Court File No. 05-CV-303001PD2

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

CANWEST MEDIAWORKS INC.

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

AFFIDAVIT OF MICHAEL J. TREBILCOCK

I, **MICHAEL JOHN TREBILCOCK**, of the City of Toronto, in the Province of Ontario, **MAKE OATH AND SAY:**

I. INTRODUCTION

1. I have been retained by the Toronto law firm of Paliare Roland on behalf of CanWest Mediaworks Inc. to prepare this opinion on the justification for a ban on all forms of direct-to consumer prescription drug advertising (hereinafter DTCA).

2. I hold the Chair in Law and Economics at the University of Toronto, Faculty of Law, where I have been a full professor since 1972. I was a Fellow in Law and Economics at the University of Chicago Law School in 1976, a Visiting Professor of Law at Yale Law School in 1985 and 2005, and a Global Law

Professor at New York University Law School in 1997 and 1999. In 1987 I was elected a Fellow of the Royal Society of Canada and was appointed a University Professor in 1990. I was awarded the Owen Prize in 1989 by the Foundation for Legal Research for my book, *The Common Law of Restraint of Trade*, which was chosen as the best law book in English published in Canada in the previous two years. I have since authored *The Limits of Freedom of Contract* and co-authored *The Regulation of International Trade; Exploring the Domain of Accident Law: Taking the Facts Seriously*; *The Making of the Mosaic: A History of Canadian Immigration Policy; The Law and Economics of Canadian Competition Policy* and *Rethinking the Welfare State: The Prospects for Government by Voucher.* I have served as Director of the Law and Economics Programme at the University of Toronto since 1976. In 1999, I received an Honorary Doctorate in Laws from McGill University and was awarded the Canada Council Molson Prize in the Humanities and Social Sciences. In the same year I was elected an Honorary Foreign Fellow of the American Academy of Arts and Sciences. In 2003, I received an Honorary Doctorate in Law from the Law Society of Upper Canada. In 2007, I was the recipient of the Mandell Medal for contribution to Law and Letters, awarded by the Attorney General of Ontario.

3. As relevant to how the current proceedings, long-standing teaching and scholarly interests of mine have related to (a) consumer protection policy, (b) choice of governing instruments, and (c) the limits of freedom of contract (including, as relevant to these proceedings, issues of coercion, asymmetric

information, externalities and paternalism). I have appended to this affidavit a list of publications and studies in these three areas, which inform the perspective I bring to bear on the issues in this case (Exhibit "A"). My full curriculum vitae is also attached herewith (Exhibit "B"). In addition to my scholarly and teaching interests in consumer protection policy, I also served as a member of the Adelaide Law School Committee reporting to the Standing Committee of Australian Commonwealth and States Attorneys-General on the law relating to consumer credit and money lending, 1967-1969; National Vice-President of the Consumers' Association of Canada from 1974-1975; Chairman of the Regulated Industries Program of the Consumers' Association of Canada from 1973-1975; member of the Academic Advisory Panel of the Department of Consumer and Corporate Affairs, 1973-1975; Chairman of the Consumer Research Council 1975-1976; and Research Director of the Professional Organizations Committee of the Government of Ontario 1976-1980. I have also been involved in the past in advising the federal government and the governments of Alberta, British Columbia and Ontario on reforms to their misleading and deceptive advertising laws.

4. I do not claim medical or scientific expertise either generally or in matters relating specifically to the efficacy of pharmaceuticals. Nor do I claim empirical expertise on the effects of DTCA. However, I do claim substantial experience and expertise in the design of regulatory policies for minimizing market failures in consumer markets, including market failures induced by false, misleading, or

deceptive marketing or promotional practices. In this opinion, I briefly review the social value of advertising (Section II) and the arguments for and against DTCA (Section III), and then explore at greater length the choice of regulatory instrument in this context. In summary, it is my opinion that an across-the-board ban of DTCA is a disproportionate response to whatever potential negative welfare effects DTCA might entail, recognizing also significant potential positive welfare effects of DTCA, and that there is a vast array of regulatory instruments available for minimizing DTCA's potential negative welfare effects and maximizing its potential positive welfare effects.

II. THE SOCIAL VALUE OF ADVERTISING

5. Three views have emerged in the economic literature to explain why consumers respond to advertising. The first sees advertising as persuasive, the second sees it as informative, while the third sees it as complementary. In a recent survey of the literature, Bagwell suggests that each of these views is, at some level, plausible. Although the persuasive and informative views offer conflicting assessments of the social value of advertising, Bagwell argues that the empirical evidence strongly suggests that no single view of advertising is valid in all settings.[1]

6. Where advertising is viewed as purely persuasive, the purpose is seen as rearranging consumers' evaluations so that they are persuaded to place a higher

[1] K. Bagwell, "The Economic Analysis of Advertising", in M. Armstrong and R. Porter (eds.), Handbook of Industrial Organization (Holland: Elsevier, 2005).

value on the advertised product. In doing so, advertising may distort consumers' decisions as compared to those that reflect their "true" preferences (as reflected in their pre-advertising demand). However, whether their pre-existing preferences can in turn be viewed as reflecting "true" preferences, given that they too were presumably shaped by various external influences, is problematic. Moreover, forms of persuasion are ubiquitous in life – for example, in teaching, journalism, politics, advocacy, family relationships and many forms of collective decision-making in the public and private sectors, so that a case needs to be made that persuasion in advertising is more socially insidious than persuasion in many of its other forms.

