

**ADDRESSING THE HEALTH SYSTEM IMPACTS OF
DOMESTIC AND INTERNATIONAL DIRECT-TO-
CONSUMER ADVERTISING IN CANADA**

by

Caitlin Roberts
BA, University of Victoria, 2006

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Abstract

This capstone provides policy alternatives for Canadian governments in dealing with the direct-to-consumer advertising (i.e. promotion to the public; DTCA) for prescription drugs. Direct-to-consumer advertising is contentious because of its negative impacts on public health and the health care system. In Canada, the federal government maintains the regulatory framework for DTCA and has faced challenges in recent years. Provincial governments do not currently engage in DTCA policy.

In this project, I provide a paradigm shift to the Canadian approach to DTCA by analysing non-regulatory options to DTCA. I offer readers options that will complement the existing regulatory system and address some gaps in policy. Through this project, I hope to instigate a more fulsome public debate on DTCA and on Canada's future approach to this important policy issue.

Keywords: direct-to-consumer advertising, DTCA, drug promotion, drug policy, health care, Canada.

Executive Summary

Introduction

Direct-to-consumer advertising (DTCA) is the promotion of drugs directly to the public. In western countries, full DTCA (i.e. brand name, description of condition, and drug benefits and risks) is only legal in the United States (US) and New Zealand. In Canada, DTCA is limited to reminder advertisements (branded ads limited to the name, price and quantity) and disease awareness commercials (contain specific disease information and symptoms). Canada, however, experiences undocumented illegal DTCA through the broadcast of full DTCA by US broadcast media to the Canadian public (Mintzes, Morgan and Wright, 2009). Little is known about the rates of illegal or legal direct-to-consumer advertising exposure in Canada or the complete impacts that this activity has on public health and the health care system. In this project, I examine DTCA in Canada and I identify gaps in existing knowledge on this subject. I also examine the Canadian regulatory system for DTCA and propose policy options to supplement the status quo.

Background

Research on direct-to-consumer advertising has found that it negatively affects several areas of health care including: patient requests for prescriptions, physician prescribing, drug information, and consumption of drugs with high risk for adverse reactions. Knowledge gaps that exist are: how DTCA affects government spending for prescription drugs, how it affects physicians and the quality of their work, how adverse reaction rates are affected by DTCA, and what the overall costs are to the health care system. There are large knowledge gaps on the negative impacts of DTCA in Canada.

In Canada, the regulation of DTCA is currently a federal responsibility retained through the Food and Drug Act, 1985 and the Food and Drug Regulations; however, research on the impacts of DTCA from the United States, New Zealand and elsewhere indicate that this form of advertising has effects on health care delivery (Mintzes et al., 2002, p.2; Kaiser Foundation, 2003, *Demand Effects*, p.1; Atherly and Rubin, 2009; t'Jong, Stricker and Sturkenboom, 2003) – a

provincial responsibility in Canada. This finding led me to conclude that Canadian policy on direct-to-consumer advertising should include provincial governments.

Problem Statement

DTCA has negative impacts on individual health and increases inappropriate use of the health care system.

Research Questions

What range of impacts does DTCA have on the health care system in BC? What strategy is British Columbia employing with the goal of addressing the negative impacts of direct-to-consumer advertising on the health care system? If the province employs any strategy, how effective is it at addressing the negative impacts of direct-to-consumer advertising? What strategies have been employed in other jurisdictions to address negative impacts of DTCA on their health system?

Methods

Three primary research methods are used in this project: textual analysis of government documents, case studies of drug programming, and interviews with experts in the field. Through the textual analysis, I was able to identify components of the status quo and identify gaps within existing regulation and enforcement. I used the case studies to help understand what types of programs work in managing drug policy. Finally, I used the expert interviews both to better understand the undocumented negative impacts of DTCA in Canada and to provide insight into the feasibility of the policy options.

Findings

Other than data from the United States and other countries, little data exists on the impacts of DTCA in Canada. Mintzes et al. (2002) and Law, Majumdar and Sumit (2008) provide the only studies of DTCA in Canada that were found during this project. After establishing that data on DTCA in Canada was limited, I decided to examine the DTCA regulatory system in order to identify whether the system has any enforcement gaps. Weaknesses of the current regulatory system include: Limitations on its ability to regulate US broadcast DTCA; its use of industry-oriented organizations to preclear Canadian DTCA; its lack of data in many relevant areas; the delays in DTCA complaint resolution; and, its reliance on public complaints to instigate non-compliance investigations.

I was unable to locate DTCA related programming outside of regulatory options, so instead I chose to examine three drug policy programs as case studies that held potential to compliment the status quo. The case studies (BC Pharmacy Services Agreement, the Do Bugs Need Drugs program and the BC Medication Management program) have demonstrated effectiveness in managing pharmaceutical spending. Two case studies were turned into policy options; however, the BC Medication Management program, while effective, is controversial with physicians and therefore is an unacceptable option. The expert interviews contributed to a greater understanding of the impacts of DTCA in BC by identifying that DTCA affects physician-patient relationships and increases demand for prescription drugs with high risk of negative health outcomes. In addition, the expert interviews identified that the current regulatory system is not providing sufficient enforcement of DTCA.

Options

Four options are proposed in this capstone: A national working group and research project, a website campaign to encourage public discourse on DTCA, financial penalties to discourage illegal DTCA in Canada, and an educational program for the public and physicians. In my analysis, I found that the working group and the education program were the most desirable options. This assessment is based on the results in two primary criteria: whether the option improves the understanding of DTCA in Canada; and how acceptable the option is to stakeholders. The financial penalty option receives low scores because it would likely result in backlash from the public, industry and physicians. The discourse option received lower scores because it carried a risk of public backlash. I recommend that the working groups and research project, as well as the education program be implemented in Canada. These options provide suitable compliments to the status quo.

Conclusions

In the policy problem, I identified that research on DTCA demonstrates it has negative impacts on public health and the health system. What I found was that very little is known about DTCA in Canada. The primary benefit of this project has been to identify gaps in knowledge and programming. Two options have been recommended to compliment the status quo and help address gaps in enforcement. This project has been a preliminary step in the development of DTCA policy in Canada. There are several limitations in this project including challenges in access to information (e.g. limited data on DTCA in Canada), limits on research data that promotes the benefits of DTCA, and no industry perspective in the expert interviews.

Dedication

To all Canadians: May you always be sceptical about the drug ads that you see.

To my family, this is for you.

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My sincerest gratitude to all of the interviewees for this project – without your insight it would not have been possible to finish this project.

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Glossary

Adverse reactions	Undesirable health effects from prescription drugs.
Catastrophic coverage	Income-based drug subsidy programs.
Dispensing fee	The amount that a pharmacist will charge for filling a prescription. This may be paid by government programs or private individuals or both.
Drug detailing	Information sessions between a pharmaceutical company representatives and a health care professional such as a physician.
Drug management programs	Programs that aim to restrict the amount provinces-territories pay for drugs: often target prescribing behaviour, drug price, etc.
Federal transfer payments	Funds given from the federal government to the provincial-territorial ones for program areas such as health and education.
Formulary	Lists of drugs that are eligible for provincial subsidy.
List price	The price that a brand name drug is listed to be sold at by the pharmaceutical company.
Out-of-pocket	Payments by individuals for drugs. Generally used when reimbursement or subsidies are not possible.
Payer	Refers to anyone who pays for drugs such as governments, private insurance companies or individuals.
Prescription seeking behaviour	Patients requesting information or prescriptions for drugs from their health care professional.
Prescription writing habits	Refers to the pattern of prescribing for a specific physician.
Special authority grant	A system used in British Columbia where expensive drugs are subsidized on a case-by-case basis. The process involves a special application by a

prescriber.

Train-the-trainer A training model where an individual who is experienced in a field trains individuals who are not experienced on relevant subjects. Those inexperienced individuals then go and train others. The model transfers knowledge from a few individuals to many.

1: Direct-to-Consumer Advertising

1.1 A Story

Imagine a young, healthy Canadian woman full of the desire to be accepted by her peers and full of the anxiety that is typical in girls her age (Sabiston et al., 2007). This woman sees an advertisement for a prescription drug (direct-to-consumer advertising or DTCA) one day in a fashion magazine that indicates it can get rid of her acne, a problem that constantly worries her. The ad shows a group of girls, like her, hanging out together. They have flawless skin and ‘perfect’ bodies and she thinks, ‘their lives must be perfect’. Her curiosity about the drug increases. ‘Can the drug really take away her acne problem?’ she asked herself. ‘Will this change everything for me?’ She does not know that the drug is not approved for treatment of mild acne, like she experiences, because of the serious health risks that it poses.

Imagine this healthy girl going to her paediatrician to ask about the drug. The physician knows that the girl probably does not need the drug and that it has some serious health risks. The doctor also knows that denying the girl this drug may mean that their relationship changes. She knows that if she does not prescribe the drug that the girl will likely go to another physician for the prescription, and that she will not be able to monitor the girl’s health after that. She considers the risks and benefits of this drug and decides to prescribe it: ‘After all’, she thinks to herself, ‘she is young and healthy, and will likely take the drug for a short amount of time’. Therefore, the girl goes home with her prescription, happy because she got what she wanted. She starts taking the drug and her acne does improve. What she does not know is that her chances of having a thromboembolic event (i.e. developing a blood clot) is increasing and the drug is having an effect on her liver cells.

Fifteen years later, still on the medication, this girl goes into the doctor’s office because she feels tired and ill. Her new physician runs tests on her to find out what is wrong and finds that she has developed liver cancer. Her body has been exposed to this drug for a decade and a half and it has caused the cells of her liver to develop cancer. The physician recommends immediate surgery to have her liver transplanted. Luckily, she gets one, but her body rejects it and she has to take steroids to suppress her body’s rejection of its new organ. She experiences numerous side effects from the steroids.

This girl's life is changed irrevocably by a lifetime of drug exposure that was never medically necessary. In addition to the cost to her life, the health care system paid for physician visits, prescription drug costs, hospital costs, transplants and rehabilitation. The company that made the drug and promoted it to her pays nothing. This story is not an anomaly and it is not meant to be a fear tactic. It illustrates that seemingly harmless advertisements for prescription drugs can carry heavy negative impacts on individual health and health care systems. Prescription drugs are a necessary and important part of modern health care, but these drugs need to be respected and they need to not be taken without seriously weighing the benefits and harms.

In this capstone I argue that DTCA creates undocumented negative public health risks and health system consequences (Mintzes et al., 2002; Atherly and Rubin, 2009; Mansfield et al., 2005; Hall and Jones 2008; Mintzes, Morgan and Wright, 2009). Building on existing Canadian law and regulation on DTCA (Canada, 2000), I further argue that health policy in Canada needs to proactively mitigate the impacts that the current system does not address. This capstone builds on the existing regulatory framework for DTCA and provides policy options to strengthen this system.

1.2 Including the Provinces in DTCA

“[I]s there any place for the provincial government in [direct-to-consumer advertising]? Or is it really in the domain of the federal government?” (Do Bugs Need Drugs AB, Ministerial Interview, January 28, 2011).

This is the most common question that I have been asked while working on this project. While health care is undeniably a responsibility of provincial and territorial governments, the federal government plays a role in public health, health funding, and food and drug safety (Canada, Canada Health Act, 2011; Canada, 1985; Canada, 2000). Their inclusion in the latter does not exclude provincial and territorial involvement. Those governments are responsible for the provision of pharmaceutical drug policy. In British Columbia, for instance, the government decides which drugs are included on the provincial formulary, sets prescribing policy with physicians, works to reduce the costs of drugs, negotiates drugs prices with pharmacies, and deals with all adverse reactions (British Columbia, Welcome to PharmaCare; British Columbia, Ministry of Finance, 2011; British Columbia, Ministry of Health). These areas of health policy are potentially affected by DTCA. As one interviewee argued, “...[provincial governments are] payers right? Their interest is, in a sense the same as Blue Cross or SunLife or whoever's the insurer right? I mean they're effectively paying for these benefits that are not really proven. So,

absolutely they have an interest.” (Physician Association Perspective, in-person interview, March 22, 2011, 12:35).

I argue that the provinces should be included in DTCA policy, because of their fiscal responsibilities in pharmaceutical policy. For this reason, I will develop policy options that reflect provincial inclusion. As prescription drug policy varies widely across the country and developing examples for each province-territory is far beyond the scope of this capstone, I will use British Columbia as an example throughout this research. That said the options may be applicable across Canada.

2: Problem Statement

The effects of direct-to-consumer advertising are experienced both by individuals exposed to the advertising and by provincial health care systems. Thus, the problem statement for this capstone is, DTCA has negative impacts on individual health and increases inappropriate use of the health care system.

2.1 Research Questions

1. What range of impacts does DTCA have on the health care system in BC?
2. What strategy is British Columbia employing with the goal of addressing the negative impacts of direct-to-consumer advertising on the health care system? If the province employs any strategy, how effective is it at addressing the negative impacts of direct-to-consumer advertising?
3. What strategies have been employed in other jurisdictions to address negative impacts of DTCA on their health system?

3: An Introduction to Canadian Health Care and DTCA

In this chapter, I conduct a literature review on health care and drug policy in Canada and DTCA. This chapter will partly answer research question one.

3.1 How Health Care Works in Canada

In Canada, health care is delivered through a system of public health insurance primarily run by provincial-territorial governments. Provincial-territorial governments manage, organize and deliver health services through hospitals, physician services, drug policy, public health programming, and a host of other services – these vary from province to province (Canada, Canada’s Health Care System [Medicare], 2010). These powers are derived from the Constitution Acts 1867 to 1982 (the Constitution). The Constitution states that “[i]n each Province the Legislature may exclusively make Laws (*sic*) in relation to Matters (*sic*) coming within the Classes (*sic*) of Subjects (*sic*) next herein enumerated; that is to say...[t]he Establishment, Maintenance, and Management of Hospitals, Asylums, Charities, and Eleemosynary Institutions in and for the Province, other than Marine Hospitals.” (Canada, Constitution Acts 1867 to 1982, 2011, Section 92[7]).

The provincial-territorial governments are encouraged to pursue further advances in health care through the Canada Health Act, 1985 (Canada, Canada Health Act, 1985, 2011). The Canada Health Act (or CHA) is federal legislation that requires the provinces to meet specific standards in order to receive transfer payments from the federal government. There are five goals in the CHA, these set national standards in: public administration, comprehensiveness, universality, portability and accessibility (Canada, Canada Health Act, 2011). Pharmaceutical policy is not included in the CHA and it varies widely across Canada.

The federal government has little constitutional power in the delivery of health services; however, it has become influential in health policy in Canada through two primary means: fiscal incentives (i.e. transfer payments through the CHA), and by adopting policy issues that are not of a local or private nature (Constitution Acts 1867 to 1982). The primary organization for health care in the federal government is Health Canada. It pursues activities in four areas (Canada, Activities and Responsibilities, 2008):

- The preservation and modernization of Canada's health care system,
- the enhancement and protection of the health of Canadians,
- to work in partnership with other stakeholders, and
- to communicate health promotion and disease prevention to Canadians.

DTCA regulation could fall under activity two and four. In 1949, the government of Canada passed legislation to protect consumers from drug advertising that was misrepresentative or misled them (Standing Committee on Health, 2004). This provided the first limitations on DTCA in Canada, a responsibility that Health Canada retains to-date.

3.2 Health Care as a Growing Share of Provincial Budgets

Provincial expenditures are increasing on an annual basis (British Columbia, Estimates: Fiscal Year Ending March 31, 2012, p.123). In 2010, approximately 45 percent of government spending went to cover the costs of health care. That is equal to 9.6 percent of Canada's GDP (Zelder and Kelderman, 2010). In 2008, the BC provincial government sparked a public debate when it amended the provincial legislation to include sustainability as a goal for provincial health care. The amendment stated,

“Sustainability

The plan is administered in a manner that is sustainable over the long term, providing for the health needs of the residents of British Columbia and assuring that annual health expenditures are within taxpayers' ability to pay without compromising the ability of the government to meet the health needs and other needs of current and future generations.” (British Columbia, Medicare Protection Act, 2011, 5.7).

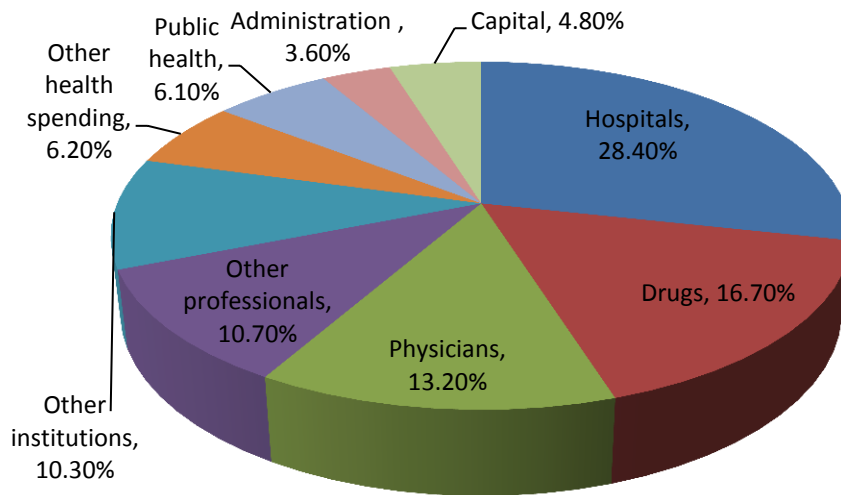
This clause clearly outlines the province's commitment to limit provincial spending on health care.

3.3 Pharmaceutical Costs

While pharmaceutical policy is not enumerated in the Constitution or in the CHA this has become a responsibility of the provincial-territorial governments. The majority of provinces-territories, except for New Brunswick and PEI are now providing catastrophic coverage for residents (Canada, Catastrophic Drug Coverage in Canada, 2009). Over time, pharmaceutical policy has become an increasingly important part of health care (Health Council of Canada, 2009). Drugs are not part of the CHA and so Health Canada is limited in its ability to use financial incentives in drug policy development at the provincial-territorial level.

Provincial governments run substantial drug programs in their territories. For example, the PharmaCare program in BC will run a \$1.1 billion dollar program in 2011 (British Columbia, Estimates: Fiscal Year Ending March 31, 2012, p.123). Prescription drugs are a significant part of the health care system. For example, Canadian data from 2009 indicates that 81 percent of the 20,600,000 doctor visits for hypertension resulted in a prescription; that 69 percent of the 9,700,000 patients visiting a doctor for non-complicated diabetes were prescribed a drug; and, that 82 percent of the 8,500,000 visits to physicians for depression ended in a prescription (Health Council of Canada, 2009).

