Direct to Consumer Advertising of Prescription Drugs in New Zealand:

FOR HEALTH OR FOR PROFIT?

Report to the Minister of Health supporting the case for a ban on DTCA

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"The power and sophistication of the pharmaceutical industry cannot be underestimated. Those who seek to counter it in the public interest need more than commitment and energy…..

In the absence of strong advocacy in the public interest, the pharmaceutical industry will continue to set the tone of public debate."

Rt Hon Helen Clark (Minister of Health 1989 -1990)

FOREWORD

Direct to consumer advertising (DTCA) is a practice pharmaceutical companies employ in order to target users or potential users of their products. DTCA may be defined as the practice of advertising medicines to lay populations in order to increase sales brand awareness and establish loyalty. New Zealand and the United States are the only two countries in the OECD that allow DTCA of prescription medicines. This can be attributed to the fact that unlike most other countries, New Zealand has no legislation that prohibits public advertising of prescription-only medicines. In New Zealand DTCA is employed for both prescription-only and non-prescription medicines. This includes pharmacist only, pharmacy only and over-the-counter medicines. Advertising of this kind is evident across an extensive range of media. Examples can be found in print and broadcast media, loyalty schemes, free sample vouchers, 0800 numbers, event sponsorship, web-sites and direct contact with consumers.

Over the last two years, many GPs have expressed increasing concern and frustration about the pressure to prescribe specific branded products, caused by DTCA of prescription-only pharmaceuticals.

In response to these concerns, a group, led by professors of general practice from all four New Zealand Schools' of Medicine, have reviewed the local and overseas literature concerning DTCA. The conclusions drawn by this group are consistent with other reviews of the effects of DTCA. Little evidence has been found that suggests a net benefit to the public health system. On the contrary, the evidence actually suggests net harm to public health and a serious risk to the financial sustainability of health systems where DTCA is permitted. This report examines the development and the current state of DTCA in New Zealand and in the United States, and the policy positions of other international jurisdictions. Further, it cites the evidence and presents the arguments that support the recommendation for a ban of such advertising in New Zealand.

This group recognises there is a clear need for greater information on health and on treatment options. The report also contains a recommendation to the government that an independent consortium of professional and consumer groups be set up. This would provide readily accessible information to assist people in making decisions on their treatment options.

Concerns have also been raised about the advertising of prescription drugs to prescribers and the advertising of non-prescription medicines and dietary supplements. While these concerns are valid and legitimate, there are a number of issues and concerns unique to the advertising of prescription medicines directly to consumers that have necessitated addressing this issue at this time.

This report contains a referenced summary of the evidence supporting the case for a ban of DTCA. Appended are details of current New Zealand Professional and consumer opinion.

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EXECUTIVE SUMMARY

Conclusions

There is convincing evidence, supported by public and professional opinion, to justify a ban of direct-to-consumer advertising of prescription-only medicines in New Zealand.

There is an urgent need for increased provision of comprehensive and readily accessible independent consumer information.

Recommendations

That the New Zealand government introduce regulations and /or legislation to prohibit the advertising of prescription medicines directly to the public, through print and broadcast media or any other means.

That the Government establishes an independent medicine and health information service free of commercial interest.

Background

Disquiet over developments in DTCA triggered a Ministry of Health discussion paper on Direct-to-Consumer Advertising (DTCA) for prescription-only medicines in 2000. Following a round of submissions, the Ministry of Health recommended that the regulations on DTCA be tightened. To date, no action has been taken. Around the time of this review, the voluntary self-regulatory framework was expanded to include a mandatory pre-vetting system for broadcast advertisements to respond to the repeated breaches occurring in direct to consumer advertisements. This system includes the option of companies having delegated authority to pre-vet their own advertisements. There is no brief or resources for any regular monitoring of DTCA compliance with the Medicines Act and regulations. Investigation of breaches only occur in response to complaints. Not surprisingly, breaches have continued. A number of recent high-profile advertising campaigns have attracted significant criticism from both consumer groups and prescribers. In the two years since the Ministry of Health discussion paper, there has been a dramatic increase in the volume of DTCA in New Zealand. At the same time, as with the US experience, a parallel increase in expenditure for those medicines advertised directly to the public has occurred.

International Developments

A number of recent international reviews of DTCA have reached the same conclusion, that the net effect on the public health of DTCA prescription medicines is adverse. A number of key themes can be found in each of these reports. These are:

- Inability of brand advertising to provide appropriate and balanced information
- Deleterious effects on health funding and resources
- Negative effects on patient-clinician relationships
- Patient safety concerns
- Inappropriate medicalisation of well/healthy populations
- Lack of evidence demonstrating the claimed benefits of DTCA.

New Zealand is virtually isolated in its permissive stance to DTCA.

- *The European Parliament* recently rejected (by a 12 to 1 majority) legislation that would have liberalised DTCA of prescription medicines in the European Union.
- *Australia, Canada and South Africa* have recently reviewed their positions and will continue to prohibit DTCA of prescription medicines.
- *The United States* is the only other country in the developed world that allows DTCA. Even though they have much stricter regulations, there is still significant political, professional and consumer concern over the failure of their regulatory framework to prevent misleading advertising and the negative financial and health effects of DTCA. The General Accounting Office (GAO), a US government research agency which is the investigative arm of the US Congress, has found that the current approach to regulation is limited in its effectiveness. It states the FDA cannot verify that it receives all advertisements for assessment (examples were given of advertisements which were disseminated without FDA awareness), or prevent some companies from repeatedly breaching the regulations. It also states that the current process is not timely enough and that misleading advertisements may have already completed their broadcast life cycle before the FDA issues its warning letters requesting their removal.

KEY FINDINGS

1 DTCA is a very effective marketing strategy and is growing exponentially

In NZ and the United States DTCA is now seen as a key part of the marketing strategy of the pharmaceutical industry. It has been very effective in developing new markets, brand awareness and increasing sales of high-cost medicines in both countries. The growth in expenditure on DTCA and the resultant increase in sales of these medicines have typically been exponential. In the majority of cases, DTC-advertised new medicines offer little advantage over existing treatments.

2 Consumer Education: DTCA does not provide objective information on risks, benefits and options to assist patients to participate in healthcare decisions

The commercial interest behind DTCA means it does not focus upon promoting choice, but instead upon creating demand for specific medicines. This conflicts with the right of the patient to have easy access to high-quality, independent, comparative information on the risks and benefits of available pharmacological and non-pharmacological treatments. The information DTCA provides does not follow any accepted guidelines for health promotion or provision of consumer health information. The New Zealand Code of Health and Disability Services Consumers' Rights describes the information that consumers are entitled to receive to make informed choices. DTC advertisements rarely discuss the range of available treatments or costs to the patient of treatment.

3 Consumer Information: Consumers need greater access to reliable independent information on prescription medicines

There is a clear need for greater availability of independent consumer information on medicines. This need has been identified in numerous international reviews and implemented in a number of countries including the United Kingdom, Australia and

the United States. It is not appropriate for this information to be delivered by individual pharmaceutical companies, because they have a commercially driven interest in promoting increased sales of prescription medicines.

4 DTCA has a negative effect on health funding which may create inequity in resource allocation

Pharmaceutical expenditure accounts for an increasing proportion of total health care expenditure in most countries. DTCA has led to disproportionate increases in expenditure on newer, more expensive medicines. In most cases there is little or no evidence of resulting improvements to health outcomes of the population. With limited public funds available for health care, such distortions put pressure on other parts of the health system. At an individual level consumers face increased costs both directly and indirectly resulting from consultations generated by DTCA.

5 DTCA has a negative effect upon the patient-clinician relationship

Evidence is available in both the US and New Zealand that DTCA adversely influences patient-clinician interactions. DTCA adds additional commercial pressure to prescribers, which can have negative effects upon trust, confidence and clinical practice.

6 DTCA compromises patient safety

DTCA focuses on newer medicines where rare but serious and long-term side effects can be unknown. This inevitably puts additional patients at risk. Rational prescribing promotes caution when using new medicines and suggests older medicines should not be replaced unless there is evidence of major advantages to be gained by doing so. There are several examples of heavily marketed medicines gaining significant market share over well-established medicines, only to be withdrawn when their true safety profile is revealed. Unfortunately, by this time, patients have already suffered adverse effects.

7 DTCA promotes the medicalisation of normal health and ageing processes

DTCA of some "lifestyle" medicines encourages the medicalisation of normal health and ageing. It promotes pharmaceutical solutions over other available alternatives that could assist people to adapt to changes associated with normal health and ageing processes. The pharmaceutical marketing industry openly admits to "creating new diseases" for their products as part of their strategy to increase sales.

8 There is increasing opposition to DTCA internationally amongst consumer and professional groups

DTCA cannot be justified on the basis of consumer demand or right to access information. Where DTCA is banned, this represents a legal restriction on the **manufacturers'** rights to promote sales of prescription-only products in certain ways. There is no legal restriction on **public** information rights - the public maintains the right to obtain any available information about medicines. Surveys have shown that there is widespread consumer mistrust of the quality and completeness of information contained in DTCA. Health professionals remain the preferred source of independent advice on medication. Most New Zealand and overseas independent consumer groups have taken positions opposing DTCA after reviewing the evidence. Some, including the UK Consumers Association and Health Action International (HAI) (a non-profit,

global network of health, and consumer groups in more than 70 countries) have gone as far as mounting campaigns strongly opposing the introduction of DTCA. In New Zealand the Women's Health Action Trust has made numerous complaints about specific advertising campaigns.

Professional opinion from overseas organisations representing pharmacists and prescribers is consistently opposed to DTCA. Surveys in countries where DTCA is either permitted or exists by default highlight prescribers' concerns about the negative influence of these advertisements. Prescribers are particularly concerned about its effect on their clinical practice and on their relationship with their patients.

9 There is increasing opposition to DTCA in New Zealand amongst consumer and professional groups

Attitudes to DTCA among professional and consumer groups at the time of the 2000 Ministry of Health review were mixed. Many seemed to adopt a "watch and wait" stance. Most professional groups favoured a tightening of regulations. The increase and effects of DTCA in the intervening 2 years have led many to reconsider their position. There is now increased opposition to DTCA amongst consumer and professional groups.

In a survey of New Zealand general practitioner opinion carried out by the authors of this paper, the majority of GPs voicing an opinion felt that DTCA was not positive*. They expressed concerns about the effect of DTCA on their relationship with patients and on their clinical practice.

10 DTCA cannot be controlled by either central or self regulation

Neither the voluntary system of self-regulation in New Zealand, nor the tighter, central regulation system in the United States have been able to ensure compliance with standards of acceptable advertising practice for DTCA. The result has been many examples of:

- Misleading advertisements containing partial, incorrect or unbalanced information
- Overstatement of medicine efficacy / failure to detail success rates
- Minimization of potential adverse effects
- Inappropriate use of emotional persuasion

Based on these findings a complete ban on DTCA of prescription drugs in New Zealand is justified. The clear need for independent information to aid informed consumer choice should be addressed by the establishment of an independent health information service.

References supporting the conclusions of the executive summary are included in the body of the main report.

*The *NZ general practitioner opinion was canvassed with full disclosure of position and intent of authors known to respondents. See Appendix 3*

INTRODUCTION

New Zealand and United States citizens are exposed directly to prescription drug advertising in a variety of forms. These include advertisements in print and broadcast media, loyalty schemes, vouchers for free samples, 0800 numbers, event sponsorship, web-sites and direct mailing to consumers as well as to a range of patient education promotional activities. No other countries in the OECD permit the advertisement of prescription medicines directly to consumers. New Zealand is the **only** OECD country that provides a comprehensive publicly funded prescription benefit scheme allowing DTCA of prescription medicines. This contrasts with the United States system, where the majority of prescriptions are funded through either private health insurance (in most cases with a co-payment for prescriptions) or direct payment. Direct to consumer advertising (DTCA) has been able to develop in New Zealand through the permissive environment created by the Medicines Act 1981. Unlike legislation in other countries outside the US, this Act has no provision explicitly prohibiting the advertisement of prescription medicines to the public.

Clearly, the purpose of DTC advertising is to increase sales by creating new markets and creating brand loyalty [1-3]. Marketing prescription medicines directly to the potential user stimulates demand. This can, in turn, influence the behaviour of prescribers.

New Zealand's policy of permitting DTCA of prescription medicines has been reviewed twice to date. The first review occurred in 1998 when the Minister of Health called for an inquiry into DTCA as a result of a rapid growth in advertising activity [4]. Following this inquiry the government decided to keep a watching brief on DTCA of prescription medicines and observe the effects of industry self-regulation before deciding on further action.

A discussion paper from the Ministry of Health released in November 2000 initiated the second review [5]. The purpose of this paper was to solicit feedback on the appropriateness of DTCA of prescription medicines in New Zealand and to form the basis for advice to the Minister of Health on any changes that may be required to the current DTCA regime.

The result of this review was continuation of DTCA with instruction to the Ministry of Health to work on more central regulation. There has been little progress, partly because it was expected that changes to legislation in a year or two would cover this area[6]. The majority of submissions in 2000 supported a ban or at least swift and significant tightening of regulations for DTCA[7]. This was especially apparent among parties that did not benefit financially from DTCA, but not amongst those that did have a commercial interest (that is, those in the advertising and pharmaceutical industries, and organizations financed by them).

GROWTH AND EFFECTIVENESS OF DTCA

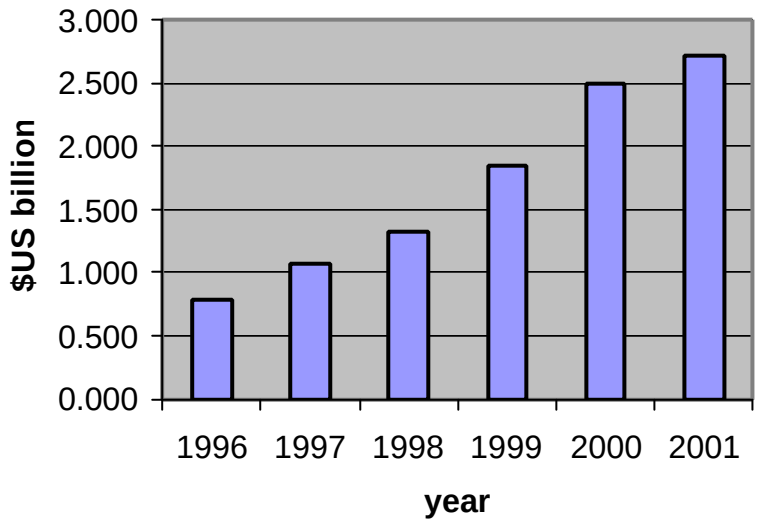
The goal of pharmaceutical companies is to maximise their profit and the return for their shareholders. The commercial imperative underlying their activities is driven by this ethos.
"Regardless of what a company is selling, they are in the business of making money and satisfying their fiduciary duties. Pharmaceutical companies are no different. They are in the business of making money by selling pharmaceuticals. For them to operate the management must generate the highest level of profitability possible to fulfill its fiduciary duty of maximising shareholder value."[8]

There is a clear and well-recognised link between DTCA and growth in prescription drug spending and utilisation[9].

Expenditure on DTCA is growing world-wide at an exponential rate

Spending on DTCA has grown exponentially over recent years (Figure 1). In 1995 in the United States $US375 million was spent on DTCA. This rose dramatically to $US791 million in 1996, then rose to 1.3, 2.5 and over 2.7 billion dollars in 1996, 1998, 2000 and 2001 respectively.

Figure 1: US Spending on DTCA 1996-2001



DATA SOURCES: US NIHCM Report 2001[10] AND US General Accounting Office Report to Congress 2002[9]

DTC advertising represents nearly a third (31.8%) of total drug promotion spending in the US in 2000 (after the retail value of free samples was subtracted)[10].

While expenditure on DTC advertising is large, revenue generated from sales of advertised medicines is greater again (Table 1). In 2001 Pharmacia earned US$12 billion worldwide from medicines sales (an 11% increase from 2000)[11]. Of this, US$3.1 billion was earned from sales of Celebrex® (celecoxib), a very heavily

advertised DTC new generation anti-inflammatory drug[11]. In the United States in 2000 more was spent promoting the drug Vioxx® (rofecoxib) (US$160.8 million) than PepsiCo spent on promoting Pepsi® (US $125 million)[10]. Each of the top 7 most heavily advertised medicines had advertising budgets greater than Nike's budget for its range of top shoes ($US78.2 million)[10].

Table 1: Products with Top DTC Advertising Budgets in the US (2000)

Drug	*Condition*	*DTC Spending Millions US$*	*Sales, Millions US$*
Vioxx® (rofecoxib)	Arthritis	$160.8	$1,518.0
Prilosec® (omeprazole)	Ulcer/Reflux	$107.5	$4,102.2
Claritin® (loratadine)	Allergy	$99.7	$2,035.4
Paxil® (paroxetine)	Anxiety/Depression	$91.8	$1,808.0
Zocor® (simvastatin)	High cholesterol	$91.2	$2,207.0
Viagra® (sildenafil)	Impotence	$89.5	$ 809.4
Celebrex® (celecoxib)	Arthritis	$78.3	$2,015.5
Flonase® (fluticasone)	Allergy	$73.5	$ 618.7
Allegra® (fexofenadine)	Allergy	$67.0	$1,120.4
Meridia® (sibutramine)	Obesity	$65.0	$ 113.2
Total		*$924.3*	*$16,347.8*

SOURCE: US NIHCM Report 2001[10]

In New Zealand PHARMAC conducted a review of 4 government subsidised prescription-only medicines currently being marketed by DTCA. A total of NZ$4,917,436 was spent on advertising these four medicines (Table 2).

Table 2. New Zealand 2001 advertising spend (at rate card) for four pharmaceuticals marketed directly to consumers

Product	Formulations	Press	Magazine	TV	Radio	Total
Flixotide®	11		$117,980	$1,711,824		$1,829,804
Lamisil®	2		$145,385	$618,836		$764,221
Losec®	4	$15,052	$145,785	$809,610	$109,834	$1,080,281
Oxis®	2		$143,793	$1,099,337		$1,243,130

SOURCE: PHARMAC [12]

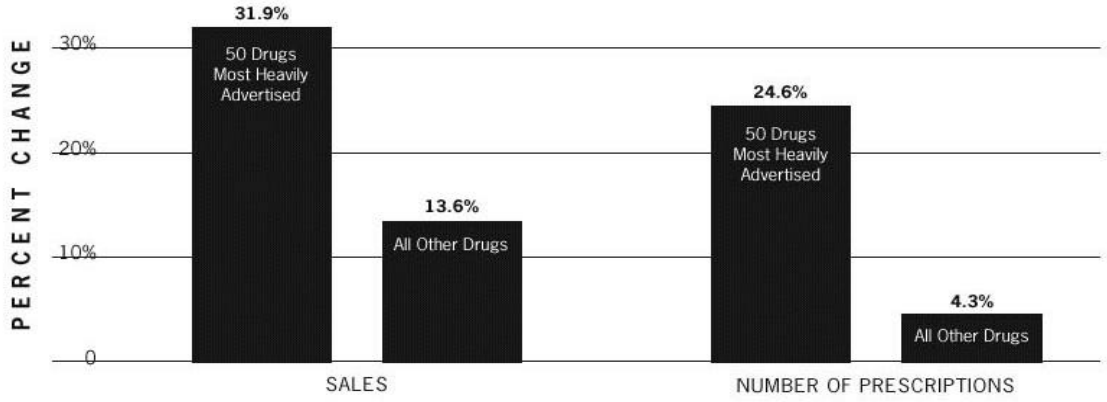
DTCA is effective as a marketing strategy

As US expenditure on DTCA increased, a corresponding increase in prescription drug sales occurred. Between 1999 and 2000 prescription drug sales increased by US $20.8 Billion. The 50 medicines with the highest advertising budgets accounted for nearly half the increase[10].

Effect on prescription volumes

Figure 2 shows an identical trend in the changes in sales and numbers of prescriptions in the United States for DTC-advertised vs. other medicines for the period 1999-2000.

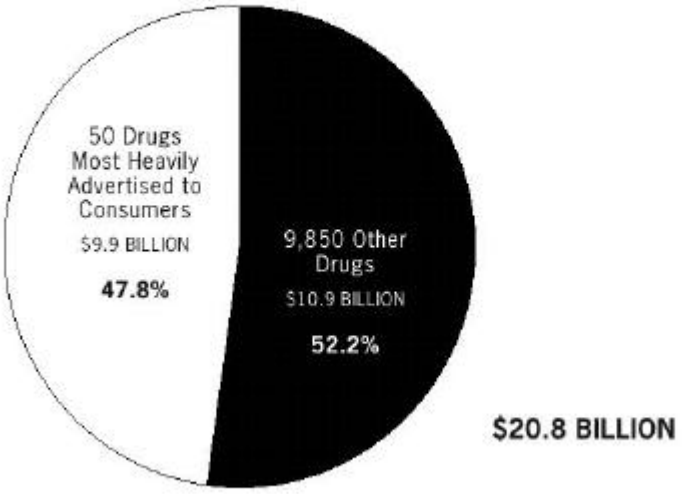
Fig 2 Change in Sales and number of prescriptions 1999 – 2000 (US)



SOURCE: US NIHCM Report 2001[10]

Figure 3 below shows clearly the contribution that DTC-advertised drugs make to this growth. The 50 drugs most heavily advertised (which represent 5% of the total number of drugs available) were responsible for 48% of the total growth in retail prescription drug sales. It is notable that figures for retail drug sales do not include mail order sales of prescription drugs, which is one of the fastest growing components of the prescription drug market in the US. Mail order sales totalled US$16.3 billion in 2000 and rose 27% to US$20.7 billion in 2001 (making up 12% of total prescription drug sales in 2001)[13].

Fig 3: Relative Contribution of 50 Most DTC Advertised Drugs to Increase in Retail Prescription Drug Sales (US) 1999-2000



SOURCE: US NIHCM Report 2001

The difference in prescriptions between advertised and non-advertised medicines for 2001 was even more striking. In May 2002 the United States National Institute of Health Care Management (NIHCM) published its latest analysis of drug cost increases for the year 2001[13]. It found that spending on outpatient prescription medicines in United States retail outlets rose 17.1% between 2000 and 2001. The analysis revealed that the increase was largely due to shifts to newer, more costly medicines (24%), as well as an overall increase in the number of prescriptions (39%) while price increases contributed only 37%. The most heavily advertised medicines again saw the highest rises in retail sales. The numbers of prescriptions written for the top 50 medicines (i.e. those contributing most to the rise in sales over one year) rose 31.7% compared to 1.1% for all other medicines between 2000 and 2001[13].

New Zealand

Evidence from the United States can be extrapolated to New Zealand as both the population and clinical practice trends are similar in both countries[14]. Evidence to date show trends in New Zealand are mirroring those in the US.

DTCA is clearly bringing patients to their doctors. The authors of this report carried out a recent survey of all New Zealand GPs. A letter was sent detailing the conclusions of the authors after review of the literature around the effects of DTCA and stating their intention to advocate for a ban. The letter asked GPs to fill in a questionnaire, asking for their opinions and experiences to be used in support of this advocacy. Fifty percent (n=1611) of GPs responded within ten days. Ninety percent of the 1611 respondents stated they had experienced consultations specifically generated by DTCA. Seventy-nine percent of respondents reported patients had frequently asked for DTC-advertised medicines (appendix 3).

In line with previous years, total dispensing volumes in New Zealand for the year 2001/02 for pharmaceuticals listed on the Pharmaceutical Schedule showed an appreciable increase over that of the previous year. Dispensings totalled 42.0 million in 2001/02, compared with 39.7 million in 2000/01, an increase of 5.7% with 2.26 million extra dispensings. A PHARMAC analysis showed that 22% of the increased dispensing was due to four heavily advertised drugs (Flixotide® (fluticasone), Losec®, Lamisil® and Oxis®). Within this same one year period, PHARMAC estimated that 10% of the increase in dispensing volume was due to population increases, and 3.9% due to new investments[12].

There was a growth in prescriptions for these four products, ranging between 13% (Lamisil®) and 253% (Oxis® – an asthma medication) table 3. The total increase in dispensing volume for these products was 42% (Table 3).

