DTCA3

DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION MEDICINES

A REVIEW OF LEGISLATION AND POLICIES IN THE DEVELOPED WORLD

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PART I: INTRODUCTION

1. OBJECTIVES OF THIS REPORT

This report is intended to address the following aspects of Direct to Consumer Advertising (DCTA) by pharmaceutical companies of medications and, in particular, prescription drugs:

1. From a health policy perspective, the policy considerations that have been identified in numerous developed countries in discussions and decisions on whether to allow, limit or prohibit DTCA;

2. A statement of the law in respect of DTCA in developed countries outside Canada and an examination of the health policy considerations and experiences that were identified in the process of legislating those laws.

2. APPROACH TO ASSESSMENT

A meaningful approach to the review of legislative and policy positions for Direct Consumer Advertising (DCTA)[1] of certain medications in developed countries outside Canada will necessarily involve more than a literal account of existing laws, regulations and policies with respect to DTCA. At the outset (Section 3), and by way of background, it will be helpful to examine briefly the historical, social and legal backdrop against which pre-existing instruments and policies relating to medicine and drugs evolved, the experience gained in their implementation, and any current or proposed modifications on which information is available. Only in this way can an opinion be formed of their relevance or otherwise to the relatively new phenomenon of DCTA as it emerged in the late twentieth century.

Sections 4 and 5 will then provide some account of experience and policies and laws regarding DTCA in a number of important fora, countries or regions during the last 2 to 3 decades. As in Canada, Great Britain prohibits DTCA of prescription drugs. DTCA of prescription drugs also remains prohibited in the other European Union member countries, even after proposed changes were considered but rejected. Among western countries, only the United States and New Zealand do not have laws limiting DTCA and within those jurisdictions debates about maintaining that status are ongoing.

Throughout this report I have attempted to distinguish objective evidence and well-documented views from materials reflecting primarily mere rhetoric or bias. On one hand, where statements favour DTCA they may in essence reflect only a commercial interest, whatever the materials advanced to support them. Opposition to DTCA, for example by health practitioners, might on the other hand be viewed by their critics merely as an attempt to obstruct progress or to preserve a longstanding professional

[1] References to the term DTCA, by itself, refer to advertising in respect of prescription drugs, unless otherwise indicated.

monopoly in imparting information on medicines to the public. Fortunately there are today a number of academic studies of experience with DTCA that throw a light on its effects, in particular an extensive investigation by Gilbody et al. published in 2005[2]; in addition, a number of relatively recent events have profiled the influence exerted by particular DTCA campaigns.

PART II: A REVIEW OF EXPERIENCE WITH DTCA

3. HISTORICAL DEVELOPMENT OF MEDICAL CARE AND MEDICATION

3.1 Early historical development

While the exuberant presentation of services, goods or wares to potential buyers is as old as commerce itself, a special situation pertains as regards medicines. That situation reflects the way in which the role of the health professional on the one hand and the "medicine maker" on the other has developed in the western world over a period of some three and a half centuries. There have been both favourable and unfavourable experiences, and these have led to the emergence of policies, law and regulations intended to serve the public interest and in part to counter directly those practices that have been considered injurious to that interest.

The view that the treatment of patients, involving variously diagnosis, treatment, advice and the provision of information, was primarily a matter for the professionally trained physician (supported by the apothecary or pharmacist), though it emerged over many centuries, was only laid down in western laws in and around the seventeenth century or later, an important element being the need to reduce the risk of charlatanism. In London, the college of Physicians was created in 1523, following continental examples, with the overall purpose of upholding and improving standards of medical practice and excluding impostors by maintaining a professional licensing system. Unlicensed persons however continued to make, sell and promote remedies directly to the public; particularly as printing came into widespread use and a newspaper press emerged, a regular trade in packaged "patent remedies" came into being. The massive outbreak of bubonic plague in London in 1663 sparked a continuous tradition of public advertising for medicines. Although the latter practice was widely condemned and satirized (for example by the author Daniel Defoe)[3], there was no regulatory response, although the college of

[2] Gilbody S., Wilson P, Watt I. (2005), Benefits and harms of direct to consumer advertising: A systematic review, Qual. Safety Hlth Care, 14: 246-250.

[3] "…it is incredible and scarce to be imagined, how the posts of houses and corners of streets were plastered over with doctors' bills and papers of ignorant fellows, quaking and tampering in physic, and inviting the people to come to them for remedies, which was generally set off with such flourishes a these, viz: "Infallible preventive pills against the plague"." "Neverfailing preservatives against the infection."…"Exact regulations for the conduct of the body in case of an infection…". Defoe D., (1722). "A Journal of the Plague Year." This is a work of fiction, but

Physicians attempted to publicize non-commercial remedies thought to be of some value against the disorder. Calls for the regulation of medicines and public advertising were ignored, though it is worth noting that they appeared at an early date:

> "…we would submit to the legislature the propriety of erecting a public board composed of the most eminent physicians for the examination analyzation and approbation of every medicine before an advertisement should be admitted into any newspaper or any other periodical publication and before it should be vended in any manner whatsoever."[4]

The foregoing illustrates the point that where medicines are presented to the public, the instruments of persuasion used and the concerns to which they give rise have in essence changed very little over the centuries. The language may have been modified but the techniques have not.

Legislation that limits DTCA, culminating in modern texts such as the relevant sections of the Canadian *Food and Drugs Act*[5], grew up progressively as a reaction to such historical antecedents as these, that continued down to the twentieth century. Such legislation was thus not conceived because of any bigotry or on theoretical grounds, but with the objective of putting an end to acknowledged abuses and risks when medicines were sold aggressively to the public.

3.2 The phase of regulatory development 1914 – 1994

The first influential moves to discourage the commercial provision of advice to the public on the medicinal treatment of illness were indeed undertaken voluntarily and professionally and they came more than two centuries later. In the Netherlands, the brothers Bruinsma published a critical volume on the subject in 1885, while in 1909 and 1912 the British Medical Association exposed numerous false claims in this field and called for restrictive laws and regulations.[6]

Between the world wars, a number of countries[7] enacted measures to prohibit the public advertising of remedies for major illnesses and epidemic diseases such as cancer and tuberculosis. Advertisements for the drug treatment of venereal diseases were prohibited in Britain by the Venereal Diseases Act of 1917, while the Cancer Act of 1939 placed similar restrictions on the promotion of drugs to treat malignant disease. A broadly based

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based on the events of the London Plague in 1664-5; the examples are fully in accordance with newspaper advertisements of the period.

[4] The Medical and Physical Journal, 1799. Cited by Penn RG (1979): The State Control of medicines: the first 3000 years. Brit. J. Clin Pharmacy; 8 293-305.

[5] *Food and Drugs Act*, R.S. c. F- , s. 3 and Schedule F

[6] British Medical Association: Secret Remedies (1908) and More Secret Remedies (1912). BMA, London.

[7] The examples of Britain and the Netherlands are noted below.

Pharmacy and Medicines Act of 1941 prohibited the advertising of any medicine to the public "in terms calculated to lead to the use of the product in the treatment of tuberculosis, Bright's disease, glaucoma, diabetes, epilepsy, cataract, locomotor ataxy, paralysis…" In addition a series of private-law systems of restriction on drug advertising were developed (for example by the mass media in the Netherlands) to ensure that public drug advertising was essentially limited to products for the relief of minor everyday disorders.

Such developments were undoubtedly one element in the distinction that had emerged quite clearly by 1940, between an "ethical" pharmaceutical industry promoting its products only to the medical profession and a "proprietary" industry selling simple minor remedies to the public.

When, prior to and following the Second World War, an increasing number of western countries adopted what was regarded as a modern form of drug legislation, the distinction between the two classes of medicines and the two types of advertising had become very clear indeed. For example, in Britain the *Medicines Act* of 1968 simply required that advertising to physicians be in conformity with the officially approved data sheet for the drug in question, the assumption being that the physician would be capable of detecting any other form of serious misstatement or exaggeration. However, regulations made under the same Act (*Labelling and Advertising to the Public Regulations*, 1978/41) provided (in their Schedule 2) lists of those conditions for which advertising to the public would not be permitted at all, or for which public advertising would be subject to specific restrictions. Curiously, if one reads these regulations critically, one has to conclude that they did not actually prohibit public advertising for the treatment of these conditions provided it did not lead to diagnosis or treatment *other than under medical* supervision. Literally, therefore, the regulations might have been read as permitting DTCA provided the reader was advised to consult a physician. They were not however so interpreted and, indeed, the British industry itself in its own voluntary code, in force from 1958 onwards, categorically stated that medicines subject to prescription must not be advertised to the public:

> "Medicines which cannot legally be sold or supplied to the public otherwise than in accordance with a prescription…must not be advertised to the general public." (ABPI, Code of Practice, London.)[8]

Also in the post-war period, consumers in western countries saw their lives "medicalized" to an extent that was previously unknown. The manner in which, from 1956 onwards, entire populations became habitual users of benzodiazepine tranquillizers (sold as "Valium", among other brand names) as a means of keeping all worry and

[8] Issued by the Association of the British Pharmaceutical Industry, and in force until a revised Code was published forty years later.

discomfort at bay – though not a consequence of explicit DTCA – is commonly cited as a classic instance of the deliberate "medicalization" of life by pharmaceutical companies.[9] However, this was not the first development of its type. The advertisement of a cure for "melancholy" published in 1734, illustrated in the advertisement reproduced in Schedule 1, was essentially adopting the same means of sales promotion in the same field.

3.3 The re-emergence of DTCA

It was only in later years that the pharmaceutical industry in certain countries[10] altered its view of this matter and started to call for DTCA of prescription medicines. Some writers trace the development only back as far as 1993, when frank advertising of such medicines became prominent in the U.S.A. (see section 4.7, below); it is, however, clear that various attempts to exert a direct influence on the public had emerged much earlier, though not necessarily in the form of explicit advertisements for specific medicines. Advertising campaigns designed to alert the public t o particular symptoms and disorders and the need for treatment, without any mention of a specific drug, had become popular in the U.S. well before 1990, and have since become widespread elsewhere even where explicit DTCA is not permitted. In the U.S., the fact that the FDA in 1997 issued specific guidelines for advertising through electronic media, simplifying pre-existent requirements as to warning texts, may have contributed to the increasingly rapid growth of DTCA after that date.[11]

The re-emergence of DTCA of drugs has generated discussions in western countries about whether the practice should be permitted and how it should be regulated. These discussions, from the regulator's perspective, have been premised on policy considerations that flow from both experience and research. The next section addresses the policy considerations identified in global, regional and national discussions of DTCA.

