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# Complementary/Alternative Health Care and HIV/AIDS:

Legal, Ethical & Policy Issues in Regulation

prepared by

Robert Crouch, Richard Elliott,  
Trudo Lemmens, and Louis Charland



Canadian  
Strategy on  
HIV/AIDS

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for the Canadian HIV/AIDS Legal Network

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## Authorship Note

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# Executive Summary

## **Why a Paper on Complementary/Alternative Therapies and HIV/AIDS?**

The last decade (particularly the past five years) has seen increased interest in the use of complementary/alternative medicine (CAM) in Canada. Research in this field has increased significantly. The federal government has created a new regulatory framework for natural health products, and there are ongoing developments at the provincial level with respect to the recognition and regulation of some complementary/alternative medicine practitioners. Community-based organizations working in the field of HIV/AIDS in Canada have been increasingly discussing what steps are necessary to ensure that people with HIV/AIDS have access to a range of treatment options and the necessary information to make informed choices about them.

A significant and increasing number of Canadians are using complementary/alternative medicine, and some evidence suggests that its use is even higher among people with HIV/AIDS, who use various kinds of complementary/alternative medicine with goals such as exercising control over one's health, dealing with depression, boosting general immunity, preventing infection or delaying the progression of HIV disease, or coping with unpleasant side effects of conventional drugs.

However, it is also clear that many people with HIV/AIDS must make these treatment decisions with limited access to reliable information about the safety and efficacy of the therapies they use, including information about possible interactions with conventional drugs and the possible effects specific to people with compromised immune systems. This raises ethical and legal questions for those who use complementary/alternative medicine, for conventional health-care professionals treating people with HIV/AIDS, for manufacturers of natural health products, for practitioners of various complementary/alternative therapies, and for governments and professional regulatory

## EXECUTIVE SUMMARY

bodies that need to strike the right balance between protecting consumers/patients and respecting their health-care choices.

### **What Is the Goal of the Paper?**

This paper is the first in a series to be produced by the Canadian HIV/AIDS Legal Network on priority legal and ethical issues related to HIV/AIDS care, treatment, and support. It is part of a three-year project on such issues undertaken with funding from Health Canada under the Canadian Strategy on HIV/AIDS.

The paper does not recommend for or against any particular complementary/alternative therapy or practice, and does not attempt to address the host of legal and ethical issues raised by the use of CAM by people with HIV/AIDS. The principal focus is on considering the approach to regulating the field of complementary/alternative medicine (both products and practitioners). The goal is to ensure that Canadian law and policy in the area of complementary/alternative health care is informed by the available data, by ethical considerations, and by an understanding of the relevant legal frameworks and principles.

### **What Does the Paper Contain?**

The paper:

- discusses the difficulties in defining the precise scope of the field of complementary and/or alternative medicine;
- reviews the available evidence regarding the use of CAM by Canadians generally;
- reviews the available evidence regarding the use of CAM by people with HIV/AIDS, identifying some of the key conclusions to be drawn regarding the prevalence of use, and how and why people with HIV/AIDS use CAM;
- comments on some specific issues relevant to Aboriginal people and traditional Aboriginal healing practices;
- provides an analysis of ethical issues raised by the use of CAM, particularly on the part of people with HIV/AIDS, by applying the principles of non-maleficence, beneficence, respect for personal autonomy, and justice, and draws a number of conclusions as to what is ethically required in law, policy, and practice; and
- examines legal and policy issues regarding the appropriate regulatory approach to CAM in the areas of federal regulation of natural health products and provincial and territorial regulation of practitioners; and discusses the issue of practitioner liability in the delivery of complementary/alternative medicine.

Three key themes emerge from the review of the available evidence and the ethical and legal analysis:

- the need for additional and better research on complementary/alternative medicine;
- the need for improved education and training of health-care practitioners, both conventional and complementary/alternative, with regard to HIV/AIDS and complementary/alternative medicine; and
- the need for a regulatory approach to products and practitioners that appropriately balances the ethical considerations.



## What Are the Conclusions and Recommendations?

The paper presents a number of conclusions and recommendations in these three key areas. Recommendations include:

- funding research into the use of CAM by people with HIV/AIDS, their knowledge about CAM, the barriers to accessing CAM for people with HIV/AIDS, and views with respect to insurance coverage;
- funding research into the safety and efficacy of various complementary/alternative products and therapies, particularly their use by people with HIV/AIDS, and with particular priority given to researching those products and therapies for which there are:
  - (a) encouraging, reliable preliminary effectiveness data,
  - (b) consistent anecdotal evidence of effectiveness,
  - (c) evidence of common use among people with HIV/AIDS, and/or
  - (d) evidence of known or potential significant adverse effects, including if used in conjunction with conventional HIV/AIDS treatments;
- supporting the development of research skills among CAM practitioners in Canada;
- ensuring that research conducted by or in Aboriginal communities regarding traditional healing practices be governed by the principles that Aboriginal people have articulated concerning their ownership and control of, and access to, the research process and outcomes, and the protection of traditional knowledge from appropriation and exploitation;
- incorporating basic education about complementary/alternative medicine into the curriculum of conventional health-care practitioners, incorporating basic HIV/AIDS education into the training of complementary/alternative practitioners, and encouraging health-care practitioners to ask patients about their use of complementary/alternative medicine as a matter of good practice and in the interest of patient well-being;
- addressing issues such as the standard of review before licensing; labeling requirements; surveillance of products once approved for sale in Canada to detect adverse effects; ensuring that those who manufacture or sell products comply with the requirements of the regulatory regime; and ensuring the independence of the Office of Natural Health Products as federal regulator, in connection with the new regulatory framework being developed for the licensing and sale of natural health products in Canada;
- the development of materials that would assist unregulated complementary/alternative practitioners to establish voluntary self-regulating mechanisms, should they wish to do so;
- funding research into various regulatory models to assess the feasibility and desirability of regulating various groups of complementary/alternative practitioners; and
- a review of provincial laws and the policies of professional regulatory bodies for conventional health practitioners with respect to complementary/alternative medicine, with a view to ensuring patients can make informed decisions about, and have access to, a range of qualified health-care practices and practitioners.

