 to Jan. 1998

\*\* based on article by Amy Bernstein,

\*\*\* : This category includes prescription medications to treat hair-loss, dandruff, psoriasis, toe fungus, & skin wrinkles

When manufacturers did proceed to claim-making ads, they still did so with caution, and heeded the physician concerns about this marketing form. A particular physician concern was that patients might arrive in the clinical encounter knowing more than the physician about a particular drug product (interview 1997), for if that would occur, it would place the physician at a disadvantageous position, which could undermine their medical authority. Such a concern seems well warranted for Edward Shorter found that patients of the late 20<sup>th</sup> century expect their doctors to be on the cutting edge of medical knowledge, and when they aren't, they lose both their "scientific credibility"<sup>15</sup>, (Shorter 1991) and the control over the patient-doctor relationship. Consequently, the advertising agencies who knew about this concern made a point of only informing consumers about a drug after they had informed physicians about it, either through medical journal advertising, Continuing Medical Education (CME) conferences, or sales visits from pharmaceutical marketing representatives. In turn, timing the use of consumer advertising in this way diminished the chances that a patient would catch a physician flat-footed, thereby decreasing the chances of provoking physician resentment vis-à-vis the use of consumer advertising.

Beyond the timing of ad deployment, manufacturers also paid attention to physician concerns about ad copy. As one advertising executive revealed, "in deploying these new ads we (e.g. manufacturers & their advertising agencies) knew that physicians were still concerned that the advertisements would weaken their medical authority, and so we made sure to always word the ads in a way that would explicitly affirm physicians' authority." Examples of such a practice included: "Ask Your Doctor if this Product is Appropriate for You", as well as, "Only Your Doctor Knows if This Medication is

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15 Steven Epstein defines "scientific credibility" as that which gives a person the power to pronounce authoritatively on a disease and its treatment (Epstein, 1995).

Appropriate for Your Symptoms." All of this underscores the point that manufacturers deployed DTC ads conservatively and incrementally. In turn, this deployment pattern helped ease the physicians into a new marketing culture, one where DTC ads were growing increasingly ubiquitous, and were increasingly directing patients to the doctor.

#### **4.3) Studying Physician Reactions to Specific DTC Ads**

Beyond studying physician opposition as an abstract concept, manufacturers also studied physician opposition to specific consumer ads, doing so through their drug representatives and the use of focus group research.

Drug representatives (also called detail men and detail women) visit doctors on a monthly to bi-weekly basis, and while their main objective is to "educate" physicians on the company's drug products, their interpersonal contact with physicians makes them privy to solicited and unsolicited feedback about the company's products and/or behavior. Consequently, if physicians were upset with a company's use of consumer advertising, the company's sales reps were likely to detect that dissatisfaction, and report it back to the company. In turn, the marketing department would use this information to adjust the advertising, so that they were less likely to antagonize physicians.

A second, and more systematic, way to elicit feedback has been through ad pre-testing, which marketers accomplished through focus group research and/or one-on-one interviews. To carry out this research, marketers recruit the medical specialists who are most likely to prescribe the drug in question (interview July 1997). For example, if the product is a cosmetic drug, then dermatologists will be selected for the research. If the drug targets cancer, oncologists will be chosen. If the drug addresses psychiatric issues, psychiatrists will be recruited, and so on. In building their sample, marketers were concerned about generalizing from too small a population pool, and so enticed physician participation by offering healthy honorariums (ranging from \$250 to \$1000 per physician, per session), as well as

fancy meals (Stolberg et al., 2000). The marketers were also concerned about regional idiosyncrasy, and so often pre-tested the ads in different regions of the country.

After the recruitment of the physicians, the next step was to elicit their responses to the ads. Towards that end, marketers presented the physicians with trial versions of an ad campaign, and requested their feedback on the individual components of each ad. The components that were tested included headlines, ad copy, photographs used, colors used, and even the placement of each component. With such feedback in hand, marketers were able to isolate the elements of an ad that were likely to offend or disturb physicians, before the advertising launch. In turn, this enabled them to change the ads, and reduced the risk of angering physicians.