7. The view that advertising is often informative is more straightforward. Many markets are characterized by imperfect consumer information. Such costs deter consumers from learning about each product's existence, price and quality. Advertising is a response to this market imperfection by conveying information to consumers, either directly (i.e., the existence of the product, prices and location) and/or indirectly (i.e., that the firm is willing to spend resources on advertising). Advertising reduces consumers' search costs by conveying information that they would otherwise have to expend resources to obtain.

8. On the third view of advertising as complementary to the advertised product, this view does not see advertising as changing consumers' preferences nor as providing information, but rather assumes that consumers already have a

stable set of preferences into which advertising enters directly in a fashion that is complementary with the consumption of the advertised product. For example, consumers may value social prestige in the consumption of a product and they derive greater prestige when the product is advertised. On this theory, while advertising is uninformative, it is nevertheless beneficial, since consumers may value it directly.

9. A key distinction in advertising theory is that between search goods, experience goods, and credence goods.[2] Economists seek to classify goods into one of these categories according to the characteristics with respect to the costs incurred by buyers in determining the quality of their purchases. Costs may be incurred in detecting quality prior to purchase (pre-costs) as well as after purchase (post-costs). Search characteristics have low pre-costs of quality detection because the buyer is able to shop around and find the best quality goods through inspection. For products with search characteristics, quality must be evident upon inspection. Experience characteristics have high pre-costs but low post-costs because crucial aspects of the product's quality are impossible to verify except through use of the product, meaning that information about quality is obtained by the buyer as a by-product of use after the purchase. This information can be used by the buyer to inform future purchases. Credence characteristics have both high pre-costs and high post-costs. This is because the buyer has to rely on third party judgments or on the seller's credentials in order to judge the quality of supply. Credence characteristics are such that the

[2] Phillip Nelson, "Advertising as Information," (1974) 82 *Journal of Political Economy* 729.

buyer may never be certain of the product's quality, even with the benefit of observations after purchase.

10. Many goods cannot easily be classified according to one of these three sets of characteristics as they will often display more than one set of characteristics. However, prescription drugs are typically classified as experience goods since buyers can only ascertain their quality after they have taken them and the outcome has been observed. Consumers are likely to gain more information through personal trial of products that treat symptoms that commonly occur in acute illness or to relieve chronic disorders. Empirical evidence suggests that much DTCA falls into this category.[3] Where repeat purchases of drugs are significant, this may create self-enforcing truth-telling incentives in the market. Other pharmaceuticals may have credence characteristics, where it will be extremely difficult for any individual to know whether changes in his or her condition for better or worse over time can be attributed to pharmaceuticals that have been prescribed or to any of the host of other situational factors. Obviously, self-enforcing incentives against false or misleading advertising are strongest in the case of search goods, where advertising claims can be verified before purchase, less strong in the case of experience goods, except where repeat

[3] See for example K. Blankenhorn, N. Duckwitz, and M. Sherr, "Power to the People: Reaching the 'Smart Market' of Empowered Consumers (IMS Health, online at www.imshealth.com/vgn/images/portal/cit_759/2012212572PowertoPeople.pdf). See also Barbara Mintzes, *Direct-to-Consumer Advertising of Prescription Drugs in Canada* (Centre for Health Services and Policy Research, University of British Columbia, 2006) at 26; Martin Roth, "Patterns in Direct-to-Consumer Prescription Drug Print Advertising and Their Public Policy Implications", (1996) 15 Journal of Public Policy and Marketing 63.

purchases are an important element of demand for a product, and least effective in the case of credence goods.

11. Some economic theories of advertising, particularly in the case of experience goods, view advertising as a signal of quality. Because expenditures on advertising are a sunk cost which cannot be recouped in the event of general consumer dissatisfaction with a product, heavy investments in advertising and brand name capital may be interpreted by consumers as signaling confidence by the advertiser as to the quality of its product.[4] Because market forces are unlikely to be fully effective in self-regulating false or misleading advertising claims in the case of experience and credence goods, most industrialized countries have extensive consumer protection laws that impose civil and criminal sanctions on false, misleading, and deceptive advertising, and in some cases (as I explore further below) impose affirmative duties of disclosure on advertisers.