A summary of the recommendations is found at the end of the paper.

## Next Steps

The paper will be sent to a broad range of individuals and organizations working in the areas of HIV/AIDS and complementary/alternative medicine. It will also be sent to appropriate government policymakers, professional regulatory bodies and practitioner associations, universities and colleges that educate health-care practitioners, and other interested parties. Those who receive the paper will be asked for their comments and input on these issues and the recommendations, and their views on how best to move forward on these recommendations.

In addition, info sheets on legal and ethical issues related to complementary/alternative medicine and HIV/AIDS care will be prepared and disseminated. The info sheets will summarize the contents of the paper in an easy-to-read format, making the report more accessible to a wider audience and providing useful tools for education and discussion on the issues raised in the report.

## For Further Information...

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Further copies of this paper can be retrieved at the website of the Canadian HIV/AIDS Legal Network at [www.aidslaw.ca](http://www.aidslaw.ca), or ordered through the Canadian HIV/AIDS Clearinghouse at tel 613 725-3434, fax 613 725-1205, email: [aidsida@cpha.ca](mailto:aidsida@cpha.ca).



# Introduction

## Background and Recent Developments

The last decade (particularly the past five years) has seen increased interest in the use of complementary/alternative medicine (CAM) in Canada. Research studies between 1995 and 1999 investigated the use of such therapies by Canadians in general and people with HIV/AIDS in particular (see below), as well as the attitudes and perspectives on their use by both people with HIV/AIDS and CAM providers. In 1996, the Tzu Chi Institute for Complementary and Alternative Medicine was founded in Vancouver, with a mandate to research the use and effects of various therapies. The Canadian AIDS Treatment Information Exchange (CATIE) has produced two guides and numerous infosheets on complementary therapies for people with HIV/AIDS.<sup>1</sup>

There have also been numerous developments in the area of law and policy. At the request of the federal Minister of Health, the House of Commons Standing Committee on Health conducted a review of the regulation of natural health products in Canada, and published its report, *A New Vision*, in November 1998. As a result of the recommendations, the federal government created an Office of Natural Health Products (ONHP) within Health Canada. In 2000, the ONHP conducted consultations across the country to solicit input on its proposals for a new regulatory framework to define and govern “natural health products.”<sup>2</sup> A first draft of the proposed regulations was released in March 2001 for public comment.<sup>3</sup>

As part of its preparatory work, the ONHP also organized a conference to establish priorities for research regarding natural health products.<sup>4</sup> In late 2000, the ONHP and the Canadian Institutes of Health Research (CIHR), the major federal granting agency responsible for funding health research in Canada, announced joint support for awards for research in various areas relating to natural health products.<sup>5</sup>

The last decade (particularly the past five years) has seen increased interest in the use of complementary/alternative medicine in Canada.

<sup>1</sup> CATIE. *A Practical Guide to Complementary Therapies for People living with HIV*, 1999; CATIE. *A Practical Guide to Herbal Therapies for People living with HIV*, 2000.

<sup>2</sup> Office of Natural Health Products, Health Canada. *Seeking Your Input on a Proposed Regulatory Framework — ONHP Consultation 2000 Workbook*. Available online via [www.hc-sc.gc.ca/hpb/onhp](http://www.hc-sc.gc.ca/hpb/onhp).

<sup>3</sup> Office of Natural Health Products, Health Canada. *Building Together: Phase 2 in Developing a Proposed Regulatory Framework for Natural Health Products*. NHPD Public Consultation, March 2001. Available on-line via [www.hc-sc.gc.ca/hpb/onhp](http://www.hc-sc.gc.ca/hpb/onhp).

<sup>4</sup> Office of Natural Health Products, Health Canada. *Natural Health Products: Research Priority Setting Conference*, 6-8 November 1999. Report available online via [www.hc-sc.gc.ca/hpb/onhp](http://www.hc-sc.gc.ca/hpb/onhp).

<sup>5</sup> ONHP, Health Canada, & CIHR. *Requests for Proposals and Opportunity Highlights*, 2000. Available online via [www.cihr.ca](http://www.cihr.ca).

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Health Canada has held a number of internal workshops and meetings of advisory groups/committees<sup>6</sup> to address issues related to complementary/alternative medicine. In addition, in 1998 there were at least three national conferences<sup>7</sup> and an international symposium<sup>8</sup> on complementary/alternative medicine that included some discussion of legal/policy issues. The same year, the Canadian Complementary Medical Association and the Association of Complementary Physicians of British Columbia organized a joint conference attended by over a hundred physicians,<sup>9</sup> and the York University Centre for Health Studies produced a lengthy report contributing to research in this field.<sup>10</sup>

Two areas of Health Canada (the Health Systems Division, and the HIV/AIDS Care and Treatment Program) commissioned several discussion papers in 2000 to help inform the thinking of Canadian policymakers in understanding and addressing issues related to complementary and alternative health care.<sup>11</sup> An additional paper on policy considerations for regulating complementary and alternative health-care practitioners was released in 2001.<sup>12</sup>