Table 3. Dispensings of pharmaceuticals subjected to DTCA

	2001	*2002*	*Difference*	*% increase*
Losec®	623,654	980,763	357,109	57
Flixotide®	508,134	585,211	77,077	15
Oxis®	21,806	76,899	55,093	253
Lamisil®	29,420	33,175	3,755	13
Totals	1,183,014	1,676,048	493,034	42

DATA SOURCE: PHARMAC[12]

These 493,034 extra dispensings accounted for 22% of the overall increase in dispensings in 2001/02. This volume growth is only from 4 of the 18 DTCA advertised products. While there were other influences on volume growth for these products (companies undertake other marketing activity and PHARMAC widened access to some), overall growth from DTC-advertised medicines would be higher if all advertised products could be reviewed. After adjusting for reference pricing changes this represents the equivalent of an $11 million increase in pharmaceutical expenditure over this 12-month period. PHARMAC estimates that Losec® and Flixotide® (fluticasone) alone account for an increase of 434,168 additional dispensings, 19% of the overall total increase in dispensings for 2001-2002[12].

Effect on Prescribers and Consumers

The United States Congress recently commissioned a report from its investigative arm, the General Accounting Office (GAO) on the regulation of DTCA by the Food and Drug Administration. Based on consumer surveys, the report estimates that up to 8.5 million US citizens in 2000 were prescribed new medicines as a result of asking their doctors for medicines they had seen advertised DTC[9]. In the recent Colmar Brunton consumer survey in New Zealand, one in eight (13%) respondents have been prompted to ask for a prescription-only medicine as the result of seeing an advertisement and 62% of these received the medicine they requested[15].

An FDA physician survey of 250 family physicians and 250 specialists (including dermatologists, allergists, endocrinologists and psychiatrists) examined physicians' most recent consultation in which a patient had initiated a discussion about a prescription drug they had seen advertised. All of the physicians could recall such an encounter (459 or 92%), and 71% of physicians felt that questions from patients about prescription drugs had increased over the last five years. Nearly 9 out of 10 patients, 86%, who initiated a discussion in response to advertising asked for a specific drug by brand name, and over half of these patients (59%) directly asked the physician for a prescription for the brand in these consultations, 57% of the physicians said they prescribed the requested drug. Many of the physicians reported feeling pressured to prescribe a drug at the visit. Physicians were three times as likely to feel 'somewhat' or 'very' pressured if a patient had requested a prescription for a specific brand name drug than if they had not (28% vs. 11%). These reports of pressure occurred in spite of generally positive opinions on DTCA, although 60% of the physicians did not report any beneficial effects on their interaction with the patient, and 18% believed that exposure to advertising had created a problem. Overall 17% felt that it made patients more aware of treatments. However only 19 physicians, or 4% felt that DTCA informs or educates patients[16].

In another United States survey of 199 physicians, physicians were approached by an average of 5 patients requesting specific medicines each week, with TV advertisements prompting requests 77% of the time. Ninety-one percent of physicians said they felt under pressure to prescribe products patients asked them about[17].

Only one survey, carried out in two cities in the United States and Canada, has ever directly measured how many patients received prescriptions for an advertised medicine that they request in a single primary care consultation. Patients filled in a questionnaire in the waiting room before the consultation and physicians filled in a questionnaire after the consultation. A total of 1472 patients participated in the study. Three quarters of patients in each city who requested an advertised medicine received a new prescription for that medicine[18]. This rate is very similar to that reported in U.S.

consumer surveys: 77% in a survey by Prevention Magazine in 2001[19]. The United States Food and Drug Administration (FDA) has also released preliminary results from its latest consumer survey on attitudes to DTC advertising[20]. The survey found that 72% of respondents had seen or heard an advertisement for a prescription medicine in the previous three months. Fifty percent of those who asked about a specific brand received a prescription for it. A survey by the National Consumers League in the United Stated found that 71% of all adults who spoke with their doctor about an advertised medication say their doctor prescribed the medication[21].

The researchers in the two-city study also assessed the physicians' confidence in treatment choice by asking how likely they would be to prescribe the same drug to a similar patient with the same condition. They found that doctors were ambivalent about 12 percent of new prescriptions not requested by patients. However, they were ambivalent about 50 percent of DTC-advertised medicines prescribed following a patient request. The researchers concluded that DTCA was a powerful driver of prescribing decisions. This study includes two settings with different levels of exposure to DTCA; in Canada DTCA is illegal but there is considerable exposure to cross-border media from the U.S., as well as lax enforcement within the country [18]. Patients from both settings with higher individual exposure to DTCA were more likely to request advertised drugs from their physicians than others with lower exposure, in a single observed consultation. Most importantly, however, the researchers were concerned about the impact of advertising on appropriate prescribing. Writing in the British Medical Journal (BMJ) they said: "If physicians prescribe requested medicines despite personal reservations, sales may increase but appropriateness of prescribing may suffer. Concerns about the value of opening up the regulatory environment to permit direct to consumer adverting in the EU and Canada seem well justified."[22]

The authors' survey of New Zealand GPs drew a response from 50% (n=1611). Sixty-nine percent of respondents felt that they had been under pressure to prescribe advertised medicines, 44% said they had switched to or started treatment with medicines they felt offered little added benefit over drugs they would normally use (appendix 3).

THE ROLE OF DTCA IN CONSUMER EDUCATION

Patient-centred medicine is considered a cornerstone of good quality modern general practice, particularly in New Zealand, and consumers wish and have a right to be involved in decisions about their treatment[14 23 24]. However DTCA is not the most effective way to assist this as drug advertisements do little to educate or inform consumers. Instead, they are designed principally to stimulate demand and to generate brand loyalty[3 25 26].

Can DTCA be considered patient education?

Pharmaceutical companies argue that they are educating patients with DTCA and that this has the potential to improve both community and individual awareness of some conditions and possible treatment. However, the 'quality' of information in DTC advertisements is such that most DTC advertising cannot be considered educational and does not lead to public understanding of the efficacy of the drug or of all of the treatment options available[27].

Educational Value

A US study of the content of DTCA concluded that most promotions provided a minimal amount of information and that DTCA could not be recommended for its

educational value[28]. A one-year review of 67 DTC advertisements in the US (1998-1999) found that 87% of advertisements described the benefits of medication in vague qualitative terms rather than with research data. In contrast, half the advertisements used data to describe side effects, generally with lists of side effects that occurred rarely. Very few advertisements mentioned costs. The authors concluded that the advertisements rarely quantify expected benefit, instead making an emotional appeal[29]. This strategy probably leaves many readers and / or listeners with the perception that the drug has a large benefit and that everyone who uses the drug will enjoy these benefits. An FDA consumer survey in 2002 found that 41% of those who recalled seeing a print advertisement said they read 'none' of the brief summary, while 10% said they read it all; 55% said the brief summary was 'very hard' or 'somewhat hard' to understand[30]. It is questionable whether it would ever be possible to present the required amount and balance of information in a 30-second advertisement.

Morgan [31] concluded that there is an unmistakable conflict of interest for drug manufacturers when "educating" patients about therapeutic alternatives. The incentives for exaggeration and persuasion are great, and the patients' ability to verify promotional claims is limited by lack of technical expertise and access to unbiased information sources. He goes on to state that economic theory and historical experience indicate that the marketplace for ideas created by consumer-directed drug advertisements will inevitably be unbalanced and biased[31].

Accuracy

DTC advertisements commonly contain misleading information. They also commonly contain inaccurate information. In the US between 1997 and 1999, 52% of DTC advertisements were found to be in violation of the Food, Drug and Cosmetics Act[32]. In a New Zealand survey of 3 months of advertisements that was reported in 2000, just under one third (31%) of all DTC advertisements for prescription-only medicines were found to be in breach of the Medicines Act as interpreted by Medsafe staff[33]. Five out of 6 television advertisements reviewed for prescription-only medicines were found to be in breach.

In the authors NZ GP opinion survey only 12% of 1611 respondents believed that DTCA is a useful means of educating consumers about the risks and benefits of prescription medicines, and only 1 in 25 felt DTCA provides the balance of information consumers need (appendix 3). In the recent Colmar Brunton poll the information in pharmaceutical company advertisements was perceived as much less trustworthy than that obtained from health professionals[15 34].

There has been a steady increase in DTCA since it began in New Zealand in the late 1980's. Information about risks and benefits is often collapsed into a statement to 'talk to your doctor and see if this is right for you,' and there has been no change in the usage of very small print which, in television advertisements, is on the screen for a very limited amount of time. Studies indicate that as the amount of risk information declines, viewers perceive the advertising more positively[35 36].

Recently, there has been a greater use of other forms of advertising such as billboards, and bus-shelter advertisements which are designed to be seen by the public during the working day. The fleeting image means the public is unable to read anything but the dominant slogan. The use of vouchers, loyalty schemes and free samples has proliferated. DTCA is continually pushing the boundaries into forms of marketing that further undermine the doctor's ability to freely discuss treatment options with a patient. In the US there are moves from supporters of DTCA to further reduce risk

information in drug advertising. Calfee, a strong supporter of DTCA in the US, recently produced a report funded by the "Coalition for Health Care Communication" (a group of medical advertising and marketing agencies). In this report he urged the FDA to 'reconsider the notion that all DTC advertisements need to balance information about risks and benefits', stating that this would 'make information dissemination more efficient' as 'advertising works best by filling the relevant holes in consumer awareness and emphasising different product features' and that risk dissemination should be focused in physician offices and pharmacies[37].

Quality

A number of quality standards have been proposed for consumer medicines and health information, in order to ensure that patients receive the quality of information needed to participate in informed health care choices. DTCA does not meet any recognised set of guidelines for health promotion, case finding or education. Examples of such guidelines include DISCERN (University of Oxford, Division of Public Health and Primary Health Care, Headington Oxford www.discern.org.uk) and the Kings Fund and Centre for Health Information (the Help for Health Trust, 2002). An abbreviated guide to the DISCERN criteria is included in the summary section. The New Zealand Code of Health and Disability Services Consumers' Rights (www.hdc.org.nz) describes the information that consumers should receive to make informed choices and give informed consent. Right 6 includes presentation of "options including expected costs, side effects, benefits and risks." The current Health and Disability Commissioner is sceptical of the claims made in favour of DTCA. He states that "Despite the claims, I have not seen evidence that DTCA advertising ultimately leads to more empowered consumers who are more likely to seek early diagnosis and treatment, receive appropriate treatment and have improved outcomes."[38] Advertisements encouraging people to ask for new medications whilst undermining their confidence in their existing medication may generate considerable anxiety. Numerous examples of this effect were described in the recent NZ GP survey (appendix 3):

"Patients feel their drug is inferior to the one on TV. Patients with asthma now all want Symbicort® even though a long acting ß-agonist (is) not indicated for them."

"I have seen 2 patients extremely concerned that they need vaccination for Hep A and Hep B. Both were beneficiaries and could not afford it anyway. Both required intensive discussion/counselling/advice to reassure them that they were not at increased risk of either of the viruses despite what the 'ad on TV shows'

"I find that it can be a nuisance as it creates doubts in patients' mind about the efficacy of the medication they may already be on."

Mass health promotion campaigns are normally rigorously evaluated in a pilot study. There are many examples of strategies to encourage early diagnosis that on inspection appear to be useful. With rigorous evaluation in fact these can be found to be of marginal benefit or unaffordable[39 40].

A University of British Columbia study surveyed 150 drug policy experts in the US, New Zealand and Canada[41]. The experts were from health professional organisations, consumer and disease/patient groups, government agencies, private insurers, managed care organisations, and the pharmaceutical and advertising industry and media. The response rate was 71%. Two thirds of those who took part judged the information provided by DTCA to be poor or very poor. Twenty-eight percent – generally from the pharmaceutical or advertising industries – said it was good to excellent. Most

(60%) thought the effects of DTCA on patient knowledge of medicines and diseases and on health care quality was negative or at best neutral.

PRESCRIPTION MEDICINES: CONSUMER ACCESS TO INFORMATION

The Nature of Prescription Medicines

Findlay, writing in a paper on pharmacoeconomics states: 'Prescription drugs are not like any other consumer product… Prescription medicines are part of a complex system of medical care that must be ruled first and foremost by science and careful human judgment, not the profit motive. The chief purpose of prescription medicines cannot be consumption for consumption's sake. More is not necessarily or always better – if better is defined as improved public health, a reduction in human pain and suffering and the prevention of premature death.'[42]

Few other industries are as heavily subsidised by the government as the pharmaceutical industry. Few other products advertised to consumers carry the same risks for serious harm and death, as do prescription medicines. The example of the DTC marketing of the anti-androgen / oral contraceptive pill Diane-35® for its beneficial effects on the complexion clearly illustrates this. In addition, few consumer products require the same level of knowledge to assess the balance of risks and benefits of the product. Education is not the same as advertising. Information from health professionals and consumer groups would carry a message very different from a company trying to sell a product. Many patients suffering from chronic diseases are vulnerable to advertising which use emotional appeals to promise relief.

CASE STUDY: DIANE-35® (CYPROTERONE ACETATE) [34]

Diane-35®, an anti-androgen / oral contraceptive pill was marketed as a solution to problem complexion, with wording similar to that used in cosmetics advertisements.

Headline: "Restore the natural balance of your skin with Diane-35®"

'Tried every treatment known to woman? Diane-35® is an effective solution for problem skin that is proven to be 93% effective.'

The contraceptive effects of Diane 35® were mentioned only in the small print and in even smaller print at the bottom of the page 'Diane-35® has a similar side effect profile to other oral contraceptives.'

A Colmar Brunton poll in 2000 showed only 20% of women surveyed after being showed the advertisement for Diane-35® realised it was also a contraceptive.

A British study had shown that the risk of venous thrombo-embolism with this product was more that eight times the risk of women not using contraceptive pills and double that of women using other new generation oral contraceptives. By November 2001 there had been 18 reports of VTE in New Zealand women using Diane-35®. Where the reasons for using the medication were known, ten were for contraception, five for acne and two for irregular periods.

In 2002 Medsafe wrote to all doctors asking them to review all women on this medication. By this time 25 000 New Zealand women were using Dianne-35® or it's equivalent Estelle-35®.

Consumer Surveys

The evidence around consumers' views of DTCA is conflicting. Surveys of public opinion which make it clear that consumers want information on medicines also show that consumers are sceptical and do not trust DTC advertisements to provide them with the information they require. They do reveal however, that consumers preferred sources of information are independent health professionals. In a survey of Canadian and United States consumers, 73% of Canadians and 68% of United States citizens indicated that doctors were their preferred information sources for medicines, with only 0.3% of Canadians and 0.7% of United States citizens indicating they found television advertising to be a useful source of information[18 22]. Another survey showed that United States consumers use their television remote button to turn off DTC advertisements more than any other[43].

With the possibility of DTCA starting in Europe, The UK Consumers Association conducted a survey of 1818 adults on the question of pharmaceutical industry advertising in June 2002[44]. The results showed:

- 81% of people believe that drug companies will spend most money on advertising the medicines that give them most profit.
- 62% of people believe that drug company advertising would not give people information about possible side effects.
- 59% of people believe that drug company advertising would try and convince people that they have illnesses they do not really have.
- 60% of people believe that advertising of prescription-only medicines would raise awareness of illnesses that people might not otherwise realise they had.
- 53% of people believe that patients would seek treatment more quickly if they had seen an advert for a prescription-only medicine.
- 25% of people believe that drug company advertising would provide unbiased and comprehensive information about treatments, including non-drug treatments and competing brands

This study has been repeated in New Zealand recently using the Colmar Brunton Omnibus telephone survey. The response from consumers was very similar (Appendix 2).

There are a number of surveys funded by organisations supportive of DTCA. These are summarised by Calfee[37 45] who concludes that consumers like seeing the advertisements. As they are sceptical of advertising in general he believes that DTCA is beneficial overall. A recent National Consumers League consumer survey in the US again found consumers generally positive about DTCA yet distrustful of their content and purpose[21].

Even proponents of DTCA acknowledge that consumers mistrust advertising[3]. Calfee, a strong supporter of DTCA, in his paper states that "roughly 70% of consumers mistrust advertising claims in general." and that "Consumers, of course, assume that information in ads is biased in favour of the advertiser"[37]. While consumers have a background level of (healthy) scepticism about DTCA in general, evidence also indicates that they believe individual advertisements. Canadian

consumer surveys showed similar results with just over 20% of respondents believing medicine advertisements on television to be either accurate or 'fairly accurate'[18]. Like the British and New Zealanders, Canadians also indicated that health professionals were the information sources on health and medicines that they found most useful, with advertisements on television indicated as useful by less than 1%[18]. A study by the Kaiser Family Foundation found that people are much more likely to judge the information in an advertisement as reliable immediately after seeing it[46]. This finding seemed to be related to the act of viewing, as it was similar among viewers randomised to one of three different advertisements – it didn't matter what participants saw, they trusted it more if they had just seen it. A recent US survey found that 48% of people believed government regulations allowed only the safest prescription medicines to be advertised on US TV[19]. Some surveys indicate consumers believe advertisements have been scrutinised or endorsed in some way by the government[18 47]. This suggests both a false belief in regulatory protection, and inadequate communication of serious product risks to viewers. This is likely to increase the credibility of prescription drug advertisements over other forms of advertising.

There remains a danger that consumers will unknowingly be influenced by advertisements that are unbalanced with overstatement of efficacy and understatement of risk - an ongoing concern both in New Zealand and the US[9].

Any attempt to restrict the pharmaceutical industry access to patients is met with charges of paternalism to which the medical profession is particularly sensitive. The industry argues that the nature of the doctor-patient relationship is changing, with medical dominance giving way to partnership and patient empowerment, and that advertising empowers consumers. They argue that the medical profession has difficulty in accepting this changing role and, rather than opposing DTCA, should "develop appropriate relationship management skills"[48]. It is true that the doctor-patient relationship is evolving and that this is a sensitive process. However, this relationship should not include an accommodation of the commercial imperative of the pharmaceutical industry. Informed choice of treatment (including medication) takes place in a therapeutic partnership between patient and the prescriber and must be built upon a base of unbiased, accurate, comprehensive and up-to-date information on all treatment choices including the full range of available treatments, both drug and non-drug. Advertising cannot provide this type of information. While there is evidence that consumers are seeking a partnership model of health care, there is no evidence that consumers see DTCA as part of that model.

Patients do indeed have a right to access high quality information on health and medicines. Information about treatments should ideally be independent - 'the kind of balanced information people need cannot by definition be provided by advertising' (Prof. Angela Coulter. Chief Executive Picker Institute Europe, UK and member G10 Medicines Group)[49]. Where DTCA is banned, this is a legal restriction on **manufacturers**' right to promote sales of prescription-only products in certain ways; it is not a legal restriction on **public** information rights. The public maintains the legal right to obtain information about medicines, including the right of access to non-promotional information from all available information sources.

Pharmaceutical companies claim that as DTC advertising is already freely accessible on the Internet, there is little argument against making it available via other media. Internet availability certainly does not legitimise information, and the flaws in this argument can readily be seen when it is applied to other forms of material currently

available on the web. Consumers must actively seek access to medical information on the Internet. When it is provided on television they have little choice but to watch, although interestingly in one study drug advertisements were the ones which most prompted the use of the mute button[43]. The Internet requires an active search for information. DTCA in print or television advertisements is passive exposure designed to generate demand. Internet searches present the inquirer with multiple sources of information in response to the query; DTCA typically fails to present any alternative options. Consumers have a different view of the trustworthiness of information supplied in TV advertisements. The NZ experience is similar. Here the focus of DTCA has been on promoting medicines as being better than existing options. "PHARMAC staff report receiving many calls from patients asking why Celebrex® (celecoxib) (a COX 2 inhibitor anti inflammatory similar to Vioxx® (rofecoxib) both used for the treatment of arthritis) is not funded, stating that they have seen it on TV therefore it must be better."[50]

Consumers need reliable independent information sources

The idea of shared, informed health care choices is important and reflects the changing nature of medical care. However, it must be built on a base of independent, accurate, comprehensive and up-to-date information on all treatment options, both drug and non-drug. It is unlikely brand advertising can ever provide the type of balanced comparative information that international professional and consumer organisations are looking for. Consumer organisations agree that medicines information should not be provided by pharmaceutical company advertising [51 52].

New Zealand Bill of Rights Act 1990 (NZBOR)

During the consultation round in 2000 the question was raised as to whether a ban on DTCA of prescription medicines would be consistent with the NZBOR Act, in particular section 14, which provides that:

s 14. Freedom of Expression – everyone has the right to freedom of expression including the freedom to seek, receive, and impart information and opinions of any kind in any form.

It has been argued this includes the right to advertise medicines to the public and a ban is inconsistent with that right. However Section 5 of the Act states that rights affirmed by NZBORA can be subject to "such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society".

The Court of Appeal in Moonen[53] established the test as to whether a limit on a freedom can be justified.

Moonen sets out a three-point test, which can be applied here, to determine whether a ban on DTCA would breach the NZBOR. The test is as follows:

1. The means used to achieve the objective must have a rational connection with the objective.

The question is whether there is a link between DTCA and the inappropriate use of prescription medicines such that public health and safety is endangered.

There is clear evidence that DTCA increases the rate of use of new drugs. Knowledge of less common or longer-term risks is necessarily limited when drugs are new. There is evidence that some DTC-advertised drugs have been the subjects of warnings of

significant new hazards discovered post approval, including potentially fatal adverse events[54-59]. There are also examples where pharmaceutical companies have continued to advertise those drugs even after major adverse events have been described (see Rezulin® case study).

The evidence summarised in this document demonstrates a clear link between DTCA and a negative effect on public health and safety. It can therefore be strongly argued that removing the cause of this negative effect through a ban on DTCA would lead to an increase in public health and safety.

There is therefore a rational connection between the limiting measure (a ban on DTCA) and the objective (increasing public health and safety) and the test is satisfied.

2. Proportionality – i.e. a sledgehammer should not be used to crack a nut.

The question is whether the right to commercial free speech, in respect of prescription medicines, outweighs negative effects on public health and safety.

The evidence summarised in this document argues strongly in favour of a ban on DTCA of prescription medicines being a proportional response to the negative effects on public health and safety. Alternatives to a ban such as industry self-regulation and central regulation are not working and have failed to mitigate these negative effects. The European Union, Australia and South Africa have recently reviewed their positions on DTCA and concluded that a ban is the most appropriate means for limiting the negative effects. The WHO has described DTCA of prescription-only medicines as unethical [60].

Given the serious nature of the negative effects, the failure of the alternatives and the international context, it is argued that a ban on DTCA of prescription medicines is a proportional and appropriate response to the negative impact of DTCA

Under a ban on DTCA of prescription medicines, over-the-counter medicines may still be advertised to the public, and prescription-only drugs may be advertised to health professionals. A ban on DTCA of prescription-only medicines is a partial restriction on rights to commercial expression that is consistent with existing restrictions on sales.

3. In achieving the objective there must be as little interference as possible with the right or freedom affected and the limitation must be justifiable in light of the objective.

A ban on DTCA does trespass on the right to freedom of expression. The question is whether any lesser interference would still achieve the objective.

Freedom of expression is rarely an absolute right and the history of Public Health has generally required a balance of public good and private interest. Examples include early debates over water quality, immunisation, tobacco and seatbelt legislation.

As discussed previously the alternatives such as strict central regulation and industry self-regulation have been tried and have failed to address the negative effects of DTCA. In this case interference with the right to the freedom of expression is unavoidable but is justified in light of the evidence.

In summary, Section 5 of the NZBORA states that rights affirmed by NZBORA can be subject to "such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society". The Court of Appeal in Moonen[53] has set out the test as to whether a limit on freedom can be justified. Under this test a ban on DTCA of prescription medicines can be justified based on an examination of all the evidence and represents a solution that best reflects a balancing of the values involved.

ECONOMIC IMPLICATIONS OF DTCA OF PRESCRIPTION MEDICINES

DTCA is not fiscally neutral. It is not a matter of one medicine gaining market share at the expense of another. DTCA threatens the equitable allocation of the health budget. Increasing expenditure in one area leads to a reduction in money available for services and treatments in other areas. DTCA significantly increases demand for a small range of more expensive medicines, which do not necessarily offer advantages over other available treatments. This is demand based on market forces rather than need. When resources are finite this creates inequity by limiting the resources available for other treatments and procedures. In this way there is potential for DTCA to affect the public's right to medical treatment in the public health sector. The pharmaceutical industry is unique. The editor of the New England Journal of Medicine wrote in 2000 *"The pharmaceutical industry is extraordinarily privileged. An industry so important to the public health and so heavily subsidised and protected by the government has social responsibilities that should not be overshadowed by its drive for profits."*[61]

DTCA has a negative effect on health funding and may lead to distortion in resource allocation in a number of ways

1. Increasing the proportion of the health budget spent on pharmaceuticals by promoting pharmaceutical solutions over other available options.

