AN ASSESSMENT OF THE HEALTH SYSTEM IMPACTS OF DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION MEDICINES (DTCA)

Volume V: Predicting the Welfare and Cost Consequences of Direct-to-Consumer Prescription Drug Advertising

Steve Morgan

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Introduction

A major trend is sweeping over the pharmaceutical industry—right before the eyes and ears of ordinary citizens. It is the trend toward the direct to consumer advertising of prescription-only drugs. It is a major change in business practice for the corporations engaged in it because, for almost a century, prescription drug manufacturers have been referred to as “ethical” pharmaceutical manufacturers because they did not advertise their products directly to patients. Rather than target patients directly, these manufacturers have traditionally targeted their marketing activities at medical professionals. In recent years, however, the profitability of this traditional marketing strategy has waned. Increased intervention by government and third-party drug benefits providers has provoked manufactures to seek audience with the end users of their products.

The watershed point for direct to consumer advertising came in 1997, when American regulators relaxed restrictions on television and radio drug advertisements. Since then, spending on the consumer-directed advertising for prescription drugs in the US has exploded to nearly US$3 billion per year, making prescription drugs one of the most heavily promoted classes of consumer product in the United States. The sheer magnitude consumer-directed prescription drug advertising in the US, compounded by the fact that American advertising often reaches Canadian audiences, has made this a health policy issue of major significance in Canada.

Should the Canadian government adopt regulations as lenient as those in the US? Hard evidence regarding the benefits and the costs of direct to consumer advertising of prescription drugs is lacking. Lack of such evidence, however, should not be taken as reason to engage in a trial and error approach to policy making. This report investigates economic theories that may be used to predict the consumer welfare and cost consequences of drug advertising. This is done in two parts. The first chapter contains a discussion of how the economic theory of consumer demand might be used to inform policymaking.

The basis for supporting advertising using standard economic theories of consumer demand and revealed preferences is weak. In a standard welfare-economic
analysis, advertising reduces the welfare of consumers in most feasible scenarios. However, economic analyses based on standard analytical tools are ill suited to measuring the costs and benefits of advertised prescription drugs. Because the average consumer of prescription drugs lacks the capacity to make rational and informed decisions regarding appropriate drug use, and because both patients and physicians have nonstandard financial incentives, the results of a standard welfare economic analyses should not be used to justify policy action. It is simply unclear what, if any, welfare-relevant information is “revealed” by free-market consumption patterns and price levels in a pharmaceutical market.

The second chapter contains a discussion of how the economic theory of the firm may be used to describe the likely impacts of direct to consumer advertising for prescription drugs. When placed in a historical context, the industry’s push toward consumer-directed advertising is clearly not a response to consumer demands for information, but rather as a response to the changing competitive environment for drug manufacturers. Specifically, recent increases in the level and sophistication of drug benefits management by third-party payers have made consumer-directed advertising virtually essential for many firms to achieve sales growth on new, patented products. A recent paper commissioned by Pfizer Inc. testifies to this, portraying consumer directed advertising as a means of countering restrictions imposed by managed care providers (Rubin and Schrag 1999).

Canadian regulations have always permitted firms to educate patients about medical conditions and to inform the public about the availability of treatments for such conditions. What manufacturers seek is the ability to mention particular brand names and to make claims about their particular products so that product selection will favour particular brands. Without this, advertising is not viable for them. With it, advertising is only viable for manufactures whose products are relatively new, typically high-cost, and patented.

The conflict of interest that drug manufacturers are in when “educating” patients about therapeutic alternatives is unmistakable. The incentives for exaggeration and persuasion are great and patients’ ability to verify promotional claims is limited. Economic theory and historical experience indicates that the marketplace for ideas
created by consumer directed drug advertisements would be imbalanced and biased. What is truly needed is investment in independent sources of evidence based educational programs that help consumers (not to mention medical professionals) to better understand the risks and benefits of treating disease with alternative drug and non-drug therapies.
Chapter 1: Welfare Economics and Direct to Consumer Advertising

Is advertising good or bad? This question has troubled policy analysts for some time. Regardless of what product is being marketed, opinions about the impacts of advertising on consumer behaviour and social welfare run the gamut. Economic theory is often cited in the debate, but it can seldom offer an unambiguous answer to the problem. Economists can only make assumptions that remove complexity from an analysis and then form arguments as to the degree to which reality corresponds with the simplified model. Confidence should be placed in the conclusions of an analysis only to the extent that the economic model resembles reality and insofar as the underlying normative assumptions are morally acceptable.

This paper contains a summary of the economic theory as it is often applied in the analysis of the welfare impact of advertising. It begins with a review of standard theories of consumer demand and the “revealed preference” approach to measuring social welfare. An analysis of advertising from this approach suggests that advertising may make consumers worse off under most, but not all, foreseeable circumstances. As measured by consumer’s willingness-to-pay for a product, less the actual price paid, consumer welfare will improve with certainty only if advertising gives accurate information about the uses and quality of a product without containing persuasive or inaccurate messages. In such a scenario, the profits generated by advertisers are related to the socially valuable information created by advertising.

Because the revealed preference approach to welfare economic analysis is ill suited to the pharmaceutical market, an alternative approach to predicting the impact of ads is discussed in the second half of this chapter. The alternative is decision-analysis, a method of explicitly modeling the behaviour of consumers and evaluating their welfare based on observable outcomes. This method replaces the implicit but sweeping assumptions of standard economic analyses with many smaller but more explicit assumptions regarding the decisions that lead to the use of prescription drugs and the outcomes of that consumption. After outlining such a model of patient behaviour, it is argued that potential welfare benefits from consumer-directed advertising for prescription drugs hinge on the completeness and accuracy of messages communicated to consumers.
as well as the ability of consumers to process that information in an efficient and rational manner.

**Welfare-Economic Analyses**

The standard economic theory of consumer demand is built on the assumption that consumers consistently and rationally maximize their personal welfare given the limits of their budget and the prices of goods and services. Said consumers carefully weight all of the costs and benefits of their consumption decisions. They make their decisions based on accurate assessments of all available information. And, when available information is incomplete, these rational agents weigh the costs and benefits of obtaining further information before making consumption decisions.

Because the consumers envisioned in standard economic theory carefully consider the trade-off between purchasing a good and using the same amount of money to purchase other goods, the maximum amount they are willing to pay for any good represents its value relative to all others. In order to assess the value of each unit of a particular good consumed, economists estimate (or conjecture) the demand for the good at various prices. A demand curve is a line that depicts the quantity of goods that a consumer is willing to purchase at each price. Such a curve is illustrated in Figure 1. The demand curve can also be looked at in terms of the “inverse” of the relationship between quantity and price. That is, it can be seen as illustrative of the maximum price per unit that a consumer would be willing to pay at different levels of consumption. Looking at a demand curve in this way gives a schedule of consumers’ willingness-to-pay per unit for each additional unit of consumption—sometimes called the “inverse demand.” Economists conduct social welfare analysis based on the preferences implied by the shape and position of this schedule of willingness-to-pay.

As depicted in Figure 1, a demand curve ordinarily slopes downward. For an individual, this is generally interpreted as a reflection of the diminishing benefit from each additional unit of a good consumed, though this can also result from a diminishing budget.
Market-level analyses are based on the “aggregate” demand for a good. An aggregate demand curve plots the total amount of a good that would be purchased by all individuals at given prices—it is simply the combination of all individual demand curves. When interpreted in terms of willingness-to-pay, the downward slope of an aggregate demand curve reflects the fact that some consumers place a higher value on a product than others. Without question, differences in the willingness-to-pay for identical items are influenced not only by differences in “tastes,” but also by the fact that some consumers have more income than others. Economists typically ignore differences across consumers—in income, tastes, or access to information—by speaking about the “representative” consumer in the market. Despite this language, it is implicitly assumed that items are most valuable to society when purchased by individuals who are willing (or able) to pay the most for them.

Interpreting the curve in terms of willingness-to-pay, the area beneath the aggregate demand curve over the range from the first to the last unit consumed is used as a measure of the gross social benefit of consumption in a standard welfare-economic
analysis. Since consumers bear financial costs to acquire the goods in question, this gross benefit of consumption is divided into the net benefit to consumers (the consumers’ surplus), the net benefit to firms (profits) and the costs of producing and delivering the products or services. These areas are illustrated in Figure 2. Both profits and costs are “hard” figures in the sense that they are measurable in terms of actual dollars that change hands in market transactions. On the other hand, the net benefits accruing to consumers from the purchase of goods are not directly observable but can be calculated if the demand curve can be estimated.