There has been increasing interest at the level of research and policy in the United States and the United Kingdom as well. In the UK, the Foundation for Integrated Medicine released a 1997 discussion document on integrated health care,<sup>13</sup> and has established an agenda for research into CAM and dissemination of that research. In the US, in 1992 Congress created the entity within the National Institutes of Health now known as the National Center for Complementary and Alternative Medicine (NCCAM). More recently, in March 2000, then President Clinton established the White House Commission on Complementary and Alternative Medicine Policy, charged with addressing research on CAM practices and products; delivery and public access to CAM services; dissemination of reliable information on CAM to health providers and the general public; and appropriate licensing, education, and training of CAM health-care practitioners. The Commission's recommendations on policy and legislation are to be presented in March 2002.<sup>14</sup> In February 2001, the NCCAM joined with the US National Library of Medicine to create a large database of literature on complementary and alternative medicine searchable free of charge on the Internet.<sup>15</sup> Its strategic five-year plan (2001-2005) identifies priorities in four areas: investing in research, training CAM investigators, expanding outreach, and facilitating integration.

In Canada, the most recent and HIV/AIDS-specific development was a national conference organized by the Canadian AIDS Society in January 2001.<sup>16</sup> Participants identified numerous priorities for action in the areas of research; education, training and communication, regulation, and delivery and access. A report of the meeting will help guide the ongoing process of developing policy and initiatives in Canada that will promote users' informed access to safe and effective complementary/alternative therapies.

This paper aims to make a further contribution to ensuring that Canada's regulatory approach ensures informed access to safe and effective health care for people with HIV/AIDS and Canadians generally.

## History of the Project

This is the first in a series of papers to be produced by the Canadian HIV/AIDS Legal Network as part of a project on Legal, Ethical and Policy Issues Related to HIV/AIDS Care, Treatment and Support. Funding for this project is provided by Health Canada under the Canadian Strategy on HIV/AIDS.

<sup>6</sup> These include the Advisory Group on Complementary and Alternative Health Care (advising the Health Systems Division of the Health Policy and Communications Branch), the Expert Advisory Committee on Complementary Medicines (which advised the former Health Protection Branch), and the Expert Advisory Committee on Natural Health Products (advising the Natural Health Products Directorate, Health Products and Food Branch).

<sup>7</sup> The Emerging Role and Impact of Alternative and Complementary Medicine on Canada's Healthcare System, 12-13 March 1998, Vancouver; The Art and Science of Healing: Complementary and Alternative Medicine Conference for Health Professionals, 14-18 November 1998, Vancouver; Complementary Medicine in the Mainstream, 23-24 November 1998, Toronto.

<sup>8</sup> Why People use Complementary and Alternative Medicine: Social Science Perspectives, 16-18 April 1998, Toronto (funded by the Population Health Fund, Health Promotion and Programs Branch, Health Canada).

<sup>9</sup> Association of Complementary Physicians of BC. Submission to the Health Professions Council of BC, 27 May 1999, at 1.

<sup>10</sup> York University Centre for Health Studies. *Complementary and Alternative Health Practices and Therapies: A Canadian Overview*. August 1999.

<sup>11</sup> Achilles R. *Defining Complementary and Alternative Health Care*. Paper prepared for Health Canada, 10 April 2000; de Bruyn T. *Taking Stock: Policy Issues Associated with Complementary and Alternative Health Care*. Report prepared for Health Canada, 31 March 2000; Advisory Group on Complementary & Alternative Health Care. Health Canada. *Towards an Integrative Health System*. July 2000.

<sup>12</sup> Casey J, Picherack F. *The Regulation of Complementary and Alternative Health Care Practitioners: Policy Considerations*. Prepared for Health Canada, forthcoming 2001.

<sup>13</sup> Integrated healthcare. A way forward for the next five years? Discussion document. The Foundation for Integrated Medicine on behalf of the Steering Committee for the Prince of Wales Initiative on Integrated Medicine. London: Foundation for Integrated Medicine, 2000 (available online via [www.fimed.org](http://www.fimed.org)).

<sup>14</sup> White House Commission on Complementary and Alternative Medicine Policy. *WHCCAMP News*, referencing Presidential Executive Order 13147, 7 March 2000, available online at [www.whccamp.hhs.gov](http://www.whccamp.hhs.gov) (accessed 7 January 2001).

<sup>15</sup> The database can be accessed via the NCCAM's website at [www.nccam.nih.gov](http://www.nccam.nih.gov).

<sup>16</sup> Towards Integrative Care: A National Strategic Planning and Skills Building Conference on Complementary Therapies and HIV/AIDS. 12-13 January 2001, Montréal.

## INTRODUCTION

This paper was originally commissioned by Health Canada as a short research paper, prepared by Lemmens, Crouch, and Charland, to provide an ethical analysis of questions raised by the use of complementary/alternative health-care practices by people with HIV/AIDS. Consultations on a draft of the paper, and further developments in Canada in the meantime, led to the scope of the paper being expanded.

Two earlier drafts of the paper were circulated to a variety of commentators, including people with HIV/AIDS who use complementary/alternative therapies, practitioners of these therapies, researchers and providers of treatment information working in community-based organizations, and lawyers familiar with HIV/AIDS issues. Based on the input received, a third draft was distributed for comment and discussed at a national workshop organized by the Legal Network in February 2001. Input was sought from HIV-positive consumers of complementary/alternative therapies, ethicists, educators and providers of treatment information, lawyers familiar with the regulation of health-care practices and practitioners in Canada, and both conventional practitioners and practitioners of complementary/alternative therapies. Following the input received at the workshop and from the selected commentators, this final paper and an accompanying series of infosheets were prepared.

### Scope and Outline of the Paper

There are a host of medical, social, and personal issues related to the use of complementary/alternative health-care practices in the general population and by people with HIV/AIDS.