III. THE ARGUMENTS FOR AND AGAINST DTCA

12. Given the caveats on my expertise noted above, I note that experts for the Attorney-General of Canada, principally Professors Steven Morgan, Joel Lexchin and Gurprit Kindra, in the current proceedings on the effects of DTCA, refer to evidence that is said to support the following claims: (a) DTCA may increase the number of patient visits to physicians; (b) may increase the total volume of prescriptions written; (c) may increase the market share for advertised drugs; (d)

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[4] See *e.g.* Benjamin Klein and Keith Leffler, "The Role of Market Forces in Assuring Contractual Performance," (1981) 98 *Journal of Political Economy* 615.

may lead to higher prescription drug prices; (e) may increase total prescription drug expenditures; and (f) may increase expenditures on other health care services such as diagnostic testing. Professors Morgan and Kindra also point out (a) that various studies find that a significant proportion of DTC advertisements contain medical or factual inaccuracies, or give greater prominence to the advantages of an advertised pharmaceutical relative to its risks and costs, including alternative treatment options involving either other prescription drugs with equal or greater efficacy and perhaps lower cost, or non-pharmaceutical treatment protocols such as changes in diet and exercise regimens that may be a more appropriate response to medical conditions of concern to patients; (b) that some patient surveys reveal significant consumer dissatisfaction with the quality of information contained in DTCA and that some physician surveys report that patient exposure to DTCA puts undue pressure on physicians to depart from treatment practices that in their professional judgment are optimal for patients' conditions; and (c) that pharmaceuticals that are subject to large expenditures on DTCA often cost substantially more (in large part because they are under patent) than established drugs that are either off-patent or have been replicated by generics of equivalent medical efficacy, and that neither doctors nor patients have effective economic incentives to prescribe the most cost-effective drugs, given that in a high percentage of cases costs are externalized to either public or private drug plans.

13. Professor Morgan concedes in his affidavit that few of the empirical studies undertaken to date of these effects of DTCA are methodologically rigorous, in that confident cause and effect relationships can be drawn. Moreover, I note that there are empirical studies by respected experts that identify various positive effects, or at least potential effects, of DTCA, including: (a) that DTCA is consistent with empowering consumers or patients to take a more proactive role in their medical treatment, which is a normative value that has been stressed is reflected in courts in developing and expanding the doctrine of informed consent and by an enhanced focus on patent-centred health in much contemporary thinking on health care policy; (b) that DTCA may alert consumers, at an early stage, to potential health symptoms and untreated problems and encourage them to seek early consultations with their doctors, enhancing the possibility of earlier and more effective intervention; (c) that DTCA has at least the potential for improving the prescribing practices of doctors, where these reflect outdated prescription practices. Hence, some patient surveys find that a significant percentage of consumers welcome exposure to DTCA and some physician surveys find that a significant percentage of physicians welcome patient exposure to DTCA as encouraging more active engagement by patients in their own medical care. [5] Expert evidence submitted by the applicant in these proceedings amplifies a number of these benefits of DTCA.

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[5] See, *e.g.*, studies reviewed by Martin Roth, "Patterns in Direct-to-Consumer Print Advertising and Their Public Policy Implications," (1996) 15 *Journal of Public Policy and Marketing* 63 and Ernst Berndt, "To Inform or Persuade? Direct-to-Consumer Advertising of Prescription Drugs," (2005) 35 *New England Journal of Medicine* 325; both attached as Appendices to Professor Kindra's expert opinion in these proceedings.

14. Professor Julie Donahue, of the Department of Health Policy and Management in the Graduate School of Public Health at the University of Pittsburgh, in a careful review of existing empirical research on DTCA (including her own) finds that despite the dramatic increase in spending on DTCA in the U.S. it still makes up a small portion of total pharmaceutical promotional spending. Data suggest that DTCA is concentrated on a small subset of prescription drugs that are newer, of high quality, with few therapeutic substitutes, that are used to treat under-treated conditions. She finds that under-treatment is a much more serious problem than over-treatment for many medical conditions. Several studies have demonstrated that DTCA increases pharmaceutical sales, primarily by expanding the number of people receiving drug treatment (what she calls class effects, rather than market-share effects). In some cases, evidence suggests this expanded use is appropriate and in other cases its appropriateness may be open to question. The ratio of benefit to cost resulting from DTCA is unknown and likely varies across drugs, depending on the safety of the drug and the severity of the treated condition. The goal of a regulatory regime overseeing DTCA of prescription drugs should be to maximize the potential benefits of DTCA while reducing the potential harm.

15. Professor Richard Frank of the Harvard University Medical School emphasizes that the modern view of clinical care has the patient as an active participant in a variety of health care decisions and that information is central to patient decision-making. Merely establishing that DTCA is associated with

increased demand tells us little on its own. For example, if the evidence suggests that the increased demand is appropriate then that would tend to suggest improved welfare; if it is not then that would imply a tendency to overuse. Professor Frank, in reviewing the empirical evidence, concludes that the net effects of DTCA on social welfare are highly uncertain and they likely vary considerably according to clinical and social contexts. He also notes that many studies critical of DTCA emphasize the potential for stimulating over-use of pharmaceuticals without paying similar attention to the potential for counteracting under-use. He is also critical of estimates of potential increases in demand for pharmaceuticals in Canada that would be induced by more permissive regulatory policies, given the already substantial exposure of Canadian consumers to DTCA from U.S. television programming, imported magazines, and the Internet. However, he notes reasons for concern about how DTCA is regulated in the U.S. and that a recent review by the U.S. General Accountability Office (GAO)[6] suggests that not enough scrutiny has been devoted to the content of DTCA promotions to ensure more evenhanded information on the benefits and risks of specific drugs.

