

05-CV-303001PD2

**ONTARIO
SUPERIOR COURT OF JUSTICE**

BETWEEN :

CANWEST MEDIAWORKS INC.

Applicant

and

THE ATTORNEY GENERAL OF CANADA

Respondent

AFFIDAVIT OF GURPRIT KINDRA

I, **GURPRIT KINDRA**, of the City of Ottawa, in the Province of Ontario, **AFFIRM THAT:**

1. I have been a professor in the School of Management at the University of Ottawa for 26 years. I teach Strategic Marketing at the MBA level on an ongoing basis. In the past, I have taught Consumer Behaviour and Promotional Management. As a visiting professor, I also teach e-Marketing at Sciences Po in Paris and Strategic Marketing at the Bucharest Academy of Economic Studies.

2. I received my Ph.D. from the University of Iowa in 1981 and my M.A. from the same university in 1982. I also hold an M.B.A. from Northwest Missouri State University (1977) and a B.Sc. from Dalhousie University (1976).

3. I have expertise in the subject of marketing, with a particular focus on consumer behaviour. Through research, teaching, and consulting work I have also gained expert knowledge of the organization of corporate entities. I have conducted my own research in this field and have published approximately 16

papers in refereed journals and 21 papers in scholarly conference proceedings; I have also prepared 21 invited presentations and technical reports as well as various working papers.

4. I am the co-author of *Consumer Behaviour: the Canadian Perspective*; this was the one of the earliest Canadian texts on the subject and was a standard textbook used in many Canadian universities from 1990 until about 1996. I was also the contributing editor of *Marketing in Developing Countries* (1984) and of *Marketing Strategies for the Health Care Sector* (1990). I am the author of an award-winning article entitled "Demarketing Inappropriate Health care Consumption in Canada."

5. Throughout my career, and particularly in the last 15 years, I have been consulted by various organizations, primarily in Canada, on issues like the use of fear in advertising and the demarketing of tobacco products. I have gained my experience in marketing as it relates to the field of health policy through my participation in research and in consulting for many organizations such as Health Canada, Industry Canada, and the World Bank.

6. In this affidavit, drawing upon my teaching experience, I have provided information and opinion on the "educational" value of advertising, as this concept is part of the standard curriculum on advertising in business schools, including the courses I have taught over many years as a professor of marketing. I have also explored the "educational" dimension of marketing and advertising through my consulting and research work.

7. In 1992, I appeared before the Parliamentary Sub-Committee on Health to discuss the labelling of beer and other alcoholic beverage containers in relation to the prevalence of fetal alcohol syndrome in Canada. In 1995, I was a co-author of an Expert Panel report to Health Canada on *Possible Effects of Plain and Generic Packaging of Tobacco Products*.

8. **Attached to my affidavit as “Exhibit 1” is a copy of my curriculum vitae.**

9. I was asked by counsel for the Attorney General of Canada to provide a detailed explanation and opinion of current concepts and practices of advertising, as a medium of marketing, by corporations that operate on a for-profit basis.

10. In Part 1 of this affidavit, I address the goals and purposes of marketing as they are currently taught and considered in Canada and other free-market economies. I also provide an opinion on why for-profit corporations engage in advertising. Further, I discuss how marketing strategies relate to consumers’ needs and wants. Finally, I consider how the role of education is viewed and employed in strategies for consumer advertising.

11. In Part 2 of this affidavit, I outline general techniques and strategies of product advertising as a marketing activity.

12. In Part 3 of this affidavit, I describe these advertising techniques and strategies as they are applied to the marketing of pharmaceuticals.

13. In Part 4 of this affidavit, I provide an opinion on the nature and techniques of advertising that have been used in a variety of advertisements to the public promoting pharmaceutical products. Counsel for the Attorney General has advised that the advertisements I have been given for comment and opinion were filed in the Court as part of the Application Record in the present case.

14. In Part 5 of this affidavit, I provide a brief description of the experience of DTCA in New Zealand and the United States and issues under consideration with regard to DTCA in the European Union.

15. Counsel for the Attorney General has advised me that this affidavit will be tendered as evidence in this proceeding, which is a challenge to the

limitation on direct-to-consumer-advertising (DTCA) of prescription drugs as contained in the *Food and Drugs Act and Regulations* in this application.

16. Where I provide a general account of the concepts and practices of marketing and advertising throughout the marketing industry in relation to a broad variety of consumer products, I have no reason to believe that these concepts and techniques differ in any way in their application to the marketing and advertising of pharmaceutical products in North America.

17. In providing this affidavit, I rely on my own knowledge and experience over the course of my career in respect of marketing, and advertising in particular. Where I draw upon information from outside my own knowledge and experience, I cite sources that are considered to be experts in the field of marketing and business, and other sources that are considered to be highly reliable, as well as authors who are widely acknowledged as authoritative. I adopt and agree with the opinions given by these sources.

EXECUTIVE SUMMARY

18. This affidavit describes general principles of marketing in the context of for-profit corporations and their application in the advertising of prescription drugs. It describes the rise of direct-to-consumer advertising, whereby prescription medications are marketed directly to the end user, the patient, rather than to the professional “gatekeepers” of prescription medications. Drawing upon a review of the recent literature and the author’s expertise as a professor and consultant in marketing, it outlines the goals, aims and intended effects of DTCA and the techniques it uses to achieve that effect.

19. The following is a summary of my affidavit:

- (a) It is widely accepted in our society that the primary responsibility of for-profit corporations is to maximize return on investment for shareholders. Drug manufacturers are for-profit corporations and hence share this primary objective.

- (b) The main goal of marketing efforts, including and especially advertising, by for-profit corporations is to maximize profits by increasing sales and/or market share. Pharmaceutical corporations are no exception: the primary motivation of DTCA, like that of all advertising, is to sell the product.
- (c) A primary mechanism of marketing, including advertising, is to create a “want” for the product on the part of the consumer that is strong enough to be felt as a “need”.
- (d) The two main strategies for advertising are “push” and “pull” techniques. “Push” strategies promote products through distribution channels to the end user. “Pull” strategies focus on the consumer by increasing desire for, and thus motivation to seek, the advertised product.
- (e) The use of DTCA has increased dramatically in recent years, and evidence is mounting that it is effective.
- (f) Advertising creates the impression of being “educational” by providing information to the consumer about a product and the need to obtain it.
- (g) However, the “education” provided by DTCA is one-sided and incomplete, despite the impression of scientific objectivity given by the medical “fine print” that accompanies these ads. The purpose of DTCA is to persuade patients of their need for a drug, circumventing the process whereby the physician initiates the prescription process.
- (h) Physicians report that patients request unnecessary drugs, or drugs that offer no benefit over their existing medications, because of the influence of DTCA. Research also shows that physicians are susceptible to these requests.
- (i) The advertisements that have been filed in the Application Record as Exhibit “A” to the Affidavit of Arturo Duran, sworn December 22, 2005 (the “Affidavit of Arturo Duran”), show the hallmarks of “classical conditioning” advertising techniques, in which desirable states are associated with the advertised product, evoking a felt need for the product regardless of an objective need.
- (j) Most of these advertisements present the reader with a daunting amount of product information, but this does not amount to genuine patient education about the nature of a condition, the full range of treatment options available, and the specific likelihood that the advertised product is appropriate in a particular patient’s case.

- (k) The experience of the two other Western countries that allow DTCA, New Zealand and the United States, confirms the limited utility of the “educational” component of DTCA and bears out concerns about the propensity of this form of advertising to create “wants” for pharmaceutical products that are not necessarily congruent with medical “need.”
- (l) DTCA is a highly effective marketing tool that supports the goals of advertisers. In my opinion, there is little evidence that DTCA is of equal benefit to the consumer.

PART I – THE GOALS AND PURPOSES OF MARKETING

A. THE PROFIT MOTIVE

20. Philip Kotler, often cited as the world’s leading expert on the subject, describes marketing as “the science and art of exploring, creating, and delivering value to satisfy the needs of a target market at a profit.”¹ He adds:

Marketing identifies unfulfilled needs and desires. It defines, measures, and quantifies the size of the identified market and its profit potential. It pinpoints the market segments that the corporation is capable of serving best, and it designs and promotes the appropriate products and services.²

21. The American Marketing Association, representing marketing professionals, states that “marketing is the process of planning and executing the conception, pricing, promotion, and distribution of ideas, goods and services to create exchanges that satisfy individual and organizational objectives.”³

22. Although such exchanges to satisfy individual and organizational objectives are in many ways beneficial to society, from the perspective of a for-profit corporation they are a means to the ultimate end of maximizing profits. Making a profit is widely accepted as the proper *raison d’être* of a corporation and its primary duty to shareholders. As Milton Friedman, the Nobel-winning

¹ Kotler, P. (2005). *According to Kotler: The world’s foremost authority on marketing answers your questions* Toronto: Amacom, p.1.