In a traditional market-level welfare-economic analysis, the net social benefit from purchases in a market is the sum of the consumers’ surplus and the firm’s profits. Profits are included on the assumption that they eventually become the income of shareholders. For this to be sensible in a domestic analysis, it must be assumed that none of the profits are “lost” by way of being exported to foreign shareholders. Additionally, analysts must assume that there are no distributional effects when wealth is transferred from the consumer to the firm (by way of prices) and then back to the shareholders (via dividends). This will only occur when all consumers own an equal share of the firm and they all purchase an equal amount of the goods sold by that firm. In the event that consumers and firm owners are not identical in these respects, consumers’ surplus and profits ought to be accounted for separately, with adjustments as necessary for distributional consequences of market transactions.

The Impact of Advertising

Advertising changes consumers’ appraisals of the advertised product—and often their appraisals of competing or complementary products. Its effect is to alter the position and shape of the demand curve, thereby changing the quantity of products that a firm is able to sell, and the price it may charge. There are three possible net effects of advertising on the price and quantity of the good sold. Advertising may increase prices and lower the quantity of goods sold; it may lower prices and increase the quantity of goods sold; or it may increase both price and quantity. A fourth scenario—wherein both the price and quantity of a good fall as a result of advertising—is not a feasible outcome.
because no for-profit firm will invest in advertising that reduces the amount it can charge and the quantity it can sell.

The infeasibility of a price-down, quantity-down scenario alludes to the simplicity of predicting the change in firm profits stemming from advertising. Observed advertising must increase profits. This is because for-profit firms always aim to maximize profits. When managers make mistakes in their marketing investments, they correct them quickly by ceasing the unprofitable campaigns. Representatives of a firm or an industry may claim otherwise when speaking to regulators, but they would not do so when talking to their shareholders.

Changes in consumer welfare are less clear than changes in profit. This is because changes in consumer welfare are made up of an observable component (a change in the amount of money they pay for goods purchased) and an unobservable component (the gross value they place on those goods). The unobservable value that consumers place on goods purchases is, as described above, gauged by their willingness to pay for the goods. However, since advertising changes consumers preferences for goods, the analyst must decide whether consumers’ willingness-to-pay before or after the advertising took place is the correct welfare measure.

If advertising “improves” consumers’ appraisals of the product in some meaningful sense, the after-advertising appraisals are arguably the superior measure of social welfare. This is generally considered the case when advertising provides consumers with objective information about the uses and quality of a product. Convincing consumers that they like a product more than they did before is not sufficient to claim that ads make consumers better off, however. If there is reason to believe that advertising builds on emotive attachment to brands, is persuasive, or is simply misleading or fraudulent, then consumers’ after-advertising preferences may be “worse” than the before-advertising preferences.
For each of the possible net changes in market price and quantity, table 1 lists the advertising-induced change in consumer welfare measured. This table lists the impact as judged using consumer preferences before advertising and after advertising. Details of the analysis for each case are presented in the appendix.

In five of the six possible cases, consumers are either made worse off as a result of the changes due to advertising or the change in consumer welfare is ambiguous because it depends on the slope of the demand curve and the relative magnitude of the price and quantity changes. It should be noted that profitable advertising will occur in a free market regardless of the impact on consumers. Some argue that this will yield an overall improvement in welfare because the increased profits to the firm outweigh the losses in consumer welfare (Dixit and Norman 1976). However, to the extent that societal objectives do not include simple transfers of wealth from consumers to shareholders, the case in support of advertising rests on evidence that consumers are indeed made better off by it. This in turn, requires that the quantity of the advertised good not fall and that the after-advertising preferences are the “right” measure of consumer welfare. As mentioned above, after-advertising preferences are generally considered “better” than before-advertising preferences when advertising provides consumers with objective information about the uses and quality of a product.

**Theories of the Information in Advertising**

If it is assumed that advertising does not alter consumers’ objectives, but that it facilitates the process by which consumers find the goods that best meet their predetermined preferences, the willingness-to-pay for a good after-advertising may be

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Table 1: The Impact of Ads on Consumer Welfare

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rationalized as the correct metric of consumer welfare. Advertising under these special circumstances can be viewed as information that lowers the total cost of a product, where total costs include the cost of searching and the risks associated with purchasing goods of uncertain value. Even if the “sticker price” of an informatively advertised good increases, the total price of obtaining it may fall, inducing consumers to purchase more of it. This “reveals” a greater preference for the good, even though consumers’ preferences really have not changed.

There are a number of economic theories regarding how consumers glean information from advertising (see, e.g., Stigler 1961; Nelson 1970 and 1974; Kotowitz and Mathewson 1979; Rubin and Schrag 1999). Since the ultimate purpose of advertising from the perspective of a firm is not to inform consumers but to increase profits, it ultimately must be determined whether “... the selling job of the producer generates information for the consumer” (Nelson 1974, p.729). One way of ensuring such an outcome is strict regulations of advertising and promotional practices. Another is to rely on the market to bring about an equilibrium wherein only informative advertising is profitable.

For market mechanisms to detect and punish misleading advertising with a frequency and severity sufficient to render it unprofitable, the consumers in the marketplace must not only be rational, they must be able to evaluate the validity of the manufactures messages at low cost. Consumers will be able to enforce truth in advertising most effectively when the advertised good fits the description of a “search good” (Stigler 1961; and Nelson 1970). The substantive transaction costs involved in markets for search goods, other than the transaction price, are the costs of locating and traveling to sellers of the desired product. Once a seller is found, all relevant characteristics of a search good can be verified at negligible cost before purchase.

Sellers of search goods post ads describing the uses, quality and price of their products in the hope of attracting consumers to their location. If a seller makes false claims in its advertisements, consumers will know this upon inspection and may choose not to purchase from that seller. Fraudulent or misleading claims about search goods are thereby kept to a minimum, unless the cost of traveling to alternative sellers of the
desired good are high—as might be the case, for example, when looking for lodgings in a remote location (Nelson 1974).

An illustrative example of search goods is the “classifieds” market for used furniture. Sellers typically post ads in the classified sections of local newspapers that describe the item for sale (e.g., pine kitchen table with four matching chairs), perhaps its condition (like new), a price ($250 obo), and contact information or a location at which the item can be inspected. A buyer who investigates the ad will be able to verify that the item is as claimed (it is, indeed, a like-new table with four matching chairs). If the ad is false or grossly exaggerated, potential buyers will choose to continue their search after inspection. The incentives for making false claims in such markets are therefore quite limited.

Few products closely resemble the definition of a search good because most goods have important characteristics that cannot be judged before purchase (at least, not at a negligible cost). Products for which characteristics cannot be verified at the point of sale are referred to as “experience goods” (Stigler 1961; and Nelson 1970). The characteristics of experience goods that are not observable at the point of transaction are referred to as the experience characteristics; these may include taste, quality, durability, safety, fit, and applicability.

When an experience good is purchased with sufficiently frequent repetition, and its experience characteristics can be learned sufficiently quickly, consumers may punish misleading claims to the point where they become unprofitable. If consumers of experience goods verify (through trial and error) that an advertising claim was false or misleading and they refuse to purchase that product (and possibly other products sold by the same firm), then the returns to making false claims may be low or even negative. In the long-run, advertisers that make exaggerated claims may not be able to finance the level of advertising that truth-telling advertisers engage in because they may not be able to generate enough repeat purchases. When an experience good is not purchased with sufficiently frequent repetition, when its characteristics cannot be learned quickly, consumers will not have sufficient opportunity to punish misleading advertisements. Restaurants that make exaggerated claims about quality might go out of business in areas visited exclusively by locals, but could survive in areas frequented by tourists.


**Prescription Drugs and the Economic Model**

Several aspects of the pharmaceutical sector shed doubt on inferences gleaned from a standard welfare-economic analysis and on common theories of the information contained in advertising. Among these are the nonstandard financial incentives of consumers in the pharmaceutical sector and their limited capacity to make prescription-drug related decisions in a manner consistent with the economic model of rationality.

Economic models of consumer demand upon which consumer’s willingness-to-pay might be interpreted as a reasonable measure of the value of a good require that the consumer consider the full cost of the item against its benefits. The use of prescription drugs, however, is inextricably tied to the consumption of other services, the most important of which—physicians’ services—are provided free of charge to Canadians. Thus, changes in consumer behaviour in the prescription drug market will not reflect the consideration of the full costs and benefits of the use of prescription drugs and their complementary services. Furthermore, most consumers have some form of insurance coverage for drugs prescribed to them. These individuals will have little incentive to consider the price of the item itself, making it impossible to infer their willingness to pay for a prescription drug from the observation of what they were willing to have their drug plan pay for it.

This is not to condemn drug insurance, it is just to point out that the relationship between perceived value and the price paid for a good may be distorted by insurance. Of course, that relationship may also be distorted by limitations on a consumer’s ability to pay for a good—which is one of the primary reasons drug insurance evolved in the first place. Indeed, many uninsured Canadians are from low-income families for whom it is possible that even medically necessary drugs are impossible to afford. For these patients, “inability to pay” may be all that is observed in market transactions (or the lack thereof).