From the perspective of good medical practice, we must ask why conventional medicine is sometimes deemed inadequate or rejected altogether; whether and to what extent various complementary/alternative health-care practices are safe and effective, and for which conditions they are safe and effective.

On a societal level, we must examine the forms and patterns of complementary and/or alternative medicine use, and the social factors that have produced the wide variety of complementary/alternative therapies now available. We also must ask to what extent we should socially support access to these therapies and what criteria we should use to determine what therapies are worthy of this support. Social support for complementary/alternative therapies can take various forms, such as recognition of these therapies in the health-care system, or the allocation of resources used to test, regulate, and control them.

On a personal level, we must consider the reasons why people use complementary/alternative medicine instead of, or in addition to, conventional therapies, and what sort of benefit or harm they perceive themselves to be receiving as a result.

This paper begins with an overview of some of the available information regarding these medical, social, and personal dimensions of CAM use, drawing upon data from Canada and other comparable settings. With this context in mind, the paper then discusses a number of ethical issues related to the use of complementary and/or alternative health-care practices, based on the four key ethical principles of non-maleficence, beneficence, respect for autonomy, and justice. This evidentiary and ethical analysis leads to a number of conclusions in the areas of research, education/training, and regulation. The last section considers the Canadian legal context for regulating complementary/alternative health-care products and practitioners; the reader can assess whether the current regulatory environment is acceptable in light of the ethical considerations outlined.

## INTRODUCTION

The paper does *not* recommend the use or avoidance of any specific complementary/alternative therapy, but rather focuses on general ethical issues that are, in principle, applicable to any medicine (complementary/alternative or conventional). In doing so, some generalizations are unavoidable, and they may not always do justice to the wide panoply of complementary/alternative therapies and the reasons for their use. Some conclusions and recommendations will no doubt need to be tailored to the specific characteristics of the various therapies. We attempt to canvass the ethical and legal issues that are of most concern to both complementary/alternative and conventional health-care practitioners, government policymakers and, especially, people with HIV/AIDS.

However, there are many legal ethical issues that are not addressed here and warrant further inquiry, including: ethical questions in the design and implementation of research studies examining complementary/alternative therapies; the inclusion of such therapies in public and private insurance plans and their availability in health-care facilities such as hospitals;<sup>17</sup> judicial recognition of complementary/alternative therapies in the context of tort cases for personal injury (eg, the car accident victim who claims chiropractic expenses or naturopathic treatments for pain or headaches rather than conventional drugs); medical decision-making for minors where complementary/alternative therapies are used or proposed; family law issues such as courts' approach to child custody disputes where a parent's reliance upon complementary/alternative therapies for their child is in issue, and claims for child support to include complementary or alternative therapies; the impact of international trade agreements on consumers' access to natural health products and to complementary/alternative practitioners, and on the ability of national governments to regulate products and practitioners in the public interest.

The principal focus of the paper is on considering the approach to regulating the field of complementary/alternative medicine (both products and practitioners). The goal is to ensure that Canadian law and policy in the area of complementary/alternative health care is informed by the available data, by ethical considerations, and by an understanding of the relevant legal frameworks and principles.

### Defining Complementary/Alternative Medicine

If a list was written of what patients care about (for example, the clinical relationship), what researchers feel is important (for example, control of bias), what clinicians hold critical (for example, clinical competence), or what matters to purchasers (for example, cost effectiveness) there would probably be no reference to the historically and politically contingent concepts of "conventional" and "complementary" medicine.<sup>18</sup>

### Terminology

Given the politically charged nature of the debate that continues to surround complementary/alternative health care, an informed, considered discussion of the relevant ethical and legal issues should take care in the use of terminology and should, where possible, avoid totalizing statements about either "conventional" or "complementary or alternative" practices or practitioners

The paper does *not* recommend the use or avoidance of any specific complementary/alternative therapy.

<sup>17</sup> For a discussion of some of these issues, see: Pelletier KR et al. Current trends in the integration and reimbursement of complementary and alternative medicine by managed care, insurance carriers, and hospital providers. *American Journal of Health Promotion* 1997; 12(2): 112-122.

<sup>18</sup> Vickers A. Recent advances: complementary medicine. *British Medical Journal* 2000; 321: 683-686 at 683.

## INTRODUCTION

as easily defined categories or groups. The available evidence regarding the safety and efficacy of health-care practices, be they conventional or considered “complementary” and/or “alternative,” varies widely depending on the therapy in question and the use to which it is put. Attitudes toward complementary/alternative health-care practices and practitioners vary among conventional medical practitioners and vice versa. While historical tensions persist, recent years have also seen considerable shifts in attitude on the part of many practitioners. There is increased interest in approaches to health care that recognize the common interest in patient/consumer well-being, however achieved. Furthermore, common notions of “alternative” shift over time:

Alternative medicine is not a new phenomenon. Indeed, in many respects, it was “medicine” before it became “alternative,” as it was only in the nineteenth century that the mainstream of modern medicine was defined.<sup>19</sup>

Nonetheless, it is necessary at this stage to draw some distinctions, if only because they persist in the real world of health-care practice and are reflected in our laws and policies. In this paper:

- The term “*conventional medicine*” is used to refer to practices that are generally accepted by both the general public and mainstream health-care professionals as part of the dominant health system in North America.
- The term “*complementary/alternative medicine*” (*CAM*) is used in a general sense to refer to those “interventions for improving, maintaining, and promoting health and well-being, preventing disease, or treating illnesses that are not part of a standard North American biomedical regimen of health care or disease prevention.”<sup>20</sup> The term “*complementary and alternative health care*” (*CAHC*) is also used because “health care” has broader connotations than the narrower term “medicine.”<sup>21</sup> As noted in a compendium recently published by the American Medical Association to educate conventional physicians, “the term ‘health care practices’ is used instead of ‘medicine’ because many widely used practices are not part of a medical system.”<sup>22</sup> In some cases, the shorter term “*complementary therapies*” is used, as the available data (discussed below) show that the great majority of Canadians who use such therapies do so as an adjunct, rather than an alternative, to conventional medical care.<sup>23</sup> Finally, where the context warrants it, the term “*unconventional therapies*” may be used as the clearest way of distinguishing such therapies from conventional medicine.
- The term “*integrated care*” (or sometimes “integrative care”) has recently entered the literature and is used to refer to approaches that incorporate the use of both conventional medicine and complementary/alternative health-care practices.