3.4 Current forms of DTCA

When approaching this field from the regulatory point of view, i.e. the area of my own experience and research,[12] I find it is necessary to realize that DTCA can take many

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[9] See for example the study by Medawar C. (1992); Power and Dependence. Social Audit, London.

[10] The movement began in the United States and was followed later in New Zealand, as discussed in this report.

[11] See Rosenthal M.B., Berndt E.R., Donohuie J.M., Frank R.G. and Epstein A.M. (2002): Promotion of Prescription Drugs to Consumers. N. Eng J. Med, 346: 498-505. See also Angell M. (2004): The Truth about the Drug Companies. Random House, New York at pp. 123-4.

[12] As Vice Chairman of the Netherlands Regulatory Authority from 1972 onwards I had the rank of Inspector of Drugs, and routinely advised the Chief Inspector on breaches of the advertising rules. From 1982 to 1992, as head of the pharmaceutical programme of WHO Europe I advised regulatory authorities both on developing regulations and on dealing with specific cases where the rules had been breached.

forms, and if one is to protect the public interest adequately they need to be looked at as a whole. It is obvious that policy on explicit public advertising, originally designed to deal with newspapers and periodicals, will today only be effective if it is also applied in an appropriate form to advertising in other media; these will include radio, television, handouts, billboards and suchlike, and that the application of this policy to the Internet (see later) will also need to be considered. Some countries, as noted later, have adopted this broad approach more clearly than others.

For the Legislator and regulator there is also the question of the right approach to non-explicit and indirect public advertising that takes many forms and sometimes seems intended to evade regulatory controls. Examples, mostly taken from my own practice, include:

a. The provision of attractive ready-written "journalistic" articles on health issues to the media or to special supplements. Indistinguishable from the contributions of staff journalists or free-lance writers these are readily accepted by many publications, especially as a means of containing staff costs.[13]

b. Contacts with the editors of dramatized TV-series, especially those having a medical or hospital background, to ensure that a particular disorder, treatment or drug is featured.

c. The sponsoring of apparently independent "front" organizations to plead the cause of a particular treatment.[14] In the United States, associations of parents of "difficult" children were heavily financed by the manufacturers of the stimulant drug Ritalin and played a prominent role in developing the use of that drug in the treatment of the so-called Attention Deficit Hyperactivity Disorder (ADHD).[15] The notion that the menopause was a pathological condition demanding the use of

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[13] Boseley S. Crackdown on drug company hype. The Guardian, February 23, 2005. The article concerns the sponsorship by Glaxo Smith Kline of a supplement on Asthma for the (London) Sunday Times. The supplement however includes an article that appeared to promote the GSK drug Seretide for the treatment of the condition.

[14] In 2003 the very large US seniors Group AARP (the American Association of Retired Persons) accused the pharmaceutical industry of funding "front" groups that purported to represent older Americans but instead pushed industry-friendly political messages. The AARP provided details of substantial drug company funding to the United Seniors Association, the Seniors Coalition and the 60 Plus Association. See Moynihan R., US seniors group attacks pharmaceutical industry "fronts". Brit med J. 2003; 326: 351.

[15] A substantial group of psychiatrists deny that ADHD is a pathological condition requiring treatment, while others consider that a number of cases do exist but that the condition is grossly overdiagnosed, particularly in the U.S. Problems have related to dependence and to misuse of this stimulant drug as well as to the apparently increasing use of antipsychotic drugs in American children given this diagnosis. See for example Breggin P.R. (2001): Talking back to Ritalin (Second Edition). Perseus Publishing, Cambridge, Mass. As regards antipsychotic use see Anon. Rapid rise in antipsychotic use for children with ADHD, US study finds. Scrip 3146, April 7, 2006, at p. 13.

estrogens was in some countries largely developed by a firm providing speakers, lunches and visual aids to meetings of local Womens' Institutes.[16]

d. Presenting the public with partial views on a still unsettled scientific debate. Bearing in mind that in all western countries all advertising must confirm to the regulatory text approved by the authorities, which is based only on accepted facts, this is a serious contravention of the rules. A striking example of this practice was reported very recently from the U.S. Following the Sanofi-Aventis company's introduction of its hypnotic Ambien (zolpidem tartrate) reports appeared to the effect that some patients using the product could not recall driving or eating while sleepwalking. In March 2006 a civil suit was filed against the company alleging that it had failed to warn of these risks. Apparently concerned that reports on these matters would harm sales of the product, Sanofi-Aventis took full page advertisements in major U.S. newspapers to persuade the public inter alia that somnambulism was a very rare side effect and that it could be a complication of insomnia itself rather than of the product.[17]

The above are only examples of techniques that have presented challenges from the regulatory point of view. A marketing expert could naturally add others. A well-researched report by Consumers International, published in June 2006 ("Branding the Cure") expresses grave concern at the extent to which these techniques are now being used in Europe by multinational companies to influence public opinion and beliefs in favour of particular forms of medicinal treatment.

3.5 Disease mongering and DTCA

"Disease mongering" is a phenomenon that is currently causing much concern in drug policy and public health circles. It is so closely linked to DTCA that it must be considered where policy is concerned.[18] The technique is an ancient one, as evidenced by the eighteenth-century example in Schedule 1. From the public health point of view one can only view it as a means of promoting drug sales by suggesting to healthy individuals that they are suffering from a pathological state requiring medicinal treatment. Because of the risks of necessary use of drugs, it is directly contrary to the interests of public health. Examples of situations in which pathological disorders have either been "created"

[16] N.V. Organon, The Netherlands; sponsor of film starring Silvia de Plath, at the time a menopausal film star. Distributed in The Netherlands, 1969, Personal records. I observed this practice at first hand at the time in my role as Research Manager of Organon in The Netherlands.
[17] See Anon. Sanofi-Aventis runs DTC adverts to counter publicity on sleepwalking risk. Scrip Nr. 3146, April 7, 2006 at p. 15
[18] See my documented account of the technique in Dukes G, (2005): The Law and Ethics of the Pharmaceutical Industry. Elsevier, Amsterdam, Heidelberg, London etc. at pp. 207-209. See also proceedings (in press) of the Inaugural Conference on Disease-Mongering, Newcastle NSW, Australia April 11 to 13, 2006. The proceedings closely parallel papers in an associated theme issue of PloS Medicine, published simultaneously by the US Public Library of Science.

or exaggerated by marketing range from the trivial to the frankly dangerous; a number of examples are presented in Schedule 2.

Tiefer in the U.S.A. has discussed the attempt by Messrs. Proctor and Gamble – originally a soap manufacturer – to promote the concept of "female sexual dysfunction" – in order to create a market for its proposed transdermal testosterone patch for women:

> "I think (they had) a marketing plan that worked for shampoo. Create a buzz, get the word out, heighten consciousness, get people talking…then it won't be seen as the company pushing its product, it will be seen as health education…."[19]

Quite apart from the risks of unnecessary treatment, the individual, as Tiefer goes on to point out, may be unnecessarily alarmed, fearing that every headache may point to hypertension and that unusual thirst indicates the presence of diabetes. In Britain, Dr. Iona Heath, outgoing Chairman of the Committee on Medical Ethics of the Royal College of General Practitioners gave evidence in 2005 to a Parliamentary Committee of this occurring in her own experience. She cited campaigns urging women undergo bone density testing to detect early osteoporosis, so-called educational publicity advising that cholesterol levels be measured and campaigns stressing the risks of hypertension. A general practitioner in Britain reported typically in 2005: "Recently I have had several patients attend as a result of being frightened by advertisements in the popular press" – the publicity in question being intended to alert the public to the risk of tinea nail infections.[20]

Closely similar is the type of disease awareness campaign that may exaggerate the frequency and severity of a particular symptom and its eligibility for medicinal treatment; while not mentioning a specific drug, such a campaign is likely to coincide with the clinical testing or medical marketing of a drug that might be used in this condition.[21]

3.6 Conclusion

All of the foregoing points in Section 3 form the backdrop against which the regulatory authorities in various developed countries or regions have engaged in formulating policy and, in most cases, have taken legislative steps to implement or retain laws in respect of DTCA, which are addressed in the next Section.

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[19] Tiefer L. (New York) as cited by Moynihan R. The Marketing of a disease: female sexual dysfunction. BMJ 330; 192-194.

[20] McAll G.L.G. Doctors may end up treating the effects of scaremongering. Brit med J. (2005); 300: 1332.

[21] See Dyer O. (2006): Disease awareness campaigns turn healthy people into patients. Brit Med J, 332, 871. The author cites the work of Woloshin and Schwarz (PloS Medicine, special issue, op. cit.) regarding the campaign by GlaxoSmithKline in the U.S. to promote awareness of "restless legs" as a disease entity, coinciding with the clinical testing of a drug (roprinirole) for use in this condition.

PART III – LAWS RELATED TO DTCA IN VARIOUS JURISDICTIONS

4. LAWS AND EXPERIENCES: GLOBAL, REGIONAL AND NATIONAL

In this Part, I set out the state of the law and experience in a variety of jurisdictions outside Canada. The laws of the jurisdictions discussed, where available in either English or French, are attached as "Annex 1" to this report). It is helpful at the outset, however, before the detailed examination of the policy considerations related to DTCA that have emerged in the developed world (in Part IV) to describe the core common bases for the DTCA policy decisions in these jurisdictions. They centre on two areas of foreseeable effects of DTCA: first, the concern about health related effects and, second, the commercial and financial effects.

4.1 Foreseeable Health Related Effects:

The possible consequences for public health of DTCA relate to its demonstrated ability to bring about rapid changes in prescribing habits, older drugs being replaced by newer products shortly after introduction of the latter to the market. Sometimes this may be to a patient's advantage; commonly it will not be. In my opinion, one has to bear in mind:

- the fact that of all new medicinal compounds introduced to the market only a small proportion offer advantages over older products in terms of efficacy or safety;
- the demonstrable fact that the true efficacy and safety profile of a new drug is rarely well-defined at the time of its introduction to the market. The full picture is only likely to emerge in the light of experience in the field.

