Provision of Viagra® by Third Party Insurers

A study of Priority setting as a Reflection of Distributive Justice

By

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A thesis submitted in conformity with the requirements
for the degree of Masters of Science
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Abstract

Provision of Viagra® by Third Party Insurers:
A study of Priority setting as a Reflection of Distributive Justice

By: Michael Gordon, MD, FRCPC; M.Sc. Thesis

Institute of Medical Sciences, Collaborative Program in Bioethics, The Joint Centre for Bioethics, University of Toronto, 2000

Research question: Should Viagra® be funded by Pharmaceutical Benefit Managers (PBM) – in this instance the Ontario Drug Programs Branch of the Ministry of Health through the Ontario Drug Benefit program (ODB)?

Purpose of study: To describe and evaluate the decision by ODB (or other PBM) about whether to fund Viagra® from the conceptual framework of priority setting.

Methodology

I have chosen as my methodology, policy analysis with a focus on the policies by which the Ontario Ministry of Health through the ODB decides on those drugs that are suitable for payment by the province. Policy research consists of examining competing inputs, complex problems, and seemingly irrational decision-making styles. It can provide policymakers with information that will help them with the difficult decisions they face. Policy research attempts to study fundamental social and other society (i.e., health care) problems in an attempt to create pragmatic courses of action for ameliorating those problems. The conceptual framework of policy analysis and its related research is therefore an appropriate approach to the issue in hand.

Viagra® was chosen because, although approved for use in Canada, it has not been approved for formulary listing and therefore funding, by the ODB. The framework for policies in Ontario will be explored and analysed as to how new drugs are reviewed and approved for the ODB formulary.

Key Concepts

The issues that will be examined in the thesis include the following:

1. The underlying values in the Canadian health care system and the foundations and principles of Canadian Medicare which appears to reasonably reflect the concepts of justice in health care.

2. Alternative options for funding components of Canadian Medicare such as the Drug Benefit program while protecting the basic tenets of Medicare. This includes a
proposed tax-based financial contribution system for health care costs that can be
general in nature or specific such as directed to funding drug programs.

3. The concept of priority setting is a way of focusing practically on the ethical concept of distributive justice. A special focus will be on the works of Norman Daniels who has developed a conceptual framework for the ethics of priority setting in the field of health care. The idea of “life-style” enhancing drugs will be reviewed in this context.

4. An overview of Pharmaceutical Benefit Managers (PBM), both public and private, and how decisions are made in various jurisdictions. The main focus will be on the Ontario Drug Program.

5. The specific issue of ViagraR will be examined in the context of being a special challenge to PBMs. The challenge to PBMs results from the fact of new and expensive drugs for conditions that are beyond the “usual” framework of drug coverage. The idea of “life-style” enhancing drugs will be further discussed in this context.

6. The concept of priority setting will then be used to focus on the specific PBM problem raised by ViagraR. Comparisons will be made with other conditions and treatments already covered by various PBM programs. Daniel’s proposed accountability for reasonableness will be explored as a viable ethical framework that is congruent with my proposals to the ODB for ViagraR coverage.

Conclusion

The ODB and other PBMs must address the issue of funding new and innovative drugs in a way that meets the clinical needs of its constituent populations in a manner that is ethically defensible. A special funding formula that allows access in a universal and reasonably equitable manner, can be developed that should satisfy Daniel’s concept of accountability for reasonableness. The latter appears to be a practical way of approaching the ethical and clinical challenges of priority setting. ViagraR can be an example by which the ODB can undertake this novel approach and therefore be prepared for future challenges from similar “life-style” enhancing drugs that will be brought forward in the future for funding.
Abbreviations used in manuscript

DQTC
Drug Quality and Therapeutics Committee

ED
Erectile Dysfunction

ODB
Ontario Drug Benefit Program

OMA
Ontario Medical Association

PBM
Pharmaceutical Benefit Managers

QOL
Quality of Life

VA
Veteran's Administration
Chapter 1: Scope and purpose

A. Research question: Should Viagra® be funded by Pharmaceutical Benefit Managers (PBM) – in this instance the Ontario Drug Programs Branch of the Ministry of Health through the Ontario Drug Benefit program (ODB)?

Purpose of study: To describe and evaluate the decision by ODB (or other PBM) about whether to fund Viagra® from the conceptual framework of priority setting.

B. Introduction

In all western countries, health care costs are a major challenge. In Canada, with its primarily publicly funded health care system, it often falls to the provincial government to decide on how financial resources are distributed within the health care system. Even though non-hospital prescribed drugs do not fall under the legislative umbrella of the Canada Health Act, all provinces have programs that provide drugs to some defined portion of the population at little or no cost. In Ontario, for example, the Ontario Drug Benefit program (ODB) provides drugs to seniors and individuals on social assistance with minimal (co-payment) cost. Through the Trillium Program introduced in 1995, which is expected to cover about 85,000 people in 1999/2000, the province provides drugs (with minimal co-payment) to those with modest incomes and no private insurance after a defined amount of money is spent on drugs (approximately 4% of family net income). The cost of drugs is escalating at a very rapid rate. According to the recent year 2000 Delta report, from 1992 to 1998 the ODB spending grew from $1 billion to $1.5 billion without any substantial increase in the number of claimants. When both government and claimant spending (through co-payments) are combined, ODB costs increased at an average annual rate of 8%(1). It is a great challenge to health care system administrators and politicians to develop systems, which govern the decision-making about which drugs are provided by drug programs.

In the past few years with the rapid growth of new technologies and new drugs for conditions that previously could not be pharmacologically treated, the pressures on health care budgets have increased substantially. Many new drugs are considerably more expensive than previous drugs or are the only effective treatment available. These new and effective drugs often exert a profound escalating effect on costs to the health care system. It is a challenge to Pharmaceutical Benefit Management programs (PBM), such as the ODB, to evaluate new drugs and decide whether the drug merits a formulary listing which results in the drug cost being funded. Each formulary listing of an expensive new drug uses financial resources that cannot be used for other treatments within the drug budget in particular and within the health care budget in general.

In the past, most PBM programs were able to compare a new drug to a previously existing drug or other therapy. In such circumstances the traditional comparative evaluations using cost-benefit or cost-effectiveness analysis were often sufficient to make the decision whether the benefits of a newer drug were worth the increased cost because of a demonstrable saving in other health care costs or because of substantially
improved and measurable outcomes. But, for some of the newer agents, used especially for conditions for which there are no good previously used standard drug treatments, it is difficult to define the financial benefit of the new drug. This problem is compounded if the drug is for a condition that is on the “margins” of what is often described as a “medically necessary” condition. Such is the case for some of the newer medications that have been described as “life style” enhancers.

With these factors in mind, it is a challenge to develop an ethically based framework that will allow policy-makers to make decisions that are transparent and clearly understood by the group making the decision and the constituency of those who are served by and those who pay for the drug program.

As an illustrative case I focus on the drug Viagra\(^R\) (Sildenafil) recently approved in Canada for the treatment of erectile dysfunction (ED). I will use the trade name of the drug as it has become so well recognized by this term in the popular press. I have decided to focus on this particular drug, because it is frequently viewed as a treatment for a condition that does not fall under the umbrella of a “medically necessary” condition. Rather, it reverses a condition, which is considered by some, because it is entwined with human sexuality, as primarily a “life-style” issue.

As part of my discussion I will include ideas and excerpts from articles that I have published on the positive attributes of the Canadian Health Care system, especially its ethical basis and an alternative tax-based proposal for funding that would maintain its ethical integrity as a publicly funded system. This is because priority-setting is an integral function of health care systems.

C. Why this drug and why this project?

The analysis of the public policy structure, procedures and conclusions related to the listing of Viagra\(^R\) in Ontario and other jurisdictions is a novel enterprise. At present the drug is not listed as a benefit on the Ontario formulary nor any other provincial formulary for funding. My thesis will focus on a number of unique processes that have not been evaluated in depth in general or specifically for a defined class of drugs or for a defined medical condition. The fact that Viagra\(^R\) is a new and expensive drug for the treatment of ED, which therefore allows those, afflicted, to experience normal sexual function. There are those who believe that sexual activity is a “life-style”/quality of life (QOL)issue and therefore its facilitation should not be a high priority for the allocation of resources. Unlike priority-setting challenges for drugs that are either in the life-saving category, or clearly can be identified to have a beneficial effect on “serious” or health status compromising conditions, ED is considered by many to be a “life-style”/QOL issue. Therefore, the use of public resources for its treatment may be considered by policy-makers to have a lower priority than medications for other more “critical” medical conditions.

The study will focus on a condition at the “margins” of health care. Viagra\(^R\) is probably one of the first in a long line of pharmaceuticals that will be available to treat conditions that may be similar to ED. These may also be looked at as “life-style”/QOL
activities, rather than conditions (or activities) for which a “medical necessity” for treatment exists. For example, treatments for, obesity, baldness and short-stature or to counter tobacco use might be considered under this category. Although some activities or conditions such as smoking and obesity may be cause serious medical conditions such as, lung disease, diabetes mellitus and heart disease, it is generally felt that the eating and tobacco use behaviours that result in obesity or lung disease are related to one’s “life-style”. Therefore, the rationale appears to be that PBMs should not pay for drugs to change detrimental eating behaviours or tobacco use, even though these activities cause serious medical conditions.

I hope to bring an original perspective to the current system of approval of drugs such as Viagra®, which at present is not one usually included in the standard drug review listing process. Currently, most drugs are reviewed for inclusion for ODB formulary listing through a combined focus; first on the drug’s clinical benefits and secondly, on cost-effectiveness(2). Drugs that affect “life-style”, QOL and personal and psychosocial issues are not easily assessed using the usual cost-effectiveness framework. By reviewing literature which does take such issues into account I propose to establish a solid ethical foundation for including Viagra® as part of the ODB formulary, even if in a limited fashion.

Through the discussion I intend to outline the various ethical approaches to priority setting in the realm of health care in general and drug programs in particular. The concept of priority setting is one of the operational outcomes to the ethical principle of distributive justice. I will use the term priority setting rather than the older term “resource allocation” even though in some of the literature that I quote the latter term is used. I hope to indicate how disparate views might affect the final policies and the decision-making process or framework by which priority setting decisions are actually made. My primary source for developing an approach will be the literature, which reflects different perspectives on priority setting issues. My other sources are from the Ontario Drug Program and include data about drugs already covered by the ODB. Also included will be therapeutic interventions outside the drug program that are pertinent to the understanding of public policy decisions.

Part of my premise for discussion is my belief that there are inherent strengths in the ethical basis of Canada’s health care system (3). As a structure for health care delivery, it has been compared operationally and ethically to America’s health care system, I believe most favourably (4,5,6). The ODB, even with its limitations as to population coverage, I believe, is a reflection of underlying ethical principles in which distributive justice is an important component. Without a commitment to concepts such as equity and universality, as evidenced by the principles of the Canada Health Act, the ODB program would probably not exist.

I hope to convince the reader that Viagra®, a new drug for a condition that has great importance to those who suffer from ED, is “worthy” of funding by the ODB. However, because it is a new and expensive drug, the costs involved puts a stress on the whole framework and under which third-party insurers define and set priorities. It is
through this novel exploration of a condition and a treatment that is not within the
traditional subjects of priority setting conflicts, that I intend to bring an original
perspective to this already controversial topic. Discussions about organ transplants, ICU
beds and open-heart surgery waiting lists are dramatic and engender strong ethical
discussions. Treatments for common and fairly mundane conditions that are an intrinsic
part of the life experience of many individuals add a new and very important dimension
to the concept of priority setting as a reflection of the ethical principle of distributive
justice.

I intend to demonstrate that the priority setting processes used by the Ministry of
Health are not always consistent internally. They do not always acknowledge some of the
basic principles in legitimacy (who makes decisions) and priority setting (on what basis
are decisions made). These should be integral to a program intended to provide a
constituency of patients with medications in a manner that is appropriate clinically,
ethically justifiable and can be understood by the population being served.

It is hoped that my recommendations can form a reasonable basis for the ODB
and other Pharmaceutical Benefit Program managers to make decisions about novel drugs
like ViagraR or for conditions that are outside those that we have already accepted as
deemed appropriate for "medically necessary" treatments. This would allow Drug
Program decision-making to be more transparent to all parties who are involved in the
process- as decision-makers and program beneficiaries. Through the framework of policy
analysis I propose to examine the process by which medications used to treat ED are
approved for funding by the Ontario Ministry of Health’s Drug Program’s Branch and
other third party insurers.

My recommendations will ultimately express an approach to policy development
that I feel is viable within the realities of the contemporary health care delivery system.
Included in my recommendations are alternatives to funding which are potentially
applicable to the ODB alone or to other components of the health care system. A proposal
for a tax-based individual contribution to health care costs was developed as an
alternative to proposed privatization of the health care system (7). The provincial
government as one means of meeting the funding needs of the ODB could potentially
adopt it. The recommendations might be used by a government health care plan or other
third party payer to construct an approach to policy that is consistent and ethically
acceptable and should reflect positive societal values. From the recommendations it
should be clear that I hold some values and principles in higher regard than others and
therefore the outcome of my deliberations will affect my final recommendations.

D. Outline of argument

In chapter 2, I describe the method of policy analysis. I am accepting one of the
many definitions of policy analysis and research as applicable to this study: "Policy
research...is defined as the process of conducting research on, or analysis of, a
fundamental social problem [or issue] in order to provide policymakers with pragmatic, action-oriented recommendations for alleviating [or resolving] the problem"(8). Policy analysis is an appropriate method for the thesis because the issues being examined are related to policies determined by the Ontario Ministry of Health’s Drug Program Branch. I hope that by using this process for analysis, the Drug Programs Branch might consider the recommendations as suitable for determining how it chooses to list drugs for the Ontario Drug Program (ODB) and what it will decide in relationship to Viagra®.

In chapter 3, I describe the underlying values in the Canadian health care system and focus on the foundations of Canadian Medicare. I believe the Canadian system reasonably reflects the concepts of justice in health care.

In chapter 4, I sketch a framework for a tax-based financial contribution system for health care costs including drugs that I will consider when I focus on my possible recommendations.

In chapter 5, I outline the process of priority setting. I focus extensively on the work of Norman Daniels because he has developed a conceptual framework for the ethics of priority setting in the field of health care. His range of discourse has included deliberations on expensive drugs or new technologies in health care as well as mental health challenges. The latter subject raises similar questions to that involved in ED- i.e. “life-style” issues.

In chapter 6, I describe how Pharmaceutical Benefit Managers, both public and private, make decisions in various jurisdictions. My main focus is the Ontario Drug Program. As a sitting member of that committee for six years with the last year as chair, I observed a wide range of decision-making processes and witnessed the development of various approaches to drug approval. The most recent change was a focus on the pharmaco-economic impact of drugs that are listed for funding on the provincial formulary.

In chapter 7, I examine the specific issue of Viagra®. This poses a challenge to PBM because it is a new and therefore expensive drug for a condition that is very prevalent in the older population and specific groups receiving benefits through social assistance (e.g., insulin dependent diabetics). It is also the first extremely effective treatment for ED, a condition that is responsible for great emotional suffering in those men who experience the condition. ED is often responsible for discordant relationships which add to the emotional suffering. Viagra® is also prototypical of treatments for conditions that may have great importance to members of the population but are often perceived by PBM administrators as being on the margins of “medical necessity”.

In chapter 8, I apply the conceptual framework from chapter 5 to the specific PBM problem raised by Viagra®. I show that it has similarities to other conditions for which the “medical necessity” for intervention may be controversial. One domain of such conditions are those in the mental health arena where the range from clear “pathological” conditions to variations in personality traits may be amenable to drug interventions.
Therefore, the idea of "life-style"/QOL modifications by medications can be explored. I also incorporate the discussion from chapter 4 on a tax-based incentive scheme. I hope to demonstrate that Daniel's proposed accountability for reasonableness is congruent with my proposals and forms a solid ethical basis for priority setting. Based on this analysis I have developed a range of policy options. I propose a recommendation that the Province or a private insurer can make in relation to Viagra\(^R\) which will allow access to the drug in a societally acceptable and financially responsible manner.
Chapter 2

Methodological approach: policy analysis

I have chosen as my methodology, policy analysis. I will focus on the policies by which the Ontario Ministry of Health decides on those drugs that are suitable for payment by the province. I have chosen Viagra®, which although approved for use in Canada, has not thus far been approved for formulary listing and therefore funding, by the Ontario’s Drug Benefit program (ODB). I will explore the framework for policies in Ontario and analyse how new drugs are reviewed and approved for the ODB formulary.

I will be drawing greatly on personal experience as the basis of my comments on ODB policies. I began working with the provincial drug programs in 1988 when I was appointed a member of the Lowy Commission: the Pharmaceutical Inquiry of Ontario. Soon after the release of its final report in 1990 I was invited to become a member of the subsequent government’s Drug Reform Secretariat. In 1994, I was invited to be a member of the Drug Quality and Therapeutics Committee (DQTC – the committee that makes provincial formulary listing recommendations to the Ministry of Health) and spent my last year, 1999/2000, as its chair. Following that, I was requested by the ODB to sit on a tri-partate committee on Limited Use drugs and have also been involved in policy meetings and discussions on various matters related to the formulary. I was recently appointed to be chair of the Ontario Medical Association (OMA) committee on pharmacy and therapeutics, which interacts with the ODB from the perspective of the medical profession’s representative body.

During the years on the various committees, I have been exposed to a wide range of activities, which has allowed me to witness the development of government policies. I have participated in policy-setting meetings, educational sessions, and clinical reviews on an individual basis and as a member of the DQTC. I have been both a presenter and a reviewer with the DQTC, and have reviewed individual and classes of drugs. I have also had access to the Masters thesis done by Anne Paus-Jensen, which evaluated the processes by which the DQTC reviewed drugs and made decisions about listing in the formulary. I was interviewed by her as an ordinary committee member and as chair, a position I held during my last year of membership.

By using the methodology of policy analysis, I hope to demonstrate the underpinnings of an approach to policy formulation and at the end, be able to make recommendations that can be used in the future for comparable situations. Much of the focus on priority setting has been on what might be viewed as extreme or dramatic components of modern health care, e.g., Cardio-Pulmonary Resuscitation, respirator care, organ transplantation, feeding tubes and euthanasia. I have decided to focus on what might be considered a very basic medical issue that may not receive the same attention as more dramatic medical issues. The issue impacts large segments of the population and reflects many basic elements of Ontario’s public policy.
The conceptual framework of policy analysis and its related research is an appropriate approach to the issue in hand. "Policy research efforts study fundamental [or basic and/or important] social [or other societal] problems in an attempt to create pragmatic courses of action for ameliorating those problems. No other type of research has quite the same focus or action orientation.... The context of doing policy research consists of competing inputs, complex problems, and seemingly irrational decision-making styles. In such a context, policy research... if done properly, with an appreciation for this context, can provide policymakers with information that will help them with the difficult decisions they face"(8).

The process of policy analysis in this particular case is what Majchrzak describes as "policy research [which] varies as to whether the focus is on problem "definition" or "solution" In addition, in this particular study, Majchrzak would likely suggest that "policy research varies as to the academic discipline of the research." In this case, I intend to take the perspective from the discipline(s) of clinical medicine. I will present my case from the perspective of bioethics and its relationship to clinical medicine, especially when it comes to the decision-making process and priority setting of drug treatments. I intend to define the problem and through an exploration of the pertinent bioethics and Drug Program literature, explore the basis of possible solutions. The main goal of the study and its methodology is to "help policymakers [in this instance the ODB program] to solve social [in this case pharmaceutical health-related] problems"(8).

Majchrzak defines the characteristics that go into policy research studies, which I have drawn upon and addressed in this thesis. These include:

1) A multidimensional focus - I have addressed this by looking at the issue from the perspective of different constructs of ethics, from the practical point of view of the insurance industry (private and public), from different clinical perspectives including mental health and from the perspective's of societal values and sexuality;

2) Uses an empirico-inductive research orientation – I have addressed this by exploring actual practices in the field of drug formulary development in the Province of Ontario, as well as in the private insurance domain and across different national and international jurisdictions. From this information and from personal experience in the Drug Program field, I have come to certain conclusions as to how contemporary policy and practice is made and how it effects decisions as to how new drugs are listed and funded;

3) Incorporates the future as well as the past – I have addressed this issue by exploring past and present practices in the Province for drugs as well as for other related treatments and have presented options for the future in terms a change on process for the decision-making for listing and funding;
4) **Responds to study users** – the study may be used by those who actually make policy or by those who are affected by the policy in place. It would provide both those who define policy and those who are the constituents served with a basis for discussion as to what framework might be used for future listings and funding of new and expensive drugs;

5) **Explicitly incorporates values** – by the nature of the direction of this study, ethical values are key to the understanding and approach to policy analysis. I could have alternatively taken a purely economic approach to the issue and avoided all concepts related to ethics or a social utility approach to the subject, with a minor perspective of ethics. I have chose to focus primarily on the ethical framework around which policy is made and therefore the study explicitly incorporates such values in the exploration and discussion.

"Policy is defined as a definite course of action selected from alternatives that guide and determine future decisions....It takes into account not only scientific information but also political, social and economic information. Frequently, policy is established, or revised, to correct perceived deficiencies in current practice"(9). "Outcome studies are required to provide objective evaluation of many long-standing, traditional practices. Whether for insurers, Congress (government), health care executives, clinicians, patients or families- a literature of "real world" findings can be developed from evaluating outcomes to support decision-making. Assessing the outcomes of care can also be used to inform policy"(10).