2. Increasing expenditure within pharmaceutical budgets by promoting newer more expensive medicines that have little if any evidence of corresponding increase in positive health outcome over existing cheaper alternatives.

3. In February 2002 the Centre for Health Services and Policy Research at the University of British Columbia, Canada carried out a review of the literature on DTCA from January 1980 to August 2001. The authors of this review concluded that there is evidence that DTCA affects consumer behaviours and prescribing, and evidence of an association between advertised products and increased costs, while also concluding "No reliable evidence exists to support hypotheses of potential health benefits or to exclude potential harm. In nearly 20 years since the first print DTCA campaign in the U.S, no reliable research evidence had been found to back industry claims that earlier drug use stimulated by DTCA reduced serious disease or hospitalization rates, that extra physician visits stimulated by DTCA led to more rather than less appropriate care, or that DTCA stimulated more appropriate use of medicines by patients. In fact, most advertised drugs are no more effective and safer than older, cheaper alternatives." [49 62].

4. Generating direct and indirect consultation costs. Consultations generated by DTCA result in costs to the health budget for Community Service and High Use Health Cardholders. Consultations also generate costs for the patient, both as the

direct cost of consultation fees and unsubsidised or partially subsidised prescriptions as well as the indirect opportunity costs of time off work to see their GP.

Pharmaceutical expenditure accounts for an increasing proportion of health care expenditure in most countries. In the US $1.1trillion is spent on health care, and 8% of this on medicines. Drug costs are growing at the rate of 15-20% per year, faster than any other health care expenditure[63]. DTCA is a major driver of this trend. The National Institute for Health Care Management in the United States, September 2000, found that DTCA medicines are the fastest selling medicines and contributed to a 19% increase in pharmaceutical spending in 1999[47].

It is argued that the economic benefits of a patient coming forward for treatment could offset the relatively small wastage factor caused by unnecessary consultation or over-prescribing. There appear to be no published studies showing reduced mortality and / or morbidity that indicate that this is so. It is unlikely that there would be any beneficial effect seen as a result of medicines that are often simply more expensive versions of those currently available. It is also argued that DTCA results in patients presenting to the doctor earlier or with previously undiagnosed illness. This is called 'case finding'. Case finding strategies should be evidence based and create complex issues in primary care. Even well designed independent case finding strategies and targets for cardiovascular disease, a prevalent, important and costly condition, are controversial[40]. While there is evidence that DTCA prompts patient visits there is no evidence that it improves health outcomes by improving compliance or through early detection of disease. In the authors' New Zealand GP survey only 16% of respondents felt that DTC helped their patients get necessary medical care at an earlier stage, and less than 25% felt there was any degree of health gain from DTCA generated consultations (appendix 3).

If DTCA regularly resulted in appropriate prescriptions for new and necessary medications, it would presumably be cost effective. Unfortunately, there is no evidence that this is the case. Morgan from the University of British Columbia in Canada carried out an economic analysis on the potential impact of DTCA using different models. He considered the potential impact of advertising of different categories of medicines. Of the different models, he found truly pioneering products offer the best chance that advertising may hold some benefits for patients by reducing costs whilst also being profitable for the manufacturer. However, very few advertised products fall into this category. According to the Canadian Patent Medicines Review Board between 1996 and 2000 only 6% of new medicines in Canada were judged to represent 'breakthrough /substantial improvement over existing therapy'[64]. Most advertised medicines are competitors in established therapeutic classes. New medicines rarely represent a significant advance in treatment. The Flixotide® (fluticasone) campaign detailed in the case study below provides a striking local example of what appears to be a commercially driven decision promoted through extensive DTCA which resulted in thousands of New Zealanders switching from a well established steroid inhaler to a more expensive one. At the time, Flixotide® was 70% more expensive than beclomethasone for equipotent doses in the usual adult range[65].

CASE STUDY : FLIXOTIDE® (FLUTICASONE)

Over a four-year period Flixotide® (fluticasone), an inhaled steroid used to treat asthma, has been advertised directly to the public of New Zealand. An initial high profile DTC campaign on television suggested to patients with asthma that their symptoms might not be optimally controlled. This was accompanied by a variety of claims of superiority of Flixotide® (fluticasone) over existing products. Examination of the accumulated evidence on comparative efficacy suggests that whilst there may be small improvements in measures of airway calibre as compared to other inhaled steroids, although the company and some experts may think otherwise, there is no convincing evidence that this is translated into clinically significant improvement in symptoms or exacerbations. The Cochrane review states: "No studies found significant differences in terms of symptoms, rescue B2 agonist use or asthma exacerbations."[66]

Patients were encouraged to visit their GPs to switch to Flixotide® (fluticasone). This campaign was very successful and Flixotide® (fluticasone) quickly gained market share. In 2002 the pharmaceutical company ran a further DTC promotional campaign for Flixotide® (fluticasone).

In addition to a high profile TV advertising campaign, promotional packages were sent to GPs and pharmacists, press releases, advertisements in the New Zealand free GP newspapers and material was posted on the company's New Zealand website. The promotional material conveyed a number of messages. It told patients that their traditional treatment Becotide®/Becloforte® (beclomethasone) would be withdrawn because it contained CFC's. Patients were encouraged to ask their doctors to switch them to Flixotide® (fluticasone) and offered an inducement of a free inhaler to "upgrade" to Flixotide® (fluticasone). The fact that generic beclomethasone would continue to be available was omitted from the advertisements.

PHARMAC mounted a legal challenge on the following basis:

- The claim that Flixotide® (fluticasone) is superior/better than Becloforte®/Becotide® or other beclomethasone MDIs cannot be supported by published evidence.
- The 25mcg per dose Flixotide® (fluticasone) MDI is ***not*** CFC free and the tiny subscript qualification on the television advertisement is not effective at communicating this fact.
- The Montreal Protocol does not compel the company to withdraw Becotide®/Becloforte® MDIs in New Zealand. An exemption for the import of Becotide®/Becloforte® can be obtained from the Ministry of Economic Development. In the UK the introduction of CFC free inhalers will be gradual and Becotide®/Becloforte® continues to be available.
- The inducement of a free inhaler is misleading and deceptive because there are associated doctors' charges that need to be paid.

Following the filing of PHARMAC's legal challenge, the company modified its TV advertisement but the withdrawal of Becotide® / Becloforte® went ahead. Since that time a generic form of beclomethasone remains available from another company.

Over a 4 year period in the UNITED STATES from 1997 to January 2001 the pharmaceutical company received repeated letters from the FDA detailing violations to regulations in respect to their advertising of inhaled and intranasal

fluticasone propionate (Flixotide® and Flixonase® in New Zealand)[9]

Comments from New Zealand GPs indicate that patients thought they had to switch to Flixotide® (fluticasone) and that they also believed Flixotide® (fluticasone) was clinically superior.

"The recent Becotide®-flixotide advertising….was extremely misleading and actually caused significant anxiety for a number of patients."

"all patients on Becotide® assume they have to switch to Flixotide."

"I had a patients with an exacerbation of asthma present to me having stopped her Becotide® inhaler one month previously. She had seen the Flixotide advertisement on TV and misinterpreted the detail regarding CFC's. She thought the ad was saying that Becotide® inhalers were bad for your health, so stopped (..Her first and only language is English)."
There were other similar comments around patients misinterpreting ads and stopping their preventer leading to exacerbation of their asthma.

CASE STUDY : RELAFEN® (NABUMETONE)

This non-steroidal anti-inflammatory drug (NSAID) was introduced to the US market in 1992. The independent consumer group Public Citizen in the US did a cost comparison with other conventional NSAIDs and concluded that the difference in average wholesale cost for nabumetone when compared to ibuprofen was seven-fold. DTCA boosted sales by 52% in just a few months – in 1995 $US11 million was spent on DTCA campaigns for nabumetone. Public Citizen stated "It is difficult to imagine a set of circumstances in which a prescription drug consumer, given accurate complete information would accept the unknown risk of toxicity and higher cost of nabumetone over ibuprofen or naproxen. There is no evidence of an efficacy advantage for nabumetone over ibuprofen."[67]

Other less easily quantified costs related to DTCA include the direct and opportunity costs of appropriate regulation. The Ministry of Health estimated the direct costs to be NZ $1-2 million annually[4]. The cost of monitoring and managing adverse events for unnecessary prescriptions will undoubtedly be significant, if difficult to quantify.

Advertising revenue

Clearly the manufacturers of the advertised medicines together with advertisers, publishers and broadcasters are the main beneficiaries of DTCA
The revenue generated for advertisers from DTC advertising of prescription medicines is significant. Based on AC Neilson research [68] in New Zealand, in 1999, $NZ33.617 million was spent on all forms of medication advertising, of which 43% was spent on prescription-only medication. By 2000 this had risen to $NZ47.623 million on all forms of medication, 37% on prescription-only medication. In 2000, TV advertising of all medicines generated revenue of $NZ29 million, $NZ11 million of which was on prescription-only medication.

The majority of this revenue will not be completely lost with a ban on DTCA of prescription medicines - the majority of DTCA of medicines is for non-prescription

medicines. While loss of revenue on DTCA of prescription medicine will have an impact it should be remembered that this income stream started only a few years ago. The costs to individuals and to the New Zealand taxpayer of continuation of the current growth in DTCA would be much greater, in both pharmaceutical spending and the costs of regulatory control of DTCA.

Sustainability and Opportunity Costs

Continuation of DTCA will result in an increase in prescription medication costs that in the opinion of the authors will be unsustainable in New Zealand. In the United States between 1999 and 2000, the number of prescriptions for the 50 most heavily advertised medicines grew at 6 times the rate of all other medicines (24.6% compared to 4.3%)[10]. Retail sales of the most heavily advertised drug - Vioxx® (rofecoxib) - quadrupled in the same period, from US$329.5 million to US$1.5 billion. This additional DTCA - generated demand combined with the other costs to the health system creates distortions in pharmaceutical spending which will put intolerable pressure on other parts of the New Zealand health system. In the recent European debate on DTCA, commentators predicted an unsustainable spiral of health care spending, with potentially devastating public health consequences resulting from the strain placed on the health systems and budgets of a number of state funded health systems in Europe if DTCA were to be introduced[52].

EFFECTS OF DTCA ON THE CLINICIAN PATIENT RELATIONSHIP

The Learned Intermediary Argument

It is often argued that as the supply of DTCA prescription-only medicine must be endorsed by a prescriber this will prevent use of medicines that are not appropriate. However, it is well known that doctors strive to please their patients and that they are receptive to patient requests to try new treatments[69 70]. There is evidence that prescribers often feel pressured to write prescriptions for DTC-advertised medicines they would not otherwise have used for that patient[18 22]. This trend is likely to continue to increase with the active promotion of the patient-centred approach (based on mutual participation and partnership in decision making) as a core feature of modern general practice[71].

In a US telephone consumer survey, patients were asked about their reaction if a physician were to deny an advertisement related drug request[72].

> 46% said they would feel disappointed
> 25% indicated they would try to influence the physician to change their mind
> 24% indicated they would seek the prescription elsewhere
> 15% indicated they would consider terminating their relationship with that physician

Some 9% of consumers in a 2002 FDA survey also said they would think about switching doctors in response to the doctors reaction to a request for a drug[30].
There are commercial pressures that influence GPs in the New Zealand fee-for-service funding model, where GPs rely on a loyal patient base for their income. The link between these patient reactions and the pressure on GP behaviour is supported by another United States study which found 91% of physicians felt under pressure to prescribe products patients asked them about[17].

DTCA undoubtedly causes patients/consumers to apply pressure to doctors to prescribe. A US survey of family physicians found that 89% of the 454 physicians surveyed did not believe DTCA enhanced the doctor-patient relationship and 71% believed physicians were "pressured to use medicines they might not ordinarily use"[73].

In a survey of physicians conducted by the Minnesota Medical Association, more than half of the respondents had felt pressured at some time to write a prescription for an advertised drug even though they felt the drug was not appropriate for the patient. Seventy eight percent said that patients requested DTC advertised drugs once or twice a week or more. A total of 70% said they felt DTCA was increasing drug costs and sixty percent of respondents said consultation time was increasing because of DTCA, and one third said they felt it contributed to a perceptible decrease in patient satisfaction with their physician. More than 43% of respondents said they believed that DTC advertising was the pharmaceutical industry practice that most affects the current practice of medicine[74].

There is New Zealand evidence of the effects of DTCA on the doctor patient relationship and clinical practice. In 1998, 61% of GPs in an IMS/NZ Doctor survey felt DTCA created disharmony within the doctor patient relationship. In the authors New Zealand GP survey in 2002, only 28% of respondents felt DTCA did not lead to difficulties in the doctor patient relationship - only 3% of GPs felt DTCA improved the quality of their prescribing (appendix 3).

These commercial pressures make it increasingly difficult for the modern GP to balance both patient-centred and evidence-based medicine.

There were several hundred free text responses in the authors' NZ GP survey. One of the key themes that emerged was the pressure on the doctor patient relationship resulting from DTCA. A few example quotes are reproduced below

"Although I always resist DTCA generated requests to initiate or change medications, these patients simply go to another practitioner (in the same practice!), who gives them anything they ask for. I spend a great deal of time explaining the evidence-based option, the non-drug-based options and the options that will lead to better outcomes at lower doses. I don't know why I waste my breath! Very rarely DTC-generated consultations to switch from brown to pink to red inhalers have alerted me to existing poor compliance/poor inhaler technique and even more rarely, the patient has taken on board the messages about improving technique and compliance"

"I have lost quite a few patients because I did not prescribe Xenical®, Reductil®, Symbicort® etc because they were not appropriate"

"Reluctance to prescribe (by me) has been seen as paternalistic, small minded and power wielding by one patient who informed me that it was their body, their right to choose and that drug companies used DTC because Doctors don't have patients' best interests at heart!!!"

"Manufacturers of Vioxx® (rofecoxib) advertised in magazines available to consumers via pharmacy that if they write away they can pick up a free sample from their GP… Sample sent to me, I sent it back – patient abused my staff claimed we were withholding vital medication just to receive an extra fee – this was not

mentioned by my staff (i.e. paying for consult to receive drug). I complained to PHARMAC who agreed probably legal but unethical, suggested complaint to RMI, did so, finally received phone call from Vioxx® (rofecoxib) suppliers claiming it was a mistake by a junior staff member (fly in the soup letter). I consider that direct trading between drug companies and the public with rubber stamping by their doctors is unreasonable. I take my duty of care more seriously"

IMPLICATIONS FOR MEDICINE SAFETY

DTCA is focused on newer more expensive medicines.

DTCA can result in rapid and widespread uptake of newer more expensive medicines about which less is known in terms of safety and efficacy on the general population.

The principles of rational prescribing caution against using very new medicines unless and until there is clear evidence for major advantages over existing effective medicines. This superior efficacy must be balanced by a well-established knowledge of safety and risks in a general patient population.

The Value of New Medicines

One of the arguments used in favour of DTCA is that it brings major advances in treatment to the attention of the public. This is based on the assumption that newly introduced medicines represent major advances in treatment. Recent summary statistics available indicate that this is not the case for the majority of newly introduced medicines. The Canadian Patented Medicines Prices Review Board puts new medicines into 3 categories.

- breakthrough/substantial improvement over existing therapy
- line extensions
- moderate/little or no therapeutic improvement

Between 1996 and 2000 less than 6% of new medicines were considered to be 'breakthrough/substantial improvement over existing therapy', while 40% were merely line extensions and 54% represented 'moderate/little or no therapeutic improvement over existing medicines'[64]. The French Drug Bulletin 'Prescrire' reviewed 2257 new medications/new indications for medications between 1981 and 2000 and judged that only 3% showed major or therapeutic gains, 9% offered some advantage, 3% were not acceptable compared to existing treatments (i.e. riskier or less effective), while 63% were assessed as superfluous because they offered no treatment advantages over previously available products[75]. A report in the British Medical Journal showed studies with positive results were much more likely to be published than studies with negative results (for example studies which do not show a drug to be superior to a placebo or older version). When studies with negative results were published the time to publication was significantly longer[76], delaying the publication of information required for comparing the efficacy of new drugs with existing agents. An example of an unpublished study of importance to the efficacy analysis of a heavily advertised drug is the North American pre-market study of the flu drug Relenza® (zanamivir). It was the largest pre-marketing trial of Relenza®. Data reported by the drug company to the FDA as part of the registration process showed no statistically significant difference in median time to improvement in symptoms when compared with placebo[77]. This research remains unpublished.

The Safety of New Medicines

Adverse reactions to medicines are believed to be one of the leading causes of death in the United States[78]. DTCA is largely focussed on new medicines. Generally when a drug first comes on the market knowledge of its harmful effects is limited compared to older medicines [54]. A senior FDA investigative official commented in 1992 that the agency has no good way of determining when clinical study summaries submitted by pharmaceutical companies misrepresent underlying safety data[79]. New medications are usually more expensive than older ones, and because they are new, less is known about them than older 'tried and true' products, particularly in the area of safety. As previously stated, rational prescribing is by nature conservative and promotes caution in the use of new medicines unless there is clear evidence for major advantages over existing medications known to be effective. There are numerous examples of DTCA-driven rapid and widespread adoption of newly licensed medicines[47]. In this way, DTCA results in rapid widespread exposure to potentially dangerous medicines before the risks are fully recognised or even in the face of evidence of those risks. There are examples of this in the US. Rezulin® (troglitazone) and Oraflex® (benoxaprofen) highlighted below are two well-known examples. While it takes time and use of a new drug to discover rare but serious side effects, DTCA results in many more people being exposed to the drug when knowledge on adverse effects is limited.

A study of new medicines introduced into the market over a 20-year period found that 3% of medicines had been withdrawn from the market and 10% had previously unrecognised important and serious adverse drug reactions requiring black box warnings[54]. From this study it is estimated that the probability of a medicine acquiring a serious warning or being withdrawn over 25 years was 20%. Over half of the withdrawals occurred in the two years following introduction[54]. Although the percentage withdrawn is small, a large proportion of the population may be exposed before the safety issues become apparent. An analysis of 5 new medicines that were withdrawn from the United States market in a single year because of safety concerns showed that almost 10% of the population (19.8 million patients) were exposed to one of these medicines before their withdrawal[55]. A recent US study examined dose changes for newly approved medicines. The study found that 1 in 5 new medicines had dose changes as a result of information that came to light in post-marketing surveillance. Of these changes 4 out of 5 were safety-motivated, net dosage decreases. The median time to change was 2 years[80]. Similar findings were reported in a European study[81]. A Pulitzer Prize-winning investigative report by Willman writing in the Los Angeles Times in 2001 investigated 7 new drugs withdrawn from the US market between 1993 and 2000. It claimed these drugs had been cited in 1002 deaths in FDA reports. These drugs alone generated US sales exceeding US$5 billion[56].

CASE STUDY : REZULIN® (TROGLITAZONE)

In 1997 a new drug, Rezulin®, was introduced for the treatment of type 2 diabetes and was heavily promoted DTC. It was quickly linked to severe liver damage and, by the end of 1997, was implicated in 6 deaths and 135 cases of severe liver toxicity. This led to its withdrawal from the UK market by the UK Medicines Control Agency at the end of 1997 just six weeks after it was made available. Despite this, it continued to be marketed and heavily promoted DTC in the United States. DTCA campaigns continued in the United States, but did not mention that Rezulin® had been withdrawn for safety reasons in another jurisdiction. This information is not required under US law, but it would be important to diabetic patients seeing the advertisements and considering the pros and cons of requesting the drug from their doctor. Rezulin® (troglitazone) was named as the probable cause of 391 deaths, 63 from liver failure, before it was finally removed from the US market[67 82]. Rezulin® (troglitazone) had not been proven to save lives or reduce the complications of type 2 diabetes. Concerns had been raised at the time of FDA approval about Rezulin® (troglitazone)'s potential for damaging the heart and the liver. At the time of approval the pharmaceutical company Chief Executive was quoted as telling investors he saw the drug as a "billion dollar blockbuster". This was correct. Rezulin® (troglitazone) generated sales totalling US$2.1 billion for the company in its 3 years on the US market[59].

CASE STUDY : ORAFLEX® (BENOXAPROFEN)

Oraflex® was a drug used for arthritis approved for marketing in the United States in April of 1982 and marketing began in May, with extensive use of DTCA. It has been estimated that 2.5 million people had received this drug within a month. Many of these people received the drug inappropriately and suffered side effects. In 1999 an editorial in the Journal of the American Medical Association commented: "The product gained a major foothold merely on the strength of a well-orchestrated marketing strategy, which included full page advertisements in the popular press. Sixty one drug related deaths occurred during the two years in which the drug remained on the market." [83].

MEDICALISATION OF HEALTH AND AGEING

The purpose of pharmaceutical company advertising is naturally to increase sales by encouraging brand loyalty and increase demand by creating new markets. A new group of medicines – the so-called 'lifestyle' medicines' have been the subject of much of the initial DTC advertising in New Zealand. Three quarters (74%) of respondents to the authors New Zealand GP survey felt that DTC advertising of lifestyle drugs encourages the medicalisation of well populations (appendix 3). "Lifestyle" medicines are usually not government subsidised and are those which are intended to be used for a problem that falls into the grey zone between medical and social definitions of health (for example male pattern baldness) and those which could be better achieved by sustained lifestyle change, for example obesity.

DTCA commonly redefines normal processes or social problems as medical problems. Pharmaceutical solutions are offered for normal physiological or ageing processes and encourage the belief that there is a quick fix drug for every condition. This results directly in the medicalisation of normal health and ageing and discourages sustainable behaviour change to address health problems, such as physical exercise and dietary change to reduce weight.

As illustrated by the case studies, DTC advertisements rarely discuss the relative merits of all available treatment options, or the side effects, or the likely efficacy of treatments. A study of the content of US advertising showed that over 90% of advertisements did not mention how likely a treatment was to work[27]. Supporters of DTCA contend that consumers are safeguarded from medicalisation, as they are required to obtain a prescription for these medicines. However, as detailed above, the combination of the commercial imperative and the tension between patient-centred and evidence based medicine means that on many occasions prescribers are inappropriately influenced by DTCA generated patient demand.

CASE STUDY: XENICAL® (ORLISTAT)

Xenical® (orlistat) is promoted in New Zealand as an anti-obesity drug. The advertisements use a variety of advertising imagery to promote the benefits of the drug.
Trial evidence suggests that, when used in conjunction with diet, weight loss of 4-9% in obese, non-diabetic subjects is possible [84-86].

Diet alone appears to be responsible for at least half this weight loss. Data from three randomised controlled trials has been pooled to determine the effectiveness of Xenical® (orlistat) compared to diet alone [84-86]. This showed that patients weighing an average of 100kg on a low calorie diet plus Xenical® (orlistat) lost on average 8.9kg compared with those on a low calorie diet plus placebo who lost 5.6 kg. Weight loss may persist for up to 2 years. Around one quarter of patients withdrew from the trials in the first year because of side effects related to decreased fat absorption – oily spotting, flatus with discharge, faecal urgency and oily stools. In New Zealand Xenical® (orlistat) is not subsidised and costs around $170 per month (prices vary slightly between pharmacies).

Thus, Xenical® (orlistat) when used with dieting on average results in an additional 3.3 kg weight loss over 12 months compared with placebo in a 100kg person. The drug costs around $2040 for 12 months supply which gives a cost per kilo lost of $NZ618. In the studies, much of the weight lost was regained when the drug was stopped[84-86].

CASE STUDY : PROPECIA® (FINASTERIDE)

This drug is a sex hormone antagonist that has been marketed for the treatment of male pattern baldness, which is a normal physiological process. To maintain any effects on hair, the drug must be taken for life.