For both these reasons the wise prescriber and patient will adopt a cautious attitude to new drugs, remaining with a well-proven older treatment unless this has such disadvantages that one needs to look out for an alternative. These issues will be dealt with in more detail in later sections of this report.

4.2 Foreseeable Commercial and Financial Effects

The industry itself has provided incontrovertible evidence that DTCA is cost-effective, its own experience in the USA leading it to increase rapidly over a decade its investment in this form of publicity. Various independent studies have confirmed its ability to convince patients and thereby to overwhelm prescribing physicians with demands for new medicines, demands which prescribers commonly find themselves unable to resist.[22] It has also been possible to calculate or estimate the ultimate financial consequences of this process for the public health service; it is notable that the Wall Street Journal in 2002

[22] See in particular Kravitz R.L., Epstein R.M., Feldman M.D. et al. (2005): Influence of patients' requests for direct-to-consumer advertised antidepressants; a randomized controlled trial. JAMA; 293: 1995-2002.

used a well-documented headline: "In Europe, Prescription-Drug Ads are banned – and Health Costs Lower."[23] It is obvious that where the patient himself or herself pays for the medicine the personal financial consequences will be no less pronounced. The consequences of these findings when seeking to delineate further health policy regarding DTCA are considered later in this report (Sections 7 and 9.2).

4.3 Global Regulation: The World Health Organization

It cannot be said that there is any global policy with respect to DTCA; the USA and New Zealand accept the practice despite some internal criticism; other western countries reject it. In the developing world and in countries with a centralized economy, where drug policies are conducted in a different situation, the position has to be viewed differently and is not truly relevant to the present issue.

In 1988 the World Health Organization published a set of *Ethical Criteria for Medicinal Drug Promotion*.[24] This initiative followed on the WHO's own previous model of managing the marketing of a health related product in 1981, when it adopted an International Code of Marketing of Breast milk Substitutes. (This followed an international outcry over marketing methods used by manufacturers' breast milk substitutes who aimed to convince mothers in developing countries that the manufactured substitutes were necessary in the place of mothers' breast milk for the health of their children. In the most cases, the women had no access to clean water to mix with the substitute, creating a great risk to the health of their babies. The substitutes also lacked the immuno-protective substances contained in breast milk). Because of opposition by the International Federation of Pharmaceutical Industry Associations[25] the text of the 1988 *Criteria* was weaker than that originally drafted. The *Criteria* are not legally binding on any country and there is no effective enforcement mechanism.

A relevant provision of the WHO *Ethical Criteria* reads that DTCA "should not generally be permitted for prescription medicines or to promote medicines for certain serious conditions that can be treated only by qualified health practitioners." The first part of this rule is intended to cover those situations where there is a legally binding list of "prescription only" medicines, the second primarily for those situations where no such list exists.

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[23] Wall Street Journal, March 15, 2002, page B1; See also Findlay, citation (sec. 7)
[24] W.H.O. (1988): Ethical criteria for Medicinal Drug Promotion. World Health Organization, Geneva.
[25] The Federation was entitled to be present at the World Health Assembly as a non-governmental organization.

4.4 The European Union and Selected European Countries

DTCA of prescription medicines has always been specifically prohibited in its entirety by the European member states.[26] Particularly from 2000 onwards, however, the pharmaceutical industry made a move to overturn this tradition as part of the development of harmonized laws and regulations throughout the Union. As a result of this, a proposal was drafted to permit the "experimental" use of DTCA for three chronic disease states (asthma, HIV/AIDS and diabetes).

At prior consultations before a scheduled debate in the European Parliament on the issue in 2002, representations advanced by delegates from the industry were countered by opponents of DTCA, including consumer representatives. Members of the Parliament had the opportunity during the consultations to view examples of DTCA television advertising from New Zealand.[27] Following these preliminaries, the proposal to permit DTCA was overwhelmingly rejected by the European Parliament by a vote of 494 to 42. Early in 2003 Europe's Council of Ministers also voted against the proposal, thus definitively rejecting it.[28] Following further pressure from industry, the European Commission then sought a compromise, permitting "experimental" use of DTCA for certain conditions of public health importance for a trial period of five years. This pilot scheme was eventually cancelled. Documents relating the developments in the European Union are attached to this report as "Annex 2".

The only current development at the European level is concerned with the dissemination of medicinal information (rather than promotion) through the Internet to the general public; Article 88A of Directive 2004/27/EC allows the EU Commission to provide a proposal on the benefits and risks of such a practice; this report is likely to take three years from the implementation date of Directive 2004/27/EC for completion.

Current European law therefore still prohibits DTCA categorically. The fact that in some member states companies have attempted to circumvent the prohibition does not alter the fact that it remains fully in force and that member states are obliged to implement it.

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[26] This applies to the 15 older member states of the European Union. Information on the situation as it applied in the past to those states from central and Eastern Europe which joined the E.U. at a later phase is not readily available, but in most of these the advertising restrictions dated from the period of centralized economy and were extremely strict. My direct experience with the relevant policies in these latter countries dates from my work at the World Health Organization (Europe), 1982-1992.

[27] I myself was present as an expert adviser at the principal consultation in Brussels.

[28] A good account of the events in 2002 in Europe is provided by Meek C. (2003): Direct-to-Consumer Advertising (DTCA) of Prescription Medicines: Fourth Quarterly Update. Royal Pharmaceutical Society of Great Britain, London.

4.4.1 Sweden

Although Sweden is a member of the European Union and therefore subject to the prohibition of DTCA under the EU Directive on Medicine Advertising, no specific provision to this effect had up to 2003 been included in Swedish law. Regulations promulgated by the Swedish Medical Products Agency NBL did not prove effective; in 2002 nearly a third of cases brought before the NBL in connection with illegal advertising related to direct advertising of prescription medicines to the public. In 2003 the authorities took steps to remedy the legal loophole.[29]

4.4.2 France

DTCA is not permitted in France but firms have conducted disease awareness campaigns to the public in parallel with specific advertising to physicians regarding new products for these same conditions. The influential medical journal Revue Prescrire has provided much evidence of the undesirability of such campaigns but there appears to have been no factual study of their influence.[30]

4.4.3 Netherlands

As in France, DTCA is not permitted in the Netherlands, but disease awareness campaigns to the public have been conducted in parallel with new product introductions to physicians. 't Jong and Stricker found a close correlation between the sales of terbinafine and the commencement and termination of an industrial disease awareness campaign on nail fungus infections,[31] the condition in question is generally treated without the use of drugs.

4.5 Australia

DTCA is prohibited under the Australian *Therapeutic Goods Act*.[32] According to some reports, Australian negotiators had been willing to forfeit the prohibition as part of the Free Trade Agreement concluded with the United States, but this has been authoritatively denied and the prohibition remained in force.[33]

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[29] See Anon. Illegal advertising on the rise in Sweden. Scrip Nr. 2908; December 5, 2003 at page 6.

[30] See for example La Revue Prescrire (2003) Nr. 244, page 800a; « Encore une campagne qui contourne la réglementation de la publicité des medicaments de prescription auprés du public ». (Relating to publicity in France for Lamisal tablets by the Swiss Novartis company).

[31] 'tJong GW, Stricker BH, Sturkenboom MC: Marketing in the lay media and prescriptions of terbinsfine in primary care: Dutch cohort study. Brit med J. 328: 931.

[32] Therapeutic Goods Act, 1989, Nr. 21, 1990; current text with amendments: Nr. 39, 2006.

[33] Grabau B. A matter of ethics. Scrip Magazine, May 2004 at p. 27

More recently, reconsideration of the issue has been urged as part of the emergent agreement with New Zealand to create a joint drug regulatory system. Views as to the outcome of the negotiations differ, but it is widely believed that Australia will retain its prohibition whatever decision is taken in New Zealand.[34]

4.6 New Zealand

New Zealand has never explicitly prohibited DTCA, but as in many other countries it simply did not develop for a long period because it had been widely assumed that it was not appropriate or necessary; ethical medicines were promoted to and prescribed by doctors, and proprietary medicines were promoted to and bought by the public. The authorities noted the WHO *Ethical Criteria* of 1988 with their provision that DTCA "should generally not be permitted for prescription medicines" but also noted that the WHO document was not legally binding.[35] The Medicines Act of 1981 and the Medicines Regulations of 1984 offered certain disincentives but only to "unbalanced" or "inappropriate" DTCA. It was further noted that a full prohibition on DTCA might constitute a limitation on the right to freedom of expression under Section 14 of the New Zealand Bill of Rights Act.[36]

Against this background, and following the U.S. example, DTCA developed rapidly in New Zealand, expenditure in 2004 reaching $NZ 38 million – some 50% more than was being spent on advertising for non-prescription over-the-counter items.

In 1998, because of the rapid growth of DTCA, and particularly the appearance of an intensive media campaign for the anti-obesity drug Xenical, the then Minister of Health called for an enquiry into DTCA. Considering that physicians had expressed very strong opposition to the practice, the Minister ultimately decided that it would keep a "watching brief" on DTCA and require from industry a commitment to self-regulation.

In 2001, following a statement in 2000 by a subsequent Minister of Health that DTCA should be restricted by law, a public consultation on the subject was held and submissions invited. Some 50% of the submissions received were from the industry or from advertising bodies and all these favoured the continuation of DTCA. Of an equal number of submissions received from other bodies (including the public and educational institutions), 77% were opposed to DTCA.[37] The decision was to continue the practice, though a tightening of the regulations was recommended.[38]

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[34] This statement is based on consultation in May, 2006 with Health Action International, based in Amsterdam, that has in recent months examined opinions expressed and developments reported from Australia on this matter.

[35] Ministry of Health, Wellington: Direct-to-Consumer Advertising of Prescription Medicines in New Zealand: Consultation Document, March 2006 at p.42.

[36] ibid at p.25, referring to the New Zealand Bill of Rights Act of 1990.

[37] See Ministry of Health Website, www.moh.giovt.nz.

[38] For a very recent overview of the situation in New Zealand, see the consultation document "Direct-to-consumer Advertising of Prescription Medicines in New Zealand" (Ministry of Health,

Very recently, the situation was reviewed once again by the Minister of Health, who invited and received replies to the consultation document. The documents related to this recent consultation are attached to this report as "Annex 3".[39]

The debate has now been reopened because of the intention by Australia and New Zealand to establish a joint drug regulatory authority.