"Policy research is the process of producing or transforming data to provide policymakers with feasible options to help solve social [should be able also to mean health care or other] problems.... It is necessitated by the immediate need for political positioning. Policymakers need approaches they can champion or propose as options. The criterion for good policy options is not only what is 'right' but also what is a product of thorough analysis and what is feasible in the policy arena. Policy research can be useful not only in answering questions but also in identifying which questions to ask. By asking pertinent questions, policy research can help define the societal [should be able also to mean health care or other] problem or frame the policy issue." "Policy research is a vehicle for social [read health care system] change focusing on variables within the social [read health care system] context that can be altered, improved or changed. If the long-term outcome of basic research is dissemination of new knowledge, the underlying objective of policy research is to attempt to make social [read health care system] change"(11).

"Policy research...is context driven, multi-methodological, and time sensitive. Context driven means that it originates with the socio-political context....It is responsive to the study users, usually policymakers, and their underlying values. Also taken into account are the collective values of society.... All policy analysis is ideological, or based on fundamental beliefs about society, government and social order and the best way to make values explicit is to include them as part of a reasoned ethical argument or debate." "Policy research employs multiple methods to achieve its goals...it begins in a context, is
followed by the technical part, and then results in politically feasible recommendations” (11).

The time-sensitive nature of policy research results in the fact that “policy decisions must be made, even if they are not totally correct. Policy research occurs when the window of opportunity is open. If the legislative debate or commission hearing is ‘now’, researchers must go with the information they have, or miss the opportunity to influence policy decisions…. ‘It is better to be roughly right than exactly wrong’”(11).

“From the point of view of policy formulation, legitimate aims include: to determine the bounds of the possible, to assist in ascribing priorities by identifying and where useful quantifying need, to assess comparable utilization patterns and costs of differing policies...and to identify socio-economic aspects of accident, disease and health in relation to prevention and the provision of services, including self-help....Action can refer to predisposing and enabling research, the decisions and proceedings that precede its formulation, or the sequential implementation of research findings....The social scientist [read researcher] who incorporates the possibility of action as a conscious aim of a research project should make him/herself aware of the contextual constraints – economic, environmental, political and social- under which relevant policy makers operate. The instruments of change need also to be taken into account....Value systems in society must of course be recognized. In health policy they provide a framework for selection among priorities, for choosing who the policy makers should be and they are crucial for providing the basic socio-cultural facts upon which policy decisions must be based....Any failure to recognize and understand the value system of a society nullifies social [read health care] research makes an appropriate action impossible”(12).

In the field of health policy research, especially as it pertains to the aged, there are scholars who believe that when evaluating policy and its impacts, we do not necessarily study the right patient population (13). This is one of the critical factors in health policy research methodology, for a study to be pertinent, the study population must reflect those for whom the policy is being evaluated or for whom modifications in policy are deemed to benefit. Modan et al for example found that in studies purportedly of the aged, many ignored important demographic factors needed to confirm that the population being studied was one for whom the policy had a focused and specific impact. This was especially noted by the authors, “By policy we usually mean a decision-making process in which the few decide for the many. The major health policy issue affecting older people in the western world is containment of health costs, while providing the best possibility of quality of life”(13). Among the many problems noted in the analysis of the concerns is that because of the difficulties in, for example, studying the very old “extrapolation is made from the young-old, who are more accessible, more co-operative, and apparently, more reliable. Yet, interviewing a relatively younger (mid-age) population may be equivalent to looking for a lost penny in a back alley under the street lamp, since only there one may find light”.

This is an important observation, which is relevant to the issue of drug policy. Many of the studies done on drugs are for populations much younger than the primarily elderly population served by the Ontario Drug Benefit Program. Conclusions from economic
evaluations may be mis-represented and issues such as quality of life may have a very different meaning to the very old compared to the younger old. The authors conclude, "It might be argued that the assumption that good data are essential for good policy, is invalid in, 'real life politics.' Indeed, certain measures in the health care area and elsewhere are dictated without substantiating evidence when external pressures are applied, especially when an on-the-spot decision must be made. ... We need data to assess needs and set priorities, and these must be based on data from the population that will be affected" (13).

This concept is reflected in the issue of Viagra\textsuperscript{R} and the ODB. According to the recently published DELTA report, more than 74% of ODB recipients are seniors 65 years or older (1). The rest are younger individuals on social assistance or other support programs. ED is a condition that primarily affects seniors and select younger individuals with very defined problems such as diabetes, paraplegia, uro-genital surgery or on certain classes of medications. Therefore, the evidence from the medical literature on which decisions about listing Viagra\textsuperscript{R} by the DQTC is made must reasonably reflect the older population. Many of the important studies were on populations with a mean age in the late 50's, which is not necessarily reflective of the elderly population primarily served by the ODB. This could have consequences both in terms of benefits of the drug, but also in terms of side effects, such as the acknowledged occasional cardiac-related death. More important might be the psychosocial effect of ED on this population and erroneous assumptions by the members of the DQTC, who are relatively young, about the importance of sexual activity in the older population. A negative bias by committee members about sexual activity in general or how it affects seniors could negatively colour their view as to whether the drug deserves to be funded by the ODB.

In an article by Hudson, the concept of a contingency-based approach for assessing policies on aging is reviewed (14). The author attempts to untangle the factors that on the one hand led to age-based entitlement policies and the contemporary factors that appear to be eroding the will of some policy members to continue to support many age-based entitlements. He notes that there are two factors that are undeniable, .... "growing numbers of elders are in reasonable economic circumstances and considerable numbers of older persons have needs that are not currently being met.... A growing imbalance exists between current population dynamics among the old and longstanding assumptions behind age-based policy" (14). The author postulates that the contemporary climate of health care resourcing must re-evaluate the classic welfare state notion of "social contingencies"- which in general are about losses, misfortunes, threats and other adverse happenings related to the aging process. The idea of funding Viagra\textsuperscript{R} through the ODB is major step beyond the older concept of contingency-based funding rather than one that examines whether an ODB "entitlement" should cover a drug for ED that affects what is perceived by many as a "life-style"/QOL issue.

I will focus on the issues that relate to health policy analysis as I examine the processes involved in decision-making at the Ontario Drug Programs Branch and other Pharmaceutical Benefit programs. I will examine the priority-setting infrastructure and assumptions that govern the way coverage decisions for new and expensive drugs are
made. I will focus on Viagra\textsuperscript{R}, used to treat ED as the means to examine this important health care system decision-making policy and priority-setting issue. The same process that applies to Viagra\textsuperscript{R} should be applicable to other drugs that pose the same challenge to the ODB and other third party insurers.
Chapter 3

Values underlying the Health Care System

The Canadian Health System

In this chapter I will examine issues related to health care systems. The underlying principles of a health care system will have a major impact on the way that drugs are provided to its constituents. The Canadian health care system has as its underlying foundation the Canada Health Act, which provides a framework to the provinces as to what must be included in provincial health care benefits. While the Canada Health Act does not specifically address drugs provided outside of hospital settings, all provinces have developed drug programs to meet the needs of some segment of the ambulatory population. The ODB is one example of a provincial system that address the needs of defined populations, because of perceived financial need or risk of suffering from un-treated illnesses.

Other health care systems approach care needs of their populations differently, with the United States having a system that has dramatically different underlying ethical and political principles governing it. In the modern world of health care delivery, the concept of priority setting has become an issue of great importance. Irrespective of the underlying principles of the health care system, the distribution of health care resources is the sine qua non of distributive justice as it affects the health care system. There are many examples within contemporary health care systems that provide alternate methods of distributing resources for the society that the system serves. In some societies, there are a number of competing or parallel delivery systems that adhere to different processes of determining how resources are distributed. As one examines the different delivery systems, it is possible to determine what over-riding principle(s) is/are responsible for the decision-making processes.

Even within the various health care delivery systems, there may be variations in how resources are distributed depending on the nature of the resource. For example, certain types of resources which are commonly used across a wide spectrum of society and for which the unit cost may be acceptable, may have little in the way of barrier or discordance about whether that resource should be made widely available. At the other extreme are medical procedures or devices for which there is a limited demand but for which the cost is extremely high. Within this category there are those expensive procedures or devices in which the outcome is extremely beneficial in contrast to those for which the cost is very high but the beneficial impact is less impressive. There is a great deal of debate in the medical, health care, economic and bioethics literature, dealing with these differing types of situations.

Within the realm of drug therapy, all G7 (the Soviet Union is excluded as the details its health care system are not readily available) national health care systems have ways of providing medications to its constituents. Clearly in contemporary medicine, the provision of drugs is one of the most important means of providing modern health care.
Their cost is one of the highest within the health care delivery system (15). The spectrum of possibilities to the provision of drugs spans at one extreme, making the cost of drugs the total personal responsibility of the recipient. At the other extreme is the provision of all drugs to all persons at the expense of some third party payer. Within North America, it was not so long ago in medical history that the cost of all of health care was the sole responsibility of the patient. Because of the devastating effects of the lack of health care access to many individuals, a patchwork of systems of coverage gradually developed which provided some degree of access to treatments and drugs to an increasingly larger portion of society.

The contrast between the health care systems of Canada and the United States, despite their close geographical proximity and strong cultural and historical ties, is an interesting study on how different cultural and societal demands and historical events can result in strikingly different health care delivery systems. As I wrote in an article published in Canadian Family Physician, “Canada's health care system is in principle a great success despite its shortcomings. All Canadians have access to care, unlike their American counterparts where as much as 18% of the population (over 45 million people) is uninsured and many millions of Americans under-insured, leaving them liable to financial catastrophe and major uncertainty. Despite provincial differences, the spectrum of care is wide. If any argument can be made it is probably that there are gaps in the system which probably should be addressed (such as drugs and oral health) if our goal is to enhance the health care status of Canadians beyond that which requires changes in social, employment and financial policy to deal with important determinants of health such as poverty and educational exposure”(16).

I believe that the differences in the two health care systems have a fundamental ethical basis. The view of what medical care is in the two countries is significantly different. At one extreme is the concept that health care is just another commodity as contrasted to it being a core entitlement of the citizenry. As I note in an article published in the Annals of the Royal College of Physicians and Surgeons of Canada, “The concept of justice within the framework of ethics, consists of access to, equity of and distribution of care. With health care presently considered to be an essential structure in Canadian society, there is a political responsibility to guarantee a system in which citizens have a semblance of equity in their access to care. This means a fair distribution of the burden of financing universal access as well as distributing the benefits. The health care system is founded on the premise that all citizens have a right to health care irrespective of employment or socio-economic status. In the United States by contrast, health care is primarily a benefit of the work place, other than for seniors through Medicare and the indigent on Medicaid and veterans through the VA system. With a decrease in the work force and a shift to part-time and contract workers, the security of health care access even for working Americans may be undermined”(3).

I continue “The structure of American Medicine, although undergoing substantial change in its method of delivery, has not significantly moved away from the concept of providing care on the basis of ability to pay rather than ability to benefit. Funding is based primarily on insurance premiums which in a regressive manner is relatively more
costly to those with the least resources, rather than progressive, derived as general funding through the income tax system. This is an indicator of the lack of adherence to the ethical principle of distributive justice. Even the highest quality not-for-profit health care organizations must be competitive with the private sector in order to stay solvent and at present, they have an increasingly limited ability to absorb non-remunerated clinical activities”.

Finally, “Canada has a single payer publicly funded system that provides health care benefits to all, and is equitable for core medical, hospital and many components of long-term care services. Preferential access to care based on patient co-payments or through private insurance is disallowed under the Canada Health Act and results in financial penalties of lost federal transfer payments to the provinces that allow it.... The opponents of Canada's system argue that it deprives those who wish to spend their discretionary resources on preferential health care. Such critics maintain that this interferes with patient autonomy to choose health care options not available expeditiously and physician autonomy to provide that care on a preferred basis. Within this argument, the principle of justice, manifested by equity of access to Canada's citizens is challenged, giving preference to the principle of autonomy. The tension between these two ethical principles is substantial. To date, the Canadian population, the federal and most provincial governments have accepted the principle of distributive justice as superceding that of patient and physician autonomy when it comes to defining the ethical essence of Canada's health care system”(3).

The impact of these differences is that the basis for the provision of health care services and the provision of drugs may be substantially different in the two countries (17). There are, however, some remarkable similarities between how decisions are made for the provision of drugs to citizens of the two countries. Within Canada, each province makes decisions about how drugs are provided to its citizens, using some similar principles but with different variations. In the United States, whether it is the publicly funded Medicare, Medicaid and the Veterans Affairs System, private insurance or Managed Care systems, some process of decision-making determines which drugs are available to its members and how the costs will be distributed to the beneficiaries. In the realm of pharmaceutical management, many American managed care organizations are struggling in a fashion similar to the ODB to develop priority setting strategies to deal with challenges such as that related to ViagraR.

Very similar principles and practices apply to western societies in addition to Canada and the United States that have well developed health care systems. The G7(Russia excluded in this discussion as noted above) countries all have health care systems that provide a range of services to its citizens including various ways of providing medications. Many fall somewhere between the range of procedures and practices that exist in Canada and the United States and sometimes present interesting models worth examining and perhaps offering options for priority setting which appear more consistent with the ethical principles of distributive justice (18).
Ontario is an example of a Canadian province that has an organized system for the distribution of drugs to certain groups of its citizens under varying circumstances. Its structure and policies and practices can form a template to examine in depth the process of priority setting for drugs as it exists within a health care system that supposedly is based on strong ethical principles. The Canada Health Act has determined the framework by which Canadian provinces have provided health care to its citizens since 1984. The five principles of the Canada Health Act are universality, accessibility, public administration, portability and comprehensiveness. Each of the principles has a strong ethical underpinning which will not be the primary focus of this paper, but which in themselves, reflect strongly on the fact that there has been a process of ethical deliberation in the development and implementation of the health care system in Canada. Despite the fact that periodically the Canada Health Act has come under attack by various lobby groups, it remains an example of health care system that depends on a consciously developed set of principles. It would appear that the framers of the system (through the Canada Health Act), and the vast majority of the population, share a common ethical view of the health care system.

In contrast, the lack of a structurally cohesive health care system in the United States has led to a mosaic of systems, working within or in parallel with other systems, so that the principles behind some systems cannot be readily identified. The present collection of systems seems to have shifted from individual responsibility as translated from personal pay to third party indemnity insurance to Managed Care. This is a reflection of a certain philosophical approach to health care that has been pervasive in the United States. One might describe the primary framework as an economic one. The product or commodity is health-related services and the providers are myriad organizations including for-profit, not-for profit and public, all competing in a marketplace system to determine how the health care products are distributed and by whom and to whom. Of interest is the intense debate presently taking place in the United States about whether Medicare, the health care insurance system for seniors, should include a drug benefit program, which at present it does not. The staggering costs of drugs that impact on older Americans are an issue of great concern and focus at present (19,20,21).

There appear to be diametrical extremes in the framework and principles by which the health care delivery is provided to the citizens of Canada and the United States. But because there are many similarities, the process by which individual drugs or classes of drugs are actually made available to participants of the various systems deserves to be examined. It may be that the decision-making process by which different classes of drugs are approved for third-party coverage, be it a public or private, may depend on values and processes that reflect a similar concept of distributive justice and priority-setting. The results may be more similar than different, even though the health care system itself is based on principles that are considerably different.
Chapter 4

A Tax-based system to fund the Health Care System and/or Drug Programs

During the past few years there have been many attacks on the concepts behind Canada’s publicly funded system. There are those who suggest that because of the growing costs of the system and federal and provincial government cutbacks, the only solution to this financial problem is to introduce a private tier to Canada’s health care system. As part of the literature that opposes such a change, some colleagues and I have suggested an alternative to global funding to health care system components. This proposed approach might provide enhanced funding for the system while maintaining the principles of universality and equity within a publicly funded system. The process can also be used to fund components of the health care system such as drug costs. This might be a more equitable way to provide drugs to citizens, rather than present systems such as the ODB, which focuses on specific populations, or work-related insurance, which leaves many citizens un-insured.

This tax-based approach could provide, “a more equitable alternative which will encourage more efficient use of health resources. As a means to increase funding, such a process could significantly meet the financial needs of the system while endorsing the principles of accessibility, universality and public administration”(22).

“The system’s guiding principles would include that it be equitable, progressive, non-punitive, easily administered and flexible. The contribution would be assessed by the provinces using information on health care services provided to the population but administered through the federal-provincial income tax system. The contributory system would require close cooperation between federal and provincial governments so that the latter could continue to be responsible for the structure and services of health plans with the federal government providing the necessary leadership and support”(22).

Once the principle is accepted that the tax system could be used in a universal manner to augment health care funding based on utilization, “there are two approaches to taxation of health care benefits. The first is to assume that the tax is a contribution to cover the cost of the program. Under this approach, a flat-rate tax would be assessed on an individual’s billable health benefits, subject to a maximum (such as $2000 per year) to recognize that individuals may have extraordinary health expenditures that compromise their ability to pay taxes. The flat-rate tax, while conceptually simple, conflicts with the principle of a "tax based on the ability to pay" – lower income people may face a greater burden relative to their annual income, compared to the wealthy. To relieve low-income earners, incomes below a specified amount could be tax exempt. Alternatively, [actual] health care benefits [or true costs incurred] may be viewed as part of the individual’s income, and subject to tax. The billable health benefits, with a taxable ceiling, could be added to the taxable income and this amount subject to the marginal tax rate at that income level. Other than adding the taxable health benefits to the taxable income, no extra calculations for tax payable are necessary. The treatment views public program benefits similarly to other incomes (as Canada Pension Plan benefits are added to
income). In principle, contributions made could be eligible for the medical expense credit. High-income earners, already paying greater income tax, partly used to finance the health care system, as with Ontario’s ‘fair share’ tax, may view this as excessive taxation”(22).

The article continues, “The threat to the viability of Canada’s public-funded health care system is significant. Many critics believe that quality is already adversely affected. The proposal for the taxation of benefits would help fund the health care system as well as enhance its efficiency. The taxable benefit concept confirms the principles of the Canada Health Act and can be combined with cost-effective principles and quality management methods. By structuring the taxation process as outlined, those most financially vulnerable to added costs will be exempt or protected from an adverse financial impact. Those with chronically high health care costs would pay more as they would with private insurance premiums but ceilings to costs could be structured to assure a non-punitive effect. Public policy could determine that especially high-risk groups such as children and the poor would not be disadvantaged by this structure” (22).

The author continues, “One concern that might be raised is that the tax may be viewed as being imposed on the ‘sick’. However, in principle, any co-insurance system, that includes a deductible for claims, would result in individuals paying for a portion of the costs incurred due to illness. Under our proposal, expenditures of low income individuals and extraordinary health care costs would be fully covered by the government....It could be argued that there might be some reduction in health care support from general taxation to be partially replaced by this use-based system thereby shifting some tax liability from the general public to those who use the system. But, against this option is the consideration that general revenues support the infrastructure of the system which is required by all, and the taxable benefit is directly related to individual utilization”.

As outlined in the article “The taxable benefit proposal confers a number of distinct advantages:

1) The consumer becomes more aware of health care service costs without facing upfront expenditures that deter the disadvantaged from accessing necessary health care services because of cash flow problems. A taxable benefit impacts only selected payers of income tax;

2) There might be a greater awareness of costs leading to greater participation of patients in the decision-making process. For example, a choice between comparable drugs with differential costs would allow the patient to consider personal cost. Reference-based pricing in British Columbia and an incentive system in the United Kingdom are examples of how patient and professional choice can impact prescribing within a publicly funded system. In contrast, private insurance-based coverage often promotes utilization because once premiums are paid, patients often feel entitled to everything that is covered unless there is some element of co-insurance. Premiums are therefore adjusted to the
costs of the insured group which results in an upward cost spiral or coverage restrictions; and

3) More components of health care can potentially be included in coverage. There would be no intrinsic economic reason to not include drugs, home care, dental treatments or other desirable care components because of cost. The National Forum on Health recommended the development of national pharmacare and home care programs. In principle, these programs could be partially covered by the increased revenues from the taxable benefit”.

In the article I and my co-authors conclude, “The taxable benefit proposal, as an alternative to increased privatization of health care, preserves the professionally sound and ethically laudible principles of the Canada Health Act. The health care system can continue to be one in which equity of access, universality and the ethical principles of distributive justice are maintained. This model should support the principles of accountability, cost-effectiveness and proper economic parameters along with clinical outcome indicators, without compromising the universality of Canada’s health care system. If proven workable, it could become a model which health care systems in other jurisdictions could emulate”(22).

Some of the criticisms of the proposal were answered in the letters to the editor and the point was made that although the proposal was an alternative to the threat of privatization, the authors felt it may have some intrinsic value to it within the already existing publicly funded system (23). Although the published tax-benefit proposal examined all health care costs, the same structure could be used only to support the costs of drug programs. This might be an option for the Drug Programs Branch if it decided to completely restructure the way that the provincial drug program were funded.
Chapter 5

Conceptual framework: Priority setting

A. Priority setting and Justice

In this chapter I will review the concepts that form the framework by which the ethical principle of distributive justice can be translated into the more practical challenge of priority setting. From there the focus will be on a process of priority setting for those responsible for decision-making. I draw heavily on the work of Daniels and his co-author Sabin, who have addressed this issue in detail and have evolved a conceptual framework which is ethically defensible and operationally practical. Much of Daniel’s work relates very closely to the specific issue that is explored in my thesis. This is the funding of an innovative and expensive drug for a common condition that may be considered treatment for a “life-style” condition rather than for one which appears to be more “medically necessary”. Some of the concepts of justice in health care explored by Daniels will be reviewed. Finally, Daniel’s concept of “accountability for reasonableness”, will be evaluated as a basis for decision making and priority setting in the health care domain.