In reported trials of the drug 58% of patients treated felt the appearance of their hair had improved compared with 35% on placebo[87]. The evidence for effectiveness is in studies of men only until the age of 41. Overall 39% of the Propecia® (finasteride) group and 22% of the placebo group were satisfied with their hair after 12 months of treatment[87].

Analysing this in terms of numbers needed-to-treat:
For one man to achieve a visible change in appearance of hair after 12 months, 4 men must take the drug[87 88].
For one man to achieve satisfaction with the hair at 12 months (above and beyond the placebo effect), 6 men must take the drug[87 88].
For every 50 men that take the drug, one will have an adverse sexual side effect[87]. The drug has significant side effects and this is downplayed in advertisements. Adverse effects include impotence (2-19%), ejaculatory disorders (2-7%), loss of libido (1%) and breast enlargement (0.4%). At the dose for male pattern baldness Propecia® (finasteride) reduces dihydrotestosterone serum concentrations by approximately 70%, increases serum testosterone concentrations by about 20% and variably decrease concentrations of prostate specific antigen (PSA). The clinical importance and long term consequences of these effects is unknown at this time[88 89].

Propecia® (finasteride) costs NZ$122 per month to the patient in New Zealand (prices may vary slightly between pharmacies). This gives a cost of $1464 for 12 months supply.

Two advertisements for Propecia® (finasteride) in Time magazine were found to be misleading by the FDA, claiming a broader benefit than had been demonstrated[90].
The statements used were:

"Starting today, you need not face the fear of more hair loss."
"One day science will create a pill for hair loss: That day is today."
The FDA found that "This implies that taking Propecia® (finasteride) guarantees the prevention of further hair loss. This implication overstates the efficacy of Propecia® (finasteride) and is inconsistent with the approved product labeling …for example according to the product information …clinical studies demonstrated a *slowing of hair loss* with Propecia® (finasteride) by patient self assessment. Merck has not demonstrated that Propecia® (finasteride) prevents hair from falling out. In fact, the product information states that 17% of men treated with Propecia® (finasteride) for 24 months experienced hair loss. "

Interestingly a similar complaint was made to the ASCB in New Zealand about a similar claim made in advertising here.
The statements used were:
"Propecia® is clinically proven to stop hair loss in men".
"Now, keeping your hair is up to you."
The complaint was not upheld by the ASCB who stated that the first claim was a factual statement and the second was 'in advertising parlance a "call to action".[91]

Practitioners are naturally keen to prescribe medicines that represent true advances. DTCA is a strong driver of the 'pill for every ill' culture. This will have serious implications for the way New Zealand and New Zealanders view health and illness, reducing autonomy, self-responsibility and the incentive to make healthy lifestyle choices.

Creating markets, even if it means redefining normal variation as a disease, is seen as all-important in the marketing strategy for new drugs. The profile of a new symptom complex is first raised through public awareness campaigns. The industry funds and helps to set up self-help and advocacy groups, and finally the new drug is heavily marketed to physicians and directly to the public. The story of Detrol® (Tolterodine) detailed in the case study below is very instructive. The pharmaceutical marketing strategy can be pieced together from the PowerPoint presentation "Positioning Detrol® (tolterodine) (creating a disease)" of the Group Vice President of Pharmacia which summarises a presentation made to the pharmaceutical marketing research group on October 7th 2002.

The most recent published example of disease invention is that of "female sexual dysfunction" as described by Moynihan in the British Medical Journal in January 2003. This paper describes the pharmaceutical company involvement in sponsoring meetings of "experts" to define the parameters of this new disease and the subsequent repeated misuse of over-inflated statistics of "disease" prevalence derived from one study. "Perhaps the greatest concern comes from the flip side of inflated estimates of disease prevalence are the ever-narrowing definitions of "normal" which help turn the complaints of the healthy into the conditions of the sick."[92].

CASE STUDY : "POSITIONING DETROL® (TOLTERODINE) (creating a disease)"

The following is derived from an internet posted PowerPoint presentation downloaded from http://www.pmrg.org/presentations.html (accessed Jan 2003) called '**Positioning Detrol: creating a disease**'[93].
Following the merger of Pharmacia and Upjohn, Detrol® (tolterodine) was "identified as the first, new, global mass marketing opportunity".

Later the presentation heading "Converting a niche product into a Mass Marketing Opportunity" is followed by:

- "Increase the diagnosis and treatment of urge incontinence"
- "Expand the appropriate patient population (beyond urge incontinence) to those with "overactive bladder syndrome" (OAB) (without incontinence)

The next part of the strategy or "**critical success factors** :"

- "Establish OAB as a serious medical condition with profound negative impact on people's quality of life… among physicians, consumers, payers and regulatory authorities"
- "Establish Detrol® (tolterodine) as the therapy of choice for OAB"

And finally:

- "Educate PCPs *(primary care physicians)* (including OBGs) how to screen for, diagnose and treat OAB"
- "Drive potential patients to physician offices by using DTC and PR with symptom recognition"

Does all of this work? According to the presentation the predicted sales for Detrol® (tolterodine) for 2002 were US$600 million (from zero in 1997).
And is the advertising misleading? Between 1998 and 2000 Pharmacia and Upjohn received 5 warning letters from the FDA. One in July 2000[94] detailed violations relating to:

- Broadened indications (they had tried to now also include stress incontinence which was not an approved indication)
- Unsubstantiated patient satisfaction claims (based on inadmissible market research on those remaining on the drug)
- Unsubstantiated compliance claims
- Misleading efficacy claims
- Minimising risk - the incidence of dry mouth is 40% (in the approved PI material) However, in the advertising material dry mouth was claimed to occur in only 30% of people taking Detrol® (tolterodine).

(The November 2001 New Zealand "New Ethical magazine" November 2001 contains a full page advertisement for Detrol® (tolterodine) with a dry mouth claim of only 17%)

- Misleading Graphic Representation of tolterodine concentration in respective tissues

Detrol® (tolterodine) appears to be as (but no more) effective as oxybutynin as an anticholinergic. However, inevitably unanswered questions remain about long-term safety and the justification of the additional cost for a 40% rather than 70% chance of a dry mouth?
A Canadian Drug Information Bulletin summarised the results of two randomised double blinded trials of Detrol® (tolterodine) and concluded that "There was no significant difference in the proportion of patients who perceived any improvement in bladder symptoms (placebo 47%, Detrol® (tolterodine) 50% and oxybutynin 49%).'[95]. Similarly, while the Cochrane review states there is some statistically significant improvement in symptoms, it notes that the clinical significance of these differences is uncertain, and the longer-term effects are not known. It also notes that "dry mouth is a common side effect of therapy."[96]
There is some evidence that behavioural and non-pharmacological approaches are even more effective, without the side effects. [97 98]

REGULATORY FRAMEWORKS FOR DTCA: THE UNITED STATES AND NEW ZEALAND

Regulation and Monitoring

New Zealand and the United States, the only two countries in the OECD that legally permit DTCA, operate different kinds of regulatory frameworks for DTCA.

New Zealand

New Zealand has permissive legislation and relies on a self-regulatory framework through the Therapeutic Advertising Pre-vetting System (TAPS) review of advertisements in broadcast media. An advertising industry appointed complaints board (ASCB) reviews any complaints. This board is set up for general, rather than medicine-specific advertisement complaint review. Investigation must be triggered by a formal written complaint.

Legislative compliance requirements

Advertisements must comply with the Medicines Act 1981 as well as the Medicines Regulations.

There is no regular prospective monitoring of the TAPS system or of advertisements compliance with the Act and Regulations by the Ministry of Health. Medsafe has neither brief nor resources for routine monitoring[99].

Complaints Procedure: Anyone may complain to Medsafe if they feel an advertisement breaches the regulations.
Penalty: The Ministry can prosecute for breaches, however this has never occurred for a DTC advertisement. It refers complaints to the ASA[34].

Industry Code Requirements

Advertisers

There is a Code for Therapeutic Advertising developed in 1999 by the Advertising Standards Authority (ASA). Anyone may complain to the ASA if they feel the code is breached. Claims are adjudicated by the ASA complaints board (ASCB) which is made up of 4 public representatives and 4 members of the advertising industry (media, advertising agencies and advertisers). A clinical pharmacologist is invited to join from time to time to advise on technical matters:

The ASCB does not have an independent funding stream from the government and is funded from pharmaceutical company levies in a 'user pays' system.

Process: ASCB obtains comments from all interested parties. Any complainant agrees to abide by the decision of the ASA and waives the right to complain under any other code or legislation[100]. The decisions of the ASCB are only voluntarily binding and are not enforceable[34 101].

Penalty: Request to modify or withdraw offending advertisement. There is provision to impose sanctions on the advertiser and / or publisher but these have rarely, if ever, been used. Decisions of the ASCB can be found on their website at: http://www.asa.co.nz/decisions

Pharmaceutical Industry

The New Zealand Researched Medicines Industry (RMI) is an association of the research based pharmaceutical industry. Membership is voluntary. It also has its own code of practice called the RMI Code of Practice (1999)[102]. Anyone may complain to the RMI if they feel the code has been breached. Almost all complaints to the RMI about breaches of this code have been from competing pharmaceutical companies and are rarely about DTCA.

Process: the RMI Code of Practice Standing Committee (COPSC) adjudicates complaints. The COPSC is comprised of 6 members: A legal representative as chairperson (judge, solicitor or QC). A medical representative (RNZCGP or NZMA), a pharmacy representative (pharmacist or clinical pharmacologist) 3 pharmaceutical industry representatives (2 company member representatives and one company manager).

Penalty: Withdrawal of advertisement, publication of corrective letter. Fine of up to NZ$30 000.

Fair Trading Act

Parties may complain to the Commerce Commission, and the Commerce Commission may, at its discretion, investigate those complaints, and in some cases fine or place sanctions on the activities of the party who is not acting in accordance with the Fair Trading Act.

Such complaints could and have been made in relation to direct to consumer advertising by pharmaceutical companies. However, the Commerce Commission has not yet decided to investigate any such complaints. As with the other regimes, this requires a party to make an actual complaint. If the Commerce Commission were to carry out such an investigation, the advertising campaign could be potentially

completed, or at the least, already have been effective by the time a decision is reached.

Since November 2000, all broadcast advertisements are supposed to go through TAPS. By October 2001, 7 complaints about advertisements which had been pre-vetted by TAPS had been upheld or upheld in part by the ASCB, two of which were for prescription medicines[100]. Many complaints recorded as 'settled' rather than 'upheld' have required changes to the advertisement because they have been considered to be in breach of the code. This inability of the pre-vetting system to pick up breaches of the code is not surprising as it is conducted by a committee comprised only of representatives of the advertising and pharmaceutical industries. Pharmaceutical companies may even apply for delegated authority to approve changes to their own advertisements for a fee if they have "a properly qualified executive to consider and approve advertisements within their own company"[103]. With self-approval clearly there is no outside scrutiny for balance and appropriateness of claims made. With no independent technical expertise, the lack of independence of a vetting process delegated to the advertiser or manufacturer is self-evident. This leaves only the complaints process as a means for determining the accuracy, appropriateness and balance of advertisements. The complaints adjudication board is a general advertising review board rather than one designed to have the technical expertise to assess information about risks, benefits and efficacy. They may invite a clinical pharmacologist to advise on technical matters but this adviser has no voting rights.

The weaknesses of the New Zealand self regulatory system are:

- Lack of independence of the pre-vetting and complaint response systems from the advertising and pharmaceutical industries. This applies to both their administration and funding stream.
- Absence of any independent technical review, at the pre-vetting stage, for completeness or balance of claims of efficacy and risks (the major concern in the United States despite a much more rigorous system of regulation)
- Lack of detailed criteria for content and presentation of efficacy, risk and cost information in advertising
- Lack of regular compliance monitoring by any central independent agency
- Lack of significant penalty as deterrent (the maximum fine for breaching the RMI code is $30 000. In contrast, 30 seconds of prime time television advertising costs between $7 000 and $13 500).
- A complaints system which requires the complainant to have full knowledge about risks and benefits of new medications with which to compare advertised claims.
- A complaints board whose remit is to review complaints about all advertised products rather than being set up specifically to review medicines advertising complaints.

A recent paper written from a marketing perspective concluded that the New Zealand self-regulatory approach complemented by parallel government monitoring provides an efficient responsive system for promoting responsible DTCA. However, the complaints system requires considerable knowledge, commitment and effort and time even for well-motivated consumer organisations[34 104]. There is no funding for anyone with the technical expertise to monitor the accuracy and balance of the content of advertisements. As in the United States, a marketing campaign may well be over by the time a complaint has found its way through the system. The public rarely, if ever,

receives corrections for misinformation presented in advertising campaigns eventually found to be non-compliant, despite the fact they may have been exposed to these messages for some months. The consumer health movement in New Zealand is not strong; neither is it funded for such a watchdog role. Initiating such complaints is not a priority for groups. The complaints system is not widely known among health professionals and consumer groups, and even less so to the general public. There were 15 complaints about prescription medicines since TAPS was introduced of which two were 'upheld' and two were 'settled' and one withdrawn because the complainant was not prepared to sign the waiver of the right to make complaints to other authorities.

Further the report by Hoek suggested that Medsafe need to develop a more active prosecution program to support the industry self-regulation model[105]. At present the attitudes of the ASA and Medsafe mean there is no significant deterrent for industry in this process. In a recent paper by Coney, a Medsafe official is quoted as stating that complaints are referred to the ASA as 'this is more cost-effective than prosecution'[34]. However, the ASA executive director and secretary of the ASCB in the same paper is quoted as saying 'we concentrate on changing future behaviour rather than punishing past conduct'[34].

No routine monitoring of the TAPS system is undertaken by the Ministry of Health to ensure compliance. The last (limited) review in 2000 of three months of advertisements revealed significant levels of non-compliance with the Medicines Act as interpreted against the guidelines.[33].

There is no independent monitoring of the fiscal or health outcome impact of advertisements.

CASE STUDY: WEAKNESSES OF THE SELF REGULATORY SYSTEM- REDUCTIL® (SIBUTRAMINE)

Reductil® sibutramine (marketed as Meridia® in the US) is advertised as the first orally administered serotonin (5-hydroxytryptamine, 5-HT) and noradrenaline re-uptake inhibitor (SNRI) drug to be used for the management of obesity. It is thought to work centrally on the desire to eat (feeling full) and thereby reduce food intake. It is also thought to increase energy expenditure by increasing metabolic rate. It has been promoted to physicians in New Zealand and has been extensively promoted by DTCA both on TV and in the print media.

There is growing international concern about the safety of sibutramine. The consumer association Public Citizen has gone so far as to call for the drug to be withdrawn from the US market on the grounds of safety[106]. On March the 6th 2002 the Italian regulatory authorities temporarily suspended the marketing authority for sibutramine following a number of reported adverse reactions, including two deaths. The matter has been referred to the European Medicines Evaluation agency. Following reports of adverse events the safety of sibutramine is currently being reviewed in several countries including France, Germany, England and most recently Canada. In addition, several European countries including France, Germany, England, the Netherlands, Denmark, Portugal, Sweden, Finland and Spain are reported to have issued statements informing the public of the market suspension of sibutramine in Italy[107]. At the time of writing Reductil® is on the Intensive Medicines Monitoring Programme (IMMP) in New Zealand.

In the US, the FDA issued a warning letter[108] accusing the manufacturers of minimising the known risks in a TV commercial. The advertising of Reductil® has also attracted criticism in New Zealand. A complaint about TV and magazine advertisements for Reductil® containing several criticisms was considered by the ASCB in August 2002[109]. A breach of the code was confirmed on the grounds the advertisers had made an unsubstantiated claim of efficacy *"Reductil® plus diet and exercise is at least three times more effective than diet and exercise alone over 24 weeks"*[109]. This claim was supported by only one reference.

A further complaint that the advertisers had not given due weight to the 18 contra-indications listed in the data sheet and to have used too small a font size, was deemed to have been resolved by the advertisers agreeing to discuss the matter with Medsafe and TAPS "in order to achieve compliance with the code". The statement that "*Reductil® does not stop you eating any kinds of food*" was ruled an overstatement that could confuse and mislead the consumer…" in this respect the advertisement was ruled to be in breach of Principle 3 of the code of therapeutic advertising, similarly it breached the same principle with the overstatement of the "weigh of life" programme. Further, the company gave an assurance that all future advertisements would carry reference to the word "obesity" as well as "overweight" to comply with information in the data sheet[109].

In January 2003 some four months after the ruling, a further full page DTC advertisement on the inside back page of Healthwise a free health broad-sheet distributed widely[110] again contained all of the offending statements and omissions detailed above. Further inquiry revealed that the TAPS approval (JD8095) for this advertisement had been given prior to the August 2002 ASCB meeting. The pharmaceutical company and publishers of Healthwise had therefore run an advertisement for Reductil® known (for over four months) to contain several breaches of the code for therapeutic advertising. In theory, member organisations of

the ASA have agreed to be bound by the decisions of the ASCB[101]. No sanctions beyond removing offending broadcast advertisements have yet been imposed by the ASCB, although apparently they can be.

FDA Oversight in the United States

The United States has a much more formal central regulatory framework. The FDA directly regulates the promotion of prescription medicines. When breaches of the regulations are detected the FDA may issue initially an "untitled" and then a "warning" letter, requiring that the advertisement be withdrawn or revised. Increasing concern at the level of the US congress has led to a request for a report from the General Accounting Office (GAO), to investigate the FDA oversight of DTCA advertising of prescription medicines. The report was called **"FDA oversight of DTC Advertising of Prescription Medicines Has Limitations"**[9]. In particular, it found that while FDA warning letters result in the cessation of the misleading advertisement, they do not prevent repeated dissemination of new misleading advertisements for the same drug. The GAO report cites the example of the FDA issuing repeated regulatory letters to Glaxo Wellcome to stop misleading advertisements for the drug Flonase® (an intranasal steroid for treatment of allergy, marketed as Flixonase® in New Zealand). These letters detailed violations relating to unsubstantiated efficacy claims, lack of fair balance and failure to provide any risk information on the major side effects and contraindications for the drug and failure to submit some advertisements to the FDA. Also cited in the GAO report is the marketing of a lipid-lowering drug by Pfizer. The FDA has issued four regulatory letters about advertisements for its cholesterol-lowering drug, Lipitor® (atorvastatin). The FDA ruled two advertisements gave the false impression that Lipitor® can reduce heart disease and falsely claimed Lipitor® is safer than competing products[9]. The report also cited other companies who failed to submit (or did not submit in a timely manner) advertisements for review by the FDA. The report noted that, even if complaints are upheld, the time taken for the regulatory process means that regulatory letters may not be issued until after the advertising campaign has run its course[9].

In the authors' view, neither the voluntary system of self–regulation in New Zealand, nor the tighter system of central regulation in the United States has the capacity to ensure acceptable standards for DTCA. Partial and misinformation is common along with overstating of efficacy, minimisation of potential adverse effects, inappropriate use of emotional persuasion and failure to consider a range of other treatments. Other US research[27] has shown that 75% of advertisements did not include information on alternative treatments or how medicines actually work and 90% of advertisements did not mention the likely success rate or duration of the treatment.

A presentation by Koerner on DTCA in the United States between 1997 and 1999, detailed 33 products that were fully advertised on United States radio and TV. Advertising for 17 of the 33 (52%) were found to be in violation of the Federal Food, Drug and Cosmetic Act and prompted regulatory letters[32]. Violations continue to be common with many advertisements found to be in violation to May 2001[111 112]. The main reasons for violation were:

- Lack of fair balance between risk and benefit information
- Risk information insufficient, omitted or not readable/prominent enough (e.g. small type against dark background)
- Safety and efficacy claims not backed up by proper scientific studies

- Confusing language and technical terms not likely to be understood by general public.

There is concern from consumer groups in the United States that the compliance section of the FDA is seriously under-resourced[112]. In 2002 DDMAC (The Division of Drug Marketing, Advertising and Communications) had 39 full time equivalent positions dedicated to reviewing drug promotion. In 2001 DDMAC received over 34,000 pieces of promotional material both DTC and physician. It does not categorise what proportion of these are DTC print and broadcast advertisements. Only five staff were dedicated to reviewing DTC advertisements with two DTC slots vacant[9]. There is a trend for fewer and fewer warning letters[112]. This reduction is not seen by Wolfe to reflect better compliance, rather the effect of additional paperwork involved in obtaining legal review of the ones that are sent[9 112]. There have been few cross sectional studies of compliance with regulations. In addition to the study between 1997 and 1999, an earlier study by Wilkes in 1992 examined 109 full-page advertisements in 10 leading medical journals and found the information was unbalanced in 40%, and had misleading headlines in 32%. In 44% the reviewers felt that the advertisement would lead to improper prescribing if a physician had no other information than that contained in the advertisement. Overall only 38% were deemed **not** to need review[113]. In 1996 Stryer and Bero published a review of 486 items distributed by drug companies to physicians. They found 42% failed to comply with at least one of three FDA regulations assessed[114]. The FDA routine monitoring system is seen to be under-resourced and only able to detect and control the tip of the iceberg of regulation violation[115].

In New Zealand there was a limited spot review of 3 months of DTC advertising (1 Nov 1999 - 7 Feb 2000). While compliance levels had increased since the extremely low levels found in the previous report, just under one third of advertisements for prescription medicines in print and broadcast media were found to be in breach of guidelines based on the requirements of the Medicines Act. Only one out of six television advertisements for prescription medicines and none of six or non-prescription medicines reviewed was compliant with advertising guidelines. The most common reason for non-compliance was inadequate provision of risk information[33]. In reality we have no idea how many advertisements provide balanced and complete information, as there is no proactive monitoring. It seems highly unlikely that the situation will be any better than in the US where proactive monitoring (albeit under-resourced) is in place. Certainly from the perspective of many of the NZ GPs responding to the recent survey by the authors, the information is far from balanced (appendix 3).

CASE STUDY : CELEBREX® & VIOXX®® (ROFECOXIB AND CELECOXIB)

Celebrex® (celecoxib) and Vioxx® (rofecoxib) are two new Non Steroidal Anti Inflammatory Medicines (NSAID) used for the treatment of arthritis. A serious side effect of all NSAIDs, including these two, is indigestion that may lead in some cases to gastrointestinal bleeding. These drugs are among the most heavily advertised medicines in the United States and also have been extensively advertised to the public in New Zealand. One of the major publicised advantages was the reduced rate of stomach problems. Combined world sales in 2000 were in excess of US$3.5 billion[10]. In that same year nearly US$240 million was spent on direct to consumer advertising of these two medicines in the United States[10]. One year later in 2001 Celebrex® (celecoxib), the top selling arthritis drug alone grossed US$3.114 billion[116]. The advertising has claimed improved efficacy and safety over traditional agents. According to the FDA warning letter there is no evidence of improved efficacy over traditional non-steroidals. Despite this Celebrex® (celecoxib) and Vioxx® (rofecoxib) captured 61.7% of the United States arthritic drug market in 2001[13]. Both advertising campaigns have been the subject of warning letters from the FDA for providing incomplete, unbalanced and misleading information[117]. The problems identified include overstating efficacy, minimisation of risk and failure to warn of serious potential drug interactions[118 119].

Much of the "evidence" for the claim of superiority for Celebrex® (celecoxib) comes from the CLASS[120] trial, funded by Pharmacia. The manufacturers distributed 30,000 reprints of this Journal of the American Medical Association article to doctors and it has been widely cited. It was subsequently suggested that the authors had misrepresented the results of this study of Celebrex® (celecoxib) when submitting it for publication, selectively omitting portions of the data relating to adverse effects. The misleading partial data from the first six months of the trial appeared to show a gastro-intestinal (GI) safety advantage of Celebrex® (celecoxib) over two other traditional NSAIDs. In fact the study lasted a year not 6 months and most of the ulcer complications that occurred in the second half of the study were in Celebrex® (celecoxib) users, negating most of Celebrex® (celecoxib)'s reported safety advantage[121 122]. The full 12-month data in contrast could not sustain such a claim. In a June 2002 British Medical Journal editorial described the study as '*misleading'* and called for *'the wide dissemination of the results of the CLASS Trial… be counterbalanced by the equally wide dissemination of the reanalysis according to the original protocol' [121]*.