4.7 The United States

Modern direct-to-consumer advertising in the United States began inauspiciously. Though not explicitly prohibited, DTCA had been little used until 1982 when the Lilly company employed it on a large scale alongside professional promotion to introduce its supposedly highly innovative anti-arthritic drug benoxaprofen (brand name "Oraflex"). Ad described in section 9.1.2. below, the drug rapidly proved to be toxic and was hastily withdrawn. As a direct result, the Food and Drug Administration declared a moratorium on DTC advertising on prescription drugs that was maintained from February 1983 to September 1985.[40] No further significant attempt to exploit the technique appears to have been undertaken until about 1992, after which several firms used it on a large scale. The growth of DTCA has since that time been spectacular and the method has been employed in most new product introductions during the last decade. As noted earlier (Section N), the FDA in 1997 issued specific guidelines for drug advertising through electronic media and it has been suggested that this further accelerated the growth of DTCA by according it a place as a recognized, though regulated, technique. Expenditure on DTCA in the United States rose from US $791m in 1996 to $2,467m in 2000.[41]

The Vioxx drama in 2004 (see Section 9.1.2. below) again led, as had the benoxaprofen issue two decades earlier, to a reconsideration of DTCA practices in the U.S.A. On this occasion the FDA did not directly restrict the use of DTCA but a number of limitations were agreed with the industry, including a delay in public advertising for an (unspecified) time after marketing.[42]

It is also notable that in 2005, more than 200 professors of medicine in the United States submitted a petition to the Food and Drug Administration proposing that DTCA be

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Wellington, March 2006) and replies submitted to this document, in particular a critical submission from four University Department of Clinical Pharmacology (Toop L. er al.) issued on April 25, 2006.

[39] Ibid.

[40] New York Times, August 5, 1982: http://query.nytimes.com/gst/fullpage.html?sec=health&res=9D02E4DC1039F36A3575BC0A964948260&n=Top%2fNews%2fHealth%2fDiseases%2c%20Conditions%2c%20and%20Health%20Topics%2fArthritis%20and%20Rheumatism

[41] Data from IMS Health and Competitive Media Reporting, as cited by Rosenthal et al. (2002), op. cit.

[42] Mintzes B. (2006) Direct-to-Consumer Advertising of Prescription Drugs in Canada. Report for the Health Council of Canada, at pp 15-16,

prohibited. Controversy continues and the FDA is currently reported to be reconsidering its policy with regard to DTCA.[43]

4.8 Japan

Limited DTCA is permitted in Japan.[44] Major firms have made use of it to a considerable extent in both the traditional media and in adapted form on the Internet. Late in 2004, the Japanese Subsidiary of Glaxo Smith Kline was using a dramatized video on its publicly accessible website to draw the attention of the public (and of health professionals) to signs and symptoms which might indicate the presence of depression, justifying the use of drug treatment.[45]

Since the pharmaceutical market and the use of medicines differs considerably in Japan from that in western countries, the relevance of detailed information on Japanese policies and practices to the present case is diminished.

4.9 South Africa

As of 2002, the South African Medicines Control Council has maintained a longstanding prohibition on DTCA, though the legal basis for this was unclear; it appeared to reply on a broad interpretation of General Regulation 11.[46] The South African Pharmaceutical Manufacturer' Association released a new Code of Practice for Marketing in 1998[47] that did not provide for explicit DTCA but did give guidance on various forms of information that could be directed to consumers (educational materials, patient aids, competitions) without directly mentioning a product; the code requests manufacturers not to initiate media articles that mention prescription products. Television Advertising aimed at professionals (and thus accessible to the public) is also permitted under the Code.

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[43] Mintzes B. (2006): Direct-to-Consumer Advertising in New Zealand: Submission to Consultation." (Unpublished report) at p. 4.

[44] See for example Asahi Shimbun website, consulted May 18, 2006: "Pharmaceutical companies can now use direct-to-consumer (DTC) ads to inform people about certain diseases, and recent deregulation allows ads to solicit subjects for drug testing. These trends have invigorated pharmaceutical companies' newspaper advertising."

[45] See Anon. GSK uses drama to spread Japan depression messages. Scrip Nr. 2001, November 3, 2004 at p. 21.

[46] Gray G and Day C. (2000): How should South Africa deal with direct-to-consumer (DTC) advertising within the context of globalization and the Internet? Position Paper prepared for Health Systems Trust, Durban.

[47] Pharmaceutical Manufacturer' Association of South Africa. Code of Practice for the Marketing of Medicines in the Republic of South Africa. August 1998.

4.10 Turkey

In Turkey direct DTCA is virtually unknown and even indirect promotion is discouraged. The "Code of Ethical Promotion Practices for Medicinal Products" drawn up by Turkey's Association of Research Based Pharmaceutical Companies (AIFD), that in its present form came into effect on November 2005[48], is unusually strict and reflects the actual situation. It includes the following clauses (cited from the English edition):

> 16.1. Prescription-only medicines advertisement (promotion) to the general public is strictly prohibited.
>
> 16.2. Reimbursed medicines shall not be advertised to general public either.
>
> 16.3 The prohibition in clause 16.2. does not apply to vaccination campaigns approved by the Ministry.
>
> 16.4. Companies are responsible for information about their products, which is issued by their public relations agencies.
>
> 16.5 Registration holders are responsible for taking the necessary steps and actions to correct promotional and promotional-looking news in the printed media about their prescription-bound products and for informing the Ministry about the outcome.

5. CAN NATIONAL EXPERIENCE BE EXTRAPOLATED?

With increasing globalization there is a tendency to consider that the experience of one society can generally be evaluated to others. There are however clear exceptions to this rule; these exceptions may sometimes be temporary, where one society has developed more rapidly than another in a particular direction but they can also reflect fundamental differences between societies. It is clear that, where DTCA is concerned, a large number of western countries have at various times examined the practice and decided against it. With the United States forming the major exception to the rule, one is bound to ask whether in this matter the U.S.A. has advanced faster and further than other countries or whether the reverse applies.

In many issues of law and policy, the United States and other western countries are on very similar tracks, yet some fundamental differences do remain. Prominent among these is the massive social influence of large U.S. corporations and their ability to influence political decisions in their favour (in part, without doubt, because of their financial and lobbying techniques).[49] On the other hand very recent developments in that country do point to an ongoing tendency to retreat from that extreme situation. Corporate scandals have been tackled seriously by the judiciary; perceived malpractices within the drug

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[48] A.I.F.D. Code of Ethical Promotion Practices for Medicinal Products, Second Edition, Istanbul, 2005.

[49] For lobbying statistics see Anon. Big pharma spends most on lobbying Congress. Scrip Nr. 3071, July 13, 2005 at p. 18.

industry have become the subject of massive litigation on a scale that could well threaten the existence of at least one major corporate; lobbying and other forms of relatively hidden influence on pharmaceutical policy have been increasingly questioned,[50] and in the specific area of medicinal advertising policy reforms have been called for.

Specifically as regards advertising to the public it is noteworthy that in July 2005, Senate Majority Leader William Frist called for pharmaceutical companies to voluntarily restrict their DTC advertising for new drugs for two years after their approval for marketing; more broadly he was requesting the Congress's General Accounting Office to analyse the FDA's oversight of prescription drug advertising, the industry's spending on such advertising, and the potential impact on utilization, health care spending and patient education and awareness.[51] These are at least signs that the U.S. situation is likely to be reconsidered in the foreseeable future and that within the coming decade some gaps between the U.S. and other eastern countries in matters of policy and practice may be narrowed by shifts of view within the U.S. itself rather than elsewhere.

PART IV: GENERAL ACCEPTED POLICY CONSIDERATIONS

6. ACCEPTED POLICY CONSIDERATIONS FOR RESTRUCTING INFORMATION, COMMERCE AND ADVERTISING: GENERAL PRINCIPLES

The following policy considerations form the expanded basis on which global, regional and national authorities have engaged and decided the issue of DTCA – and almost all in favour of limiting the practice. These policy considerations concern the nature and objectives of advertising, especially in the modern western world, the goal of ensuring public health and avoidance of risk, and the nature of the modern practice of medicine and the public's demand for information.

6.1 The concept of truth

As noted above, public advertising for goods or services is widely regarded as a commercially permissible activity in a society based on liberal principles. The one general limitation to which the advertiser is considered subject is the *requirement to tell the truth*. Truth, unfortunately, in an age of highly developed marketing, is sometimes a flexible commodity; it can be extremely difficult to determine where truth ends and exaggeration, improper suggestion or subtle falsification begin.

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[50] Dukes G. The Law and Ethics of the Pharmaceutical Industry. (2005) Elsevier: Amsterdam, Heidelberg etc. at pp. 60-61, also Pear R (2003): Drug companies increase spending on efforts to lobby congress and government. New York Times, June 1, A1, 33, and sources cited there including statement by Sen. R.J. Durbin.

[51] Anon. Senator Frist wants voluntary ban on DTC ads for new drugs. See scrip. 3072, July 15, 2005 at p. 15.

The more sophisticated or technically advanced the product and the more complex the evidence as to its properties, the greater the difficulty experienced by the audience in recognizing and defending itself against misleading advertising. These considerations certainly apply to a large extent to medicines where the factual material claiming to demonstrate the relative superiority of one drug as compared with another, whether in terms of efficacy or safety, is commonly of great complexity; many a physician will fail to understand it, and even statisticians may disagree strongly as to its significance.

> When in 2002 a number of women (or their representatives) who claimed to have been injured by the third-generation contraceptive "pill" brought a legal action against the manufacturers in Britain, the High Court was faced by head-on disagreement between some of the world's most prominent statisticians as to the evidence that this project raised the risk of thromboembolism to a significant extent as compared with the older products.[52]

6.2 Demonstrable risk

When evidence establishes that the selling or advertising of a particular product or the promotion of a particular practice indication actually causes injury, regulators consider that they have a firm policy basis to impose a legal prohibition on that activity in the public interest. The limits set in almost all countries to the sale and promotion of alcohol and more recently tobacco reflect this principle; over a much longer period rules have applied for the same reason to the introduction and marketing of "dangerous drugs" and in the course of the twentieth century, particularly in the light of a series of drug disasters, rules have been applied to all medicines.[53]

Where DTCA is concerned, the now extensive experience with this practice in New Zealand and America provides a basis for the assessment of the risks actually associated with it, and some of these have already been touched on in this report. The issue will be considered in more detail in Section N. below.