Health care has always been a treasured commodity. For those living in North America, the contemporary concept of access to necessary health care services has been one of the tenets of a society that was expanding and wealthy, compared to most of the rest of the world. The fact that in the United States, the actual distribution of health care services left large segments of society without adequate health care services or insurance was considered one of deficiencies of the system. The development of Canadian medicare was one of the steps in this country that assured a higher level of equity of access to health care services than was available in the United States(3,4,5,6,24).

The idea of “rationing” in the public’s eye and perhaps even in the consciousness of most physicians, is relatively new. Health care services have always been distributed in uneven ways. But the level of awareness of the limitations of service delivery especially as health care has become “organized”, is much greater in recent times than it has been in the past. Already in the 1970’s and 80’s in the United States, during a very expansionist period of health care developments, scholars were focusing on the issues of health care resources and the need to “ration” them (25,26,27). As Victor Fuchs noted in a New England Journal editorial in 1984, “The United States has always rationed medical care, just as every country always has and always will ration care. No nation is wealthy enough to supply all the care that is technically feasible and desirable; no nation can provide ‘presidential medicine’ for all its citizens. Moreover, medical care is hardly unique in this respect. The United States ‘rations’ automobiles, houses, restaurant meals- all the goods and services that make up our standard of living....The basic method of rationing goods and services in this country (United States) is through the market....The growth of federal insurance programs substantially diminished the role of income as a rationing device”(25).
Fuchs, in his analysis, traces the changes in the view of health care resources and its distribution as third party payers, especially governments, took away some of the personal responsibility for health care payments. The results were a change in the market dynamics of health care provisions so that larger issues had to be addressed such as, "when a third party is paying, the patient will want additional care and the conscientious physician will provide it, even though its cost to society exceeds the benefit to the patient....This divergence between what is good for the patient (given insurance) and what is efficient for society as a whole is a key element in current concerns over health-care spending----but the basic problem remains: how to provide insurance without pushing the use of resources to the point at which the additional cost far exceeds the additional benefits"(25).

This type of deliberation in one of America's leading medical journals more than 15 years ago is a reflection of an increasing awareness of the conceptual framework that surrounds all decisions to provide health care resources to a defined population. Although the terms used by Fuchs do not appear to reflect complex philosophical or ethical principles, they in fact do, even though much of the discussion appears to be couched in a framework familiar to clinicians. The ethical basis for priority setting (often referred to by the more emotive term, "rationing") usually refers to the principle of distributive justice, that has gradually become commonly used even by those who do not perceive themselves as "ethicists"(28).

The principle of distributive justice, is one of the basic pillars of Beauchamps and Childress' (29) four ethical principles (the other three are autonomy, beneficence and non-maleficence) that are commonly accepted in North America. Within this concept is the belief that whatever issue is being considered as an ethical challenge, there should be a consideration that some element of fairness be included in the ethical deliberations. Long before Beauchamps and Childress proposed the four ethical principles, the concept of justice and within it the construct of distributive justice had become one of the important considerations in many systems used to define an ethical framework for human and societal action.

As an ethical principle, distributive justice is usually associated with some concept of "fairness" by which the various participants in the health care system can understand and accept how and why certain decisions are made and feel comfortable with them. This is usually translated in practical terms into what is usually called priority setting: the process by which the wide array of health care resources are allocated and funded through a variety of means that are acceptable to society (30).

In contemporary health care systems, especially as they exist in developed countries, the process of priority setting appears to be more complex now than in the past. This is especially the case as governments and large third-party insurers have taken on much of the role in determining how the health care resources they are responsible for are allocated to those they are mandated to serve.
Given the realistic need for priority setting in all health care systems, it is important to understand the ethical foundations by which these decisions are made. A component of this decision-making process is one by which decision-makers view how they develop a system of priorities among the various health care intervention choices. Within the priority setting process, it would be reasonable to expect that those making the decisions do so in a legitimate fashion and that most observers would acknowledge a basic fairness in decision-making.

To be considered legitimate, those responsible for making the allocation decisions should have the mandate, supported by the appropriate political and legal process required to do so, and the involved parties (the public or group of beneficiaries) should accept the qualifications and responsibilities of those required to make the decisions. For the process to be considered fair, an outsider reviewing the process should be able to understand the criteria and foundation assumptions by which the particular set of decisions are made.

B. Concepts of Justice

Most individuals have a concept of justice, even if they do not analyse its meaning or implications on an everyday basis. Early in childhood development one hears children exclaiming to their parents or siblings, “it’s not fair” and many parents take special pains to act equitably when parcelling out food at meals, gifts on holidays or praise for accomplishments. Within our school systems, workplaces and recreational facilities, most participants express a need for and a sense of “fairness” in the way that books are distributed, rest breaks are arranged or who gets to play on the team. When treated “unfairly”, most individuals seek some sort of intervention to rectify the situation either at the local level or, when it affects large numbers of people, at the societal or governmental level.

Because there are many different factors that go into the concept of distributive justice when there are conflicts and perceptions of unjust distribution of goods, services, attention or acknowledgement, it requires a critical evaluation of the different perspectives of justice for an acceptable outcome to be reached. According to the 2nd edition of the Encyclopedia of Bioethics, there are, “five major conceptions of justice...1) a libertarian conception, which takes liberty to be the ultimate political ideal; 2) a socialist conception, which takes equality to be the ultimate political ideal; 3) a welfare liberal conception, which takes contractual fairness or maximal utility [utilitarianism] to be the ultimate political idea; 4) a communitarian conception, which takes the common good to be the ultimate political ideal and, 5) a feminist conception, which takes a gender-free society to be the ultimate political ideal” (31).

Even though there are variations in how the different constructs deal with particular principles or issues, they are all concerned with an idea of obligation to act or provide and not necessarily with what the basis of the action or provision might be. They also try to define what it is that people should be provided with or what they “deserve” but differ on the criteria by which such decisions are made. A brief description of the
essential features of the various conceptual foundations of the commonly viewed theories of justice include the following:

The libertarian construct of justice is based on such concepts as equality of opportunity, equality before the law with the essential feature focusing on the minimal amount of restraint required for individuals to act with each other. For example, the “right to life” within the libertarian construct does not obligate some external agent to provide you with the means to live but rather it is the right to not be killed. Similarly with property rights, it is the liberty to acquire property through various mutually agreed upon methods of acquisition or contractual agreement, not the expectation of property or goods provided by an agency (such as the government) merely because of a defined or determined “need”. Libertarians look to the concept of charity rather than justice as the way to deal with those in dire need.

In contrast, those with “classical” socialist construct of justice look at equality or equity as a pre-eminent goal. The classical Marxian concept of the basis for the distribution of society’s goods is, “from each according to his ability, to each according to his contribution” and then eventually, “from each according to his ability, to each according to his need.” This is a reflection of a philosophical assumption that if all work becomes intrinsically satisfying and worthwhile, it would not matter what work one is doing, as all have a comparable level of satisfaction and societal worth. Part and parcel of the socialist construct if it were applied to western societies is that democratic principles would be paramount in the decision-making and dividing up of roles in society. Within the socialist construct the concept of private property appears to be in perpetual conflict. Whether personal property, for example, might be owned has been controversial in socialist thinking.

The contractual perspective of justice is the mainstay of what is often called “welfare liberal justice”. It would seem that those espousing welfare liberalism wish to combine the best aspects of the liberty construct with that of socialism which results in a framework in which contractual fairness and mutual respect are the dominant features. The thoughts of Immanuel Kant are prototypical for this perspective. It allows freedom of individual pursuits as long as they can be universally applied and do not interfere with the freedom of individual pursuits of others. Another view that is not always congruent with the contractual perspective of justice is the utilitarian perspective, as espoused by Jeremy Bentham and John Stuart Mill, in which the maximization of total societal happiness or satisfaction is the goal. They suggested that justice could be derived from the idea of social utility. Among the reasons that there has been objection to the utilitarianism construct is that within this construct, society as a whole is regarded as if it were just one person- which must disregard individual differences and preferences in the playing out of justice deliberations. The contemporary concept of Quality Adjusted Life Years, or QALYs, often used to compare the “value” of various treatments, has its roots in writings of Mill. He used the term ‘quality adjusted utility’: “it is quite compatible with the principle of utility to recognize the fact that some kinds of pleasure are more desirable and valuable than others. It would be absurd that, while in estimating all other things,
justice. by the would required Encyclopedia Program.

It is possible that decisions are made in which decisions, mg and expensive therapies, whose use may not be seen as core or crucial to the well being of the population being served by the Ontario Drug Program.

Although on the surface appearing somewhat similar to socialist concepts of justice, the communitarian construct depends on the idea of the common good. Without trying to define specific modalities of arriving at the underpinnings of “just” acts or decisions, it is the impact on the “common good” that must always be considered as having a priority in the decision-making equation. Within the communitarian construct it is possible that decisions are made in which goods may not be distributed in an equitable fashion but the decision to define the basis of distribution reflects the values and needs of the community that is served by the decision-making process. There is not intrinsic commitment to “equity” within the communitarian construct, but rather a reflection of the beliefs and values of the population service, using various methods beyond those in the “standard” democratic process to define those collective values.

A more contemporary construct of justice is feminist justice which, although derived from previous works including those of John Stuart Mill, focuses on the need for contemporary society to eliminate gender as a consideration in any deliberations that has to do with the distribution of rights, duties or goods. How feminist justice principles might interact with the other justice constructs might depend on whether or not the others require specific gender-related roles or attitudes, which if so, might force them to be in conflict with feminist justice principles.

One might say that although on the surface there appear to be substantial differences among these divergent constructs of justice, there may very well be a great deal of overlap and congruence with their various features. As concluded in the Encyclopedia of Bioethics, “if the ideal of liberty of libertarian justice can be shown to require the same rights to welfare and equal opportunity that are required by the welfare liberal conception of justice...it may be possible to reconcile, at a practical level, the differences between welfare liberal justice, socialist justice and feminist justice. If this can be done, all that would be necessary to reasonably resolve disputes about justice would be to clarify what the shared practical requirements of these conceptions of justice are, and simply to act on them....It would (therefore) seem reasonable...to determine what level of health care would be required by a right to welfare and a right to equal opportunity”(31).

C. Justice, Health and Health Care

One interesting approach is to explore the “level” of health care resources required for justice to be achieved. Norman Daniels explores the various possibilities of finding the suitable “level” of health care that is compatible with the various constructs of justice. I have drawn on his works and concepts to help explore the specific issue faced by the Ontario Ministry of Health. This includes how the ODB deals with the basis for coverage for new, innovative and expensive drug therapies, whose use may not be seen as core or crucial to the well being of the population being served by the Ontario Drug Program.
Daniels draws on concept(s) described by the contemporary philosopher Rawls in determining how so-called “primary goods” could be allocated in a just or “fair” manner. Rawls did not focus specifically on health care but rather formulated his concepts for most ordinary human social goods including, “rights and liberties, powers and opportunity, income and wealth, and the social bases of self respect”. Part of Daniels’ interpretation of how Rawls would approach health care as a primary good would be achieved by imagining “people behind a veil of ignorance trying to determine how they should allocate health-care services over their lifetimes....People are to imagine themselves ignorant of their actual age so that they could be young or old....(He) claims that people...would reserve certain life-extending technologies for their younger years and thus maximize their chances of living a normal life span, even if that meant reducing the medical resources that would be available in their old age”(31,32,33).”

The result of accepting such a conceptual framework for health care resource distribution and such a procedure for determining the morally appropriate level of health care that would respect an equitable right to health care would require: “ 1) a focus on death-preventing level of health care for the young, 2) a focus on life-enhancing health care for both young and old, and 3) a willingness to cut back on death-preventing health care for the old to some extent when it conflicts with 1) and possibly when it conflicts with 2) as well....Yet these consequences remain indeterminate until we specify the amount of resources that are to be devoted to health care rather than to meeting the various other needs and wants that people have” (31).”

In order to determine and utilize health care resources effectively there appear, according to this way of thinking, two options, “One...is to specify an optimal and affordable level of health care and then guarantee this level...to all legitimate claimants. The other is to specify a decent minimal level of health care and guarantee that level...to all legitimate claimants, but then allow higher levels of health care to be purchased by whoever has the income and desire to do so. Of course, both these options will leave some people dissatisfied (31).”

It is of contemporary interest that these two options are exactly those behind the present debate on health care delivery systems and very pertinent to the existing situation in Ontario and the rest of Canada. The concept of the so-called “private tier” of medicine is based on the second construct by which whatever the “decent minimal level” is, those who wish to, should be able to purchase beyond that with their own personal means. In the arguments for and against these disparate positions, a number of issues appear to surface. Beyond the theoretical ethical implications of service delivery under the two systems, empirical results suggest that the consequences of the “private tier” concept may compromise the concept of the “decent minimal level”. Current evidence suggests that there is erosion of the public tier that provides the “decent minimal level” through the preferential treatment to those in the “private tier”. Those who are served by the private tier often respond with a diminished commitment to the welfare of the public tier and the “common good” (3,4,5,6,24,34,35,36,37).
This two option dialectic is framed as follows: "assuming...that we are trying to
determine the morally appropriate level of health care required by a right to welfare and a
right to equal opportunity, it is surely the case that nothing less than a guaranteed decent
minimum level of health care to all legitimate claimants would be morally acceptable.
But, is a multi-tiered option for health care morally permissible, or is the option of an
equal level of health care morally required?....Once we recognize how numerous are the
morally legitimate claimants on the available resources, it becomes clear that all that we
can hope to do is provide a decent minimal level of health care to all claimants....
Morally, we would seem to have no other choice than to favor the same level of health
care for everybody...[by appealing] not to the ideal of equality itself, but rather to the
goal of providing all legitimate claimants with a decent minimal level of health care....Within this context, no one can have more than equality if everyone is to have
enough....There remains the question of how to specify this minimum level of health care
that all legitimate claimants are to receive....How much of the available resources should
go to providing everyone with a decent minimum of health care rather than providing for
the satisfaction of people's other needs and wants....[The] specific requirements of just
health care would be further supported if it can be shown that the rights from which these
health-care requirements are derived are themselves the shared practical requirements of
libertarian, welfare liberal, socialist, communitarian, and feminist conceptions of justice”
(31).

There are clearly those who would argue against the conclusion that the “equal-
health care” option is the one most consistent with a morally defensible approach to
justice as it pertains to health care priority setting. This is especially the case when one is
considering health care resource issues that may be at the “margins” of the health care
debate- i.e. of individual import but perhaps at a lower level of impact on the society as a
whole. This is one of the arguments for the multi-tiered or private tier proposals for
certain aspects of surgery, reproductive technologies and drugs (3,4,5,6,24,34,35,36,37).
With these questions in mind, Daniels weaves an ethically compelling argument around
which the concepts of priority setting and a reasonable framework for the distribution of
health care resources can be used to discuss specific issues in health care delivery.

In his article Justice, Health, and Health Care, Daniels progresses from his initial
use of Rawls' concepts of justice which does not provide a particular argument for a
societal reason to give health care a special place among primary goods. He proposes the
reasons by which one could justify giving health care such a high priority. He provides a
broadly based overview of how health care fits into the conceptual framework of Health.
This perspective is very helpful to the development of an argument that places health care
in a context, which justifies its place as a special social value. It is of interest that Daniels
appears to lean towards universality in health care delivery as an important basis for
assuring that the justice concepts within his arguments can actually be achieved.
However, he does refer to public and private mixes of health care delivery services as
potentially capable of carrying out the mandate of providing the necessary health care
services, which he supports as integral to a just society(38).
The author explores the reasons why society might be willing to be more generous in its provision of health care than it might for other important factors that might be important for health as one of its determinants (education, food, shelter, poverty etc.). He examines the basis for this apparent societal willingness to provide health care. He tries to determine what the parameters might be that would assure that this societal commitment is maintained or expanded and remains acceptable to the public and the constituents served by the health care system whether public, private or mixed.

The answer to the first question as to what special moral importance there is for health care is that primarily it "derives from the way in which protecting normal functioning contributes to protecting opportunity. Specifically, by keeping people close to normal functioning, health care preserves for people the ability to participate in the political, social, and economic life of their society. It sustains them as fully participating citizens—normal collaborators and competitors—in all spheres of social life....Maintaining normal functioning preserves...their broader, fair share of the normal opportunity range, providing them with opportunity to revise their plans of life over time" (38).

It is of interest that, from Daniels' perspective, health care is so important not because better function makes people more content or happier, but because the "appropriate principle of distributive justice for regulating the design of a health care system is a principle protecting equality of opportunity....There is something attractive about locating the moral importance of meeting health care needs in the more objective impact on opportunity than in the more subjective impact on happiness....Health care is of 'special' moral importance on this account because it helps to preserve our status as fully functioning citizens....Since medical needs are more unequally distributed than these other needs (food, shelter, etc.) and can be catastrophically expensive, they are appropriately seen as the object of private or social insurance schemes"(38).

Daniels states, "the account supports the provision of universal access to appropriate health care – including traditional public health and preventative measures through public or mixed public and private insurance schemes. Health care aimed at protecting fair equality of opportunity should not be distributed according to ability to pay. Rather, the burdens of financing such a system should be distributed according to ability to pay, e.g. through progressively financed health services or insurance schemes. Even in premium-based systems, which are not financed according to ability to pay, the burden of financing should not fall heaviest on those who are ill, e.g. through co-payments or risk-related premiums....Properly designed universal coverage health systems will be constrained by reasonable budgets, since health care is not the only important good. Reasonable resource constraints will then require judgements about which medical needs are more important to meet than others. Priority setting and rationing is a thus requirement of justice, since meeting health care needs should not and need not be a bottomless pit"(38).

Of interest is the position that Daniels takes about rationing based on age criteria. He echoes some of the reasoning of Daniel Callahan (39) when he suggests that "fairness
between age groups is appropriately modelled by the idea of prudent allocation over a life span. This account implies that 'pure' rationing by age (where age is not proxy for another trait) is permissible under certain special circumstances, namely, where scarcity works to reduce the chance of the young reaching normal life expectancy while giving those already old a chance at a very long life, and where there are no more prudent options than implementing rationing by age. Since we all age, differential treatment at different stages of life does not involve treating persons differently over their whole lives, provided we have stable and prudent policies" (38).

Daniels pursues his treatise with the question of which health inequalities are unjust—assuming that society has some interest in providing care and treatments to its members to help assure equality of opportunity. He focuses this argument primarily on the health rather than health care and reviews the impact of the social determinants of health as being perhaps more important that the formal health care system. He discusses the concepts of justice and the mal-distribution of opportunity to participate as a healthy individual because of non-medical factors which impact greatly on the health and well being of individuals—such as poverty, educational level and place in the social structure. He claims that the social determinants must be addressed adequately for the health care system issues to be properly dealt with. This is a very important concept, but beyond the scope of the present thesis.

D. Legitimacy and fairness

Other concepts that are of special importance to Daniels and his frequent co-author Sabin, are those of "legitimacy" and "fairness" when it comes to health care systems. According to the authors, the legitimacy issue focuses on who should be responsible, and what is the basis for their responsibility, for the process priority setting—a person, a group or an organization. The fairness concept relates to what constitutes a sufficient reason for a patient or a clinician to accept as "fair" a priority setting decision that affects care (40). They contrast the legitimacy issue faced by private health care organizations with those in public systems by saying, "At one level, the legitimacy problem in those [public] systems has a clearer answer. The public agencies that set limits are publicly accountable in the sense that they are ultimately under democratic recall. Nevertheless, much of what we have said...about explicit reason giving and accountability, as well as about mechanisms for appeal and dispute resolution, carries to these public systems as well. In these systems accountability is often hidden in the black box of 'budget' decisions" (41). It is of interest that the recent discussions between the Canadian federal government and the provincial governments about increasing funding to the health care system is being examined within a framework of greater accountability by the provinces on how they use federal funds.

When addressing the concept of "fairness" the authors indicate that they "mean people who in principle seek to co-operate with others on terms that are mutually justifiable....Fair minded people accept the rules of the game—or sometimes seek rule changes—that promote the game's essential skills and the excitement that their use produces. Such rules aim at the 'common good'...having rules...that fair-minded people
accept does not eliminate all controversy about the application of those rules....It does...narrow the scope of controversy and the methods for adjustment....In ...health care, whether through public or private insurance schemes, fair-minded people will seek reasons they can accept as relevant to meeting consumers’ needs fairly under resource constraints....The fair-minded search for mutually acceptable rules narrows the scope of disagreement and the grounds on which disputes can be adjudicated”(40).

In viewing the ODB through the lens of Daniels’ and Sabins’ concepts of legitimacy and fairness, many criteria are already met; if not fully, then certainly in spirit. In terms of legitimacy, those involved in reviewing potential candidate drugs for ODB formulary listings have the mandate and much of the expertise required to make their recommendations. There might be some questions as to the make-up of the committee and whether it effectively reflects community perspectives. However, the acceptance of input from advocacy and other community groups has had an impact on the committee’s decision-making as has been the case in their sensitivity to issues related to HIV/AIDS drug listings. More recently an arrangement was arrived at with AriceptR that allows a trial period funded by the manufacturer before the ODB pays, under defined circumstances. There was a great deal of public advocacy that stimulated the government to find a mechanism for funding the drug with a decreased financial risk. Drug manufacturers are given a full explanation as to how to develop convincing submissions and are informed as to why a submission was not accepted. There is an appeal process, which in practice often results in reversal of DQTC decisions.