² *Ibid.*, p. 1.

economist, observed, “There is one and only one social responsibility of a business — to use its resources and engage in activities designed to increase its profits so long as it stays within the rules of the game, which is to say, engages in open and free competition without deception or fraud.”⁴

23. The profit imperative applies to pharmaceutical corporations no less than to other for-profit firms. Pharmaceutical corporations develop drugs that address the health needs and desires of consumers. Sales of those drugs must be sufficient to recoup the enormous capital investment and other operational expenses that drug development entails, while generating enough surplus revenue to create the requisite profit. Therefore, the marketing of health care products is not exempt from the profit motive. Although these products may have a higher value for health and well-being, “The commercial interest is clear. All advertising, by definition, aims at some effect on the consumer. Advertisers in any category hope to sell more of what they offer and healthcare advertisers are no different.”⁵

B. THE BASIS OF MARKETING DECISIONS

24. Whatever else a corporation does, it must generate enough profit to satisfy owners or shareholders to stay in business. Profit derives from income from sales, minus operating and other expenses. Obviously, the greater the sales revenue, the greater the potential profit. Therefore, corporations must seek to maintain or increase their revenue from sales. For a corporation to remain solvent, there must be sufficient demand for the products or services it sells. Marketing is the primary means by which corporations create that demand.

25. In order to maximize their profits in the short run or to maximize wealth for the share-holders in the long run, a corporation engages present and

³ Bennett, P. D. (1995). *Dictionary of Marketing Terms* (2nd ed.) Lincolnwood, IL: NTC Publishing Group, p. 166.

⁴ *Ibid.*, p. 106.

⁵ White, H. J., Draves, L. P., Soong, R., & Moore, C. (2004). 'Ask your doctor!' measuring the effect of direct-to-consumer communications in the world's largest healthcare market. *International Journal of Advertising*, 23(1), p. 53.

future customers in an ongoing relationship. Nurturing of this relationship is crucial for generating sales, profits, and market intelligence. Marketers engage in this form of relationship-building through the use of numerous tools such as segmentation, positioning and product differentiation, with the cooperation of other functional areas such as finance, accounting and production, and within the constraints of legal and cultural environments.

26. Typically, marketing plays a central role in the strategic planning and activities of corporations, requiring them to stay informed about consumers' perceptions of what constitutes an "ideal brand" in a given product category, as well as their perceptions of various brands in relation to the most "desired" features in a product category.

27. Typically, marketing involves the fine-tuning of various elements related to product, pricing, "place" (or distribution) and promotion to "satisfy" the wants and needs of customers in one or more segments of the product market.

C. THE CONCEPT OF CONSUMER NEED

28. Although the main goal of marketing is to bring about a mutually beneficial exchange between a seller who has a product available for purchase and a buyer who has a "need" for that product, the concept of "need" has a special meaning in marketing. Strictly speaking, a basic "need" might reflect a physiological necessity, such as food, clothing, or shelter. Corporations whose products satisfy those basic needs do employ marketing strategies. But "needs" for flavoured toothpaste, digital cameras, and ice cream are of a different order. They should more properly be termed "wants," but a "want," to a marketer, is a "felt need that is shaped by a person's knowledge, culture and personality."⁶

29. For example, if we are hungry, we are subject to a basic need to eat something. Now, what do we eat? A salad? Or cotton candy? Both will satisfy the hunger, and therefore the need. But marketing can shape wants so

that salad is chosen over cotton candy, or vice versa, fairly consistently. This raises the question of the capacity of marketing to influence consumers to make bad choices, and hence the issue of the need for consumer protection from the power of marketing.

30. Through marketing research, corporations attempt to understand their customers felt needs, whether those customers are professionals buying expensive automobiles, children buying toys, or corporations buying office telephone systems. Marketers must anticipate trends in the industry for which they are marketing, because those trends suggest potential consumer needs and, therefore, selling opportunities.

31. Philip Kotler emphasizes the centrality of the role of marketing in defining customer needs:

Manufacturing exists to support marketing. The corporation can always outsource its manufacturing. What makes a corporation is its marketing, offerings, and ideas. Manufacturing, purchasing, R & D, finance and the other corporation functions exist to help the corporation achieve its goals in the customer marketplace Marketing exists before there is a product. Marketing is the homework that the corporation does to figure out what people need and what the corporation should make.⁷

32. Successful corporations recognize that they must be highly sophisticated in their search for unmet consumer needs. As Kotler says:

To understand buyers, it is necessary for marketers to study the behavioral and organizational sciences. Marketing researchers must use their knowledge of demography, psychology, culture, and social influence to understand customer needs, perceptions, preferences, and behaviors, in order to develop more effective marketing strategies.⁸

⁶ Berkowitz, E. N., Crane, F. G., Kerin, R. A., Hartley, S. W., & Rudelius, W. (2003). *Marketing* (5th Canadian ed.). Toronto: McGraw-Hill Ryerson, p. 13.

⁷ Kotler, P. (2005). *According to Kotler: The world's foremost authority on marketing answers your questions*. Toronto: Amacom, p. 4-5.

⁸ *Ibid.*, p. 6.

D. THE “EDUCATION” OF CONSUMERS

33. People learn throughout their entire lives. Most human behaviour, including consumer behaviour, is learned. All learning involves behavioural change. To confirm that someone has learned something, all we can observe is that change in behaviour; learning cannot be observed directly. Learning might be described as “any change in an individual’s response or behavior resulting from practice, experience or mental association.”⁹

34. Learning can be selective and intentional — that is, the result of actively searching for information in a certain situation. It can also occur, without much conscious involvement, through exposure to various stimuli in our environment. Behavioural psychologists use the “classical conditioning” model to explain learning as a process by which a given stimulus is repeatedly paired with another stimulus that already elicits a known response.

35. In marketing, classical conditioning is used to associate a product with a desirable stimulus. The Marlboro cigarette advertisements, one of the most successful marketing campaigns in advertising history, are an excellent example. The Marlboro cowboy projects masculinity and security; thus the cigarette that he smokes acquired this positive association. Many beer advertisements use classical conditioning in a similar way by depicting young people having an apparently wonderful time in each other’s company. The advertisements emphasize youth, joy, friendship, and sexual attraction. The beer that the advertisement promotes acquires, through classical conditioning, some of the allure of the social situation the ad depicts. This type of learning is generally valued as “low-order” learning.

36. Some marketing theorists speak of a chain of four variables through which consumers learn from experience. Those variables are: drive, cue, response, and reinforcement. A drive is the need that prompts an individual to do

⁹ Adams, J. A. (1980). *Learning and memory, an introduction*. Homewood, IL: Dorsey Press, p. 6-7.

something; such as thirst. A cue is a stimulus the individual observes. The response is the action, prompted by the cue that satisfies the drive. The reinforcement is the reward. Thus, a hungry individual (drive), sees a McDonald's sign (cue), buys a hamburger there (response), and delights in his feeling of satiation (reward).¹⁰

37. Some consumer learning is more conscious or intentional in nature, occurring as consumers become acquainted with sources of information about products and services and providing evaluative criteria to use in assessing alternatives. Someone interested in buying a new automobile, for example, might look for reviews in magazines and newspapers about the performance of various automobiles. He or she might subscribe to a magazine that focuses on automobiles, or might look for online reviews or join a newsgroup that offers detailed information about automobiles. As the prospective car-buyer learns more, his or her criteria for choosing a car will become more detailed and more personal. He or she may, for example, have a sense of how much power the new car should have to best balance driving needs with a wish to drive an automobile with good fuel economy. This type of learning is frequently labelled as "higher-order" learning.

38. In my discussion of the specific applications of marketing principles in pharmaceutical advertising in Part 3, and in my analysis of current examples of DTCA in Part 4, I will attempt to show that the notion of "education" in DTCA of health products is to an important degree illusory, as the depth of the "education" provided is not a sufficient basis for well-informed decisions about the management of a medical condition.

¹⁰ Berkowitz, E. N., Crane, F. G., Kerin, R. A., Hartley, S. W., & Rudelius, W. (2003) *Marketing* (5th Canadian ed.) Toronto: McGraw-Hill Ryerson, p. 130.

PART II – MARKETING PRACTICES AND TECHNIQUES: GENERAL PRINCIPLES

A. ACHIEVING A WIDE REACH

39. Advertising is part of a “promotional mix” that includes public relations, publicity, sales promotion, and direct selling. Advertising is used to reach a large number of potential purchasers over a wide range of locations. Television advertising reaches large audiences: during 2004, Canadians watched about 23.2 hours of television each week.¹¹ The wide reach of mass advertising is key to its impact. Also, the scale of a large advertising campaign in itself makes a powerful statement about the advertiser. Through large, highly visible campaigns advertisers project a sophisticated and successful “personality” and thereby endow their products with an aura of legitimacy. This is enhanced by the artfulness and technical sophistication of contemporary advertising, particularly in visual media.

40. The major shortcoming of advertising is its high cost. Although the cost per consumer exposure may be low, the total cost of running a television advertising campaign or of placing large advertisements in mass-circulation newspapers and magazines is high. Estimates of Canadian advertising expenditures in all media for the year 2004 range from \$4.9¹² billion to \$11.9 billion.¹³ Similar estimates for spending in the United States range from \$143.2 billion¹⁴ to \$263.8 billion.¹⁵ Despite the high costs, marketers continue advertising because of the evidence that the sales generated by advertising more than compensate for the size of an advertising budget, at least over the long term.