6.3 The concept of "misleading" advertising

There is a striking unanimity between those national laws and cases with which I am familiar relating to advertising in their holding that:

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[52] Queens Bench Division, High Court, London; Judgement by Mr. Justice Mackay, July 29, 2002. For a general account of these proceedings see Dukes G (2005): The Law and Ethics of the Pharmaceutical Industry. Elsevier, Amsterdam, Boston and Heidelberg, at p. 36.

[53] The history of the principle drug disasters and the regulatory response to them has been reviewed by Dukes MNG, Mildred M and Swartz B (1998): Responsibility for Drug-Induced Injury (Second Edition). IOS Press, Amsterdam, London etc.

- an advertisement shall not be misleading (i.e. it shall not breach the principle of honesty considered above)
- an advertisement can be misleading by virtue of the omission of relevant facts that could influence a potential buyer's judgment
- an advertisement as a whole can be misleading even though the individual elements in the text or presentation may be correct.[54]

In considering the case of DTCA in this report (notably in section 10.2 below) it can be helpful to bear these undisputed principles in mind.

7. FINANCIAL JUSTIFICATION FOR RESTRUCTIONS ON BUSINESS PRACTICES

Where the community is financially disadvantaged as a result of particular commercial practices there may be valid policy grounds for restricting or prohibiting the latter. That principle has been clear in national laws in western society for a matter of centuries; one sees it clearly at work, for example, in the manner in which Britain intervened in the affairs of the East India Company in the eighteenth century and emergent industry in the nineteenth.

There are numerous and diverse examples of control at the present day. Financial firms, for example are subject to regulation designed to prevent their becoming excessively large, with too great a potential for abuse of power or for exerting excessive influence on the public economy and consumer choice. At the European level, public interest groups are currently urging curbs on the influence of major corporations on E.U. economic policies. Judith Richter (op. cit.) has provided a helpful analysis of financial principles that provide a basis for restricting business practices today, pointing inter alia to the risk that major corporations can enrich themselves unduly at the expense of the community.

Where drug advertising is concerned, a valid policy basis for imposing some form of restriction is the evidence that certain forms of promotion result in a considerable and unjustified increase in expenditure that the health system and the community as a whole cannot afford; Britain in the eighties imposed firm restrictions on its own pharmaceutical industry with respect to both profits and advertising expenditure. That similar controls have not been imposed much more widely appears to be due more to the growth of a commerce-friendly society than to any lack of justification. Findlay (2001) has provided impressive evidence that in the United States the mass advertising of prescription drugs

[54] See for example: Fueroghne, Dean K. (1995). Law & Advertising: current Legal Issues for Agencies, Advertisers and Attorneys. The Copy Workshop, Chicago Ill.; Baker, Samm Sinclair (1968). The Permissible Lie: The Inside Truth About Advertising. Cleveland, OH: The World Publishing Company. See also: Advertising Law and Ethics, Department of Advertising of the University of Texas at Austin (website consulted, May 30, 2006): http://advertising.about.com/gi/dynamic/offsite.htm?site=http%3A%2F%2Fadvertising.utexas.edu%2Fresearch%2Flaw%2Findex.html

has led to considerable and indefensible increases in drug expenditure.[55] While in the US as a whole DTCA expenditure amounted to only one sixth of that on advertising to professionals and in 2002 accounted for only 2.2% of overall drug sales,[56] it has to be borne in mind that DTCA was concentrated on a relatively small number of new products. For the nasal spray Nasonex, the cost of DTCA amounted to nearly 20% of sales.[57] DTCA has functioned moreover to catalyse and increase the response to promotion directed simultaneously at physicians.

The increasing need for governments to seek a balance between many different and sometimes competing interests -- social, commercial, financial, etc. – means that it has been relevant for governments, when considering a policy issue like DTCA, to weight up these various aspects against one another. The cost of drug therapy has become a concern of all governments, and with it the question of industry prices, profits and the use made by industry of its income; a very substantial proportion of that income goes to advertising, that essentially is paid for by the health community and that in turn results in an ongoing rise in health expenditure as drugs are used and over-used to an increasing extent.

8. SUGGESTED BENEFITS OF DTCA AND ALTERNATIVE MEANS OF SECURING SUCH BENEFITS

Prominent among the arguments raised by proponents of Direct to Consumer Advertising is the view (and alleged evidence) that it is in various ways beneficial to the community. On the other hand, various non-commercial experts have considered this material in detail, and their almost unanimous view is that these "benefits" are all but lacking.[58] Even if there are benefits to DTCA, as its proponents suggest, in my opinion there are alternative means of securing those benefits while supporting the policy to limit DTCA because of its detrimental aspects. Because of the wealth of sound material on this subject, and my understanding that other experts in this matter will address these issues in detail for the Court, only a few aspects will be considered briefly here.

8.1 Early use of new medicinal discoveries

Were every new medicine to represent a step ahead in treatment, its early introduction with the support of DTCA might be welcome. In fact however:

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[55] Findlay S. (2001): Prescription Drugs and Mass Media Advertising. National Institute of Health Care Management, Washington DC.

[56] See Rosenthal et al. (2002) op. cit. at p. 500. The figures may be slightly distorted by the fact that the cost of distributing samples to prescribers is included in the cost of professional advertising.

[57] Data from Competitive Media Reporting and Scott-Levin as reported by Rosenthal et al. (2002) op. cit. at page 503.

[58] Mintzes B., (need to provide correct cite for her January 2006 document to the Health Council of Canada at pp. 24-28 – (we have it)).

- Data relating to the efficacy and safety of a new medicine are at the time of its introduction never complete and rarely sufficient to demonstrate any superiority that it may have over existing products. Serious risks can and do emerge later. This point is further developed under section 9.1.2. below.
- Retrospective studies of new drug introductions show that only a small proportion of new drugs ultimately prove to represent an advance in medicine. When an independent journal in France summarized in 2002 the therapeutic status of 2500 new preparations or new indications that it had reviewed during the previous twenty years it rated only 76 (3%) as major or important therapeutic gains while nearly 1600 were condemned as superfluous in that they had added nothing new to therapy.[59]

It follows that, as a general principle, sound policy exists for a cautious and gradual introduction of a new drug into medicine. Patients are not well served by an advertising technique that urges them to switch to a new medication as soon as it becomes available.[60]

8.2 Early Diagnosis

Prominent in the case presented for DTCA is the argument that some disorders are much under-diagnosed because the early symptoms are not recognized and/or the patient experiencing them fails to consult a physician sufficiently early or at all. By alerting the public to such situations, DTCA is claimed to ensure that illness is treated at a sufficiently early point in time. Although one might expect that result in some instances, to date, I know of no controlled study showing that DTCA does indeed have this positive effect.[61]

It is entirely true that some conditions are under-diagnosed or are recognized too late for treatment to be fully effective. Under-treatment is a recognized problem, but it may call for educational and other measures, preferably from an independent source (see section 8.4 below). Under-treatment pales into insignificance, however, when set alongside the major problem of over-treatment[62] and the use of medicines for non-pathological conditions (see section 3.4).

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[59] Drugs in 2001, *Prescrire International* 2002: 11 (58): 58-60.
[60] Lexchin J. (2002): Should doctors be prescribing new drugs? Int. J. Risks & Safety Med; 15: 213-222.
[61] The study by Weismann et al. in the U.S.A. was uncontrolled. See Weissman J.S. Blumenthal D., Silk A.J. et al. (2003). Consumers' reports on the health effects of direct-to-consumer drug advertising. Health Affairs: web exclusive: W3-82. For an earlier overview of advertising control see US General Accounting Office (2002): Report to Congressional Requesters: FDA Oversight of Direct-to-consumer Advertising has limitations. Publication GAO-03-177.
[62] See for example Anon. Report reveals yawning European prescription gap. Scrip 3101, October 26 2005.

8.3 Meeting a demand for information

There is no doubt that in recent decades the public in most Western countries has become more eager to have free access to information on a wide range of topics, and to form its own views on these matters rather than necessarily accepting the views of recognized experts such as doctors. The rapid development of the public media and more recently of the Internet provides the opportunity for such access both to basic facts and to a range of views that the public may choose to accept or reject.

In the view of the pharmaceutical industry its companies are particularly well placed to provide well-documented information on their products, particularly when they are new and unfamiliar, and it can play this role through DCTA. The suitability (or otherwise) of the industry as a purveyor of information is considered later in this report (section 8.2). From a policy perspective, a separate question is that of imbalance. The resources available to major pharmaceutical companies to provide information are such that it is very likely to outweigh and overshadow the information from any other quarter; using the powerful techniques of commercial persuasion it is also likely to be more seductive. A single illustration of this situation is provided in section 3.4 but there are very many more.

8.4 Improvement in compliance

Lack of compliance with prescribed therapy, that is, patients who do not follow their physician's recommended course of treatment, is a recognized medical problem, but I have not succeeded in finding any evidence whatsoever that DTCA improves compliance, nor am I aware that other reviewers have found evidence to this effect.

8.5 Improvement in the doctor-patient relationship

It is suggested that DTCA might improve the doctor-patient relationship, it is not clear in what way this may happen; in surveys some physicians stated that they were irritated by the pressure which, as a result of DTCA, patients exerted on them to prescribe. In the U.S. the preliminary results of a survey by the FDA's Division of Drug Marketing and Communication in 2002 did not find any positive impact on the doctor-patient relationship.[63] The relationship is changed, but it is certainly not improved.

[63] Aikin K.J. (2002): FDA: DTC Advertising of Prescription Drugs: Preliminary Survey Results. The final results are similar and now available: see FDA's DDMAC website: http://www.google.no/search?hl=no&q=DDMAC&btnG=Google-s%C3%B8k&meta=

9. DEMONSTRABLE ADVERSE EFFECTS OF DTCA

Opponents of DTCA have raised a long series of arguments relating to the risks which they perceive emerging. While some dangers have been demonstrated, other risks are theoretical (although foreseeable) at this point. I attempt to distinguish between hypothetical risks and whatever dangers have actually been demonstrated in practice, the emphasis being laid on the latter. As in Sections 6 and 7, I also distinguish between health issues on the one hand and commercial and financial matters on the other.