From the perspective of professionals involved in the ODB process there are many opportunities to provide input to the ODB. All physicians can express their concerns directly to the Drug Programs Branch and these suggestions often lead to changes in policy or process. Some years ago, the process for obtaining Acyclovir, a drug used to treat Herpes Zoster, was so complex, that it was clear that many potential elderly patients would be deprived of benefit because of poor policy development. Input from various geriatric specialists (myself included) led to a change in policy that resulted in rapid access to the drug under appropriate and easily complied with conditions. The recently formed Limited Use Committee (with representatives of OMA, Pharmacy associations and MOH) is another example of an attempt to find solutions to identified problems using the concepts of fairness and legitimacy.

From the patient’s perspective, there are difficulties getting direct access to the Drug Programs Branch although direct enquiries are answered. It is primarily through one’s physician or through and advocacy group (like the Canadian Association of Retired Persons) that concerns are best addressed. Physicians who take their fiduciary responsibility seriously often write on behalf of patients if they believe that funding for necessary medications is being denied inappropriately. From personal experience, if the argument is well founded, the ODB often provides the benefit to the patient.

Improvements in legitimacy and fairness might be achieved by more formal involvement on the DQTC by community representation or stronger defined relationships with representative bodies of community groups. The DQTC members themselves could
benefit from more clearly defined criteria for some of the decision-making processes and a clearer understanding of the place of economic evaluations as opposed to values-based judgements. These suggestions were noted in the work by Paus-Jenssen (2) and are congruent with my own experience as member of the Committee. The concept of an ODB “ombudsman” might also be considered. It would be someone who could respond to individual concerns about coverage decisions.

E. “Medical Necessity” as a pre-requisite for funding

The Canada Health Act uses the term “medical necessity” as a way of defining which conditions ought to be funded by the public system. Many scholars use the term when justification for treatments is being sought. The term itself has led to many difficulties in interpretation. The simplistic “face value” approach means to many, that if a physician recommends a treatment, that alone is sufficient to determine “medical necessity”. The difficulty with that definition is that it eliminates any clearly defined limits as to what might be of benefit to some patient as determined by some physician. More sophisticated definitions of “medical necessity” usually include such concepts as “evidence-based” medicine (EBM) to define those processes that have been shown in some sort of objective and reproducible fashion to provide some clinical benefit to a defined group of patients. This approach too has limitations when it comes to funding, as there is no implied fiscal or comparative relationship built into the evidence-based approach. Technological advances and new classes of medications continue to broaden the scope of medical effectiveness thereby expanding the range of interventions that would fulfill the criteria for “medical necessity”.

Daniels defends the societal commitment to providing care: “In aiming at normal functioning, [Daniels’] approach views the prevention and treatment of disease and disability as the primary rationale for what we owe each other by way of assistance in co-operative health care schemes. Enhancing otherwise normal conditions—even when they put us at a disadvantage compared to others through no fault of our own— is then viewed as “not medically necessary””(42). Daniels, in this instance, focuses on the debate of whether growth hormone should be provided only for short children with true hormone deficiency or also to those with “normal” but modifiable short stature. He uses a similar argument in trying to define the limits to the treatment of individuals with mental disorders, only some of which he feels merit support for treatment because they are defined as “illnesses” rather than aberrations in personality (43). How he would address the issue of ED would be of interest. It a disorder with numerous etiologies, some of which are more clearly defined than others. Where would it fit in his scheme of illnesses or disabilities for which “medical necessity” might be a criterion and for which equality of opportunity might be a substantive feature to determine whether support for treatment is merited?

Another method of determining the relative merit of various treatments is to include some degree of measurement of the financial value of a range of comparative treatments. This might at least allow decision-makers to include some financial equation to assist in determining relative merits or values to different but similar therapies. The
limitations of this approach are that it is most useful when comparing certain categories of treatments. Another level of determination would be to try and put a value on a treatment in terms of other modalities of care within the system including entities such as quality of life. Various scales and equations have been used to try and give some objective value to what is provided medically so that decision-makers can have some measure of objectivity when it comes to making a policy decision. The use of QALYs is an example of an attempt to develop a health care “coinage” that allows policy makers to compare one category of treatment with another and measure all the resources that go into a supporting and defined unit of measure—the Quality Adjusted Life Year. We know from experience and the literature, that the actual determination of QALYs is often very difficult, and the range of societal or third party insurer willingness to pay a defined amount for a treatment-related QALYs is very inconsistent (44,45,46).

An interesting case reflects the willingness of third party insurers to fund one category of clinical symptoms that have an impact on one aspect of quality of life while not willing to fund the costs of drugs for ED. An excellent example is the contrast in funding decisions between Celebrex® (celecoxib) and Viagra®. Both were released about the same time in North America. Few health care insurance companies would financially support the use of Viagra®, because for many insurers, sex is considered a “life-style” activity. However, Celebrex®, a drug for arthritic pain control (not considered a “life-style” issue) received financial support. The need of a patient for Celebrex® to provide pain relief in order to play tennis would probably be considered within the acceptable reasons for its use. In contrast, financial support for Viagra® for a diabetic with ED whose quality of life would be greatly enhanced would be denied. The definition of “lifestyle/quality of life” is interesting when comparing these two classes of medications. Their almost simultaneous release on to the market was met with different responses from insurers. Both are very expensive drugs and their real and potential impact on costs to the health care system is substantial (47).

F. Mental Health Practice as a Model for Funding

Although there are differences in opinion as to what constitutes “medical necessity” in the general medical domain, within the realm of mental health there seems to be greater controversy. The dilemma is the boundary between bona fide mental illness and other disturbances of emotional and psychosocial abilities. The latter seem to be more questionable as to whether or not attempts at their rectification should fall under the rubric of medicalization. The question raised by Sabin and Daniels is, “should mental health insurance coverage, across the many domains cover only disorders found in the DSM-IV [one formal classification system for mental illnesses], or should it be extended to treatment for ordinary shyness, unhappiness, and other responses to life’s hard knocks?”(43). Within this rubric of mental health conditions, one might add ED due to psychological causes, secondary to drugs used to treat mental illnesses or due to marital discord.

According to the authors, because of the wide variation in mental health related disorders, “many insurance administrators believe that judgments about medical necessity
in mental health are less precise than similar judgments in other areas of medicine. As a result they fear that if mental health services were given parity with other medical services... insurance funds will be siphoned into a 'bottomless pit'. Through the process in which they researched and wrote the article, the authors note that the 'process revealed a recurrent conflict between what we call 'hard-line' and 'expansive' views of medical necessity...we believe that [the conflict] frequently reflects unrecognised moral disagreement about the targets of clinical intervention and the ultimate goals of psychiatric treatment' (43).

Sabin and Daniels develop a premise that defines three different models underlying health care coverage in the sphere of mental health but potentially valid in other domains; "normal function", "capability" and "welfare". They suggest that "failure to distinguish among these models may contribute to the difficulty advocates encounter in their efforts to promote non-discriminatory insurance coverage for mental health services."

The authors write, "[in] the normal function model, the central purpose of health care is to maintain, restore, or compensate for the restricted opportunity and loss of function caused by disease and disability. Successful health care restores people to the range of capabilities they would have had without the pathological condition or prevents further deterioration....The model prescribes compassion for those who are less fortunate in the natural lottery that distributes capabilities, but makes the health sector responsible for correcting only those conditions which in DSM-IV (48) - terms can be diagnosed as 'a symptom of a dysfunction,' that is, a mental disorder....Treating illness and enhancing human capabilities may both be desirable social goals, but they should not be confused with one another....The normal function model holds that health care insurance [or coverage] should be restricted to disadvantages caused by disease and disability unless society explicitly decides to use it to mitigate other forms of disadvantage as well." Physicians or insurers (private or public) who want to restrict the scope of access to health care coverage, usually use the normal function model as the one that underpins their concept of "medical necessity."

The authors describe the capability model as one, which considers a broader role for health care, one that "holds that the distribution of personal capabilities like confidence, resilience, and sociability in the natural lottery should not be taken as given. Health care should strive to give people equal personal capabilities, or at least give priority to those whose diminished capability (whatever the cause) puts them at a relative disadvantage." This model "makes relative disadvantage in one's ability to function the morally relevant characteristic for determining insurance coverage.... The capability model...would use health care to help people become equal competitors, free from disadvantages regardless of etiology...it does not require that an impairment be 'a symptom of a dysfunction [underlying disorder]'" (43).

The last of the three models, the "welfare model", poses the concept that "if people suffer because of attitudes or behavior patterns they did not choose to develop and are not independently able to alter or overcome, they should be eligible for insurance..."
coverage.” The welfare model makes its central focus for diagnosing a mental disorder as “present distress [a painful symptom] – but like the capability model...in not requiring that the distress be a ‘symptom’ of a mental disorder.” The authors continue, “The capability and welfare models provide expansive physicians with a rationale for interpreting treatment of the conditions that DSM-II (49) called ‘neuroses’ and.....[have been] described as the ‘humanistic’ tasks of psychiatry as medically necessary.”

How do these concepts get translated into principles on which to organize an ethically sound health insurance program? There appears to be a universally accepted desire by public and private health care insurers to find ways to restrict the substantial growth of funds to pay for health care needs. Therefore, a well-structured system of priority setting will be required on which to determine what resources will be allocated for what range of treatments. The concept of a limited supply of money will mean that whatever decisions are made in one domain of health care financing will have an impact on the opportunity to fund another area of health care and in the broader sense, other societal needs.

In keeping with this understanding, Sabin and Daniels state, “A clear and well-grounded model of medical necessity will be crucial for the design of a just and practical insurance system.... To be useful, a model for defining medical necessity must pass three tests: Does it make distinctions the public and clinicians regard as fair? Can it be administered in the real world and does it lead to results that society can afford?"

According to the authors, “the normal function model meets these three criteria best.” The authors focus on the ability to clearly diagnose a mental condition, which for all practical purposes is based on the current DSM-IV, which provides boundaries that are generally accepted within our society as to what constitutes mental health illnesses. The authors comment, “while morally acceptable definitions of the scope of health care lead to costs that strain every society, the normal function model at least allows society to draw a plausible boundary around the potential scope of insurance coverage for mental health care. Although the capability and welfare models capture basic moral insights, we believe that they cast too broad a net and pose severe problems for administration and cost.... Public support for mental health insurance coverage, historically tenuous at best, might be compromised further if the public believed that third-party resources were subject to even more moral hazard than exists at present.” They quote Clinton’s American Health Security Act as being congruent with the normal function model in that “coverage will be provided only if an individual ‘has or has had during the 1-year period preceding the date of such treatment, a diagnosable mental or substance abuse disorder.”

The authors warn that, “if the health care reform process ultimately interprets ‘medical necessity’ in accord with the normal function model, insurers will need to clarify the implications of the model for clinicians and the public....An example might read like, ‘those mental health services which are essential for the treatment of...mental health disorder(s) as defined by DSM-IV in accordance with generally accepted mental health practice.’....A model for determining medical necessity allows us to determine
what conditions are eligible for insurance coverage, but does not tell us how much of the total health care budget should be devoted to mental health. A health plan, state or nation might decide it could not afford to provide all treatment(s) eligible for coverage, and that it needed to set priorities (or ration). To think rationally about how to finance, administer, and set priorities within mental health insurance, we must first be clear on what the insurance is for” (43).

Sabin and Daniels continue, “Any model of medical necessity will ultimately have to be applied by clinicians at the front line.... We recognize that the concepts of disease and disability have been subject to extensive philosophical and sociological criticisms.... Society, however, needs a publicly acceptable and administrable system for defining the boundaries of health insurance coverage. The conception of mental disorders embodied in DSM-IV provides a workable definition of these boundaries.... (It) is not free from error or bias [but]...it is...the result of a highly public process open to scientific scrutiny, field testing and repetitive criticism over time.”

The authors conclude, “Conflict about health insurance can occur at three levels. First, parties may differ about the goals of health care itself, as when expansive clinicians clash with hard-liners. Second, empirical conflicts may occur over how interventions (means) may relate to outcomes (ends). Finally, even with a well-clarified model for defining medical necessity, society will continue to struggle over how much medically necessary care it will provide. All three levels of conflict pose major challenges. If we do not make clear distinctions among them, however, we will make no progress towards creating useful answers”(43).

G. Unsolved rationing problems

One of the challenges in trying to define the parameters of priority setting as a reflection of the principle of distributive justice is bridging the gap between theoretical considerations and the realities of actual decision-making. This issue was discussed in depth by the ethicist Normal Daniels in a 1994 issue of the Hastings Center Report, which was followed by responses from various scholars in the field. Daniels, in framing the “four unsolved rationing problems”, focuses on those ethical dilemmas that face planners and clinicians on a daily basis- whether in the midst of a clinical decision or when making policy (50). In his opening remarks, Daniels states something that perhaps has not been adequately acknowledged especially in North America- that is: “...rationing is pervasive, not peripheral, since we simply cannot afford, for example, to educate, treat medically, or protect legally people in all the ways that their needs for these goods require or that accepted distributive principles seem to demand. Whenever we design institutions that distribute these goods, and whenever we operate those institutions, we are involved in rationing”.

The importance of this statement is that for many, the concept of health care rationing is anathema, and seems to imply an unusual situation, especially in North American society. One could argue that before we discuss rationing in health care, we should explore as a society, what level of communal support and transfers of wealth (i.e.,
through taxes or other means) would we accept in order to avoid or minimize the need to ration any health care resource. Clearly, many factors go into the societal values that at any given time result in a conclusion that there are not sufficient funds available for one level of care or another. Such a challenge is far greater than the challenge of priority-setting for health care services, but covers all domains of society’s system for distributing its collective wealth and resources.

The ethical challenge in health care rationing noted by Daniels is to define the principles by which decisions are made and accept the result of any rationing decision so that “meeting the educational, health care, or legal needs of some people, for example, will mean that the requirements of others will go unsatisfied.... When we ration, we deny benefits to some individuals who can plausibly claim they are owed them in principle; losers as well as winners have plausible claims to have their needs met and...the general distributive principles appealed to by claimants as well as by rationers do not by themselves provide adequate reasons for choosing among the claimants”(50).

Daniels has outlined four of the most important rationing problems and these have been subsequently addressed by others who have attempted to expand on and resolve some of the intrinsic issues that appear to be inherent in the defined problem. By reviewing these, the challenges faced by health care planners who represent society’s interests may be better understood.

The first of these defined problems is the Fair Chances/Best Outcomes Problem, which Daniels notes arises in micro and macro contexts. He postulates the micro problem as: “Which of several equally needy individuals should get a scarce resource, such as a heart transplant?” At the macro level, it’s the choice between treatments at the health care budget level, where one treatment “restores patients to a higher level of functioning, [it would presumably be considered to have] a higher net benefit.” In both of these situations, patients who have the better chance at the individual or at the group level of benefit would be considered by those whose level of benefit might be less profound, to have an unfair advantage because those not receiving the treatment are being “asked to forgo any chance of significant benefit”.

Phrased in terms of the challenge of the subject of this paper, this translates into: 1) which drugs should be made available for which medical conditions, and 2) what criteria should be used to determine the availability of which drug class or individual drug product when there a number from which to choose?

Daniels suggests that it is a real challenge in developing an acceptable resolution at the intuitive and substantive level as to what constitutes an acceptable methodology. In her response to this dilemma, Frances Kamm proposes a complex formula of various weightings to the variables involved(51). According to Kamm, “there is no perfect fit between intuitions and method-generated answers, but as long as the answers fall within the range that is intuitively accepted and there is intuitive support for the method itself, there may be no problem”. Kamm goes on to say that the “correct view on the question of distribution of scarce resources involve, at least, deriving how much weight to give to
such factors as differential outcome, aggregation to different people’s needs and helping the worst off first.” She continues with trying to define different interpretations of micro versus macro distinctions— including: “1) individual versus social benefits; 2) here-and-now decisions versus long-term policy; 3) one-person decisions over time versus one-person decisions among multiple persons; 4) outcomes relevant to medicine versus broader social considerations and 5) part-of-life decisions versus whole-life decisions”.

Kamm suggests that when it comes to outcomes, “if the difference in the appropriate type of outcome is small, it may still be a relevant difference, given the importance, from the personal point of view of the candidate with the lesser expected outcome, that he not lose his equal random chance for the scarce resource. when the difference in outcomes increases....a point is reached where the difference becomes (more) relevant....should either lead to giving one party a higher proportional chance for a resource or determine the distribution of the scarce item...(but) we should decide as we do for the sake of the individual whom we can benefit more, rather than for the sake of increasing social outcomes.....the moral weight of the difference in outcome is less than if the difference in outcome were a good distributed over more people. It also means that giving the better outcome may be less important then helping someone avoid a worse fate than someone else”(51).

From Kamm’s response, it appears evident that an easily applied equation by which these decisions are made is quite elusive, but the necessary factors that have to be considered are highlighted and should not be ignored by those who make health care priority setting decisions.

A second among the unresolved conflicts that Daniels highlights is the Priorities Problem— that is to say, how much priority should we give to treating the sickest or most disabled patients?

Daniels notes that many factors go into the concept of giving priority to the sickest or most disabled. This depends partially on the quality of benefit to the different groups involved and whether or not the differences in outcome are substantial. For example, under battle situations, the sickest may not be treated first because their likelihood of survival may be terribly small despite the desperateness of the situation. A soldier with a much lighter injury could be treated with a better outcome and likely return to active service if attended to immediately. This is often the case in major disaster situations where the issue of triage does not necessarily give precedence to the worst off.

In keeping with the concept of “helping the worst off”, Kamm questions the definition of the term itself— does it mean most urgent, or the possibility of the worst quality of life without treatment? She raises the concept of when in the time-line of life would such a need take precedence. It could conceptually result in a position where, “The young will be needier than the old, and the younger will be needier than the older.” There are many components to the equation of dealing with the worst off scenario which include not only the age of the persons being compared but the potential benefit of the treatment offered to one individual at one age compared to another and between groups.
Kamm suggests that, "If there is not too much difference between those who are worst off and others, and if there is a lot at stake in possible good outcome for all parties, we should give equal chances or give chances proportional to how badly off each person would be if not aided" (51).

**The aggregation problem**

According to Daniels, this challenge is posed as, "*when should we allow an aggregation of modest benefits to larger numbers of people to outweigh more significant benefits to fewer people?*

In order to approach conceptually this challenge it would be important to ask how one would determine the concept of "benefit". The implementation of this process of thinking in terms of distributing resources in some sort of rational and ethical framework in which so-called benefits come into the equation, was the underlying rationale for the Oregon plan, noted by John Broome in his reply to Daniels' four problems article (52). The Oregon plan was a process that was motivated by the structure and funding of the state Medicaid program in Oregon. It was an attempt to assure maximum care of what might be considered the most appropriate and beneficial type to the population at hand, utilizing ethical principles using the input from the community being served. As Broome notes it is "the most explicit scheme that has yet been devised for rationing medical services".

The state of Oregon had as its goal the objective according to Broome, "of using its limited medical resources to do the most good possible. It tried to estimate the benefit that each treatment provides, and ranked the more beneficial ones higher than the less beneficial. A treatment that can be expected to extend a patient's life for many years would be ranked higher than one that extends life a short time. Quality of life was also taken into account. A treatment that extends a patient's life and leaves her in good health would be ranked above one that extends a patient's life but leaves her disabled" (52). There are many intrinsic anomalies noted in the Oregon plan that may result in some discrimination against individuals with disabilities. It also raises the question as to what does it mean to "do the most good" - which Daniels implicitly questions.

Broome suggests that Daniels "describes the conflict too narrowly.... [Daniels] calls it a conflict between doing the most good and fair chances, whereas doing the most good can conflict in a more general way with fairness. In many situations, fairness requires that medical resources be divided fairly among people, so that people get fair amounts. The question of fair chances only arises if a particular resource cannot be divided into fair amounts for some reason." Broome uses the concept of "claims" to address the issue of "fairness". He says that "fairness is about mediating the claims of different people." A claim is distinguished from other reasons that a resource might be provided because "a claim is owed to the candidate....Not all the reasons that are owed to the candidate...must be claims." He suggests that "each candidate's claim should be satisfied in proportion to its strength...Claims...have a conditional nature. When a person has a claim to a resource, it does not mean she has a right to it, because none of
the resource may be available....But, if the resource is available, she should get a share of it....One plausible view [of claims] is that needs generate claims: if a person needs a resource as opposed to simply being able to get a benefit from it, that may give her a claim to it"(52).

Daniels’ fourth problem that remains unresolved is that of The Democracy Problem. When must we rely on a fair democratic process, as the only way to determine what constitutes a fair rationing outcome?

Mary Ann Baily tries to respond to Daniels’ questions (53). She posits that the democracy question “becomes a series of questions: Does the theory of justice allow all parts of a rationing scheme to be judged fair or unfair? If not, what are the practical rules that determine when the process-related criterion kicks in? What constitutes a fair process in this context?...[But]...the questions fail to reflect the real democracy challenge policymakers face. The first problem is, which theory of justice should be applied?....There is no consensus in the United States on the theory of justice that should be used in policy decisions....Moreover, even if people did agree on a theory of justice, they would probably still disagree on how to translate it into health care rationing rules because of the differences in their feelings about various states of health and in their beliefs about the facts....Individual preferences also influence views on health care rationing....The rules one would personally choose, given one’s own preferences over health states, may not be the rules one considers appropriate when everyone will be forced to contribute to the cost of implementing them....Moreover, a person’s views about what care is morally required, and for whom, may (indeed should) take into account effects on people other than those who actually received the care...i.e. mental health care for a depressed mother enables her to be a better parent to her children: timely treatment for an infectious disease spares others from infection and so on....Efficiency also matters. If treatment for a condition is considered morally obligatory and the condition can be prevented at a modest cost, it is reasonable to believe that access to the preventative treatment should be guaranteed on grounds of efficiency, whether or not a moral case can be made for including it”(53).