A number of other terms (some more value-laden than others) are also used in the literature to refer to both conventional medicine and complementary/alternative health care. Complementary/alternative health care is sometimes referred to as “unconventional,” “holistic,” “natural,” “unorthodox,” or “unvalidated.” Conventional medicine is sometimes referred to as “biomedicine,” “allopathic,” “Western medicine,” “mainstream,” “orthodox,” or “scientific.” The variety of terms reflects the difficulty in defining the exact boundaries of the field of complementary/alternative health care, one of the first hurdles in informed policymaking:

The goal is to ensure that Canadian law and policy in the area of complementary/alternative health care is informed by the available data, by ethical considerations, and by an understanding of the relevant legal frameworks and principles.

<sup>19</sup> Feasby C. Determining standard of care in alternative contexts. *Health Law Journal* 1997; 5: 45-65 at para 14 (QL).

<sup>20</sup> American Medical Association. *Cultural Competence Compendium* (Section V: “Complementary and Spiritual Practices”). AMA, 1999; at 246. Available online via [www.ama-assn.org](http://www.ama-assn.org).

<sup>21</sup> de Bruyn, supra, note 11 at 3.

<sup>22</sup> American Medical Association, supra, note 20 at 246.

<sup>23</sup> It may be appropriate to speak of “complementary and alternative therapies” in the aggregate. But in the case of a given individual using a given unconventional therapy for a given purpose the terms are mutually exclusive: either the therapy is used as a *complement* to conventional treatment or as an *alternative* to conventional treatment: Druss BG, Rosenheck RA. Association between use of unconventional therapies and conventional medical services. *Journal of the American Medical Association* 1999; 282(7): 651-656; Katz DL. Conventional medical care and unconventional therapies [Letter to the editor]. *Journal of the American Medical Association* 2000; 283(1): 56.

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Alternative medicine is not a new phenomenon. Indeed, in many respects, it was “medicine” before it became “alternative.”

Research and policy development begins with a definition of what constitutes CAHC.... Definitions and boundaries are inextricably linked. A good definition will provide clear boundaries; clear boundaries will provide a good definition. But the boundaries are blurred between CAHC and conventional medicine; and, current definitions rely on an outdated perception of health care and of conventional medicine.<sup>24</sup>

### What Makes a Therapy “Complementary” or “Alternative”?

The most common approach to defining complementary and/or alternative medicine is to do so in a manner similar to the way we define a concept such as “health.” We often define “health” not positively but negatively, as the absence of disease. Similarly, one way to define complementary and/or alternative medicine is to say that it includes those treatment modalities that are not thought to be part of current conventional medical practice (as is done in this paper). This approach was adopted by Eisenberg et al in their widely cited study of complementary and/or alternative medicine use in the United States. They define complementary and/or alternative medicine as “medical interventions not taught widely at U.S. medical schools or generally available at U.S. hospitals.”<sup>25</sup> A similar definition has been suggested by the British Medical Association.<sup>26</sup> It has also been adopted by the National Center for Complementary and Alternative Medicine (NCCAM) at the US National Institutes of Health: “Complementary and alternative medicine practices are best described as those not presently considered an integral part of conventional medicine.”<sup>27</sup> A definition that has a more positive tone is that proposed by Ernst et al<sup>28</sup> and adopted with slight modifications by the Cochrane Collaboration: “diagnosis, treatment and/or prevention which complements mainstream medicine by contributing to a common whole, by satisfying a demand not met by orthodoxy or by diversifying the conceptual frameworks of medicine.”<sup>29</sup>

What is common to all of these, however, is that the reference point is conventional medicine as taught at conventional medical schools or as provided in conventional hospitals. Complementary and/or alternative medicine is defined derivatively and in relation to medical orthodoxy. As Fisher and Ward point out, to speak of “alternative” medicine is much like speaking about “foreigners,” since “both terms are vaguely pejorative and refer to large, heterogeneous categories defined by what they are not rather than by what they are.”<sup>30</sup> Some argue that this approach unfairly privileges conventional medicine and makes it more difficult for complementary and/or alternative medicine practitioners to achieve public legitimacy. Also, the accuracy of this definition is increasingly questionable:

The 1990s have been a period of accelerated growth in the use of CAHC and this definition, developed at the beginning of the decade, is already obsolete since many alternative therapies are now taught in most medical schools in the US and in Canada.... In addition, selected therapies are being integrated into hospital systems throughout North America.<sup>31</sup>

What underlies this approach of defining complementary and/or alternative medicine in contrast to mainstream medical practice? There are two princi-

<sup>24</sup> Achilles, *supra*, note 11 at 3.

<sup>25</sup> Eisenberg DM et al. Unconventional medicine in the United States: prevalence, costs, and patterns of use. *New England Journal of Medicine* 1993; 328: 246-252 at 246.

<sup>26</sup> As reported in: *Integrated healthcare*, *supra*, note 13.

<sup>27</sup> NCCAM [US]. *Expanding Horizons of Healthcare: Five-Year Strategic Plan, 2001-2005*. 2000. Available online via [www.nccam.nih.gov](http://www.nccam.nih.gov).