¹¹ Newspaper Association of America (2006). Canadian advertising expenditures — all sources. www.naa.org/thesource/29.asp (assessed June 19, 2006).

¹² Statistics Canada, Advertising and related services 2000–2004. www40.statcan.ca/l01/cst01/serv17.htm (accessed June 19, 2006).

¹³ Newspaper Association of America (2006). Canadian advertising expenditures — all sources. www.naa.org/thesource/29.asp (assessed June 19, 2006).

¹⁴ TNS Media Intelligence. Ad spending by media: full year 2005 vs. full year 2004 U.S. www.tns-mi.com/news/02282006.htm (accessed June 19, 2006).

¹⁵ Newspaper Association of America. U.S. advertising expenditures in media 2003 and 2004. www.naa.org/thesource/20.asp (accessed June 19, 2006).

41. Another shortcoming of advertising is that it provides the opportunity for one-way communication only. Marketers can partly circumvent this difficulty by providing contact information such as a website URL or toll-free number that allows consumers to make contact with the advertiser.

42. With the advent of new information technologies, marketers are able to reach various segments of the consumers through innovative means such as banner ads (on the Internet), viral marketing, buzz marketing, text-messaging on cell phones and a host of other emerging vehicles such as pod-casts and “placements” in “blogs” and other social and business environments that exist in the physical and electronic worlds.

B. “PUSH” AND “PULL” STRATEGIES

43. Generally, promotional techniques may be classified as “push” or “pull” strategies. A “push” strategy involves promoting a product through distribution channels to the end consumer. This type of marketing induces retailers and other sellers to stock a product in their inventory and promote it to the end consumer. “Pull” marketing focuses directly on end consumers, and attempts to increase their desire for the product. Customers then demand that stores carry the product, and stores demand the product from the manufacturer.

44. Generally, all promotional activities targeted at the consumer can be classified as “pull” strategies, while all promotional activities targeted at “middlemen,” as well as retailers’ attempts to influence consumers through sales, gifts, samples and coupons, can be viewed as a “push” strategies.

C. “PRODUCTS” AND “BRANDS”

45. Marketers promote a “product” or a “brand” — or both. One well-known definition of brand is “a name, term, sign, symbol, or design, or a combination of them, intended to identify the goods or services of one seller or

group of sellers and to differentiate them from those of competitors.”¹⁶ Examples of brands include Dell computers and Levi’s jeans. In the pharmaceutical industry, ZOLOFT, PROZAC, NEXIUM, and CRESTOR are brand names. Brand promotions seeks to persuade a target market to select one firm’s brand over that of a competitor.

46. Product-claim advertising may be “informative,” appearing in the introductory stage of a product’s life-cycle to make consumers aware of a new product, what it can do, and where to find it. The objective of these advertisements is to inform a target market about a product of which they were previously unaware. Product-claim advertising can also be “competitive,” stressing the advantages of one brand over another. Sometimes these advertisements are explicitly comparative, as in a recent television campaign comparing Mac computers to PCs. A classic example of comparative advertising is the case of “Coke versus Pepsi.”

47. Frequently, advertising of specific prescription drugs is “awareness” oriented. With new drugs, their purpose and availability need to be made known. With older, established, drugs, there are always new cohorts of patients who have newly become affected by a condition and are just starting to inform themselves about their problem and the treatments available for it.

48. Reminder advertisements simply reinforce consumers’ awareness of an established product and are usually used to promote recognizable products in a mature phase of their life-cycle.

D. “CONNECTED” MARKETING

49. “Connected” marketing — sometimes known as “viral,” “buzz,” or word-of-mouth marketing — is based on the assumption that recommendations from satisfied customers are a powerful mean of generating new business. New

¹⁶ Kotler, P., Keller, K. L., & Cunningham, P. H. (2006). *Marketing Management* (12th Canadian ed.). Toronto: Pearson Prentice Hall, p. 331.

personal communications technology — email, blogs, cellphones, and so forth — has made buzz marketing more effective. *The Blair Witch Project*, a movie released in 1999, was almost entirely promoted by word-of-mouth, largely stimulated by the film's website. A small investment of US \$15,000 secured 75 million visits to the website in the first week of the film's release.¹⁷

50. Similarly, *Cosmo Girl* magazine and Mattel's Fisher Price toys were able to generate very high levels of success in their promotional campaigns based on exceptionally cost effective viral/buzz marketing techniques. "Seeding trials" have been also used by the pharmaceutical industry whereby opinion-leading physicians (i.e., loyal adopters) are encouraged to use word-of-mouth (also called "buzz") to promote the drug in question among their colleagues.

51. Using the label "Phase IV" trials (also called "postmarketing trials"), marketers can provide opinion leaders in medicine with drug samples or encourage them to prescribe the product in order to elicit feedback from patients. In return for their cooperation, the doctors are promised free access to the drug or their patients as well as other exclusive "VIP" services and assistance. The selected doctors presumably take satisfaction in their opinion-leader status; in return, the drug manufacturer gains exclusive insights that will help them fine-tune their marketing efforts.

E. ADVERTORIALS

52. Some advertisements aim to disguise their intention. "Advertorials" are print ads that proffer editorial content that reflects well on the brand and closely resembles the regular editorial content of a newspaper or magazine. Advertorials are "soft" articles that, unlike regular news articles, do not mention a product's shortcomings, since advertisers have no interest in paying to undermine their own products. Many magazines and newspapers do not accept advertorials that look entirely like a regular story; medical journals editors, for

¹⁷ Kirby, Justin, and Paul Marsden. (2005). *Connected Marketing: The viral, buzz and word of mouth revolution*. London, UK: Elsevier.

example, may be concerned about the potential for readers to mistake advertorials for scientific material and thus require some distinguishing feature on the page, such as the word “advertisement” inserted somewhere. In electronic media, the potential for “hard” and “soft” copy to mingle becomes even greater. Display ads “pop up” next to news copy on the Web sites of daily newspapers — such as an ad for CRESTOR, a cholesterol-lowering agent, appearing next to an article titled “Health officials urge sharply lower cholesterol levels,” written by a well-respected medical reporter.¹⁸

PART III – MARKETING PRACTICES IN THE PHARMACEUTICAL INDUSTRY

A. SPENDING ON PHARMACEUTICAL ADVERTISING

53. Spending by pharmaceutical manufacturers on advertising is substantial, and is increasing at a rapid rate. A recent issue of *Brandweek* reported that in January–February 2006 “advertising on prescription drugs increased 11% compared to the same period in the prior year. In the first two months of 2006, pharmaceutical companies in the U.S. spent \$680 million advertising drugs. In 2005, that number was \$613 million, according to the most recent numbers from Neilson Monitor-Plus.”¹⁹

54. A high rate of spending on advertising for prescription drugs is maintained in the various forms of drug marketing outlined in the following subsections. *Prescription Drug Trends* reports that 66% of advertising expenditures were directed toward physicians and 34% toward consumers in 2004. Spending for direct-to-consumer advertising — typically to advertise newer, higher-priced drugs — was 15 times greater in 2004 than in 1994.²⁰

¹⁸ Adams, M. (2004). Pharmaceutical advertising turns national newspapers into drug industry puppets. www.newstarget.com/z001482.html (accessed June 24, 2006).

¹⁹ Edwards, J. (2006). New pharma ad rules result in ...more ads.” *Brandweek* 47(19), p. 4.

²⁰ Kaiser Family Foundation. (2005). *Prescription Drug Trends* [factsheet #3057-04] (November), p. 2. www.kff.org (accessed June 19, 2006).

55. Drug advertising seems to achieve its aim of increasing sales. According to a study reported in *Marketing Health Services*, from 1999 to 2000 prescriptions for the 50 most heavily advertised drugs were up 24.6%, as compared to a 4.3% increase in all other pharmaceutical products.²¹

56. Pharmaceutical advertising affects not only the volume of prescription drug sales but also patterns of prescribing; the accepted opinion is that “[b]oth prescription use and shifts to higher-priced drugs are affected by advertising.”²²

57. Current indications are that expenditures on DTCA in the United States have reaped a high rate of return. The Kaiser Family Foundation reports that “[a]fter accounting for the fact that drugs with higher sales are more likely to be advertised to consumers and have higher levels of promotion to physicians ... increases in DTC advertising were associated with significant growth in sales for the classes of drugs studied: for every 10% increase in DTC advertising, drug sales within the classes studied increased on average by 1%.”²³ An analysis of sales in relation to advertising expenditures for the 25 top-selling classes of drugs showed that “each additional dollar spent on DTC advertising in 2000 yielded \$4.20 in additional pharmaceutical sales in that year.”²⁴ **Attached to my affidavit as “Exhibit 2” and “Exhibit 3” respectively are copies of Kaiser Family Foundation reports from 2003 and 2005 on the issues of DTCA and pharmaceutical drug sales.**

58. There is also evidence that spending on advertising not only boosts sales of drugs newly on the market, but also allows manufacturers to obtain a new lease of life for older products. One example is the sleeping aid LUNESTA,

²¹ Findlay, S. (2002). Cited in Parker, R. S., & Pettijohn, C. E. (2005). Pharmaceutical drug marketing strategies and tactics: a comparative analysis of attitudes held by pharmaceutical representatives and physicians. *Health Marketing Quarterly*, 22(4), 27. p. 31.