Figure 1: Breakdown of National Health Care Spending by Category



1

On a national scale, prescription drugs are a multi-billion dollar annual expense. In 2006, pharmaceuticals consumed 16.7 percent of total national health care expenditures just behind 28.4 percent for hospitals and more than the 13.2 percent spent on physicians (Canadian Institute for Health Information [CIHI], 2007). In 2006, total government spending on prescription drugs had grown to \$25.3 billion dollars a year (CIHI, 2007).

Provincial budgets for pharmaceutical drugs are growing rapidly. For example, in BC in 1996, the province spent \$372 million on pharmaceuticals; by 2004, the province was spending \$713 million (Pharmaceutical Task Force Report, 2008). In 2011, as was previously mentioned, \$1.1 billion dollars was provided in the provincial budget for PharmaCare. If the trend of growth

¹ CIHI, 2006.

in pharmaceutical spending continues, any factor that affects this spending (e.g. consumption per person, number of people consuming, prices of drugs, etc.) will be an important policy issue at the provincial level.

Past efforts to curb costs through a national policy on pharmaceutical drugs have been relatively unsuccessful. For example, the National Pharmaceutical Strategy, that set out to achieve unity on pharmaceutical policy, was an agreement reached in 2005 between provincial-territorial-federal health authorities (excluding Quebec; Canada, National Pharmaceutical Strategy, 2006). If successful this strategy would have affected several areas relevant to DTCA including a national drug formulary, evaluation of drug safety and effectiveness, purchasing strategies, best prescribing, and analysis of cost-drivers and cost-effectiveness. Some progress has been made on the National Pharmaceutical Strategy since 2005; however, this progress has mainly been pursued by individual governments and not as a collective action (Physician Association Perspective, in-person interview, March 22, 2011, 16:15; Health Council of Canada, 2009).

3.4 Initiatives Being used to Relieve Pressure on the System

To deal with the financial burden of pharmaceutical drug programs the provinces have adopted drug management programs. These programs seek to minimize unnecessary expense, while "...supporting optimal drug therapy." (British Columbia, Our Mission, *n.d.*). In BC, these include but are not limited to Reference Based pricing, Provincial Academic Detailing, Education for Quality Improvement in Patient Care (EQIP), and Do Bugs Need Drugs². Each of the programs will be examined briefly in this section.

The Reference Based (RB) pricing program is designed to constrain drug costs. The RB program limits provincial subsidy for drugs to the most cost-effective options in a class. So, for example if drug X is the most cost-effective of a class to treat Y illness, then drug X will be the one that the province will subsidise. This program is currently being used for five drug classes (British Columbia, Reference Drug Program, *n.d.*). This option constrains prescribing, but physicians retain professional autonomy to write the prescriptions they feel are most appropriate for their patients. The main leverage to reduce prescribing for expensive drugs is the cost incurred by the patient.

BC's Provincial Academic Detailing (PAD) and EQIP programs are designed to change prescribing behaviour through education. PAD provides evidence-based drug information to

² An antibiotic education program.

physicians through trained pharmacists (British Columbia, Goal 1). This program is designed to counter-balance information given to physicians through drug detailing³. Whether PAD is effective enough to counteract the effects of both DTCA and drug detailing was questioned during one interview. The interviewee argued,

“You’ve got a huge influence on patients...you know an enormous amount of dollars spent on the DTCA side and not nearly the same resources, financial or human, to counter that with academic detailing, but it’s still one way you’re going to go at it....” (Physician Association Perspective, in-person interview, March 22, 2011, 8:28).

EQIP provides physicians with information on how they prescribe to patients compared with best practices for prescribing (British Columbia, Goal 1). On EQIP, one interviewee had the following comment,

“So a physician actually received a profile that says this is how their prescribing status for example...drawn from claims data, MSP data. And showing what they’re spending and what the prices actually are for drugs. Physicians don’t even know the different price differences among drugs – there’s no way for them to get it....” (Physician Association Perspective, in-person interview, March 22, 2011, 10:20).

Between EQIP and PAD, BC is providing physicians with information on prescription drugs.

Do Bugs Need Drugs is an education program that teaches patients about appropriate antibiotic use. It also teaches them about what they can do to prevent having to take these drugs. The program additionally provides educational materials for health care practitioners, such as doctors (BC Centre for Disease Control, Provincial Services Health Authority, *n.d.*). The Do Bugs Need Drugs program has been in use in BC since 2005 and is starting to show some impact on patient behaviour. As one interviewee argued, “...the Do Bugs Need Drugs model. And that’s probably been...the culture seems to be changing right? I don’t need the antibiotic every time I go in for the sniffles....” (Physician Association Perspective, in-person interview, March 22, 2011, 11:53).

While there is evidentiary data for each of the programs on their effectiveness, there does not appear to be data documenting the cumulative effects of all these programs. It is challenging to know what overall impact they have on prescribing and drug consumption. Keeping that in mind, I will move on to a discussion of direct-to-consumer advertising.

³ An informal drug information session between a representative from a pharmaceutical company and a physician.

3.5 What is DTCA

According to the Food and Drug Act, 1985 advertising is, "...any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device..." (Canada, Food and Drug Act, 1985). Direct-to-consumer advertising is the promotion of prescription drugs to the public⁴. DTCA can come in many forms, but the most commonly studied are broadcast media (e.g. television and radio), print (e.g. magazines) and internet.

Direct-to-consumer advertising of prescription drugs occurs in many countries around the world. The United States (US) and New Zealand (NZ) are the only western countries where DTCA is fully legal (Health Council of Canada, 2006). The European Union (EU) has recently struggled with questions of what limitations to put on DTCA (Silversides, 2009). Australia allows minimal forms of DTCA; however, infractions of these restrictions – i.e. illegal DTCA – have occurred in the country (Hall and Jones, 2008). Western countries have seen a proliferation of both DTCA and regulation in recent Decades. DTCA in developing countries appears more complex than western countries as regulation and monitoring can be less stringent and access to drug information more difficult to obtain (Semin, Aras and Guldal, 2006). The focus for this capstone; however, will be on DTCA in Canada.

DTCA is most frequently used for newly developed drugs indicating that drug companies use it to recoup their return on investment (ROI; Lexchin and Mintzes, 2002; Mintzes, Morgan and Wright, 2009). A 2003 report found that every \$1 invested in DTCA results in a return of \$4.20 in sales in that drug class (Kaiser Foundation, 2003). DTCA is concentrated on a small subset of drugs developed by the industry. In 2009, it was found that the top 15 advertised drugs in the US typically represent more than half of all of the advertising funding (Atherly and Rubin, 2009). DTCA is used when drugs are primarily in their first year on the market. Iisuka (2004) found that DTCA drugs are typically, new and for under-treated diseases.

There are three types of DTCA: full DTCA, reminder ads and disease oriented ads. Full DTCA is typical of ads produced in the United States. These usually contain the drug name, illness to be treated, benefits and harms. Health Council of Canada (2006) states that reminder ads usually contain some information about the drug such as its name, price and quantity for consumption; disease oriented ads, alternatively, indicate symptoms of specific diseases to encourage the public to identify whether they may have the illness and encourage them to talk to

⁴ This refers to drugs listed under Schedule F of the Food and Drug Act, 1985. All drugs in this Schedule require a prescription in order to be obtained (Food and Drug Act, 1985, p.832).

their doctors about available treatments. Full DTCA, is not currently permitted in Canada (Food and Drug Act, 1985); however, reminder and disease oriented ads are permitted if they comply with restrictions in the Act and Regulations.

To-date little research has been conducted to examine whether one type of DTCA is more effective than the other at inducing prescription-seeking behaviour. Lee-Wingate and Ying (2010) found in their self-reporting survey that respondents were more motivated by help-seeking (or disease awareness) DTCA than product-claim (full) DTCA. Their findings indicate that disease awareness commercials are more likely to persuade the public to visit a doctor about a condition than full DTCA. I was unable to collect other existing research on the relative effectiveness of the three types of DTCA.

3.6 Effects of DTCA on Patient and Physician Behaviour, Health Outcomes, and its Potential Impacts on the Health Care System

“You know the advertisements can bring people into the [physician] office, often informing them with the symptoms that they should be mentioning in terms of a specific diagnosis and even a recommendation for what they might ask for to treat them.” (Academic Perspective, in-person interview, March 16, 2011, 1:24:18).

Research from recent decades demonstrates the behavioural effects of DTCA. The quote above identifies how DTCA affects people’s behaviour – it encourages them to go to their doctor for prescriptions and prepares them to interact with their doctors.

Figure 2: DTCA's Effects on Public Health and the Health Care System



Figure three identifies the sequence of events that take place in order for DTCA to be effective. It first impacts on people's opinion of their health status⁵ leading them to question whether they have an illness or if they require the advertised drug. They then seek guidance from the health care system, usually through their physician. Each time an individual's is induced to seek drugs based on exposure to DTCA this has spin-off impacts on the health care system. Impacts include increases in physician visits, requests for drug subsidies and adverse reactions.

While it is clear that DTCA increases prescription seeking behaviour, it is not clear at what rate this occurs. Research on the rates that DTCA impacts behaviour have varied results. It has been found that DTCA increases prescription seeking behaviour in approximately 25 percent of those exposed to it (Mintzes et al., 2002, p.2; Kaiser Foundation, 2003, *Demand Effects*, p.1). In Atherly and Rubin (2009), the authors found that four percent of patients made an appointment to get a drug that they saw advertised (p.650). t'Jong, Stricker and Sturkenboom (2003) found a correlation between the initiation of a DTCA campaign for onychomycosis, a fungal infection of the nail, and a 2.3 percentage increase in physician visits for the condition. During the campaign, prescriptions for terbinafine, a treatment for onychomycosis, increased by 7.5 percent (p.931). Mintzes et al. (2002) found that physician prescribing habits are also influenced by DTCA. They found that when a patient requested a specific drug, Vancouver physicians prescribed that drug 62 percent of the time. When asked whether they would prescribe the same drug for another patient with the same health condition, for DTCA drugs, the physicians were ambivalent about making the same choice again 50 percent of the time (p.3). Another survey of BC physicians found that four out of five doctors were against the use of DTCA (British Columbia Medical Association, 2007, p.27). DTCA increases physician and prescribing rates which affects the health care system by increasing costs in both categories. Mintzes et al., (2002) demonstrated that physicians were ambivalent in half of the prescriptions they wrote by request, indicating a high percentage of prescriptions resulting from DTCA are inappropriate. This means that unnecessary costs are borne by the system because of DTCA.

To understand how DTCA impacts pharmaceutical industry sales, I will turn to work by the Kaiser Foundation (2003). This organization found that on average DTCA has an elasticity of 0.10. For every 10 percent increase in DTCA for a drug class, there would be an increase in drug sales of one percent. For example, between 1998 and 1999 advertising for proton pump inhibitors⁶ in the US rose by 60 percent (\$30.4 million); over the same time the sales of proton

⁵ Raises their concern that they may be ill.

⁶ A drug treatment for ulcers.

pump inhibitors rose by 36 percent (\$1.5 billion; p. 6). These findings indicate that DTCA affects the public's behaviour both in terms of prescription seeking and physicians visits; however the extent of this effect is unclear. Research conducted by IMS Consulting found that television DTCA results in a sharp increase in prescriptions for 1-2 weeks after exposure and then has a gradual increase on the total number of prescriptions for up to week 36 after exposure (IMS Consulting, 2007, p.2). Print media, on the other hand increases more gradually, but continues to effect prescription rates for 74 weeks after exposure (IMS Consulting, 2007, p.2). IMS concludes that an increase of 10% in spending on DTCA per week will effect prescription rates 103 weeks after exposure (2007, p.2). There is a clear return for industry investment in DTCA and parallel to this return, is an increase in the costs associated with pharmaceutical policy for the health care system in Canada.

It is unclear as well whether DTCA is effective on groups of people at varying rates. Van den Engh and Bonertz (2010) argue that higher exposure rates to DTCA results in a greater impact on prescription seeking behaviour. Datti and Carter (2006) found that cohorts older than 75 years were less likely than younger cohorts to request a DTCA promoted drug; however, when they requested the drug, they were more likely than the younger cohorts to receive them. Bell, Kravitz and Wilkes (1999) found that several factors – including awareness of current DTCA campaigns, a positive attitude towards DTCA, a less-positive evaluation of personal health, a higher trust of regulatory bodies, and health insurance coverage – were associated with DTCA effectiveness (p.655-656). As data on the variability of DTCA's effectiveness by group of people has received limited research attention this should be a focus of future research.

There are several areas where the impacts of DTCA are clear. For example, there is good cause to question the health benefits of the drugs being advertised. In a 2002 report Lexchin and Mintzes found that from 1996-2000 415 prescription drugs were introduced to the Canadian market. Of these, only eight percent were considered to be breakthrough⁷ drugs. Another 40 percent of the drugs were considered to be line extensions⁸ of existing drugs and 56 percent of the drugs offered moderate, little or no improvement over existing products (Lexchin and Mintzes, 2002). Their research indicates that only eight percent of drugs coming onto the market in Canada provide any new therapeutic value; therefore, the likelihood that these drugs improve health outcomes over existing treatments is low.

⁷ Offered substantial improvements over existing treatments (Lexchin and Mintzes, 2002, p.194).

⁸ Offered only minimal improvement over existing treatments (Lexchin and Mintzes, 2002, p.194).

Mintzes, Morgan and Wright (2009) highlight the risks common to DTCA drugs. Of the top eight advertised drugs in Canada in 2005/06 four had black box warnings⁹ in the US. In those same years advertising to consumers for these top eight drugs represented 59.2 percent of advertising spending in Canada. Health Canada's drug warning system, Safety Advisories, had reports on five of those eight drugs (Mintzes, Morgan and Wright, 2009). Case studies of DTCA drugs can also highlight some of the risks that the promotion entails. Vioxx, a pain treatment medication, was previously promoted to the public directly (Vioxx: Lessons Learned for Health Canada and the FDA, 2005). In 2004 after being on the market for five years in Canada and the US, the drug was withdrawn because it increased the likelihood of cardiovascular events (heart attacks and strokes). This drug resulted in thousands of heart attacks and deaths and yet was promoted as a safer drug than others in its class (Vioxx: Lessons Learned for Health Canada and the FDA, 2005; Academic Perspective, in-person interview, March 16, 2011). Estimates from the US indicate that 140,000 heart attacks resulted from consumption of Vioxx (Graham, et al., 2005). The Vioxx experience demonstrates that DTCA can increase the risk that prescription drugs pose to public health and the health care system.

Another factor which has negative implications for people is that DTCA often includes inappropriate or incorrect information. Common infractions in the US include: a lack of balance between the risks and benefits of the drug; insufficient risk information, or risk information was omitted, not readable or not prominent; safety and efficacy claims that are not accurate or backed by scientific studies; and confusing/technical language was used that is unlikely to be understood by the general public (Lexchin and Mintzes, 2002; Mintzes, Morgan and Wright, 2009; Hall and Jones, 2008; Donohue, Cevasco and Rosenthal, 2007; Mansfield, et al., 2005; Atherly and Rubin, 2009; and Mintzes, et al., 2002). In a 2009 commentary, the World Health Organization expressed their concern when they stated:

"The distinguished doctor who has been introduced as the "inventor of the artificial heart" turns to the camera and says, "Just because I'm a doctor doesn't mean I don't worry about my cholesterol." He then recommends people use an anti-cholesterol drug, Lipitor... But it relied on the audience being unaware of several important facts: Robert Jarvik, the distinguished "doctor" in the boat, had never been licensed as a medical doctor, could not legally prescribe anything and was not the inventor of the artificial heart (at least according to three former colleagues at the University of Utah)... Welcome to the world of direct-to-consumer advertising." (World Health Organization, 2009).

The public's misinformation about DTCA has been well documented (Mintzes, Morgan and Wright, 2009; Hall and Jones, 2008; Donohue, Cevasco and Rosenthal, 2007; Mansfield, et

⁹ This is they are considered to have potential life threatening side effects by the Food and Drug Administration (FDA).

al., 2005; Atherly and Rubin, 2009; and Mintzes, et al., 2002; WHO, 2009). Bell, Kravitz and Wilkes (1999) demonstrate that public awareness about DTCA regulations were low in the US, with 50 percent of respondents assuming the ads had to be pre-screened, and that 43 percent of respondents assumed that only safe drugs could be advertised (p.654-655). Indicating that public misconceptions about DTCA could lead to ill-informed drug consumption and potential conflict between patient and physician.

Major prescription drug recalls over drugs (e.g. Zelnorm and Vioxx) that have been heavily advertised to the public demonstrate that DTCA can increase exposure and therefore increase the risks that these drugs pose to public health. Their advertisement will also increase the burden that these drugs have on the health care system (Mintzes, 2009; and Donohue, Cevalasco and Rosenthal, 2007; Food and Drug Administration, 2010).

This section highlights: the impacts that DTCA can have on patient and physician behaviour and what factors play into the effectiveness of DTCA; how DTCA increases health risks by increasing patients' desire for risky drugs; what some common infractions by DTCA of US regulations were; and, the potential negative impacts of DTCA on the health care system in Canada.

3.7 Potential Benefits from DTCA

Some researchers such as Calfee, 2002 and Ham, 2008 have argued that DTCA improves the public's access to important information about illnesses and treatments. It is unclear, however, given the previous section, whether the public is getting good information and thereby benefiting from the information available in DTCA. Block (2007) conducted a cost-benefit analysis of DTCA in the US. He found that DTCA for anti-depressants resulted in a six percent increase in the number of appropriately diagnosed individuals (i.e. six percent of people who see DTCA for anti-depressants are depressed and receive appropriate treatment because of their exposure). 94 percent of new prescriptions for anti-depressants because of exposure to DTCA are inappropriate (i.e. 94 percent of patients prescribed anti-depressants based on their exposure to DTCA are not depressed; p.517). Block argues in his findings that that the value of treating depressed individuals through exposure to DTCA outweighs the costs of treating those who do have depression (Block, 2007). Thus, he concludes that DTCA has an overall net benefit.

Jureidini, et al. (2008) disagree with Blocks' conclusions arguing that his calculation "...ignores the subset of patients who might not have [made an appointment without exposure to DTCA]; follow-up appointments by these new patients to monitor medication; and mental health

referrals,” they also argue that “...it is considered poor medical practice to prescribe a course of antidepressants to patients believed to be experiencing clinical depression without providing any additional follow-up care.” (Jureidini et al., 2008, p.563). Blocks’ analysis, therefore, misses several key calculations for health care cost-benefits analysis.

Researchers have in the past and continue to investigate potential benefits of DTCA. This capstone does not deny that there may be benefits to public health. The greater body of scientific research on DTCA identifies the negative impacts that it poses to public health and the health care system. It is for this reason that this capstone will be centred on the negative impacts of DTCA.