Many other issues must be considered within the democracy problem including “whether the preferences and values have been elicited so as to reflect the individual’s authentic beliefs...and the unconscious confusion of the individual and the community...decisions about fair rationing rules...typically concern the allocation of communal resources...how to allocate communal resources in the face of such differences [in views and opinions of the public].” According to Baily, “achieving an allocation of resources that reasonably accommodates disparate values, preferences, and needs, is in fact, the daily business of communal life, one which we perform routinely at every level of social interaction....[But]...we have no simple, universally accepted method(s) for solving these allocation problems, and probably never will....[But]...we do have many strategies for managing them in real-world situations, including situations in which there are profound differences in moral values among those involved....The social history of American bioethics has led it to emphasize the rights of individual patients in treatment decisions, contributing to a perception that rationing health care is inherently
unjust except in extreme cases of absolute scarcity....Economics dictates that if Americans [can read any society] want to guarantee that they and those they care about will always have access to something, they must give up the idea that they can have access to everything; they must recognize that because the cost of health care is shared communally, care priorities must also be determined communally. The policy challenge is to define these priorities in accord with considerations of morality, efficiency and enlightened self-interest”(53).

Daniels, in an article on Rights to Health Care notes, “What does emerge from my survey is that any more promising approach will have to rest on a careful analysis of the kind of social good that health care is and will have to be sensitive to the ways in which it is permissible to trade it off with other social goods. Health care needs behave in peculiar ways compared to other needs and wants for which we have developed distributive theories. Therefore, they need special analysis. It is unclear how much of the apparatus of justice as fairness can help us with that task of analysis. I am left with a common philosophical embarrassment. I have taken a fairly simple intuition couched in terms of a right to health care, namely that we ought to have access to adequate health care, regardless of our income level, and I have shown that it seems surprisingly (if not impossibly) difficult to flesh out that right within the framework of theory that should, more than others, be able to accommodate it”(33).

H. Accountability for Reasonableness in Priority setting

As a potential solution to the problems noted above, Daniels has more recently developed a concept by which decision-makers can address the many challenges in the allocation resource and priority-setting domains. He says that despite philosophical arguments that might promote one approach or another in terms of possible theoretical decision-making systems, realistically “we must arrive at legitimate and fair resolution(s) of disputes about them [distributive issues] in decision-making at various levels within our health care system, and we must do so in real time.” He notes that the “fair” process that he has proposed called ‘accountability for reasonableness’…is an attempt to connect views about deliberative democracy to decision-making at various institutional levels in our complex health systems” (38). One could say that, accountability for reasonableness is a method by which policy makers can operationalize the concepts of legitimacy and fairness.

In their article “Making Pharmacy Benefits Accountable for Reasonableness”, Daniels and Sabin define the framework of a priority-setting approach that would include providers and consumers in a process whereby the parameters for provision of drugs are clearly defined and accepted. Much of the focus would be suitable for a private benefits provider, but they were able to modify their recommendations to be applicable to a public provider as well. They note that pharmaceutical management should be based on principles that are applicable to health care funding in general and suggest that “managing access to pharmaceuticals is a microcosm of the limit-setting problems of health care systems as a whole....If we are right accountability for reasonableness is a solution to the legitimacy problem in health care systems as a whole; then it should be
possible to illustrate what such accountability would mean in practical terms in pharmacy benefit management”(54).

Daniels develops the concept of accountability for reasonableness which has become the primary focus of his attempt to deal with the concept of priority-setting in the realm of general health care treatments, with a special focus on pharmacological treatments and access to drugs that are funded by a third party(38,54). He outlines four steps, which he believes are necessary to achieve this goal:

1. Decisions regarding coverage for new technologies (and other limit-setting decisions) and their rationales must be publicly accessible.

2. The rationales for coverage decisions should aim to provide a reasonable construal of how the organization (or society) should provide “value for money” in meeting the varied health needs of a defined population under reasonable resource constraints. Specifically, a construal will be “reasonable” if it appeals to reasons and principles that are accepted as relevant by people who are disposed to finding terms of cooperation that are mutually justifiable.

3. There is a mechanism for challenge and dispute resolution regarding limit-setting decisions, including the opportunity for revision decisions in light of further evidence or arguments.

4. There is either voluntary or public regulation of the process to ensure that conditions 1-3 are met (38).

Daniels and Sabin highlight the reality that the increasing cost of drugs is due to a number of factors(54). These include an increase in volume of drugs with the shift in the demographic distribution of ages to the older group and an increase in unit cost of drugs especially newer ones that are more costly than older ones. The latter may have clinical benefits that appear to merit their being used in lieu of older but cheaper drugs. This process continues at a rapid rate as medical advances that identify new disorders become more sophisticated and as newer and effective pharmaceuticals become available. Examples in contemporary medicine include the newer SSRI anti-depressants, which have replaced older tricyclics, newer lipid lowering drugs, anti-hypertensives, drugs used for peptic ulcer disease and new arthritis drugs. For example, following the introduction of the newer treatments for elevated lipids, the cost of the drugs to the ODB rose 342% as a result of a 272% increase in the number of claimants using cholesterol-lowering drugs between 1992-1998 (1).

With this in mind, Daniels and Sabin suggest a process by which the “goal is to hold both purchaser and administrators accountable for the reasonableness of the pharmacy benefit.” The authors go on to describe various scenarios that would result in a reasonableness that include as examples, prior authorization, tiered co-payments and limits of quantity, which they explore in terms of acceptable and workable frameworks. They note that unlike the private sector “the public sector has a distinct opportunity to
establish rules that promote legitimacy and fairness in a way that will influence the way pharmacy benefit management is done in the private sector as well”(54).

In another article by Sabin and Daniels, the issue of insuring new technologies is addressed(42). The treatment in question was growth hormone for under-stature children. The issues could be directly compared to that of ViagraR- i.e. 1) the treatment works; 2) it is possible to categorize a range of conditions for which it works- some are more readily framed as “diseases”; 3) many physicians recommend the treatment; and 4) it is expensive and many insurers are reluctant to pay for the medication. This is especially true for the group of short-stature children that appears to be part of their genetic make-up with the assumption that greater height is a “life-style or quality of life” issue and not a true medical matter.

As noted in the article, there is a “high degree of variation among insurers and the discordance in the recommendations between insurers and pediatric endocrinologists; they “cannot establish whether current practices are right or wrong.” The authors reiterate the 3 conditions which must be met to assure the decisions related to this drug (and presumably a drug like ViagraR) is legitimate and fair: “1) The rationale for the decision is clearly stated and publicly available, 2) the rationale must make clear how the policy supports providing ‘value for money’ in meeting the varied health needs of a defined population under reasonable resource constraints and 3) there is a mechanism for challenge, dispute resolution, and the introduction of new facts and arguments”(42).

In their Health Affairs article on accountability in managed care reform, Daniels and Sabin note that the issues in private insurance or managed care structures, “have their analogues in public [universal coverage] systems such as the National Health Service in Great Britain and the Canadian single-payer system(40). At one level, the legitimacy problem in those systems has a clearer answer- the public agencies that set limits are publicly accountable in the sense that they are ultimately under democratic recall— but...in these systems accountability is often hidden in the black box of ‘budget’ decisions.” The authors go on, “Whether in public or mixed systems, establishing the accountability of decision-makers to those affected by their decisions is the only way to show, over time, that arguably fair decisions are being made and that those making them have established a procedure we should view as legitimate....Accountability to the public for reasonableness is necessary to facilitate the broader democratic processes that regulate the system”.

Daniels takes on the challenge of trying to determine when might limits to health care be fair? Daniels acknowledges the social determinants of health. He comments that “A just society will also have to meet health care needs fairly under reasonable resource constraints....Specifically, it will have to make decisions about priorities among competing health care needs; it will have to ration or limit access to beneficial health care. All such decisions create winners and losers. They are the subject of widespread moral disagreement and conflict.” The author argues for “supplementing general principles of justice with an account of fair process that is useful at the various institutional levels at which decisions about limits are made. Without this account, limit-
settlers, whether in public agencies or private health plans, face a problem of legitimacy: under what conditions do they have the moral authority to set such limits?... If, however, the process they abided by was fair, then even in cases where there was disagreement about underlying principles and how to apply them, people could agree that the outcome of the fair process should count as fair"(40).

Daniels appears to believe that adhering to the previously noted four principles will "convert private decisions made by health plans or insurers, or decisions made by experts and bureaucrats in public agencies into part of a larger public deliberation about a major, unsolved public policy problem, namely, how to use limited resources to protect fairly the health of a population with varied needs, a problem made progressively more difficult by the successes of medical science and technology....It involves a form of institutional reflective equilibrium, a commitment to both transparency and coherence in the giving of reasons. The quality of decision-making improves if reasons must be articulated. Fairness improves over time, both formally, since like cases are treated similarly, and substantively, since there is systematic evaluation of reasons....Over time, people will understand better the moral commitments of the institutions making these decisions"(40).

In so formulating his treatise, Daniels frames the process in a way that should be readily understood and applied in practical terms to health care system decision-makers. However, it is to my mind overly optimistic to assume that those with diverse views will readily accept the process without constant challenge reflecting the self-interest of individuals and groups. It may be that the challenges are crucial to the efficacy and acceptance of the process as suggested by Daniels. The issue that is more difficult to address is what value systems, held by those who make decisions, are reflected in the decisions that are made and how do these values reflect those of the constituents being served by the health care system program in question? Paus-Jensen, in her thesis, remarked on the importance of the personal values held by DQTC committee members and how they impacted on their decision-making, at least as much as their understanding of the economic factors that they were asked to consider (2). It is because of this conundrum, that some scholars have suggested the need for greater input from the constituents being served by the system, rather than relying on policy-makers alone to try and anticipate or reflect the values of the constituents they serve. This has led to the concept of communitarian input to the health care decision-making process (55, 56). The Oregon process was an example of such an approach to priority setting (57,58,59,60).

A review of Daniels’ and Sabin’s propositions in their series of articles makes it apparent that the framework and rationale for policy decisions by the ODB for the listing of ViagraR have not been completely elucidated. Much of the decision-making has centred on clinical criteria and cost-effectiveness and other economic analyses. For drugs like ViagraR and others that have clinical impacts that are not clearly deemed to be "medically necessary", the possibility for listing as a covered benefit is reduced. There has been no enunciated ethical framework by the Drug Programs Branch that defines why a drug like ViagraR which fulfils the clinical criteria for effectiveness would not be made
available to ODB recipients. A clear policy statement which defined why Viagra might or might be covered would be very helpful to members of the DQTC in making their recommendations. It would also be useful for the public who have to understand the rationale for the decision when they are forced to pay for an effective treatment that they feel has a major beneficial impact on their lives.

Of interest to the issue of quality of life as a rationale for listing on a publicly funded drug formulary is a recent report about the Australian Pharmaceutical Benefits Scheme (PBS). It states, "The list of benefits is comprehensive, providing suitable therapy for most medical conditions in which medicine is an accepted form of treatment and diagnosis by a medical practitioner is appropriate." However, "some health economists have criticized the PBS for not focusing sufficiently on quality of life (QOL) definitions of effectiveness and assert that several clearly effective drugs have been rejected on the basis of price"(61).
Chapter 6

Pharmaceutical benefit management

In this chapter I will explore the workings of pharmaceutical management programs in general with the primary focus being on the ODB. This is because of the relevance to clinical practice in Ontario and within the Canadian Health Care system and because of my personal involvement with pharmaceutical decision-making in the province for more than a decade.

A. The Ontario Model

Using the Ontario system as the model, which will be used for this study, it is worth reviewing the structure and framework of its drug distribution system. Ontario’s citizens receive their prescribed medications from a number of sources, only some of which are provided by the publicly funded health care system. For Ontarians who are hospitalized, their drug needs are provided without personal cost as part of Ontario’s commitment to the Canada Health Act. For ambulatory medication needs, the vast majority of Ontarians receive their drugs through employment supported drug benefit programs. A small number of Ontarians do not have a work-related drug program but have incomes that make them ineligible for the comprehensive governmentally supported systems. This population can qualify for Ontario’s Trillium program, which allows for low income Ontarians to be reimbursed for high drug costs. This program, introduced in 1995 has grown from serving 8,000 recipients in 1995, to 37,000 in 1998, of which 59% were female (1).

For those Ontarians who are over the age of 65 years or who qualify for social assistance because of low incomes or government defined disabilities, there is Ontario’s Drug Benefit (ODB) Program. The ODB’s total budget has been $1.211, $1.289, and $1.566 billion in the years 1996/97, 1997/98 and 1998/99 respectively. The breakdown was about 2/3 for the senior program and 1/3 for those on social assistance in the first two periods and a similar dollar amount (~$365.5 million) for social assistance in 1998/99. There was an added amount during that period of about $91.5 million in the Special Drugs Program (i.e., AIDS, thalassemia, cystic fibrosis) and $44 million for the Trillium Drug Program. Thus there has been a continuous increase in the ODB expenditures since 1996 and an expansion of coverage to include otherwise uninsured Ontarians through the Trillium program (Personal communication from Ministry of Health Drug Programs Branch and DELTA report-ref.1).

The ODB drug formulary is very substantial. As of the 1999/2000 period there were 3,171 products listed in the formulary of which 2,861 were general listings, and 310 or ~10% of items were covered as limited use products. There are 20 therapeutic classes of drugs covered (e.g., anti-infectives, cardiovascular drugs which includes 90 subclassifications of drugs - antivirals, anti-lipemic agents). General listing drugs may be provided without any special permission or documentation by any licensed physician (or dentist) in the province. Limited use products require the physician to document criteria
which are determined by the DQTC for which the particular drug product may be considered appropriate when compared to general listing drugs. Limited use products fall into a number of categories: 1) new classes of drugs for which the benefits have not yet been clearly determined by the evidence available; 2) new drugs within established classes for which the relative merit compared to other drugs in the class has not been clearly determined or 3) new drugs or 'me-too' drugs for which the cost is substantially higher. Over time there is often a transition from limited use drugs to general listings. The last category of drug consists of those not listed on the general or limited formulary but for which the prescribing physician believes there is a medical necessity. They are covered by a category called section 8. To access drugs through this mechanism, the physician may write a letter to the Drug Programs Branch requesting the drug in question for a specific patient while outlining the compelling evidence why it should be reimbursed by the government.

Over the years, virtually every class of drug has been covered in one way or other by the ODB. There has been a steady transition of drugs from the limited formulary category to general usage. Thus, within the acceptable standard of care, very few medical needs are not met by formulary listed drugs. However, of special interest is the fact that no drug has ever been approved for the purpose of treating ED. Until the advent of Viagra\textsuperscript{R}, it was possible for the DQTC to reject alternative treatments for ED on the basis of limited efficacy, which is one of the criteria used by the committee to accept or reject drugs for ODB coverage.

The number of new products listed in 1996 was 66 from single source (i.e., trade name drugs), 83 from multiple source (generics) with 34 that were listed as Limited Use (i.e., new and expensive drugs with special indications). In 1997 the numbers were 41 single source, 110 multiple source and 14 limited use; in 1998 the numbers were single source 70, multiple source 132 and limited use 34. In the 1999 (the latest year with figures) the numbers were single source 45, multiple source 154 and limited use 45. (personal communication ODB) These numbers reflect the large number of new drugs that are becoming available as an outcome of the contemporary drug industry and the major developments in the generic drug industry. Many of the newer drugs have limited indications and higher cost and therefore are initially, if not permanently, listed as limited use products, with formal criteria and indication(s) for use that must be verified by the prescribing physician.

It is very common for a new single source drug to gain an initial limited use listing unless the drug is a breakthrough drug for which there are no suitable alternatives. Even if it is a new drug with unique properties, the ODB is likely to give it a limited use listing, if it is not clearly a life-saving drug and is very expensive. This process is to limit the circumstances under which the drug is used—especially until more experience is gained with the use of the drug or drug class, if it is a new one. For example, when the new generation of neuroleptic agents (major tranquilizers) became available in the mid-1990's (respiridone and olanzapine) they appeared to be very expensive alternatives to older medications, many of which were already available as generic formulations such as haloperidol and thioridazine. However, with increased experience with the newer classes
of drugs in various populations (schizophrenics and the elderly) it became evident that these newer drugs were effective with fewer serious side effects than the older medications. Despite their increased drug acquisition price, the pharma-economic data, cost effective analysis and quality of life data supported the switch by the ODB from limited use status to general listing.

The formulary is reviewed on a regular basis through a process that relies on the DQTC, a multi-disciplinary committee of experts. The committee advises the government as to which drug products should be listed for coverage. The committee also relies on expertise from a combination of external reviewers and reviews by committee members as to the potential benefit of drugs and their value to citizens of Ontario.

Informal discussions at the committee table during the years 1995-1999, during which time I was a member, revealed that there was a disparity of opinion among committee members as to whether the Ontario Drug Program should be funding medications for ED at all. The degree of disagreement among committee members was never formally documented. The opinions ranged from: those who felt coverage should not be provided for anyone; those who felt that it might be provided to a limited group of individuals with clearly defined conditions that result in ED and those who felt that the drug should be made available to most individuals with the complaint of ED. Prior to the introduction of Viagra®, none of the available products had a high degree of efficacy. It was therefore relatively easy for the DQTC to refuse listing the then available products without challenging the underlying premises or principles by which the various committee members were determining formulary listing.

With the introduction of Viagra®, for the first time the committee would have to face the reality of assessing a medication whose efficacy for ED could not be disputed. Not only did it appear to be effective for a wide range of medical conditions causing ED, but also it was clinically safe and easy to use. Moreover, it was already approved for use in Canada as well as the United States and many other western countries. The important and essential question facing the Drug Programs Branch, was did the DQTC have the appropriate clinical, administrative and ethical framework by which to decide on whether the drug should be approved for formulary listing and reimbursement by the province? What criteria did the Drug Programs Branch expect the Committee to use in its deliberations? Could the members of the committee separate their personal biases as to what medical conditions should be covered by the Drug Benefits Program and what should be their role in deciding on the nature of that coverage on behalf of the citizens of Ontario?

In the past, the DQTC had not been faced with the challenge of making a recommendation on a drug that was actually efficacious for ED. In addition, recommendations often reflected a range of personal biases of committee members as to whether the treatment of ED should or should not be considered part of “medically necessary” therapy. The question of the basis and process of decision-making that existed within the committee is anecdotal and therefore remains unknown.
B. Ontario’s Drug Quality and Therapeutics Committee (DQTC)

The DQTC is the working committee of the Ontario Drug Benefit program. It is responsible for reviewing drug submissions from industry and assessing whether the submitted drug merits listing on the provincial drug formulary, and if so within which category (general or limited use). The committee itself is comprised of members who represent clinicians whose presence is deemed to represent the clinical knowledge and expertise required to evaluate drugs whose use is directed primarily to seniors and secondarily to those on social assistance. Therefore, there are usually at least one or two specialists in geriatric medicine on the committee, pharmacists and primary care physicians with an interest in the elderly and the general population that would encompass the age range and social circumstances of those requiring social assistance.

Because of major classes of drugs covered by the ODB formulary, there is usually a member with special expertise in infectious disease, psychiatry, rheumatology, cardiology, and/or gastroenterology. Attempts are made to include other physicians whose background supports the expertise requirements in drug evaluation so that the committee includes physicians with backgrounds in clinical epidemiology and/or clinical pharmacology. Because of the limited number of specialities that can be represented on the committee itself, many external consultants provide expertise to the committee on specific drug submissions or on working groups deemed necessary by the committee to evaluate a specific problem, issue or class of drugs.

The membership for the 1999 calendar year consisted of representatives with each of the following qualifications: cardiology, infectious disease, neurology, family and community medicine, internal medicine, clinical pharmacology, clinical epidemiology, health economics, geriatric medicine, community pharmacy and pharmacokinetics. There was the same membership for 2000 with the addition of a committee member with special expertise in psychology. The 1999/2000 chair is a geriatric specialist with expertise in clinical epidemiology and health economics.

The presence of a clinical pharmacologist on the committee and as external consultants and of a community pharmacist insures the expertise and perspective of those dispensing drugs in the community setting and to provide the expertise to evaluate pharmacological data especially when dealing with generic drug submissions. For the latter, the ODB has a process to assure “interchangeability” as defined by the legislation governing generic drug substitutions by a pharmacist.

The support staff includes the Director of Drug Programs and the executive secretary and Associate Director and senior consultant to the DQTC (personal communication from Drug Programs Branch). The Ministry staff provides administrative support for the committee and is responsible for the detailed workings of the committee and the interface between the committee’s activities and recommendations and the government to whom the committee makes it recommendations.
New committee members are considered based on recommendations of the sitting members, past members, the Chair and consultants in the field. The application process includes a review of the attributes and merits of the applicants, which ultimately must be accepted by the government with an appointment process that includes an Order in Council (formal legislative appointment). Therefore, the legitimacy of the committee, in clinical expertise, is probably achieved as much as might be expected. One could argue that the process by which members are recommended might be expanded and that a more rigorous peer review process might be developed. But, the committee in general has consisted of competent, committed members who expertise complements each other. The members clearly expend a great deal of effort fulfilling the committee’s mandate.

One could argue that a deficiency of the committee is not who are its members as much as who is not formally represented. There is no formal representation of anyone with expertise in social science that might provide a greater understanding of the impact on some drug class submissions, e.g., those drugs that have a major influence on disadvantaged groups. There is no formal representation from economics or from ethics, even though many of the decisions have profound economic impacts and priority setting is implicit in the Committee’s activities. There is no formal consumer group representation. There is, however, a feedback and consultation system in place to receive input and views from people with such views and expertise, but not within the formal activities of the committee, which means their direct impact on deliberations is missing. One of the recommendations of Anne Paus-Jenssen in her review of the committee was the inclusion of a community member. One of the problems with such a step lies in deciding what constitutes a fair representation of community interests. Is it possible to find one individual to represent those varied interests(2)?