Concerning rationality, the economic model of consumer behaviour assumes that consumers weigh the pros and cons of available alternatives in a consistently optimal way. However, it has long been acknowledged that decisions concerning the appropriate use of prescription drugs are beyond the capacity of ordinary individuals. Processing the information needed to make rational drug-related decisions requires specialized medical, pharmacological, and statistical knowledge. While it may be argued that the legislated
involvement of an informed intermediary—physicians—implies that prescribing decisions will be rationally made, consumer-directed advertising aims to alter consumers’ behaviour directly, so it is their incentives and rationality that is central to the debate.

If one took seriously the proposition that consumers are in good position to evaluate the information presented to them by competing sellers of prescription pharmaceutical products, one would still need to prove that the market could provide balanced and accurate information. Upon inspection of an unlabelled bottle of pills, it should be clear drugs are not like the economic model of “search goods.” The uses and quality of a drug cannot be verified at the point of purchase. To enforce truth in advertising, the market mechanism would have to rely on consumers’ ability to verify the use and quality of the product through experience, and to do so before repeating the purchase of the drug. Again, the characteristics of drug products make it unlikely that this will occur.

Verifying the safety and efficacy of a drug is a unique task, one that is complicated by feeling of fear, confusion, or desperation that often accompanies illness. Even when a drug is purchased and ingested, it will generally be difficult (arguably, impossible) for an individual consumer to determine its safety, efficacy, and side effects profile. This is in part because there is seldom a counterfactual against which to compare. That is, a person cannot simultaneously be treated with and without a medicine to determine whether nature, placebo, or the drug was responsible for resulting health improvement or deterioration. The only way to reasonably determine how a drug changes the probabilities with which patients reach different health outcomes is through rigorously designed scientific trials.

Given the unusual difficulties for individual consumers to determine the quality of drug products, it is unlikely that the market mechanism will punish persuasive or misleading advertising with sufficient speed and severity to ensure that manufacturers make only accurate claims about product safety and efficacy. Indeed, a long history of observed pharmaceutical marketing practices offers evidence that the market mechanism cannot ensure truth in drug advertising. The clearest evidence comes from the pre-regulation era of drug promotion, when products of little value—often of potential harm—were widely promoted as panaceas by charlatans and quacks (Temin 1980).
Evidence of less than acceptable informative content remains ample in the marketing practices routinely engaged in by today’s large pharmaceutical companies, despite the fact that these firms are subject to forms of government- and self-regulation that render misleading and persuasive advertising less profitable than it would be in an entirely unregulated market.

**The Informative Quality of Drug Advertising Under Current Regulation**

The single largest component of drug promotion is the pharmaceutical sales force. According to IMS Health, sales representatives visited Canadian physicians 3.2 million times in 1998—about 50 sales visits per practicing physician. Canadian physicians rank interactions with sales representatives as either the first or the second most important source of prescribing information (Lexchin 1993). In Canada, enforcement of existing regulations governing claims made by sales representatives, and the gifts that they leave with physicians, is ceded to self-regulation by the pharmaceutical industry association, Rx&D (formerly the Pharmaceutical Manufacturers’ Association of Canada). Rx&D has no formal process of auditing of monitoring claims made by sales representatives.

While there have been no systematic analyses of the quality of information provided by sales representatives in Canada, international experience suggests that the informational quality of these sales efforts is likely to be poor. In Finland, the U.S., Australia, and France (the only countries in which there have been published analyses of detailer practices), sales representatives mentioned adverse effects of the drugs they were promoting less than 30% of the time; mentions of contraindications were even more seldom (Lexchin 1997, Anonymous, 1999). A US-based study found that 10% of statements by sales representatives were inaccurate, all of which conveyed positive information about the drug (Ziegler et al. 1995).

Where consumer-directed advertising is not permitted, the second most important channel of drug promotion is the sponsorship of academic meetings, continuing medical education events, and information seminars. Educational grants given to finance these activities—even if “unrestricted”—have been shown to influence the decisions of those designing and implementing the programs. As economic theory would predict, educational events systematically favour the sponsor’s products (Ubel et al 1995; Sheldon and Smith 1993; Spingarm et al 1996; Wazana 2000). In Canada, these events
fall under the self-regulatory authority of the industry association, Rx&D. Enforcement of the associations Code of Marketing Practices is based on investigations launched in response to complaints about marketing activities. If the committee finds that a company violated the Code, the company is fined on a sliding scale—from $1,000, for the first violation, up to $15,000 for the fourth violation in a given year. Most fines occur because entertainment supersedes education at these events. Recently, for example, Bayer Inc. was fined for offering a 50-minute seminar at a golf and country club followed by a round of golf, tour of a brewery and dinner (Sullivan 2000). There has not been an independent review of the self-regulatory process in Canada. A review of a similar self-regulatory process in the UK suggested that it had no deterrent effect on marketing activities in violation of accepted practices (Herxheimer and Collier 1990).

Journal advertising is another critical component of drug advertising. Journal ads typically comprise of large, glossy advertisements found on cover pages and amidst the editorial and scientific content of professional journals. In Canada, detailed information regarding the appropriate indications, doses, cautions, contraindications, side-effects and risks is printed on separate pages, usually at the very back of the journal. This information is invariably printed in compressed fonts—often seven-point, which looks like this, but sometimes six-point, which looks like this. Because it is generally inconvenient to search for and then read the information that “accompanies” journal ads, the informational content of this promotional activity is skipped by most readers (Lexchin 1994).

Journal advertisements fall under the jurisdiction of the Pharmaceutical Advertising Advisory Board—a semi-autonomous organization consisting of representatives from the pharmaceutical and advertising industries, the medical and pharmacy professions, medical publishers and consumer organizations. Manufactures may voluntarily seek pre-screening by the Board—doing so often because it is a requirement for publishing certain journals, including the Canadian Medical Association Journal. Two studies have examined published ads that had been pre-screened by the Board. One found that, of 131 pre-approved ads in Canadian medical journals, 47 (or 36%) breached the Board’s Code of Advertising Acceptance (Hagerman, 1992). Another survey of 111 pre-screened ads found that risks were mentioned in only half of the ads,
almost always in the context of a statement about lack of side effects; whereas benefits were discussed 91% of the time (Kline, 1992).

Where consumer directed advertising is permitted, it is second only to the pharmaceutical sales force in terms of promotional expenditures. Spending on consumer-directed advertising in the US was US$2.5 billion in 2000, compared with US$468 million on journal ads. Since it is still officially illegal elsewhere, evidence concerning the informative content of direct-to-consumer advertising must stem from the US or New Zealand. Four published studies have assessed the informative content and quality of consumer-directed print advertising in the US. Consumer Reports (1996) asked clinical experts to review 28 recent magazine ads. They found that 33% contained factual inaccuracies; half did not convey needed risk information in advertising copy and only 40% were honest about efficacy, risks and benefits. Roth (1996) asked a panel of pharmacists to assess 39 ads. These ads represented more than 90% of consumer-directed print ads published in the US between 1993 and 1995. Thirty-five percent did not contain a fair balance of benefit and risk information, and 15% made no mention of risks in advertising copy. Parker and Delene (1998) looked at the content of 110 print ads published between 1992 and 1995. They found that 45 percent of the ads were for drugs for three conditions: hair loss, menopause, and allergy.

Bell and colleagues assessed the presence or absence of key elements of information in all (320) print advertisements for prescription drugs placed in 18 leading consumer magazines over a 10-year period (Bell et al, 2000). Although most ads named the medical condition (95%) and described at least one symptom (60%), few (27%) mentioned any causes or risk factors for the disease, and still fewer (12%) mentioned the prevalence of the indication. Details about the advertised product were also scarce. Of the 320 ads, 65 percent did not mention how the drug works, 89 percent did not mention the required treatment duration, and 91 percent did not contain information about the overall treatment success rate.

A US Food and Drug Administration review of the regulatory experience with broadcast ads since late 1997 is the only overview thus far of the quality of US consumer-directed broadcast ads (Koerner, 1999). Seventeen of the 33 drugs (52%) advertised on television and radio from late 1997 until early 1999 were found to violate the Food and
Drug Administration regulations. Most of these violations reflected inadequate risk communication, overstatement of benefits, and a lack of fair balance between presentation of benefit and risk information. A review of the degree to which television, radio and print ads complied with New Zealand’s regulatory requirements for accuracy and completeness of information similarly found that noncompliance was similarly frequent, particularly for broadcast advertising, and that inadequate or absent risk information was the most common reason for noncompliance (Pratt 2000).

**Decision-Analytic Methods of Evaluating Drug Advertising**

There are alternatives to the revealed preference approach to the economic analysis of advertising. Among these are decision-analytic methods of assessment, wherein the decisions of consumers are modeled individually and then aggregated into a measure of the overall welfare impact of advertising. Whereas the standard economic analysis is simplified by assuming that observed market transactions reveal all that is needed for welfare analysis, a decision modeling approach explicitly describes many of the assumptions that go into an assessment of the value of observed consumption patterns.