16. Dr. Don Fulgosi, a practicing psychiatrist for 35 years in Toronto specializing in psychopharmacology, also emphasizes the extensive exposure that Canadian consumers already have to DTCA on U.S. television channels, U.S. magazines sold in Canada, and the Internet. He notes that so-called "me

[6] U.S. Government Accountability Office, "Prescription Drugs: Improvements Needed in FDA Oversight of Direct-to-Consumer Advertising," November 2006.

too" drugs often offer significant benefits to patients, given subtle but significant differences in the way patients react to similar drugs. He also emphasizes that the problem of under-treatment of serious psychiatric disorders is much more serious than the problem of over-treatment. With respect to concerns that public funds should not be allocated towards treatment of conditions that should not be a social priority, then there is no reason why these drugs need to be listed in government formularies or that their costs need to be fully reimbursed. The question of who pays for the drugs is a separate question from whether advertising of drugs should be permitted.

17. Dr. Richard Dolinar, an endocrinologist who has practiced in Arizona for 35 years, reviews the evolution of the U.S. regulatory regime for DTCA, and states his opinion that it provides a workable model. U.S. DTCA, which has undergone extensive review in recent years in public hearings before the FDA and elsewhere, is required to be truthful and to present a "fair balance" between benefits and risks. Despite the extensive review of DTCA by the FDA and others in the U.S. in recent years there is little disposition to reimpose a prohibition. He states that in his experience, DTCA has educational value, and assists in bringing patients into doctors' offices for treatment – particularly for hard-to-reach populations. Recent survey evidence reports that it is popular with patients, and increasingly accepted by doctors. He notes his own experience of DTCA leading to interactions and diagnoses for individual patients that might not otherwise have occurred. He notes that increasingly, patients combine information from

DTCA with other sources such as the Internet so they can come to doctors' offices equipped to discuss pros and cons of available therapies. Criticisms of particular examples of DTCA are better met, in his view, by the regulator applying the "fair balance" requirement in whatever manner is deemed appropriate rather than by an outright prohibition.

18. By way of summary of the state of the empirical literature, Professor Meredith Rosenthal, of the Harvard School of Public Health, points out in a recent comment on the welfare effects of DTCA,[7]

> Thus far the debate has been supported primarily by indirect evidence – that is, evidence not of the positive or negative effects of DTCA on public health or welfare, but of its effects on consumer awareness, attitudes, perceptions, and self-reported behaviour, and physician attitudes and self-reported behaviour. To date, no published analysis has established whether DTCA stimulates new utilization that is primarily appropriate or cost-effective or the opposite. Obviously it is not the case that the health services research community has missed the point, but that the methodological challenges of conducting such a study are substantial."

In a similar vein, Frank Auton, in a recent survey of the empirical literature, concludes:[8]

> Despite the weight of argument presented, there is still insufficient definitive, independent and objective evidence to allow a final decision to be made on this issue. At best, the evidence to date of value or harm should still be regarded as inconclusive.

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[7] Meredith Rosenthal, Comment: "The economics of direct-to-consumer advertising of prescription-only drugs: prescribed to improve consumer welfare?" (2004) 9 *Journal of Health Services Research and Policy* 39 – 41.

[8] Frank Auton, "Direct-to-Consumer Advertising (DTCA) of Pharmaceuticals: An Updated Review of the Literature and Debate Since 2003," *Economic Affairs* 2006.

IV. THE CHOICE OF REGULATORY INSTRUMENT

19. With this brief review of the arguments and evidence for and against DTCA as backdrop, I now turn my attention to the question which is largely ignored by Professors Morgan and Kindra in their expert opinions in the current proceedings - that is, whether there are regulatory and related options open to governments that are likely to maximize the social benefits of DTCA, while minimizing its potential adverse effects. In other words, is an across-the-board ban proportionate to what we currently know about the balance of social benefits and costs associated with DTCA, or is some other mix of policy interventions feasible that is likely to generate a net improvement in social welfare?

20. In my comments I attempt to separate two dimensions of pharmaceuticals that have attracted concern from opponents of DTCA: (a) issues relating to quality and (b) issues relating to cost. With respect to quality issues, the criticism is often made in debates over DTCA, including criticism advanced by Professors Morgan and Kindra in their expert opinions in these proceedings, that DTCA often offers incomplete information about pharmaceuticals being advertised, emphasizing their benefits and underemphasizing their risks or limitations, and failing to address alternative pharmaceutical and non-pharmaceutical treatment options. However, the argument that DTCA is one-sided in extolling the virtues of the products being advertised, while under-emphasizing their risks or limitations and the benefits of alternative products and procedures, is a charge that can equally be directed at much or most of modern consumer advertising

(leaving aside false and misleading advertising which is already subject to criminal and civil sanctions). Consumer-directed advertising, whether it relates to automobiles, vacations, fashion clothing, consumer electronics, etc., by its nature tends to emphasize the advantages or service of the product being advertised. It would be naïve to expect advertisers to attach similar prominence to the limitations of a product, let alone the virtues of competitors' products or services. Most consumers understand this, discount the value of advertising accordingly, and supplement it with other sources of information, including their own experience or the experience of friends and family members, with the advertised product or alternatives to it.[9] Thus, the claim of bias in DTCA, standing alone, hardly warrants a ban on all forms of DTCA, any more than it would warrant a ban on all other forms of consumer advertising where it would be equally plausible to claim that the advertising is one-sided or incomplete in the information conveyed relative to the information consumers require to make fully informed choices over all their alternatives. At most, such a claim would warrant a more vigorous application of a "fair balance" requirement.