The conceptual framework of the committee’s role is to critically evaluate drug submissions for inclusion into the provincial formulary, and then to make recommendations to the Drug Programs Branch and through it to the government. This is a very important arrangement. It means that the committee itself has no authority over the drug program or formulary itself, but is merely acting in an advisory capacity. Ultimately, therefore, all decisions about formulary inclusions or exclusions become political decisions, with the possibility of influence from sources external to the DQTC such as lobby groups and the pharmaceutical industry.

An example is the intense lobby efforts from such organizations as the Canadian Association of Retired Persons (CARP) about the inclusion of AriceptR (used to treat memory deficits in Alzheimer’s Disease) in the formulary. There was resistance on the part of the DQTC to list this drug because, although studies did demonstrate some efficacy, its effects were modest and did not benefit many patients who took the drug. There did not appear, from the available literature, to be any way of discerning which patients might receive some benefit from what was a very expensive drug. Due to intense lobbying and strong public interest in the drug, the government (through the Drug Programs Branch) developed an arrangement with Pfizer (the manufacturer) to provide three months’ trial of the drug in an attempt to demonstrate efficacy in individual patients. If this occurred, the Government would fund future drug costs for individual
recipients as a Limited Use product. In effect this compromise introduced a trial
prescription program co-funded by the private sector.

The implications of this advisory role are that at times recommendations of the
DQTC are ignored and drugs listed despite recommendations to the contrary which may
have an impact on future decisions. In addition, the industry may choose to use legal
tactics to influence the government’s decisions. This occurred, for example, when one of
the generic companies developed a generic form of Enalapril (Vasotec®) which initially
was accepted by the province as an “interchangeable” product (lower cost) but Merck
Frosst however challenged the patent and the decision was reversed, thus removing the
generic form from the market. The industry may attempt to use its legal clout in other
ways such as by threatening to take legal action against committee members,
undermining the committee’s ability to carry out its mandate without fear of legal reprisal
(62).

On a periodic basis the Drug Programs Branch holds an external review of the
activities of the DQTC, during which its processes and members are reviewed. This
external review process is important in establishing and maintaining the concept of
legitimacy of the committee’s members and activities.

C. Cost-effectiveness in the realm of priority setting

A very popular contemporary approach to the challenge of priority setting
is the use of cost-effectiveness as the method of determining optimal use of resources
(63,64,65). Cost-effectiveness analysis (CEA) is a process by which the equation of
health outcomes and resources can be compared and measured in terms that are
reasonably objective. Within that equation is the concept of efficiency by which
presumably the “best” or “most efficient” use of whatever resources are available is the
goal, thereby achieving the best health care outcomes across a myriad of potentially
valuable health care achievements (63,64).

One of the problems that has come to light as more emphasis has been placed on
CEA is that it does not always take into account views and values that reflect social or
ethical perspectives. These might be important to society or to the beneficiaries of the
health care system whose resources are being allocated. According to Ubel et al, “One of
the promises of cost-effectiveness analysis is that it can demonstrate how to maximize the
health care benefits attainable within a specific budget. Despite this promise, cost-
effectiveness analysis has been criticized for setting health care priorities in a way that
violates people’s values. For example, many people value equity in the distribution of
health care resources, yet equity is not accounted for in cost-effectiveness analyses....The
methods and ethical assumptions of cost-effectiveness analysis are not necessarily
acceptable to many people when limitations are placed on health care budgets....Basing
health care policies on cost-effectiveness alone can lead to inequities or the appearance of
inequities....Given the increasing frequency with which health care decisions are
influenced by budget constraints, it is important to recognize people’s discomfort with
policies based on cost-effectiveness. If cost-effectiveness analysis is to have a larger role
in health care policy, an attempt must be made either to convince the public of its merits or to balance a consideration of its merits with a greater concern for equity"(64).

Menzel et al, in their attempt to find ways to broaden the view of CEA, make some valuable observations and suggestions, "It is not surprising that conventional CEA provokes many of the same ethical objections that plague utilitarianism in general: that it gives inadequate attention to the individual person and too much to the aggregate good, and that it is insensitive to issues of distributive justice involving the least advantaged....Because of these oversights, recommendations emerging from CEA can stand starkly at odds with the values of justice and non-discrimination....CEA should explore how social values might be better incorporated into the 'effectiveness' side of economic analysis....In societal value, the focus is explicitly on interpersonal trade-offs-decisions about what services to provide among the wide array of possible services that often affect different groups of people....For the omission of a factor to be ethically objectionable, one has to be able to articulate some argument for the preferences it generates, not merely point out that people hold those preferences....We suggest that including societal values along with individual health utilities presents the opportunity for an ethically more adequate resolution of this whom-to-ask issue. A strong case can be made for eliciting societal values from representatives of the general public, but preference input about societal values needs to be kept distinct from input about individual utility and health-related quality of life ratings"(65).

The authors conclude with, "CEA in health care should broaden its conception of the array of values that might be accounted for in the 'effectiveness' side of its ledger, adding societal values to the mix. If and when empirical research and ethical analysis of selected societal values reveals them to be clear, quantifiable, of sufficient societal importance, and not irrational or ethically discriminatory, the structure of CEA should be adjusted to allow for their inclusion....It is time for health economics to recognize the relevance of these values and the ethical issues to which they speak. It is also time for bioethicists to assist with the considerable task of discerning them in as precise and usable a form as possible"(65).

The place therefore of CEA in the complex decision-making process is not as clear is some might have wished. It would be nice to have a process by which those responsible for the use of health care resources could produce data that would provide clear guidance to the allocation decisions. Although CEA, and its important components of evidence-based-medicine and QALY tables, add a great deal to our understanding of the relative costs and potential comparative merits of different interventions, from the societal decision-making perspective, they are insufficient. As Singer notes, "The pressing research challenge is to develop and evaluate an interdisciplinary methodology for priority setting decision making that incorporates but goes beyond EBM and CEA; integrates the various theoretical approaches to priority setting of philosophy, law, political science, economics and clinical epidemiology, proves useful to priority setting decision makers; and is perceived as fair by the communities whose resources are at stake"(63).
D. Cost-effectiveness and the ODB

In Ontario, the ODB made a commitment to pharmo-economic evaluation of drugs as part of the DQTC review process with its introduction in 1994. Much of the impetus came from discussions with representatives from the Australian drug program and the initiatives taken by Dr. Allan Detsky, then a member of the DQTC. Prior to the development of the Ontario guidelines, a process was undertaken to develop national guidelines in Canada, which were the culmination of meetings held under the auspices of the Canadian Collaborative Workshop on Pharmaco-economics. The resultant guidelines became the responsibility of the Canadian Co-ordinating Office for Health Technology and were subsequently used as the basis for the Ontario guidelines(66).

The rationale behind the introduction of the economic guidelines was to provide an economic framework by which new drugs could be evaluated. It was expected to be in a manner that was consistent across the pharmaceutical industry and to provide third party payers with the economic information required to assist in decision making. According to Detsky, “Cost effectiveness analysis was invented for the sole purpose of allocating scarce resources in settings where market forces did not exist or resulted in allocations that were far from optimal... With the growth of the health care sector as a predominant force within public expenditures, it is understandable that one of the principal applications of cost-effectiveness analysis in the 1990s is in the health care field”(67). It was noted that the most important reason for the introduction of standardised economic evaluations was “to be used by manufacturers to help gain formulary reimbursement...because the major purchasers of pharmaceutical products have changed drastically over the last quarter century...[the purchasers are] third-party payers in most countries...and are more demanding than their predecessors—they want proof of value for money—and manufacturers have had to respond to this” (61).

One of the questions that might be asked is whether this process and its foundational assumptions add substantially to the process of decision making. It clearly has produced a whole new “industry” and area of special learning with its own literature. According to the health economist Bob Evans, “Pharmoeconomics is a ...pseudo-discipline... conjured into existence by the magic of money, with its own practitioners, conferences and journals. There are a lot of drugs, and there is a lot of money, so that the ‘field’ is booming”(67). Despite this somewhat cynical view of the process, it is becoming an important part of the deliberation process. At the ODB, it is expected that some degree of economic analysis takes place, primarily for innovative drugs, or “me-tos” that are of higher cost than others in the same drug class. According to Paus-Jenssen and Detsky, “the guidelines serve to inform pharmaceutical manufacturers what information the purchaser needs in order to justify adopting new products. It is this use that recognizes that the real ‘consumer’ of pharmaceutical products is not the patient but rather the ‘body’ acting as agent for the patient in the decision-making process....The provision of guidelines by the third-party payers to manufacturers should be viewed as extremely helpful information to manufacturers”(67).
The model proposed by Paus-Jenssen and Detsky does not ignore quality of life issues. They say, “a purchaser’s guidelines may directly inform the manufacturer about which quality-of-life instrument it prefers, for example, whether it wants clinical effects converted into monetary benefit measures” (67). Torrance et al note that “No single measure of health-related quality-of-life has yet been accepted as the gold standard....Therefore, if this type of outcome is being measured, it normally advisable to include one reasonably precise, reliable and valid scale” (66).

In Paus-Jenssen’s review of the DQTC, she found that, although considered an important component of the formal review of drugs, economic analysis played a far lesser role than she might have expected. She noted that “economic factors play only a modest role. Although the ODB requires a pharmo-economic analysis as part of drug submissions from pharmaceutical companies, the actual usefulness and impact on the process of evaluating drugs is limited at best” (2). The author continues, “economic analysis plays an important, but limited role....Its application to the process is valued in principle, but appears to be limited in practice” (2).

The author goes on to define the most important factors in decision-making and concludes, “the clinical factor was the most dominant factor in the decision-making process at the DQTC. The quality of the data that was submitted by the manufacturer had a large influence on how the product was received; poor quality submissions were frequently viewed suspiciously”(2). Most important for the discussion related to ViagraR is Paus-Jenssen’s recognition of the importance of committee members’ personal values and their views of society, as these factors influenced their decision-making process. She says, “The context in which the DQTC makes its recommendations also influences the final recommendation that is reached. Ontario’s formulary listing is a form of resource allocation, and as such is influenced by values and politics. The DQTC could not remove itself entirely away from this fact; each recommendation made was influenced to some degree by value judgements. This finding confirms work in the field of resource allocation, and has important policy implications”(2).

The limitations of economic deliberations in decision-making and the acknowledgement of many factors ranging from clinical experience and interpretation and personal value systems, suggests that the process of priority setting is multi-faceted and complex. Daniels’ attempt to address these issues results in his approach to priority setting with his proposed framework of accountability for reasonableness. The limitations of economic analysis as recognized by Torrance et al and the reality of the variable factors that were documented by Paus-Jenssen, reinforce the need for an eclectic, flexible but responsive and responsible approach to priority setting, which Daniels proposes in his accountability for reasonableness.

E. Cost-effectiveness guidelines - the Australian Model

Mooney is a scholar with a special interest in the communitarian view of priority setting (55). He suggests that some important concepts should be recognized in dealing with the challenge of priority setting. He has suggested that in addition to individual
claims, for an ethical system to exist in which resources are distributed in an equitable and ethical fashion, communitarian claims should also be part of that consideration (55). Mooney chose to explore this approach as a result of being involved with the members of the Pharmaceutical Benefits Advisory Committee (the PBAC) which is the Australian equivalent to Ontario’s DQTC. The interaction with the PBAC was to help “tease out from the group, beyond the now statutory requirement to examine incremental cost effectiveness ratios, what considerations this group bring to their decision making and what relative weights they are attaching to these different considerations.” Mooney felt that the PBAC understood very well the economic and quantitative considerations that go into decisions but that “what they required was to be able to be explicit about two things: first, the nature of their decision making and second, the characteristics (or attributes) and values that they were taking into account in reaching their decisions. The key in all of this appears to be a requirement for explicitness in determining or eliciting these characteristics and the values attached to them”(55).

Mooney questions, “Could it be that health economists are missing the target when approaching the priority setting task? Instead of rewording the arguments in support of QALY league tables...for the n th time, there may be a need to reconsider our own disciplinary stance. There is a worry that while health economists are extolling the virtues of QALYs, Cost Utility Analysis (CUA) and marginal analysis, the policy makers are not listening because they do not see the world of priority setting in the way that health economists think they do or that health economists think they ‘should’ see it.” He goes on to suggest that from various studies there may be “a general willingness to make quite significant sacrifices [the citizens and taxpayers] in terms of efficiency and health maximization, to achieve goals of equity and social justice...and that QALY league tables...disregard process considerations that the population may feel to be of great importance in the treatment of severe illness and...that there is...growing evidence in the research literature that, when health services are consumed, patient utility or welfare may extend beyond health and beyond what might conventionally be termed outcomes and that the processes of care can also be utility bearing”(55).

He goes on to suggest that “it does not follow however, that health or ill-health alone represents an adequate ethical basis for deciding how to allocate resources within health care...and...there is a concern that ‘needs’ as the basis for allocating society’s resources in health care are insufficiently determined by the values of the community whose needs are to be served by the health service. There are many ways of conceiving of needs but most commonly, in health care resource allocation, these relate to either some burden of illness approach or ‘capacity to benefit’….Furthermore... there is little attempt to use the community’s values to determine what is legitimate in this context. Needs are defined by medical doctors, by health service planners and occasionally by politicians rather than by the community”(55).

F. Legitimacy and Fairness and the ODB

It is worth examining the Drug Programs Branch to determine if it meets the criteria for legitimacy and fairness in providing pharmaceuticals to the constituents of the
ODB. The issue of legitimacy is very important. It is usually not difficult to determine whether the organization responsible for making decisions has the legitimacy to do so. As noted earlier, the structure of the publicly funded ODB is likely to have the characteristics of legitimacy in its decision-making process.

Although there may be some difficulties in getting all parties to agree as to who will process the information for the various drugs, generally a group acceptable to most constituents can be assembled. The real challenge is for this "legitimate" committee to be provided with criteria sufficiently clear that their decisions will fall into an ethically acceptable framework for decision-making. The quantitative tools and knowledge that may be required for some aspects of priority setting may be intrinsic to the various members of the committee. Therefore, clinical epidemiologists and clinical pharmacologists may be able to provide clearly differentiating qualities of various drug submissions. It is usually not difficult to decide which of two drugs that provides exactly the same benefit and side effect profiles but with different costs should be covered by the formulary. That is the whole rationale behind the generic drug substitution program: same drug- less money. The step beyond that would be "similar drug" (same class of drug)- less money. Examples of this are which drugs for osteoporosis or which antibiotics are on the formulary as a general listing and which have limited use status, to promote utilization of the least expensive but appropriate equivalent of the same class of drug.

Difficulties begin to arise when drugs are in different classes with the same goals (anti-hypertensive, anti-depressants, hypoglycemics etc.) but different costs for each classes. For these situations, quantitative systems are more easily developed. There is usually no question among the committee members, by their understanding of priority setting, that the conditions for which the drugs are competing are those for which the committee has a mandate to provide therapeutic options within the structure of the health care system and drug formulary.

It is the issue of being fair-minded that is the real challenge to the committee. The members have to understand which of the conditions that is deemed suitable to merit drug treatments, take a priority over other conditions. A major challenge exists when there are different medical conditions for which drug program beneficiaries might derive clinical benefit. It is often very difficult to provide a hierarchy of priorities for formulary listing. No one has defined for the DQTC which medical condition might deserve a lower priority for the listing of therapeutic drugs. For example, there is no clear direction that anti-hypertensive medications have a higher priority than anti-anginal drugs or medications for skin conditions or certain gastro-intestinal conditions. Each of these and many other conditions have been informally but not explicitly deemed to merit drug therapies provided by the ODB for its beneficiaries. For example some classes of drugs have been removed from formulary status presumably because they had less merit for potential benefit than other available drugs. Vitamins and mineral supplements were an example. It was assumed that the contents of these vitamins and mineral supplements were potentially available through dietary means. Therefore, it should not be necessary for the ODB to provide them and that there would be no untoward negative health effects
on the beneficiaries of the program. It did not consider the actual dietary practices of the population in question.

For example, older people rarely drink enough milk to fulfill their calcium or vitamin D requirements. Therefore the decision to de-list Calcium and Vitamin D from formulary listing is counter productive as these two products have been shown to have a beneficial effect in the prevention and treatment of osteopenic bone disease and osteoporosis in older women. Yet, the biphosphonate (Didrocal-a combination of a biphosphonate and calcium), used to treat already established osteoporosis is available through the formulary. It is possible that it would be more cost-effective to provide Vitamin D and Calcium than to treat all the manifestations of osteoporosis, including bone fractures, a substantial proportion of which might be prevented by this simple preventative treatment(68). Another example that was recently addressed was that drugs such as neuroleptics, used to modify behaviour in patients afflicted with dementia due to Alzheimer’s disease were provided through the formulary but Donepezil (Aricept) which provided an opportunity for improved mental function for a proportion of Alzheimer sufferers or successfully decrease the progressive decline of the disease,(69,70,71,72) was not initially covered by the ODB program.

The government has not adequately enunciated a value system that defines the priority-setting exercise so DQTC members can, in a consistent manner, review drug submissions. For the conditions for which clear negative impacts on morbidity and mortality are established, drugs appear to be readily available. Controversies in formulary listings often result for drugs used to treat conditions for which there is a less clear understanding of the product’s impact, especially when the main outcomes are on psychosocial factors or quality of life.

A very good example of this controversy is whether so-called “life-style” related drugs should be covered by the formulary. This would be in contrast supposedly to those conditions that are not related to “life-style”. The dilemma here is defining the difference between a “life-style” activity (in this case sexual function) or condition (in case ED) that interferes with the “life-style” activity and one that falls into that other class, which might be considered a non-“life-style” category. The problem with this attempt at differentiation of categories is that the major illnesses for which the formulary provides drugs have a very strong “life-style” component to their aetiology and/or impact on function. For example ischemic heart disease for which the many anti-anginal drugs are provided has a very strong life-style component related to personal eating, smoking and exercise habits. Chronic lung disease for which the formulary provides many drugs including broncho- dilators and antibiotics is due primarily to smoking, which is usually deemed to be a “life-style” choice. Yet nicotine patches or gums are not covered by the formulary because “smoking” is considered to be a “life-style” activity. This decision seems to ignore the potential benefits of smoking cessation to the development of chronic lung disease for which formulary drugs are provided and the proven efficacy of smoking cessation programs which use nicotine patches (73).
The provision of analgesics by the formulary is also an example of a blurred concept of what level of “life-style” relationship should be considered in drug listing decisions. If a person requires analgesics for arthritis, irrespective of its genesis, presumably the ODB deems that meritorious in its qualification for benefit. If the analgesic is used to treat a musculo-skeletal injury as the outcome of jogging or tennis or skiing is that not being used for a “life-style related” state? It becomes difficult to rationalize why arthritis should be treated so that a person can enjoy jogging and why ED should not be treated so that the person can enjoy sexual activity.

G. ODB and Accountability for Reasonableness

The ODB and DQTC are partially successful in reflecting Daniels’ framework as outlined in his four principles. It is worth re-iterating them at this point for reference:

A. Decisions regarding coverage for new technologies (and other limit-setting decisions) and their rationales must be publicly accessible.

B. The rationales for coverage decisions should aim to provide a reasonable construal of how the organization (or society) should provide “value for money” in meeting the varied health needs of a defined population under reasonable resource constraints. Specifically, a construal will be “reasonable” if it appeals to reasons and principles that are accepted as relevant by people who are disposed to finding terms of cooperation that are mutually justifiable.

C. There is a mechanism for challenge and dispute resolution regarding limit-setting decisions, including the opportunity for revision decisions in light of further evidence or arguments.

D. There is either voluntary or public regulation of the process to ensure that conditions 1-3 are met (38).

The DQTC process comes under a structure of public regulation – the various pieces of legislation that govern the drug program’s ability to interchange generic drugs and the guidelines for drug submission that are provided to all manufacturers. There are educational meetings provided to the industry to improve their ability to comply with ODB expectations for submission. When submissions are turned down, the manufacturer is provided with a letter of explanation. There is an appeal process for manufacturers when their drug is not listed as requested. There is also an appeal process for doctors on behalf of their patients when drugs thought to be beneficial are not listed on the formulary.

There are other ways that the ODB program fulfils many of the criteria and suggestions put forward by the authors in term of accountability for reasonableness. The ODB funds various categories of drugs that require various levels of pre-authorization ranging from none, to pre-determined criteria (limited use) to a specific letter for a specific person – appeal process (section 8). All citizens in the defined populations and
all licensed physicians are entitled and have access to the system. Anne Paus-Jenssen has highlighted some of the limitations in the deliberative process of the DQTC and makes some suggestions that might improve the process as well as the legitimacy and priority setting framework(2).

Newsletters from the ODB focus on the rationale for ODB decisions. A recent one was sent to all physicians outlining the results and rationale of meetings held between the Drug Programs Branch, the Ontario Medical Association (OMA) and the Ontario Pharmacists Association. It focused on the Limited Use process, which has been under review for over a year. As a member representing the Drug Programs Branch and as the present sitting chair of the OMA committee on pharmacy and therapeutics, I have been intimately involved in the discussions and genesis of the present Limited Use program policies and procedures. Although there are attempts to explain the rationale behind the policy decisions, there is probably a lower level of true understanding of the implications and reasons behind the decision-making than ideally should be the case. This has lead to opposition by some members of the medical profession of the rule structure around limited use products and a reluctance to write section 8 letters for individual patients, which means the patient may end up having to pay for a beneficial but un-funded drug.