Figure 3 illustrates a model of the processes related to a consumer’s purchase (or not) of a prescription drug. This model—itself a major simplification—depicts several aspects of drug related decision-making that are not necessarily accounted for in the market-level analysis. It explicitly categorizes the population according to the presence of the disease for which an advertised drug is indicated, exposure to advertising, choice of care type, the clinically indicated drug, and the appropriateness of the drug prescribed.
In a decision-modeling approach to analysis, health outcomes and financial costs for each “trajectory” through the decision tree are calculated, and reported at the terminal nodes of the tree (the far right-hand side or Figure 3). Figures should reflect current and expected clinical and financial outcomes resulting from the corresponding courses of therapy. The symbols at the terminal nodes in Figure 3 depict the expected number of individuals to take a given path multiplied by the magnitude of costs and the likelihood of positive or negative health outcomes per person that followed that trajectory. The most costly trajectories will be those with the highest level of formal care, most drug use and worst expected health outcomes. Health outcomes correlate to the appropriateness of the drug ultimately consumed by the patient.

The information required for a complete analysis of this type is extraordinary. One must have information regarding the behaviours of those who seek formal care and those who do not, as well as knowledge about who is exposed to advertising and who is not. Furthermore, once the detailed information about behaviours and outcomes
associated with the status quo is gathered, one must estimate the model that would likely occur in a “with advertising” scenario. While exposure to drug advertising cannot (one hopes) change the physiological wellness of the population, it will change the expected (average) behaviour of consumers and their physicians.

Advocates of consumer-directed advertising argue that it will encourage more appropriate drug use, promote a higher level of compliance with prescribed therapies and get more patients into needed treatment. Under such circumstances, the net gains to Canadians would be clear. Drug costs would rise, but not as quickly as the quality of treatment. Opponents of direct to consumer advertising of prescription drugs argue that it will create false expectations about drug safety and efficacy, place strains on the physician-patient relationship and lead to inappropriate drug use. If this occurred, total health care costs would rise as the quality of treatment declined.

As discussed above, the central question appears to be whether advertising can deliver objective and accurate messages to consumers who will then process it in an efficient and rational manner. The promise of this appears poor.
Chapter 2: Industrial Economics and Direct to Consumer Advertising

It is possible to predict some of the likely effects of consumer-directed advertising by using the theory of firm behaviour rather than that of the consumer. The preceding chapter contained some of this theory insofar as we discussed consumers’ ability to detect and punish misleading claims with a frequency and severity to render them unprofitable. The root of that argument was that firms would only engage in profitable advertising. Modeling firm behaviour based on the profit motive has the advantage that this assumption better fits the pharmaceutical industry than economists’ assumptions regarding consumer demand.

The pharmaceutical sector simply does not meet economists’ standard assumptions regarding the consistent and rational maximization of consumer welfare subject to resource constraints. On the other hand, if any industry fits the assumption that the objective of a firm is to maximize profits, it must be the pharmaceutical industry. According to Fortune magazines’ annual tabulations of median returns on equity, the pharmaceutical industry has ranked number one, two or three in 20 of the past 23 years—and number one in eight of the last 12 years! If their profitability was just a happy coincidence, prescription drug manufacturers could always lower their prices. It is more likely that profitability in the pharmaceutical sector is the result of deliberate and well-planned corporate strategies. Hypotheses about the likely impact of the consumer-directed drug advertising that are based on the theory of the firm are quite likely to stand the test of empirical experience.

Historical Context

To begin the investigation of direct to consumer advertising from the perspective of the theory of the firm, the first question to ask is “why now?” If consumer-directed advertising is a profitable use of pharmaceutical company resources, why have they not been more interested in it before? Advocates of consumer-directed advertising argue that the recent change in business strategy has to do with the evolution of the consumer into what is portrayed today as a sophisticated and demanding agent. Another reason, one consistent with the fact that independent consumer groups have opposed consumer-
directed drug advertising, is that consumer-directed advertising has only recently become
the most profitable means for the industry to promote sales. Evidence for this may be
found in the history of the modern pharmaceutical industry.

At the beginning of the 20th century, drugs on the market could roughly be
divided according to whether they were promoted directly to the public or not. The
ancestors of today’s prescription-only medicines were (and remain) known as ethical
pharmaceuticals. “Ethical,” referring to a drug or medicine “advertised only in the
professional press, not to the general public, and often available only on a doctor’s
from the American Medical Association’s original (1847) code of ethics that categorized
an ethical drug as one with a known formula, and which was not advertised to the public
(Starr 1982). Such “ethical” standards contrasted with the practices of manufactures of
proprietary and patent medicines.

Proprietary and patent medicines were intensely promoted consumer goods
typically made with secret recipes. Many comprised of little more than coloured water
(Young 1961). Those with medicinal contents contained one or more of a limited set of
ingredients—usually alcohol, though sometimes cocaine or opium. Despite the lack of
true clinical value, proprietary and patent drugs were advertised heavily as panacea-like
treatments for all kinds of conditions, from the serious (e.g., to treat cancer and heart
disease) to the nebulous (e.g., to treat being female) (Young 1961). The manufacturers of
these nostrums competed directly with the medical profession, often inviting consumers
to write to the company for direct medicinal advice, their promotional efforts playing on
the public’s fear of surgical interventions and the desire for quick, cheap cures (Starr
1982).

Muckrakers in the press and medical profession exposed the fraud, addiction, and
poisonings that were occurring in the market for proprietary and patent medicines with
widely publicized reports and publications between 1900 and 1906 (Young 1961; Temin
1980; Starr 1982). These accounts of malevolent business practices provoked widespread
appeals for strict drug regulations. Even large ethical manufacturers allied with the
British and American medical professions to lobby for adulteration laws regulation—at
least in part because they stood to gain in a more regulated marketplace (Abraham 1995).
The public support for government intervention in the pharmaceutical marketplace gave the political impetus for the US Food and Drugs Act of 1906 and Canada’s Proprietary or Patent Medicine Act of 1909. Milestones in Canada’s drug regulation are illustrated in table 1.

Table 1: Milestones in Canadian Drug Regulation

<table>
<thead>
<tr>
<th>Date</th>
<th>Legislation</th>
<th>Restrictions on marketing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1875</td>
<td>Inland Revenue Act</td>
<td>Adulteration and mislabeling forbidden</td>
</tr>
<tr>
<td>1909</td>
<td>Proprietary or Patent Medicine Act</td>
<td>All drugs listed in national pharmacopoeia; formulas registered; ingredients listed in label; certain ingredients banned</td>
</tr>
<tr>
<td>1919/20</td>
<td>Food &amp; Drugs Act</td>
<td>Prohibition against representing any product as a cure</td>
</tr>
<tr>
<td>1934</td>
<td>Amendment</td>
<td>Consumer-directed advertising prohibited for drugs used to treat serious illnesses</td>
</tr>
<tr>
<td>1939</td>
<td>Amendment</td>
<td>Prescription-only status introduced</td>
</tr>
<tr>
<td>1941</td>
<td>Amendment</td>
<td>First list of prescription-only drugs developed</td>
</tr>
<tr>
<td>1953</td>
<td>Amendment</td>
<td>Maintained prohibition on advertising of prescription-only drugs and treatments or preventatives of a list of specified serious diseases.</td>
</tr>
<tr>
<td>1963</td>
<td>Amendment</td>
<td>Clinical evidence of efficacy and safety required in order to obtain a marketing license.</td>
</tr>
<tr>
<td>1978</td>
<td>Amendment</td>
<td>A limited exception introduced to the prohibition against advertising prescription drugs to the public to allow comparative price advertising: name, price and quantity advertising allowed.</td>
</tr>
</tbody>
</table>

Technically, drug adulteration and mislabeling was covered under the 1875 Inland Revenue Act (Curran 1953). However, adulteration—to produce an alteration in a drug’s strength or purity from the avowed standards—was difficult to prove when the formula of a medicine (proprietary or prescribed) was unknown. Canada’s Proprietary or Patent Medicine Act facilitated the enforcement of the otherwise-impotent adulteration laws by requiring that all drugs be listed in an official pharmacopoeia,¹ have their formula registered with the government, or contain a detailed list of ingredients on their label (Goyer 1986, Curran 1953). The 1909 drug laws also banned the use of cocaine, and created a list of ingredients that, if present in the product, must be indicated on the label. Moreover, in 1919, the act was amended to set limits on the allowable dosage of certain

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¹ A pharmacopoeia is a book containing an official list of medicinal drugs and instructions for their preparation and use. There were no Canadian pharmacopoeia before the 1940s, so Canada’s adulteration regulations required that prescribed drugs by in British, US, French, or selected professional formularies.
ingredients and to prohibit firms from representing any product as a “cure”—a commonplace promotional term that had no scientific validity.