<sup>28</sup> Ernst E et al. Complementary medicine – a definition. *British Journal of General Practice* 1995; 45: 506.

<sup>29</sup> Cochrane Collaboration, as cited in NCCAM, *supra*, note 27 at 2, n3.

<sup>30</sup> Fisher P, Ward A. Complementary medicine in Europe. *British Medical Journal* 1994; 309: 107-111 at 107.

<sup>31</sup> Achilles, *supra*, note 11 at 3.



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pal reasons why a healing practice falls outside the boundaries of conventional medicine and is thought of as “unconventional.”

### ***Different explanatory framework***

First, the underlying explanatory framework of an unconventional healing practice may be different from that of modern biomedicine. By “explanatory framework” we mean the entities and processes that are referred to in explaining the cause of a disease and the mechanism of action of a possible therapy.

For example, modern biomedicine considers bacteria to be a cause of certain illnesses and can provide a detailed account of the processes that are involved when bacteria enter the body, invade tissue, and cause the range of symptoms associated with the particular illness. Moreover, practitioners of modern medicine will be able to explain why, and through what mechanisms, an antibiotic works to combat the bacterial infection and restore health based on principles of human physiology and cell biology.

Therefore, a healing practice will be considered alternative if its explanatory framework includes entities and processes that are *not* part of the biomedical tradition as informed by the most current scientific information. Prime examples are Ayurvedic medicine, Traditional Chinese Medicine, and some Aboriginal healing traditions, all of which are founded in frameworks or cosmologies that are substantially different from the mechanistic understanding of illness that is modern Western science. In a sense, such health practices are truly “alternative” to the medical paradigm currently dominant in Canada (although they may not be considered “alternative” by those for whom they are part of their own cultural heritage).

It should be noted that an explanatory framework that is different from conventional, Western biomedicine is not necessarily incompatible with a conventional biomedical explanation. It simply means that there is a different way of thinking about the “diagnosis” and “treatment” of ill health.

### ***Not biomedically validated***

Second, even if the explanatory framework of a healing practice is similar to that used by modern biomedicine, it may still be considered “unconventional” if its claimed effect or mechanism of action is not validated by conventional scientific methods. A prime example is the use of some herbal mixtures, or other combinations of natural substances, as anti-cancer agents. In some such instances, we know that the herbal preparation has some form of biological activity that can be described in a manner consistent with the explanatory framework of conventional biomedicine. But there is insufficient evidence to support claims of its effectiveness in preventing or treating cancer, and often there is no known mechanism of action for the substance.

The controversy surrounding the use of Laetrile in cancer patients is a case in point. During the 1970s, tens of thousands of patients used Laetrile, a substance derived from apricot pits, to treat cancer and cancer pain and as a preventative anti-cancer agent. After numerous reports of Laetrile toxicities and little evidence of effectiveness, studies were carried out by the United States National Cancer Institute that failed to demonstrate any clinical anti-cancer effect. Laetrile stands as one of the more famous and (at one time) widely used alternative medicines that was eventually demonstrated to be ineffective within the explanatory framework of Western biomedicine.<sup>32</sup> The Di Bella Multitherapy among cancer patients in Italy serves as a more recent example.<sup>33</sup> The Di Bella saga highlights how even therapies of physicians operating within the medical profession and based on products used by

One way to define complementary and/or alternative medicine is to say that it includes those treatment modalities that are not thought to be part of current conventional medical practice.

<sup>32</sup> Office of Technology Assessment. *Unconventional Cancer Treatments*. Washington, DC: Government Printing Office, 1990, at 102-107.

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conventional medicine can be considered alternative because the way the products are used is not recognized as valid by the scientific standards of conventional medicine.

### **“Unconventionality” depends on goal of therapy**

Whether or not an unconventional therapy corresponds to an alternative or conventional explanatory framework may depend upon the condition for which the complementary and/or alternative medicine is being used. For example, the mechanism through which chiropractic spinal manipulations help diminish lower back pain is consistent with the framework used by conventional biomedicine. But neither chiropractic theories nor a conventional biomedical framework can adequately explain why spinal manipulation can help with more systemic conditions, such as the deafness and heart condition that the originator of the chiropractic movement, Daniel David Palmer, apparently cured by chiropractic means in his first two successful patients in the 1890s.

Thus, some unconventional medicine is alternative to a conventional biomedical model with respect to its use for some conditions, but not necessary alternative for other conditions. Determining whether a therapy is consistent with, but not validated by, a conventional medical framework, or whether it is truly “alternative” in its explanatory framework, depends upon whether mainstream, scientific biomedicine can explain how the practice promotes health.

### **Definition for this paper**

The widely-accepted definition of CAM offered by the US National Institutes of Health and the Cochrane Collaboration is

a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period.<sup>34</sup>

We have outlined the ways in which a therapy can be considered to be “other” than intrinsic to the dominant system. For the purposes of this paper, our definition of “complementary/alternative health care” will include therapies that either

- rest upon an explanatory framework that is, in at least some fundamental respects, substantially different from the modern scientific worldview; or
- may have a possible mechanism of action understandable within conventional medicine’s explanatory framework but have not been validated by biomedicine.