3.8 Growth of DTCA in Canada and how this will Affect the Health Care System

As was previously mentioned, two types of DTCA are legal in Canada: reminder ads and disease awareness commercials (Canada, Food and Drug Regulations, 2011). Legal advertising in Canada is growing rapidly. DTCA spending has tripled in Canada in the past 15 years from \$11 million in 1995 to over \$36 million in 2006 (Mintzes, Morgan and Wright, 2009, p.3). In addition to these legal advertisements, Canada experiences unknown amounts of illegal advertisements. Illegal DTCA in Canada includes full DTCA and any ads that contravene the Food and Drug Act and Regulations (Academic Perspective, March 16, 2011; Law, Majumdar and Soumerai, 2008; Health Council of Canada, 2006). The most challenging illegal DTCA comes across the border from the US. In a 2010 correspondence Health Canada notes, “...there are practical issues involved in enforcing the Canadian law with respect to advertising materials that originates in the US and which is made available in Canada” they go on to state that, “DTCA materials that are found in contravention of the [Food and Drug Act] and associated Regulations may be subject to compliance and enforcement actions based on the risk to health that the product may pose to the general public.” (Marketing Health Product Directorate, personal communication, October 7, 2010). Health Canada’s ability to enforce the DTCA regulations for cross-border advertising is questionable. It is important, therefore, to understand how much US media Canadians are exposed to and what the rates of DTCA exposure are in the US. This will allow us to understand at least tangentially, what rates of exposure to US DTCA Canadians may experience.

Canadian exposure to US media is estimated to be about 30 percent (Mintzes, Morgan and Wright, 2009) and up to 85 percent of Canadians in a 2008 study reported having seen prescription advertising in the previous year (Law, Majumdar and Soumerai, 2008, p.2). However, these estimates do not provide a clear picture of how much cross-border exposure is

occurring. This could amount to significant exposure given that the pharmaceutical industry in the US spends approximately \$5 billion annually on DTCA (Donohue et al, 2007, p.673). Polls from the US indicate a high exposure rate among Americans, 81 percent in 2002 (Kaiser, 2003, p.1). The United States is experiencing a proliferation of DTCA. After 1997 when the Food and Drug Administration rules on DTCA were relaxed DTCA expanded rapidly. Spending on DTCA in the US grew 330 percent between 1997 and 2005 and DTCA was estimated to be 14 percent of the total promotional budget for the industry (Donohue, et al., 2007). One interviewee argued of cross-border DTCA that, "...it even is at the point now where we'll get illegal ads where it's a product that's not even approved for our market place...." (Academic Perspective, in-person interview, March 16, 2011, 22:40). Proliferation of DTCA in Canada and the United States will only increase the exposure to this promotion that Canadians experience; thus, increasing the impacts of DTCA that were discussed in previous sections.

3.9 Chapter Summary

This chapter has established several key findings. First, that pharmaceutical policy is a contentious area of responsibility in Canadian health care and that both federal and provincial-territorial governments likely have a role to play in its development. Second, that the expense of health care is a growing concern for governments and that pharmaceutical drug costs are the second most expensive part of this system. Third, that several initiatives are being used to manage health care expenses, but their overall impact on changing prescribing and prescription seeking behaviours is unknown. Fourth, that DTCA affects people's drug seeking and physician's prescription writing behaviour and that these are having an overall impact on the health care system by increasing doctor's visits, prescription rates and adverse reactions causing negative health outcomes. Finally, that DTCA is expanding in Canada

Questions that remain are: How does the current regulatory system for DTCA work and how well is it working? What are some potential case studies in modifying patient prescription seeking and physician prescribing behaviour? In addition, what do experts in DTCA and think about this policy problem? These questions will be answered in the findings chapter.

4: Methodology

This section outlines the methods that I have used in this project. A rationale is provided for each method presented. In this section, I will discuss: the ethics process, my use of semi-structured interviews for ministerial and expert interviewees, and the case studies and textual analysis I conducted.

4.1 Ethics

Ethics approval was obtained for all methods involving human participants through Simon Fraser University's Office of Research Ethics.

4.2 Ministry Interviews

I conducted semi-structured interviews during this project with staff from the BC government, Health Canada and staff who run the case study programs. This method helped to answer research question two. This was the appropriate method for gathering this data because most of this information is not documented or available to the public. The interviews were conducted by telephone or e-mail. Participants were recruited through cold calls and e-mails and their information was collected through on-line searches using terms such as: direct-to-consumer advertising, Canada, pharmacare, health, and advertising. In total I conducted seven interviews with ministerial and government staff members. See Appendix B for the consent script and Appendix C for the interview schedule.

4.3 Textual Analysis of Government Documents Supplemented by Findings from Expert and Ministerial Interviews

In this section, I studied policy documents and government and expert interviews on DTCA in Canada. This section provides an understanding of the status quo in Canada and the challenges it faces in enforcement. It helped to answer research questions one and two. I highlight some gaps that need to be filled in order for effective DTCA policy to work in Canada. Excerpts from expert and ministerial interviews have been added to the textual analysis section. These

excerpts help to answer some questions of how the status quo works that the policy documents could not answer.

4.4 Case Studies

Using the background information and data gained from ministry interviews, I developed descriptive case studies. These help to answer research question three. The case studies were developed based on the methods outlined in *Case Study Research: Design and Methods* (Yin, 2009).

Three main principles for developing case studies are highlighted by Yin (2009, p.101). These are:

1. Use multiple sources of evidence.
2. Create a case study database.
3. Maintain a chain of evidence (research question to case study conclusion).

These principles are central to the development of case studies during this project because they ground the case studies in a theoretical base.

To develop the case studies I did not limit my searches to programs that addressed direct-to-consumer advertising as I was unable to identify alternatives to regulation in any of the jurisdictions that I considered. I decided early in this project that regulation alone could not be a solution to the impacts of DTCA. I came to this conclusion because countries that have high levels of DTCA regulation still have many problems. For example, the US which allows full DTCA but also has a sophisticated set of regulations commonly experience infractions of this regulation.

Another challenge in creating the case studies was obtaining sufficient data to be able to analyse them. While I identified many potential case studies to use in the capstone, I had to reject most because data was difficult or impossible to obtain. Examples of some rejected potential case studies are in the Table 1.

Table 1: Potential Case Studies that were Rejected

Project Name	For Further Information
Canada’s national tobacco product labelling program.	http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/fact-fait/fs-if/stronger-bonifiees-eng.php
Quit Now	http://www.quitnow.ca/
HealthLink BC	http://www.healthlinkbc.ca/aboutprogram.stm

Though these programs may have provided viable case studies for this project, without proper data it was not possible consider including them. I selected three case studies based on provincial drug programming in British Columbia. Though none of the case studies deals directly with DTCA, I have identified for each how they could impact DTCA's effectiveness at the provincial level.

4.5 Expert Interviews¹⁰

The expert interviews were used to inform the findings, and policy option chapters. This method helped to answer research questions one and three. In the findings section the expert interviews were used to help understand the potential negative impact of DTCA on the health care system in Canada. In the policy option chapter, they were used to reveal participants' opinions on the value and reasonableness of each of the policy options. Their input helped to shape my recommendations.

The expert interviews added richness to this study that would not have been available otherwise. As Hochschild (2005) argues, "...a central purpose of elite interviews is to acquire information and context that only that person can provide about some event or process" (p.124). These interviews were challenging for me because I lack experience compared to the expertise that these participants have in the area of DTCA and health care. For this reason, Hochschild (2005) recommends that in preparation for expert interviews researchers, "...know as much as possible about the context, stance, and past behaviour of the interview subject before beginning the conversation..." (p.125). Before each interview, I collected as much publicly available information as I could on the participant and their organization; thus, I began the interview as fully prepared as possible. Academic researchers, staff from the British Columbia Medical Association and provincial government staff were interviewed for this capstone.

Though the expert interviews were challenging, they were immensely helpful in understanding the relationship between DTCA and the health care system in Canada. The findings in this section tie directly to the policy options that I propose in this capstone. In each of the groups of interviewees, I have highlighted relevant themes from the discussion and then used data from the interviews to substantiate these themes. I conducted three interviews: An academic who specializes in DTCA; a staff member from a physician association who has previously worked in DTCA policy; and finally, staff members working at the provincial Ministry of Health

¹⁰ In this capstone I use the term expert interviews instead of elite interviews. I selected to use the term expert interviews instead of elite interviews in order to prevent prioritization of one group of interviewees over another.

were interviewed. See Appendix B for the consent script and Appendix C for the interview schedule.

4.5.1 Data Analysis

For each of the expert interviews I conducted thematic analysis and highlighted significant themes. In order to emphasize the position of the expert interviewees I selected key quotes from their interviews that were identified with the themes. These quotes provide qualitative evidence to the findings of this project.

5: Findings

5.1 Textual Analysis of Government Documents Supplemented by Findings from Expert and Ministerial Interviews

5.1.1 Government Bodies

The Health Product and Food Branch (HPFB) of Health Canada manages DTCA in Canada. It is responsible for administering and directing compliance with DTCA regulations (Canada, 2010, Guidance Document). Two organizations within HPFB work in direct-to-consumer advertising; these are the Marketed Health Product Directorate (MHPD) and the Health Product and Food Branch Inspectorate (HPFBI or Inspectorate). The MHPD is responsible for post-approval safety surveillance, trends and risk communication for all regulated food and drug products (Canada, 2011). It is responsible for policy on DTCA, and deals with all health and safety issues around food and natural health products and drugs. The HPFBI provides inspection services and is responsible for DTCA compliance (Canada, 2007; Canada, 2010, Guidance Document). When the Inspectorate receives a complaint of non-compliance for DTCA, they investigate to determine whether a specific campaign is non-compliant and then determine what steps are required concerning that campaign. Mechanisms available to HPFBI include (Canada, 2010, Guidance Document, p.9):

- Warning letters,
- Requests for immediate cessation of the campaign,
- Issuance of risk communication,
- Suspension or cancellation of marketing authorization (i.e. approval for sales in Canada),
- Prosecution.

Health Canada also runs tests on suspected non-compliant campaigns that they will use to indicate the severity of the mechanism they should use. The general test for non-compliant campaigns are, "...MHPD determines non-compliance...and assesses the health risk posed by the advertising material at issue." (Canada, 2010, Guidance Document, p.10). The HPFBI does not have inspectors that specialize in DTCA (Academic Perspective, in-person interview, March 16, 2011, 1:01:15) which raises concern over the inspectors' ability to take all necessary factors into

consideration when investigating DTCA non-compliance. The HPFBI and MHPD are responsible for ensuring that federal regulation on DTCA is upheld.

5.1.2 The Food and Drug Act and Regulations

The federal Food and Drug Act, 1985 (F&D Act, or Act) and the Food and Drug Regulations (F&D Regulations or Regulations) establish what types of DTCA for prescription drugs are legal. The Regulations restrict the types of advertising that can be produced and distributed in Canada thereby limiting the types of DTCA that Canadians can legally be exposed to. Health Canada is also responsible for enforcing these laws (Michols, 1996).

- Section 2 of the Act, defines advertising is, "...any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device." (Marketed Health Product Directorate, personal communication, October 7, 2010).
- Drugs cannot be promoted for uses that are beyond their **indication of use**: "...the limitations for use of a health product, including the disease state, condition(s) or symptoms(s)...for which the health product is intended and authorized to be used by Health Canada." (Canada, 2010, Guidance Document, p.3).
- Section 9(1) of the Act outlines that advertising subject to this legislation cannot be, "...false, misleading or deceptive, or...likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety" (Marketed Health Product Directorate, personal communication, October 7, 2010).
- Section C.01.044 of the Regulations state that, "Where a person advertises to the general public a Schedule F Drug (prescription drugs), the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug." (Canada, 2010, Guidance Document, p.15).

As was discussed previously, reminder and disease awareness ads are permitted under these regulations. These commercials do not legally contain any verbal or written information about a drug's therapeutic benefits or risks. Typically these advertisements end by instructing viewers to consult their doctor (Health Council of Canada, 2006).

5.1.3 Preclearance Agencies

Health Canada takes "...a risk based approach in its compliance and enforcement activities..." (Health Canada, Regulatory Requirements for Advertising, 2011). Canada uses a

voluntary system of preclearance for DTCA (there is no requirement for companies to submit their ads for approval). Health Canada has devolved preclearance responsibility for DTCA to two agencies (Marketed Health Product Directorate, personal communication, October 7, 2010): the Pharmaceutical Advertising Advisory Board (PAAB), and Advertising Standards Canada (ASC). Both agencies provide advisory opinions on DTCA of prescription drugs.

PAAB and ASC recommend ads to Health Canada after their review process that they believe are compliant with federal regulations (Advertising Standards Canada, personal communication, March 1, 2011). This does not account for all advertisements that are distributed through Canadian media, however, as the process is voluntary (Marketed Health Product Directorate, personal communication, October 7, 2010). The process of preclearance gives government, researchers and the public a view of one group of DTCA marketers. As one interviewee argued,

“...it’s up to the companies to voluntarily whether they want to submit to either of those agencies in order to see whether those agencies consider whether this would be legal according to the current interpretation of the law. So it’s a, that tells you, that would give you a subset and certainly it should be public....” (Academic Perspective, in-person interview, March 16, 2011, 3:56).

Discussions with both the PAAB and the ASC identified that DTCA commercials submitted to these organizations are protected by confidentiality rules (PAAB, personal communication, March 20, 2011; ASC, personal communication, March 1, 2011). For example, it was not possible to find out how many ads are pre-screened and fail to meet the requirements.

Advertisers are encouraged but not required, “...to use the independent Canadian advertising preclearance system” (Marketed Health Product Directorate, personal communication, October 7, 2010). This leaves room for commercials to be aired in Canada that are not compliant with the Regulations. Though US-based broadcasters and publishers could use the preclearance system there is no mechanism currently for the government to determine if they do and if so what percentage of the total this represents. I conclude that the current system offers many opportunities for non-compliant DTCA to go undetected.

5.1.4 Enforcement

Enforcement of DTCA law in Canada has proven challenging. One challenge is that the interpretation of the Regulations has changed substantially over time. One interviewee argued,

“[t]here was a massive change in interpretation of a regulation that was brought in in 1975. So you had 25 years where that was a way that companies could only list the name, price and quantity, so in print...a list of basically products and their prices as a way of promoting generic drugs. Then, in the year 2000 the first of those [TV] ads, the first one I saw was

December 31, 1999 – it was a Zyban ad for quitting smoking and it was linked to the new year.... And then in the few months afterwards there'd be press coverage on this and there would be people quoted as saying, 'in Canada you're allowed to say the name, but not the indication' or vice versa." (Academic Perspective, in-person interview, March 16, 2011, 10:28).

The reason for these interpretations has remained unclear. Health care provider organizations such as the BC Medical Association and the Canadian Nursing Association have argued for a complete ban on DTCA or strict enforcement of the Regulations (British Columbia Medical Association, 2007; Canadian Nurses Association, 2004). The Regulations themselves are quite limiting (to the name, price and prescription quantity for the drug), but Health Canada has interpreted this in a manner that allows for a wide array of ads. For example, Viagra (sildenafil citrate) commercials that feature suggestive imagery about the purpose of the drug but do not list benefits, uses or harms (Globe and Mail, 2008).

Cross-border advertising is another problem for enforcement. As was previously mentioned, the federal government has identified that it does not have the jurisdiction to regulate US distributed DTCA. It is unknown exactly how much advertising is coming across the border from the US through television, print media and the internet. At this time analysis of Canadian exposure to cross-border DTCA is limited. The problem of cross-border exposure was described by one interviewee in the following way,

"...the policy response that we've had in Canada is...o.k. the cross border stuff we sort of pretend it doesn't exist makes no sense really.' ...[i]f something is illegal in Canada the government can block it. Pharmaceutical manufacturer that's selling their products in Canada, they're US ads, they could be blocking with a Canadian IP address from seeing those ads, they just don't because nobody forces them to." (Academic Perspective, in-person interview, March 16, 2011, 1:35:58).

While it is true that the Canadian government does not have outright control over US broadcasters, there may be other options to influence the frequency of US distributed DTCA in Canada. For example, one interviewee argued that, it is possible to block certain IP addresses based on location from access to internet DTCA. This is used by countries all around the world. For example, the British Broadcasting Corporation (BBC) restricts access to their on-line media by IP address; therefore, if you are a Canadian, in Canada, trying to access their programming on-line you will not be successful in doing so (BBC, Doctor Who, 2011). This paper is not advocating for the federal government to restricted internet access to US media; however, the example does demonstrate that there are options within the means of the federal government if there was political will to take action on this issue.

This section has outlined the status quo and its current policy gaps.

5.2 Case Study Findings

5.2.1 BC Pharmacy Services Agreement

This case study demonstrates the province's ability to leverage its purchasing power to have private interests conform to provincial health policy. The provincial government has leverage over pharmaceutical companies because of their purchasing power. In addition, third party payers, such as health insurance companies, are affected by government policy. This case demonstrates that the provinces could work with pharmaceutical industry to reduce the amount of illegal DTCA in Canada.

The BC Pharmacy Services Agreement (PSA) involved three large stakeholders (Pharmaceutical Services Division [c], Ministerial Interview, March 1, 2011):

- the BC government,
- representatives from the BC Pharmacists Association, and
- representatives for the Canadian Association of Chain Drug Stores (CACDS).

Before the negotiation of the PSA for generic drugs in British Columbia was being sold these at 50 percent of the list price for their brand name drug. This was widely known to be one of the highest rates being paid for generic drugs in the world (British Columbia, Generic Drug Pricing, 2010). British Columbia's Pharmaceutical Services Division has a policy to, "[d]evelop new strategies to control costs, [while] preserving the diversity of drugs that PharmaCare covers." (British Columbia, Addressing the Challenges). One of the ways that it was able to do this was through the PSA.

The negotiations took place between 2009-2010. This agreement reduced the price paid for generic drugs in BC from 50 percent of the list price to 35 percent (British Columbia, Pharmacy Services Agreement, 2010, p.4). The process was considered relatively successful compared with similar efforts elsewhere. In Ontario, the provincial government legislated the price of generic drugs instead of negotiating with stakeholders (McDowell, National Post, 26 March 2010). The animosity created between the provincial government and pharmacies over this legislation reached such an unreasonable level that the Assistant Deputy Minister who spearheaded the work received death threats (White, Benefits Canada, 26 March 2010; CBC, 2010, *New drugs prices in Ont. take effect July 1*). One staff member at the BC Ministry of Health Services argued that the stakeholders welcomed the opportunity to negotiate generic prices after what had happened in Ontario (Pharmaceutical Services Division [c], Ministerial Interview, March 1, 2011).