The component of the ODB and DQTC process which fall short of Daniels’ proposal is the clearly defined priority setting criteria or goals as set out by the Ministry of Health. The economic imperative is not clearly defined. The DQTC is expected to take into account the economic factors that may impact on the cost of the drug to the Province and the relative economic benefits that one particular drug may have compared to another. It must consider also the opportunity costs involved in funding one drug as opposed to not funding it. However, issues related to quality of life and the definitions of what constitutes a condition for which medications should be provided is not clearly enunciated to the DQTC members. Yet it is clear, as Paus-Jenssen pointed out in her study, in addition to the importance of clinical factors, personal values of the committee members play an important role in the decision-making process of the DQTC. Whether this has a positive or negative influence on decision-making has not been formally addressed by the Drug Programs Branch. As membership of the DQTC changed over the years that I sat on it, there was no question that different values became more or less important as a reflection of the views and personal opinion of the committee members and the chair (2).

Without a clear understanding of the views and perspective on their role from committee members or results from community surveys, it is suggested that the DQTC members or other insurance committees will have to base their decision-making on some firm and defensible principles. Therefore, personal views of DQTC members as to whether ED is a condition for which the Drug Programs Branch (or private insurer) should provide drugs should not be allowed to influence the drug-listing decision. They must be given clear direction from the Ministry of Health based on some process of priority-setting. The priority-setting direction should allow committee members to separate their personal views about whether ED is a medical condition or not or whether treatment that enhances the ability to participate in sexual relationships should be part of
the Province's (or third party insurer's) health and/or drug insurance program. Committee members who feel that their religious beliefs, for example, might bias their views on drugs used for sexually related activities should declare that bias during deliberations.

Whether the operations of the DQTC are clearly understood and accepted by the public is not clear. Various community lobby groups have had an effect on ODB policy. The DQTC understands that their recommendations may not be accepted for "political" reasons by which they interpret the effect on the government of factors beyond their clinical, pharmo-economic and quality of life rationale for recommending acceptance or rejection of a drug for listing. The "community" includes lobby groups representing different constituents (disease specific, social class specific, or demographic specific). They do have an influence on the deliberations of the DQTC and the decision-making of the Drug Programs Branch and the Provincial Ministry of Health.

If the Ministry of Health decides that they would like to be more clear about the priority setting process and be more congruent with Daniel's framework, some improvements to the drug approval process can be made such as increasing "community" involvement in considering priorities. If they decide to move partially in that direction, some components of Daniels' proposal already exists or may be readily adopted, which would move in the direction of "accountability for reasonableness" as the basis for decision-making.

I will address accountability for reasonableness and an approach to priority setting as it pertains to Viagra® in the final chapter on policy options.
Chapter 7

The Specific Case of Viagra

In this chapter I will focus specifically on ED, a common condition that impacts negatively on quality of life. I will then focus on Viagra, an effective, innovative and expensive drug treatment and the approach taken by PBMs including the Ontario Drug Programs Branch in deciding on whether or not to fund this drug to treat this condition. In my discussion I will focus on three main issues: effectiveness of the drug; coverage decisions by the ODB and other third party insurers and the rationales used to decide on coverage.

A. Effectiveness

• Why Erectile Dysfunction – ED (Impotence)?

I chose to study ED (in the past known as impotence) because it is a condition that is common that is often not spoken about by patients to their doctors, and has many ramifications at the individual, inter-personal levels and ultimately societal level. ED is complex in its meaning to individuals and is an important component of human sexuality. The latter subject receives great public interest. There is a wide range of views as to where human sexuality belongs within the realm of human function and therefore, treatments for sexual dysfunction have often been a challenge to decision-makers. One only has to look at issues such as abortion or the impact of sexual "impropriety" among public figures to understand that sexuality often results in societal responses that at times appear to be out of keeping with the actual importance of the event in question(74,75).

An example of the discordance that often exists between different components of human sexuality and society’s views of priorities and values is what happened in Japan after Viagra became available. The previous ban on the use of oral contraceptives for Japanese women was lifted following an outcry related to the rapid approval of Viagra in that country (76). From the many books and magazine articles that deal with human sexuality that line the shelves of bookstores and magazine stands, it is clear that sexual activity plays a very important role in human existence. In parallel with myriad “how to” articles and manuals for those seeking to improve their sexual performance, there are investigators who are trying to unravel the psychological from the physiological aspects of human sexuality, with a special focus on women as well as men (77).

For many years, ED was considered to be primarily psychological in origin and much of the focus on treatment was directed towards psychological methodologies. As more information became available that better defined the patho-physiology of ED, treatment methods changed to be more physically directed(78). However, until Viagra became available, the modalities of treatment were either poorly effective, cumbersome (intra-penile injections, vacuum devices) or required surgery, which although helpful did not result in an adequately normal physiological function(79,80,81).
A reflection of the difficulties that have faced men in acknowledging and dealing with ED is that the prevalence of the problem is usually "grossly underestimated...It is estimated to affect three million Canadian men, and accounts for approximately 300,000 physician consultations each year, but prior to the introduction of sildenafil (Viagra®) only 10% of affected men sought treatment...Diabetes and hypertension are also age-related risk factors for ED...an estimated 50-75% of diabetic men will eventually experience ED" (82). An indication of the universal quest for potency enhancing agents is indicated by the fact that a story about the potency and aphrodisiac benefits of a liquor distilled from the mandrake plant was a lead story in a recent issue of the Globe and Mail(83).

The other feature of ED and its treatment is that because it is related to sexuality, there appears to be a rather interesting response to it in terms of funding for treatment when compared to treatments for a whole range of other medical conditions. By categorizing ED as a condition the correction of which results in a "life-style" activity (i.e. the ability to have an erection-based sexual experience), a negative bias is introduced as to whether or not to fund it use. It is as if there was a dissociation between human activities and disorders into those which are "medical conditions", and those which are merely "life-style" issues with sexual activities seeming to fitting into the latter. This separation of disorders of sexual function from disorders of other organ systems is interesting. It likely reflects some unusual and deep-seated discomfort with the whole process of sexual activity as being something that the "public" should not be involved with. Therefore, by its "private nature" it should not be funded by public or other third party drug programs.

The nature of sexuality and how attitudes and comfort levels with sexuality develop is of great interest to many scholars. Whether there are influences that can promote healthy attitudes towards sexuality or influences that can undermine or compromise healthy sexual development has been studied for many years (84,85,86,87,88,89,90). There have been sexual programs introduced into the educational system at all levels including at the health care professional level in an attempt to demystify human sexuality and to encourage healthy sexual development. Individuals carry with them a wide range of views as to the place of sexuality in society and each individual brings his or her attitudes to sexuality in whatever role is being fulfilled. This includes those, whose role is to decide on issues such as public or third party funding for sexually-related conditions, including ED.

- **Sildenafil(Viagra®)**

To further understand the concept of effectiveness, it is worth looking in detail at Viagra®, the drug that is at the centre of the present controversy. The drug will be reviewed within the framework of priority setting. It was released in the United States in March 1998 and since then, all drug insurers whether public or private, have struggled with the challenge of what to do in terms of funding, with the public demand for the drug.
The drug’s action have been reported in many articles in peer reviewed medical journals and has been shown to be very effective and well tolerated (91). Its use spans a range of causes for ED. These include those that are attributed to psychogenic and organic causes. Some studies confirm specific benefits to patients with diabetes mellitus, a condition well known to cause ED with some recent evidence about benefits to patients after major prostate surgery, the side effects of anti-depressant therapy and spinal cord injury(92,93,94,95,96). Although there are concerns about its possible implication in some cases of myocardial infarction (97), this has been dealt with by making recommendations about its use in patients with known angina who take nitrates therapy, now considered a contra-indication to the use of Viagra® (98).

According to a British Medical Journal editorial in Sept. 1998, “The popular interest in Viagra is not solely the result of media hype and the drug’s association with sex….The level of demand was predictable, given a prevalence of erectile dysfunction of over 50% in men age 50-70, and the unacceptability, poor effectiveness or unavailability of existing treatments, such as implants, intracavernosal injection, intraurethral pellets, vacuum devices and sex therapy. To most sufferers a tablet treatment must have seemed too good to be true”(99).

According to the editorial, there was already good evidence of its effectiveness in a wide range of causes of ED with no noted effect on sex drive, the latter being an important factor in defining its use. At that time the pooled safety data showed no significant serious side effects of the drug and other than the very specific and potentially very serious interaction with nitrates, no major precautions were necessary for users. Since this editorial, many more articles supporting the effectiveness of the drug in specific populations have been published (91-96) Also, its use in women at the time of this writing was not yet available, although subsequently such studies do suggest very little if any benefit (100,101).

The important questions raised in the BMJ editorial included, “Researchers must continue to examine effectiveness and safety in long term use and in patient groups excluded from previous studies…and…questions also arise about who the drug does not work for, who would benefit from potentially curative treatments such as surgery or therapy, and what impact successful treatment has on quality of life as well as on mental and physical health.” The author continues, “The immediate challenge posed…in the United Kingdom involves the need for rational decision making about availability on the NHS or from medical insurers….Erectile dysfunction is a cause of misery, relationship difficulties, and significantly reduced quality of life for many men and their partners. Whatever the availability of [Viagra] in the NHS, the effectiveness of this treatment and the high prevalence of this distressing disorder make it inevitable that it will be taken by large numbers of men”(99).

A companion commentary in the same issue of the BMJ notes that the government has not adequately addressed the issue of rationing treatments, of which Viagra® may just be the first of many(102). Smith, in the article states, “the reality is that patients are denied the treatment they need every day of the week. What’s more, coming
through the pipeline are a series of “lifestyle” drugs that will be attractive to those who want to be thinner or to soup up their slowing brains. Recognizing that the founding principles of the NHS cannot be maintained, many would opt for the abandoning of comprehensiveness rather than universal coverage, quality, and free access at the point of entry.” The author continues that “what is unacceptable, is that these decisions are made piecemeal, on the hoof, behind closed doors, according to unknown criteria. We need a comprehensive, transparent, continuing debate that is based on evidence and values....There will be no end to the debate and no neat resolution, but the process will be of vital and continuing importance....No expert can trade off a man’s impotence against a couple’s infertility against adequate care for psycho-geriatric patients against chemotherapy for childhood cancer. These trade offs depend on the values of our society, the agreed purposes of the NHS and many other issues....The government cannot be blamed for failing to provide, but it can be blamed for obscuring and avoiding the debate.” This is exactly the point made previously about the two components of an ethical basis for priority setting-i.e. legitimacy and priority-setting (102).

Further articles from Britain comment on the issue of rationing facing all the European nations, following the licensing of Viagra® (103). They highlight the intense debate across Europe and the contrasts between European countries themselves and the United States. In Beecham’s September 1998 overview of what was happening in a number of countries, Britain, France, Netherlands, Italy, Switzerland, Spain, Germany and Israel had at that time indicated that the public systems of those countries would not pay for the drug. Some countries had agreed to pay for the medical fees of doctors doing the medical evaluation required for the drug to be prescribed even if the drug itself were paid for privately.

Only the United States, at the time the article was written, had some jurisdictions in which there was some reimbursement for Viagra® under defined circumstances. Beecham notes that, “The US Department of Health and Human Services has said: ‘If Viagra is determined by a doctor to be medically necessary, Medicaid should pay for it.’ However, half of the state run Medicaid programs, including New York’s and Wisconsin’s are refusing to pay for the drug....Florida says it will reimburse only a maximum of four pills a month.” The author continues, “Health insurers [in the United States]say that drugs like [Viagra®] may improve quality of life but are not ‘medically necessary’. Generally, insurers set three requirements: that the ED has a medical cause; that the doctor certifies in writing that the patient is impotent; and that a limit is placed on the number of pills prescribed per month.” Other issues noted in the article are the limit to the number of prescribed doses, ranging from the eight pills a month suggested by Pfizer to six funded by Oxford Health Plans, based on the NEJM article, “which determined that men taking [Viagra®] had successful sex 5.9 times per month on average.” It noted that Kaiser Permanente, one of the largest HMOs in the US, reversed a decision to pay a portion of the cost of the drug because of financial reasons. It also noted that there were a number of proposed class action suits against HMOs by disgruntled members including women who maintained that the increased demand for sexual interactions was resulting in an increased demand for contraceptives which were inadequately provided for.
As a follow-up to the observation by Beecham that there appeared to be legal actions in the U.S., an Associated Press wire story released in March 1997 confirmed that more American men were suing health insurers over Viagra\textsuperscript{R}(104). According to the article, a federal judge in Philadelphia was suing QualMed over their limit of four pills per month paid for by their health plan. "Scholl, 54, is one of a small, but growing number of American men suing their health insurers for denying or restricting coverage of the Viagra pill... Nine dollars a pill is expensive, said Scholl... and there's something about having to pay to have sex that doesn't seem right. At least not to pay that much." The article continues, "Most of the largest HMOs have been sued over their Viagra\textsuperscript{R} policies including Aetna, Humana, Prudential and Kaiser Permanante." At the time of writing the cases had not gone to trial. But the article notes, "Legal experts say there's more at stake than just Viagra\textsuperscript{R} coverage. The cases will help determine whether insurance should pay for so-called "lifestyle" treatments that may not be medically necessary.... Wall Street analysts presume the real reason insurers won't cover the drug is they're looking to cut costs.... A spokesman for... Humana, said HMOs have a right to determine which drugs they will pay for... and most plans have labelled Viagra\textsuperscript{R} a lifestyle drug, which does little to improve health of most men."

One American writer suggests that the issue with Viagra\textsuperscript{R} is less so the drug itself but what the attitudes are in society about human sexuality. Rosen notes in a \textit{Lancet} commentary, "In sum, sildenafil [Viagra\textsuperscript{R}] is reasonably effective and safe in the treatment of erectile dysfunction. Its introduction has also raised important questions about the role of sexuality in society, and medicine's role in addressing this fundamental human need"(105).

Sir Douglas Black, in a guest editorial in a 1999 issue of the \textit{Journal of Medical Ethics}, questions the British Medical Association assertion that, "all such innovations need a careful consideration before being made generally available"(106). Black suggests that, "'careful consideration' conceals unanswered questions, perhaps the most important being, consideration by whom? And using which criteria?" He then defines the factors that must be taken into account in the decision-making process, which as expected include the medical, economic and ethical. He then suggests that this issue is complex and is merely a marker for future demands on innovative drugs that will become available. He notes the difference conceptually for which physicians as part of their sphere of practice do not have the answer is "that between expressed demand and objective need. Societal opinion, and especially politically correct opinion, is strongly set in favour of accepting almost any demand, based on the autonomy of the demanding person; and against professional assessment of needs, which is seen as paternalistic, and even as a conspiracy against the people.... But it would be no great advantage if groups of doctors were simply replaced by groups of lawyers or managers." Black suggests that, "the advice of health professionals can cover only a part of this complex problem; it will have to be complemented by the views of economists, administrators, sociologists, lawyers... and also lay representation. Such groups may at times have influence though they may have to wait some time to see it"(106).
There have been some recent studies, which have attempted to compare Viagra\textsuperscript{R} to other standard therapies for ED dysfunction in order to demonstrate that they fall within the usually acceptable framework for pharmo-economic benefit. One study published in the BMJ and one in the Annals of Internal Medicine in 2000 demonstrated cost-effectiveness of Viagra\textsuperscript{R} when compared to another standard treatment\textsuperscript{107,108}. The accompanying editorial, while acknowledging the quality of the study, raise the ethical issues in terms of priority setting \textsuperscript{109,110}. McGarvey, the author of the Annals editorial asks, “Should health insurance pay for the treatment of erectile dysfunction at all? By extension, should health insurance pay for the growing array of diagnostic and therapeutic interventions aimed at various conditions that are coming to be termed ‘lifestyle enhancing’, including infertility and sexual dysfunction.” The author concludes the editorial with the question, “What, really should health insurance do for us and as a society\textsuperscript{110}?” Freemantle, in his comments in the BMJ says, “Having established and described what the drug may achieve in use and at what cost, it is then a difficult political rather than technical decision whether it is made available\textsuperscript{109}.”

Therefore, the issue of effectiveness of the drug does not seem to be in question. What appears to be the challenge to Drug Program Managers is, does effectiveness for a condition that may be defined as on the margins of “medical necessity” or as a “lifestyle” condition, merit funding by the drug program?

B. Coverage Decisions by ODB and other Third-Party Insurers

With these factors in mind, it would be useful to determine if the process by which drugs used to treat ED fulfill the expectations of fairness in the process of priority setting vis a vis other drugs approved for other conditions for listing on Ontario Drug Benefit (ODB) formulary. Viagra\textsuperscript{R} is not covered by the ODB. Without an ODB formulary listing, the Ontario Ministry of Health will not cover the cost of a drug. The implications of a non-listed status is that for those normally covered by the ODB, those who can afford to pay for the drug privately can have their ED treated and those who cannot pay will not have access to the drug treatment. Reference to other third party insurers will also be made including those in other North American and European jurisdictions.

\begin{itemize}
  \item Private Prescription Plans and Viagra\textsuperscript{R}
\end{itemize}

The August 1998 edition of the Watson Wyatt Canada newsletter discussed the challenge of Viagra\textsuperscript{R}\textsuperscript{111}. It notes that, “[Viagra\textsuperscript{R}]...is a wake-up call for Canadian employers who have yet to develop a decision-making process for including or excluding the expensive new therapies, released almost monthly, under their supplementary health plans....Some benefit plan sponsors may be surprised to discover that once Viagra\textsuperscript{R} can be purchased in Canada, it will be probably be automatically covered under their drug plan...because the most common definitions of eligible expenses in Canadian drug plans are prescribed (anything dispensed with a prescription), requiring a prescription (which can only be dispensed with a prescription) and medically necessary. There is often a short
list of exceptions...[adding ViagraR to the list of exceptions]...is not the answer because it exclusion may neither be suitable nor consistent with coverage decisions regarding other new drugs....Because ViagraR is expensive, and it straddles the line between medically necessary and lifestyle enhancing, employers are faced with a real problem....how can they ensure that the plans they sponsor provide meaningful drug coverage to employees while, at the same time, minimize cost increases resulting from inappropriate or unnecessary use and the high price new drugs?”

The newsletter continues, “Before change is contemplated, each organization must first be able to articulate why it maintains a drug benefit plan for employees. Is the benefit plan meant to simply pay for drugs, or is it intended to provide what is necessary for the health of employees and their families? The first approach may call for implementation of flexible benefits and health care spending accounts. The second may lead to behavioural/wellness initiatives....Plan sponsors should consider how the plan deals with drugs that are medically necessary, life-sustaining, preventative or used to primarily enhance lifestyle. In many cases, including ViagraR...the boundaries between these categories can be blurred....Plan sponsors must evaluate the possible coverage options, and the pros and cons of each of these alternatives....Employers must take the initiative and develop policies and procedures for administration for their drug plans...[so that] the allocation of scarce benefit dollars will satisfy both corporate objectives, and the needs of employees and their families(111).”

In the September 1999 edition of HRMagazine, the issue of drug benefits was directed to Human Resource managers (112). It notes that, “Decisions about covering ViagraR ‘are all over the map’ [according to Express Scripts/ValueRx, which manages prescription programs for employers, HMOs and insurance carriers]....‘some are covering, some are not’.... ‘some require prior authorization. Some are covering...for certain medical conditions. We’re recommending six tablets per month...based on research published in the New England Journal of Medicine.” Another HR consultant, Arthur Shinn, in the same article says, “almost half the sponsors are excluding ViagraR on a temporary or permanent basis. Most HMOs have excluded ViagraR from coverage or limited the number of pills patients may receive.... Quantity limits are common...we’re ....seeing six to eight tablets (per month) using prior authorization- a procedure whereby medical necessity is confirmed....There may be age restrictions or requirements for prior authorization by certain specialists for patients under certain ages.” A survey quoted in the article done by Henry J. Kaiser Family Foundation, “nearly half [of those polled] thought insurers should cover ViagraR, while 40 percent said they shouldn’t and 11 percent said they didn’t know”(112).

The controversy as to whether ViagraR used to treat ED, which results in, a “lifestyle” improvement is sufficient reason to fund the drug. The article focuses on the cost implications if coverage is implemented. It is says that, “without appropriate controls ViagraR could increase prescription costs for health care insurers and employers 3 percent or 4 percent”(112).
C. Coverage Rationales

Various authors have commented on whether drug plans should cover ViagraR and have acknowledged the debate in the health economics and ethics literature. According to Moreno, “For any drug, device, or procedure to qualify as ‘therapy’ and to be a proper part of the medical profession’s armamentarium, at least two conditions must be satisfied: the safety and efficacy of the proposed intervention must have been subjected to methodologically sound research, and the condition to be addressed must be a medical problem. ViagraR has been found to be effective in improving male sexual performance, even startlingly so....Somewhat more challenging is the question of whether the inability to achieve an erection is a medical problem...Sexual dysfunction is surely of as much subjective concern to the adult male with no obvious primary disease as it is to the male who has suffered impaired function due to traumatic injury or serious disease. It is...true that sexual activity is not necessary in the life of an individual in the same sense that digestion or respiration are necessary, but the same may be said of many functions that are the object of intense medical, surgical, and rehabilitation efforts....Adult males’ self-perceived well-being has a great deal to do with their ability to express themselves as sexual beings....There is, therefore a prima facie case for considering ViagraR to be a therapy [and]...whatever counts as therapy should be presumed to be a candidate for reimbursement in a prescription plan” (113).