Unlike the labeling and adulteration standards, which could be interpreted as a natural extension of exiting foodstuffs regulation to the pharmaceutical market, the regulations governing allowable ingredients, doses and marketing claims signified a legislative belief that the pharmaceutical market was somehow distinct from all others. Restrictions on ingredients, dosages, and claims signified the first substantive departure from the hypothesis that an adequately informed pharmaceutical marketplace could function adequately by responding to the perceived needs and desires of lay consumers. Scientific evidence of safety and efficacy was emerging as a means of judging the social merit of a drug product and the admissibility of claims made about its use.

The Canadian government further limited marketing activities in 1934, with amendments to the Food and Drugs Act that prohibited consumer-directed advertising for drugs used in the treatment of serious illnesses, such as cancer and diabetes. This was the first step in the process of requiring medical supervision over the use of non-narcotic drug use. The prescription-only category of drugs was not, however, created in Canada until 1939. It was created under public outcry surrounding the sulfanilamide tragedy of 1937, wherein 107 Americans—mostly children—died from the toxicity of the solvent used in Massengill’s Elixir Sulfanilamide, a liquid version of a drug commonly used (with and without prescription) to treat streptococcal infections.

Temin (1980, p. 44) notes that economic theory might have predicted that market competition would be sufficient to ensure that only safe medicines survive in the marketplace. According to the economic rationale, consumers would not repeat the purchase of medicines that did not work or, worse, did them harm. Thus, dangerous or ineffective products will not survive in a competitive marketplace. The Sulfanilamide tragedy illustrated reasons for additional safeguards in the pharmaceutical sector: the damages done while competitive forces are at play could be substantial and irreversible.

Amendments to Canada’s Food and Drug Act passed in 1939 gave the Canadian government direct authority to define the terms of sale of any drug. General advertising of such prescription-only drugs would be prohibited. The Canadian government established the first list of prescription-only drugs in 1941, and would seek input
regarding product scheduling from the Canadian Medical Association in the decades to follow (Goyer 1985; Curran 1953; Canada 1963). This contrasts with the American approach, wherein the decision of whether to sell by prescription only was left to manufacturers from 1938 to 1952—during which time most products were labeled and promoted as prescription only drugs.² Interestingly, many manufacturers chose to market products within the ethical traditions (as was required of prescription-only drugs) even when they had been granted nonprescription status in Canada. This gave rise to a class of drugs on the Canadian marketplace referred to as “ethical nonprescription drugs” (Canada 1963).

The balance of market and regulatory mechanisms created by drug laws in the late 1930s might reasonably have been expected to result in adequate market outcomes. Because there were relatively few drugs to choose from, most of which were supplied by a number of competing companies, physicians could be expected to accumulate sufficient scientific knowledge about a given medicine to prescribe appropriately, and consumers could exercise some choice over competing suppliers. Following the war, however, an unprecedented number of products would be brought to market; and, for the first time, these products would be exclusively by patent holding firms. The resulting competition in advertising between firms producing similar—but not chemically identical—products, combined with the unique incentives of the physician decision-maker, reduced the efficiency of market mechanisms.

Before the war, most countries (including the US) did not grant patents for chemicals that were deemed to occur naturally or for chemicals previously isolated but not patented. Firms could patent manufacturing processes for natural substances, but competitors could alter slightly the production process and then legally bring the same end product to market. Following the war, the US pharmaceutical industry lobbied for new rights to patent end products—many of which were expected to be forthcoming from knowledge accumulated during wartime research efforts (Bogner 1996). In 1948, the

² Inconsistencies wherein prescription-only drugs were being repackaged (or not) and made available without a prescription lead to the 1952 Durham-Humphrey Amendment to the US Food and Drugs Act, which set a standardized list of drugs that were deemed unsafe for use without medical supervision.
industry won the right to patent synthetic versions of natural substances; and in 1952, the industry won the right to patent new uses of existing products.

An explosion of products entered the market in the 1950s and 1960s. Innovative products were patented and marketed on an exclusive basis by the innovators—or licensed exclusively to firms with professional sales forces. Competing products entered the market by patenting chemicals that were similar to the pioneer in structure and therapeutic qualities—the so-called “me-too” products of the pharmaceutical industry. These firms also marketed their products on an exclusive basis, choosing to compete with pioneers in the realm of marketing rather than in that of price competition. This industrial strategy was made possible by the unique decision-making structure in the prescription-only sector that gave the “ethical” marketing traditions some economic advantages.

Distributing a product through the prescription-only route sent an indirect, but obvious, signal of therapeutic value to the end user—the prescription itself embodying the professional endorsement of the patient’s trusted physician. However, the ethical marketing traditions also placed an emphasis on product differentiation rather than price competition. Whereas patients made up a diverse target audience for marketing activities, the members of which would have incentive the and the ability to compare prices of competing consumer-oriented products, physicians were an easily identified, relatively homogeneous marketing audience that did not pay for the products they selected. Moreover, each prescribing physician had the potential to make product selection decisions on behalf of hundreds of end consumers. Tailoring drug promotion to the ethical traditions therefore made it possible for manufacturers to compete more intensely in marketing activities than they did in pricing (Canada 1963; Walker 1971; Temin 1980). Since the medical profession had taken a strong position in opposition to general advertising, there was potentially much to be lost, and little to be gained, by consumer-directed promotional activities for prescription drugs (as allowed in the US) or for the “ethical non-prescription” drugs in Canada (Starr 1982; Canada 1963).

Beginning in the late 1950s, and running right through the 1960s, public hearings were held in Canada, the US, and the UK to explore the price of drugs and the conduct of
pharmaceutical companies. Among other things, reports were concerned about the pharmaceutical marketing practices that were informing the prescribing process (Temin 1980, Lang 1974, Canada 1963). With the number of products on the marketplace exploding in the 1950s and 1960s, the din of promotional materials was feared to have drowned out scientific discourse and scrutiny (Canada 1963; Walker 1970; Temin 1980).

There were 5,727 products launched in the US between 1948 and 1959. Of these, 2,795 were mixtures of two or more existing ingredients, 1,356 were new dosage forms of existing products, 1,085 were new brands of existing products, and 491 were new chemical entities (Canada 1963, p. 186). Even at half the rate of US product launches, it is estimated that a new drug product was launched in Canada every two days through the late 1950s and early 1960s. The typical Canadian product launch was described as a “crash promotional campaign,” with all the ballyhoo necessary to create almost immediate acceptance of the new product by prescribing physicians (Canada 1963). The emphasis on marketing was clear. In 1960, 40 of the largest manufacturers selling drugs in Canada spent 30 percent of revenues on advertising and promotions—while spending 9 percent on research and development (Canada 1963). While the social value of advertising was portrayed as a means of informing doctors about developments in the industry, gifts, entertainment, and travel were often-cited means of enticing physicians to prescribe particular products and brands that had no therapeutic advantage over lower cost alternatives. Finding ways to protect consumers from the cost of using products of questionable therapeutic value became a policy objective following the inquiries.

Analogous to the prescription-only regulations of the 1930s, regulations governing the effectiveness of medicines would be brought in under a wave of public concern surrounding a highly publicized drug tragedy. This time, the birth defects caused by pregnant women’s use of the sleeping pill, thalidomide, precipitated the passing of regulations requiring evidence of safety and efficacy in the US (1962) and Canada (1963). Formal safety review processes were already in place in the US (since 1938), and

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3 Among the Canadian inquiries were the 1963 Combines Investigation Report; the 1963 Restrictive Trade Practices Commission report; the 1965 report of the Royal Commission on Health Services; and the 1967 reports of the Special Committee of the House of Commons on Drug Costs and Prices.
in Canada (since 1952), but the new regulations required that firms offer clinical proof of safety and efficacy before being permitted to market their products.

The efficacy regulations of the 1960s retained the hierarchical decision structure—from government to physician to patient—while giving government greater authority to limit entry to the pharmaceutical marketplace. The scientific definition of clinical effectiveness on which the government would base market restrictions formalized the theretofore-implied distinction between pharmaceuticals and commodity goods. Personal preferences or the impressions of individual physicians and patients would no longer justify the existence of a product in the pharmaceutical marketplace. The physician-patient agency relationship remained, but as Temin (1980) notes, the efficacy laws sent a message that “not only can consumers not rely on the general market to weed out inferior products, they cannot even rely on the highly educated medical market—that is, practicing physicians—to weed out worthless drugs.” (Temin 1980, p.128)

The 1962 amendments to the US Food, Drug and Cosmetics Act, also clarified rules concerning prescription drug marketing. According to the amendments, public advertising campaigns for prescription drugs would be permitted provided they met four criteria. Allowable ads (1) must not be false or misleading; (2) must present a “fair balance” of information about the risks and benefits of using the drug; (3) must contain “facts” that are material to the product’s advertised uses; and (4) must contain a “brief summary” of every risk identified in the product’s approved labeling (Henney 2000). Though rare in the US before, general advertising of prescription drugs following the 1962 clarifications was virtually nonexistent until the 1980s.