The provincial government was able to leverage its relationship with pharmacists and its buying power to reduce the price paid for generic drugs. In applying MMP to DTCA, the provinces might be able to use the leverage of their buying power to encourage compliance in the industry.

5.2.2 Do Bugs Need Drugs Alberta and Do Bugs Need Drugs BC

This case study will examine how education can change an individual's perspectives on drug consumption. This case will help to answer the question: How do we get a knowledgeable population that is not frightened by drug advertisement?

Do Bugs Need Drugs (DBNDs) was initiated as a pilot project in Alberta in 1998-1999 and as a full program in BC in 2005. The programs were designed to address overuse of antibiotics in respiratory tract infections (RTIs) (Blondel-Hill, from notes presented to the Interscience Conference on Antimicrobial Agents and Chemotherapy, 1999). DBNDs are community education programs that promote appropriate use of antibiotics to the public, school-aged children, health care professionals, parents, and assisted living clients (BC Centre for Disease Control, 2010).

DBNDs has demonstrated that decentralized health education can positively affect health knowledge and patient and physician behaviour. The factors that influence antibiotic consumption are similar to those of DTCA: external factors influence consumer behaviour, and consumers pressure health care professionals to prescribe specific drugs to address an existing or perceived illness (Do Bugs Need Drugs Alberta, January 28, 2011). If the public and practitioners can be taught about inappropriate antibiotic use, they may also be taught about appropriate drug consumption. This program may be able to mitigate the impacts of DTCA by arming the public with knowledge about it.

5.2.3 BC Medication Management Project

This case study offers a post-exposure to DTCA perspective on mitigating its impacts. In this case, the BC Medication Management program (MMP) could be used to identify inappropriate prescribing that occurred between patient and physician. It will not dissuade individuals from seeking prescriptions the first time, but it may do so in subsequent times by increasing their knowledge about their overall drug needs. This program is designed to relieve some of the pressure placed on physicians in terms of prescribing and transfer this responsibility to pharmacists.

The BC MPP highlights the role that pharmacists can play to enhance prescription appropriateness and cost-effectiveness. In this program pharmacists take greater responsibility in the overall medication plan for specific patients and bring sober second thought to why specific drugs were chosen. The BC Medication Management Project is a pilot project; a collaboration between the Pharmaceutical Services Division at the Ministry of Health Services and the BC Pharmacy Association. The services provided through this program include (BC Pharmacy Association, 2010):

- Preparing and reviewing patients' medical history,
- Identifying any medication management issues,
- Monitoring the effects of therapeutic regimes and modifying these as necessary,
- Preventing new medication management issues,
- Documenting care, and
- Communicating and collaborating with the patient's other health care providers (e.g. their physician).

Physicians will continue to offer these services, but now some pharmacists will do so as well. Pharmacists have "unique drug therapy training, knowledge and skills" (BC Medication Management Project, 2010) that they can use to improve individual's medical therapy. These services are offered at select pharmacies around British Columbia; the pilot project hired 276 pharmacists in 114 pharmacies through a competitive application process (Pharmaceutical Services Division [d], Ministerial Interviews, March 18, 2011). The program provides training for participating pharmacists so that there is standardization in practice of care. This program is too new to be evaluated; however, it demonstrates how drug management projects could be done provincially. Virani, Flanagan, Roelants, and Baker (2010) found that a study of medication management for post-discharge hospital patients in the Fraser Health Authority resulted in a net cost reduction of \$4,642 per patient when compared with patients who did not receive medication management. Their work demonstrates that medication management can provide a reduction in expected health service resource utilization. The use of MMP demonstrates that pharmacists can play a role in increasing the appropriateness of medication. If this was applied to DTCA impacts, this program may be a positive resource to address the negative impacts of DTCA on the health care system.

In the next section, I explore the range of impacts of DTCA on the health care system with three expert groups including a physician association, government representatives, and an academic expert on DTCA.

5.3 Semi-Structured Interview on the Possible Impacts of DTCA

5.3.1 Physician Association Perspective

“... In the end it comes down to a physician putting a pen down to a prescription pad and writing it.” (Physician Association Perspective, in-person interview, March 22, 2011, 16:15).

Physicians should undeniably be part of the discussion on DTCA. Their perspective is unique in the discussion on DTCA because they are the primary means through which it operates. As the quote above indicates, physicians a profession affected by DTCA in the health care system. Though the public is the primary audience of this drug promotion, it could not work without the compliance of physicians to prescribe requested drugs. But how does DTCA affect physicians? I asked this question during my interview with a staff member at the physician association and they argued the following,

“For most physicians, it’s in the same realm of any patient who’s coming in having googled their disease, or bringing up other research they’ve done, but mostly so for DTCA is physicians see it as probably a barrier to good quality care and it impedes what could otherwise be a very smooth interaction with their patients. So whereas a physician would rather spend time, you know, taking the history, doing the physical exam, you know, making a diagnosis and then recommendations to the patient, they’re...having to spend any time re-educating a patient on why they do or don’t need a drug that they’ve heard about on television...then we’ve got a barrier.” (Physician Association Perspective, in-person interview, March 22, 2011, 4:47).

According to this interviewee, one impact of DTCA on the health care system is that it takes time from diagnosing and treating a patient. It therefore impacts the quality of care that physicians can give to their patients.

Theme 1: DTCA affects the physician-patient relationship.

During the physician association interview, the interviewee argued that existing programs (such as EQIP and PAD) may already counteract some of DTCA’s impact on physician care. The interviewee argued, “EQIP has actually shown, already, some savings in prescribing patterns over what otherwise would have been projected.” (Physician Association Perspective, in-person interview, March 22, 2011, 19:48). Likewise, evidence-based information on DTCA holds the potential to change prescribing behaviours. “DTCA campaigns can lead to more patient visits, more diagnoses for conditions treated by advertised drugs, and more prescriptions for those drugs...” but we do not know how this affects prescribing appropriateness (British Columbia Medical Association, 2007, p.26).

Theme 2: Information can be a powerful tool to change physician behaviour, but we lack sufficient data on DTCA.

The interviewee's perspective on the efficacy of EQIP provides insight into what could be done in DTCA policy. If better information were available on DTCA's impacts there may be savings at the provincial level. This could occur because research demonstrates that DTCA can lead to an increase in prescribing. If better information on drugs and the impacts of DTCA were available to physicians, this may counteract the effects of DTCA. To this end the interviewee argued,

“[a] research project, I think is complimentary to any of these [other policy options]. I do not think there's either or here. I would do [that option] regardless. If only to get hard numbers around how much...you could phrase it as, how much the failure of government to enforce existing regulations is costing provincial health care systems. There you go right. That's a...that would be a powerful statement.” (Physician Association Perspective, in-person interview, March 22, 2011, 44:41).

5.3.2 Government Perspective

The federal government is, “...committed to ensuring that information in a health product advertisement is not false, misleading or deceptive.” (Marketed Health Product Directorate, personal communication, October 7, 2010). The government of Canada argues that they, “...are committed to strengthening Canada's safety system for food and health products as an important part of our Food and Consumer Safety Action Plan. A key element of improving the safety system is modernizing the legislation for food and health products.” (Marketed Health Product Directorate, personal communication, October 7, 2010).

Theme 3: The Food and Drug Act and Regulations require modernization in order to improve food and health product safety in Canada.

Though the federal government states its commitment to ensuring the safety of Canadians through federal law and regulations, I observe that according to Health Canada, several element of the current system limit their ability to do so (Marketed Health Product Directorate, personal communication, October 7, 2010):

1. The federal government has no authority over US distributed DTCA.
2. Health Canada is under a lot of pressure in regards to DTCA as it is a complex issue with stakeholders holding opposite positions on policy development, and
3. the current system relies on voluntary preclearance mechanism and data that the government has access to from these agencies is limited (Advertising Standards Canada, personal communication, March 11, 2011; Pharmaceutical Advertising Advisory Board, personal communication, March 20, 2011).

Theme 4: Though the federal government currently is responsible for DTCA in Canada, the challenges it faces have left a policy gap.

This is a gap that can be filled by the provinces; however, at this time, provincial governments do not appear interested in direct-to-consumer advertising. The Pharmaceutical Services Division noted in a correspondence that, “[t]he BC Ministry of Health Services relies on the federal rules around advertising of prescription drugs in Canada.” (Pharmaceutical Services Division [a], Personal e-mail communication, 2010). Further discussions with Ministry staff indicated that DTCA was not an area of policy that they considered relevant to their positions (Pharmaceutical Services Division [c], Ministerial Interview, March 1, 2011). The British Columbia government notes that they do require prescription drug policy to limit costs and promote overall health and that these may have unintended effects on DTCA (Pharmaceutical Services Division [c], Ministerial Interview, March 1, 2011).

Theme 5: Though the provincial government acknowledges their responsibility for prescription drug policy, they have not engaged in DTCA policy.

This reluctance on the part of the provincial governments to engage in direct-to-consumer advertising policy is at this time a challenge to forward developments in this area. I believe that the reluctance of the provinces is, in part, a result of the fact that to-date there has been little effort to highlight the relevance of this policy area to their work. The policy options that I propose in this paper focus on identifying the provinces’ role in DTCA policy.

5.3.3 Academic Perspective

Though the health system impacts of DTCA have not yet been fully documented, some health impacts have been. For example, the interviewee noted that the Vioxx (rofecoxib) ‘disaster’ is a clear example of the impacts that DTCA can have on the health care system. They argue,

“...I find it interesting the sort of statements that there isn’t any harm from [DTCA] because in fact those statements were being made before the Vioxx disaster and they’ve continued to be made after the Vioxx disaster. If you bring it up as an issue, then it’s dismissed as a red herring, but in fact you’re looking at a large increase in the use of a product which ended up leading unnecessarily to thousands of heart attacks and deaths.” (Academic Perspective, in-person interview, March 16, 2011, 32:16).

Theme 6: DTCA encourages the consumption of prescription drugs with significant health risks.

High-risk drugs like Vioxx can cause major health impacts as was explored in previous chapters. They can also increase expense to the health care system through the use of health care services such as the emergency visits, physician appointments and use of specialists such as oncologists and cardiologists.

It should be reasonable to assume that the federal system of DTCA regulation would prevent high-risk drugs from being promoted directly to the public as the benefits are for most people not outweighed by the consequences of it (Mintzes, Morgan and Wright, 2009). The current regulatory system, however, has some flaw that includes an overly complex system, underfunding and a lack of specialization for DTCA in staff members. During the interview, the Academic Perspective interviewee argued,

“Then [a complaint about illegal DTCA] goes to the [Health Products and Food Branch] Inspectorate and we have nobody in the Inspectorate who is specialized in dealing with information in advertising. So what happens at the Inspectorate level is if there’s if there’s a concern about an advertising campaign... what happens then is that the complaint will be sent to the regional office where the company has its head office. So you can have advertising billboards for Celebrex – 10th avenue [Vancouver] and it’ll go to Montreal, the complaint, because that’s where Pfizer will have its head office. And then at that regional office the person from the Inspectorate is dealing with inspection of factories, dealing with good manufacturing practices, all kinds of stuff, tampering, all kinds of things and [DTCA non-compliance]. And I don’t know whether it goes to the top of the pile or the bottom of the pile, but I six months later – our first communication back” (Academic Perspective, in-person interview, March 16, 2011, 1:01:15).

Theme 7: The current regulatory system is flawed in several ways including an over-complicated system of procedures, underfunding and a lack of specialization for DTCA in staff members.

The status quo is challenging in many ways; however, because the federal government does not have responsibility for health care delivery there is little incentive to make this area of policy a priority.

Theme 8: DTCA’s effectiveness may be impacted by provincial pharmaceutical policy.

The Academic interviewee was able to illuminate how provincial policy may affect the effectiveness of DTCA. For example,

“There’s a comparison between BC and Ontario where in BC [consumption of Vioxx] was flat because they weren’t paying for it at all to begin with and then eventually the provincial government just paid for them third line. You had to fail on two other drugs to get them. And it’s a special authority procedure so it’s where the doctor has to put in an application and have it approved. And in Ontario they actually had an increase in hospitalizations from stomach bleeds over... that paralleled in the number of increases the increase in use of these drugs and the whole class. And in BC you didn’t have it happen, you didn’t have that population increase and you didn’t have the increase in stomach bleeding.” (Academic Perspective, in-person interview, March 16, 2011, 40:37).

This case highlights how provincial drug management policies can limit the influence of DTCA. It is a promising start, but it is unknown how valuable these programs are for mitigating DTCA’s effectiveness because no one is tracking this impact.

5.3.4 Chapter Summary

This chapter has allowed for the development of eight key themes on DTCA in Canada. I have found that our existing regulatory system contains loopholes and flaws that require new policy options. In addition, this chapter highlights existing pharmaceutical programming that offer insight into effective mechanisms to manage drug costs and consumption. I discussed how this programming may be applicable to DTCA policy.

In the next chapter, I will take these findings and develop four policy options. I will then analyse them to identify which option(s) will be the most appropriate for this policy problem.

6: Policy Options and Analysis

The options I propose in this capstone assume that the status quo will be maintained. The options are designed to be applied in conjunction with the status quo. Some themes that I identified in the Findings chapter will *not* be addressed in the Policy Option chapter. The reasons for this are explained below.

Theme 3: The Food and Drug Act and Regulations require modernization in order to improve food and health product safety in Canada.

Theme 7: The current regulatory system is flawed in several ways including an over-complicated system of procedures, underfunding and a lack of specialization for DTCA in staff members.

Considering the limitations of the status quo, it would be fair to ask why I have not selected to change it. My answer is that researchers and public health advocacy groups have been advocating for changes to the status quo for years (British Columbia Medical Association, 2007; Canadian Nurses Association, 2004; and Canadian Medical Association, 2002); yet, DTCA in Canada has proliferated rather than decreased during this time (Mintzes, Morgan and Wright, 2009). Amendments to the Food and Drug Act in 2005 did not change the relevant promotion clauses (Canada, 2004) and though Health Canada argued that modernization was a key element in improving food and drug safety in Canada, they did not indicate that this would occur any time in the near future. I believe that there is currently no policy window to change the status quo. For now, I recommend that the status quo be upheld and that complimentary options be considered to modernize DTCA policy in Canada.

The criteria for this analysis were selected based on information from literature reviews, textual analysis and the expert interviews. Further significant criteria were considered, but not included because of time and capacity restraints of the researcher. These other criteria included: produces consumer and/or prescriber behavioural change (effectiveness), legal feasibility and vertical equity.

Table 2: Criteria Matrix

Criteria	Description	Measure
<p>Effectiveness</p> <p>Reduces public exposure to DTCA</p>	<p>Does the option reduce the prevalence of DTCA?</p>	<p>1. Qualitative: (Measure: Yes, Somewhat or No).</p> <p>Yes: Reduces DTCA in Canada to legal ads. Somewhat: Provides the public with resistance strategies. No: Status quo is upheld.</p>
<p>Informational Value</p> <p>Improves understanding of DTCA in Canada</p>	<p>Does the option collect information about DTCA in Canada?</p> <p>This criterion is the most significant because as the findings have demonstrated: what DTCA in Canada is and how it affects people and the health care system is a significant unknown</p>	<p>1. Qualitative: (Measure: Yes, Somewhat or No).</p> <p>Yes: Canada-specific data is collected. Somewhat: Some aspect of DTCA in Canada is collected. E.g. public opinion or advertising rates. No: No new information is collected.</p>
<p>Cost</p> <p>Administrative</p>	<p>How much would the option cost to run?</p>	<p>1. Quantitative: (Measure: Low, Medium or High)</p> <p>Low: >1,000,000 Medium: 1,000,000-5,000,000 High: 5,000,000+</p>
<p>Stakeholder Acceptability</p> <p>Industry resistance</p> <p>General practitioner (GP) resistance</p> <p>Public resistance</p>	<p>Will any of the stakeholder groups be likely to resist implementation of the program?</p>	<p>1. Qualitative: (Measure: Yes, Somewhat or No).</p> <p>Yes: High likelihood of acceptability. Somewhat: There is a chance that they will resist. No: low likelihood of acceptability.</p>

In order to properly assess the options I have weighted two of them, the effectiveness criterion and the information value criterion, more heavily. The reason for this weighting arose from the expert and other interviews that I conducted as well as the literature review in this project. These criteria were highlighted during this process and so I have selected to value them more in my analysis. An explanation of the weighting scheme is in the table below.

Table 3: Criteria Weighting

Criterion	Weight
Reduces public exposure to DTCA	Green = 2 Yellow = 1 Red = 0
Improves understanding of DTCA in Canada	Green = 4 Yellow = 2 Red = 0
Administrative Costs	Green = 2 Yellow = 1 Red = 0
Stakeholder Acceptability	Green = 4 Yellow = 2 Red = 0

Table 4: Policy Analysis Matrix

Options	Reduces public exposure to DTCA	Improves understanding of DTCA in Canada	Administrative cost	Stakeholder acceptability
Working group (8)	No (0)	Yes (4)	High (0)	Yes (4)
Improve discourse (7)	Somewhat (1)	Somewhat (2)	Low (2)	Somewhat (2)
Financial penalty (5)	Yes (2)	Somewhat (2)	Medium (1)	No (0)
Education (7)	Somewhat (1)	Somewhat (2)	Low (2)	Somewhat (2)

6.1 Option 1: Fund a Working Group on DTCA in Canada

Overall, the most significant challenge of DTCA in Canada is the lack of data and knowledge on DTCA. Though I identified theme 2 and 6 in the findings chapter, they were observed at all points of this research project.

Theme 2: Information can be a powerful tool to change physician behaviour, but we lack sufficient data on DTCA.

Theme 6: DTCA encourages the consumption of prescription drugs with significant health risks.

A lack of information for physicians, the public and health policy staff on DTCA, makes moving forward with policy action in this area challenging. This option will fill this gap.

For this option I suggest a working group composed of high-level federal-provincial-territorial representatives, as well as researchers with expertise in the areas of drug promotion, direct-to-consumer advertising, and public health. The working group will be based on a hub and spokes model of research collaboration where planning occurs at the central level (hub) and the research is carried out by the individual provinces and territories (spokes; Lee, Renaud and Hills, 2003). This model will address three themes derived from the Findings chapter.

Theme 4: Though the federal government currently is responsible for DTCA in Canada, the challenges it faces have left a policy gap.

Theme 5: Though the provincial government acknowledges their responsibility for prescription drug policy they have not engaged in DTCA policy that directly relates to their work in health service delivery.

Theme 8: DTCA's effectiveness may be impacted by provincial pharmaceutical policy.