21. Moreover, the logic of the critics' position would seem to warrant a ban on drug advertising directed to physicians (apparently about 65% of all pharmaceutical promotional expenditures in the U.S.), where it is equally claimed, including by Professor Morgan in a recent paper with Barbara Mintzes

[9] See John Calfee, "Public Policy Issues in Direct-to-Consumer Advertising of Prescription Drugs", (2002) 21 Journal of Public Policy and Marketing 174.

and Morris Barer,[10] that much commercial advertising directed to physicians is inaccurate, incomplete, or biased and that empirical evidence suggests that this significantly and detrimentally influences physicians' prescription practices. Indeed, Dr. John Abrahamson, in an affidavit submitted on behalf of the intervenors in these proceedings, goes much further in cataloguing a whole range of activities relating to the production of medical research and information where he claims that commercial pharmaceutical interests exercise undue influence and bias research and informational outputs, e.g., sponsorship of clinical trials; research based on such trials published in medical journals; clinical practice guidelines; continuing medical education; public relations campaigns by community or non-profit organizations sponsored by the pharmaceutical industry; as well as marketing efforts directed to physicians. If all apprehension of commercial influence or bias were to be removed from all these avenues of medical research and information and communication, a ban on DTCA would be but a small element in a much grander strategy for the complete restructuring of the medical research industry. However, bans, because of their crude prophylactic character in all these contexts, are much more likely to engage the law of unintended consequences than more finely targeted or tuned regulatory intervention.

22. This point is illustrated by the claim made by Professor Morgan and other opponents of DTCA that most DTCA relates to so-called "me-too" drugs, not

[10] Steven Morgan, Barbara Mintzes and Morris Barer, "The economics of direct-to-consumer advertising of prescription only drugs: Prescribed to improve consumer welfare?" (2003) 8 *Journal of Health Services Research and Policy* 237 – 244.

breakthrough drugs, with limited or no incremental therapeutic value relative to existing or established drugs, including generics (a claim sharply disputed by Professor Julie Donohue and Doctors Fulgosi and Dolinar in their affidavits in these proceedings). If this is the case, why not simply ban the sale of such drugs altogether and not merely their advertising either to physicians alone or to physicians and prospective patients? These extreme measures would, of course, ignore the fact that, for example, low priced generics only exist because of investments in R & D that the patent system encourages, so that relying on the availability of low-cost generic alternatives to valuable pharmaceuticals in the presence of severe legal constraints on the ability either to sell or market such pharmaceuticals is almost certainly unrealistic.

23. Having noted the inherent bias of much, and perhaps most, consumer advertising of an infinite variety of products and services, let me acknowledge that in a variety of contexts, in the interests of truth in advertising, we have gone beyond attaching criminal and civil sanctions to false, misleading and deceptive advertising, and have imposed on suppliers of goods or services an affirmative duty of disclosure. For example, the federal *Consumer Packaging and Labeling Act* and regulations under the *Food and Drugs Act* require that various prepackaged foodstuffs contain information on labels or packages pertaining to ingredients, nutritional characteristics, etc. Under the federal *Hazardous Products Act*, where products may present hazards as well as benefits to consumers, but are not so hazardous or generally risky as to warrant a product

ban altogether, the *Act* provides for conditions under which such products can be marketed, including appropriate hazard warnings. Under provincial consumer credit legislation dating back to the 1970s, advertisements of the availability of consumer credit to consumers must include the effective annual interest rate, so that consumers are assisted in understanding the true cost of credit and in comparing the true cost of credit from one source with terms on offer from competing suppliers. Again, securities laws in most jurisdictions require various forms of affirmative disclosure of material information bearing on the valuation of securities in publicly traded companies.

24. Similarly, the *Food and Drugs Act* and regulations thereunder require that commercial advertisements of prescription drugs directed to physicians must be vetted by a committee of stakeholders to ensure that they provide a balanced set of information on the product being advertised. To the extent that experience in the past in the U.S. and New Zealand, where DTCA is permitted, suggests that DTCA may involve biases in the information conveyed,[11] again there is ample regulatory latitude for regulating the content and format of such advertisements, perhaps requiring prior approval of all advertisements, more effective post-approval monitoring of advertisements to ensure compliance, and more effective sanctions for non-compliance (see GAO Report, November 2006). Finally,

[11] According to Hoek, Gendall and Calfee, "Direct-to-consumer advertising of prescription medicines in the United States and New Zealand: An analysis of regulatory approaches and consumer responses" (2004) *Int. J. Advertising* 23: 197-227, there are differences in the U.S. and New Zealand regulatory regimes which affect the nature of advertising in these countries. New Zealand, which reportedly has no "fair balance" requirement, is said to have more emotional advertising with significantly less disclosure of risks. On the other hand, New Zealand fares better with speed of regulatory response.