Moreno goes on to say, “The principal argument against reimbursing for ViagraR has been...payment for this quality-of-life-enhancing drug would set an expensive precedent that would further endanger the future affordability of health care coverage....We clearly are already supporting a myriad of medical interventions that improve quality of life. Singling out for exclusion an intervention that enables sexual performance suggests a denigration of the importance of this aspect of life that is rooted in Puritanism rather than psychology, which teaches that there is nothing frivolous or prurient about knowing that one has the ability to function sexually....I can see no reason to distinguish this intervention from others that are likely to be in great demand, apart from some ill-considered prejudices about the importance of sexual function...unless there is a compelling public health reason to limit ViagraR use, such as a demonstrated connection to sexually transmitted disease, there is no place for judgement about what counts as ‘suitable’ use for personal sexual expression” (113).

Another issue raised in the article is the inconsistency between the arguments and policies among insurers when coverage for ViagraR is compared to that for birth control pills. One argument noted to justify the differences in reimbursement is that, “birth control is optional, whereas impotence is not.” Others quoted counter the argument and state that, “if a plan covers ViagraR, it should cover birth control....Women are saying there’s a double standard, that insurers are offering to treat male lifestyle issues but not ours. It opens a Pandora’s box of other lifestyle-related issues” (112).
Comments from Insurers

Ed Kaplan, another consultant quoted in the article, "suggests viewing all aspects of sexual reproduction- impotence, infertility and contraception- as a whole....If a company...is not consistent, it's taking some risk...you could get into costly lawsuits....According to guidelines [Kaplan] gives its clients, the treatment of male impotence falls into the same category as treatment of infertility, breast reconstruction or other health care services that are not medically necessary but are commonly requested by plan participants. If an insurer has paid for impotence treatments in the past, including behavioural health counselling for sexual inadequacy or for expenses related to penile implants, the coverage of Viagra\textsuperscript{R} would be consistent"(112). Another "spin" on the issue in the United States is noted in the article, "lawsuits may become a costly side effect of Viagra\textsuperscript{R} for insurers and employers. Some health care consultants worry that employees may claim that denial of Viagra\textsuperscript{R} would impair a major life activity and, therefore, violate the Americans with Disabilities Act."

Among the recommendations by the consultants quoted in the article are, "I tell clients who are not paying [for a treatment or drug] that they have to maintain their benefits budget....They have to budget so that everyone can have reasonable access to care....They [employees or beneficiaries] must pay for lifestyle drugs such as Viagra\textsuperscript{R} so that health plans can cover life-saving procedures such as organ transplants." Another consultant suggests that "although covering lifestyle drugs may be costly in the short term, it may pay off in the long run by retaining valuable employees"(112). Of course this view of coverage is quite different in terms of balances of interests than a publicly funded drug program where attractiveness to employees is not an issue. But, attractiveness to the voting public could result in decisions that might be viewed positively by them at the time of an election.

From these comments it should be evident that there is no consistent, well defined rationale for coverage of Viagra\textsuperscript{R} from public and private PBMs. There appears to be a mixture of bias based on views about sexuality, what 'medical necessity' means, and what constitutes a 'life-style' activity as compared to a \textit{bona fide} medical condition or "essential" human activity. Underlying all the arguments is one that appears to form the basis of the rationales just noted - the enormous cost related to the funding by third-party insurers of this drug. It is not only Viagra\textsuperscript{R} that PBMs are concerned about, but future medical treatments (including drugs) for which similar arguments for coverage could be made. The costs for such treatments could result in substantial financial liabilities for health care insurance systems.
Chapter 8

Policy options and Recommendation

In this chapter I will outline a number of possibilities that can be considered by the ODB program and other third party insurers. I will refer to the ideas and arguments noted in chapters 4, 5 and 6 in order to frame the range of possibilities and finally suggest one that might be considered as possible to implement by the ODB program.

It is a great challenge to make the transition from a theoretical construct in ethics to a practical implementation. No matter what ethical principles are referred to in the development of policies or practices, the realities of conflicting principles and political considerations must always be kept in mind. The goal of an ethical analysis of possible options is to bring to a conscious level, the issues that should be acknowledged and addressed when decisions are made. Even if the final policy does not conform totally to an ethical framework, the fact that ethical principles or issues are considered in its development is an important achievement. The challenge of a civil society is for policymakers to appeal to and respond to the ethical foundations of the society in which they operate.

By examining some of the ethical considerations in priority setting, I hope to make recommendations that might be acceptable to those making policy in the realm of pharmaceutical benefits, especially, but not exclusively for the citizens of Ontario.

A. Range of Policy Options for ODB

Ideally, the ODB’s approach to coverage for the costs of Viagra\textsuperscript{R}, should be consistent with a well thought out and articulated policy approach to drugs in this category or others that pose similar challenges to this drug. This might be an opportune time to develop a priority-setting process that is acceptable to the government and to the citizens of Ontario. As there are likely to be other drugs that pose comparable challenges to the ODB and DQTC in the near future, a well thought out and consistent approach to Viagra\textsuperscript{R} would be a worthwhile enterprise.

The approach that the ODB should take on its decision whether or not to cover prescriptions for Viagra\textsuperscript{R} should be one that is consistent with well articulated goals, objectives and priorities of the Drug Benefit program. With such an approach, the Drug Programs Branch should be able to respond to criticisms of its decision and the Ministry of Health and government should be able to withstand the criticisms from the many stakeholders involved in and effected by the ODB. Moreover, if the decision and process developed is properly formulated, it should be able to cope with other drugs that may have a similar impact on the ODB and for which comparable arguments can be effectively used to justify the decision.
This would be a situation where Daniels' accountability for reasonableness proposal makes sense. Many of the factors outlined by Daniels are already in place within the ODB structure and function. In order to more meet more fully, the criteria for accountability for reasonableness, the government would have to carefully consider the issues and, if necessary, provide resources to fulfill the process. Their goal would be to get a good sense of the values and priorities of ODB recipients, citizens who are not ODB recipients and the physicians responsible for prescribing the drug, in order to be able to provide that evidence as part of the decision-making process infrastructure. If this were done in a credible fashion, and if the government could then clearly define the implications for various types of coverage equations, it could probably develop a formula by which Viagra\textsuperscript{R} would be made available under a given set of circumstances to Ontarians. Such a process, if proven successful for Viagra\textsuperscript{R} could then form the basis for future decisions about drugs used to address "life-style" activities or conditions.

Alternatively, the provincial government could decide to restructure completely the way it funds the ODB so that all drugs including Viagra\textsuperscript{R} are funded the same way. The tax-based formula for drug costs (or all health care costs) described in chapter 4 could be developed and introduced into the province. Even though I believe that such a structure for funding the drug benefit program has many positive attributes in terms of equity, accountability and fairness, I believe that the political environment in Ontario and the philosophical perspective of the present government would not support such an initiative.

- **Three Options for Viagra\textsuperscript{R} Funding Policies**

Therefore the options that the government (ODB) might consider include the following:

1. **Do not fund Viagra\textsuperscript{R}, on the basis that it is a drug for a "life-style" activity and its use is not "medically necessary".**

In order to take this position, it will be necessary for the Ministry of Health and Drug Programs Branch to clearly define the difference between "life-style"-related drugs or treatments and those for "medically necessary" conditions. They would require complex explanations to differentiate treatments for "life-style" activities from those that focus on other "quality of life" issues. For many, sexuality is one of the important factors in quality of life, one of the criteria often used in determining the merits of funding for drugs. Policy-makers can expect enormous public and professional opposition to using this rationale as a basis for the decision. The many areas of inconsistency will include the fact that Ontario's health care system already funds many procedures, treatments and drugs that would have to be considered as much "life-style" or "quality of life" treatments as anything else.

The most obvious areas of similarity, because of the sexual focus, would be birth control pills, currently reimbursed by the ODB for recipients on social assistance. For most women (and often their partners), the use of the birth control pill is primarily so that
sexual relationships do not result in unwanted or unplanned pregnancies, which allows for unfettered sexual enjoyment and fulfilment. This would be convincingly argued as a “life-style”/QOL issue. Other drugs that might be referred to in the argument would be medications for dermatological conditions (acne vulgaris for example) that are not “medically necessary” but do have an impact on quality of life for those afflicted. NSAIDs for the use of sports-injury related conditions would also be an area of concern. It would be very difficult to differentiate, in most people, the relationship between the physical activity (a pick-up hockey game or an injury related to the chronic use of work-related vibrating machinery) and “medical” conditions that might benefit from NSAIDs. The other non-drug treatments for sexually related conditions would also have to be justified. These include vasectomies, tubal ligations, insertion of IUDs, insertions and removal of penile prostheses which are all related to “life-style” (sexual) activities and are already covered under Ontario’s Health Insurance Program (OHIP).

There are also non-sexually related conditions that are clearly connected to “life-style/quality of life” such as dermabrasion for acne vulgaris and some elements of non-cosmetic plastic surgery and post-surgical scar revision. These too are covered under OHIP.

Sabin and Daniel’s exploration of a framework for funding mental health disorders has many similarities to defining the basis for funding for sexually-related dysfunctional conditions. ED, as one of a number of problems related to the achievement of “normal” or “optimal” sexual activity, can be likened to the various forms of mental health problems, some of which do and some do not appear to qualify for inclusion in a mental health care coverage program. To fall back on the normal function model defined by the authors, “the central purpose of health care is to maintain, restore or compensate for the restricted opportunity and loss of function caused by disease and disability. Successful health care restores people to the range of capabilities they would have had without the pathological condition or prevents further deterioration…The normal function model holds that health care…coverage…should be restricted to disadvantages caused by disease and disability unless society explicitly decides to use it to mitigate other forms of disadvantage as well” (43).

This definition appears to be relevant to ED. The approach could potentially be translated into a very limited definition of “disease or disability” for which there are objective measures. Examples might be when ED is secondary to diabetes mellitus, prostate surgery or a clearly defined neurological damage, rather than more common and less readily defined causes such as those that are “psychological” or related to “aging”. The problem in trying to use a restrictive model in ED, is that for an increasing number of cases, it is possible to find a definable cause that can be attributed to a “disease or disability” (such as diffuse vascular disease). This expands the number of conditions for which coverage might be deemed to be appropriate under Daniels’ proposed “normal function” model.

The status of drugs provided for by the ODB particularly in the realm of sexual activity is very interesting when viewed from the perspective of “life-style” vs. “medical
necessity". Birth control pills (BCP) are covered by the ODB formulary, primarily for those recipients on social assistance but also for those receiving Trillium benefits. In 1997/98, 348,330 claims were made for BCPs for a total Drug Programs Branch cost of $6,528,772 and in 1998/99 there were 301,287 claims for a total cost of $5,758,545. (personal communication from Ministry of Health). There are no stipulations or restrictions on the use of the drugs. One does not have to demonstrate whether the sexual activity for which they are being used is one directly and solely related to family planning, or whether it is for the "life-style" related enjoyment of sexuality without the concerns of unwanted pregnancy. The senior aged beneficiaries of the ODB do not use birth control pills. Its presence on the formulary, must acknowledge that younger ODB beneficiaries may be using the pill in order to enhance their sexual enjoyment, when alternatives to the pill for family planning methods are potentially available. One could choose to make a utilitarian and economic argument to justify the provision of birth control pill to this population. Some might suggest that the economic and social cost of unwanted pregnancies or the need for abortions in this population is such that it is economically and socially beneficial to the province to provide the pill, irrespective of the fact that it might be used for a personal "life-style" benefit.

There are other treatments that might be examined for which the Province of Ontario provides treatment, which might considered similar in nature to that provided by Viagra® for ED. The question might be asked whether treatments for those conditions are so dissimilar to that of ED that no fair comparison can be made or whether they are close enough that they can act as a model to measure the commitment of resources for those conditions. Examples that might be considered comparable in terms of being related to sexuality and "life-style" which were covered by OHIP in 1998/99 include:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cost ($)</th>
<th>Total #</th>
<th>Total Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IUD insertion</td>
<td>46.80</td>
<td>472</td>
<td>21,808</td>
</tr>
<tr>
<td>Surgical implantation; Penile Prosthesis</td>
<td>48.85</td>
<td>59</td>
<td>2,882</td>
</tr>
<tr>
<td>Removal Prosthesis</td>
<td>94.76</td>
<td>55</td>
<td>5,212</td>
</tr>
<tr>
<td>Revision of prosthesis</td>
<td>219.89</td>
<td>46</td>
<td>10,115</td>
</tr>
<tr>
<td>Intracorporeal injection for impotence</td>
<td>25.33</td>
<td>20,571</td>
<td>521,169</td>
</tr>
<tr>
<td>Vasectomy</td>
<td>98.58</td>
<td>23,687</td>
<td>2,335,121</td>
</tr>
<tr>
<td>Tubal ligation</td>
<td>142.34</td>
<td>16,587</td>
<td>2,361,102</td>
</tr>
<tr>
<td>Scar revision</td>
<td>66.68</td>
<td>61</td>
<td>4,068</td>
</tr>
<tr>
<td>Minor plastic surgery</td>
<td>127.51</td>
<td>1,666</td>
<td>212,444</td>
</tr>
<tr>
<td>Major plastic revision</td>
<td>508.11</td>
<td>61</td>
<td>30,995</td>
</tr>
</tbody>
</table>
Therefore the Province of Ontario already pays a substantial amount of money for procedures that are related to sexuality and sexual practice that one might construe as being no less a "life-style"-related intervention than the use of Viagra for ED. One could, on the other hand, argue that other than surgery related to the insertion of a penile prosthesis and intracorporeal injections, the other ODB sexually related funding has as its main purpose contraception. The unencumbered enjoyment of sexual activity would therefore be a by-product of the treatment and not its main purpose. This could consequently be used as a way of differentiating the treatment of ED from the provision of oral contraceptives or fallopian tube surgery or vasectomy.

Therefore, depending on whether or not it is accepted that the treatment of ED is sufficiently similar to other types of sexually related therapy, this option could be consistent with Daniels' accountability for reasonableness framework. The real challenge for its "reasonableness" would be a reflection of how convincing the argument is made as to whether or not ED is comparable to other sexually related conditions and the nature of the deliberations related to funding. They would have to be consistent and convincing to those making the decision and to the constituents served by the program.

2. Fund Viagra on a limited basis using objective diagnostic criteria to define those eligible for coverage.

Such an approach might make sense to many of the recipients of ODB benefits and the citizens of Ontario. On the surface it appears that one might be able to carve out a defined and limited group of potential recipients for which the use of Viagra might appear to be "medically necessary". The list might include such conditions as postsurgical, clear neurological (paraplegia, multiple sclerosis) diabetes-related or any conditions that have been clearly defined as causing ED. The problem with this approach is that for almost all causes of ED, there are now ways of defining the patho-physiology, which means that whichever group is left out of the funding formula, there will be a reason to challenge that decision as being "discriminatory" or not "evidence-based". Even trying to limit the justifying categories to "physically-based" conditions will lead to problems. Those with so-called "psychological" causes of ED may have defined conditions (DSM-IV) or may have concurrent physical conditions to justify treatment such as the countering of ED that is a side effect from "medically necessary" psychotropic medications.

As long as we fall back on the concept of "medical necessity" as the basis for funding treatments, it will always be very difficult to limit treatments for potentially responsive conditions based on the aetiology of the condition. For example, the health care system does not limit treatments for lung disease to those whose condition was not caused by smoking, or liver disease to those whose condition was not related to alcohol use. We do not limit orthopaedic surgery to those whose conditions was not caused by a sports injury, or the treatment of angina and ischemic heart disease to those who did not eat high fat diets. The whole issue of "life-style" causes of disease or conditions that might be construed as "life-style"-related and the issue of health care insurance coverage for
such conditions or activities comes up periodically in the political sphere. It would be virtually impossible to tease out the "life-style"-related causes of illness and the other genetic, environmental and "good or bad fortune" causes as a way of defining health care coverage. This might become increasingly difficult if with the further development of our genome knowledge, we find that there are genetic relationships between many conditions that we now consider related to choice (e.g., alcohol or substance dependency, and obesity).

Daniels' concept of accountability for reasonableness might be useful in trying to find a rationale to cover this wide range of medical conditions that is not dependent on the idea of "medical necessity". The conditions would merit treatment so that the recipients could presumably be provided with maximum opportunities in terms of their life wishes and expectations. The greatest challenge to this concept as a basis for drug treatments is that the recipient may yearn for an opportunity for life that is very subjective but may not be perceived as having great "value" or "opportunity" to those making medical decisions or funding clinical or drug programs. How does one grade the personal desire for sexual ability and fulfilment in terms maximizing individual opportunities? Even with these limitations, the public might accept some framework of defining those whose ED is caused by conditions that are felt to be worthy of public coverage. This could be consistent with the accountability for reasonableness concept even with its inherent problems.

3. **Agree to cover Viagra** for all those for whom a physician believes that coverage is suitable, but put limitations on the financial liability of the government.

In the absence of a total revamping of the way that the government (or other third-party) insurers construct their decision-making process, it is likely that decisions will continue to be made using the tools and processes presently available. But, within that framework, it is possible to move incrementally closer to a more comprehensive and accountable process of decision-making. If the changes to the rules for coverage and the equation of recipient financial responsibility are rational, it is likely that ODB recipients and the citizens of Ontario might accept a shift in funding policy for this class of drugs. An example of a poorly formulated approach to restrict access to Viagra was implemented by the Department of Veteran's Affairs. They required patients to be seen by urologists before the drug could be prescribed(114). This is clearly at attempt to use the long waiting list for urological consultations as a means of cost control, a transparently poor use of urologist's resources and thinly disguised cost-reducing strategy that ignores the needs of the patient.

The government could probably make a credible case for providing coverage for the drug but limiting its financial liability because of its other health care and drug program responsibilities. Reasonable ways to limit the government's financial liability can be accomplished in two ways: The first is to limit the number of pills prescribed per period (e.g., month). This alone could be used to determine the projected financial cost to the government based on the prevalence of the disease, the number of potential users of
the drugs and the cost of the doses allowed. The usual co-payment could be included, as part of patient costs, but this is minuscule when compared to the price of the drug.

The second approach would be to determine an adequate but special co-payment for pills provided in such a way that sufficiently limits the financial risk to the government. The problem with this approach alone is that the number of pills requested by patients could be such that without some limit, the costs could sky-rocket and there might be a benefit for some recipients to obtain pills and then provide them to un-insured individuals.

B. Recommendation: A Combined Approach—both pill limitation and special co-payment

The most likely successful approach, that would be consistent with Daniels' accountability for reasonableness, would be a combination of the two approaches noted above: a limit to the number of pills provided through the benefit program and a special co-payment sufficient to limit the government's financial liability to a defined amount. There are many equations that can be used to come up with a dollar amount that might be financially acceptable to the Ministry of Health and acceptable to the citizens of Ontario, which includes ODB recipients. The range could be: a number based on the "generally accepted use" or Medical literature with the currently implemented co-payments; or, a set number of pills and a specially developed co-payment system that would be used for Viagra\textsuperscript{R} and future drugs of this nature. The co-payment component would have to be specially developed so as to address the final financial liability of the government based on the figures available for expected utilization.

The first step would be to create a special co-payment system that could be used for Viagra\textsuperscript{R} and for other drugs that in the future that may be deemed to be in the same category of "life-style/quality of life" drugs. The characteristics of such drugs would have to be clearly defined. This will be necessary in order to differentiate such drug products from others that may not fall within this category and would normally be eligible for general or limited use listings.

Once the "special" co-payment system is in place (it might have to have a flexible structure so that costs do not exceed the Drug Programs Branch financial commitment to the product), the actual number of pills that would be provided within the program should be determined. This could be structured based on a modelling of prevalence of the disease, published utilization figures and the final acceptable cost to the program. So, if for example, it is deemed that there would be 50,000 eligible men in Ontario, at a dispensing of 1/pill per week at $10.00/pill, the cost to the system would be $26 million dollars a year. An increase to 6 pills per month would increase the cost to $36 million. If the co-payment were 20% of the cost of the pill, the government liability would be reduced to $20.8 million and $28.8 respectively and if it were 50% it would be $13 and $18 million. Using such modelling techniques, the government could limit its liability for this medication and at the same time appear responsive to this domain of needs. They
could also hope that competitors would develop alternative but comparably efficacious medications at a lower cost.

The downside to this recommendation is that for a group of individuals with a limited financial base, there would be the issue of placing financial barriers to their benefiting from a normalization of sexual function. This could potentially be dealt with by allowing a small number of pills to be provided without a co-payment and using a higher co-payment for drugs beyond that number. Different economic impact models could be developed for these scenarios.

By developing a process by which drugs of this nature can be integrated into the Ontario Drug Program, the government can fulfill the ethical basis for priority setting. It would demonstrate that it has the legitimacy to make the decisions because of its general provincial fiduciary responsibility and its use of “experts” in the field, to help in that decision-making process. Moreover, it would demonstrate that the decision-making process is not dependent on the personal “opinions” or the “values” of the DQTC members or government officials. The decision would also not be predicated on a limited definition of “medical necessity” as the reason to provide drugs to enhance personal sexual function or other important “life-style”/QOL activities. Rather, the decision would be a reflection of well deliberated goals of the health care system that in general reflect the values of the beneficiaries (society) that it serves.

By more clearly defining the broad classification of drug products for this range of conditions, the government is then in a position to develop a funding system that will allow it to use its resources in a “fair” manner that to most constituents would appear responsible and ethically sound. Through such a process, the Drug Programs Branch’s decision-making process would be more consistent with Daniels’ proposed accountability for reasonableness. This would be a major step forward in assuring the constituents of Ontario, that the funds used to benefit its citizens are being used in a consistent, responsible and understandable manner.
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