²² Kaiser Family Foundation. (2005), p. 2.

²³ Kaiser Family Foundation. (2003). *Impact of direct-to-consumer advertising on prescription drug spending*, 1. www.kff.org/rxdrugs/upload/Impact-of-Direct-to-Consumer-Advertising-on-Prescription-Drug-Spending-Summary-of-Findings.pdf (accessed June 19, 2006).

²⁴ *Ibid.*, p. 2.

introduced in 2005 but “based on a remedy first approved in Europe two decades ago. ... LUNESTA garnered \$330 million in sales in its first nine months on the market thanks to TV spots featuring a diaphanous cartoon butterfly flitting in and out of moonlit bedrooms. ... Sepracor spent \$215 million last year advertising LUNESTA.”²⁵

B. “PUSH” VERSUS “PULL” STRATEGIES

59. As with other types of products, the marketing of drugs can be of the “push” or “pull” variety. However, in Canada, as in many other jurisdictions, “push” advertising of drugs does not extend to the end consumer, but only to a “gatekeeper” such as the physician, pharmacist, or insurer.

60. “Detailing,” discussed below, is a “push” approach. Advertisements placed in professional magazines aimed at physicians and pharmacists constitute “push” marketing, as are the often more subtle promotion of particular drugs through professional conferences sponsored by drug companies. DTCA, on the other hand, constitutes “pull” promotion, which aims to create consumer demand so that patients request prescriptions for particular drugs from their physicians.

61. Although “push” strategies have traditionally dominated drug advertising, “pull” strategies are rapidly gaining ground. One indication of this trend is that medical journals are losing their share of the drug promotion market. The journal *Medical Marketing and Media*, in an article entitled “Deep Freeze” reported that, in 2005, advertisements in medical and surgical journals had increased by only 1% over the previous year and had grown by only 4% in total since 2000. The report noted that this weak performance had undoubtedly been influenced “by the rapid ongoing expansion of pharmaceutical sales forces during much of the five-year period noted and by direct-to-consumer ad expenditures that are now running at approximately eight times those of medical/surgical

²⁵ Langreth, R. (2006). “Pill pushers.” *Forbes* 177 (10), pp. 94-102.

journals.”²⁶ **Attached to my affidavit as “Exhibit 4” is a copy of this report, entitled D.**

62. “Push” and “pull” strategies have the potential to work well together in drug marketing, as they do in other industries. Gonul and colleagues note the potential synergies in “capitalizing on interactions between patients and physicians through a concerted marketing effort targeted at them simultaneously through different promotional channels.”²⁷

C. “DETAILING” AND OTHER “PUSH” TECHNIQUES

63. “Detailing” is the classic drug marketing approach whereby a corporation’s sales representatives visit physicians and pharmacists to describe the merits of their products. In 1998, nearly 65% of total pharmaceutical promotional spending was allocated to face-to-face selling in physicians’ offices. Nearly 57,000 pharmaceutical representatives were engaged in this work in the United States.²⁸ By 2004, that number had grown to an estimated 80,000 representatives.²⁹

64. A considerable amount of the money spent by pharmaceutical companies in their marketing efforts goes toward “sales promotion” items such as pens, pencils, mugs, and calendars, all bearing the company name or logo. Parker and Pettijohn, citing Nucifora, report that “business gifts represented 20% of promotional [budgets], followed by employee relations and events (12.2%), trade shows (8.7%), and public relations (8.5%).”³⁰ Philip W. Yoon has argued that unsolicited gifts create a form of social discomfort when the recipient does not reciprocate in some way, and that even small gifts can therefore lead a

²⁶ May, E.M. (2006). Deep freeze. *Med Marketing Media* 41 (4), p. 61.

²⁷ Gonul, F.F., Carter, F. & Petrova E. & Srinivasan K. (2001). Cited in Campo, K., De Staebel, O., Gijbsbrechts, E., & van Waterschoot, W. (2005). Physicians’ decision process for drug prescription and the impact of pharmaceutical marketing mix instruments. *Health Marketing Quarterly*, 22(4), p. 91.

²⁸ Hradecky G., ed. (1998, 1999). Quoted in Wright R.F. & Lundstrom, W.J. (2004). Physicians’ perceptions of pharmaceutical sales representatives: a model for analysing the customer relationship.” *Int J Med Marketing* 4 (1), p. 30.

²⁹ Hradecky (2001), quoted in Wright & Lundstrom (2004), p. 30.

³⁰ Nucifora (1998), quoted in Parker & Pettijohn (2005), p. 28.

physician to prescribe the pharmaceutical representative's products.³¹ **Attached to this affidavit as "Exhibit 5" is a copy of Parker and Pettijohn's article, "Pharmaceutical Drug Marketing Strategies and Tactics: A Comparative Analysis of Attitudes Held by Pharmaceutical Representatives and Physicians".**

65. Drug detailers often give physicians free samples of the drugs they wish to promote. In 2004, the retail value of drug samples distributed to American physicians was \$15.9 billion (US).³² Physicians may then give these samples to patients, and wait to hear from those patients about the drug's effectiveness. These gifts seem to be well worth their cost to the pharmaceutical manufacturer. One news magazine reported that physicians who have frequent contact with a drug company representative were 13 times more likely to ask that a particular drug be added to an insurance plan's lists of approved drugs.³³ Two other studies suggested that providing physicians with free sample resulted in more prescriptions for those products than for generic versions of the drug.³⁴

66. Given that in general, pharmaceutical sales representatives are not required to have medical or pharmacologic training, the quality of the technical information that pharmaceutical representatives provide physicians has been questioned. Researchers from the University of California at San Diego found that 11% of statements made by pharmaceutical sales representatives during presentations at a university teaching hospital were false. The erroneous statements were all favourable to the drug being promoted.³⁵ **Attached to my affidavit as "Exhibit 6" is a copy of Ziegler et al.'s article "The Accuracy of Drug Information From Pharmaceutical Sales Representatives", which contains the results of this study.**

³¹ Yoon (2004), quoted in Parker & Pettijohn (2005), p. 30.

³² Kaiser Family Foundation. (2005), p. 2.

³³ Shapiro and Schultz (2001), 58-61, quoted in Parker and Pettijohn (2005), p. 29.

³⁴ Waud (1992) and Sibbald (2001), quoted in Parker and Pettijohn (2005), pp. 29-30.

³⁵ Ziegler, M. G., Lew, P., & Singer, B. C. (1995). The accuracy of drug information from pharmaceutical sales representatives. *JAMA* 273(16), pp. 1296-1298.

D. TYPES OF BRAND ADVERTISING

67. Most pharmaceutical advertisements are brand-specific: they promote a specific drug (e.g. ZOLOFT or PROZAC) for a given condition (depression). Brand promotion advertisements take one of three forms: “product-claim ads,” which mention a drug’s name, benefits and side-effects; “reminder ads,” which promote brand-name recognition; and “help-seeking ads” which “[inform] consumers that treatments are available for particular health or medical conditions.”³⁶

68. The “help-seeking” ads do not name a specific drug, but simply mention a condition, such as eczema, and state that a medical treatment is available. The consumer is usually advised to see his or her physician for treatment. These advertisements assume that the manufacturer’s product is so familiar and well-known that a physician, as a matter of routine, will likely recommend it to the consumer.³⁷

69. Pharmaceutical firms have used “condition branding”, whereby a specific disease or treatment regimen is associated with a single company or a brand. For example, following the release of ZANTAC (a remedy for stomach ulcers), GlaxoSmithKline attempted to increase the size of the target market by expanding the list of conditions for which ZANTAC might be viewed as useful³⁸. Heartburn was considered an optional disease to “target”, but GSK worried that this condition might be viewed as undeserving of a prescription medication. As a result GSK “positioned” heartburn as Gastroesophageal Reflux Disease (GERD) and promoted the “disease” through a newly created Glaxo Institute of Digestive Health. This Institute “sponsored research awards in the “area of gastroesophageal health, discussed GERD in the context of other more serious gastrointestinal diseases, involved powerful third-party advocates such as the

³⁶ Richardson, L., & Luchsinger, V. (2005). Direct-to-customer advertising of pharmaceutical products: Issue analysis and direct-to-consumer promotion. *J Am Acad Business, Cambridge*, 7 (2), p. 101.

³⁷ Ibid.

³⁸ Parry, Vince. (2003). The Art of Branding a Condition. *Medical Marketing and Media*, pp. 43-49.