### **Categories of Complementary/Alternative Health Care**

One recent attempt to systematically classify unconventional therapies was completed by the United States National Institutes of Health in its 1994 report, *Alternative Medicine: Expanding Medical Horizons*.<sup>35</sup> The NIH identified six broad categories of complementary and/or alternative medicine, which it subsequently reduced to the following five major domains:

- (1) alternative medical systems (eg, traditional Oriental medicine, Ayurveda, Aboriginal systems, homeopathy, naturopathy);

<sup>33</sup> See: Buiatti E et al. Results from a historical survey of the survival of cancer patients given Di Bella Multitherapy. *Cancer* 1999; 86: 2143-2149; Traversa G et al for the Italian Study Group for the Di Bella Multitherapy Trials. The unconventional Di Bella cancer treatment – a reflection on the Italian experience. *Cancer* 1999; 86: 1903-1911; Cassileth BR. Alternative and complementary medicine – separating the wheat from the chaff. *Cancer* 1999; 86: 1900-1902; Calabresi P. Medical alternatives to alternative medicine. *Cancer* 1999; 86: 1887-1889.

<sup>34</sup> Cited in: Zollman C, Vickers A. ABC of complementary medicine. *British Medical Journal* 1999; 319: 693-696.

<sup>35</sup> Washington, DC: Government Printing Office, 1994.

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- (2) mind–body interventions (eg, meditation, hypnosis, art therapy, prayer, and mental healing);
- (3) biologically based therapies (eg, herbal therapies, special diet therapies, orthomolecular therapies, animal substances such as shark cartilage or bee pollen);
- (4) manipulative and body-based methods (eg, chiropractic, osteopathic manipulation, massage therapy);
- (5) energy therapies (Qi gong, reiki, therapeutic touch).<sup>36</sup>

Several participants at the workshop organized by the Legal Network in February 2001 noted that this schema of classifying complementary/alternative health care remained rooted to some degree in a “biomedical” framework, and pointed out that some of these distinctions seem artificial and irrelevant from the perspective of a holistic approach to understanding health and illness that informs many complementary/alternative therapies.

We have only briefly touched on the problems involved in identifying and defining the boundaries of “complementary and/or alternative medicine.” Without identifying the features that separate unconventional practices from conventional medicine, it will be difficult to carry out systematic research and to craft policy. The need for a clear analysis of the defining features of the different forms of alternative therapies becomes more pressing as complementary and/or alternative medicines move quickly into mainstream medical practice.

It will also be crucial to recognize the fundamental differences that exist among different forms of complementary/alternative health care in order to determine which should be submitted to stricter regulation, which could be submitted to efficiency studies, etc. Further clarification of defining features of CAM may also lead to the conclusion that some distinctions are artificial and incoherent. We agree with the recommendation in a report by the York University Centre for Health Studies that “further research be undertaken on the issues of definition, key characteristics and a framework for organizing the diverse range of complementary and alternative therapies and practices.”<sup>37</sup>

### Recommendation I

**The Canadian Institutes for Health Research (CIHR), the Office of Natural Health Products (ONHP), and other research funding agencies should fund further research into clarifying appropriate definitions and key characteristics of “complementary/alternative health care,” as well as developing an appropriate conceptual framework for organizing the wide range of therapies and practices that fit within this category in order to guide consumers, providers, and regulators.**

It will be crucial to recognize the fundamental differences that exist among different forms of complementary/alternative health care in order to determine which should be submitted to stricter regulation, which could be submitted to efficiency studies, etc.

<sup>36</sup> National Center for Complementary and Alternative Medicine (NIH). Major Domains of Complementary and Alternative Medicine (fact-sheet). Available online via [nccam.nih.gov](http://nccam.nih.gov) (accessed 22 January 2001). See also: NCCAM. *Expanding Horizons of Healthcare*, supra, note 27 at 3-4.

<sup>37</sup> York University Centre for Health Studies, supra, note 10 at 45.





# The Use of Complementary/Alternative Health Care

It is estimated that anywhere from 70 percent to 90 percent of the world's population relies on "alternative" medicine as one form of health care, suggesting that on a global level such medicine is in fact conventional, not alternative.<sup>38</sup> A recent computerized search of the medical literature found prevalence rates ranging from nine to 65 percent in random or representative samples of the general population in various countries, but the researcher noted that the prevalence of using CAM seemed to depend on factors poorly controlled for in these surveys, so the true prevalence remains uncertain.<sup>39</sup> Since the late 1970s, the World Health Organization has supported increased training and research related to "traditional medicine" or "indigenous" healing practices, and since the 1980s has encouraged the incorporation of specific measures governing the practice of traditional medicine into national health legislation.<sup>40</sup> In the context of the HIV/AIDS epidemic, there has been further recognition of the important role that traditional healers can and should play in both HIV prevention and the provision of care, treatment, and support to those infected and affected.<sup>41</sup>

This chapter reviews the patterns and prevalence of complementary and/or alternative medicine. The first section reviews data regarding complementary/alternative medicine use by Canadians generally. (For purposes of comparison, important research results from studies in other similar settings such as the United States, Australia, and the United Kingdom and other European countries are summarized in Appendix A.) The second section reviews the

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<sup>38</sup> *United States, Alternative Medicine: Expanding Medical Horizons – A Report to the National Institutes of Health on Alternative Medical Systems and Practices in the United States, 1992* (the Chantilly Report), cited in: York University Centre for Health Studies, supra, note 10.

<sup>39</sup> Ernst E. Prevalence of use of complementary/alternative medicine: a systematic review. *Bulletin of the World Health Organization* 2000; 78(2): 252-257.

<sup>40</sup> For a recent review of the experience in numerous Asian countries in integrating conventional and traditional health care in national legislation and policy, see: Bodeker G. Lessons on integration from the developing world's experience. *British Medical Journal* 2001; 322: 164-167.

<sup>41</sup> For example, see: UNAIDS. Collaboration with traditional healers in HIV/AIDS prevention and care in sub-Saharan Africa: a literature review. UNAIDS Best Practice Collection. Geneva, September 2000 (available online via [www.unaids.org](http://www.unaids.org)).