This process is exemplified by a local advertising agency, which pre-tested consumer ads for a Multiple Sclerosis drug. For this product the ad agency recruited numerous neurologists (the medical specialists identified as the most likely to prescribe the drug), who offered valuable feedback on the ad. One particularly salient feedback pertained to the ad's headline, for, one after another, physicians expressed discomfort (which ranged from medium to serious) with the headline "Are You Losing Your Mind?". The neurologists felt that such a headline was inappropriate in addressing the sufferers of Multiple Sclerosis, for it was likely to exacerbate the patients' anxieties. Consequently, the feedback led the agency to change the headline to "Are you experiencing performance issues?," a headline that physicians found much more palatable, and which drastically diminished the odds of a physician backlash against either the ad, and/or the drug manufacturer who deployed it.<sup>16</sup>

#### **4.4) Monitoring the Physicians' Prescribing Behavior**

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16. Another benefit derived from the interviews is that they informed advertisers about the interaction between doctors and patient, information that the agencies used to strengthen their advertising efforts. Specifically, some advertising executives discovered that when doctors and patients discuss particular drug options, physicians tend to discredit ads as a viable source of information and direct patients to acquire knowledge from magazine articles and/or editorials. Subsequently, this led to the manufacturers' deployment of advertorials, veiled advertisements that take the guise of unbiased editorials. This veiled advertisement is used to inform the reader about a specific medical condition, and to recommend a specific drug therapy for the illness, a therapy that happens to be a drug product of the advertorial's sponsor. Then, a few pages later, the message is reinforced with a full-blown ad for the same sponsor's medical product.

After an ad has been pre-tested the next step is to launch it and monitor its effects on prescribing behavior. Previously drug manufacturers pursued such monitoring through their sales reps, who would report on physician reactions to both new drug products and the manufacturer's marketing behavior. However, in the early 1990s the manufacturers' surveillance power became considerably stronger, due to tremendous advances in computer technology. More specifically, as computers became faster and cheaper, medical organizations (such as the AMA) turned to computerizing their databases, which made it more accessible to pharmaceutical manufacturers and/or their advertising lackey.

Particularly salient to this story are the pharmacies, the American Medical Association (AMA), and the Drug Enforcement Agency (DEA), for each of them compile information on the physicians, which they sell to pharmaceutical companies (Stolberg et al., 2000). Pharmacists, in particular, compile and sell information on each prescription they fill, information that enables the drug company to

"identify the highest and lowest prescribers of a particular medicine in a single ZIP code, county state or the entire country. They can learn, for example, which antidepressants a particular psychiatrist favors" (Stolberg et al., 2000)

Although the pharmacy records don't identify physicians by name, it does identify their DEA code (which the DEA issues to each doctor in order to track controlled substances). Moreover, this code is matched with physician names in the AMA physician database, which contains a personal biography for every doctor practicing in the United States, and which the AMA routinely sells to drug manufacturers.<sup>17</sup> Consequently, the access to these databases enables manufacturers to link individual physicians with their prescribing behaviors, thereby granting them an effective way to measure marketing efficacy, whether the marketing is consumer advertising or physician-targeted marketing. For consumer advertising this was particularly important, for tracking the prescribing behavior enabled manufacturers to detect the negative reactions that physicians might be having to consumer

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advertising, information that would help them 1) track down the cause of the reaction, and 2) adjust the ad campaign accordingly.

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<sup>17</sup>. The AMA biographies also provide information about each physician's academic and personal interests, which manufacturers use to determine how they will attempt to influence specific physicians.

## **SUMMARY**

The medical profession has long opposed the drug manufacturers' use of consumer advertising, and, for most of the 20<sup>th</sup> century, that opposition deterred manufacturers from using the ads. However, that ceased to be true in the early 1990s, and uncovering why has been this paper's central goal. Towards that goal, I have identified four contributing factors, with the first being the rise of HMOs, and their cost-cutting approach to healthcare. This event had effectively circumscribed the physicians' prescribing power, and weakened their leverage vis-à-vis the pharmaceutical companies. Secondly, the drug manufacturers actively studied the medical profession, so as to a) better understand the physicians' general concerns about consumer advertising, and b) use that knowledge to create ads that were less likely to provoke the medical profession. Third, prior to launching particular ads the manufacturer would test the ads in physician focus groups, so as to, again, identify and avoid any element that might provoke a negative reaction. And fourth, after deploying the ads, manufacturers monitored physician prescribing practices, so as to ensure that the consumer ads didn't negatively affect physician prescribing behavior, and/or their perceptions of the manufacturers.