Canadian courts under products liability law have imposed extremely demanding duties on product manufacturers to warn consumers of unusual hazards that may be associated with use of their products (see e.g. *Lambert v Lastoplex Chemicals Company Ltd.* [1972] S.C.R. 569, *Buchan v Ortho Pharmaceuticals Canada Ltd.* (1986) 25 D.L.R. (4th) 658 (Ont. CA); *Hollis v Dow Corning* [1995] 4 S.C.R. 634. Relatively liberal class action procedures in several provinces increase the prospect of massive civil liability for inadequate warnings of potential adverse effects from mass-promoted drugs.

25. As to quality and safety concerns more generally with pharmaceuticals that might be the subject of DTCA, it bears emphasizing - even if this is to state the obvious - that consumers of prescription drugs enjoy the protection of a number of legal regimes that often are not present in the case of other heavily advertised consumer products. First, as Professor Morgan notes, all drugs that have been the subject of extensive DTCA in the U.S. are patented. While he is sceptical of the incremental therapeutic value of many of these drugs, the fact remains that under the *Canadian Patent Act*, as with patent laws in most other countries, a drug cannot be patented unless the Canadian Patent Office is satisfied that meets the base-line standard of being "new, useful, and non-obvious." Second, even after a pharmaceutical or the innovation embodied in it is patented, it cannot be marketed until it satisfies an elaborate set of pre-clinical and clinical tests and trials relating to its safety, efficacy and quality and is approved for sale by Health Canada, including, in many cases, the mandatory

inclusion of warnings to physicians and patients as to potentially adverse side-effects (described by Ann Sztuke-Fournier of Health Canada in her affidavit in these proceedings). Third, no prescription drug can be obtained or used by a consumer unless a licensed physician has issued a prescription for it, thus requiring consumers to access the drugs through an expert agent or "learned intermediary". Fourth, a prescription can only be filled by a licensed pharmacist, who again brings specialized expertise to bear in advising consumers of possible side-effects or negative interactions with other medications that he or she is presently using. There are very few other consumer products that are subject to such an elaborate set of quality-oriented checks and balances.

26. With respect to price and/or cost concerns, opponents of DTCA argue that pharmaceuticals that are likely to be the subject of the heaviest DTCA are patented me-too drugs with very little or no incremental therapeutic value over established drugs that are unpatented, or off-patent, or have been the subject of replication by generics (a claim that is contentious) but that neither physicians nor patients have any financial incentives to minimize pharmaceutical expenditures because, in relation to prescription drugs, these are typically covered either by government drug plans or employer-based extended health care plans. According to Professor Morgan in his expert opinion filed in these proceedings, provincial drug plans in Canada finance approximately 40% of national prescription drug expenditures, federal drug plans and social insurance plans such as Workers Compensation each fund 3% of national expenditures,

private insurance plans, which are predominantly employment-based, finance 34% of national expenditures on prescription drugs, while the remaining 20% of expenditures are financed by payment out-of-pocket by patients. By way of contrast, apparently only about 21% of prescription drug costs in the U.S. are funded by government.

27. However, Professor Morgan neglects to point out that provincial drug plans in Canada have developed elaborate policies to ensure that only cost-effective pharmaceuticals are covered, including mandatory substitution policies that require pharmacists to substitute lower cost medically-equivalent drugs on a plan's formulary and reference pricing policies that only provide coverage for the least-cost, medically-equivalent drug, leaving patients to bear the cost of more expensive drugs. These mechanisms are reviewed in detail in a recent paper by Natalie de Paulsen, Lisa Minuk and Colleen Flood, "Criteria for Listing on Provincial Drug Formularies" (see Exhibit "C"). Many employer-based extended health care plans also contain constraints on what pharmaceutical expenditures are covered by such plans, and parallel in many respects the constraints observed under government drug plans. Indeed, given that excessive or wasteful expenditure on pharmaceuticals, particularly when equally efficacious but lower cost pharmaceuticals are available, entail costs both for employers and the general body of employees, in terms of foregone wages or other benefits, there are strong collective incentives for parties to these private plans to minimize inappropriate pharmaceutical expenditures.

28. While it may be the case, as Jean Belleville (an actuarial consultant) points out in an affidavit submitted on behalf of the intervenors in these proceedings, that rising private health care costs, and in particular the rising cost of prescription drugs, raise challenges and potential conflicts for employers and employees in collective bargaining contexts, both sides face rational incentives to minimize those costs, reflecting appropriate trade-offs of costs and benefits. There is no reason in principle why parties should not be able to bargain collectively for the most effective and efficient drug coverage and drug cost reimbursement mechanisms for employees. The fact that this is done collectively hardly puts them at a disadvantage compared to individual patients. For the remaining 20% of expenditures that are financed from out-of-pocket payments by patients, clearly patients do face direct financial incentives to minimize wasteful or excessive pharmaceutical expenditures. Thus, the argument that both physicians and patients face non-standard economic incentives to externalize excessive pharmaceutical expenditures onto third parties is not compelling when one examines the incentives of these third parties and accounts for the residual expenditures on prescription drugs made through out-of-pocket payments by patients themselves.