Similarly, evidence to support the advantages of Vioxx® (rofecoxib) comes mainly from the results of the VIGOR study[123]. As detailed in the FDA warning letter[117], whilst this study does seem to show an improved GI safety profile, the manufacturers have consistently omitted from their detailing and advertising material the finding of significantly increased cardiac problems. In the VIGOR study a four to five fold increase in myocardial infarctions (heart attacks) in those taking Vioxx® (rofecoxib) compared with traditional NSAIDs was found. As pointed out in the FDA warning letter, in the VIGOR study the incidence of all serious adverse events was higher in the Vioxx® (rofecoxib) treatment group than in the naproxen comparison group (9.3% and 7.8% for Vioxx® (rofecoxib) and Naproxen respectively)[117]. It is doubtful that these medicines offer any additional benefits over the traditional NSAIDs that the manufacturers advertising campaign seeks to replace with Celebrex® (celecoxib) and Vioxx® (rofecoxib) at a much higher cost [121 122 124 125]. A recent meta-analysis combining both studies found the relative risk of serious adverse events (including death, admission to hospital, and any other life threatening / seriously disabling event) was higher with patients taking Vioxx® (rofecoxib) or Celebrex® (celecoxib) than in

patients taking traditional NSAIDs[122]. The study estimated that for every 78 patients who took Vioxx® (rofecoxib) or Celebrex® (celecoxib) instead of traditional NSAIDs, one of those patients would experience a serious adverse event they would not otherwise have had[122]. Despite this the commercial success of these agents continues to be spectacular.

Given the problems faced by the FDA in holding the manufacturers to account, it is of great concern that there is no central agency in New Zealand scrutinising or monitoring such advertisements for completeness, accuracy or balance. Use of these agents has been minimised thus far in New Zealand by PHARMAC's decision not to subsidise them. They are too expensive for many patients to buy for themselves. However, advertisements continue to be high profile and both individuals and clinicians have asked PHARMAC to provide subsidised access.

Disease Awareness Advertising

In some countries where DTCA of prescription medicines is banned, other forms of pharmaceutical company communication to the public are allowed. In those countries critics of DTCA claim pharmaceutical companies continually push the boundaries of the legislative restriction on advertising of prescription medicines[126-128]. In those countries generic or disease awareness advertising is allowed, while in others there are loopholes in the ban on DTCA which allow companies to 'advertise'[92 129]. Companies have been very creative in exploring ways of advertising their products directly to the consumer. This creates similar problems and regulation difficulties to brand advertising.

In the Netherlands the government has taken action to combat DTCA campaigns launched by drug companies despite the fact that it is theoretically illegal there[49]. It is believed by many that the recent attempts to introduce limited disease awareness advertising in the EU was really a way to introduce DTCA to Europe[49].

The following case studies were published in the British Medical Journal (April 13 issue 2002) in an article entitled Selling sickness: the pharmaceutical industry and disease mongering Commentary: Medicalisation of risk factors by Moynihan R, Heath I, Henry D, Gotzsche PC[130].

CASE STUDY: MALE PATTERN BALDNESS

This case study was printed in the British Medical Journal on April 13 2002 in an article entitled Selling sickness: the pharmaceutical industry and disease mongering Commentary: Medicalisation of risk factors by Moynihan R, Heath I, Henry D, Gotzsche PC[130].

"Around the time that Merck's hair growth drug finasteride (Propecia®) was first approved in Australia, leading newspapers featured new information about the emotional trauma associated with hair loss. The global public relations firm Edelman orchestrated some of the coverage but largely left its fingerprints off the resulting stories. An article on page 4 in the *Australian* newspaper featured a new "study" suggesting that a third of all men experienced some degree of hair loss, along with comments by concerned experts and news that an International Hair Study Institute had been established. It suggested that losing hair could lead to panic and other emotional difficulties, and even have an impact on job prospects and mental wellbeing. The article did not reveal that the study and the institute were both funded by Merck and that the experts quoted had been supplied by Edelman, despite this information being available in Edelman's publicity materials in May 1998. "

***CASE STUDY: OBESITY*[129]**

This case study was printed in an article in the summer 2003 issue of 'Consuming Interest' the Journal of the Australian Consumers Association.

"*Xenical® and the 'Healthy Weight Taskforce'* (HWT) was marketed as being the 'first ever network of primary healthcare professionals to have formed in response to the rising levels of excess weight and obesity in Australia'. The taskforce evaluated the available methods of weight loss, including pharmaceutical products and weight loss programs. The findings were presented as a matrix designed to assist healthcare professionals and consumers identify current models of 'best practice'. A pharmaceutical product (Xenical®) was considered to be the most effective and appropriate form of weight loss. The findings and educational materials produced by the Healthy Weight Task Force were broadly promoted to the mainstream media and directly to general practitioners.

What was not stated in any information provided by the HWT was that the pharmaceutical company, Roche, funded the project. It also did not state that the recommended product, Xenical®, was produced by Roche. In fact, this information was only revealed on 'Media Watch', a program broadcast on ABC TV in Australia which examines the media portrayal of current events.

The HWT material was in breach of the Australian code in numerous ways.

The Australian code also states that information must be produced in a 'balanced and correct way'. The information presented by the HWT is biased towards to pharmaceutical and pharmacy products and towards a medical management of the problem. The matrix presented did not mention any of the side effects associated with the treatments described. It is interesting to note that in assessing safety, the taskforce stressed that Weight Watchers, a non-pharmacological method of weight loss, could possibly encourage restrictive eating behaviours -- but there was no mention of the side-effects of Xenical®. According to the drug's official product information, side effects can include 'increased flatulence, oily discharge from anus and abdominal pain'. While concerns are raised about the safety of other non-prescription products, especially those not supervised by doctors, no comment was made about the potential long-term physiological effects of taking this product or even of short-term discomfort."

CASE STUDY: ERECTILE DYSFUNCTION

This case study was printed in the British Medical Journal on April 13 2002 in an article entitled Selling sickness: the pharmaceutical industry and disease mongering. Commentary: Medicalisation of risk factors by Moynihan R, Heath I, Henry D, Gotzsche PC[130].

"Double page advertisements told Australians recently that 39% of men who visit general practitioners have erection problems. The advertisement featured an unhappy couple, who looked to be in their 30s or 40s, on opposite sides of a double bed, with the accompanying text: "Erection problems: hard to talk about, easy to treat." As with much disease mongering, the key strategy here was to make the condition seem as widespread as possible.

The 39% claim in the advertisement was referenced to an abstract of a survey finding. The full version of the published survey revealed that the 39% figure was obtained by tallying all categories of difficulties, including men who reported having problems only "occasionally," and the average age of those reporting complete erectile dysfunction was 71 years. Another recent Australian study, not cited in the advertisement, estimated that erection problems affected only 3% of men in their 40s, and 64% of men in their 70s.

The advertisement's fine print cited a host organisation, Impotence Australia, and two other groups but did not mention that the advertisement was funded by the manufacturer of sildenafil (Viagra®), Pfizer. Impotence Australia had at that time only recently been set up with a grant of $A200 000 (£74 000; $105 200; €119 400) from Pfizer. Its executive officer told the press, "I could understand that people may have a feeling that this is a front for Pfizer.""

CASE STUDY: DISEASE AWARENESS CAMPAIGN

This case study was printed in the *British Medical Journal* on April 13 2002 in an article entitled Selling sickness: the pharmaceutical industry and disease mongering Commentary: Medicalisation of risk factors by Moynihan R, Heath I, Henry D, Gotzsche PC[130].

"A confidential draft document leaked from a medical communications company, In Vivo Communications, describes a three year "medical education programme" to create a new perception of irritable bowel syndrome as a "credible, common and concrete disease." The proposed 2001-3 education programme is part of the marketing strategy for GlaxoSmithKline's drug Lotronex® (alosetron hydrochloride).
In Vivo is one of a handful of companies specialising in corporate backed "medical education," and the leaked plan provides a rare insight into the highly secretive world of drug promotion, with its new emphasis on "shaping" medical and public opinion about the latest diseases.

According to the documents, the education programme's key aim is this: "IBS [irritable bowel syndrome] must be established in the minds of doctors as a significant and discrete disease state." Patients also "need to be convinced that IBS is a common and recognised medical disorder." The other main messages are about promoting the new "clinically proven therapy".

The first step is to set up an "Advisory Board, comprising one KOL [key opinion leader] from each state of Australia." Its chief role would be to provide advice to the corporate sponsors on current opinion in gastroenterology and on "opportunities for shaping it." Further work would include developing "best practice guidelines" for diagnosing and managing irritable bowel syndrome and attending overseas meetings. Another strategy was to produce a newsletter in the pre-launch period to "establish the market" and convince the "specialist market" that the condition is a "serious and credible disease."

For general practitioners, In Vivo recommends a series of advertorials in leading medical magazines, featuring interviews with members of the company's advisory board, because "The imprimatur of [board] members is invaluable in reassuring [general practitioners]. . . that the material they receive is clinically valid."
Other groups to be targeted with promotional material include pharmacists, nurses, patients, and a medical foundation described as already having a "close relationship" with In Vivo. A "patient support programme" is also planned for 2002-3, so that the company will "reap the loyalty dividend when the competitor drug kicks in.""

INTERNATIONAL POSITIONS ON DTCA

Reviewing the published literature, there is significant international opposition to DTCA from professional and independent consumer groups. The European Parliament has recently rejected - by a 12 to 1 majority - legislation aimed at liberalising DTCA in the European Union (EU). Australia and South Africa have recently reviewed their positions and will continue to ban DTCA. Alongside this, there is growing concern and increasing opposition in the United States, the only other country in the OECD that allows DTCA, with much stricter regulatory controls than New Zealand.

DTCA was the subject of a Lancet editorial in April 2002. The author concluded, *"The potential disadvantages from DTCA, as judged by experiences in the United States and New Zealand, outweigh any claimed benefits"*[131].

European Union

On 23 October 2002, the European Parliament, by a vote of 494 to 42, rejected a proposal that would have weakened the EU's ban on advertising prescription-only medicines to the public. The European Commission (EC) had proposed allowing pharmaceutical companies to promote prescription-only medicines to the public for three disease groups: HIV/AIDS, asthma, and diabetes. This involved two key changes to pharmaceutical advertising regulations: amendments to a clause that had originally forbidden advertising of prescription-only drugs and deletion of a clause with a list of specific diseases that manufacturers could not advertise treatments to the public. The proposal has provoked considerable debate in Europe on the advantages and disadvantages of allowing pharmaceutical companies to advertise directly to consumers.

Both the European Parliament's Committee on Industry, External Trade, Research and Energy and the Committee on Environment, Public Health and Consumer Policy had already rejected the Commission's proposals.

The issue of marketing of pharmaceuticals through 'medicalisation' received extensive publicity in the UK. In April 2002 the *British* Medical Journal (BMJ) devoted much of one issue (Volume 324, Issue 7342) to exploring "the process whereby more and more aspects of human life are redefined as medical problems". One paper argued that medicalisation is fast being replaced by 'disease-mongering', as pharmaceutical companies help widen the definitions of illness in order to expand markets for new products[130].

United States

In the United States there has been growing disquiet over the effects of DTCA on both health funding and the medicalisation of health. There is growing political, professional and consumer concern around the effects of DTCA in the United States, with attempts being made to introduce legislation to curb or even stop DTCA[132].

In May 2002 a group of Democrat Senators introduced a Bill aimed at limiting the amount of marketing expenses pharmaceutical companies could claim as tax deductions. The Bill's supporters said it would help reduce drug costs because DTCA partly explained the double-digit percentage rise in drug prices in the United States.

The Wall Street Journal (WSJ) reported growing criticism of DTCA in the United States in a series of articles on drug promotion in March 2002. The journal reported that the car manufacturer General Motors (GM) spent $55 million in 2001 on the prescription-only heartburn drug Prilosec® (omeprazole) for its workers, a rise of 14% in one year, which the company attributes to DTCA[133]. Prilosec® is one of the most heavily advertised branded medicines in the United States. GM executives claim that prescriptions for Prilosec® are often unnecessary and wasteful – 92 per cent of prescriptions are for workers who had not previously tried over the counter medicines, lifestyle changes or cheaper alternatives first. Patients do not necessarily need as potent a drug as a proton pump inhibitor on their first visits. Prilosec® costs 13 times more than a leading generic equivalent. Prilosec® captured 67% of sales in the anti-ulcer/gastrointestinal reflux market in the US in 2001[13]. The WSJ quoted a GM executive as saying: "Are drug company ads driving up healthcare costs? You bet. Not everyone with heartburn needs the purple pill". GM claims to have saved $US36 million since launching a campaign to encourage greater use of generics. The WSJ notes that health insurers are growing increasingly alarmed at the rate of prescribing cost increases. The Chief Pharmacy Officer at the insurer Wellpoint Health Networks told the WSJ: "The drug trends we see are not sustainable and they threaten the

affordability of health care. Direct-to-consumer ads make medicines cost more." Wellpoint is launching a scheme whereby patients will have to pay more of the cost of advertised medicines. Persuasive medical data will be needed if the insurer is to meet the cost. Blue Cross Blue Shield has launched its own advertising campaign promoting generic medicines [133].

In October 2002 the US General Accounting Office (GAO) was asked by Congress to provide a report on DTCA. The purpose of the report was threefold:

- To evaluate the effect of DTCA on prescription drug spending and utilisation,
- To evaluate the extent and effectiveness of the FDA oversight of DTCA
- To compare spending by pharmaceutical companies on DTCA with spending on all other promotional activities and on research and development.

The report concluded that DTC advertising increases both prescription drug utilisation and spending on DTC-advertised drugs compared with non-advertised drugs. They also reported that though effective at halting the dissemination of advertisements it reviews and identifies as misleading, the FDA's oversight of DTCA had significant limitations. The key findings were:

- That some pharmaceutical companies have failed to submit advertisements to the FDA in a sufficiently timely manner to allow review.
- That there is such a time delay from identification of misleading advertisements to the FDA's request to remove it from dissemination that the ad campaign has often run its course before the regulatory letter is issued.
- FDA oversight has not prevented some companies from repeatedly disseminating new misleading advertisements, often for the same drug.
- While pharmaceutical companies still spend more on research and development than advertising, in the four years to 2001, DTC advertising spending increased 145% while research and development spending increased 59%.

Canada

Despite intensive lobbying by the pharmaceutical industry in Canada, the country's health minister, Anne McLellan, made it clear in an interview with the Ottawa Times political weekly that she does not intend to relax the current advertising rules. She said: "We have no intention of changing the present policy"[134]. The current rules prohibit the use of branded drug advertisements that mention prescription-only medicines as treatments for specific diseases. McLellan has concluded that DTCA has a negative impact on the doctor-patient relationship because patients put pressure on their physicians to prescribe advertised medicines.

Australian Review

A recent review [135] examining a possible liberalisation of Australia's ban on DTCA of prescription medicines made the following points:

- In the United States around 41 percent of the $US 1.8 billion spent on prescription drug advertising in 1999 was spent on advertising just 10 products[47]. A corresponding similar effect on the costs of publicly funded medicines could occur in Australia if it shared a similar advertising regime
- The bulk of United States advertising is concentrated on a few new, higher-priced medicines and on medicines used to treat some of the more common serious conditions

- If there was a relaxation of the regime in Australia it would be unlikely that there would be advertising of older but still effective alternatives as it would be difficult to build these advertising costs into selling prices and
- The public might place too much credence in the advertisements just because government had allowed them to be made
- DTCA of prescription medicines is not supported by organisations representing doctors, pharmacists or veterinarians

The review concluded that "it could not support a relaxation of the current prohibition that would result in a situation such as those occurring in the United States and New Zealand, which cannot be assessed as providing a net public benefit, despite some individuals being helped".

The World Health Organisation

The WHO published recommendations on advertising of medicines in 1988[60]. The aim was to develop a set of international guidelines for the promotion of medicinal products that could be used as a guide for governments, professional associations, media etc as a basis for developing their own regulations. Aside from industry marketing codes, this WHO Ethical Criteria for Medicinal Drug Promotion is the only international standard for drug promotion. Successive World Health Assemblies have endorsed its implementation since 1988. This standard recommends against DTCA, stating that: "Advertisements for the general public...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, for which certain countries have established lists"[60].

DTCA directly contravenes this recommendation.

Public and Professional Support for a ban on DTCA

Independent Consumer Groups

While pharmaceutical companies have commissioned and funded research on consumer attitudes to DTCA, even industry journal articles acknowledge that these surveys are inherently biased[136].

Independent consumer groups in both the United States and Europe continue to oppose DTCA. In contrast, there is no evidence of independent consumer groups seeking DTC advertising. Indeed some of the strongest opposition has come from consumer organisations[137].

In April 2002 an umbrella group "Medicines in Europe" was launched, with the aim of highlighting concerns about the changes proposed by the European Parliament. The group is based in France, with membership from leading national and European consumer and patient groups. Members also include funding organisations responsible for paying for medicines and independent journals for health professionals. The group has highlighted several concerns about the medicines review taking place within the EU. A spokesperson said, "What consumers and patients actually need is reliable, comparative information on medicines, alternative therapies, and health in general. Yet patients and consumers believe that drug advertising, which, by definition, is designed to increase consumption, does not give them the reliable information they need"[49].

In April, the Wall Street Journal reported that the American Association of Retired Persons (AARP) was to launch an advertising campaign aimed at countering the effects of DTCA[138]. However, the Journal also reported that AARP was forced to revise its $US10 million campaign as some of the television networks balked at the wording being carried in the advertisements. Specifically they objected to the statement "Do not let advertising sell you medicines you don't need". AARP's director of brand management said, "The message we want to get across is we just don't want people to be unduly influenced by advertising into thinking they need a drug that they do not need"[138].

In New Zealand, the Women's Health Action Trust (WHAT), a well-established consumer group has a long history of opposition to DTCA. It has made a number of submissions on this issue to the Ministry of Health for over a decade and has raised concerns about particular campaigns. It also successfully took a complaint about a Depo-Provera® print advertisement to the ASCB. The organization has a strong interest in the development of quality health information and has developed consumer information resources for the New Zealand Guidelines Group (based on evidence-based guidelines). When developing consumer information it uses tools for quality information developed by the King's Fund in the UK, and the DISCERN instrument available on www.discern.org.uk. Much DTCA in New Zealand would not meet these criteria. The Code of Health and Disability Services Consumers' Rights places emphasis on the need to provide complete information including information about options. WHAT believes that DTCA does not support informed decision-making but uses emotive claims to manipulate consumers into asking for particular medicines[104].

Professional Opinion

A United States survey in 1997 of physicians found most doctors did not favour DTCA through either print (80%) or television (85%) media. Seventy-one percent felt DTCA pressured doctors to use medicines they would not ordinarily use[73]. The American Medical Association's governing body approved a resolution that states "…many broadcast ads are misleading, using imagery to suggest clinical effectiveness far beyond what clinical evidence supports". [139]

The Centre for Health Services and Policy Research at the University of British Columbia faxed a survey to 150 drug policy experts in the United States, New Zealand and Canada[41]. The experts were from health professional organisations, consumer and disease/patient groups, government agencies, private insurers, managed care organisations, and the pharmaceutical and advertising industry and media. The response rate was 71 percent. Two thirds of those who took part judged the information provided by DTCA to be poor or very poor. Twenty-eight percent of respondents, mainly from the pharmaceutical or advertising industries, said it was good to excellent. Most respondents thought the effects of DTCA on patient knowledge of medicines and diseases and on health care quality were negative or at best neutral. Respondents from all sectors thought DTCA leads to increased drug costs and more doctor visits.

In the recent authors' survey of New Zealand GPs only 1 in 10 of the 1611 respondents believed that DTCA of prescription drugs by pharmaceutical companies was positive (appendix 3). Seventy-nine percent felt negatively towards DTCA, a figure similar to the 1997 US doctor study by Lipsky[73].

CONCLUSIONS

In 2000 the Ministry of Health produced a discussion paper on Direct-to-Consumer Advertising (DTCA) for prescription-only medicines. In the intervening two years there has been an exponential increase in the volume of DTCA in New Zealand. Despite the introduction of a system of self-regulation there have been many instances where advertisements have been criticised for containing incomplete, misleading and unbalanced information. In the United States and New Zealand, in parallel with the increase in DTCA, there has been a marked and disproportionate upward trend in expenditure on DTC-advertised medicines without any convincing evidence of corresponding improvements in health outcomes.

In the view of the authors, the weight of evidence in the current literature is against DTCA of prescription medicines. There is evidence to support claims of the harmful effects of DTCA. There is no evidence to support the claims for the beneficial effects of DTCA on health outcomes.

DTCA was the subject of a Lancet editorial in April 2002. The author concluded, ***"The potential disadvantages from DTCA, as judged by experiences in the United States and New Zealand, outweigh any claimed benefits"[131].***

- Evidence continues to accumulate indicating DTCA is very effective at selling medicines and is growing rapidly

- DTCA does not, and by its nature cannot, provide the impartial objective information on risks and benefits patients need to actively participate in healthcare decisions

- DTCA has a deleterious effect on health funding and leads to distortion in resource allocation

- DTCA has repeatedly been criticised for misrepresentation - by over promoting the efficacy of new medicines whilst minimising side effects, safety issues and cost

- DTCA potentially compromises patient safety - DTCA leads to widespread rapid adoption of new medicines before risks and adverse events are fully recognised

- DTCA has a negative effect on the clinician-patient relationship, bringing a commercial pressure on prescribers which impacts on trust and confidence and unduly influences clinical practice

- DTCA promotes the medicalisation of normal health and ageing

Neither self-regulation in New Zealand nor the central-regulation of the US has been effective at overseeing DTCA of medicines. Further, it is argued that that by the very nature of brand-specific DTCA, it will never be possible to do so.

One key question in the debate over the regulation of DTCA is whether commercial free speech should be given priority over public health goals, especially in as important an area as the treatment of disease. Restrictions on the availability of prescription medicines are essential for protecting public health. This is recognized in New Zealand law, and is the basis for restrictions on the sales of prescription

medicines. These have been imposed in recognition that these products are potentially harmful and use must be limited to appropriate situations in which benefits are likely to exceed risks. Access to these medications requires the prescription from a limited range of heath professionals acting in the capacity of a learned intermediary. It is clearly potentially dangerous to allow commercially driven demand to override this function. However as detailed, evidence from the US, from Canada and from New Zealand prescribers suggests this is exactly what is happening as a direct result of DTCA.

It is of concern that in the draft documents for the proposed Australian – New Zealand harmonisation of therapeutic products advertising, the recommendations around advertising and regulation of prescription only medicines assume the continuation of DTCA (as disease awareness campaigns in Australia) and seem positive about the strengths of self regulation[101]. Given the level of concern in both countries it is disappointing that the wider implications of DTCA are not being considered.

What are the options?

No change

There is significant and growing dissatisfaction with the status quo. This has been expressed by both health professionals and independent consumer groups and is in line with most informed world opinion.

Strengthen the regulation of DTCA of prescription medicines

Self-regulation has not and cannot provide timely and independent review of the technical information necessary to determine whether advertisements contain adequate and appropriately balanced information on efficacy, safety and cost. The recent Australian legislative review of medicines, poisons and controlled substances concluded that "self-regulation is not a viable alternative for regulating advertising of prescription medicine as it is unlikely to achieve the objective of the control."[135].

The other option for regulation is management by a government agency. This has the advantages of increased independence, transparency and accountability. However, this option has a number of major failings in terms of both costs and effectiveness. More formal regulatory systems would increase direct and opportunity costs for the government and health sector. It might be imagined that government management of the process has the potential to ensure full compliance, however it is clear that even a well-funded formal regulatory system such as the FDA in the United States cannot effectively control DTCA. This has been forcefully pointed out in the recent GAO report to Congress which details repeated breaches of the regulations by a number of very large companies, despite multiple warning letters from the FDA. To make matters worse, the time delay in carrying through the due process to withdraw offending advertisements gives advertisers several weeks of broadcasting exposure[9]. Already published and distributed magazine advertisements which are subsequently found to be in violation of the regulations cannot be recalled and may mislead and create inappropriate demand for many months or years.

Even if regulation were to ensure factual completeness, the other problems remain. There is clear evidence that DTCA stimulates demand for the advertised brand drugs, many of which offer little benefit and less clear safety profiles over existing products. As has been argued, this has deleterious effects on resource allocation within an

already stretched health system, unduly influences the prescribing process, and leads to further medicalisation of health.