The purpose of this working group initially would be to plan for and oversee a national research project on DTCA. The national working group should commission proposals to have researchers collect DTCA data in each province-territory. Implementation of the research project would be the responsibility of the research organization that wins the bid for the project.

I recommend the project be run over three years. This will allow for a reasonable amount of time to identify and document DTCA in Canada and give the working group time to identify policy options for future policy development in Canada. It will also open a dialogue between government stakeholders on DTCA and health care in the country. I recommend that the working group meet at a minimum of twice per year. By meeting twice per year this will motivate the provincial, territorial and federal authorities to engage in the data collected to date and keep them

interested in the subject. After the three-year research project has been completed, the working group should identify their next direction.

A senior staff member in the Marketed Health Product Directorate, such as a manager, should take the lead position as the federal representative in this working group. This position would primarily be occupied with facilitating the two annual meetings and maintaining communication with the participating provinces and territories.

Table 5: Option 1 Time Allotment Federal Representative

Time	Task
5 hr/month	Preparation for two annual meetings
1 hr/month	Two annual meetings
8 hr/month	Communication with provincial and territorial project staff
Total 14 hr/month¹¹ 10 percent of position	

Representatives from the provinces-territories will come from each of the Ministries of Health. These individuals should have enough expertise on pharmaceutical policy as well the time to devote to the project. I recommend having assistant deputy ministers (ADMs) from the pharmaceutical divisions of the provincial and territorial ministries of health be the representatives on this working group. These individuals would attend the annual meetings as well as be updated by the research teams in their province on the project's progress. The assistant deputy minister should also be assisted by a director or manager who can support the work that goes on at these meetings.

Table 6: Option 1 Time Allotment Assistant Deputy Minister

Time	Task
5 hr/month	Communicate with deputy minister and working group
1 hr/month	Monthly update from research project manager and research analysts
2 hr/month ¹²	Two annual working groups

¹¹ The monthly hours are prorated in order to identify what percent of the person's job will be dedicated to this project. To identify how much time annually the two meetings will occupy of the federal representative's job, for instance, I took the total number of meeting hours (14 hours per year) and divide it by 12. This way I am able to indicate on a monthly basis how much their time allotment would go to those meetings.

Time	Task
Total 10.5 hr/month 7 percent of position	

The ADMs will take part in the two annual working group meetings, and they will take part in a monthly update with the manager and research analysts. Finally, they will have to provide communication with the working group from time-to-time and will inform the deputy minister about the project's progress.

The director or manager who will assist the assistant deputy minister will have similar responsibilities to the ADM.

Table 7: Option 1 Time Allotment Director/Manager

Time	Task
5 hr/month	Communicate with deputy minister and working group
1 hr/month	Monthly update from research project manager and research analysts
2 hr/month	Two annual working groups
Total 10.5 hr/month 7 percent of position	

The research will be carried out by an independent research body. The research team will be composed of a manager and research analysts in each province. In order to provide a cost estimate for analysis in this capstone I have developed the following teams.

Most of the work will be carried out by the research analysts. I recommend that these staff be able to dedicate their full position to this project. Research analysts will carry out administration (maintaining and developing contacts and relationships and conducting meetings with the director, manager and other stakeholders), project design (researching DTCA to understand it better and identifying where and how data will be collected), material development (creating surveys and interview schedules), data collection (conducting surveys, interviews, etc., collating data) and report drafting (writing the findings). The amounts in the table below are per staff member and many of the hours have been prorated over the three year project timeline in order to indicate the time allocation in monthly amounts.

¹² I have assumed that with travel time, etc., the director will dedicate 24 hours over the year to the two annual working group meetings, that is 7 hours per meeting and 5 hours for travel time. The 2 hours above is the 24 hours prorated over 12 months in order to determine what percent of their time the ADMs will dedicate to this project.

Table 8: Option 1 Time Allotment Research Analysts

Time	Task
56 hr/month	Administration
11 hr/month	Project design
11 hr/month	Material development
51 hr/month	Data collection
11 hr/month	Report drafting
Total 140 hr/month 100 percent of position	

The manager will take part in all aspects of the project including acting as a supervisor to the researchers, updating the director/manager on project progress, undertaking project planning on a monthly basis, preparation for all of these meetings, and attending the two annual working group meetings. I have established a likely time delineation for each of these tasks.

Table 9: Option 1 Time Allotment Manager (Research Team)

Time	Task
40 hr/month	Supervise the researchers
10 hr/month	Planning
5 hr/month	Update director and other stakeholders on project progress
10 hr/month	Two annual working group meetings
25 hr/month	Preparation time
Total 90 hr/month 65 percent of position	

6.1.1 Analysis of Option 1: Working Group

6.1.2 Reduces Public Exposure to DTCA - No

This working group and research project will not affect the public's rate of exposure to DTCA. It will have the potential to identify where to target efforts for future DTCA policy. For example, the research project will need to identify where and how frequently magazine ads are running full DTCA campaigns. Policy efforts could then target those magazines in order to reduce their content of illegal DTCA.

6.1.3 Increases Understanding of DTCA in Canada – Yes

This project will increase Canada's overall knowledge base on DTCA. As has been demonstrated throughout this project, data on DTCA in Canada is challenging to acquire and in many cases does not exist. Health Canada has demonstrated that it lacks significant sets of data,

in the areas of (Marketing Health Product Directorate, personal communication, October 7, 2010):

- How much money is spent on DTCA annually in Canada;
- Where and how frequently DTCA is disseminated in Canada;
- How much Canadian and American produced DTCA is disseminated in Canada annually; and,
- What the effects of DTCA are on the health care system in Canada.

The fact that Health Canada is "...committed to ensuring information in a health product advertisement is not false, misleading or deceptive" (Marketing Health Product Directorate, personal communication, October 7, 2010) but is not aware of how many DTCA advertisements run in Canada annually is a concern because it is difficult to understand how they are able to meet that commitment without sufficient information. Without this data it has been very difficult to establish concretely: How much DTCA is occurring in Canada; how much of this is legal versus illegal according to the Food and Drug Act and Regulations; how this effects consumer behaviour; what the spin-off effects are on prescribers; what the effects are on the health care system in Canadian provinces, and finally, what the overall health impacts are of DTCA. As good data is central to evidence-based policy making (Brownson, Chiqui, and Stamatakis, 2009), I propose this research project option in order to promote good DTCA policy development in the future.

6.1.4 Cost - High

The cost estimates for this option are for the three-year period that the research project will be undertaken. After this is completed, the working group should identify what their future role will be.

Table 10: Option 1 Staff Costs per Province

Staff	Cost
ADM	\$11,000 ¹³
Director/Manager	\$6,000 ¹⁴
Manager	\$54,000 ¹⁵
Research analysts	\$56,000 x 2 people = \$112,000
Total Annual per province	\$183,000 x 3 years = \$549,000

Table 11: Option 1 Staff Costs for the Federal Representative

Staff	Cost
Federal representative	\$8,000
Total Annual	\$8,000 x 3 years = \$24,000

In addition to staff costs there will also be incidental expenses incurred. The expected incidental expenses are:

- Interview costs (paying for professional [physician, pharmacist, etc.] time, travel to sites, transcription)
- Annual working group meeting costs (food, travel to location)
- Surveys (printing, postage for sending and return of paper surveys)

Table 12: Option 1 Total Project Costs

Item	Cost
Interview costs \$79,500	<p>Physicians (10 per province) = \$100/interview = \$1,000 x 13 provinces/territories = \$13,000</p> <p>Pharmacists (10 per province) = \$50/interview = \$500 x 13 provinces/territories = \$7,500</p> <p>Travel cost (to each health region) = -\$600 per trip to Northern, Interior and Vancouver Island health regions = \$1,800 -\$50 per trip to Fraser and Vancouver Coastal health regions = \$100 -\$100 for food = \$2,000 travel X 13 provinces/territories = \$26,000</p> <p>Transcription (for 20 interviews) =</p>

¹³ Based on \$155,000 annual salary, but rounded to the nearest thousand.

¹⁴ Based on \$82,500 annual salary, but rounded to the nearest thousand.

¹⁵ Based on \$82,500 annual salary, but rounded to the nearest thousand.

Item	Cost
	-\$130 per transcript x 20 = \$2,600 =\$2,600 transcription x 13 provinces/territories = \$33,800
Annual working group meeting costs \$105,800	Food \$30 per person x 30 people = \$900 \$900 per meeting x 2 meetings per year = \$1,800 Travel \$4,000 per director and manager flight round trip x 13 provinces and territories = \$52,000 per meeting \$52,000 per meeting x 2 meetings per year = \$104,000
Surveys \$5,300	Printing \$.30 per survey x 900 = \$270 \$270 x 13 provinces/territories = \$3,500 Postage \$1 per survey return = \$900 \$900 x 13 provinces/territories = \$1,800
Staff costs per province \$549,000 x 13 \$7,137,000	\$7,137,000
Staff costs for the federal representative \$24,000	\$24,000
Total cost \$7,351,600 Per year cost 2,450,000	

6.1.5 Stakeholder Acceptability - Yes

Industry will have little to contest in this option. Because the option seeks to study DTCA in Canada and not to prove its value one way or another it is unlikely that the government will experience push back from the pharmaceutical industry. On the other hand, existing data on DTCA in Canada is held by private companies that have strong ties to the pharmaceutical industry and staff may find that their progress is hindered because such organizations are unwilling to share their data (Pharmaceutical Advertising Advisory Board, 2011; Advertising Standards Canada, 2011). Canadian advertising preclearance agencies do not give out data of a proprietary nature (Pharmaceutical Advertising Advisory Board, 2011; Advertising Standards Canada, 2011). Similarly, market research groups have at times denied data access to academics that are critical of the industry (Academic Perspective, in-person interview, March 16, 2011, 5:30).

General practitioners are also unlikely to resist this option. When asked about this option the representative from the physician association argued,

“[The] research project, I think is complimentary to any of these [other policy options]. I don’t think there’s either/or here. I would do [that option] regardless. If only to get hard numbers around how much...you could phrase it as, how much the failure of government to enforce existing regulations is costing provincial health care systems. There you go right. That’s a...that would be a powerful statement.” (Physician Association Perspective, in-person interview, March 22, 2011, 44:41).

Because of this statement, it is likely that GPs will support this option.

Finally, **the public** will be unlikely to contest this research. The working group and research project should be as scientific as possible in order to convey to the public that the findings are valid.

6.2 Option 2: Improve Public Discourse on DTCA

Despite federal legislation limiting DTCA Canadians know little about this regulatory regime. For example, van den Engh and Bonertz (2010) studied the impact of DTCA in remote communities in northern BC and found that while 16 percent of respondents thought that Canadian law forbade DTCA, 17.5 percent thought that DTCA was legal and 65.5 percent did not know whether DTCA was legal or illegal in Canada (p.129). These results are not surprising given the amount of broadcast, radio, internet and print DTCA that they are exposed to – 40 percent of respondents reported seeing 10 DTCA ads or more in the previous year (van den Engh and Bonertz, 2010, p.128). As the Academic Perspective interviewee argued,

“[i]t would be completely understandable that people would think [DTCA] was legal because they see it...any newsstand is full of magazines that have these ads in them. So it’s a kind of interesting area, because it’s an area where there’s a difference between what’s in the law and how it’s being enforced and we’re quite different from other countries that have the same law as us in terms of where we’ve in a public policy...”

Interviewer: In terms of enforcement? Or...?

Yes, enforcement and the reinterpretation of the price advertising clause. So that’s one where as a result of that interpretation we have ads on the TV that, I’ve shown them at meetings in Europe and people are really...can’t believe that that’s the case [that those advertisements are allowed on TV].” (Academic Perspective, in-person interview, March 16, 2011, 7:13).

This option could serve to provide the public, practitioners, interested groups and the government with information that would help with theme five.

Theme 5: Though the provincial government acknowledges their responsibility for prescription drug policy they have not engaged in DTCA policy.

In addition, this policy option will help inform the public on DTCA regulation in Canada, which was identified as a problem in the background. The dialogue should be between federal-provincial-territorial governments and the public. The purpose of the option is: To bring DTCA

onto the national and provincial policy agenda; to inform the public about the legality of DTCA and the consequences of it; to capitalize on the expertise and interest of professional groups for pharmacists, physicians and nurses; and, to prepare the political agenda in Canada for the challenges ahead if the Food and Drug Act undergoes modernization that further limits DTCA.

This policy option contains two major components:

1. To get DTCA on the agenda for the annual health ministers meeting.
2. To establish DTCA pages on federal-provincial-territorial health websites.

The first component is to get direct-to-consumer advertising on the agenda for the annual health ministers meetings. These meetings, organized by the Canadian Intergovernmental Conference Secretariat (CICS), constitute a forum for the ministers to discuss the challenges faced by them in the delivery of health care services and to address these challenges by, "...sharing best practices and seeking more opportunities for collaboration." (Canadian Intergovernmental Conference Secretariat, 13 September 2010). Though these meetings are not designed for federal representatives to attend, they have done so in the past. This presents an opportunity for federal representatives from the Marketed Health Products Directorate to work collaboratively with the CICS to bring DTCA onto the provincial-territorial agenda.

I recommend that the Marketed Health Product Directorate of Health Canada take a leadership role in initiating this policy option. MHPD should make a presentation to the health ministers at the meeting that outlines the status of DTCA law in Canada. It should also include a discussion of the challenges faced by Health Canada in enforcing the law within the current regulatory and programmatic framework, and highlight the negative impacts that this may be having on the health care system of the provinces-territories. The main purpose of this presentation will be to bring to the attention of the health ministers the impact that DTCA has on their Ministry and health services. In addition, representatives from professional groups such as the Canadian Nurses Association and the Canadian Medical Association should be invited to the meeting. They should be invited to present on how DTCA affects their profession. This will be an initial step to get DTCA onto the provincial-territorial agenda. At this meeting, the MHPD needs to solicit support from the health ministers for the next component. At this meeting, the MHPD should also invite representatives from the Health Council of Canada, as well as the Canadian Institutes of Health Research (CIHR) in order to solicit their support. These organizations have the organizational capacity and health knowledge to be strong supporters of this option. Staff from the Marketed Health Product Directorate should work to gain the buy-in of these organizations in order to retain them as partners in developing the materials for the next

component. The time commitment of the federal representative is below, prorated over a year and by month.

Table 13: Option 2 Time Allotment Federal Representative

Time	Task
1.2 hr/month	Attending the two meetings
0.8 hr/month	Preparation time for the first meeting with the presentation.
8 hr/month	Communication with provincial and territorial project staff
Total 10 hr/month 7 percent of position	

A team of staff members should be assembled from each of the provinces and territories at this meeting to work on the next component. These teams need someone to lead the project (manager), someone to write the materials (communications), and someone who will coordinate with the federal representative and the other provincial-territorial teams (administrative assistant). The following tables indicate the tasks and time allocation for each member of the provincial-territorial teams. These teams should work collaboratively to develop materials for the websites, share ideas and challenges and provide a forum for government staff to share their ideas on DTCA. After a year, the teams will compile a final report to be presented to the health ministers updating them on the findings of the project. At this time, the health ministers will be able to decide next steps for their involvement in DTCA policy.

Table 14: Option 2 Time Allotment Manager

Time	Task
0.3 hr/month	Meet with other provincial-territorial teams via teleconference.
4 hr/month	Oversee project/supervise communications staff member
1.25 hr/month	Final report review
Total 5.55 hr/month 3 percent of position	

Table 15: Option 2 Time Allotment Communications

Time	Task
2 hr/month	Meet with other provincial-territorial teams via teleconference
12 hr/month	Develop website materials and plan for national campaign
16 hr/month	Collect and analyse data
2.5 hr/month	Write final report
0.83 hr/month	Edit final report
Total 33 hr/month 25 percent of position	

Table 16: Option 2 Time Allotment Federal Representative

Time	Task
10 hr/month	Coordinate program activities
Total 10 hr/month 7 percent of position	

Part two of this option is to set-up a direct-to-consumer advertising page on Health Canada’s website as well as on the provincial-territorial websites. The team of staff from the provinces and territories, in collaboration with the CIHR and the Health Council of Canada will develop unified messages to include on the websites.

These webpages will be primarily designed to inform the public about direct-to-consumer advertising in Canada. Content on the sites should include information about Canadian law and regulations on DTCA; a discussion about how it can affect patient and physician behaviour; and, links to existing drug information websites. An example of existing drug information websites is HealthLink BC¹⁶. Research will need to be conducted by the communications staff in each province in order to identify what content to include on the site. By developing these resources on DTCA and linking them to existing resources on relevant health issues, this option will set the stage for initiating a dialogue with the public on direct-to-consumer advertising.

The final elements of this component are two tools that should be included in the federal-provincial-territorial webpages. First, they should include a tool for the public to submit their opinions, ideas and comments to the government. I recommend using an on-line comment form tool where the public can submit this feedback directly through the website as opposed to through their personal e-mail. This will allow for quicker submissions and may encourage some individuals to engage who would otherwise not. Second, a discussion board on each of the

¹⁶ See, <http://www.healthlinkbc.ca/>

webpages should be included in order to facilitate person-to-person discourse on DTCA. This will give the participating governments a sense of how the public thinks about direct-to-consumer advertising and what proportion of the public are advocates for more DTCA, for less DTCA or do not care.

6.2.1 Analysis of Option 2: Improve Discourse

6.2.2 Reduces Public Exposure to DTCA - Somewhat

This option does not provide mechanisms to limit the public's exposure to DTCA. Instead, it sets the stage for the federal-provincial-territorial governments to take bolder steps in addressing the issue of DTCA in Canada. If the federal government were to take a more stringent position on DTCA in Canada, it is likely that they would encounter major resistance from the pharmaceutical industry and even a pro-DTCA campaign. Researchers such as Durhane Wong-Rieger and John Calfee as well as economists such as Adam E. Block have argued that DTCA's benefits outweigh its negative impacts (Calfee, 2002; Block, 2007; and, Wong, 2009) and other researchers, professional organizations and governments are likely to argue its negative impacts outweigh its benefits (Marketed Health Product Directorate, personal communication, October 7, 2010; CAN, 2004; BC Medical Association, 2007; Mintzes, Morgan and Wright, 2009). This option will prepare the public for public debate on this issue in the future. In addition, Bell, Kravitz and Wilkes (1999) found that there was compelling evidence for the need to educate the public about the essential nature of DTCA, including its promotional purpose and limitations on regulation (p.656) because their study participants demonstrated significant misunderstandings about DTCA.