American College of Gastroenterology and fielded a public relations effort called Heartburn across America.”³⁹ The outcome was very impressive: ZANTAC sales exceeded \$2 billion (65% for GERD treatment), and the number of physicians who saw GSK as a leader in GI healthcare doubled. **Attached to my affidavit as “Exhibit 7” is a copy of Vince Parry’s article, “The Art of Branding a Condition”, which discusses this example.**

E. “CONNECTED” ADVERTISING OF PHARMACEUTICALS

70. The technique of “buzz” advertising is gaining increasing relevance in the marketing of prescription medications. A number of pharmaceutical brands (e.g. VALIUM, PROZAC, VIAGRA) are household words. The interest of popular media in venturing into intimate topics that reflect consumers’ personal health and interpersonal lives can be leveraged, or serendipitously exploited, by pharmaceutical manufacturers to create interest in products that, until relatively recently, could not have been discussed in “polite company.” For example, reference to a contraceptive method on the popular television series *Seinfeld* may have prepared the ground for a product re-launch:

The female contraceptive that inspired an episode of “Seinfeld” and launched the phrase “spongeworthy” into the national lexicon is returning to store shelves after more than a decade. The Today Sponge, marketed by Allendale Pharmaceuticals, gained re-approval by the Food and Drug Administration April 22 [2005] ... The company plans an aggressive public relations and buzz marketing blitz.⁴⁰

71. New high-speed communications technologies are also fostering innovative approaches to “buzz” marketing, or “viral” campaigns as they are called in the context of global electronic communications. Here, a striking example is Bayer’s campaign to promote brand awareness of Ascensia, a glucose-monitoring device. The Ascensia campaign involved the creation of the “Ascensia Dream Fund,” which provides resources for a diabetes sufferer to

³⁹ Ibid., p.44.

⁴⁰ Thomaselli, R. (2005). Pop-culture phenomenon, Today Sponge is back. *Advertising Age* 76 (18), p. 12.

achieve a life-long ambition. The highly successful inaugural campaign used interactive satellite, telephone and Internet communications to follow the progress of a diabetic patient as he competed solo in round-the-world sailing race.⁴¹

F. THE RISE OF DIRECT-TO-CONSUMER ADVERTISING

72. The direct-to-consumer advertising of prescription drugs has been defined as “any promotional effort by a pharmaceutical company to present prescription drug information to the general public in the lay media.”⁴² By creating a felt need in the end user, the patient, who must request the cooperation of his or her physician in order to obtain the product through a medical prescription, DTCA is “pull” strategy for drug promotion.

73. Currently, only two Western countries, the United States and New Zealand, allow DTCA.⁴³ There are also ongoing discussions in the European Union about whether to allow DTCA.

74. Spending on DTCA advertising is growing with notable speed in the United States. Estimates vary, but most place spending on DTCA at well over US \$4 billion.⁴⁴ *Medical Advertising News* noted a 7.8% increase in DTCA spending in 2005 compared with 2004.⁴⁵

75. The year 1997 has been described as a “watershed” moment in DTCA in the United States.⁴⁶ That was the year that regulators first relaxed restrictions on radio and television broadcasters for prescription drug advertising.

⁴¹ “Betting on buzz.” (2004). *Pharm Exec* 24 (3), p. 118.

⁴² Wilkes, M.S., Bell, R.A., and Kravitz, R.L. (2000). Direct-to-Consumer Prescription Drug Advertising: Trends, Impact, and Implications. *Health Affairs*, 19(2),

⁴³ Finlayson, G., & Mullner, R. (2005). Direct-to-consumer advertising of prescription drugs: help or hindrance to the public’s health? *J Consumer Marketing* 2 2(7), p. 429.

⁴⁴ Krisantis, T. (2004). DTC’s Big Surge. *Med Marketing Media*, 39 (12), p. 49.

⁴⁵ Anonymous. (2006). “DTC takes a back seat.” *Med Ad News* 25 (5), p. 1-12.

⁴⁶ Morgan S. (2005). Canadian prescription drug costs surpass \$18 billion.” *CMAJ* 172 (10), p. 1324.

The boom in broadcast DTCA followed. By 2003, expenditures on DTCA were seven times higher than expenditures on advertising in professional journals.⁴⁷

76. More is spent by pharmaceutical manufacturers on DTCA than Pepsi-Cola, Coca-Cola and Cadbury Schweppes combined spend in promoting their soft drinks. Expenditures on DTCA also surpass the total amount Unilever spends on global advertising for its complete product line, including Dove, Knorr, Lipton, Lux, Pond's, Slim-Fast and Wish-Bone.⁴⁸ **Attached as "Exhibit 8" is a copy of Richardson and Luchsinger's article "Direct-to-Consumer Advertising of Pharmaceutical Products: Issue Analysis and Direct-To-Consumer Promotion", which discusses this issue.**

77. There are reasons to expect spill-over of the effects of American DTCA in Canada. Canadians are exposed to many American television and radio broadcasts and to American magazines and newspapers. There has certainly been an exceptional increase in spending on prescription drugs in Canada. From 1996 to 2004, spending more than doubled, from \$7.6 billion to \$18.0 billion.⁴⁹

78. The case typically made in favour of DTCA of prescription drugs is that it empowers patients by "educating" them about medical conditions and the treatments available to manage them. However, several studies that have looked at DTCA question the legitimacy of this claim.^{50,51} Physicians have found the effect of DTCA to be largely negative. Patients, they say, demand drugs that they have seen advertised without realizing that the advertised drug may be no more effective and yet more expensive than the drug they are currently taking. **Attached to my affidavit as "Exhibit 9" is a copy of Lexchin and Mintzes'**

⁴⁷ Ibid.

⁴⁸ Richardson & Luchsinger (2005), p. 100.

⁴⁹ Morgan S. (2005). Canadian prescription drug costs surpass \$18 billion." *CMAJ* 172 (10), p. 1323.

⁵⁰ Bell, R. A., Wilkes, M., & Kravitz, R. (2000). [Electronic version.] *The educational value of consumer-targeted prescription drug print advertising*, 4(12). Retrieved June 17, 2006, from PubMed database.

⁵¹ Lexchin, J., & Mintzes, B. (2002). Direct-to-consumer advertising of prescription drugs: the evidence says no. *J Public Policy Marketing*, 21 (2), p. 194.

article, “Direct-to-Consumer Advertising of Prescription Drugs: The Evidence Says No”, which discusses this issue.

79. Reports from government agencies in both Canada and the United States suggest that recently introduced drugs do not, generally, represent significant advances over previous treatments. From 1996 to 2000, the Canadian Patented Medicine Prices Review Board examined 415 new patented drugs. Only 6% were found to deliver substantial improvements over existing treatments. More than half of the new drugs resulted in little or no improvement for patients.⁵²

80. From 1978 to 1991, the US Food and Drug Administration (FDA) assigned drugs to one of three categories: Category One, which delivered important therapeutic gains; Category Two, which delivered modest gain; and Category Three, which delivered little or no gain. The FDA placed only 50 of 312 new drugs in the Category One. The implication is that 262 drugs, or 84%, offered at best modest gains.⁵³

81. The accuracy of the educational material contained in direct-to-consumer advertisements is also a point of contention. In 1996, *Consumer Reports* magazine assessed the accuracy of 28 direct-to-consumer magazine advertisements. The magazine found two-thirds of the advertisements generally accurate. But in the main promotional text of those ads, only half conveyed information about adverse reactions, and only 40% percent were truthful in claims concerning efficacy and the balance between risk and benefits.⁵⁴

82. Another study conducted the same year in the United States yielded similar findings. Among 50 advertisements, representing 90% of all DTCA in American magazines and newspapers from January 1993 to mid-1995, more than a third did not offer a fair balance between benefit and risk information

⁵² Ibid.

⁵³ Ibid.

⁵⁴ Anonymous. (1996). Drug advertising: Is this good medicine. *Consumer Reports*, 61 (6), p. 62-3.

in the main body of the advertisement. More than half of the advertisements lacked directions on how to use the medication, and only 12% provided information about potential misuse.⁵⁵ **Attached to my affidavit as “Exhibit 10” is a copy of Roth’s article “Patterns in Direct-to-Consumer Prescription Drug Print Advertising and Their Public Policy Implications”, which contains the results of this study.**

83. Survey findings reported in *Prevention* magazine indicated that most people felt the information provided by DTCA was unclear. Sixty-one percent of respondents agreed strongly or mostly agreed that DTCA would confuse people about the risks and benefits of advertised drugs. These results imply that most people have difficulty interpreting the information in the advertisements.⁵⁶

84. The results of a study conducted at Harvard University suggests that even physicians may glean false impressions about drugs after being exposed to DTCA.⁵⁷ This survey asked 85 doctors about two classes of drugs. The information in the scientific literature about drug classes differed dramatically from information that appeared in promotional advertisements. Although they were not conscious of it, most of the doctors who claimed to gather their information about the drugs from professional sources held opinions that had in fact been based on the promotional material. **Attached to my affidavit as “Exhibit 11” is a copy of Avorn et al.’s article “Scientific versus Commercial Sources of Influence on the Prescribing Behavior of Physicians”, which contains the results of this study.**

85. DTCA is often used to promote recently approved drugs, for which little long-term safety data is available. It is common knowledge that a number of

⁵⁵ Roth, M. S. (1996). “Patterns in direct-to-consumer prescription drug print advertising and their public policy implications.” *J Public Policy Marketing*, 15 (1), p. 63-75.