9.1 Health risks

The main policy basis for limiting DTCA is the risk it poses to health, as argued and demonstrated mainly during the last decade. This risk can be considered under three headings.

9.1.1 Risks of unnecessary treatment

One prominent and unfortunately very profitable DTCA technique involves the "creation" of disorders in situations where a pathological state does not truly exist and no treatment can be justified. The benzodiazepine bonanza[64] of the sixties is the classic example that set the pattern for others, notably the SSSI antidepressants of more recent years. Mintzes (2002) has documented the manner in which a condition of worry, anxiety or unhappiness can, as a consequence of suggestive advertising, be "medicalized" into a psychiatric disorder supposedly requiring drug treatment.

> "In October 2001, GlaxoSmithKline ran an advertisement in the *New York Times Magazine* for paroxetine (known as Paxil in the United States). A woman is walking on a crowded street, her face strained, in a crowd otherwise blurred. The headline reads, "Millions suffer from chronic anxiety. Millions could be helped by Paxil". No doubt many New Yorkers felt anxious in the aftermath of the attack on the World Trade Center, experiencing symptoms highlighted in the advertisement, such as worry, anxiety, or irritability. At what point does an understandable response to distressing life events become an indication for drug treatment and market opportunity?"[65]

[64] It must be realized that the benzodiazepines attained their massive popularity at a time when there was as a rule no DTCA; their population-wide was attributable in part to their dependence-producing properties and in part to other marketing techniques. See Medawar C. (1992): Power and Dependence. Social Audit, London.

[65] Barbara Mentzes: Direct to consumer advertising is medicalising normal human experience, Brit med J. 2002; 324:908-911

These techniques are hardly different from those evident in the historic drug advertisement shown in Schedule 1, e.g. where, for example, a state of "melancholy" was represented as reflecting a grave and multifaceted disorder affecting the entire body. Overmedication is an increasing problem in western society and there seems to be no doubt that emphatic direct-to-consumer advertising is one of its major causes.[66]

"Medicalization" is not necessarily in all cases entirely without benefit, e.g. where life is thereby temporarily rendered more tolerable for a subject in a difficult situation from which he or she sees no easy escape, but long-term experience with the benzodiazepines since 1956 points to the real risk of either physical or psychological dependence, underlining the desirability of medical supervision of such situations but also throwing much doubt on the acceptability of the persuasive process. The important point, however, is that in those cases where no disorder actually exists, the "creation" of a supposed drug-demanding disorder is of itself a risk-inducing activity since no medicine – and especially no prescription medicine – is entirely harmless.

9.1.2 Replacement of a well-proven medicine by a newer product

As noted above, the profile of a newly introduced drug is only very rarely complete. Information on its properties, including its undesirable side-effects and interactions, continues to accumulate from the field over a considerable period. The urge created by DTCA to replace older remedies by newly introduced products thus not uncommonly exposes the patient to still undocumented risks. The withdrawal of benoxaprofen and Vioxx are among the best documented instances of this problem. Unjustified replacement of an older medicine by a newer product is also likely to raise costs, often substantially (see Section 6).

The health risks of DTCA can best be documented from practical examples. The most convincing evidence that DTCA can cause avoidable injury is derived from events relating to a number of new products which were the subject of extensive public advertising and were subsequently withdrawn from the market because of their adverse effects and lack of clear advantage over existing products. Bearing in mind that (as agreed by both proponents and opponents of DTCA) this form of advertising greatly boosts the level of use of a new product, *it follows that a proportion of those injured would not have been harmed had they not been influenced by direct advertising*.

If, therefore one can prove all these elements (injury, lack of benefit, positive influence on sales) it can reasonably be concluded that DTCA was injurious. A relatively early example of this relates to the introduction by Lilly in the USA around 1982 of its anti-arthritic drug benoxaprofen (Oraflex, Opren), supported by both professional promotion and DTCA; through both channels it was emphatically claimed that the product

[66] Internet sites dealing with over-medication are numerous and some are well documented. For an overview see Dobbs L.: Over-medication: a growing crisis - Aggressive marketing a major culprit. Tribune Media Services, 2 October 2003. Reproduced by the International Center for the Study of Psychiatry and Psychology.

represented an entirely new approach to arthritic disease and could actually slow progression of the disorder. Within a short period this sales approach generated more than US$1 million a week in sales. There was similar experience in Britain, but in the Netherlands the regulatory authority, of which I was at the time the Vice-Chairman, rejected the product because of misgivings concerning safety and efficacy data. Shortly afterwards severe adverse reactions were indeed reported in elderly users, including some 200 deaths from hepatic disorders in Britain alone. The drug was withdrawn worldwide having fulfilled none of its promises.[67]

A similar occurrence, on a much larger scale, related two decades later to the drug Vioxx (Rofecoxib) from the Merck company. The drug had no therapeutic advantages over earlier products used in arthritis and the publicity accorded to it was purely in terms of its claimed greater safety.[68] The so-called VIGOR trial, published in 2000, had indeed shown that rofecoxib induced less risk of complicated ulcers than did earlier non-steroidal anti-inflammatory drugs, but there was also an increase in heart attacks, involving more patients than those who benefited in terms of a reduced ulcer risk. The cardiac risk led to the drug's withdrawal after some years on the market. In 2000, Merck spent more advertising Vioxx to the U.S. public than Pepsi-Cola Co. spent advertising Pepsi. Vioxx was also advertised to the New Zealand public. DTCA was not the only factor associated with rapid expansion of Vioxx use in either jurisdiction, but there is no doubt that it played a major role."[69]

In such a case one can readily prove the presence of three related elements (the potential for injury, lack of significant advantage, positive influence on the sales of a new drug), demonstrating when considered together that DTCA has proved injurious. Both David Graham of the FDA[70] and Mintzes (already cited above) have also provided a convincing estimate of the appalling extent to which Vioxx led to fatalities, and Mintzes has estimated the role of DTCA in this tragedy; the data are undoubtedly available to the Court and will not be repeated here.

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[67] The benoxaprofen events are well-documented in the literature, e.g. Dukes M.N.G. (1996) (Editor): Meyler's Side Effects of Drugs (13th Edition), 236-237 and sources cited there. I should add that at the relevant time I was Vice-Chairman of the Netherlands Committee for Evaluation of Medicines and had access to all the documentation and to the proceedings leading to rejection of the drug. I was also a member of the drug evaluation agency for the three Benelux countries, which jointly followed the same course and rejected benoxaprofen.

[68] The greater safety related to a lesser propensity to induce gastric distress.

[69] Mintzes B. (2006): Direct-to-Consumer Advertising in New Zealand: Submission to Consultation." (Unpublished report).

[70] Graham D.J., Campen D., Hui R. et al. (2005), Risk of acute myocardial infarction and sudden cardiac death in patients treated with cyclo-oxygenase 2 selective and non-selective non-steroidal anti-inflammatory drugs; Nested case-control study. Lancet; 365(9458): 475-481.

9.1.3 Creation of anxiety and fear

Numerous papers have pointed to the health consequences where an essentially healthy individual has been persuaded by "disease mongering" that he or she is in need of medicinal treatment. This issue has been considered in Section 3.5. above.

9.2 Commercial and financial risks

DTCA is itself expensive, and it is an effective instrument in raising financial expenditure, to the cost of the public health services and the individual. In the countries where DTCA has been prominent, the commercial interest has weighed heavily, and where a balance has been sought, the commercial interest has almost certainly been over-represented simply because of the ability of the business sector to present its case very convincingly.

My own search of relevant Internet information on the subject, for example, shows how in this forum the case in favour of DTCA is massively emphasized as compared with other views.[71] Quite apart from the health issue, considered in the sections above, the financial aspect of DTCA has been viewed as a serious policy consideration. The cost of drug therapy has become a concern of all governments, and with it the question of industry prices, profits and the use made by industry of its income; a very substantial proportion of that income goes to advertising that essentially is paid for by the health community, and that in turn results in an ongoing rise in health expenditure as drugs are used and over-used to an increasing extent.

In such a situation it is realistic to ask whether any country can afford to allow DTCA. Most western countries are approaching or have reached the point where health expenditure has to be curtailed; the over-use of medication and the reckless manner in which excellent and proven medicines are rapidly replaced by others which are no better but are considerably more expensive is an obvious area in which economies must be made. It is not surprising in view of such policy considerations that the great majority of western countries have come to the conclusion already that there is no place for DTCA.

[71] In May 2006, together with a pharmacy student in Oslo, I informally conducted a series of Internet searches on the terms Direct to Consumer Advertising/Pharmaceuticals (and synonyms). 83 sites expressing views on the acceptability and merits (or otherwise) of the technique were identified. Of these 55 (and probably 3 others) appeared to originate with commercial sources, i.e. pharmaceutical companies, their trade organizations, or advertising or marketing firms.

PART IV: GENERAL DISCUSSION AND CONCLUSION

10. DISCUSSION

10.1 The public's need for drug information

There is no doubt that, as point out earlier in this report, "in recent decades the public has become more eager to have free access to information on a wide range of topics, and to form its own views on these matters rather than necessarily accepting the views of recognized experts such as doctors" (Section 5.2). From a health policy perspective, this fact, much emphasized by industry in pressing the case for DTCA, is generally regarded as a healthy development that should be facilitated wherever possible. The doctor is not infallible and a balanced doctor-patient dialogue is today regarded as likely to lead to the best possible outcome. The emphasis must however be on "balance", and balance is only likely to be attained if neither party has been misled in its quest for information; this issue is considered below.

10.2 The eligibility of the pharmaceutical industry as a purveyor of information

Precisely because the public's need for sound information on drugs is so evident, one needs to ensure that it is provided in a reliable manner and from a trustworthy source. Even from first principles one might have reason to doubt that a source which has so much to gain from rapidly maximizing the sales of new and high-cost products is a suitable source of objective information. Any misgivings that one might have on that issue are unhappily confirmed when one examines the experience over a decade with DTCA in the United States. The FDA has on numerous occasions (documented in detail in the FDA records available on line) called firms to order for improper behaviour regarding promotion of prescription items to the public.[72] Equally, as concluded in a report issued very recently by Consumers International, entitled "Branding the Cure" (attached to this report as "Annex 4**"**), drug companies show poor transparency in their promotional practices and regularly fail to adhere to existing self-regulation codes.[73]

As Mintzes has also noted in her 2006 paper for the Health Council of Canada, violations of the U.S. Regulations on DTCA are common. Her statistical analysis (p.15) may be cited here:

> In 1998, television ads for more than half of advertised products were judged by the FDA to violate US regulations. From 1997 to 2002 inclusive, 93 brands were advertised on television and radio. During the time, the FDA issued 61 untitled or Notice of Violation letters. The main reasons were over statements of

[72] Warning Letters and Notice of Violation Letters to Pharmaceutical Companies, http://www.fda.gov/cder/warn. The letters are arranged by year.