***It is therefore recommended* that the New Zealand government introduce legislation or regulation to ban all advertising of prescription medicines directly to the public in any form.**

This will provide the greatest benefit to public health at the least cost and bring New Zealand in line with the rest of the developed world. In particular this would facilitate the proposed Australia–New Zealand harmonisation of regulations around medicines and foods. However, in the opinion of the authors **it is of the utmost importance that this is a complete ban.** As the examples from other countries demonstrate, disease awareness and generic advertising are driven by the same commercial imperative to sell more medicines and expand markets. Therefore this will have the same negative effects as brand advertising. Given the fact that pharmaceutical companies are accused of pushing the boundaries in this type of advertising[129 130 135], the same need for costly and stringent regulation would exist. Other countries seem unable to control this form of advertising adequately by regulation[126 128 129].

All agree there is a need for greater consumer information on health. This includes high quality independent and comparative information on medicines. This in turn will inform rational dialogue between consumers and their health providers and facilitate appropriate medicine use.

***It is therefore recommended* that the New Zealand government establishes and funds a comprehensive and independent medicine and health information service.**

This should have clear guiding principles such as the internationally accepted standards for consumer health information found in DISCERN (see box) as well as adhering to the spirit of the New Zealand Health and Disability Services Code of Consumers' Rights.

THE DISCERN QUALITY CRITERIA FOR CONSUMER HEALTH INFORMATION ON TREATMENT CHOICES

(The Discern rating instrument is available on www.discern.org.uk)

A good quality publication about treatment choices will:

1. Have explicit aims
2. Achieve its aims
3. Be relevant to consumers
4. Make sources of information explicit
5. Make date of information explicit
6. Be balanced and unbiased
7. List additional sources of information
8. Refer to areas of uncertainty
9. Describe how treatment works
10. Describe the benefits of treatment
11. Describe the risks of treatment
12. Describe what would happen without treatment
13. Describe the effects of treatment choices on overall quality of life
14. Make it clear there may be more than one possible treatment choice
15. Provide support for shared decision-making

There are sufficient resources within New Zealand to provide consumer information effectively, appropriately and efficiently. A consortium approach is recommended with input/governance from appropriate consumer and health professional bodies who are independent of commercial interest, and can demonstrate a history of independence from pharmaceutical industry influence.

Implementation

There is New Zealand expertise available within health professional and consumer groups to form such a consortium. Many (listed below) have expressed an interest in participating. The cost of such a service will be more than offset by the savings both on unnecessary drug costs and of otherwise trying to properly regulate DTC advertising. This cost alone has been estimated by the Ministry of Health to run into millions[4]. A vehicle for pharmaceutical companies to contribute to patient information could perhaps be provided through a pharmaceutical company levy to part fund such a service. Using the public health dollar in this way is likely to have a much more positive and productive effect on health outcomes in two important ways:

- Potential for improved individual health outcomes resulting from more informed consumers who have been provided with a balance of information on drug and non-drug treatment options and are better able to participate in their health care decisions.
- Potential for improved population health outcomes resulting from the promotion of appropriate and rational use of medicines.

Expressions of interest in participating in establishment of such a service have been received from:

National Preferred Medicines Centre (PreMec), Consumers Institute, Christchurch Hospital Drug Information Services, Best Practice Advocacy Service (BPAC), Women's Health Action Trust (WHAT), Royal New Zealand College of General Practitioners (RNZCGP), Auckland and Otago University Schools of Pharmacy,

The precedent for this type of service exists in a number of countries, most notably the NHS Direct (United Kingdom) and the newly established Australian Medicines Line which is a national telephone information service, providing Australians with access to independent, accurate and up-to-date information about medicines including prescription medicines, over-the-counter medicines, complementary medicines and herbal and natural therapies[140]. The American Association of Retired Persons (AARP) has also recently launched an online independent consumer information guide for prescription medicines (www.aarp.org/wiseuse/oregon-research.html).

A New Zealand service must be easily accessible to all New Zealanders and may involve a variety of options, including the Internet and an 0800 number system as used by the National Poison Centre.

Recommendation 1: That the New Zealand government introduce regulations and /or legislation to prohibit the advertising of prescription medicines directly to the public, through print and broadcast media or any other form.

Recommendation 2: That the Government establishes an independent medicine and health information service free of commercial interest.

Implementation of these two recommendations would move New Zealand from its current anomalous position to one of world leadership in the promotion of the appropriate and rational use of medicines.

SUPPORT FROM NEW ZEALAND PROFESSIONAL AND CONSUMER ORGANISATIONS

The following organisations have expressed support for the call to introduce legislation prohibiting direct to consumer advertising of prescription medicines in favour of an independent health and medicines information service:

Professional Bodies:

The Royal New Zealand College of General Practitioners (RNZCGP)
The Independent Practitioners Association Council (IPAC) and its constituent IPAs
The New Zealand Thoracic Society
The Deans of the Division of Health Sciences University of Otago (Medicine, Pharmacy, Dentistry and Physiotherapy)
The Department of Pharmacy University of Auckland
The National Preferred Medicines Centre Inc (PreMeC)
The Best Practice Advocacy Centre (BPAC)
The NZ Public Health Association
Some but not all New Zealand Clinical Pharmacologists
In addition, the New Zealand Medical Association and the New Zealand Council of Colleges and its member organisations are considering their positions

Independent consumer organizations:

The Consumers Institute
Greypower
Women's Health Action Trust

RELEVANT INTERESTS OF THE AUTHORS

Professor Toop has been a member of PTAC and past chair of the National Preferred Medicines Centre, editor of the Canterbury Preferred Medicines List and has a long term interest in the area of prescriber education

Dr Richards is a Senior Lecturer in General Practice. She has been a past member of the Christchurch Preferred Medicines Committee, and has a research interest in the area of prescriber education.

Professor Tilyard is Chairman of the Best Practice Advocacy Centre and Executive director of Southlink Health

Tony Fraser currently works at the Best Practice Advocacy Centre developing prescriber education programmes to promote the responsible use of medicines.

Professor Dowell has previously worked in an advisory capacity to a Prescribing Research Unit in the UK, and has published research in the area of prescribing and ethnicity.

Associate Professor Arroll has a research interest in the promotion of rational use of medicines

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REFERENCES

1. US DTC advertising producing investment returns. SCRIP 1999;2446:17.
2. Liebman M. Head-to-head marketing ... may the best-promoted drug win. Medical Marketing & Media 2000;35(11):93-100.
3. Hodnett J. Targeting consumers. Medical Marketing & Media 1995;30(11):91-95.
4. Ministry of Health. Direct-to-consumer advertising of prescription medicines in New Zealand. A discussion paper. Wellington: Ministry of Health, 2000.
5. Ministry of Health. Health Report. Wellington: Ministry of Health, 2000.
6. Jessamine S. Medsafe; 2002. [personal communication]
7. Ministry of Health. Summary of submissions on the direct-to-consumer advertising of prescription medicines in New Zealand. Discussion paper. Wellington: Ministry of Health, 2001.
8. Perkins L. Pharmaceutical companies must make decisions based on profit. Western Journal of Medicine 2001;175:422-423.
9. GAO. Prescription drugs. FDA oversight of direct-to-consumer advertising has limitations. Washington DC: United States General Accounting Office, 2002, October.
10. NIHCM Foundation. Prescription drugs and mass media advertising, 2000. Washington, DC: The National Institute for Health Care Management Research and Educational Foundation, 2001.
11. Pharmacia. Pharmacia Corporation reports 16% increase in fourth-quarter earnings-per-share (EPS) and 29% EPS growth for full-year 2001. Available from www.pharmacia.co.jp/news_e/data/files/20020206e.pdf accessed on 10.02.2003.
12. PHARMAC. Analysis of the increase in dispensing volumes in 2001/02: Wellington: PHARMAC; 2002.
13. NIHCM Foundation. Prescription drug expenditures in 2001: another year of escalating costs. Washington DC: National Institute for Health Care Management; 2002.
14. Grant C, Forrest C, Starfield B. Primary care and health reform in New Zealand. New Zealand Medical Journal 1997;110(1037):35-39.
15. Colmar Brunton, Social Research Agency. Consumer opinion: Prescription Medicines Information. Prepared for Dept of General Practice Christchurch School of Medicine and Health Sciences. New Zealand;2003.

16. Aiken KJ. Direct-to-consumer advertising of prescription drugs: physician survey preliminary results: Rockville, MD.: Division of Drug Marketing, Advertising and Communications, FDA; 2003.
17. Spurgeon D. Doctors feel pressurised by direct to consumer advertising. BMJ 1999;319(7221):1321.
18. Mintzes B. An assessment of the health system impacts of direct to consumer advertising of prescriptions medicine (DTCA) Volume III: Patient information on medicines: a comparative patient/doctor survey in Vancouver and Sacramento: Vancouver: Centre for Health Services and Policy Research, University of British Columbia; 2001.
19. Slaughter E.5th Annual Survey, Consumer reaction to DTC advertising of prescription medicines: DTC advertising and self-care, Honoring requests for prescription medicines. Prevention Magazine Report;2001-2002:18,46.
20. FDA. DTC preliminary survey results: attitudinal and behavioral effects of direct to consumer advertising. Rockville, MD: Centre for Drug Evaluation and Research, Food and Drug Administration; 2000.
21. National Consumers' League (US). Survey: Direct to consumer advertising of prescription drugs. Washington,DC.: NCL; 2003.
22. Mintzes B, Barer ML, Kravitz RL, Kazanjian A, Bassett K, Lexchin J, et al. Influence of direct to consumer pharmaceutical advertising and patients' requests on prescribing decisions: two site cross sectional survey. BMJ 2002;324(7332):278-279.
23. Emanuel EJ, Emanuel LL. Four models of the physician-patient relationship. JAMA 1992;267(16):2221-2226.
24. Toop L. Primary care: core values. Patient centred primary care. BMJ 1998;316:1882-1883.
25. Liebman M. Three scenarios for direct-to-success advertising. Medical Marketing & Media 2000;35(4):72-76.
26. Shapiro MF. Regulating pharmaceutical advertising: What will work? Canadian Medical Association Journal 1997;156(3):359-361.
27. Bell R, Wilkes M, Kravitz R. The educational value of consumer-targeted prescription drug print advertising. Journal of Family Practice 2000;49(12):1092-1098.
28. Bell R, Kravitz R, Wilkes M. Direct-to-consumer prescription drug advertising, 1989-1998. A content analysis of conditions, targets, inducements, and appeals. Journal of Family Practice 2000;49(4):329-335.

29. Woloshin S, Schwartz L, Tremmel J, Welch H. Direct-to-consumer advertisements for prescription drugs: what are Americans being sold? Lancet 2001;358(9288):1141-1146.
30. Aiken KJ. Direct-to-consumer advertising of prescription drugs: preliminary patient survey results. Rockville, MD.: Division of Drug Marketing, Advertising and Communications, Food and Drug Administration, 2002.
31. Morgan S. An assessment of the health system impacts of direct to consumer advertising of prescriptions medicines (DTCA). Volume V. Predicting the welfare and cost consequences of direct to consumer prescription drug advertising. Vancouver: Centre for Health Services and Policy Research, University of British Columbia; 2001.
32. Koerner C. The regulation of direct-to-consumer (DTC) promotion of prescription drugs: Rockville, MD.: Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration; 1999.
33. Pratt P. The results of a regulatory compliance survey of direct-to-consumer advertisements for medicines. Wellington: Medsafe; 2000.
34. Coney S. Direct to consumer advertising of prescription pharmaceuticals: a consumer perspective from New Zealand. Journal of Public Policy and Marketing 2002;21(2):213-223.
35. Morris LA, Brinberg D, Klimberg R, Millstein L, Rivera C. Consumer attitudes about advertisements for medicinal drugs. Social Science and Medicine 1986;22(6):629-638.
36. Morris LA, Brinberg D, Klimberg R, Rivera C, Millstein L. The attitudes of consumers toward direct advertising of prescription drugs. Public Health Reports 1986;101(1):82-89.
37. Calfee JE. Public policy issues in direct-to-consumer advertising of prescription drugs. Washington D.C.: American Enterprise Institute; 2002.
38. Paterson R. Submission to the Ministry of Health review of direct to consumer advertising 2001.
39. Imperial Cancer Research Fund Oxcheck Study Group. Effectiveness of health checks conducted by nurses in primary care: final results of the OXCHECK study. BMJ 1995;310:1099-1104.
40. Toop L, Richards D. Preventing cardiovascular disease in primary care. Targets are fine in principle, but unrealistic. BMJ 2001;323:246-247.
41. Mintzes B, Kazanjian A, Bassett K, Lexchin J. An assessment of the health system impacts of direct to consumer advertising of prescriptions medicine (DTCA).

Volume IV. Pills, persuasion and public health policies. Vancouver: Centre for Health Services and Policy Research, University of British Columbia; 2001.

42. Findlay SD. Direct-to-consumer promotion of prescription drugs. PharmacoEconomics 2001;19(2):109-119.
43. Hawkes N. America hits mute button. TimesOnline Available from http://www.timesonline.co.uk/printFriendly/0,,1-2-454810.00.html accessed on 24.10.2002.
44. Consumers Association (UK). DTCA survey results. London: Consumers' Association; [2002].
45. Calfee JE. What consumer surveys show about direct-to-consumer advertising of prescription drugs. Greenwich, CT: Coalition for Healthcare Communication, 2001.
46. Brodie M, . Understanding the effects of direct-to-consumer prescription drug advertising. Menlo Park, CA.: The Henry J. Kaiser Family Foundation; 2001.
47. NIHCM Foundation. Prescription drugs and mass media advertising. Washington,DC.: National Institute for Health Care Management; 2000.
48. RMI. Response to the Ministry of Health discussion document on direct to consumer advertising of prescription medicines in New Zealand. - Executive summary. Researched Medicines Industry Association; 2001. Available from: http://www.rmianz.co.nz/html/views/subs/dtc2001_execsumm.html accessed on 10.02.2003
49. Hayes L, Mintzes B, (Editor). Providing prescription medicine information to consumers: is there a role for direct-to-consumer promotion? DTCA Symposium Report. Amsterdam: Health Action International Europe; 2002. Available from: http://www.haiweb.org/campaign/DTCA/symposium_reports.html
50. PHARMAC. Submission to Ministry of Health, Direct to consumer advertising review. Wellington: PHARMAC;2001.
51. EFA. Better Information on prescription medicines needed, but not from industry. EFA News 2002 February.
52. Health Action International Europe and European Public Health Alliance. Joint statement on the proposed relaxation of the EU ban on direct to consumer advertising of prescription medicines: Amsterdam:HAI; 2002. Available from: http://www.haiweb.org/campaign/DTCA/jointstatement.html
53. Moonen G. Moonen vs Film and Literature Board of Review. Brookers: New Zealand Court of Appeal, 1999.

54. Lasser KE, Allen PD, Woolhandler SJ, Himmelstein DU, Wolfe SM, Bor DH. Timing of new black box warnings and withdrawals for prescription medications. JAMA 2002;287(17):2215-2220.

55. Wood AJJ. The safety of new medicines. The importance of asking the right questions. JAMA 1999;281(18):1753-1754.

56. Willman D. How a new policy led to seven deadly drugs. Los Angeles Times 2000 December 20.

57. Willman D. Drug After drug, warnings ignored - PROPULSID. Los Angeles Times 2000 December 20.

58. Willman D. Lotronex: officer foresaw deady effects. Los Angeles Times 2000 December 20.

59. Willman D. Rezulin: Fast-track approval and a slow withdrawal. Los Angeles Times 2000 December 20.

60. World Health Organisation. Ethical criteria for medicinal drug promotion: Geneva: World Health Organisation; 1988.

61. Mordock J. The future of customer relationships. Pharmaceutical Executive 2000;20(8):114-115.

62. Mintzes B. An assessment of the health system impacts of direct-to-consumer advertising of prescription medicines (DTCA). Volume II Literature Review. Vancouver: Centre for Health Services and Policy Research, University of British Columbia; 2001.

63. Peters J. Hard to swallow: the high cost of direct-to-consumer advertising. Minnesota Medicine 2001;84(1):10-15.

64. Patented Medicine Prices Review Board. Annual Report 2000. Compliance and excessive price guidelines. Ottawa: PMPRB;2000. p.26-31.

65. PHARMAC. New Zealand Pharmaceutical Schedule. 2002. Wellington: PHARMAC; August 2002.

66. Adams N, Bestall J, Jones P. Fluticasone versus beclomethasone or budesonide for chronic asthma. Cochrane Database of Systematic Reviews, 2002; Issue 2.

67. Meek C. Direct-to-consumer advertising (DCTA) of prescription medicines: a review of international policy and evidence. London: Council of Royal Pharmaceutical Society of Great Britain; 2001.

68. Cited in Chen Palmer & Partners. Consistency of restrictions on medicine advertising with the Bill of Rights Act. Wellington: Chen & Palmer, Public Law Specialists; 2000.

69. Avorn J, Chen M, Hartley R. Scientific versus commercial sources of influence on the prescribing behavior of physicians. American Journal of Medicine 1982;93(1):4-8.

70. Cockburn J, Pit S. Prescribing behaviour in clinical practice: patients' expectations and doctors' perceptions of patients' expectations - a questionnaire study. BMJ 1997;315(707):520-523.

71. McWhinney I. Core values in a changing world. BMJ 1998; 316 (7147): 1807-1809.

72. Bell R, Wilkes M, Kravitz R. Advertisement-induced prescription drug requests: patients' anticipated reactions to a physician who refuses. Journal of Family Practice 1999;48(6):446-452.

73. Lipsky MS, Taylor CA. The opinions and experiences of family physicians regarding direct-to-consumer advertising. Journal of Family Practice 1997;45(6):495-499.

74. Minnesota Medical Association. Pharmaceutical issues survey for Minnesota physicians. Survey Results; 2000. Available from: http://www.mmaonline.net/Protected/pharmresults.htm

75. A look back at 2000. Overabundance and deregulation. Prescrire International 2001;10(52):52-54.

76. Stern JM, Simes RJ. Publication bias: evidence of delayed publication in a cohort study of clinical research projects. BMJ 1997;315:640-645.

77. Product Information. RELENZA (Zanamivir for inhalation): Rockville,MD.: FDA; 1999. Available from: http://www.fda.gov/cder/foi/label/1999/21036lbl.pdf accessed on 10.02.2003.

78. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. JAMA 1998;279(15):1200-1205.

79. Sigelman D. Unsafe drugs: congressional silence is deadly. Public Citizen Health Research Group Health Letter 2001October; 3-6.

80. Cross J, Lee H, Westelinck A, Nelson J, Grudzinskas C, Peck C. Postmarketing drug dosage changes of 499 FDA-approved new molecular entities, 1980-1999. Pharmacoepidemiology and Drug Safety 2002;11:439-446.

81. Heerdink ER, Urquhart J, Leufkens HG. Changes in prescribed drug doses after market introduction. Pharmacoepidemiology and Drug Safety 2002;11:447-453.

82. Gale EAM. Lessons from the glitazones: a story of drug development. Lancet 2001;357(9271):1870-1875.

83. Hollon MF. Direct-to-consumer marketing of prescription drugs. Creating consumer demand. JAMA 1999;281(4):382-4.

84. Davidson MH, Hauptman J, DiGirolamo M, Foreyt JP, Halsted CH, Heber D, et al. Weight control and risk factor reduction in obese subjects treated for 2 years with orlistat. JAMA 1999;281(3):235-242.

85. Hill JO, Hauptman J, Anderson JW, Fujioka K, O'Neil PM, Smith DK, et al. Orlistat, a lipase inhibitor, for weight maintenance after conventional dieting: a 1-y study. American Journal of Clinical Nutrition 1999;69(6):1108-1116.

86. Therapeutics Initiative. New drugs V. Orlistat (xenical). Therapeutics Letter 2000; Issue 34.

87. Kaufman KD, Olsen EA, Whiting D, Savin R, De Villez R, Bergfeld W, et al. Finasteride in the treatment of men with androgenetic alopecia. Journal of the American Academy of Dermatology 1998;39:578-589.

88. Cassels A, Wright J, Mintzes B, Jauca C. Direct-to-consumer advertising. Finasteride for male pattern hair loss. Canadian Family Physician 2001;47:1751-1755.

89. Drake L, Hordinsky M, Fiedler V, Swinehart J, Unger W, Cotterill P, et al. The effects of finasteride on scalp skin and serum androgen levels in men with androgenetic alopecia. Journal of the American Academy of Dermatology 1999;41(4):550-554.

90. FDA. Warning letter to Merck & Co. re propecia. NDA 20-788(MACMIS ID # 6807). Rockville,MD.: FDA; 2001. Available from: http://www.fda.gov/cder/warn/warn1998.htm accessed on 10.02.2003.

91. Advertising Standards Complaints Board. Complaint decision. Complaint # 02/155. Propecia (Merck Sharp & Dohme). Wellington: ASCB;2002. Available from: http://www.asa.co.nz/decisions/decisions.htm accessed on 10.02.2003.

92. Moynihan R. The making of a disease: female sexual dysfunction. BMJ 2003;326(7379):45-47.

93. Wolf N. Positioning DETROL (Creating a Disease*)*.Powerpoint presentation to Pharmaceutical Marketing Research Group October 7 2002. Available from: http://www.pmrg.org/presentations.html accessed on 10.02.2003.

94. FDA. Warning Letter to Pharmacia & Upjohn re Detrol (tolterodine tartrate tablets) NDA 20-771 MACMIS ID #9318. Rockville, MD.: FDA; 2000.

Available from: http://www.pharmcast.com/WarningLetters/December2000/PNU1200.htm accessed on 10.02.2003.

95. Therapeutics Initiative. New Drugs VI. Therapeutics Letter 2000 July/August; Issue 36.
96. Hay-Smith J, Herbosin P, Ellis G, Moore K. Anticholinergic drugs versus placebo for overactive bladder syndrome in adults. Cochrane Database of Systematic Reviews 2002; Issue 4.
97. Burgio K, Locher J, Goode P, Hardin J, McDowell B, Dombrowski M, et al. Behavioural vs drug treatment for urge urinary incontinence in older women: a randomized controlled trial. JAMA 1998;280(23):1995-2000.
98. Burgio K, Goode P, Locher J, Umlauf M, Roth D, Richter H, et al. Behavioural training with and without biofeedback in the treamtent of urge incontinence in older women: a randomised controlled trial. JAMA 2002;288(18):2293-2299.
99. Poutasi K. (Director General of Health); 2003. [personal communication]
100. Advertising Standards Complaints Board. Complaints decisions. Available from: http://www.asa.co.nz/decisions accessed on 10/.02.2003
101. Trans-Tasman Group. Therapeutic Goods Administration (TGA). Draft report of a review of advertising therapeutic products in Australia and New Zealand: Woden ACT:TGA; Australia;2002 August.
102. Researched Medicines Industry (NZ). Code of Practice. Wellington: RMI; 1999.
103. Advertising Standards Authority Inc NZ. Available from: http://www.asa.co.nz/ accessed on 10.02.2003.
104. Coney S. 2002. [Personal communication]
105. Hoek J, Gendall P. Direct-to consumer advertising down under: an alternative perspective and regulatory framework. Journal of Public Policy and Marketing 2002;21(2):202-212.
106. Public Citizen. Letter to Tommy Thompson, Department of Health and Human Services re reductil (sibutramine). Washington DC.: 2002 March 19. Available from: http://www.citizen.org/publications/release.cfm?ID=7160 accessed on 10.02.2003.
107. Health Canada. Advisory. Health Canada investigates safety of MERIDIA (Sibutramine). 2002 March 27. Available from: http://www.hc-sc.gc.ca/english/protection/warnings/2002/2002_21e.htm accessed on 10.02.2003.

108. FDA. Letter to Knoll Pharmaceutical Company re NDA 20-632 Meridia (sibutramine hydrochloride monohydrate) capsules. MACMIS ID #7204. Rockville, MD.: FDA, 1998. Available from: http://www.fda.gov/cder/warn/warn1998.htm

109. Advertising Standards Authority. Decision 02/179 AWAP 02/11- Abott Laboratories (NZ) Limited - Reductil. Wellington: ASA. Available from http://www.asa.co.nz/decisions/dec02179.htm accessed on 10.02.2003.