As discussed above, restricting marketing activities to professionals only—in the US and Canada—was not without economic advantages during the post-war therapeutic revolution. Since the 1980s, however, changes in the pharmaceutical marketplace appear to be eliminating some of the traditional advantages of the ethical pharmaceutical marketing strategy. Unlike previous structural changes that stemmed from changes in the regulatory environment, recent changes in the pharmaceutical marketplace are the result of the evolving sophistication of providers of third party pharmaceutical benefits.
As illustrated in figure 1, per capita pharmaceutical sales growth has been steady from the creation of the prescription-only regulations through to today. Spending may even be described as explosive since the mid 1970s, an era during which pharmaceutical benefits were being extended to an increasing percentage of North American consumers. The rapid rate of pharmaceutical expenditure growth, combined with the tightening fiscal reality of the 1980s, was sufficient to galvanize efforts to control pharmaceutical costs by managers of drug benefits provided under private and public drug plans. Having experienced some measure of cost control with other components of the health care sector, managed care organizations and government providers of drug benefits implemented widespread policies aimed at slowing pharmaceutical cost growth in the 1980s and 1990s.

Figure 1 plots two series of data to give an indication of trends in the Canadian pharmaceutical industry. The first is the historical value of manufacturers shipments of medicinal and pharmaceutical preparations per capita from 1935 to 1974. This captures the wholesale cost of both prescription and non-prescription products over this period. The second (darker) series is the per capita retail value of prescription only products in Canada. Though the series differ, they indicate trends in the growth rate in real expenditures per capita in Canada.

In addition to policies aimed at improving the prescribing practices of physicians, formularies (lists of drugs covered or not covered by a plan) and/or incentive-pricing

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policies\(^5\) are now employed by approximately 90 percent of managed care plans in the US (Reese 2001), and by most provincial drug plans in Canada. The increased emphasis on cost control appears to have forced manufacturers to seek audience with patients in order to promote sales of particular brands (Pinto et al 1998). A recent paper commissioned by Pfizer Inc. appears to confirm this: it portrays consumer directed advertising as a direct means of countering the restrictions imposed by managed care providers (Rubin and Schrag 1999).

The first advertising campaigns for prescription drugs aimed at the public began in the US in the early 1980’s. These included both product-specific ads, such as the campaign for Rufen (ibuprofen) with a coupon a patient could bring to their doctor for a price rebate, as well as press and public relations campaigns (Clark et al. 1982) Eli Lilly aggressively marketed its anti-arthritic drug benoxaprofen (Oraflex) to the public as well as to health professionals in 1982. Five months after its introduction, Oraflex was withdrawn because of liver and kidney toxicity, including deaths associated with its use (Mintzes 1998). Motivated by this unfortunate beginning, the US Food and Drugs Administration declared a temporary moratorium on direct-to-consumer advertising of prescription drugs in 1983.

After consultation and review, the moratorium on consumer directed ads was lifted in 1985. A gradually growing number of firms launched consumer directed campaigns in the late 1980s and early 1990s. However, since the cost of broadcasting a “brief summary” of risks over television and radio was prohibitive, major promotional campaigns were limited. Broadcast ads were generally limited to either branding ads that mentioned a product’s name but made no health claims, and were therefore not required to include the brief summary, or disease-oriented advertising suggesting that patients “ask their doctor” about treatments for a specific condition but did not mention a product name. Both types of ads were (and remain) legal marketing practices in Canada.

In 1997, the pharmaceutical industry persuaded the US Food and Drugs Administration to amend the disclosure requirements for broadcast ads. The amendments allowed manufactures to state only the major risks in their presentation provided they

\(^5\) An incentive pricing policy gives patients the choice to pay extra for drugs that cost more but are therapeutically similar to first-line medicines, as defined by the plan.
made “adequate provision” for the dissemination of approved drug information—e.g., through an Internet site or a 1-800 phone number. With relaxed broadcast disclosure requirements, spending on consumer-directed prescription drug advertising exploded. It is now approaching US$3 billion per year, 70 percent of which is spent on television advertisements, making prescription drugs one of the most heavily promoted classes of “consumer products” in the US. The value of this advertising depends on whether advertising supplied by pharmaceutical companies provides needed information that is not otherwise available from physicians, pharmacists, benefits providers, or government agencies.

**What can be expected from Direct to Consumer Advertising?**

To address the likely impact of direct to consumer advertising, consider the likely motivations and behaviours of firms under alternative regulatory regimes. Incentives are assessed under laws that permit the mention of brand names and claims about indications and effectiveness—referred to as US-style laws—and under laws that only allow disease advertising without mention of any brand names—referred to as Canada-style laws. The purpose of this distinction is to illustrate the coincidence of social and industrial incentives under a “Canadian-style” regulatory system. Most of the desirable consequences that are purported to stem from drug advertising would occur under such circumstances.

Rather than generalize the likely motives and impacts of ads across all possible sub-markets in the pharmaceutical sector, three broad cases of product are considered. Firm incentives will vary across categories of product, as will the likely impacts of advertising on health status and costs. The first category is that of “breakthrough-pioneering” drugs that meet legitimate health care needs not previously met (pharmacologically or otherwise). The second category is of “competitors,” new drugs that enter markets to compete with existing treatments for the indicated medical condition. Finally, a third category is separated from the above two: it is that of drugs to treat a “lifestyle” condition—whether breakthrough or not. Firm incentives and likely cost-impacts for each category are summarized in Table 2.
<table>
<thead>
<tr>
<th>Firm Motives</th>
<th>Breakthrough-Pioneer</th>
<th>Competitors</th>
<th>Lifestyle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Costs</td>
<td>To persuade consumers about the need to contact doctor for treatment—its brand by default.</td>
<td>To persuade patients to demand its particular drug for treatment. (Not possible by law.)</td>
<td>To persuade consumers about the need to contact doctor for treatment if a pioneering treatment.</td>
</tr>
<tr>
<td>Medical Costs</td>
<td>Increased costs through volume.</td>
<td>(Disease ads unlikely)</td>
<td>Increased costs through volume.</td>
</tr>
<tr>
<td>Diagnostic Services</td>
<td>Increased costs due to advertising induced visits.</td>
<td>(Disease ads unlikely)</td>
<td>Increased costs due to advertising induced visits.</td>
</tr>
<tr>
<td>Hospital Costs</td>
<td>Increased cost of diagnostic services depending on advertised drug.</td>
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<td>To persuade consumers about the need to contact doctor about condition; to persuade consumers about its brand’s merits; to increase willingness to pay; and to serve as a barrier to future competitors.</td>
<td>To persuade patients to demand its particular drug for treatment; to persuade consumers about its brand’s merits; to increase willingness to pay; and to serve as a barrier to future competitors.</td>
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<td>Increased costs through price per case treated and possibly through volume.</td>
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Before discussing the scenarios, it is worth noting what must be true in all cases. First, the advertising firm must be selling a patented product or have monopoly power that prohibits direct competition with its product. For, if a firm advertised for a product that is available in generic form, much of the return to advertising investment would be stolen by its direct (generic) competition. Moreover, the markups on generic drugs are generally insufficient to support marketing expenses of their own. Therefore, only patented and branded products will be promoted by the means of competitively supplied advertising—consumer-directed or otherwise.

Following from the firm’s need to recoup the costs of investment, it can be predicted with certainly that long-run drug costs in any scenario must increase by an amount greater than the amount spent on advertising. This must occur because for-profit drug manufacturers are not charities. They engage in advertising only when it is expected to be profitable. When firms make mistakes in judging that profitability, or when competing firms trump their marketing efforts, the investment in advertising stops quickly (Aitkin and Holt 2000; Goetzl 2000). Over the long run, firms continue with the mix of promotional efforts that generate the highest returns. Although it is possible for firms to get caught in a destructive cycle of competition through advertising—wherein all competitors are made worse off than they would be if none of them advertised—this cannot be the case in the pharmaceutical industry. It is the industry that is lobbying for the removal of laws prohibiting consumer-directed advertising. These highly profitable multinational corporations would not ask governments to remove laws that make them better off.

For a firm to simply recover the costs of advertising it must sell as sufficient quantity of the advertised drug at a price sufficiently greater than the cost of producing the product. However, the amount spent by consumers (or benefits providers) does not all accrue to this cost-recovery process. The final cost of a drug includes markups and fees that flow to wholesalers, distributors, and retailers. Thus, just to meet the advertising costs, gross expenditures on the advertised drugs must grow proportionately more than the firm’s investment in advertising. Of course, there is nothing stopping a firm from charging or selling more than is necessary simply to recoup costs; but, at a minimum, economic theory implies that consumer-directed advertising in the US is currently
inflating long-run drug costs by the $3 billion per year spent on the ads. The same is true of any expenditure on direct to consumer drug advertising that occurs in Canada.