6.2.3 Improves Understanding of DTCA in Canada – Somewhat

This option provides governments in Canada with the opportunity to see how DTCA affects individuals in their provinces and territories. This option will give a voice to the public to identify when they have experienced DTCA exposure, which drugs they have had promoted to them and how they felt about it. It may be that public opinion on DTCA is positive as patient advocacy groups and the public have been asking for better drug information for some time (Academic Perspective, in-person interview, March 16, 2011). Public opinion polls from the US

indicate that a large proportion of Americans¹⁷ consider DTCA as a resource for drug information (Kaiser, 2008). It is important for governments to understand public opinion on DTCA and this will provide a forum for that public opinion to be heard.

The Physician perspective interviewee presented with this option said:

“The public may not, frankly, care. I don’t know that it’s going to be something that they’re going to say we absolutely have to be...you know the public’s not going to rally around stopping these ads right, because a certain portion of them are always going to want access to the newest drugs and don’t see any problem with this....” (Physician Association Perspective, in-person interview, March 22, 2011, 33:49).

This statement highlights the risk that the public may not be interested in discussing DTCA, but also that they may take this discussion as an attempt to censor drug information that they believe that they have a right to. Therefore, though this option will improve understanding of DTCA in Canada it may instigate negative public opinion.

6.2.4 Cost - Low

Table 17: Option 2 Staff Costs Provinces/Territories

Item	Cost
Manager	3 % x \$83,000 = \$2,490
Communications	25 % x \$55,500 = \$13,750
Administrative Assistant	7 % x \$40,500 = \$2,835
Total \$19,075	

¹⁷ 48 percent of respondents in the Kaiser survey stated that they use DTCA as a source of drug information either: a lot, somewhat, or not too much. 47 percent stated that they never use DTCA as a source of drug information. (Kaiser, 2008)

Table 18: Option 2 Total Cost for Policy

Item	Cost
Staff costs provinces/territories	\$19,075 per province x 13 province/territories = \$247,975
Federal representative	7 % x \$82,500 = \$5,890
Total \$254,000	

6.2.5 Stakeholder Acceptability - Somewhat

This option is likely to encounter **industry resistance**. The materials developed for this option will need to make a distinction between legal and illegal direct-to-consumer advertising. Because DTCA is legal so long as it does not violate the Food and Drug Act and Regulations, the materials in this option should make the distinction between legal and illegal advertising. This will prevent any legitimate grievance on the part of the industry to argue that this program is beyond the mandate of the provincial and federal authorities involved and that DTCA empowers patients by informing them of their treatment options. The governments involved in the program should not underestimate the strength of this patient empowerment argument, but should instead work to highlight the inherent bias in DTCA and advocate for an impartial source of drug information.

GPs and their representative associations should be consulted on this option during its development. Even if the GPs do not resist this option, their insight into DTCA, its effects on their patients and their relationships with their patients should be incorporated into the website and anti-advertising campaign. It is unlikely that GPs will resist this option because it will help relieve the burden of DTCA that they are currently bearing alone. Many research projects discuss the impact that DTCA has on physician-patient relationships, and on the physician’s ability to do their job correctly (i.e. appropriate prescribing, working within time limits, etc.; Health Council of Canada, 2006; Lexchin and Mintzes, 2002; Mintzes, et al., 2002; Datti and Carter, 2006). This option should be presented as an opportunity to mitigate some of this impact.

The public is unlikely to resist this option as it will provide them with more information than they currently have. During the Academic perspective interview, the interviewee mentioned that they thought,

“...[education] is sort of part of the whole management side and that we could be putting much more money provincially into having independent information on medicines and that anytime you have a survey of the public, ‘what do they want’ they want that kind of

information, that's clear." (Academic Perspective, in-person interview, March 16, 2011, 2:14:01).

This option would provide the public with information about DTCA that they do not currently have. The public would likely see this positively.

6.3 Option 3: Use Financial Penalties to Encourage DTCA Compliance

In this policy option, pharmaceutical manufacturers, pharmaceutical industry representatives and representatives from private health insurance companies (such as Blue Cross) are brought together by the province in order to negotiate advertising content. The provincial governments will use the leverage of their provincial drug formularies to encourage pharmaceutical companies to restrict their DTCA in Canada to what is legal. Both the provincial-territorial governments and third parties such as Blue Cross are payers in the health care system – meaning that they provide coverage for specific drugs. It is in their best interest to ensure that unnecessary drugs are not consumed. This policy option will deal with two key themes from the findings chapter.

Theme 4: Though the federal government currently is responsible for DTCA in Canada, the challenges it faces have left a policy gap.

This third option addresses some of the limitations of federal regulatory enforcement. While the federal government is responsible for health, product safety and regulations (Marketed Health Product Directorate, personal communication, October 7, 2010) it does not manage pharmaceutical policy. This responsibility falls to the provinces as they provide in-hospital prescription drugs, select which drugs will be allowed on their provincial formularies and provide catastrophic¹⁸ and other drug subsidies for eligible residents (Ministry of Health Services, Welcome to PharmaCare, *n.d.*).

Theme 5: Though the provincial government acknowledges their responsibility for prescription drug policy, they have not engaged in DTCA policy.

This policy gap may be filled by the provincial government and other interested stakeholders who have an interest in provincial health policy and leverage to encourage pharmaceutical companies to comply with Canadian law. Responsibilities for health care provision place the provinces in a strategic position for negotiating than the federal government, and may allow them to convince pharmaceutical companies to comply with federal DTCA regulation and law. The physician association staff member I interviewed argued,

¹⁸ Catastrophic drug coverage is subsidization for drug costs based on financial need. This program has replaced drug subsidies based on age in most provinces in recent decades (Hanley and Morgan, 2009).

“Advertising negotiations, that might be possible because you have two sets of interests that are maybe equally matched. You know on one side you have private health insurance companies and public drug formularies – payers – and on the other side, manufacturers. That may be where the political magic happens. If payers feel like they’re paying too much because DTCA is costing them, then they may be willing to put time and resources into tighter regulations despite industry opposition working in the other direction.... I think it’s an easy argument to say existing regulations need to be enforced. I mean you’re doing something illegal right now and that needs to stop and that’s probably the first place to start. I think there’s promise in that.” (Physician Association Perspective, in-person interview, March 22, 2011, 40:42).

It is important to remember that the provinces and territories have a financial interest in having these negotiations successfully completed. As one interviewee argued, “...when provincial governments are negotiating over paying for a drug or not, they’re negotiating with companies that are advertising that may be costing them a lot of money provincially.” (Academic Perspective, in-person interview, March 16, 2011, 40:20). This provides a strong motivation for provincial governments to invest in and see that these negotiations are successful. Provinces would need to be convinced that they do have an interest in DTCA policy. This may be possible if the impact of the status quo on the health care system is better understood.

The negotiations should take place in each province or territory between government authorities and the pharmaceutical industry. In order to make these negotiations as powerful as possible an intergovernmental agreement between the federal-provincial-territorial authorities will be required to maximize negotiating power. If the representatives from these governments come to agreement on the mechanisms and penalties used in these negotiations, they could present a united front in these negotiations and their position would be strengthened. On this topic the Academic interviewee argued,

“...provincial governments, like they would be in a stronger position if they were all banding together and we had one national pharmacare plan.... So in a way they would be in a stronger position if they said you know if they were saying, ‘we’ll pay for these drugs but only under specific conditions ...like we don’t want to see you running any illegal advertising in Canada. If you are, we’ll stop paying for your drug.’ They actually have a fair bit of power as being you know a single payer.” (Academic Perspective, in-person interview, March 16, 2011, 48:05).

The provinces and territories have mechanisms available to them in this option. First, the provinces can select to ban drug from being listed on their provincial formulary until the company has proven that they are not distributing illegal DTCA in Canada. The provinces-territories could select to do this indefinitely, or for a set period, e.g. 12-months at which time they will again review the situation. Health insurance companies often use the provincial formulary as a reference for what they will cover for their customers and the financial penalty would be increased by the participation of these private insurers. By working with private health insurers, such as BlueCross, government will strengthen their leverage in this negotiation. In

order to not penalize patients who may require specific drugs for their treatment, if a patient requires a drug that has been removed from the provincial formulary due to non-compliance issues their physician can apply for a special authority grant (Pharmaceutical Services Division, What is Special Authority).

The second mechanism available to provinces and territories is to impose financial penalties on non-compliant companies. Instead of banning drugs entirely from being listed on the provincial or territorial formulary, the government would reduce the price that they were willing to pay for specific drugs. By establishing a new price that will be paid for drugs that are being illegally advertised the provinces and territories this would in essence impose a tax on that activity. This would allow the provinces to continue to list and use the drug in question while at the same time providing an incentive for the companies to become compliant. This second mechanism is useful as there are some classes where one drug cannot be substituted for another, such as anti-retroviral drugs (HIV/AIDS), where it would be challenging for the provinces-territories to ban non-compliant companies from being listed on the formulary. Where only one treatment exists for an illness, the provinces and territories will likely be unable to penalize companies by removing their product from the provincial formulary. This second mechanism, however, offers to address illegal DTCA while preserving the therapeutic benefits of these drugs.

The primary targets in this policy option are the pharmaceutical companies that advertise through American distributed media. These are the advertisements that are least likely to be subject to enforcement of Canadian law (Marketed Health Product Directorate, personal communication, October 7, 2010). Canadian produced and distributed advertisements on the other hand are much more likely to comply with Canadian law. The restrictions on DTCA in Canada impact the volume of DTCA distributed through Canadian broadcasters and other media so greatly that in 2005 CanWest MediaWorks initiated a charter challenge of the federal law arguing that it put them at a competitive disadvantage to their US counterparts (Women and Health Protection, 2006). The CanWest case demonstrates that if they are enforceable, the laws and regulations limiting DTCA can have an impact on the viability of advertising directly to consumers.

Staffing for this option would include high-level negotiators from the Ministries of Health in each provinces-territories. The negotiating team will require an ADM and executive director, in addition to research staff and an administrative assistant. I propose a team of five people be brought together in each province-territory to be part of this process. The assistant deputy minister will bring authority to the process and will be able to make difficult calls on behalf of the Ministry when they are required. The executive director will bring their knowledge

of specific drugs including the demand for them and options for alternatives. The researchers will ensure that companies that claim to be compliant are actually complying with regulation. Finally, the administrative assistant will provide overall support for the negotiations. These negotiations will take place twice a year. They will only be required to occur with the companies that are not compliant with legislation. This information will be based on the findings of the researchers.

Table 19: Option 3 Time Allotment Provincial-Territorial Staff

Position	Time allocation
Assistant deputy minister	4 hr/month = 2 % of position = .02 x \$155,000 = \$3,100
Executive director	6 hr/month = 4 % of position = .04 x \$82,500 = \$4,400
Researchers	140 hr/month = 100 % of position = \$55,500 = \$55,500 x 2 = \$111,000
Administrative assistant	2 hr/month = 1 % of position = .01 x \$40,500 = \$405
Total \$118,905	

The hours allocated to each month are prorated. Except for the researcher positions, the team members will have minimal involvement in the negotiations. The majority of the time allotted for the ADM, executive director and administrative assistant will go to the meetings that occur twice per year.

In addition to provincial efforts in this option, the Health Products and Food Branch Inspectorate (HPFBI) at Health Canada must take a greater role in compliance monitoring and enforcement of federal regulations. While the provinces-territories will have some monitoring capacity, in that they will verify the compliance of pharmaceutical companies during negotiations and reviews, the federal government should increase its presence for the public and patient health advocacy groups to be in contact with them over non-compliance. I recommend a minimum of two new positions be created in the HPFBI, which are dedicated specifically to DTCA compliance issues. These positions would be full-time positions dedicated to compliance inspection and enforcement.

Table 20: Option 3 Time Allotment Federal Staff

Position	Time Allocation
Investigation Specialist	140 hr/month = 100% x \$55,500 = \$55,500 x 2 = \$111,000
Total \$111,000	

6.3.1 Analysis of Option 3: Financial Penalties

6.3.2 Reduces Public Exposure to DTCA – Yes

If this option is successful, it will affect Canadian’s exposure to direct-to-consumer advertising, as DTCA in Canada would be restricted to legal commercials. Although that result is imperfect in terms of protecting Canadians from exposure to DTCA, it would be in line with federal regulation. I expect that the volume of DTCA allowed under federal legislation and regulation is minimal compared with the full DTCA coming through the US to Canada. If full DTCA were to be eliminated (or mostly reduced), Canadian’s exposure to DTCA would be reduced.

6.3.3 Improves Understanding of DTCA in Canada – Somewhat

This option will improve the provinces understanding of how frequently drugs on their formulary are subject to DTCA. Data can be collected from negotiation meeting notes and combined with information from the MHPD in order to build a national picture of how much, with what frequency, and for what drug classes DTCA is occurring in Canada. Overtime, it will be possible to see whether there is a decline in the trend to advertise drugs to the public. This trend line will inform the federal-provincial-territorial governments how far this approach to the problem of DTCA is effective at reducing the prevalence of DTCA. This criterion is labelled as somewhat for this policy option as there will be no health care system impact data collected.

6.3.4 Cost – Medium

Table 21: Option 3 Total Costs

Item	Cost
Provincial-Territorial staff	\$118,905 x 13 provinces/territories = \$1,545,756
Federal staff	\$111,000
Total \$1,656,765	

In addition to these costs, there may also be legal expenses due to a court challenge (see the next section). It is not possible to estimate what the legal costs would be in this particular situation.

6.3.5 Stakeholder Acceptability - No

This policy option is arguably the most radical of options proposed in this capstone and thus it is likely to be unpopular with all three stakeholder groups.

For **industry**, it will put the provinces into an adversarial relationship with the pharmaceutical companies and there will likely be a court challenge or other repercussions for the provincial-territorial governments. The pharmaceutical industry may challenge the option arguing that DTCA is a federal responsibility; however, as health care is a primarily provincial matter, the provinces could convincingly argue that they are within their constitutional rights to negotiate on this matter.

GPs should definitely be consulted on this option before it goes forward. This option will likely affect physician autonomy in prescribing by limiting the drugs that are covered by the province-territory on their formulary. This is a problem that will need to be addressed according to the physician association interviewee (Physician Association Perspective, in-person interview, March 22, 2011).

The public will likely resist this option, as it will limit the drugs available to them through the formulary. These same drugs will, of course, still be available to be prescribed by physicians, but they will not be subsidized at the same rate for compliant drugs. Patients have a long history of pressuring provincial-territorial governments to cover drugs that they want to be listed on the formulary. The most recent example comes from Ontario where a woman, whose breast cancer was considered too small to be covered for drugs by the provincial drug plan, launched a social media campaign to pressure the government to cover her health costs (Howlett, Priest and Baluja, 2011). This individual was able to stir up pressure on the government, despite a lack of evidence for the therapeutic value of the drug. This will not necessarily occur in option 3, but identifying to the public the reason for this approach may lessen the possible negative public response.

6.4 Option 4: Relieve Pressure on the Health Care System through Education

The final policy option that I will present in this capstone is an education program. Research on direct-to-consumer advertising shows that DTCA increases prescription seeking behaviour and prescription writing habits (’t Jong, 2004; Mintzes et al., 2001; Datti and Carter, 2006). This can have an effect on the physician patient relationship as found in the current research and highlighted in the literature review and expert interviews of this capstone.

Theme 1: DTCA affects the physician-patient relationship.

Research to-date also demonstrates that specific groups are particularly vulnerable to these effects. These groups include but are not limited to individuals who do not understand how regulation on DTCA works because they believe that the ads are pre-screened (Bell, Kravitz and Wilkes, 1999) and patients who use prescription drugs more frequently (Huh and Becker, 2002). This option is designed to act as a barrier between DTCA and the consumer by making consumers more aware of the effects DTCA has on them. Research also demonstrates that physician prescribing is impacted by patient request for drugs. This option would target physicians to prepare them for patient requests and would provide them with an additional source of drug information.

Theme 6: DTCA encourages the consumption of prescription drugs with significant health risks.

As we observed in the case studies educational initiatives have been used elsewhere to change drug consumption behaviour. For instance, in BC and Alberta the provinces have employed the Do Bugs Need Drugs program to reduce antibiotic use.

In the same way that patients place pressure on physicians to prescribe them DTCA drugs, patients also pressure physicians to prescribe antibiotics. As was demonstrated in the case study, education can modify patient prescription seeking behaviour and physician prescribing behaviour. The Medication Management program (MMP) was also effective; however, in that program the education is undertaken by pharmacists. I have selected to model this option on the Do Bugs Need Drugs program because it has the ability to target specific public groups on a larger scale than the Medication Management program. In addition to these concerns, the physician perspective interview identified the MMP as,

“...a real sore spot for the [physician] profession, so anything that’s sort of working on that... we are in discussions with the Ministry and the Pharmacy Association on how to best serve... you know make this program into something that works for everyone and I’m hopeful that those discussions will lead somewhere more positive than what’s been

happening before. But for that reason I would probably leave that aside for a minute because it's sort of a sore spot." (Physician Association Perspective, in-person interview, March 22, 2011, 39:48).

This perspective makes the MMP less desirable as a policy option. If the program is still controversial and in development it is not likely a good option to consider at this time.

The education program will be run at the provincial and territorial levels. The program should be housed within either the Ministry of Health or the Ministry of Healthy Living. The program will be led by an advisory board composed of at least one member from each of the following groups: physicians, nurses, pharmacists, education experts, DTCA experts and government representatives. The advisory board will meet four times a year or as required. This advisory board will work together to develop a strategic plan for the program. They will identify what types of educational materials will be required for the program. On this topic, the academic perspective can provide some advice,

"I think [that education] is sort of part of the whole management side and that we could be putting much more money provincially into having independent information on medicines.... And that it's sort of not there in the sense that we have the web that people use to search for information; and not much guidance in terms of what's trustworthy or not trustworthy information or even information to answer your own questions. So there's a side of that, that's the information itself.... The other one that I think is really interesting is how about linking that to healthy scepticism. To sort of some kind of framing that allows people to see the marketing messages within a more sceptical view.... [T]here have been some groups in the US that have directly deconstructed that. And I think that that's an interesting model." (Academic Perspective, in-person interview, March 16, 2011, 2:14:01).

The advisory board will have to make this determination based on the cultural, political and economic characteristics of their province. The advisory board will additionally give general direction to the content of the materials. Staff in the program will take the guidance given by the Board and will develop the materials. These will then be returned to the advisory board for approval.

The content of the educational materials should be centred on two important areas: advertising awareness, and drug class information. Advertising awareness will educate participants:

- On the purpose of DTCA,
- the techniques used by advertising companies to make the ads convincing, and
- the information which is not included in the ads (e.g. risk information).