110. Advertisement for Reductil® Healthwise 2003(Jan-Feb):19.

111. Wolfe SM. Direct-to-consumer advertising -- education or emotion promotion? New England Journal of Medicine 2002;346(7):524-526.

112. Wolfe S, Sasich L, Zieve A, Vladeck D. Comments on docket no. 02N-0209 FDA enforcement of drug advertising and enforcement laws. Washington, DC.: Public Citizen Health Research Group, 2002.

113. Wilkes M, Doblin B, Shapiro M. Pharmaceutical advertisements in leading medical journals: experts' assessments. Annals of Internal Medicine1992;116(11):912-919.

114. Stryer DB, Bero LA. Characteristics of materials distributed by drug companies: an evaluation of appropriateness. Journal of General Internal Medicine 1996;11:575 - 583.

115. Public Citizen Health Research Group. Testimony of Sidney M Wolfe, MD Director, Public Citizen's Health Research Group, Senate Commerce Committee Subcommitte on Consumer Affairs Hearing on direct-to-consumer (DTC) advertising. (HRG Publication #1583): Washington, DC:. Public Citizen, 2001. Available from: http://www.citizen.org/publications/release.cfm?ID=6785 accessed on 10.02.2003.

116. Pharmacia. Fourth Quarter earnings Statement, 2001.

117. FDA. Warning Letter to Merck & Co Inc. NDA 21-042 MACMIS ID # 9456 Vioxx (rofecoxib) tablets. Rockville, MD.: FDA, 2001. Available from: http://www.pharmcast.com/WarningLetters/Yr2001/Sept2001/Merck0901.htm accessed on 10.02.2003.

118. FDA. Letter to G.D. Searle & Co. re NDA 20-998 Celebrex (celecoxib) capsules, NDA 19-908 Ambien (zolpidem tartrate) tablets MACMIS ID #8518: Department of Health & Human Services, 2000. http://www.pharmcast.com/WarningLetters/November2000/GDSearle1100.htm accessed 10.02.2003.

119. FDA. Letter to G. D. Searle & Co. re NDA 20-998 Celebrex (celecoxib) capsules MACMIS ID #9514: Department of Health & Human Services, 2000. Available from: http://www.pharmcast.com/WarningLetters/November2000/GDSearle1100.htm accessed on 10.02.2003.
120. Silverstein FE, Faich G, Goldstein JL, Simon LS, Pincus T, et al. Gastrointestinal toxicity with celecoxib vs nonsteroidal anti-inflammatory drugs for osteoarthritis and rheumatoid arthritis. JAMA 2000;284(10):1247-1255.
121. Juni P, Rutjes AW, Dieppe PA. Are selective COX 2 inhibitors superior to traditional non steroidal anti-inflammatory drugs? BMJ 2002;324(7349):1287-1288.
122. Wright J. The double-edged sword of COX-2 selective NSAIDs. Canadian Medical Association Journal 2002;167(10):1131-1137.
123. Bombardier C, Laine L, Reicin A, Shapiro D, Burgos-Vargas R, Davis B, et al. Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis. New England Journal of Medicine 2000;343:1520-1528.
124. Celecoxib in osteoarthritis and rheumatoid arthritis: as disappointing as Rofecoxib. Prescrire International 2001;10(52):46-49.
125. University of Kentucky Pharmacy Services. COX-2 inhibitor Restrictions and criteria for use: University of Kentucky, 2003. Available from: http://www.mc.uky.edu/pharmacy/dic/criteria/cox-2.htm accessed on 10.02.2003.
126. Mintzes B. 2003, January. [Personal communication].
127. Mansfield P. DTCA in Australia 2003. January. [Personal Communication].
128. Herxheimer A. 2003, January. [Personal communication].
129. Ballanden N, Goddard M. The hard sell. Consuming Interest: Journal of the Australian Consumers Association 2003;94(Summer):6-9.
130. Moynihan R, Heath I, Henry D, Gotzsche PC. Selling sickness: the pharmaceutical industry and disease mongering. Commentary: Medicalisation of risk factors. BMJ 2002;324(7342):886-891.
131. Editorial. Just how tainted has medicine become? Lancet 2002;359:1167.
132. Anonymous. Free rein for drug ads? A slowdown in FDA review has left consumers more vulnerable to misleading messages. 2003 February. Available from : http://www.consumerreports.org accessed on 10.02.2003.

133. Burton TM. Pushing pills: reining in drug advertising - backlash is brewing among companies who believe flashy ads drive up costs. Wall Street Journal 2002 March 13.
134. McGregor G. Ban on drug ads to stay: McLellan. Minister refuses to loosen regulations despite lobbying by manufacturers, media. Ottawa Citizen 2002 Saturday March 23.
135. Galbally R. National competition review of drugs, poisons and controlled substances legislation. Final Report Part A. Woden, ACT: Commonwealth of Australia Therapeutic Goods Administration; 2001.
136. Sibley CE. Scattershot studies, self-serving sponsors. Can't we get better DTC advertising research? Medical Marketing & Media 2000;35(2):96-100.
137. Watson R. Consumer groups fight plans for 'direct to patient' drug advertisements. BMJ 2001;323:889.
138. Greene K, McGinley L. Television: AARP to alter TV ad that touts more scrutiny of drug purchases. Wall Street Journal 2002, MAy 14;Sect B6.
139. Disclosure in direct-to-consumer advertising: American Medical Association House of Delegates, 2001.
140. National Prescribing Service Limited. Medicinesline. Available from: http://www.nps.org.au/ accessed on 10.02.2003.

APPENDIX 1: ACADEMIC PHARMACY PERSPECTIVE

DIRECT TO CONSUMER ADVERTISING (DTCA) OF PRESCRIPTION MEDICINES: AUCKLAND SCHOOL OF PHARMACY PERSPECTIVE

This submission is made on behalf of the School of Pharmacy, University of Auckland, one of two tertiary sites for pharmacy education in New Zealand. We are well placed to comment on current and emerging roles for pharmacy, and the potential impact of DTCA on professional development.

In their response to the 2000 Ministry of Health discussion paper on DTCA, the Pharmaceutical Society of New Zealand and the Pharmacy Guild maintained that there was little impact on the profession of pharmacy. In their view this was because it is the prescriber who makes the decision on whether or not to prescribe an advertised prescription medicine. The submission acknowledged that there are valid arguments both for and against DTCA but that on balance those in support outweighed those against. Concerns were expressed about insufficient controls over the advertising of non-prescription medicines and 'natural and complementary medicines'. An argument in favour of DTCA was the direct education provided to consumers about medicines through this form of promotion.

The views of the New Zealand pharmacy professional organisations are at variance to those in Australia and the United Kingdom, where the relevant bodies have strongly opposed DTCA. The arguments against DTCA have been stated elsewhere, such as a negative effect on the clinician–patient relationship, lack of objective information to the consumer, increasing 'medicalisation' of normal health issues, and negative effects on funding. We fully support these arguments against DTCA.

Traditionally, the main professional roles of community pharmacy have centred on the effective and efficient distribution of medicines through dispensing of prescribed medicines, and sale of non-prescription medicines. In both of these roles the education of patients/consumers on the safe and effective use of medicines is paramount, as is the separation of the prescribing and dispensing functions. The pharmacist acts as an important 'backstop' in the quality use of medicines, with a professional obligation to ensure choice of the correct product and dose, as well as the avoidance of adverse drug reactions and interactions.

During the past decade there has been a marked expansion of the professional cognitive roles of community pharmacists and a growing realisation on the part of governments of the value of professional pharmacy services. Examples of these roles include the development of medication review services, pharmacist prescribing advisers, expansion of the list of pharmacist-only and pharmacy-only medicines, introduction of supplementary prescribing authority, and development of pharmaceutical care services. Uptake of these opportunities has been variable worldwide but New Zealand pharmacists

have expressed a willingness to develop a number of new services and pharmacy education has changed rapidly to accommodate these aspirations.

Professional pharmacy services will continue to evolve and it is widely agreed that the future role of community pharmacists could be as 'medication mangers' rather than simply suppliers of medicines. For example, it is envisaged that electronic prescribing and robotic dispensing will be firmly established by the end of this decade. These initiatives will free up time to allow the pharmacist to undertake a more clinical, patient-focused role.

It is interesting that all Western countries have experienced a sharp surge in both prescription numbers and escalating prescription drug expenditures over the past few years. In the United States and elsewhere, there has been a commensurate growth in 'mail order' pharmacy. While this development may seem attractive in cutting costs, the downside is the loss of direct interaction between the pharmacist and patient and the added value of face-to-face communication and medication counselling. There seems also to be a link between the growth in mail-order dispensing and the growth of DTCA. If the desired end-result of DTCA is increased consumption of pharmaceutical products, then the appeal of cutting out the 'middle-men' in the distribution chain is clearly appealing. Fortunately, mail-order pharmacy has not yet had a major impact in New Zealand.

One of the arguments in support of DTCA is that it enhances consumers' rights to information about treatment and in the education of consumers. A counter-argument is that medicines are not 'ordinary items of commerce', and that the consumer can best benefit from the services of a 'learned intermediary' who advocates on their behalf. Our point is that this 'learned intermediary' is a role that pharmacists are well placed to provide, in collaboration with their prescribing colleagues.

A typical and emerging scenario is the patient who is receiving prescription medicines from more than one prescriber (e.g. general practitioner, specialist, midwife), who is also self–medicating with non-prescription medicines, and with natural/complementary therapies. Pharmacists are uniquely placed to provide advice, and have the requisite understanding of medicines, in order to assist such patients in optimising the benefits and minimising the risks associated with their therapies. Pharmacists can provide independent, informed and unbiased advice to patients about their medications.

In terms of DTCA, we support the view that the commercial imperative underpinning this practice cannot provide independent and unbiased information to consumers. DTCA creates demand for specific drugs, and sometimes engenders unrealistic expectations on the part of patients. While the prescriber has ultimate authority in the choice of medicine for a particular patient, it is very difficult for the prescriber to contradict a direct request from a patient for a particular product they have seen advertised.

To counteract the view that DTCA enhances consumers rights to information, we wish to propose the development of a 'Medicines Information Consortium' in New Zealand, with representation from prescibers, pharmacists, the Ministry of Health, consumers, and

relevant industry partners. Such a consortium could be readily assembled to provide the independent advice that consumers obviously require.

An additional consideration is that as further professional roles for pharmacists evolve we are likely to see 'pharmacist prescribing' in some form. Whether this be by an expansion of the range of Pharmacist Only Medicines, by a supplementary or dependent prescribing role, or by independent prescribing authority, only time will tell. As such roles emerge, pharmacists will also be exposed to the pressures of DTCA (in fact they already are for Pharmacist Only Medicines).

The Pharmacist Only Medicines category (also known as Restricted Medicines) poses some difficulties for pharmacists. These agents are 'intermediate' between Prescription Medicines and Pharmacy Medicines, they require physical separation from other stock to prevent direct consumer access and a record of patient details (name, address) in the transaction. Examples include oral non-steroidal anti-inflammatory agents, vaginal antifungals, and nasal corticosteroids.

The pharmacist is obliged to ask the patient questions relevant to the condition and choice of treatment. In essence, this category is analagous to 'pharmacist-prescribed' medicines. In reality, many of these agents are heavily promoted directly to the consumer. DTCA of these medicines often undermines the professional judgement of the pharmacist. Patients often resent the questioning and record-keeping associated with their sale and cannot understand when the pharmacist declines to recommend the advertised product they have requested. The assumption is that because it's not a Prescription Medicine, it must be safe!

The position of pharmacists with respect to DTCA of Pharmacist Only Medicines mirrors the concerns of medical prescribers with DTCA of Prescription Medicines We restate the point that medicines are not 'ordinary items of commerce' and that a separation of the choice of best medicine from any financial imperatives imposed by DTCA is both clinically and ethically responsible.

In summary, we support the arguments against DTCA articulated in the wider submission. In particular, we are concerned at the negative impact on health-professional/consumer relations and the lack of an independent, objective input into the prescribing and use of medicines engendered by DTCA. We highlight the potential role of pharmacy to provide independent, unbiased advice, and to advocate for patients as a 'learned intermediary' in the prescribing of medicines.

Professor John Shaw
Head, School of Pharmacy,
The University of Auckland
18 December 2002

Appendix 2

Prepared for:	**Christchurch School of Medicine**
Author(s):	**colmar brunton**'s Social Research Agency
Issue Date:	

PRESCRIPTION MEDICINE INFORMATION:

NEW ZEALAND CONSUMER VIEWS

Background and Method

Background

Christchurch School of Medicine commissioned colmar brunton **to conduct research among the general public to obtain information on:**

- sources of information used for prescription medicines and other treatments
- perceptions of the trustworthiness of sources of information about prescription medicines
- attitudes towards drug company advertising
- effect of drug company advertising on behaviour
- level of support for an independent health information service as an alternative to pharmaceutical advertising.

Research Method

The research was conducted using **colmar brunton**'s telephone omnibus survey.
The omnibus survey is a survey of the general public aged 15+ living in private households with telephones. The omnibus is conducted in the 15 main centres[1]. At least 97% of this population are from the Statistics New Zealand defined urban zones of these 15 centres.

Households were selected at random from the entire list of available phone numbers in each centre. Respondents were selected at random using the 'next birthday' respondent selection technique. Only one interview was conducted per household, and up to two call-backs were made to respondents not available at the time of the call (before replacement). Fieldwork was conducted between the 15th and 20th January 2003.

Data has been weighted at the data processing stage (by known Census data for the population) to ensure a representative sample of New Zealanders aged 15 years plus in the 15 main centres. In total, 500 interviews were conducted. The maximum margin of error, at the 95% confidence level, on a sample size of 500 interviews is +/-4.4%. Note: All demographic differences mentioned throughout this report are statistically significant at the 95% confidence level.

The questions were developed by the Christchurch School of Medicine and endorsed by the New Zealand Consumers Institute. They were based on the United Kingdom Consumers Association survey carried out in 2002[2], with modifications to reflect the fact that DTCA of prescription medicines is already occurring in New Zealand (it is not allowed in the UK). In addition a question was added from a North American survey about trustworthiness of information sources[3]. Consumers were also asked to indicate whether they would favour banning DTCA to be replaced by an independent source of medicines and health information.

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[1] These are Auckland, Whangarei, Hamilton, Rotorua, Tauranga, Gisborne, Hawkes Bay, New Plymouth, Wanganui, Palmerston North, Wellington, Nelson, Christchurch, Dunedin, and Invercargill. .[2] Consumers Association. DTCA Survey Results: UK Consumers' Association. [3]. Mintzes B. An Assessment of the Health System Impacts of Direct to Consumer Advertising of Prescriptions Medicine (DTCA) Volume III: Patient Information on Medicines: A Comparative Patient/Doctor Survey in Vancouver and Sacramento: Centre for Health Services and Policy Research, University of British Columbia, 2001..

Executive Summary

This section summarises the key findings of this research.

- General Practitioners are the most commonly used source of information on prescription medicines. In addition, they are also much more commonly mentioned as a **main** source of information than any other. Pharmacists, hospital doctors, TV and magazine/newspaper advertisements are also popular choices for information.

- A similar pattern emerges when looking at the perceived reliability and accuracy of information given by various sources - GP's are, by far, seen as the most trustworthy and reliable source of information. This is followed by hospital doctors and pharmacists, well above other sources such as Healthline and Drug Companies.

  Sources such as magazine/newspaper and TV advertisements, as well as the Internet, are perceived as providing considerably less reliable and accurate information than GP's.

- A high agreement level is evident in response to the statement that drug companies spend most money on advertising medicines that give them the most profit. Agreement also tends to be high towards the statement that drug company advertising does not always give all the information about possible side effects.

  A high proportion of the New Zealanders surveyed disagreed that only the safest medicines are advertised on television, in addition to the fact that drug company advertising provides unbiased and comprehensive information about treatment, including non-drug and competing brands.

- Around 10% of the New Zealanders surveyed have been prompted to ask for a prescription-only medicine as the result of seeing an advertisement. Of those, the majority received the medicine they asked for from the doctor.

- Opinion is divided in terms of banning prescription medicine advertising in favour of a health information service. Around half of respondents would support the ban, while two in five would not.

Research Findings

This section details responses to each of the questions.

Sources Used to Obtain Information

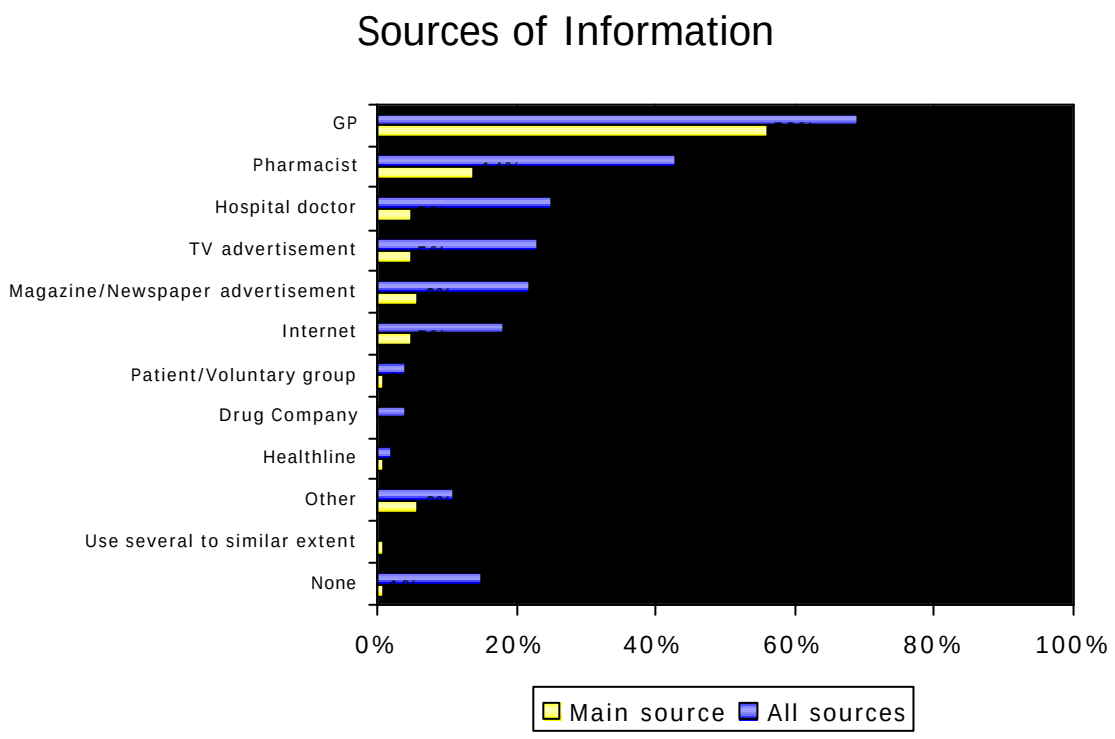
Firstly, all respondents were asked:

"In the last 12 months, which sources have you obtained information about prescription medicines or other treatments from?"

Respondents were then asked:

*"Which, if any, was your **main** source of information?"*

Responses to both of these questions are shown in the following chart.



Base: All respondents (N=500)

A General Practitioner is the most common information source for finding information about prescription medicines over the past 12 months, with 69% of respondents using this source. This is followed by a pharmacist (43%), hospital doctor (25%), TV advertisement (23%) and a magazine or newspaper advertisement (22%).

When looking at the main source of information, the majority of New Zealanders surveyed (56%) said their GP was their main source, followed by a pharmacist (14%).

Demographic variations are as follows:

GP

- Females are significantly more likely to have used GP's as a source than males (77% vs. 60% males)
- Tauranga residents are significantly more likely than average to have used GP's as a source of information (100% vs. 69%), and to say that their GP is the main source (89% vs. 56%)
- Respondents who are retired are significantly more likely than average to have used GP's as a source of information (85% vs. 69%), and to say that their GP is their main source (76% vs. 56%)
- Homemakers are significantly more likely than average to have used GP's as a source (88% vs. 69%)
- Respondents aged 50 years and over are significantly more likely than average to have used GP's as a source of information, and to say that their GP is the main source
- Asians are significantly less likely than average to have used GP's as a source of information (39% vs. 69%), and to say that their GP is the main source (36% vs. 56%).

Pharmacist

- Females are significantly more likely to have used pharmacists as a source than males (50% vs. 36% males)
- Tauranga residents are significantly more likely than average to have used a pharmacist in the past 12 months for information (92% vs. 43%), while Gisborne residents are more likely than average to say that a pharmacist is their main source of information (70% vs. 14%)
- Respondents aged 35-39 years are more likely than average to say that a pharmacist is their main source (26% vs. 14%)
- Blue Collar respondents (30% vs. 43%) and Hamilton residents (23% vs. 43%) are less likely than average to have used a pharmacist for information in the past 12 months.

Magazine/Newspaper advertisement

- Females are significantly more likely to have used a magazine or newspaper advertisement as a source than males (29% vs. 15% males)
- Students (21% vs. 6%) and respondents aged 15-19 years (22% vs. 6%) are significantly more likely than average to say that magazine/newspaper advertisements are their main source.

Internet

- Christchurch (31% vs. 18%) and Palmerston North residents (49% vs. 18%) are significantly more likely than average to have used the Internet as a source of information over the past 12 months
- Those in a high socio-economic group are more likely than average to say the Internet is their main source (11% vs. 5%)
- Those in a low socio-economic group (9% vs. 18%) and Blue Collar workers (7% vs. 18%) are significantly less likely than average to have used the Internet as a source in the past 12 months.

None

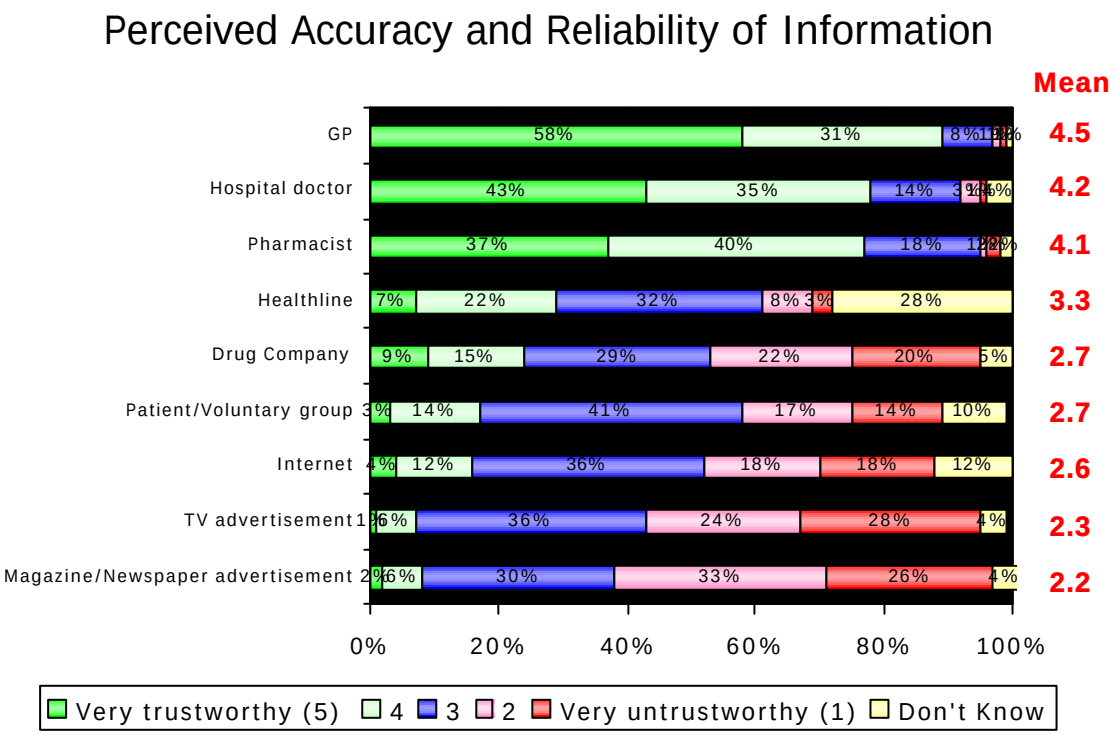
- Males, students and single respondents are significantly more likely than average to have used no sources in the past 12 months.