[73] Consumers International, Branding the Cure: a consumer perspective on Corporate Social Responsibility, Drug Promotion and the Pharmaceutical Industry in Europe, (2006) London.

> efficacy and minimalization of risks…Repeat violations are also common. Schering-Plough's advertising of loratadine (Claritin) was found to violate FDA regulations 11 times from 1997 to January 2001. The FDA cited Glaxo Wellcome 14 times for illegal advertising of two forms of fluticasone propionate (Flovent and Flonase) and Pfizer four times for broadcast and print ads for atorvastatin (Lipitor).[74]

The firms involved are not obscure undertakings of secondary importance. Most are precisely the research-based multinationals from which one might hope to expect a better record in such matters but their ability to secure major earnings by the early sale of new products, by whatever means, appears to have proved too great a commercial temptation to resist. To find Glaxo Smith Kline in Britain, for example, publicizing an asthma remedy in a story book purporting to comprise educational material for asthmatic children (thereby contravening both the industry code and the relevant regulations)[75] is, to say the least, discouraging.

10.3 The control of industry-based information

Bearing in mind the inevitable (and entirely natural) tendency of a sales-oriented industry to place its own commercial interests above those of the population as a whole, any flow of information emanating from such an industry will need to be subject to careful control. The principle has long been accepted in Britain as regards the information provided to health practitioners, the basic principle being that professional promotion for any drug must be consistent with the contents of the "data sheet" that has been examined and approved by the national drug regulatory agency. Even the implementation of this long-established principle proves however to be so labour-intensive and costly that it has often been deficient and has sometimes actually been cut down or even completely abandoned.[76] Above all, official attempts to censor or correct public advertising generally provide to be no match for the astute tactics of a commercial marketing operation.[77] For one thing, official measures are almost always taken *after* an advertising campaign has been undertaken and has begun to exert its effect. Again, when promotion

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[74] B. Mintzes, *supra*.

[75] Tayal U., Children's book at centre of row over drug advertising campaign. BMJ 327; 23 August 2003 at p. 412. Promotion to children was prohibited both by the 1994 Medicines Act and by the then current version of the AESGP (industry) Code of Marketing Practice.

[76] Because of my continuing close links with the Netherlands Inspectorate for Medicines I know that advertising control virtually ceased in 2002 because of shortage of capacity. I have also been verbally informed of the very limited capacity to check drug advertising in the USA but I have no direct documentation on the matter.

[77] When the highly unfavourable results of the 2002 "Women's health study" on menopausal oestrogen therapy threatened to reduce the turnover of such products, the manufacturer Wyeth issued full-page advertisements in 180 U.S. newspapers suggesting inter alia the need to use the lowest effective dose. The pharmaceutical press suggested that the campaign was intended to pave the way for the introduction of new Wyeth products using lower estrogen doses. See Scrip Nr 2858; June 3, 2003 at p. 15.

takes the form of sponsored or ghost-written materials in the public media it may for a long time fail to be recognized for what it is, and here too any restrictive measures are likely to be taken long after the promotion has had its commercially desired effect.[78] Specific restrictions can readily be circumvented, e.g. visual tools can easily be used to convey messages that would not be admissible in textual form.[79]

Where *voluntary codes of practice for marketing* have been instituted by industry, sometimes with procedures for enforcement, they generally relate exclusively to promotion of prescription products to professionals[80] or conversely the advertising of over-the-counter medicines to the lay public. For example the code of practice of the European Federation of Pharmaceutical Industries, ratified in 2005, explicitly provides that:

> "The EFPIA Code is not intended to restrain or regulate the provision of non-promotional medical, scientific and factual information; nor is it intended to restrain or regulate activities directed towards the general public which relate solely to non-prescription only medicines." It avoids dealing with the issue of DTCA. The ABPI Code in Britain on the other hand explicitly rules that "Medicines which cannot legally be sold or supplied to the public otherwise than in accordance with a prescription, or which are legally limited to promotion for sale or supply only on prescription, must not be advertised to the general public" (1991 edition, Art. 22.1). However subsequent clauses do make some provision for the supply of factual and balanced information to the public. Art. 22.4 appears to anticipate DTCA within limits, ruling that "the introduction of a new medicine should not be made known to the general public until all reasonable steps have been taken to inform the medical profession of its availability."[81]

Other voluntary codes refer to the marketing of "over-the-counter" (OTC) products to the public.[82] Such codes are not without their value since the most critical reviewers of a

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[78] The 1996 paperback "Feminine Forever", was at the time the single most persuasive instrument in converting western women to hormonal replacement therapy. Attributed to the gynaecologist Robert Wilson it was at the time known in inner circles to represent a successful piece of corporate sponsored disease mongering; but not for another forty years was it widely recognized and criticised as such. See: Writing Group for the Women's Health Initiative: Risks and benefits of estrogen plus progestin in health menopausal women. JAMA 2002; 288: 321-33. See also: Moynihan R. The Marketing of a disease: female sexual dysfunction. BMJ 330; 192-194.

[79] The public promotion of a hormonal product for mild acne in Canada involved misuse of a clause in Canadian law permitting reminder advertising. The visual element suggested the use of the product in healthy young women whereas it had been official registered only for cases of resistant acne with hormonal imbalance. See Mintzes (2006) at pp. 5-6.

[80] The industry codes in use in Britain and Australia are most widely cited but very similar codes are found in most western countries; they also exist at the European and global level .

[81] See http://www.iapco.org/publications/c22_efpia_document.pdf

[82] For example that issued by the Proprietary Association of Great Britain. The PAGB Code is publicly available on the Association's website:

firm's drug advertising are often its competitors but it would be fair to say that the standards created by such codes and the procedures created to enforce them are variable and, of course, by their very nature, they are only developed voluntarily.

Code of practice created by the media are in use in some countries and have proved of similar value. They have the advantage over purely voluntary industry-based codes that they can "require" prior examination and licensing of material, i.e. a process of censorship; the media will refuse to disseminate advertisements which fail to gain such approval.[83]

Taking these processes as a whole, and viewing experience with them across the world, my opinion is that they have some effect but are also deficient. An organization such as Healthy Scepticism[84] has repeatedly called attention to the often serious defects of drug advertising as a whole, despite all the constraints on it. The saving grace where advertisements to physicians are concerned is that their professional training and experience enable them in many matters to reject unacceptable or unfounded claims or statement; that safeguard is absent where DTCA is concerned.

10.4 Advertising and the Internet

The Internet requires separate consideration and cannot be adequately dealt with in the present text, but it is clearly relevant to the future of DTCA and to the determination of policy. Most references to medicines and medicinal treatment on the Internet do not represent explicit DTCA but many can be traced back to industrial sources, and the borderline between DTCA and Internet information is becoming ever less clear. At the present time an Internet search for information on a particular disorder or drug is likely to produce reference to many hundreds of websites; the source and objectivity of a particular website relating to the merits of a particular drug or treatment is often entirely unclear to the user, but careful content analysis shows that the proportion of such sites that are clearly industry-sponsored considerably outweighs the number emanating from fully independent and reliable sources. Material intended for a medical readership is not usually distinguished from that intended for public consumption.

It has sometimes been argued, mistakenly, that official regulation of material entering this global forum is not truly possible and that is therefore illogical to introduce a prohibition

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http://www.pagb.co.uk/pagb/downloads/advertisingregulations/PAGB%20Summary%20Medicines%20Advertising%20Codes.pdf.

[83] In the Netherlands such a system was created as early as 1930 to control newspaper advertising for over-the-counter medicines. It may be noted that a clause in the pioneering Netherlands Medicines Act of 1958 was intended to replace this private law system, introducing a state Board of Censorship for all drug advertising. It remained unimplemented after the industry advanced the view – never tested in Court – that it would impede freedom of expression and therefore be unconstitutional.

[84] Formerly known as MaLaM (the Medical Lobby for Appropriate Marketing: based in Australia but operating worldwide).

of DTCA since it could be evaded by using the Internet as a channel. In fact, control of material on the Internet is possible in various ways – it has simply not to date been widely developed. One may note that:

- There is now trend in recently developed (industrial) codes of promotional conduct to set certain standards for Internet sites.[85]

- In the United States the Food and Drug Administration has on various occasions required firms to modify or withdraw promotional material; examples can be found on its Internet listing of warning letters, referenced earlier in this report.

- In Canada too, on at least one occasion, Health Canada has insisted on companies modifying material on Internet sites based in Canada; the case of which I am aware related to Diane-35 and dates from 1999.

One important difference between placing information on the Internet and advertising in the mass media is that unwanted intrusion is much less likely to occur. The reader of a political article in a newspaper or the viewer of an entertainment programme on television may find his chosen activity interrupted by unanticipated, uninvited and highly emphatic messages regarding a drug or the possibility that he may be suffering from an unrecognized illness demanding treatment. The user of the Internet, on the other hand, is only likely to be confronted with such an industrial message if he searches specifically for information on the subject in question, e.g. the treatment of diabetes or the causes of headache. A process of public education on the selective and critical use of the internet – there are already some good national examples – can do much to prepare the user for the industry-based drug information with which he may be confronted there.

This distinction between intrusive media advertising and material lying in wait on the Internet is naturally not absolute. Some pharmaceutical companies appear to be exploiting the possibility of purchasing space on general Internet websites, e.g. devoted to sports, automobiles or entertainment, so that, just as in media advertising, the public finds itself confronted with uninvited promotional material on whatever topic the advertiser chooses to display. It would however seem entirely possible to tackle such techniques by regulations imposing penalties on a national website accepting such paid promotional material where it contravenes DTCA standards.

As noted earlier, this report cannot deal fully with the Internet challenge, and the manner in which it is to be handled, and the latter will need to evolve as marketing techniques develop further. It would however seem fair to conclude provisionally that Internet developments do not provide a sufficient reason to tolerate otherwise inadmissible DCTA in the media.