## **THE FUTURE OF DTC ADS IN AMERICA**

Now that the genie is out of the bottle, it is doubtful that the situation will reverse itself. What seems particularly certain is that there is little that the medical profession can do about it, for now that the profession has allowed itself to be studied, the manufacturers know exactly how to manage the physicians' opposition. Moreover, there is nothing the profession can do to retract that knowledge. In addition, it seems the physicians' powerlessness will only grow, for those with the greatest resistance to DTC ads were physicians of the pre-DTC era. As those physicians cycle out of the profession, the professional resistance to the ads will continue to diminish.

While physicians are unlikely to bring about change, change might emerge from consumers, and this for two reasons. First, the recent prescription drug scandals (such as those relating to VIOXX & the

prescription of anti-depressants to kids (Harris 2004)) might prompt consumers to realize the extreme dangers associated with prescription drugs, which, in turn, might lead them to pressure the FDA into strengthening regulations around the marketing of prescription drugs. Secondly, consumers might be prompted to act by the growing healthcare expenditures. More specifically, as the marketing continues to drive up medical expenses, consumers might start thinking twice about always demanding the latest and most expensive medication, opting instead for older generation drugs that are just as effective, but cheaper. This would diminish the effectiveness of consumer advertising, and potentially prompt the manufacturers to use different marketing strategies. However, for either of these possibilities to occur, American consumers would have to become more savvy about drug industry marketing, as well as far more politically mobilized.

## **DTC ADVERTISING IN THE REST OF THE WORLD**

As of June 2007, New Zealand was the only other country that permitted consumer advertising for prescription drugs. However, that permission might be withdrawn, as the country's health minister recently concluded that the potential benefits of the marketing do not justify the harms, and discussed plans to end it (Mansfield 2005). That political fight is one well-worth watching, as it might provide valuable insight on how consumer advertising could be retracted from the American scene.

Elsewhere, in 2004 the Canadian parliamentary inquiry "recommended against direct to consumer advertising because 'Drug advertisements could endanger rather than empower consumers by minimizing risk information and exaggerating benefits' and 'could contribute to increased or inappropriate drug consumption'"(ibid.). This development is of debatable consequence, however, for while the ads haven't been legalized in Canada, Canadians are, in fact, exposed to them every day, via their consumption of American media, which includes television programming, newspapers and magazines. Moreover, there doesn't seem to be anything that can be done about this situation, effectively linking the plight of Canadians with that of the Americans.

While the Canadian and New Zealand cases are interesting in their own right, drug manufacturers are undoubtedly more interested in the European case, for if they can get their way with the European Union (EU) bureaucracy, manufacturers could target their ads at over 450 million consumers. However, the manufacturers' attempts have been rebuffed thus far, for in 2003 the EU Health Ministers rejected the proposal to legalize a limited use of DTC ads (Watson 2003). Undoubtedly, the drug manufacturers will persist in their lobbying efforts, and should they succeed, the deployment of the ads will vary from country to country, a variance that will be mediated by three overarching factors: 1) the economic pressure on drug manufacturers, 2) consumer receptivity to the advertising, and 3) the medical profession's resistance to the advertising.

Regarding the economic pressures, in the United States the pressures came primarily from the emergence of "Managed Care", where medical bureaucrats placed increasing importance on the cost-benefit analysis of treatments. This shift, in turn, benefited the generic drug manufacturers, thereby increasing the pressure on brand name drug manufacturers (Vallee 2002). While similar economic pressures might arise in Europe, economic pressures could also arise from other sources, such as tougher drug approval regulations, and/or the growing use of alternative medicines.

If such economic pressures emerge, the second necessary factor will be consumer receptivity. In order for consumer ads to work, they will need to be targeted at a population that is 1) predisposed to receive and integrate medical knowledge, and 2) predisposed to use medical knowledge in the clinical encounter. These characteristics were present among the Americans of the late 20<sup>th</sup> century (Vallee 1999), and this explains why the drug consumer advertising has been so successful in America.

Assuming the consumer factor is met, the third factor mediating the use of the ads would be the resistance of that country's medical profession to such marketing, along with the drug manufacturers' ability to manage that resistance. As demonstrated in this paper, the manufacturers' ability to use consumer advertising in the U.S. was mediated by the role played by the AMA and individual

physicians, who willingly helped drug manufacturers study and better understand the physicians' opposition to consumer ads.