Reliability of Information

Respondents were then asked:

"I'd like you to imagine that you were looking for information about a prescription medicine or other treatment. Please could you tell me for each of these sources how much you would trust them, when it comes to the accuracy and reliability of the information. In giving me your answer, please use a scale of 1 to 5, where 1 is "very untrustworthy" and 5 is "very trustworthy", and 3 is neither trustworthy or untrustworthy".

Results are shown in the chart below.



Base: All respondents (N=500)

General Practitioners are perceived to be the most trustworthy in terms of accuracy and reliability of information. 58% of respondents say they believe the information given by GP's is "very trustworthy" and 91% believe it is trustworthy to some extent (either a 4 or 5 on the scale out of 5). Hospital doctors and pharmacists are the next most trusted, with 43% of respondents saying the information from hospital doctors is very trustworthy and 37% saying the same about pharmacists.

The least trusted sources of information include magazine or newspaper advertisements, with just over one quarter (26%) of respondents saying they believe the information is very untrustworthy. In addition, 59% believe it is untrustworthy to some extent (either a 1 or 2 on the scale out of 5). TV advertisements and the Internet are also less trusted with 28% and 18% respectively, saying the information is very untrustworthy.

Demographic differences are highlighted below:

GP

- Females rate the trustworthiness of GP's significantly higher than males (mean score of 4.5 out of 5 vs. 4.4 males)
- Lower White Collar workers rate GP's significantly higher than average for providing trustworthy information than average (4.6 vs. 4.5).

Hospital Doctor

- Napier/Hastings residents rate a hospital doctor significantly higher than average in terms of trustworthiness (4.8 vs. 4.2)
- Hamilton (3.8 vs. 4.2) and Whangarei residents (3.3 vs. 4.2) rate a hospital doctor significantly lower than average.

Pharmacist

- Asians rate pharmacists significantly lower than average in terms of trustworthiness (3.6 vs. 4.1).

Healthline

- Whangarei residents rate the Healthline significantly higher than average in terms of trustworthiness (4.3 vs. 3.3), while Hamilton residents rate significantly lower (2.8 vs. 3.3)
- Respondents who are retired rate Healthline significantly lower than average in terms of trustworthiness (2.8 vs. 3.3).

Drug Company

- Females rate drug companies as significantly more trustworthy than males (2.8 vs. 2.5)
- Gisborne residents rate drug companies as significantly more trustworthy than average (3.6 vs. 2.7), while those who are retired (2.1 vs. 2.7) and in high socio-economic groups (2.4 vs. 2.7) rate significantly lower.

Internet

- Palmerston North (3.4 vs. 2.6) and Nelson residents (3.6 vs. 2.6) rate the Internet significantly higher than average
- Hamilton residents rate significantly lower than average (2.2 vs. 2.6), as do females (2.5 vs. 2.7 males).

TV advertisement

- Asians (2.7 vs. 2.3) and Pacific Island people (2.9 vs. 2.3) rate TV advertisements significantly higher in terms of trustworthiness than average
- Students (2.6 vs. 2.3) and single respondents (2.5 vs. 2.3) also rate significantly higher than average
- Respondents employed in an Upper White Collar occupation (2.1 vs. 2.3) and those in a high socio-economic group rate significantly lower than average (2.0 vs. 2.3).

Magazine / Newspaper advertisement

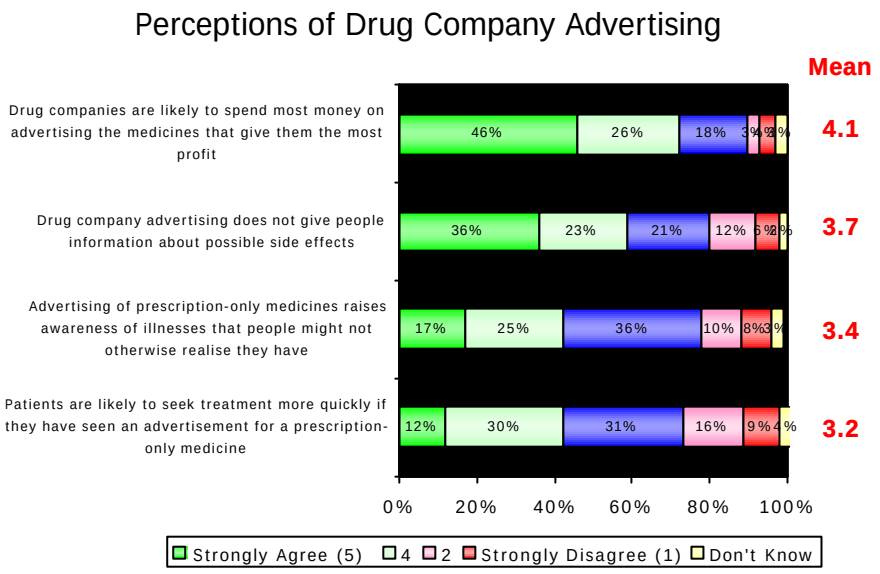
- Maori (2.7 vs. 2.2 overall) and Asians (2.6 vs. 2.2) rate magazine or newspaper advertisements significantly higher than average
- 18-24 year olds also rate magazine or newspaper advertisements higher than average (2.6 vs. 2.2)
- Respondents in a high socio-economic group rate significantly lower than average (2.0 vs. 2.2).

Perceptions of Drug Company Advertising

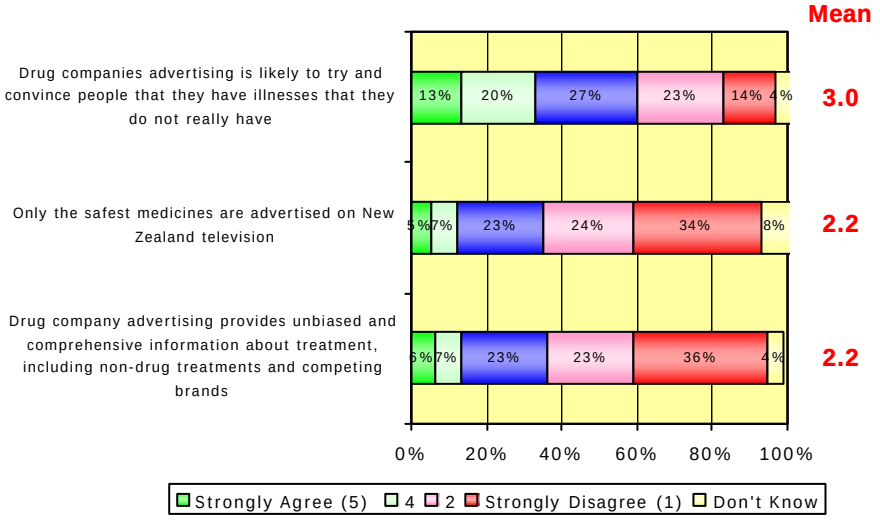
Respondents were then told:

"Drug companies currently advertise prescription-only medicines to the public in New Zealand. Here are some statements people have made about drug company advertising. For each statement, please tell me how much you agree or disagree with it by using a scale of 1 to 5, where 1 is "strongly disagree" and 5 is "strongly agree". If you neither agree or disagree, please rate it as a 3."

Results are shown in the following charts.



Base: All respondents (N=500)



Base: All respondents (N=500)

Almost half (46%) of respondents agree strongly that drug companies are likely to spend most money on advertising the medicines that give them the most profit. An additional 26% agree to some extent (a 4 on the scale out of 5) with the statement. 59% of respondents agree to some extent (a 4 or 5 on the scale out of 5) that advertising by drug companies does not give people information about possible side effects.

A similar level of agreement (42% either a 4 or 5) is evident when comparing the statements "advertising of prescription-only medicines raises awareness of illnesses that people might not otherwise realise they have" and "patients are likely to seek treatment more quickly if they have seen an advertisement for a prescription-only medicine". However, a higher proportion of respondents (25%) disagree to some extent (either a 1 or 2 on the scale out of 5) with the statement relating to patients seeking treatment more quickly than the statement that advertising raises awareness of illnesses (18% disagreement).

Disagreement is highest with the statement that "Drug company advertising provides unbiased and comprehensive information about treatment, including non-drug treatments and competing brands", with 59% disagreeing to some extent (a 1 or 2 on the scale out of 5) and 36% disagreeing strongly. Disagreement is also high for the statement that "only the safest medicines are advertised on New Zealand television"; 58% of respondents disagree to some extent, of which just over one third (34%) disagree strongly.

Differences across demographic variables are shown below:

Drug companies are likely to spend most money on advertising the medicines that give them the most profit

- Upper White Collar workers show significantly higher agreement with the statement than average (mean score of 4.3 out of 5 vs. 4.1 overall)
- Blue Collar workers (3.8 vs. 4.1) and respondents who are unemployed (3.2 vs. 4.1) show significantly less agreement than average
- Pacific Island people (3.5 vs. 4.1) and Whangarei residents (3.1 vs. 4.1) also show significantly lower agreement than average.

Drug company advertising does not give people information about possible side effects

- Whangarei residents (4.9 vs. 3.7) and those who are retired (4.3 vs. 3.7) show significantly higher agreement than average
- Gisborne residents show lower agreement than average (2.8 vs. 3.7).

Advertising of prescription-only medicines raises awareness of illnesses that people might not otherwise realise they have

- Pacific Island people (4.0 vs. 3.4) and respondents who are unemployed (4.2 vs. 3.4) show significantly higher agreement than average
- Respondents in a high socio-economic group show significantly less agreement than average (3.1 vs. 3.4).

Patients are likely to seek treatment more quickly if they have seen an advertisement for a prescription-only medicine

- Respondents living in Auckland show higher agreement than average (3.4 vs. 3.2), while those living in Wellington (2.9 vs. 3.2), Whangarei (2.0 vs. 3.2) and Gisborne (2.4 vs. 3.2) show lower agreement than average.

Drug companies advertising is likely to try and convince people that they have illnesses that they do not really have

- Respondents living in Whangarei (1.9 vs. 3.0) and homemakers (2.5 vs. 3.0) show lower agreement than average.

Only the safest medicines are advertised on New Zealand television

- Pacific Island people (2.9 vs. 2.2 overall) and Asians (2.8 vs. 2.2) show higher agreement than average
- Wanganui residents (3.6 vs. 2.2), those who are unemployed (3.0 vs. 2.2) and in a low socio-economic group (2.4 vs. 2.2) also show higher levels of agreement than average
- Whangarei residents show lower levels of agreement than average (1.2 vs. 2.2).

Drug company advertising provided unbiased and comprehensive information about treatment, including non-drug treatments and competing brands

- Pacific Island people (3.8 vs. 2.2) and respondents who are unemployed (2.5 vs. 2.2) show higher agreement than average
- Single respondents (2.4 vs. 2.2) and students (2.6 vs. 2.2) also show higher agreement than average
- Respondents who are employed full-time (2.0 vs. 2.2) or in Upper White Collar occupations (1.9 vs. 2.2) show less agreement than average.

Advertising Effectiveness

Respondents were also asked a question relating to whether television advertising prompted them to ask for a prescription-only medicine:

"Has an ad ever prompted you to ask for a prescription only medicine from your doctor?"

Results are shown in the following table:

	All respondents (N=500) %
Yes	13
No	86
Don't Know	1

Just over one in ten (13%) respondents have been prompted to ask for a prescription-only medicine as the result of seeing an advertisement.

These respondents (N=64), were then asked:

"What happened next? Did you..."

	%
Receive a prescription for the medicine you requested	62
Receive a prescription for another medicine	17
Not receive any prescription	19
Don't Know	1

Base: All respondents who were prompted to ask for prescription medicine (N=64)

Three in five (62%) respondents who had asked for a prescription-only medicine after seeing an advertisement received a prescription for the medicine requested. One in five (17%) received a prescription for another medicine, while the remaining 19% did not receive a prescription.

All respondents were then read the following statement:

"In New Zealand it has been suggested that instead of allowing drug companies to advertise prescription medicines, a health information service should be provided for consumers allowing easy access to an independent source of up to date information. This would include the comparative risks, benefits and costs of different types of drug and non-drug treatment. Would you support banning advertising of prescription medicines (on TV, radio and in magazines and newspapers) in favour of such a service?"

Results are shown in the following table:

	All Respondents (N=500) %
Yes	51
No	41
Don't Know	8

Opinion is divided over support for banning advertising in favour of a health information service. Just over half (51%) of respondents would support banning the advertising of prescription medicines in favour of a health information service, while 41% would not support the idea. The remaining 8% don't have an opinion.

Respondents who live in Whangarei (92% vs. 51%) and Wanganui (89% vs. 51%) are significantly more likely to be in favour of banning prescription medicine advertising in favour of a health information service than average, as are Blue Collar workers (63% vs. 51%).

APPENDIX 3: NEW ZEALAND GP SURVEY

Direct to Consumer Advertising of Prescription Medicines

Opinions and Experiences of New Zealand General Practitioners

Dr Dee Richards Senior Lecturer Christchurch School of Medicine & Health Sciences
Professor Les Toop* Christchurch School of Medicine & Health Sciences
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Departments of General Practice
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2002

BACKGROUND

New Zealand and the United States are the only two industrialised countries permitting direct to consumer advertising (DTCA) of prescription drugs. The US has a centrally controlled system of regulation. In contrast, New Zealand has a self-regulatory process.

Senior academic staff from the three Departments of General Practice at the University of Otago became aware of increasing concern and frustration expressed by New Zealand general practitioners. GPs indicated they were feeling the effects of the pressure to prescribe specific branded products as a result of DTCA of pharmaceuticals.

In response to these concerns, the NZ academic group, led by three Professors of General Practice, reviewed the overseas and New Zealand literature on DTCA.
The conclusion of this review was that DTCA was not in the interest of the public health in New Zealand. Prior to advocating for government to reconsider a ban on such advertising the group decided to explore the opinions and level of support for their position from all NZ GPs

AIM

To seek the impressions, attitudes and experiences of NZ GPs on the effects of DTCA of prescription medicines
To determine whether these views and opinions were consistent with the published evidence from the literature.

METHODS

A standard one page postal questionnaire was sent to all 3200 GPs in New Zealand. A covering letter signed by the three Professors explained the questionnaire was designed to canvass the opinions and experiences of New Zealand GPs and their patients. The letter clearly stated the position of the three Professors based on their review of the literature and their intention to use the information to support a recommendation to government to reconsider a ban on DTCA of prescription medicines.

The questionnaire was anonymised so respondents could not be identified.

The questionnaire asked basic demographic details about age, sex and tenths worked in general practice.

Using a standard method, GPs were then asked to respond to 13 statements (seven negative, six positive) indicating their level of agreement to each. The majority of the statements were adapted from those used in similar surveys done in the US and Canada[18] [73]. Statements were designed to explore the following areas:

- Level of activity specifically generated by DTCA
- Influence of DTCA on practice and the doctor patient relationship
- Perceived usefulness of consultations generated by DTCA

- Other questions were designed to gather information around the claimed benefits of DTCA:
- Improved compliance
- DTCA as a positive information / education tool
- Improved health outcomes
- Earlier presentation for necessary medical care
- Improved quality of prescribing

Statements about DTCA and its influence on New Zealand General Practice were phrased both positively and negatively to avoid the tendency to response bias (respondents tending to agree with a statement rather than disagree with its opposite).

There was a free text section at the end of the questionnaire where GPs were also asked to provide any comments (positive or negative) on their experiences with DTCA.

The questionnaire was sent to 3200 GPs on November 15 and 16 2002.

RESULTS

The response rate at 10 days was 43%, after 10 days rising to 50% (n=1611) at the four week close off
Average age of respondents 45.7 years
39% of respondents were male 61% female
Average no. of tenths in general practice 8

Responses to statements (see Table 1)

- 90% of respondents stated they had had consultations specifically generated by DTCA

- 68% of respondents felt consultations generated by DTCA were often unnecessary

- 79% of respondents reported patients frequently asked them for DTC advertised medicines

- 69% of respondents felt they had been under pressure to prescribe advertised medications

- 44% of respondents said they had switched to or started a medication with an advertised drug that they felt offered little benefit over drugs they would normally use

- 57% of respondents believed consultations generated by DTCA resulted in little health gain by patients

- 12% of respondents believed DTCA was a useful means of educating consumers about the risks and benefits of prescription medicines

- 50% of respondents felt DTCA could lead to difficulties in the doctor patient relationship

- 4% of respondents feel DTC ads provide the balance of information consumers need
- 16% of respondents feel DTC ads have helped their patients get necessary medical care at an earlier stage
- 13% of respondents felt DTCA improved compliance
- 74% of respondents felt that DTC advertising of lifestyle drugs encourages the medicalisation of well populations
- 3% of respondents felt DTCA improves the quality of their prescribing
- 10% of respondents believe that DTCA of prescription drugs by pharmaceutical companies is positive

Free Text comments

Several hundred free text comments were volunteered. More than two thirds of these describing the negative effects of DTCA**.**

The most common positive comments related to the opportunities provided for health checks in middle aged men presenting to discuss erectile dysfunction and the opportunity for education.

The major negative effects commented on were the confusion and anxiety generated by misleading advertisements, requests for inappropriate (particularly obesity) medicines and failure of the costs of unsubsidised medications to be given due prominence in the advertisements.

DISCUSSION

The response rate of 50% without reminders from all New Zealand GPs demonstrates the current level of interest and strength of feeling around DTCA. Most postal surveys in New Zealand attract much lower response rates.

Limitations on interpretation

It is important to recognise that the opinions canvassed were from 1611 respondents or a half of all NZ general practitioners. It is possible that having read the statement of position and intent of the authors some of those favouring DTCA may have chosen not to reply.

The survey contained six questions about professional practice. It was possible that GPs would feel unwilling to acknowledge practice that is not evidence based or consistent with best practice principles. This applied particularly to statements where they were asked to indicate whether they felt under pressure to prescribe DTC advertised medications or to change medications or start medications they would otherwise not have used. For this reason the survey format used an anonymised postal questionnaire rather than a telephone questionnaire or postal survey with identifiable respondents. There were equal numbers of positive and negative statements in this area. The spread of responses to these questions indicate that this strategy was successful and GPs were comfortable disclosing information which might reflect negatively on their practice:

Both positive and negative statements about DTCA were used in order to reduce the likelihood of response bias. It can be seen from the responses that internal validity is supported by the consistency of responses to both positive and negative statements about DTCA. Respondents were equally likely to agree with negative statements as to disagree with positive statements about DTCA.

CONCLUSIONS

The key findings of the survey indicate that DTCA puts pressure on GPs to prescribed advertised medications about which they feel ambivalent. Responses indicate many GPs feel DTCA creates unnecessary anxiety and can negatively affect the doctor patient relationship. Only a minority of GPs responses support the positive claims for DTCA (that it improves compliance, results in patients presenting earlier and improves the quality of prescribing).

It is clear from the responses to the question about overall impressions that the 1611 general practitioner respondents feel negatively about DTCA in a ratio of nearly 8 to 1, with a further 10% undecided.

Results, covering letter and questionnaire

TABLE 1: RESULTS

GP responses as % (n =1611)

	Strongly agree	Slightly agree	Neither agree nor disagree	Slightly disagree	Strongly disagree	Don't know
Consultations generated by DTCA are often unnecessary	**35**	**33**	**13**	**13**	**6**	**1**
Patients frequently ask me for DTC advertised drugs which aren't appropriate	**40**	**39**	**9**	**8**	**4**	**0**
I have felt under pressure to prescribe advertised medications	**32**	**37**	**10**	**10**	**12**	**0**
As a result of a patients request I have switched to/started medication with an advertised drug which I feel offers little benefit over treatment I'd ordinarily use	**14**	**30**	**15**	**14**	**28**	**0**
In general consultations generated by DTCA lead to little health gain for patients	**32**	**25**	**18**	**17**	**7**	**1**
DTC Advertising is a very useful means of educating consumers about the balance of risks and benefits for prescription medicines	**3**	**9**	**9**	**15**	**63**	**0**
In my experience consultations in which patients seek advertised medications can lead to difficulties in the Dr patient relationship.	**19**	**31**	**22**	**15**	**13**	**1**
DTC Ads currently provide the balance of information consumers need	**2**	**2**	**7**	**15**	**73**	**1**
Generally DTC Ads have helped my patients to get necessary medical care at an earlier stage	**2**	**14**	**19**	**21**	**43**	**2**
Generally DTC Ads have led to better compliance by my patients	**1**	**12**	**27**	**18**	**34**	**8**
Ads for lifestyle drugs may encourage the medicalisation of well populations	**40**	**34**	**12**	**6**	**5**	**2**
Generally DTC Ads have improved the quality of my prescribing	**1**	**2**	**13**	**14**	**69**	**1**
Overall I feel direct to consumer marketing of prescription only drugs by pharmaceutical companies is positive	**3**	**7**	**10**	**19**	**60**	**1**

12/11/02

Dear Colleague

IMPORTANT ISSUE PLEASE READ

Enclosed is a short survey seeking your impressions, attitudes and experiences of direct to consumer advertising (DTCA) of prescription medicines.
A number of concerned academic General Practitioners are urging the government to reconsider a ban on such advertising. Only two countries allow advertising of prescription medicines to the public - America and New Zealand. It is allowed here by default rather than by design simply because there has never been any legislation prohibiting it. As recently ago as last month, the European Parliament threw out (by a massive 12 to 1 majority) legislation aimed at allowing DTCA in Europe. Australia, South Africa and a number of other countries have reviewed and reaffirmed their bans.

The recent explosion in the quantity and type of advertising (most obviously on prime time TV) in NZ has concerned both prescribers and independent consumer groups. A Ministry of Health review in 2000 showed 5 out of 6 TV advertisements examined broke the voluntary advertising code. The recent increase in the use of drug company web-sites to advertise and to gain direct access to patients is a further example of the major push to gain direct marketing access to patients If you are interested in reading more, there is an excellent review of a symposium on DTCA held in Europe earlier this year which can be downloaded from http://www.haiweb.org/campaign/DTCA/index.html. Speakers at this meeting gave papers canvassing the safety issues around advertising and early uptake of new drugs with unknown safety profiles, of the difference between marketing and education, of the insidious effects on doctor patient relationships, the medicalisation of health and normal ageing and on additional costs to taxpayers and to health care systems

In order to support the case for a ban it is important to gather current evidence of the effects this advertising has had in New Zealand. You will see that the questions are predominantly about the effects DTCA has had on you as a prescriber and on your patients. Most of the questions are adapted from similar overseas questionnaires

We would be very grateful if you could spend a couple of minutes filling this out and returning in the reply paid envelope.

NZ GP OPINION: DIRECT TO CONSUMER ADVERTISING (DTCA) BY PHARMACEUTICAL COMPANIES

Age___yrs Sex M/F Tenths in clinical practice____ Have you had consultations specifically generated by DTCA? Yes/No

	Strongly agree	**Slightly agree**	**Neither agree nor disagree**	**Slightly disagree**	**Strongly disagree**	**Don't know**
Consultations generated by DTCA are often unnecessary						
Patients frequently ask me for DTC advertised drugs which aren't appropriate						
I have felt under pressure to prescribe advertised medications						
As a result of a patients request I have switched to/started medication with an advertised drug which I feel offers little benefit over treatment I'd usually use						
In general consultations generated by DTCA lead to little health gain for patients						
DTC Advertising is a very useful means of educating consumers about the balance of risks and benefits for prescription medicines						
In my experience consultations in which patients seek advertised medications can lead to difficulties in the Dr patient relationship.						
DTC Ads currently provide the balance of information consumers need						
Generally DTC Ads have helped my patients to get necessary medical care at an earlier stage						
Generally DTC Ads have led to better compliance by my patients						
Ads for lifestyle drugs may encourage the medicalisation of well populations						
Generally DTC Ads have improved the quality of my prescribing						
Overall I feel direct to consumer marketing of prescription only drugs by pharmaceutical companies is positive						

Can you describe (on reverse) any memorable examples of your experiences (positive of negative) with DTCA?

PLEASE SEND BACK IN THE REPLY PAID ENVELOPE TO THE DEPT OF GENERAL PRACTICE IN CHRISTCHURCH

APPENDIX 4: LETTERS OF SUPPORT

Public Health Association of New Zealand

Royal New Zealand College of General Practitioners

Thoracic Society of New Zealand

IPA Council of New Zealand

National Preferred Medicines Centre

Grey Power

Women's Health Action