The advertising awareness part of the educational materials should be interactive and use examples of DTCA to give the participants the opportunity to test their new knowledge against examples. The second area of teaching, drug class information, should contain specific

information about drug classes that are relevant for each group. For instance, the advisory board should identify the most common drug classes for elderly people and then balanced information about these drugs should be included in the educational materials. This component of the program will satisfy a frequently requested policy for fair and balanced drug information. By targeting, the educational materials to specific groups the program will maximize the time spend with these participants by arming them to deal with the DTCA that is mostly likely to affect them. One group that the program should target is physicians. In the Do Bugs Need Drugs BC program it has been possible to target and have physicians participate by advertising in medical journals and through organizers of physician continuing education (Do Bugs Need Drugs BC, January 20, 2011). It is important that physicians be included in this education program as they are the primary prescribers in Canadian health care and are affected by the influence of DTCA over patients. It may be possible to partner with medical schools on including these modules in physician training. In the DBNDs case study, the programs demonstrated their ability to partner with nursing program successfully. Similarly, the education option may offer the opportunity to include media awareness and drug information education to new medical practitioners.

The cost will be kept low because the teaching is not delivered by program staff but by other organizations. For example, if the program wants to educate school children about DTCA, it could work with the Ministry of Education to develop material that can be delivered in provincial classrooms. Teachers would then deliver the program as part of provincial curriculum and their salaries would be paid for by the Ministry of Education. The program would pay for staff time to develop materials and train the teacher in the program. It would also pay for the cost of printing/making educational materials. This later aspect will encourage more uptake. It is important to make the program available to as many people who are willing to teach it (Do Bugs Need Drugs Alberta, January 28, 2011). In this way, the program is able to run on a modest budget.

While this voluntary adoption approach has been used in other programs successfully (Do Bugs Need Drugs BC and Alberta) it does require work to convince groups to participate. The program staff may find they encounter difficulty in developing immediate buy-in. The individuals who the program will target to be the advocates/teachers are generally very busy people. For example, in the Do Bugs Need Drugs program, one interviewee commented,

“...public health nurses were involved to a certain capacity initially in parts of the province, their jobs have now been added to significantly over the years and to such a point that they are no longer able to be as actively involved in the program as much as they once were. So, finding man-power to actually implement the program has probably been our largest challenge.” (DBNDs BC, January 20, 2011, ln 186-189).

A staff member (program coordinator) who works for the project will advocate in the community to specific groups for uptake. This staff member will build relationships with educational organizations (such as the Ministry of Education and school boards), health care facility management (such as regional authorities for health and nursing programs at universities) and community groups (such as the YMCA). A second staff member (evaluation analyst) will be in charge of data collection and evaluation. Data that should be collected includes, but is not limited to how many people participate in the program annually. How many were exposed to full DTCA? How many were convinced to see a doctor after watching a promotional ad? How many received a prescription and how many did not? At what rate were the program learning outcomes achieved by participants? To run an educational program of this scope at least two staff members are required. Additional staff may be required depending on the scale of the program.

This option uses a train-the-trainer model. Individuals are trained to deliver program materials on their own (Do Bugs Need Drugs BC, January 20, 2011). Strategically placed individuals such as teachers and nurses are identified by staff to participate in the program. These individuals then become trainers for the program, teaching the supplied materials to groups of individual that they have access to such as students and patients (Do Bugs Need Drugs BC, January 20, 2011). Program materials would be available on-line through a specific website and would be free and available to all who were interested in using them. In addition, the program would develop materials that targeted specific vulnerable groups such as children, the elderly and the ill.

Educational materials can be shared between provinces and territories as they are in the Do Bugs Need Drugs programs. It is economically advantageous to share resources. Do Bugs Need Drugs Alberta is able to save money on printing materials by buying them in bulk and then selling them at cost to BC. During their interview on this topic a representative for DBNDs Alberta argued,

“[w]ell, the materials do cost something, but you know there are tremendous economies of scale and partnering with BC. Like our print materials...the costs come way down if we’re printing for both provinces, so that’s been a big plus – it’s really helped to contain costs. (Do Bugs Need Drugs Alberta, in-depth interview, In 309-311).

This, however, could only work if provinces were willing to share resources.

Finally, evaluation should be built into the program through a feedback mechanism at the delivery level. For example, a public health nurse could present the course at a community centre. At the beginning of the course the instructor could administer a test that identifies each participants existing level of knowledge. At the end of the class, the participants could take the

test again, identifying whether the participant’s knowledge increased after completing the course. This test could be written or could be oral in order to be inclusive of different literacy levels.

6.4.1 Analysis of Option 4: Education

6.4.2 Reduces Public Exposure to DTCA - Somewhat

While this option will not reduce the public’s exposure to DTCA, it may provide a means to reduce the effectiveness of DTCA. Evidence from the Do Bugs Need Drugs programs indicates a correlation between the program’s initiation and attitudes towards antibiotic consumption. For example, educational interventions in Edmonton demonstrated that they reduce self-reported expectations for an antibiotic prescription by approximately 10 percent and that participants increased their knowledge on the topic by 10 percent (Carson, et al., 2002). These antibiotic intervention programs also target physician prescribing. The BC program found that physicians in BC, where the program is offered, were less likely to treat bronchitis (a viral respiratory infection) with antibiotics than were physician in the rest of Canada (BC Centre for Disease Control, 2008, p.4).

6.4.3 Improves Understanding of DTCA in Canada – Somewhat

Initiating an education program will improve governments’ understanding of DTCA in Canada by providing a forum for Canadians to speak on this subject. This project will allow researchers to collect public opinion data on DTCA, to test the public’s knowledge in this policy area, and to gauge how DTCA has affected participant’s lives. By using this program in part to collect data, Canadian governments will be provided with a snap shot of DTCA in Canada.

6.4.4 Cost – Medium

Table 22: Option 4 Total Costs

Item	Cost
Staff salaries	Program coordinator = \$82,500/year Evaluation Analyst = \$55,500/year Administration assistant = \$40,500/year
\$178,500	Total: \$178,500
Advisory board stipends ¹⁹	\$100 per hour per specialist x 5 specialists x 3

¹⁹ Based on an estimate of a 4 hour meeting.

Item	Cost
Government representatives = no compensation \$6,000	hours per meeting = \$1,500/meeting 4 meetings per year x \$1,500 = Total: \$6,000
Print materials \$90,000	Goal: 9,000 participants/year. Capacity: 15 people/session = 600 sessions/year Materials = \$10/person. Total: \$10 x 9,000 = \$90,000
Provincial total \$274,500	
National total \$274,500 x 13 = \$ 3,568,500	

Though the costs for this program are Medium, it should be noted that unlike option 1 and 2, this option would be permanent. The \$3,500,000+ annual cost would be experienced every year and so this needs to be taken into account when recommending options.

6.4.5 Stakeholder Acceptability - Somewhat

The experiences of staff in the Do Bugs Need Drugs program can provide an idea of how **industry** will react to a similar program for DTCA. Neither program has been seriously challenged on a regular basis by industry. At the same time, educational initiatives are not immune to industrial resistance. For example, Do Bugs Need Drugs Alberta was recently threatened with lawsuit over some content in their educational material. They told their story during our interview:

“The second year of the grant we were also asked to create something for the adult members of the school community.... But part of that document came out very strongly against the use of non-alcohol-based hand sanitizers.... But the manufacturer of that product who had convinced at least Edmonton and Calgary public schools when they, I think, met with some resistance from one of those school boards, threatened to sue us about the information that was on the website... we were told to change the wording, so that’s what were in the midst of doing right now. So you talk about industry influence? There’s one right there. It’s dollars....” (Do Bugs Need Drugs Alberta, Ministerial Interview, January 28, 2011, ln 339-352).

DTCA is likely to be more controversial than the antibiotics one. One interviewee argued,

“[t]he antibiotics [education programs], you see politically in a way those ones are more palatable because those are not the big sellers in terms of drugs. They’re mainly generic drugs and they’re mainly short term use; they’re not the chronic use expensive drugs that are really the big....”(Academic Perspective, in-person interview, March 16, 2011, 2:14:01).

If selecting this program option, program staff need to expect a reasonable amount of industry resistance to it. The staff can protect the program by not identifying any specific ad in the materials and by providing evidence-based research for the drug information.

GPs will likely not resist an educational program such as this one, as there are many educational programs that currently exist that target GPs, such as EQIP and PAD. GPs and their associations should be consulted during the development of this program in order to capitalize on their knowledge and experience with DTCA. Moreover, physician groups may support this option as indicated in the Physician perspective interview, "...given that the provincial government's role is so limited in controlling DTCA, but their interest is great because they pay for so many of these drugs that probably education of physicians and patients is their best that they can actually do something for it." (Physician Association Perspective, in-person interview, March 22, 2011, 12:08).

The public is unlikely to resist this program, as it does not limit their access to prescription drugs as option 3 does. It will also provide them with additional information about drugs and DTCA, which I found, was a desirable product in option 2. This option will likely only benefit the public and so it is unlikely that resistance will occur.

7: Recommendations

I recommend that policy options one (working group) and four (educational) be implemented immediately. While the working group does not reduce the public's exposure to DTCA, it will help policy makers fully establish what public health and health care problems have been and are being caused by DTCA. It will therefore increase our understanding of DTCA in Canada. When this project is complete the federal government, along with the provincial governments will better understand what DTCA means in Canada. This will prepare them for future policy development in this area. In addition, if provincial health care systems are substantially affected by DTCA this project will make the case to include the provinces in DTCA policy, an inclusion that I believe is necessary for good health policy. The cost of the program will be spread between the provinces and thus individual the financial burden of running the research project is reasonably low. If some provinces are unable to afford the cost of running their part of the research project, Health Canada can work with CIHR or the Canadian Institute for Health Information to find funding to support that research. Finally, this option poses little threat for industry resistance. In all, my research demonstrates that the data from this project will fill a large existing data gap.

The second option that I will recommend is an educational program. This program, though it primarily falls within the 'somewhat' category in my analysis will be a positive influence on the status quo. At this time, the public has not really been engaged by government on DTCA. The only discourse on DTCA that the public is currently exposed to is that of the DTCA itself. If Canadians are not offered an alternative policy option to DTCA, how can government expect them to care about this in future policy development? In addition, if the public is not made aware of the tendency for DTCA to exclude important health information they will likely not suspect that it does so. These are areas that an educational program can make a difference in for this policy area. For these reasons, I recommend its implementation.

8: Conclusions

DTCA is an important but often overlooked factor in health care in Canada. The research and analysis that I completed for this project was conducted with the dual goal of bringing DTCA on to the policy agenda, and advancing policy oriented research in this area. The often-casual way that direct-to-consumer advertising is referred to by political bodies and the significant regulatory and enforcement gaps that exists are a source of concern. As policy developers, we should be on our guard when presented with information on drugs from biased sources, because the US experience demonstrates that often-important health information is omitted or underplayed indicating that this is not an adequate source for drug information. The CanWest court case of 2005 and annual increases in DTCA spending indicate that this is an area of public policy that will become increasingly substantial as time goes on. If the public believes that DTCA is a legitimate source of drug information, it may be difficult to limit drug promotion to the public in the future. For these reasons, I believe that DTCA policy is at a critical point in its development; action must be taken now, if it is to be taken at all. That is why it is my belief that it is the duty of Canadian policy makers to act of DTCA policy as soon as possible.

8.1 Limitations

The focus of this capstone has shifted several times as I learned more about the subject of direct-to-consumer advertising. Some of the limitations of this project are:

- **Access to information.** As has been a theme in this project data on DTCA in Canada is limited. There is a chance that important aspects of DTCA in Canada have been overlooked in this project because of limitations on information access and gaps in knowledge on the effects of DTCA on public health and the health care system.
- **Balanced views of DTCA.** The majority of research on DTCA is focused on the negative consequences of DTCA. Though I have endeavoured to include these perspectives in this project, it was challenging to find research data that advocated for the benefits of DTCA.
- **Industry perspective.** Efforts were made to include an industry perspective in this research; however they were unsuccessful because of time constraints and the complexity of finding willing participants.

8.2 Future Studies

The important contribution of this Capstone has been to identify what we do not know about direct-to-consumer advertising in Canada. While the recommendations that I have identified are important, they are first steps in modernizing Canadian DTCA policy. Future research projects in this area should consider what can be done to make the status quo more effective. This will only be applicable if the working group finds that DTCA does have negative consequences for public health and the health care system in Canada. If this is not the case then future research should consider what other policy options are available to Canadian governments. Other future studies should include: how DTCA impacts different groups (e.g. the chronically ill, women, and under privileged groups); whether there is any difference in effectiveness between the three types of DTCA; whether DTCA provides any health or health system benefits; and, finally, what the scope and impact of on-line DTCA.

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10: Appendix A – Interview Transcripts

In order to limit the length of this capstone I have not included most interview transcripts in this work. I have included one, below, as an example. All other transcripts are available upon request.

The following interviews were conducted for this project:

- Academic Perspective, a DTCA and health care researcher.
- Physician Perspective, a representative from a physician association.
- Drug Use Optimization, BC Pharmaceutical Services Division.
- Pharmacy Services Agreement, BC Pharmaceutical Services Agreement.
- Marketed Health Product Directorate, Health Canada.
- Advertising Standards Canada, DTCA preclearance.
- Pharmaceutical Advertising Advisory Board, DTCA preclearance.
- Do Bugs Need Drugs BC, antibiotic use education program.
- Do Bugs Need Drugs Alberta, antibiotic use education program.

10.1 Academic Perspective

The following are excerpts from an interview conducted on March 16, 2011.

“There’s a subset of ads that either Advertising Standards Canada, or the Pharmaceutical Advertising Advisory Board and...it’s up to the companies to voluntarily whether they want to submit to either of those agencies in order to see whether those agencies consider whether this would be legal according to the current interpretation of the law. So it’s a, that tells you, that would give you a subset and certainly it should be public, it’s crazy that it’s confidential.” (Academic Perspective, in-person interview, March 16, 2011, 3:56).

“It would be completely understandable that people would think it was legal because they see it...any newsstand is full of magazines that have these ads in them. So it’s a kind of interesting area, because it’s an area where there’s a difference between what’s in the law and how it’s being enforced and we’re quite different from other countries that have the same law as us in terms of where we’ve in a public policy...”

Interviewer: In terms of enforcement? Or...?

Yes, enforcement and the reinterpretation of the price advertising clause. So that’s one where as a result of that interpretation we have ads on the TV that, I’ve shown them at meetings in Europe and people are really...can’t believe that that’s the case [that the advertisements are allowed on TV].” (Academic Perspective, in-person interview, March 16, 2011, 7:13).

“I’d been in a consultation on DTCA in 1999 which...by Health Canada, and where they were actually putting forward compromise solutions for introduction and it was mainly industry there...they weren’t able to get agreement and partly, the industry was still pushing for the whole thing, in terms of introduction. And then those who weren’t in line with the industry were looking at it more from a public health perspective were saying wait...we should be stepping back and looking at what are we trying to achieve with the legislation and in terms of regulation of promotion in general because

there's also major problems with enforcement of promotion to physicians. So we should be sort of stepping back from what's going on and looking at you know if we want to make a policy change, what is the aim of the policy change and which direction should we be looking at? Rather than this is the status quo, this is the US and we should be going for something in the middle." (Academic Perspective, in-person interview, March 16, 2011, 8:39).

"There was a massive change in interpretation of a regulation that was brought in in 1975. So you had 25 years where that was a way that companies could only list the name, price and quantity, so in print...a list of basically products and their prices as a way of promoting generic drugs. And then in the year 2000 the first of those ads, the first one I saw was December 31, 1999 – it was a Zyban ad for quitting smoking and it was linked to the new year. I immediately fired off a complaint to Health Canada about this illegal brand name advertising – I couldn't believe it. And then in the few months afterwards there'd be press coverage on this and there would be people quoted as saying, 'in Canada you're allowed to say the name, but not the indication' or vice versa." (Academic Perspective, in-person interview, March 16, 2011, 10:28).

"...it's the Ralph Nader consumer group, they repeatedly will start action against the FDA for non-enforcement of duty, non-administration of duty, non-enforcement of the law. And generally they just announce a case and often whatever it was the FDA wasn't doing, they'll do. So we have a different situation here because it's much harder to sue the government. And it does mean I think that they're under pressure from the industry in terms of legal action but not really under pressure from the public." (Academic Perspective, in-person interview, March 16, 2011, 17:29).

"...there was a tobacco advertising case that came to the Supreme Court in 1995, and it's been since then that the pharmaceutical...I mean directly the pharmaceutical industry referred to it as a reason that this law was also challengeable and that may also be you know I don't know because it's hard to get a clear answer on something like this why the shifts in enforcement have occurred, but I've certainly had people from Health Canada say that they are concerned that there could be another challenge." (Academic Perspective, in-person interview, March 16, 2011, 19:50).

"...I find it interesting the sort of statements that there isn't any harm from [DTCA] because in fact those statements were being made before the Vioxx disaster and they've continued to be made after the Vioxx disaster. If you bring it up as an issue, then it's dismissed as a red herring, but in fact you're looking at a large increase in the use of a product which ended up leading unnecessarily to thousands of heart attacks and deaths." (Academic Perspective, in-person interview, March 16, 2011, 32:16).

"One of the options was that when provincial governments are negotiating over paying for a drug or not, they're negotiating with companies that are advertising that may be costing them a lot of money provincially." (Academic Perspective, in-person interview, March 16, 2011, 40:20).

"Nobody has actually done that kind of an economic analysis of what is the actual, what is the actual cost...or what is the benefit like the industry will claim that you get more... you know people recognize their symptoms earlier, they then go into the doctor, they get earlier care, you're averting hospitalizations and it's saving money. On the other hand you could say that we may end up being actually more vulnerable to higher costs than say they are in the US because we combine a situation where we have...we don't pay any charges to go into the doctor so in terms of if you have something that's out there that's stimulating extra doctor visits that are not bringing in that benefit, that it can end up costing the province a lot more. That if it's also causing an increase, you look at something like Vioxx and Celebrex, what you had was in Ontario and Quebec...actually between Quebec and Alberta I think it was you really didn't have limits in terms of provincial payments for those drugs for people who were say over sixty-five. You had a large expansion in the number of people who were taking non-steroidal anti-inflammatory drugs, so the class that these are part of because you had these two newer drugs that were being so heavily promoted and they were being promoted as being safe and people who couldn't use those drugs safely otherwise. So you saw this real increase in the whole class. There's a comparison between BC and Ontario where in BC it was flat because they weren't paying for it at all to begin with and then eventually the provincial government just paid for them third line. You had to fail on two other drugs to get them. And it's a special authority procedure so it's where the doctor has to put in an application and have it approved. And in Ontario they actually had an increase in hospitalizations from stomach bleeds over...that paralleled in the number of increases the increase in use of these drugs and the whole class. And in BC you didn't have it happen, you didn't have that population increase and you didn't have the increase in stomach bleeding. And the irony is that they were being sold as being safe in terms of stomach bleeding, but they weren't safer than nothing.... So if you look at that you already have evidence that fuelled by promotion in Ontario, they actually ended up with more hospitalizations of elderly people from stomach bleeding." (Academic Perspective, in-person interview, March 16, 2011, 40:37).