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[85] A new Australian code of conduct that came into force at the beginning of 2003 stated that publicly available websites could carry brand names and appropriate product information provided the intent was educational rather than promotional. Information directed towards health care professionals must be available only on password-protected secure sites. See: Scrip Nr. 2821; February 5, 2003 at p. 17.

10.5 Alternatives to DTCA

From a health policy perspective, as pointed out in Section 8 above, DTCA only confers *very limited* benefits on the community as a whole; in essence:

- there is indeed a certain proportion of individuals who fail to recognize in good time that they are suffering from conditions which call for medical consultation and treatment. Physical or mental states ranging from diabetes or venereal disease to cancer or AIDS may as a result be treated too late.

- physicians may fail to update their treatment routines; a small proportion of new drugs do offer advantages as compared with older products and deserve to replace them.

The medical and health communities are generally aware of these problems and on numerous occasions educational campaigns have been set up to tackle them, though one can always find situations in which more needs to be done. The public authorities are also as a rule less well-equipped than are commercial companies to measure the health and economic effects of their information activities, and such work is often cut back or discontinued entirely when finances are in short supply. Despite this, in my opinion, there are a number of good reasons to consider that public information on these matters is much to be preferred to commercially-based material. Notably:

i. the selection and priority of topics must be determined by the public health interest and not by the fact that a particular manufacturer has chanced to come with a new drug that he is anxious to sell

ii. the provision of information by the public health system is considerably less expensive than that through drug advertising. This is not always appreciated since the figures are not readily accessible. Not only are exotic marketing campaigns themselves more expensive (and paid for from the public purse through new drug pricing) but they result in an increase in public drug expenditure as older drugs are unnecessarily replaced by newer and more costly items.

iii. above all, the provision of information from the public authorities ensures that the content is as objective as it can be in the light of current knowledge.

Over a long period, public education programmes relating to diseases and to treatment have been conducted with success in many fields – for example campaigns for the early recognition of venereal disease or of AIDS. Under the auspices of the health authorities, the teaching hospitals and the health professions, the fields in which under-diagnosis or persistence of outdated therapy remain genuine problems can be identified and the public guided accordingly and reliably at a small fraction of the cost involved in DTCA.

11. Overall conclusion and opinion

It is not difficult for an impartial technical observer or advisory body to build up a reasonably well documented view of the alleged benefits and known detriments of Direct to Consumer Advertising; much of the evidence that one needs is now to hand, and it is generally possible to distinguish genuine from spurious argument. As noted at the outset of this report, I base my opinion in this matter primarily on factual evidence. I have rejected mere opinions and also rejected rigorously the large volume of biased or defective material that one encounters. Regretfully, I have concluded that much of the defective material that reaches me proves to have originated with the pharmaceutical industry itself, its associations or institutions, or bodies or journals associated with it in some manner. Such material appears to have primarily a propagandistic purpose, seeking to make a case for DTCA despite the lack of sound basis for such a case.

That having been said, however, I realize that there is a fundamental divergence of view between the commerce-orientated and the health-orientated sectors of society on the matter.

Within the world of commerce and marketing, a technique such as DTCA is widely and genuinely viewed as the inevitable way forward. It boosts sales, both directly and by catalyzing other forms of promotion; thereby it promotes employment, shareholder profit, exports, funding for research and welfare generally. All these arguments are meticulously documented and they are advanced, with all the force inherent in modern marketing, in economic, public and political circles, embroidered where appropriate with considerations of supposed public benefit.

I gained my own personal knowledge of the foregoing circumstances in February 2000, when I attended, unofficially, the greater part of a commercially organized marketing conference on DTCA in London. For the entire time I attended the meeting was devoted to the concept of DTCA as an unstoppable development, a potent weapon in raising the sales of pharmaceuticals dramatically. Legal and political restrictions were presented as outdated and ill-conceived obstacles which were about to collapse. Singularly lacking was any consideration of the public interest, except insofar as "public benefit" was presented as a useful argument to defeat the opposition.

Within academic and health professional circles, and to a large extent within the consumer and patient movement, a diametrically opposite view holds sway. There is concern about the unmet need for truly objective information on medicines and treatments, the financing of health, the affordability of illness, and the slowness with which therapy for many major diseases advances; increasingly, one encounters the view that the flow of money in this entire field of pharmaceuticals is wrongly directed.

For the policy maker, the challenge is to weigh up these two opposing points of view and then to make a choice between them or seek to determine whether any compromise is

possible. It is perhaps understandable that in a country such as the U.S.A., having a vast and productive pharmaceutical industry (with an important export trade policy and a powerful lobby) as well as a political bias towards free and venturesome commerce, policy has leaned towards the commercial view. Even with respect to that country however one must note the extensive misgivings regarding DTCA, excessive corporate influence and drug prices that have been expressed in recent years. As noted earlier, it is entirely possible that a retreat from some of the recent extremes of policy is on the horizon in that jurisdiction.

For any other country however, from the perspective of developing policy in this area, the detriments are likely to considerably outweigh the benefits. In a country such as Canada a policy that limits DTCA may rein in, to some extent, the more aggressive sales methods of some U.S. based firms, but it seems most unlikely to injure the interests of the somewhat more modest but entirely healthy national industry. A policy of limiting DTCA of prescription drugs can serve the interests of the people of Canada with their effective and affordable health services and acceptable prices for medicines.[86] To summarize briefly the conclusions of this review regarding the global scene:

- DTCA has been shown to shift prescribing patterns heavily in the direction of new products, irrespective of the merits of these products and at a point in time when their safety has been inadequately demonstrated by experience in field. In those countries where it has been practised, DTCA must for that reason be considered to have been responsible for placing consumers, as patients, at increased risk for avoidable injury and death.

- By shifting prescribing to new products in situations where there is no justification for such a change the public health budget has been obliged to shoulder an additional financial burden for which no sound reason can be advanced.

- The number of instances in which public advertising for prescription drugs has been found to be misleading is legion. While industry associations have maintained codes of marketing ethics that have some limited effect in that firms maintain a critical view of their competitors' claims, one finds that major firms engaging in DTCA have repeatedly transgressed basic rules of truth and honesty. It is as if these firms, all of which are anxious to maintain a positive reputation with the public, have assumed that this can be achieved by image-building alone, while little effort is made to earn the desired reputation by appropriate behaviour.

- In view of the many and often subtle manners in which DTCA is carried out, it proves extremely difficult for the authorities to exercise sufficient control over the process to ensure that standards are maintained.

[86] As a non-Canadian observer, one notes with interest the extent to which patients from the USA currently travel to Canada to purchase American drugs at lower prices than those prevailing in their home country.

- The supposed public benefits of DTCA prove on close examination to be virtually non-existent. Real benefits in these fields can be conferred much more surely and at much lower cost by public action and education.

- The ongoing development of public information and promotion via the Internet provides insufficient reason to abandon restrictions on DTCA in the traditional media.

One would have wished to conclude the present review with the conclusion that the relatively new technique known as Direct-to-Consumer Advertising of prescription medicines represented a modern and meaningful approach to the issue of public emancipation. Unfortunately, an analysis of experience in those few countries where DTCA has for a time been permitted – and some others where it has in some form merely slipped through the meshes of the law – does not provide such a positive picture. As exercised to date, DTCA has proved to be costly for the community, to introduce substantial and well-documented risks to health, and to confer very modest if any tangible benefits. I can only agree with the emphatic view of the Canadian House of Commons Standing Committee in April 2004 that there is a need, not for DTCA, but for reliable information to the public from "sources that do not benefit from product sales"[87] – in other words an emulation of European rather than American practice.

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[87] Standing Committee on Health (April 2004): Opening the Medicine Cabinet; First Report on Health Aspects of Prescription Drugs. Ottawa: House of Commons.

Schedule 1

Extract from a long advertisement in the London Country Journal, Saturday April 27th 1734. The many advertisements to the public on the same page exhibit trends familiar from present-day DTCA. They include disease-mongering, suggestive illustrations, warnings regarding the seriousness of the prognosis if untreated, promises of lasting relief and assurances of good tolerance. This particular text attributes anxiety and depression primarily to gastrointestinal dysfunction. Advertising cures for mild mental conditions were particularly common.

The so much Famed HYPO-DROPS

which in a few Days infallibly cure Hypochondriack Melancholy in MEN and Vapours in WOMEN, so as never to return again, be they ever so severe, or of many Years standing, and even after all other Remedies have proved ineffectual; for they for they immediately strike at the very Root or true Cause, as well as remedy the Effects of those perplexing Maladies, and all their Variety of Symptoms, by which they mimick, by turns, almost all the Diseases poor Mortals are afflicted with, and have their Rise from a deprav'd Appetite, vitious Ferment in the Stomach, and Indigestion of Food, whence proceed Crudities and flatulence or windy Disorders in the first Passages, foul Belchings, Cholick, Uneasiness in the Bowels, and ill Fumes, which offend the Nerves. And, by Consent of Parts, affect the Head, and produce sometimes Giddiness, Dimness of Sight confused Thoughts, pertinaceous Watchings , troublesome Sleep, Frights, groundless Fears and the deepest Melancholy with direful Views and terrible Apprehensions; at other Times, Fits, flushing Heats, Reachings, Faintness Lowness and sinking of the Spirits, Palpitation of the Heart, Startings, Trembling and Twitching in the Limbs and other Parts, with many convulsive Disorders , sharp Pains fixed or wandering, Pain and Weakness in the Back and other, almost innumerable and grievous Symptoms, which miserably affect vast Numbers of both Sexes.....

Schedule 2

Some examples of conditions created or "medicalized" by advertising during the twentieth century

Consumer's condition	Pathology created or developed by marketing	Firm(s) or product(s) involved
Bad breath	Halitosis	Listerine[R]
Sadness or Shyness	"Social Anxiety Disorder"[88]	Glaxo Smith Kline (antidepressants)
Menopausal discomfort	"Oestrogen deficiency"	Ayerst; Organon
Less than avid sexual desire	"Female sexual dysfunction"	Wyeth; Proctor and Gamble
"Difficult" children	"Attention deficit hyperactivity disorder"	Novartis (Ritalin[R])

[88] Doward J. and McKie R: Revealed: secret plan to push "happy" pills. Observer (London), November 7, 2004.