⁵⁶ Lexchin J. (1999). Direct-to consumer advertising: impact on patient expectations regarding disease management. *Dis Manage Health Outcomes* 5 (5), p. 277.

⁵⁷ Avorn, J., Chen, M., & Hartley, R. (1982). Scientific versus commercial sources of influence on the prescribing behavior of physicians. *Am J Med* 73 (1), p. 4–8.

drugs that pharmaceutical corporations advertised widely and directly to consumers in the American market were later withdrawn for safety reasons; these include ORAFLEX, REZULIN, PROPULSID, BAYCOL,⁵⁸ and, more recently, VIOXX. A US study demonstrated that of the 548 new drugs introduced to the American market between 1975 and 1999, 2.9% were later withdrawn for safety reasons. The FDA issued so-called “black-box” warnings (to alert physicians to serious and potentially life-threatening risks) for another 8.2% percent of those drugs.

86. From a marketing perspective, a successful ad campaign is one that generates higher sales. Therefore, one implication of a successful marketing campaign to launch a new drug that subsequently proves to be unsafe is that millions of people may use the drug before it is withdrawn. Nearly 20 million Americans, for example, used at least one of the five drugs withdrawn from the US market between September 1997 and September 1998.⁵⁹

87. Leaving safety issues aside, DTC-advertised drugs, are typically newer market entries and cost more than older drugs. Thus, some health system experts believe the DTCA costs both patients and pharmaceutical insurance plans more money than would the continued use of well-established medications.

88. Huang reported in the *Journal of the American Medical Association* that nearly 33% of respondents who had seen an advertisement for a brand-name drug ask their physician for that product.⁶⁰

89. The success of “pull” advertising of drugs may put doctors in a dilemma. Parker and Pettijohn cite a 2002 survey in which 63% of responding physicians reported that they had felt pressured to prescribe drugs that patients requested as a result of seeing them advertised.⁶¹ A physician’s refusal to

⁵⁸ Lexchin & Mintzes, p. 195.

⁵⁹ Wood (1999). The safety of new medicines: the importance of asking the right questions. *JAMA* 281 (18), p. 1753-4.

⁶⁰ Huang (2000), quoted in Parker and Pettijohn (2005), p. 31.

⁶¹ Paul, Handlin, & Stanton (2002), cited in Parker & Pettijohn (2005), p. 32.

prescribe a drug demanded by a patient may strain the physician–patient relationship. The literature suggests that the advertising of drugs will cause some patients to “doctor shop,” going from physician to physician until they find one who will prescribe the medication they think they need.

90. In a US telephone survey, patients were asked how they would react if a physician refused to write a prescription for an advertised drug they had requested. Twenty-four percent responded that they would seek a prescription elsewhere, and 15% said they would consider finding a new physician.⁶² A national survey conducted in 1998 in the United States indicated that 11% of Americans agreed completely, and 17% agreed somewhat, that they would switch doctors to get the medication they desired.⁶³

91. Physicians frequently do accede to a patient’s request for a prescription. In one 2005 study, University of California researchers had actors make a total of 298 unannounced visits to physicians, complaining of either depression or an adjustment disorder, both often treated by antidepressants. Some of the “patients” asked for a specific brand of drug, some asked for a class of drug, and some made no request. Antidepressants were prescribed for 53% who asked for a specific brand, for 76% who asked for a class of drug, and for 31% who made no request. The authors concluded: “These results underscore the idea that patients have a substantial influence on physicians.”⁶⁴

G. THE “EDUCATIONAL” ASPECTS OF DTCA

92. Consumer education involves the formal effort to provide consumers with skills and knowledge to allocate their resources wisely in the marketplace. Drug advertisements, in one degree or another, provide information about products and therefore to some degree enhance consumer education. Whether it makes consumers more knowledgeable about the

⁶²Bell, R. A., Wilkes, M., & Kravitz, R. (1999). Advertisement-induced prescription drug requests: Patients’ anticipated reactions to a physician who refuses. *J Fam Practice*, 48 (6), p. 446-52.

⁶³SCRIP. (1998). *U.S. DTC ads work*. 2370: p. 16-17.

appropriateness of any product for their objective circumstances is another issue. Because DTCA is often defended on the basis of its usefulness in educating patients, it makes sense to examine how much “education” DTCA actually provides from the marketing perspective.

93. Marketers attempt to gain as much exposure for their promotional campaigns as possible. An advertisement that goes unread will “educate” no one, and so marketers place great emphasis on achieving an effective presentation. As one researcher noted with regard to the technical improvement of DTCA in the United States, “Anecdotally, since the introduction of DTCA in 1981, there have been substantial alterations in advertising copy (i.e., increased product detail and more quality-of-life appeals) and a heightened amount of eye-catching artwork and photographs.”⁶⁵

94. DTCA often appeals to lifestyle aspirations rather than providing education. For example, a DTC advertisement for VALTREX, discussed in Part 4, uses a “classical conditioning” advertising technique, in which a desirable state (in this case, warmth, intimacy, being outdoors) is associated with the advertised product, evoking a felt need for the product regardless of an objective need. The image is warm and comforting, but the visual image does not educate patients with genital herpes about whether VALTREX should be their drug of choice.

95. Classical conditioning is also used in an advertisement for the antidepressant drug ZOLOFT in the November 14, 2005, issue of *People* magazine. The advertisement employs several cartoon panels to talk about a woman who reportedly overcame her depression by using ZOLOFT. The figures in the cartoon are represented only as faces. Each bears a remarkably happy and contented expression, as though sadness and unhappiness are unknown visitors. All of the figures appear very young, although the advertisement relates the story of “Cynthia,” described as a 57-year-old divorced woman. The

⁶⁴ Kravitz (2005), quoted by Gottlieb, S. (2005). Consumer advertising influences doctors’ prescribing, study finds. *BMJ*, 330 (7498), p. 983.

advertisement depicts the desired state of happiness, a condition that the reader may then connect with ZOLOFT. The viewer “learns” that using the brand will enhance her happiness. There is no substantial education here about the nature or treatment of depression.

96. In discussing the “porous” boundary between persuasion and information in DTCA, Berndt notes that this form of advertising has “considerable potential” as “an instrument promoting public health.” However, in reality, Berndt notes, the proportion of consumers who read the medical “fine print” of DTC advertisements is very low. Berndt quotes Aiken: “Indeed the proportion of persons who saw a print ad but read the summary “not at all” or “a little” reportedly increased from 56% in 1993 to 73% in 2002.⁶⁶

97. Moreover, the likely impact of providing a more reader-friendly version of this information is debatable: the messages conveyed by an attractive image are likely to overwhelm any genuinely informative content.⁶⁷ **Attached to my affidavit as “Exhibit 12” is a copy of Berndt’s article “To Inform or Persuade? Direct-to-Consumer Advertising of Prescription Drugs”, which discusses this issue.**

PART IV – A REVIEW OF ADVERTISEMENTS IN THE APPLICATION RECORD

98. I have been asked to review the advertisements that I understand were filed in the Application Record as Exhibit “A” to the Affidavit of Arturo Duran in the present case. They are all direct-to-consumer advertisements created by pharmaceutical marketers. Several of them appeal to lifestyle aspirations by presenting attractive images of how a consumer might, ideally, like to live and spend time. Throughout the following analyses, I offer interpretations of the

⁶⁵ Basara, L.R. (1996). The impact of a direct-to-consumer prescription medication advertising campaign on new prescription volume. *Drug Information J*, 73, p. 715-729.

⁶⁶ Aiken, A.J. (2003) quoted in Berndt, E. R. (2005). To inform or persuade? direct-to-consumer advertising of prescription drugs. *N Engl J Med*, 352 (4), p. 327.

intended meaning and effect of these advertisements as a matter of my professional and academic opinion.

99. An advertisement for the antiviral agent VALTREX that appeared in *Men's Health* [**Affidavit of Arturo Duran, Exhibit "A", Application Record, pp. 17-19**] is a good example of an advertisement that appeals to a desirable lifestyle; here, a healthy lifestyle is conjured with suggestions of close family connection, activities in the "great outdoors," and the leisure to take pleasure in the present moment.

100. As indicated previously, the justification generally offered for DTCA is that it educates consumers. The text in the main portion of the VALTREX advertisement is supplemented by more detailed "product labelling," as required by FDA regulations.⁶⁸ The advertisement provides the name of the condition (genital herpes), some information about the mechanism of action of the drug, and the treatment regimen (daily, for an indefinite duration), and possible side-effects. Whether or not substantial numbers of the audience will read the "fine-print," this clinical and apparently objective content may provide reassurance to readers that expert advice is being offered. The advertisement does not purport that the drug is curative, but only that it will help to prevent recurrences. Through the pleasant associations of the image, the advertisement promises emotional, personal and social relief from the unpleasant fact that, as the ad states, there is no cure for herpes. The fact that the advertisement does not list symptoms of herpes infection mirrors the desired effect of the drug, which is to keep the socially unacceptable manifestations of this chronic infection hidden.