Breakthrough-Pioneering Products

A truly pioneering product is one that is safe and effective in satisfying a legitimate health care need that was theretofore unmet. Under laws that permit only “disease” advertisements, a firm with a breakthrough-pioneering drug product will have incentive to advertise if doing so brings sufficient numbers of patients into contact with physicians for the purposes of treating the indication—and if physicians prescribe the pioneering product to a sufficient number of those patients. If the target patient population already consults physician with significant frequency, targeting marketing practices exclusively at physicians may be the most profitable means of promoting sales of the product. If, however, a target population does not consult with physicians on a routine basis, disease advertising may be a profitable means of promoting sales of a breakthrough-pioneering product. This may be considered a coincidence of social and private incentives in the sense that the firm’s incentive to bring patients into contact with physicians for the theretofore untreated medical condition may closely align with the social objectives of having said condition treated.

Because lay individuals may mistake themselves for being in the appropriately indicated group for advertised drugs, the health care system will bear some costs for physicians’ services and diagnostic tests used by individuals that do not become customers of the advertising firm. The extent to which the ads attract only the appropriate patient cohort will determine the net benefits of the increased visits to physicians. If the ads were reasonably precise in their ability to target appropriate patients, then it can be expected that population health would improve and long-term health care costs would fall. However, there is nothing in economic theory that rules out the possibility that manufacturers of breakthrough-pioneering drugs will design disease ads to broaden their target markets as wide as possible. Firms generate the same revenues when selling to patients with potential to benefit from treatment as they do selling to those who will not benefit from treatment. One can therefore expect corporate sponsored disease ads to use persuasive tactics (such as celebrity spokespersons or
emotive images) to obtain the largest possible market for their product. Though not all patients who seek care due to ads will be prescribed the drug, some who are not necessarily appropriate candidates for the drug treatment will nevertheless receive it. The costs of diagnostic services will be born by the health care system regardless.

Despite the incentive to broaden the target audience, disease advertising for breakthrough-pioneering products has the potential to generate positive health outcomes that justify changes in health system costs. The coincidence of private and social objects is greatest when ads may not mention brand names or make claims about effectiveness. The ability to name the brand and make claims about its efficacy changes the likely impact of consumer-directed advertising and the incentive for firms to engage in it—even for firms promoting breakthrough-pioneering products.

The ability to make claims about effectiveness will increase the means by which pioneering firms may persuade consumers to seek the drug. This will be especially true for conditions in which patients may be managing their illness by other means—such as diet and lifestyle changes. The ability to “brand” the product has the further effect of increasing consumers’ appraisals of the drug’s merit, thereby increasing the possibility of the patient seeking treatment, and it may also serve to impede potential competitors.

If a firm can establish a link between its corporate identity (brand) and treatment for the condition, it may create a barrier for competing brands or future generic entrants. When such banding is sufficiently well built, firms perpetuate their revenue streams through line-extensions—often also through OTC versions of the prescription-only drugs. Thus, spending on advertising to promote a brand when it is a breakthrough product may increase revenues for the firm not just in the short term, but also in later stages of the product life.

The effect of brand-related marketing is generally to increase the amount paid for drugs to treat the indicated illness. Brand building will increase the volume of purchases in the short run and increase the price per case treated by in the long run. Changes in the complementary medical and diagnostic services will also tend to be greater under branded advertising for breakthrough-pioneering products than with disease-advertising because branded advertising has the potential to be more intensive and more persuasive, thereby bringing a wider audience into treatment.
Competitors in Existing Therapeutic Classes

Relative to the case of breakthrough-pioneering products, the likelihood of disease advertising by competitors in established therapeutic classes is low. When treatment options have long been available for a given condition, disease advertising is not likely to bring sufficiently large numbers of new patients into treatment. Even when the target audience does not otherwise seek treatment on a regular basis, a firm in an established therapeutic class will not be able to exclude its competitors from stealing sales generated by its disease advertisements. For, once patients had sought treatment from a physician, they may be prescribed a competing product. Thus, competing products will not generally be promoted by means of unbranded disease advertising. The mentioning of brands is essential to recouping the cost of advertising when multiple drugs may be used to treat a condition.

When firms are permitted to advertise by brand, products will be marketed with claims about effectiveness that are tailored to give impression of superiority. The effect of such advertising is to increase consumers’ loyalties to and their willingness-to-pay for a particular product. If sufficient brand-loyalty is established, the patients’ appraisals of the products may be pitted against those of practitioners and payers who might suggest alternative methods of treatment. The effect will be inflationary, as reliance on promoted products increases and use of older often non-patented products declines. There is no guarantee that the change in the cost of treatment will be accompanied by proportional improvements in health outcomes.

It is often claimed that increased advertising of products to treat common indications will increase the number of patients seeking treatment and the number of patients complying with their prescribed medicines. It should be noted, however, that both of these claims are true only insofar as the ads will increase the number of patients seeking the advertised brand of treatment and complying with (or asking to be switched onto) the advertised brand. Sales increase for the advertising firm in either regard. Whether increased rates of treatment result from such advertising is an empirical question that must be answered with an eye to the treatment appropriateness. Moreover, “increased compliance” with treatment may simply be an increased turnover from patients taking older products to manage or treat chronic illness toward newer
treatments—motivated only by consumers’ appraisals of the therapeutic merits of old versus new drugs that, in turn, are based on advertising claims by the new drug manufacturers. Recall that only patented drug products can be profitably advertised.

**Lifestyle drugs**

Lifestyle drug products are separated from the other categories because they are not drugs that perform a medically necessary function, regardless of whether they are breakthroughs or simply competing drug options. Therefore, the costs to the health care system by way of increased visits to physicians, diagnostic tests, and hospital admissions (due to adverse drug reactions and side-effects) are all of dubious merit when judged from the perspective of the public payer for health care in Canada.

Firms will engage in “disease” advertising if they have a pioneering lifestyle product. Unlike the potential gains to disease advertising for medically necessary treatments, there are no major benefits to the public health care system from increased decisions to treat lifestyle concerns—such as toenail fungus and male-pattern baldness. While the individual consumer of the drugs may believe the publicly funded complementary medical services are of value, they do not pay for them. Brand-oriented advertising for lifestyle drugs will increase demand for products because the claims made to promote a particular brand will be designed to increase consumer appraisals of the treatment option beyond that which is possible under a disease advertisement. The social benefit from competition in advertising between branded products used in the treatment of lifestyle conditions is questionable. Increased costs of treatment stemming from more rapid uptake of advertised brands cannot result in bona fide improvements in health outcomes. They may, however, result in improved consumer utility—but such utility is not a tradition objective of health care policy.

**Discussion**

Truly pioneering products offer the best hope that direct to consumer drug advertising can improve health and reduce health costs while at the same time being profitable to the firm. In this category, advertising has the potential to bring patients into “needed” treatment that would not otherwise receive it. It should be noted, however, that very few products fit the breakthrough-pioneering category. In the average year since
1988, fewer six new products launched into the Canadian marketplace were classified as substantial improvements over existing drug treatments (PMPRB various years). A vast majority of new drugs launched in Canada since 1988 have fallen into the category of “me-too” products (37 per year) or line-extensions (32 per year). Since many drugs classified by the Patented Medicine Prices Review Board as substantial improvements entered the marketplace to compete with existing drug treatments, the annual number of truly pioneering therapeutic options entering the Canadian marketplace is very small: certainly less than six.

Information about the likely kinds of drugs to be advertised most heavily can be inferred from patterns of consumer-directed advertising in the United States. Table 3 contains a list of the 25 drugs most heavily promoted through DCTA in 1999. Along with the share of total DCTA accounted for by the individual products, Table 3 indicates whether the product is unique in its overall therapeutic class or within its more narrow pharmacologic family. Only six products in the top 25 are pioneering for their pharmacologic category; and only (Viagra) one is pioneering for its therapeutic class. The remainders are competitors entering established treatment categories.
Table 3: 1999 – Top Drugs by Spending on Direct to Consumer Advertising