## **THE THEORETICAL CONTRIBUTIONS TO THE STUDY OF MARKETS**

This case study makes five theoretical contributions to the study of markets. First, it demonstrates that governments aren't the only entities that limit industry conduct. While Fligstein (2001) posited that governments play a central role in controlling industry behavior, here we saw that physicians also significantly influenced the pharmaceutical industry. Consequently, future research on markets should pay close attention to the way that non-governmental actors shape the marketing behavior of other industries. For instance, which non-governmental actors influence the marketing behavior of toy manufacturers, record companies, or food manufacturers? The range of behavior in each of those industries is influenced by more than just government regulations, and greater attention to those influences will give us a more comprehensive understanding of marketing behavior.

Secondly, the analysis revealed that the influence of non-governmental actors changes over time. More specifically, while the physicians' deterrence effect was nearly non-existent in the 1850s, by the 1920s it had become dominating, only to weaken again in the late 1980s. Thus, it behooves us to avoid reifying the deterrence effect of any particular actor, and view the deterrence effect as being dynamic over time.

Third, we saw that the change in deterrence effect was mediated by a number of different factors, including those that were intrinsic to the medical profession. More specifically, the profession's original power, vis-à-vis drug companies, was the result of 19<sup>th</sup> century organizing activities, which consolidated the profession, and strengthened its unity, credibility, prestige, wealth and political power. Their unanimous unity against consumer ads, in the 1920's, seems to have been particularly important, for its absence in the 1980s significantly undermined their leverage over the drug manufacturers.

Fourth, I showed that another factor mediating the deterrence effect is the industry's work to manage or defuse it. In their pursuit of consumer advertising, the drug manufacturers actively studied the physicians' opposition, so as to understand how to skirt and defuse it. Thus, future research should study the way that industry tries to identify and defuse the opposition to its marketing activities.

Fifth, we saw that the deterrence effect was also mediated by the economic context. More specifically, while the physicians held a lot of leverage during most of the 20<sup>th</sup> century, that leverage was diminished by the healthcare inflation, which brought on the HMO industry, and the curtailing of physician prescribing authority. Thus, in trying to understand why an actor's influence changes over time, it's vitally important to place the change within its economic context.

## **APPENDIX 1 - Methods**

In pursuing this project I relied on four types of data: 1) secondary sources, 2) congressional records, 3) interviews, and 4) consumer ads appearing in the print media.

The secondary sources consisted of mainstream and academic articles published on the issue. For the latter I conducted article searches in Pubmed and JSTOR, using “DTC ads”, “DTC advertisements”, “Direct-to-consumer advertising”, “consumer advertising and pharmaceutical”, “drug advertising”, “pharmaceutical advertising”, and “prescription drug advertising.” For my search of mainstream media I used Lexis-Nexis to find all DTC articles that were written in newspapers from 1985 to 1998. The mainstream and academic articles enabled me to identify 1) the overall form of the marketing phenomenon, 2) the main actors who struggled over the emergence of DTC ads, and 3) their motivations and concerns.

The Congressional records I used were those covering the FDA’s moratorium on Direct-to-Consumer advertising.<sup>18</sup> Importantly, the records provided congressional testimonies from the FDA hearings, which, in turn, helped to a) identify the key agents who struggled for and against the emergence of DTC advertising, and b) elucidate the concerns and motivations of the respective individuals.

For this project I interviewed 17 individuals, between April 1997 and January 1999, including 6 practicing physicians, as well as 11 key informants from a local award-winning ‘healthcare’ ad agency. The latter included individuals from a wide assortment of positions, including advertising directors, studio managers, client representatives, traffic personnel, as well as a client representative who previously worked in the marketing department of a major drug manufacturer. Interviewing these employees helped me better understand the perspective of those working within the pharmaceutical industry, as well as illuminate how the industry sought to mollify physician concerns.

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<sup>18</sup>. The agency imposed this moratorium between 1983 and 1985, in order to evaluate how legalizing the ads might impact consumers and the healthcare system.

The fourth component of my research approach was surveying the DTC ads that were published in the mainstream print media. For this task I identified and tracked every prescription drug ad that appeared in TIME magazine between January 1989 and December 1996. Aside from tracking which products got advertised and when, I also coded each ad according to their format: e.g. “educational” ads, “Brand-awareness” ads, and “claim-making” ads. The significance of those categories is discussed in section 4.2. TIME magazine was chosen because it is a general interest magazine, and, as such, represents an ideal site to track how the ads were disseminated to the general public. I picked January 1989 as the start date because that was the first month that claim-making ads were used. As for the end date, December 1996 was selected because it was the last month before the legalization of TV consumer advertisements, which ushered in a new and very different phase of the marketing phenomenon. Conducting this media survey served to link the analysis to the actual use of the ads.

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