"Well, I thought your policy proposal that I thought was very interesting to say that look provincial governments are negotiating with the companies over reimbursement of specific drugs. Every time a new drugs comes to market the company will apply to each provincial government to get it reimbursed...provincial governments, like they would be in

a stronger position if they were all banding together and we had one national pharmacare plan.... So in a way they would be in a stronger position if they said you know if they were saying, 'we'll pay for these drugs but only under specific conditions. So we don't want to see you're going...like we don't want to see you running any illegal advertising in Canada. If you are, we'll stop paying for your drug.' They actually have a fair bit of power as being you know a single payer." (Academic Perspective, in-person interview, March 16, 2011, 48:05).

"What I found interesting is it's something that actually in New Zealand PHARMAC [a crown corporation that manages all of the drugs in New Zealand] tried to bring in. They tried to bring in an agreement within their and they weren't able to in the end but they had proposed it... So in New Zealand PHARMAC tried to bring a clause into all of their contracts to say that they wouldn't pay for the drugs if they were being advertised to the public and they were unsuccessful.

Interviewer: And what was the cause of their, um, what caused them to be unsuccessful?

I think that, um, I don't think that there was a legal challenge to that I think it was a threat that because direct-to-consumer advertising... essentially they were it was that they were overstepping their mandate because direct-to-consumer advertising is legal in New Zealand that they could not... they were not able to bring something into their contract that prevented the companies from carrying out a legal activity. (Academic Perspective, in-person interview, March 16, 2011, 49:40).

Interviewer: Cause the one thing that...one of the reservations that I had about that option even though I thought it would be interesting given the success of the generic drug agreement was that because brand name drugs are so different in some ways in the sense of having options or alternatives to move to, if you were to say to one specific drug company well if we see advertisements for this drug or for drugs that are being made by your company that are on our reference list then we're not going to allow them to be on there anymore. Then there is a risk that there isn't necessarily an alternative to move to for the province, so in a way it could be an empty threat.

Right so let's say if you had a situation so in many drug classes you have a whole range of different things available so it's not really...it's no big deal. If you're in a situation where you're saying look, you've got even as a second line drug for somebody who's seriously ill who's failed on first line drugs, like let's say HIV/AIDS drugs that somebody has failed on first line therapy, they have to go to second therapy...so you would have, the provincial government would have a problem in terms of saying that they wouldn't buy the drug, if they advertised, if the company advertised it. Now if the advertising activity is illegal then I think that they have a bit more something, you know a bit more of a negotiating power.... They could levy their own financial penalties for instance. That there are other ways that you can kind of get at saying, 'look you're only going to pay for things under certain conditions, you'll pay a specific price under these conditions and not under other ones'. So it's possible that they would have problems bringing that in certain cases and that you might have, there'd be a legal challenge right away but they might win the legal challenge as well. (Academic Perspective, in-person interview, March 16, 2011, 53:00).

"Like education alone is unlikely to be successful if you have no enforcement of regulations." (Academic Perspective, in-person interview, March 16, 2011, 56:42).

"Then it goes to the [Health Products and Food Branch] Inspectorate and we have nobody in the Inspectorate who is specialized in dealing with information in advertising. So what happens at the Inspectorate level is if there's if there's a concern about an advertising campaign...let's say there's a complaint made about a direct-to-consumer advertisement let's say it goes to Health Canada in Ottawa it goes to the [Marketed Health Products Directorate] maybe via one of the self-regulatory agencies a complaints been made to them and then...what happens then is that the complaint will be sent to the regional office where the company has its head office. So you can have advertising billboards for Celebrex – 10th avenue [Vancouver] and it'll go to Montreal, the complaint because that's where Pfizer will have its head office. And then at that regional office the person from the Inspectorate is dealing with inspection of factories, dealing with good manufacturing practices, all kinds of stuff, tampering, all kinds of things and [DTCA non-compliance]. And I don't know whether it goes to the top of the pile or the bottom of the pile, but I six months later – our first communication back" (Academic Perspective, in-person interview, March 16, 2011, 1:01:15).

"And it is a point to say that we have a problem in Canada that regulation of marketing is at a federal level, administration of health services is at a provincial level; so the idea to say that provincial governments might want to consider getting involved, I think that it makes sense from a policy perspective...but it's interesting that that's not the response that you've had." (Academic Perspective, in-person interview, March 16, 2011, 1:19:19).

"You know the advertisements can bring people into the [physician] office, often informing them with the symptoms that they should be mentioning in terms of a specific diagnosis and even a recommendation for what they might ask for to treat them. If you have that combined with the sales representative also having given the same message to the doctor

and provided them with free samples that you know you probably get an interactive effect in terms of bang for the marketing buck. I know there was just this really interesting documentary on Yaz and Yasmin... where one of the things they did was interviewed young women who'd had prescriptions for Yaz and asked what their doctor had told them when they were giving them the prescription and it was amazing because essentially they told the interviewer marketing messages... things like you know it's better for your skin, it helps against mood swings, things that were these extra kind of essentially marketing messages that they were saying they were getting from their doctor – not even from the ads.” (Academic Perspective, in-person interview, March 16, 2011, 1:24:18).

“But I see it as in some ways... it has a side that is you know because of that sort of market expansion side to it of bringing people into the doctor that it's got the whole sort of disease mongering side. The sort of shift in threshold of what kind of condition you might consider a medicine for is a real problem with it as well.... Or even the side where the distinction between normal life and something that might require a prescription medicine has really been shifted.” (Academic Perspective, in-person interview, March 16, 2011, 1:26:18).

“In a way you have... the other thing that direct-to-consumer advertising will do is it provides the idea of the pill as the magical solution... is actually supported as well. And what's amazing is in the US, they have stronger requirements in terms of mention of harm in pharmaceutical advertising, generally, than we do – right? They have what's called fair-balance provision. That means in the DTC ads they have to in the audio as well as the visual they can't just flash text that says 'may cause death', they actually have to say it. Our enforcement of our law and the codes that are used to enforce our law are much more similar to New Zealand's. Every ad you see in New Zealand would be illegal in the US. They don't have harm information in the audio at all.” (Academic Perspective, in-person interview, March 16, 2011, 1:32:44).

“I thought it was very interesting that you looked at it and you said 'o.k. in a way we have a policy problem at the federal level in the sense that the policies that have been brought in to deal with... mainly within the last decade and a half we've had a grown in this marketing technique that really was hardly around before the 1990s... the policy response that we've had in Canada is... o.k. the cross border stuff we sort of pretend it doesn't exist makes no sense really.' In the sense that we know that technically those ads could be replaced that other ads at other times that have been illegal in Canada that have come from the US... I think there was a time period, for instance, where they had cigarette ads and we didn't... I know that they replace some ads with Canadian ads, like technically there's no problem with doing it... If something is illegal in Canada the government can block it. Pharmaceutical manufacturer that's selling their products in Canada, they're US ads, they could be blocking with a Canadian IP address from seeing those ads, they just don't because nobody forces them to.” (Academic Perspective, in-person interview, March 16, 2011, 1:35:58).

“I think that that kind of advertising on television came in after the tobacco advertising decision here and after we'd already had our first consultation spearheaded by the federal government about introducing this advertising. So I think that there was a political decision not to go there.” (Academic Perspective, in-person interview, March 16, 2011, 1:39:27).

“You have this major mismanagement among older people where a lot of older people are being harmed by polypharmacy – really a massive, massive problem with misprescribing among the elderly. That could certainly be managed way better than it is now.” (Academic Perspective, in-person interview, March 16, 2011, 1:50:01).

“[France's] sales representative charter, it's kind of interesting because it's a model that's not that far from what you're talking about... some of the things you're talking about. The industry association and the Haute Autorité de Santé (HAS) which is sort of... it's not part of the government it's more like crown corporation, but they set allowable prices for... and for different medicines they might reimburse them 100 percent, 80 percent, 60 percent, 20 percent or not at all. So they'll set the reimbursement level depending on whether they think there's an added therapeutic value or not. And HAS actually is involved a bit in drug information and drug guidelines and actually they evaluate each drug to see if it has added therapeutic value compared to what exists beforehand. So it's an agreement between them and the Sales Representative Association – the Charter – that if the company does not respect the Charter there's a threat of reducing the allowable price. So I thought it was a similar model [to your option] in terms of economic sanctions.” (Academic Perspective, in-person interview, March 16, 2011, 1:58:06).

“I think [that education] is sort of part of the whole management side and that we could be putting much more money provincially into having independent information on medicines and that anytime you have a survey of the public, 'what do they want' they want that kind of information, that's clear. And that it's sort of there are not there in the sense that we have the web that people use to search for information; and not much guidance in terms of what's trustworthy or not trustworthy information or even information to answer your own questions. So there's a side of that, that's the information itself. Yes, again it would probably be one of those cost effective interventions. The other one that I think is really interesting is how about linking that to healthy scepticism. To sort of some kind of framing that allows people

to see the marketing messages within a more sceptical view. There might be some way of looking at that within the background of tobacco advertising, for instance is it more effective to ban the advertising or is it effective to allow it to run and then run anti-ads? And I think, o.k. first choice is probably to ban the advertising. Running anti-ads isn't a bad idea, there's been some interesting stuff in the US...there have been some groups in the US that have directly deconstructed that. And I think that that's an interesting model. But for it to work it has to be...there's a volume effect that has to be taken into consideration. So, if you tax pharmaceutical advertisers and you say, 'everytime an ad runs on US TV in Canada we're going to tax you because we're paying for your drugs. We're going to tax you a certain amount that will allow us to pay for an equal amount of advertising space for anti-ads about your product.... The antibiotics ones, you see politically in a way those ones are more palatable because those are not the big sellers in terms of drugs. They're mainly generic drugs and they're mainly short term use; they're not the chronic use expensive drugs that are really the big.... 'Are you taking more than five drugs at once? This is called polypharmacy and your medicines could be interacting with each other. Bring your brown bag to your pharmacist we have a day coming up.' Those kind of things, those are not product specific, but they are more like a general context one...hard to know what would be effective.'(Academic Perspective, in-person interview, March 16, 2011, 2:14:01).

11: Appendix B – Interview Consent Forms

Where required, one of the following consent forms was used for interviews.

11.1 Expert Interviews

Elite Interview Consent Form

Addressing the Health System Impacts of Domestic and International Direct-to-Consumer Advertising in Canada

SFU Study Number: 2010s0720

Elite Interviews

Principal researcher: Caitlin Roberts
Masters of Public Policy candidate
Simon Fraser University, Vancouver, Canada

Supervisor: Judith Sixsmith
School of Public Policy
Simon Fraser University, Vancouver, Canada

You are invited to participate in a research study being conducted by Caitlin Roberts, a student in Simon Fraser University's Master of Public Policy program. This research will complete a requirement to earn a Master of Public Policy degree. The supervisor for this research is Judith Sixsmith (jsixsmit@sfu.ca), Professor for the School of Public Policy, Simon Fraser University.

Purpose of the research: The purpose of this interview is to discuss the policy options which I have proposed to address the negative health system impacts of direct-to-consumer advertising for prescription drugs. I hope to collect your expert opinions on the policy options and use this information to inform the recommendations of this research study. Your participation in this interview will provide insight into the feasibility of the policy options which I have formulated for this project. By participating, you are contributing your expertise to policy recommendations in a significant area of health policy.

Voluntary participation:

Your participation in this research is entirely voluntary. · You will be asked questions about the topic described above and may be asked for your own opinions. This will take between 30 minutes and one hour and will be audio recorded with your agreement. · Whether you participate or not in this research, it will not affect any past or future relationship with the investigators or Simon Fraser University.

Confidentiality: Your anonymity will be protected through the following strategies:

- A pseudonym will be substituted for your name in the transcripts, reports and any publications related to this project.
- When your organization is referred to in the transcript, the highest level (e.g. Ministry) will be substituted for the branch or division you work for.

While I will protect your anonymity, I cannot promise confidentiality if the interview takes place by phone or e-mail as they are not confidential mediums.

The audio data collected during this interview will be stored on a flash drive or made into a hard copy and kept in a secure, fire-proof cabinet when not in use. The data will be stored for a period of two (2) years following the completion of the study and then it will be destroyed.

Risks: I have not obtained permission from your employer to conduct this interview; however, there are no risks associated with the study other than those encountered by you in the aspects your everyday life. Refusal to participate will not have an adverse effect on your employment, or the results of the study. You are free to stop your participation and exit the interview at any time and you do not have to provide a reason for this.

Questions: Research results can be obtained by contacting Caitlin Roberts, caitlinr@sfu.ca. If you would like a copy of the transcript of your interview, one will be provided to you upon request. This study has been approved by the Department of Research Ethics at Simon Fraser University. If you have any concerns or complaints about this project, please contact Dr. Hal Weinberg, Director of SFU's Office of Research Ethics, at hal_weinberg@sfu.ca or 778-782-6593.

Consent:

I have read or heard aloud the details of the study and what it will mean if I participate. I have had a chance to ask questions and all of my questions have been answered. I understand that the interview will be audio recorded and transcribed to make sure that my responses are reported correctly. I also understand that parts of the interview will be included in the final capstone (thesis) report or other publications, although my name and identifying information will not be included. I understand that I can stop or cancel my participation at any time.

I, _____ (print name) agree to participate in this study.
Signature: _____ Date: _____
(DD/MM/YYYY).

11.2 Ministerial Interviews

Ministerial Interviews Telephone/E-mail Consent Script

Name of participant: _____

Thank you for considering participating in this study. The purpose of this interview is to discuss the policies and strategies which _____ (organization name) is currently using which relate to advertising. You have been selected because of your expertise in _____ (name area of expertise). The information collected during this interview will be used to develop case studies for this research project. I am the primary researcher for this project and I can be reached at caitlinr@sfu.ca.

This will take between 30 minutes and one hour and will be audio recorded with your agreement. Your participation in this interview will provide significant insight into how your organization reacts to advertising which negatively effect your health system. By participating, you will have the opportunity to voice your opinion in an important area of public policy.

Your anonymity will be protected through the following strategies:

- A pseudonym will be substituted for your name in the transcripts, reports and any publications related to this project.
- When your organization is referred to in the transcript, the highest level (e.g. Ministry) will be substituted for the branch or division you work for.

While I will protect your anonymity, I cannot promise confidentiality as phones and e-mail are not confidential mediums.

If you would like a copy of the transcript of your interview or a copy of the final report one can be obtained by contacting me at caitlinr@sfu.ca. The audio data collected during this interview will be stored on a flash drive or made into a hard copy and kept in a secure, fire-proof cabinet when not in use. The data will be stored for a period of two (2) years following the completion of the study and then it will be destroyed.

If you have any concerns or complaints, please contact Dr. Hal Weinberg, Director of SFU's Office of Research Ethics, at hal_weinberg@sfu.ca or 778-782-6593. The faculty supervisor for this research is Judith Sixsmith jsixsmit@sfu.ca.

I have not obtained permission from your employer to conduct this interview; however, there are no risks associated with the study other than those encountered by you in the aspects of your everyday life. Refusal to participate will not have an adverse effect on your employment, or the results of the study. You are free to stop your participation and exit the interview at any time.

If you agree to participate in this study please print a copy of this form, put a check mark beside 'yes', and put your signature and the date below. After you have signed the document, please scan and sent it to

caitlinr@sfu.ca. If you do not have access to a scanner, you can send the document to the following fax number 778-782-5288, attention Caitlin Roberts.

If you do not agree to participate in this study, please indicate this verbally or by e-mail to the primary researcher.

Consent:

I have read or heard aloud the details of the study and what it will mean if I participate. I have had a chance to ask questions and all of my questions have been answered. I understand that the interview will be audio recorded and transcribed to make sure that my responses are reported correctly. I also understand that parts of the interview will be included in the final capstone (thesis) report or other publications, although my name and identifying information will not be included. I understand that I can stop or cancel my participation at any time.

Do you agree to participate in this study?

Yes _____

No _____

Signature _____

Date _____

(DD/MM/YYYY)

Addressing the Health System Impacts of Domestic and International Direct-to-Consumer Advertising in Canada
2010s0720

12: Appendix C – Interview Schedules

The following interview schedules were used as guides for the interviews conducted in this capstone.

12.1 Ministerial Interviews

Introductory script

During this interview I will be conducting a semi-structured interview. I have developed several topics which are designed to elicit open-ended responses. There may be times during the interview in which I ask you for further clarification about a response or I press you for further information about a particular topic. These actions are designed to ensure that I better understand your responses and will result in less interpretation on my part during my analysis of your data.

At the end of the interview I will provide time for us to debrief about the interview and for you to add any additional information which you feel should have been covered during the interview.

Topics

Observations of direct-to-consumer advertising

4. Drug families
5. Languages
6. Canadian regulations

Observed benefits/harms

Human impact/health service impact

Existing programs which control for the impacts of direct-to-consumer advertising

1. By the province
2. By health organizations
3. Non-governmental/non-profit
4. Observed benefits of the programs?

Programs to counteract other advertising campaigns

- E.g. Smoking and alcohol.

Barriers to minimizing the harmful effects of direct-to-consumer advertising

- Dynamics of health care delivery
 1. Demand for products and services
 2. Patient-driven care

Debrief

12.2 Expert Interviews

Introductory script

During this interview I will be conducting a semi-structured interview. I have developed several topics which are designed to elicit open-ended responses. During the interview I will also use a methodology called multiple sorting task. During this part of the interview I will ask you to rank the policy options based on several evaluation criteria.

There may be times during the interview in which I ask you for further clarification about a response or I press you for further information about a particular topic. These actions are designed to ensure that I better understand your responses and will result in less interpretation on my part during my analysis of your data.

At the end of the interview I will provide a place for us to debrief about the interview and for you to add any additional information which you feel should have been covered during the interview.

Topics

Experience and expertise concerning direct-to-consumer advertising for prescription drugs or more general direct-to-consumer advertising.

3. What has it meant: organizational and health effects, public pressure, industry pressure.
4. Future challenges

Multiple sorting task conducted with policy options

7. Cost (financial/human/administrative)
8. Effectiveness
9. Political/stakeholder feasibility
10. Legal feasibility
11. Ease of administrative implementation
12. Participant generated criteria

In-depth discussion of options

5. Preferred options

Other Thoughts

Debrief