<table>
<thead>
<tr>
<th>Brand (Drug Name)</th>
<th>Share of Total 1999 Spending</th>
<th>Primary Indication</th>
<th>Pioneering in class?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claritin (loratadine)</td>
<td>9%</td>
<td>Allergy</td>
<td>No</td>
</tr>
<tr>
<td>Prilosec (omeprazole)</td>
<td>5%</td>
<td>Ulcer</td>
<td>No</td>
</tr>
<tr>
<td>Xenical (orlistat)</td>
<td>5%</td>
<td>Obesity</td>
<td>No</td>
</tr>
<tr>
<td>Propecia (finasteride)</td>
<td>4%</td>
<td>Baldness</td>
<td>YES</td>
</tr>
<tr>
<td>Zyrtec (cetirizine)</td>
<td>4%</td>
<td>Allergy</td>
<td>No</td>
</tr>
<tr>
<td>Lipitor (atorvastatin)</td>
<td>3%</td>
<td>Lipid lowering</td>
<td>No</td>
</tr>
<tr>
<td>Zyban (bupropion)</td>
<td>3%</td>
<td>Smoking cessation</td>
<td>YES</td>
</tr>
<tr>
<td>Flonase (fluticasone)</td>
<td>3%</td>
<td>Inhaled steroid</td>
<td>No</td>
</tr>
<tr>
<td>Viagra (sildenafil)</td>
<td>3%</td>
<td>Erectile dysfunction</td>
<td>No</td>
</tr>
<tr>
<td>Nasonex (mometasone)</td>
<td>3%</td>
<td>Inhaled steroid</td>
<td>No</td>
</tr>
<tr>
<td>Ortho-tricyclen (estradiol/levonorgestrel)</td>
<td>3%</td>
<td>Birth control pill</td>
<td>No</td>
</tr>
<tr>
<td>Meridia (sibutramine)</td>
<td>3%</td>
<td>Obesity</td>
<td>No</td>
</tr>
<tr>
<td>Glucophage (metformin)</td>
<td>3%</td>
<td>Oral anti-diabetic</td>
<td>No</td>
</tr>
<tr>
<td>Allegra (fexofenadine)</td>
<td>3%</td>
<td>Allergy</td>
<td>No</td>
</tr>
<tr>
<td>Valtrex (valacyclovir)</td>
<td>3%</td>
<td>Antiviral</td>
<td>No</td>
</tr>
<tr>
<td>Detro (tolteridone)</td>
<td>2%</td>
<td>Bladder control</td>
<td>No</td>
</tr>
<tr>
<td>Zocor (simvastatin)</td>
<td>2%</td>
<td>Lipid lowering</td>
<td>No</td>
</tr>
<tr>
<td>Prempro (Conjugated estrogens and medroxyprogesterone)</td>
<td>2%</td>
<td>Post menopausal hormone therapy</td>
<td>No</td>
</tr>
<tr>
<td>Zomig (zolmitriptan)</td>
<td>2%</td>
<td>Migraine</td>
<td>No</td>
</tr>
<tr>
<td>Flovent (fluticasone)</td>
<td>2%</td>
<td>Inhaled steroid</td>
<td>No</td>
</tr>
<tr>
<td>Paxil (paroxetine)</td>
<td>2%</td>
<td>Antidepressant</td>
<td>No</td>
</tr>
<tr>
<td>Celebrex (celecoxib)</td>
<td>2%</td>
<td>NSAID</td>
<td>No</td>
</tr>
<tr>
<td>Singulair (montelukast)</td>
<td>2%</td>
<td>Asthma</td>
<td>No</td>
</tr>
<tr>
<td>Aricept (donepezil)</td>
<td>2%</td>
<td>Alzheimer’s</td>
<td>No</td>
</tr>
<tr>
<td>Accolate (zafirlukast)</td>
<td>2%</td>
<td>Asthma</td>
<td>No</td>
</tr>
</tbody>
</table>
Even for those products that are pioneering within their therapeutic category, the case in favour of US-style drug advertising is not strong. As discussed above, brand-oriented advertising detracts from the coincidence of private and public objectives that occurs in the promotion of new treatment options. Branding products for the treatment of any illness, however under-treated, will trend to inflate the short and long run costs of drug treatment relative to that which would occur with unbranded disease awareness. Claims to the contrary—that consumer directed prescription drug advertising is strictly a means of educating patients about the need to treat illnesses—are inconsistent with the fact that manufacturers will not promote treatment options that they do not sell. Kaldor (1950) summarized the social utility of advertising *qua* information:

“As a means of supplying information, it may be argued that advertising is largely biased and deficient. Quite apart from the making of deliberately faked claims about products which legislation and professional etiquette have never yet succeeded in suppressing, the information supplied in advertisements is generally biased, in that it concentrates on particular features to the exclusion of others; makes no mention of alternative sources of supply; and it attempts to influence the behaviour of the consumer, not so much by enabling him to plan more intelligently through giving more information, but by forcing a small amount of information through its sheer prominence to the foreground of consciousness” (Kaldor 1950 p.5).

No reasonable individual can refute the clear conflict of interest that drug manufacturers are in when they claim to be educating patients. As compared to viable alternatives for informing patients about medical conditions and appropriate prescription drug use, competitively supplied brand-oriented advertising will lead to unnecessarily high costs for drugs and medical services. What is needed for the health and welfare of Canadians is not more advertising, but a source of unbiased information about medical conditions and the relative costs and benefits of alternative ways of treating them.
Appendix: Standard Economic Analysis of Consumer Welfare

Case 1: Price Rises and Quantity Falls

Unlike the measurement of profits, the measurement of consumer welfare generally depends on which demand curve is the “right” demand curve. The “after-advertising” and “before-advertising” cases are illustrated in Figures 4A and 4B. Consumers who continue to purchase the product after the advertising takes place will pay more per unit purchased (the shaded rectangle to the left of $Q_A$ in both figures). Consumers who no longer purchase the product because of its higher price will lose the surplus they would have enjoyed if the product were still available at the before-advertising price. The sizes of this reduction in consumers’ surplus are depicted by the shaded areas between positions $Q_A$ and $Q_B$ in Figures 4A and 4B. The net loss in consumer surplus is greater using the after-advertising demand function because it places a higher value on the units of consumption “squeezed out” by the higher post-advertising price.

The net change in social welfare from the advertising-induced increase in price and reduction in demand is negative regardless of which demand curve measures the social value of transactions. This is because the losses to consumers in terms of forgone consumers’ surplus (Figures 4A and 4B) are greater than the firm’s rise in profit level (Figure 3). However, despite the fact that the advertising in question would result in a reduction in social welfare, firms would still advertise. For-profit firms maximize profits; they are not charitable organizations that aim to maximize social welfare.
Scenario 2: Price Falls and Quantity Rises

The change in profits stemming from a decrease in price and an increase in quantity is illustrated in Figure 5. As is always the case, net profits must be greater after advertising if advertising is indeed observed; otherwise, the firm would not engage in it.

The changes in consumer welfare in this situation are illustrated in figures 6A and 6B. Judged from the after-advertising demand function, illustrated in Figure 6A, consumer welfare increases unambiguously because consumers are getting more of the good at a lower price than they paid before. Some of this benefit (the rectangular area left of $Q_B$) occurs because of the reduced price on purchases that would have otherwise been made, while the remainder (the triangular area between $Q_B$ and $Q_A$) is the increased consumers’ surplus generated on new purchases.

Figure 6B illustrates the fact that, judged from the before-advertising perspective, consumers may be made worse off even when prices fall and quantities rise. This is because the price paid for some of the units of the good purchased after advertising but not before advertising will exceed the consumers before-advertising willingness-to-pay.
Consumers making these purchases run a consumers’ deficit rather than a consumers’ surplus. This is illustrated in Figure 6B as the lightly shaded triangle above the demand curve, immediately to the left of $Q_A$. If this deficit exceeds the increased surplus and the value of savings on previously purchased goods (the shaded rhomboid in Figure 6B) then the net change in consumer welfare will be negative. Otherwise, consumer welfare will increase.

As was the case in the preceding scenario, the net gains to the firm will be greater than the potential loss to consumers. A traditional welfare-economic analysis of advertising would therefore conclude that the net gains to society are positive when prices fall and quantities rise, regardless of which demand curve was the “right” measure of the value of consumption.

**Scenario 3: Price Rises and Quantity Rises**

The third possible case to be analyzed within the standard welfare economic framework is when both prices and quantities increase because of advertising. The unambiguous increase in the firm’s profits is illustrated in Figure 7. Changes in consumer welfare, however, are somewhat ambiguous; they depend on which demand curve is the “right” measure of welfare.

The analysis base on the after-advertising demand curve is illustrated in Figure 8A. Here, the change in consumers’ surplus may be ambiguous because consumers are now paying more for every unit that was purchased in the pre-advertising scenario, but they are also receiving newly generated surplus on the units not previously purchased. The loss on previously purchased goods is the lightly shaded rectangular area to the left
of $Q_B$ and the gain on new purchases is the dark shaded triangle between $Q_B$ and $Q_A$. Depending on the shape of the demand curve, either of these could be bigger than the other.

The same analysis based on the before-advertising demand function is illustrated in Figure 8B. As illustrated, if consumers are convinced to purchase more units at higher prices than the “before advertising” demand function indicates the items are worth, then consumers run a welfare deficit on each additional purchase made. This deficit is the shaded rhomboid area below the price line and above the demand curve between $Q_B$ and $Q_A$. Consumers also lose some of the consumers’ surplus on purchases that would have been made before advertising due to the increase in the price paid for those units of consumption. This is the shaded rectangular area to the left of $Q_B$.

As was the case in the previous scenarios, when prices and quantities rise, the change in net social welfare—consumer welfare plus firm profits—is positive because the increase in profits to firms outweighs losses to consumers.
References