29. In addition, while Professor Morgan notes that the federal Patent Medicine Prices Review Board (PMPRB) in Canada categorizes new prescription drugs into various classifications of therapeutic novelty and distinguishes breakthrough drugs from so-called me-too drugs, he importantly fails to note that the PMPRB

also regulates the prices at which all patented drugs may be sold for in Canada, and most importantly more tightly constrains these prices in the case of non-breakthrough patented drugs (the very rationale for the PMPRB's classification system). This is a major policy difference from the U.S. where no such pricing regulation of patented drugs exists (and explains much of the cross-border trade in pharmaceuticals).

30. I acknowledge that each of these systems or mechanisms may be susceptible of improvement: for example, perhaps patents are too freely granted for pharmaceuticals that offer modest or negligible therapeutic advantages over existing drugs, but if this is so this calls for reform to the patent system. Perhaps Health Canada is insufficiently stringent in the approval conditions it applies to new prescription drugs and is insufficiently vigilant in post-market monitoring, but if this is so then this calls for reforms to Health Canada's vetting, approval and post-market monitoring regime (although I note here obvious trade-offs entailed in more protracted pre-market approval processes between reducing risks of adverse medical effects and denying consumers with serious and untreated health conditions more timely access to many generally beneficial drugs). Perhaps the PMPRB is insufficiently stringent in the price caps it imposes on new patented drugs, especially non-breakthrough or so-called me-too drugs, but if this is so this calls for reform of the PMPRB's regulatory regime. Perhaps provincial and federal drug plans have not been aggressive enough in constraining what pharmaceutical expenditures will be covered by these plans, but if this is so this

calls for reform to these plans. Similarly, if employer-based drug plans have been insufficiently aggressive in constraining wasteful or excessive pharmaceutical expenditures, then parties to these plans face strong economic incentives to reform these plans, in part in the light of the experience under government drug plans. Perhaps Health Canada and the committee that operates under its aegis have been insufficiently vigilant in vetting promotional advertising of pharmaceuticals to physicians, but if this is so this calls for reforms to this mechanism. Where DTCA has been permitted (i.e., the U.S. and New Zealand), perhaps the regulatory authorities have been too permissive in regulating the content of such advertisements, in monitoring for compliance, and in imposing effective sanctions for noncompliance, but if so this calls for reforms to these mechanisms (see GAO Report, 2006). Finally, general false and misleading advertising laws might be more vigorously enforced against false claims in such advertisements if this is the nub of concerns with DTCA.

31. Professor Lexchin's review of alternatives to complete prohibition (at paras. 100 to 116 of his affidavit) does not provide convincing reasons to reject a model of regulated advertising. While policy-makers might well feel that industry self-regulation does not ensure adequate protection of patients, his main criticism of government regulation and oversight (whether directly or by an independent agency) appears to be that authorities have not been given adequate resources in jurisdictions where DTCA is permitted. That may or may not be true – the GAO Report, 2006 attributes a large part of the delay in the FDA sending out

warning letters to lengthy waits for them to be reviewed by internal lawyers – but surely if it is true, this is an issue for the government to address by devoting whatever resources appear to be required. There is nothing inherent in DTCA that makes it more difficult than other advertising to police – indeed, it is very visible, and likely much easier to police than detailing. If delay in resolving complaints is an issue, the appropriate combination of resources and agency powers (such as the ability to enjoin advertising that contravenes the law) can address it.

32. In short, none of these concerns relating to DTCA lead quickly, naturally, or convincingly to the conclusion that an across-the-board ban on all DTCA is justified as the most proportionate response to whatever problems have been demonstrated to date with DTCA, but rather much more targeted or surgical interventions that deal with the specific source of the problem. Indeed, the current response seems quite exceptional. The only recent case that I can recall where such an advertising ban has been imposed in the case of products otherwise permitted to be sold is the case of cigarette advertising, where scientific evidence overwhelmingly points to the negative health and addictive effects of persistent smoking. Even in this case only a partial ban on cigarette advertising has been sustainable to date: see *RJR. Macdonald v. Canada* [1995] 3 S.C.R. 199 and *Canada v. JTI-Macdonald* 2007 SCC 30. Surely, no one can responsibly argue that prescription drugs across the board present health and

addiction hazards of the kind associated with cigarettes so as to warrant a similar ban on advertising.

33. In addition, an explanation is required as to why that case is overwhelmingly stronger than for the infirmities or limitations exhibited in consumer advertising at large of products that may present both benefits and hazards to users, e.g., power tools, household or garden chemicals, fast or fatty foods, alcohol, snowmobiles, motorcycles, off-road vehicles, automobiles, sky diving, skiing, wilderness treks, etc., where we assume that not only on efficiency grounds but on grounds of individual liberty and autonomy, we should accord broad scope for individual choice even though we may not always agree with, endorse, or choose to follow choices that our fellow citizens may often make. The contrary view entails an especially strong form of paternalism that bears a special burden of justification (as I discuss in the chapter on Paternalism in my book, *The Limits of Freedom of Contract* (Harvard University Press, 1993)).