101. A promotion that appeared in *People* magazine for DETROL LA (long-acting) [**Affidavit of Arturo Duran, Exhibit "A", Application Record, pp. 32-34**], a drug used to mitigate frequency and urgency of urination, is also a lifestyle advertisement that promises some degree of liberation from the personal

⁶⁷ Berndt, E. R. (2005). To inform or persuade? direct-to-consumer advertising of prescription drugs. *N Engl J Med*, 352 (4).

⁶⁸ *Ibid.*

burden of a socially problematic chronic condition. It depicts a group of people (three women and two men) eating at what appears to be an outdoor buffet. The photograph focuses on an older woman, who is apparently the one who suffers from an overactive bladder, the condition that DETROL LA treats. She looks extremely comfortable in this situation, and seems to assert a motherly presence, since she is clearly older, and by implication wiser, than the two other women.

102. In the ad she says: "I used to worry a lot about people finding out I have a bladder control problem. Now I worry more about leaving room for dessert." DETROL LA, the advertisement implies, has alleviated this anxiety-producing condition. Not only is the woman freed from that anxiety, but she is able to provide comfort to the other figures in the photograph. Her experience with her condition and its successful management has accorded her some degree of superiority over the others in her social group. By allowing herself the luxury of "leaving room for dessert," she has learned, in her older years, how to live life more fully. The reader may draw the inference that the drug has made this personal growth possible for her.

103. According to the precepts of classical conditioning as applied in advertising, the intention of the ad would appear to be to induce the reader — particularly if she is a woman with a bladder control problem — to associate the product with positive attributes and circumstances. Thus DETROL LA is associated with a sense of comfort, relaxation, and inner confidence. The apparent implication of the image is that DETROL LA can alleviate anxiety by offering the reader the same quality of life as the woman in the advertisement is experiencing. This advertisement, like the VALTREX ad, is accompanied by a full page of information about the product. This information does not describe the pathogenesis of overactive bladder or the full range of pharmaceutical and non-pharmaceutical interventions in its management.

104. An advertisement for an asthma drug, ADVAIR, appeared in *Men's Health* magazine [**Affidavit of Arturo Duran, Exhibit "A", Application Record,**

pp. 20-22]. This advertisement appeals to lifestyle desires to some degree, since the presumed sufferer is shown, in a tightly cropped headshot, looking happy and comfortable and not at all like a person fighting for breath. If she has asthma, it is not affecting her now, and if ADVAIR is responsible for her easy breathing, then any asthma sufferer might wonder what the drug could do for him or her.

105. In contrast to the VALTREX and DETROL LA advertisements, this one emphasizes the provision of information. However, its apparent intention is still to nudge the reader towards the doctor and his or her prescription pad. The first page includes a kind of multiple-choice symptom test in which readers can rank the frequency with which they have recently had difficulty breathing. Consumers, the advertisement explicitly notes, can discuss this test with their doctor to see if they need better symptom control, and hence a change of medication.

106. A second page in the advertisement contains detailed technical information, in the model of product monographs published in professional references for physicians and pharmacists (e.g., the *Compendium of Pharmaceuticals and Specialities* published by the Canadian Pharmacists Association). Although this technical page may create an impression of full scientific disclosure, it is unlikely to be either read or to be found genuinely useful to the average reader. Moreover, the advertiser would not expect the average reader to have any basis of expertise or training in the application of this technical information to his or her particular case; this lies within the clinical expertise of the medical clinician, not the average consumer.⁶⁹

107. Another advertisement, in *Prevention* magazine, promotes COREG, a drug that regulates left ventricular dysfunction in people who have had heart attacks [**Affidavit of Arturo Duran, Exhibit “A”, Application Record, pp. 59-61**]. This advertisement prominently features the words “Ask about COREG,” written as though they had been produced by a heart monitor. The

⁶⁹ Ibid., p. 327.

“electrical” writing appears regular and firm, suggesting that the heart being monitored is working well, and thus intended to provide reassurance to readers suffering from ventricular dysfunction. The first page of the advertisement is informative, but, as will all such ads, does not provide information on the full range of treatment options available. Like the ADVAIR advertisement, two additional pages of detailed technical information follow. Given that this information is presented in extremely fine print and has not been rendered into a “plain English” presentation, it is unlikely that it would be read or understood by most readers.

108. Another advertisement from *Prevention* promotes NEXIUM, a drug that “heals the damage that acid reflux disease produces in the lining of the esophagus” [**Affidavit of Arturo Duran, Exhibit “A”, Application Record, pp. 38-41**]. The picture in first page of this advertisement takes a different tack from those discussed previously. It depicts a person who, judging from the expression on her face, is in distress. She is wearing a dark scarf on which is written, “Behind this scarf acid could be burning the lining of her esophagus.” Images of suffering sometimes cause fear or compassion. But this image is more likely to evoke compassion in the viewer. The woman appears to be tall and in good shape, an attractive person with whom the reader might wish to identify. The long scarf provides a sense of the length of the esophagus and of the amount of tissue damage that this person might be experiencing.

109. The intention of the design of this advertisement would appear to be to give a person with any level of discomfort arising from acid reflux the impression that the pharmaceutical corporation understands his or her pain. Furthermore, the suggestion that esophageal damage is “hidden” may cause anxiety in the reader, prompting him or her to seek out a medical assessment and inquire about the possible protective effects of NEXIUM. Two pages of information follow, the first mentioning a 7-day free trial program for the drug and providing contact information, the second giving detailed, drug-monograph-style information about acid reflux disease and about the drug.

110. CRESTOR, a cholesterol-lowering drug, is featured in an advertisement from *People* magazine [**Affidavit of Arturo Duran, Exhibit “A”, Application Record, pp. 29-31**]. The first page features a clever, prominent image of a broad arrow pointed straight down. At the top of the advertisement are the words, “Ask your doctor if lower is better.” Towards the bottom of the page, on the head of the arrow, are the words “If your doctor says, ‘Lower is better,’ aim lower with CRESTOR.”

111. This is a very strong image. The downward-aimed arrow is designed to convey a palpable sense of inevitable movement. By association, this inevitability could be transferred subconsciously to the need to lower one’s blood cholesterol levels. The reader might easily be left with the impression that taking CRESTOR and lowering cholesterol are one and the same thing, and that both are imperative. At the same time, the ad defers to the authority of the physician, and hence impresses upon the reader the urgent need to seek out expert opinion about his or her condition. The page following the advertisement contains the drug monograph, again in fine print.

112. Another advertisement from *Prevention* magazine promotes CADUET, a drug that combines blood pressure medication (NORVASC) with a cholesterol-lowering drug (LIPITOR) [**Affidavit of Arturo Duran, Exhibit “A”, Application Record, pp. 42-45**]. The image is simple: two hands, the left one holding a single pill, and the right holding two pills. Text between the hands asks the reader to “Find out about the single pill that treats two.” The picture implies that one pill is indeed easier to manage than two. Therefore, the key selling proposition in the advertisement is “convenience” and “efficiency.”

113. The advertisement also points out that CADUET is “a single pill. A single prescription. A single copay [copayment for a drug purchased under a drug plan]. The implication is that having a single pill offers a number of conveniences beyond the greater ease of swallowing. As with most of the direct-to-consumer ads reviewed here, the drug offers implies social and lifestyle

advantages in addition to the potential to ameliorate the clinical symptoms of a medical condition. The usual finely-printed drug information follows.

114. Another advertisement in *Prevention* is for LUNESTA, a sleeping tablet **[Affidavit of Arturo Duran, Exhibit “A”, Application Record, pp. 56-58]**. An attractive woman is shown asleep, with a pleasant expression on her face. The simple words “Peaceful, restful sleep” are printed above her. The woman appears to be in a wonderful state, one that any viewer might wish to attain. There is also a great deal of skin showing in the advertisement, which the viewer might find alluring. The apparent intention of this ad is that the viewer will find this image pleasurable and will therefore associate LUNESTA with pleasurable sleep. A full page of drug information follows the advertisement.

115. Another advertisement in *Prevention* refers to OXYTROL, a drug delivered via a skin patch to manage overactive-bladder conditions **[Affidavit of Arturo Duran, Exhibit “A”, Application Record, pp. 46-48]**. The advertisement asserts that most medicines that treat overactive bladders cause dryness of the mouth. This, of course, causes one to drink fluids, which causes the bladder to fill and requires that one go frequently to the bathroom in spite of the treatment. The ad copy says that because OXYTROL comes in a patch form, the medication is released slowly, preventing dryness of the mouth. Thus the advertisement makes a claim to substantial product advantages over competing brands.

116. The picture depicts a circle of four images, in which a woman takes conventional medication, experiences dry mouth, drinks water, and goes to the bathroom. Someone who was experiencing that cycle would likely feel that the drug manufacturer has understood his or her predicament. This creates a pleasant and comforting feeling of “connection,” which would transfer to the consumers’ expectations of what might be expected from OXYTROL. The image also speaks to the absurdity of a treatment that causes the very problem it is designed to prevent, thus asserting its superiority over competitors.

117. Although I cannot offer a medical opinion on the safety and effectiveness of the products that appear in the advertisement interpreted here, it would seem reasonable to assume that certain consumers will benefit from the use of any or all of them. By and large, the advertisements are intended to highlight a problem and its intended “solution” and to cause the consumer to interact with his or her physician in a way that will lead to the adoption of the proposed “solution.” Although this may indeed have benefits for the consumer, from the marketing perspective the “success” of a campaign is not measured in terms of benefits to human health and well-being. If an advertising campaign, together with other promotional activities, does not lead to an increase in sales and profits, then the campaign has failed. To return to the basic principles outlined at the beginning of this submission, a corporation’s primary responsibility to shareholders is to maximize profits; thus, the marketer’s fundamental goal is to promote the sale of that corporation’s product, regardless of the consumer’s objective need.

118. All of the advertisements provided by CanWest Mediaworks Inc. contain a daunting amount of technical information. The provision of such information is required by current regulations pertaining to drug advertising; by providing them, advertisers are satisfying a technical requirement. This does not mean, however, that they are satisfying the objective of “consumer education.” Despite the volume and detail of information given, the supplementary technical pages to the drug ads are not necessarily *informative*. Their appropriateness for a general consumer audience is highly doubtful. Moreover, the technical information provided is, albeit detailed, narrow: it pertains, quite reasonably, only to the drug being advertised. It does not inform consumers of the full gamut of treatment and prevention approaches available, or of behavioural changes that could be made to manage the condition in question. And it cannot replace the expert and highly specific intervention offered by a physician in assessing the suitability of the drug given the particularities of an individual patient’s case, symptoms, circumstances and risk profile.

PART V – DTCA IN OTHER JURISDICTIONS

119. New Zealand is, along with the United States, one of only two Western countries that permit DTCA for prescription drugs. These jurisdictions have examined the question of how valuable the consumer education occasioned by DTCA actually is. A review of DTCA produced by staff members of four New Zealand medical schools raised questions about the effectiveness of DTCA as an educational tool. The report, which looked at DTCA over the three-month period from November 1999 to February 2000, found that one third of all advertisements in the print and broadcast media were “in breach of guidelines based on requirements of the Medicines Act. ... The most common reason for non-compliance was inadequate provision of risk information.”⁷⁰

120. Seventy-nine percent of physicians surveyed in New Zealand responding to one poll reported their patients had frequently asked for DTC-advertised medicines.⁷¹ As one doctor stated, “I have lost quite a few patients because I did not prescribe Xenical, Reductil, Symbicort, etc., because they were not appropriate.”⁷² Results of a survey of general practitioners in New Zealand showed that many were uneasy about the pressure to write prescriptions on demand. As one physician put it, “I find that it can be a nuisance as it creates doubts in patients’ minds about the efficacy of the medication they may already be on.”⁷³

121. It appears that, despite the complaints of some physicians, DTCA in New Zealand has been quite effective from a marketing perspective. It has resulted in patients asking their doctors to provide them with advertised drugs — even when the physician does not concur with the “need.” Three quarters of the

⁷⁰ Toop, L., Richards, L., Dowell, T., Dowell, M. T., Fraser, F., & Arroll, B. (2003). *Direct to consumer advertising of prescription drugs in New Zealand: For health or for profit? Report to the Minister of Health supporting the case for a ban on DTCA*. Christchurch, NZ: University of Otago, p. 34.

⁷¹ *Ibid.*, p. 5.

⁷² *Ibid.*, p. 20.

⁷³ *Ibid.*, p. v.

physicians surveyed felt that DTCA of lifestyle drugs “encourages the medicalisation of well populations.”⁷⁴

122. The report’s first recommendation was that the New Zealand government “introduce regulations and/or legislation to prohibit the advertising of prescription medicines directly to the public, through print and broadcast media or any other form.”⁷⁵ The committee, remaining sensitive to the importance of patient education, had a second recommendation: That the government establish an independent medicine and health information service free of commercial interest.

123. In the United States in 2000, the *Journal of Family Practice* published a paper entitled “The Educational Value of Consumer-Targeted Prescription Drug Print Advertising.” **Attached to my affidavit as “Exhibit 13” is a copy of this article.** After examining the content of 320 advertisements encompassing 101 drug brands DTC advertisements, the authors concluded that “most of the promotions provided only a minimum amount of information.”⁷⁶ Virtually all provided the name of the condition in question, and most gave information about symptoms, but few provided information about precursors or prevalence, attempted to clarify misconceptions about the conditions, or described the drug’s mechanism of action. The success rate, the duration of the treatment, alternative treatments, or behavioural changes that might enhance health were rarely mentioned.⁷⁷

124. The researchers believed advertisements could address 11 educational points. For 101 of the brands the researchers examined, the average number of educational points their advertisements actually addressed was only

⁷⁴ Ibid., p. 23.

⁷⁵ Ibid., p. 48.

⁷⁶ Bell, R. A., Wilkes, M., & Kravitz, R. (1999), 2.

⁷⁷ Ibid., p. 1.

3.2.⁷⁸ The authors concluded that “A time may come when DTC advertising is recommended for its educational value, but that day is not yet at hand.”⁷⁹

125. In October 2002, the United States General Accounting Office (GAO) issued a report entitled *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations*. The report discussed DTCA in general terms and then focused on a situation that was compromising the Federal Drug Administration’s regulation of DTCA promotion. As the report described, a recent change in the Department of Health and Human Resources’ policy for reviewing regulatory letters had sharply reduced the FDA’s effectiveness in issuing “untitled” and “warning” letters to pharmaceutical manufacturers in breach of FDA regulations on DTCA. The letters had been held back for some time, pending internal review of draft copies. The GAO report urged that letters be sent with more dispatch, thus more quickly arresting promotions that violated regulations. This was all the more important because DTCA campaigns are often short. Any delay in sending a letter might permit a promotion to run its course before the corporation received a letter.

126. Since the mid-1990s, pressure to promote DTCA in the European Union has increased. When the European Parliament rejected DTCA in Europe in 1998 it noted that drug spending in the United States had increased by \$43 billion between 1993 and 1998, with nearly a quarter of that spending going toward the 10 most advertised drugs.⁸⁰

PART VI – CONCLUSION

127. The main beneficiaries of DTCA are pharmaceutical companies, advertising agencies, and the media in which DTC advertisements appear.

⁷⁸ Ibid., p. 4.

⁷⁹ Ibid., p. 5.

⁸⁰ Houlton 2003, cited in Richardson, L., & Luchsinger, V. (2005). Direct-to-customer advertising of pharmaceutical products: Issue analysis and direct-to-consumer promotion. *J Am Acad Business, Cambridge*, 7 (2), p. 101.

Although proponents of DTCA justify its use on the basis that it provides information to consumers, allowing them to make good choices about how to manage their health, the available evidence does not support this claim. Rather, there are strong indications that DTCA does not inform consumers well, does not necessarily result in better treatment, has the potential to damage the relationship between physician and patient, and can drive up the overall cost of drugs.

128. The main goal of marketing efforts, including and especially advertising, by for-profit corporations is to maximize profits by increasing sales and/or market share. Pharmaceutical corporations are no exception: the primary motivation of DTCA, like that of all advertising, is to sell the product.

129. DTCA complements traditional “push” strategies in drug marketing with a “pull” strategy, creating a powerful synergy between the patient’s desire for a product and the physician’s gatekeeping capacity in the prescription of drugs. Through the physician’s prescribing authority, the patient’s want is formalized as a medical need.

130. Through the presentation of medical information, DTCA assumes an air of clinical authority. However, despite the scientific and technical “fine print” that accompanies DTCA, the “education” it provides is one-sided (largely ignoring the competition); incomplete (silent on alternative approaches to treatment); and self-interested (motivated by the objective of increasing profit).

131. The sample DTCA materials that have been filed as part of the Application Record in this proceeding show the hallmarks of “classical conditioning” advertising techniques, in which desirable states are associated with the advertised product, evoking a felt need for the product regardless of an objective need.

132. Physicians report that patients request unnecessary drugs, or drugs that offer no benefit over their existing medications, because of the influence of DTCA. Research also shows that physicians are susceptible to these requests.

133. The experience of the two other Western countries that allow DTCA, New Zealand and the United States, confirms the limited utility of the “educational” value of DTCA and bears out concerns about the propensity of this form of advertising to create “wants” for pharmaceutical products that are not necessarily congruent with medical “need”. DTCA is a highly effective marketing tool that supports the goals of advertisers.

134. I make this affidavit in response to this application, and for no other or improper purpose.

AFFIRMED before me at the City of
Toronto, in the Province of Ontario on
this 28th day of June, 2006.

Commissioner for Taking Affidavits

GURPRIT KINDRA

CANWEST MEDIAWORKS INC.

AND

THE ATTORNEY GENERAL OF CANADA

Applicant

Respondent

**ONTARIO
SUPERIOR COURT OF JUSTICE**

Proceeding Commenced at Toronto

**AFFIDAVIT OF GURPRIT KINDRA
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