34. I note, in this respect, that in recent proposed amendments to regulations governing labeling and advertising of over-the-counter (OTC) drugs Health Canada identified the following benefits with policies promoting accurate labeling and advertising:[12]

- Claims associated with products for which manufacturers have been granted market authorization by Health Canada would be shared with the Canadian public through advertising and labeling. Therefore, consumers would have increased access to science-based information through advertising and labeling regarding the

[12] *Canada Gazette, Part I*, November 2005, p. 3832.

self-care products they use. This would provide consumers with an increased ability to make informed choices about their health.

- This proposed amendment is in keeping with the following guiding principles outlined in the External Working Group's Majority Report on Schedule A and section 3, as posted on the Health Canada Web site: optimize health outcomes, improve access to validated health information, and facilitate responsible self-care.
- This amendment reflects the Canadian public's desire to participate in and make informed decisions about their health care. It permits consumers to have greater awareness of potentially beneficial health products.
- A Canadian public better informed about self-care products may have less need to use the health care system.

35. Health Canada has now released *Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)*, including specific guidance on how to disclose risk information, and these may provide a useful model for how Health Canada might choose to regulate DTCA of prescription drugs. The *Consumer Advertising Guidelines* dated October, 2006, and a Health Canada Notice regarding risk information dated March 30, 2007, are attached as Exhibits "D" and "E" respectively.

36. Finally, there are concerns about the realism of a continuing ban on DTCA in Canada. As Kathy Gardner, Senior Vice-President, Integrated Media Research and Corporate Promotions, Canwest, points out in an affidavit on behalf of the applicant in these proceedings, the number of adult Canadians who are exposed to DTCA on U.S. TV stations, likely approaches or even exceeds 90%. In addition, Canadians are regularly exposed to DTCA in the approximately 600 U.S. published magazines available for sale in Canada. As well, many consumers are exposed to DTCA through largely unregulated Internet

advertising. It should also be noted that regulations under the Canadian Food and Drugs Act are interpreted by Health Canada as already permitting some forms of DTCA: specifically a) "condition" or "help seeking" advertisements that invite consumers to ask their physicians about new, unidentified drug treatments for identified symptoms or disease conditions; and b) "reminder" advertisements which refer to the name of the drug without referring to the intended use. The latter, particularly, are subject to criticism as being much less helpful and informative than an advertisement allowing the manufacturer to present information about the benefits of the drug and its intended use, subject to being required to disclose material risks. "Reminder" ads are only really effective for products with high brand-name recognition, and have been criticized in the U.S. as circumventing disclosure requirements. Attached as Exhibit "F" is a copy of an article from the *New York Times* dated April 30, 2007, commenting upon a recent "reminder" advertising campaign run in Toronto for Viagra. For contrast, I attach as Exhibit "G" a copy of Viagra's "product claim" ad as reflected on its U.S. website (Viagra.com) accessed July 23, 2007. Looking at the description of the Canadian "reminder" ad and the U.S. internet ad, I am at a loss to understand the public policy rationale behind the respondent's decision to allow the former but prohibit the latter.

37. In conclusion, let me emphasize that my views on the appropriate regulatory strategy towards DTCA are not premised on the assumption that it is always and in every case a benefit to consumers, or that consumer welfare

would be unambiguously enhanced by a completely unregulated environment for DTCA. Rather, my views are based on the premise that the opposite assumptions are simply not borne out by the evidence and cannot be justified, i.e., that DTCA is in all or most cases detrimental to consumer welfare and therefore justifies the exceptional regulatory response that all direct-to-consumer prescription drug advertising should be banned, in effect disempowering consumers from a more active role in their own medical treatment and constraining significantly their individual autonomy. The limiting version of the argument made by opponents of DTCA would have a group of bureaucrats decide what information consumers should be permitted to have access to about prescription pharmaceuticals that might potentially address their medical concerns, or even perhaps decide which drugs should be available to them on any basis. This form of prohibitory approach to regulation may in exceptional cases be warranted, but the opponents of DTCA bear a heavy burden of justification in demonstrating that prescription drugs fall within such an exceptional category. I would finally add that the prospect of relaxation of similar prohibitions on professional advertising (e.g., lawyers, dentists, etc.), in large part as a result of court rulings (see especially *Rocket v. Royal College of Dental Surgeons of Ontario*, [1990] 2 S.C.R. 232, a case in which I was an expert witness), also attracted similar portents of doom,[13] but almost none of the feared negative effects have materialized. These prohibitions have now been largely

[13] See Albert Hudec and Michael Trebilcock, (1982) "Lawyers Advertising and the Supply of Information in the Market for Legal Services," 20 *University of Western Ontario L.R.*, 53, 1982.

replaced with more nuanced codes allowing for effective and informative advertising of professional services.

SWORN before me at the City of Toronto, in the Province of Ontario this 24th day of July, 2007.

A Commissioner, etc.
BRYDIE BETHELL

Michael John Trebilcock

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