Respondents in British Columbia were five times more likely than respondents in Atlantic Canada to have tried an alternative therapy.

67 percent of Canadians felt the federal government should regulate natural health products to ensure their safety and quality.

available information regarding use by people with HIV/AIDS, including data from both Canada and other countries. Finally, the third section examines what is known about *why* and *how* people use complementary/alternative therapies, since these are important considerations in an ethical analysis and in developing an appropriate regulatory approach.

## Use of Complementary/Alternative Health Care by Canadians

Over the last decade, research has repeatedly shown that a significant and rapidly increasing number of Canadians have used complementary/alternative health care of one sort or another.

A poll of 2000 people by the Canada Health Monitor found that in the first six months of 1990 one in five Canadians had used some form of alternative therapy.<sup>42</sup> Another study examined the use of alternative medicine in rural households in Alberta during 1992, and found that women were more likely to see an alternative care provider than men, and that utilization of alternative providers seemed clustered in families.<sup>43</sup> Data gathered in Statistics Canada's 1994-1995 National Population Health Survey of almost 18,000 Canadians found that:

- In the year preceding the survey, 15 percent of respondents over the age of 15 had consulted an alternative health-care provider (including a chiropractor).
- The use of CAM increased with schooling, ranging from 11 percent for those with less than a high-school education to 16 percent for those educated at college or university.
- The most pronounced difference in use was between women with low incomes (12 percent) and women in the highest income group (20 percent).
- There were geographic differences: women in British Columbia were almost five times more likely to visit an alternative health-care provider than women in the Atlantic region. Researchers suggested these differences might be partially explained by variations between provincial health plans in the extent of coverage for alternative services.
- Respondents with diagnosed chronic conditions, especially those with more than one, were far more likely to seek alternative care than those with no chronic conditions: 26 percent of respondents with three or more chronic conditions had consulted an alternative health-care provider within the last year, compared with only nine percent of those with no chronic conditions.<sup>44</sup>

Another study also analyzed the 1994-95 National Population Health Survey data, and reported that approximately five percent of the Canadian population used alternative therapies (excluding chiropractic). This figure rose to 13.8 percent if chiropractic care was included in the category of "alternative" therapies.<sup>45</sup>

In a 1995 survey by Reader's Digest/Roper Health Study,<sup>46</sup> almost 40 percent of Canadians surveyed said they had sought advice from practitioners of alternative medicine, primarily chiropractors, acupuncturists, herbalists, and homeopaths. A further 11 percent said they had seriously considered such options and 62 percent said they would explore such options if conventional treatments failed to provide satisfactory results. The survey also found that older respondents were most likely to have tried an alternative medicine, often for chronic bothersome (but not debilitating) conditions, and that respondents in British Columbia were five times more likely

<sup>42</sup> Northcott HC. Alternative Health Care in Canada. In: Singh Bolaria B, Dickinson HD (eds). *Health, Illness and Health Care in Canada* (2d ed). Toronto: Harcourt Brace & Company, 1994, at 487-503.

<sup>43</sup> Verhoeve MJ, Russell ML, Love EJ. Alternative medicine use in rural Alberta. *Canadian Journal of Public Health* 1994; 83(3): 308-309.

<sup>44</sup> Millar WJ. Use of alternative health care practitioners by Canadians. *Canadian Journal of Public Health* 1997; 88(3): 154-158; Buske L. Higher earners seek more alternative care. *Canadian Medical Association Journal* 1997; 157: 996.

<sup>45</sup> So J. Utilization of alternative therapies by the Canadian population: a preliminary study. In: Muldoon J (ed). *Taking Charge of Health: Exploring Alternative Health Care*. Proceedings of a conference sponsored by Trent University, Sir Sandford Fleming College, and the Haliburton, Kawartha and Pine Ridge District Health Council, cited in: York University Centre for Health Studies, supra, note 10 at 258-259.

<sup>46</sup> Cited in: Nonprescription Drug Manufacturers Association of Canada. NDMAC Consumer Profile: The Nonprescription Drug User, undated. Available online via [www.ndmac.ca](http://www.ndmac.ca).

than respondents in Atlantic Canada to have tried an alternative therapy (52 versus 10 percent).

According to a 1997 Angus Reid/CTV poll of a representative cross-section of 1200 Canadian adults:<sup>47</sup>

- During the 1997 calendar year, 42 percent of Canadians had been using some form of complementary/alternative therapy.
- Of those who reported using such therapies, 55 percent had been using them for more than five years, while 19 percent had started using them within the last five years.
- Use was higher among Canadians in the 35-54 age bracket (49 percent), among women (46 percent), and among those with self-reported annual income above \$60,000 (52 percent).
- The poll also found that 67 percent of Canadians felt the federal government should regulate natural health products to ensure their safety and quality.

Another 1997 survey by the Canada Health Monitor reported that 56 percent of Canadians had used a natural health product in the previous year.<sup>48</sup> The Nonprescription Drug Manufacturers Association of Canada has reported that, based on its survey of 5500 adults, the proportion using herbal remedies has doubled from 15 percent in 1996 to 30 percent in 1998, and that people using these products are also more likely to be using conventional over-the-counter drugs (90 percent of respondents versus 81 percent of the general population) and prescription drugs (78 percent of respondents versus 72 percent of the general population).<sup>49</sup>

The most recent, comprehensive information about the use of complementary/alternative medicine by Canadians comes from a 1997 study by Ramsey et al, published in 1999 by the Fraser Institute.<sup>50</sup> According to that study:

- 73 percent of respondents had used at least one complementary and/or alternative therapy in their lives, and 50 percent of respondents had used at least one complementary and/or alternative therapy in the previous 12 months.
- The three most common forms of complementary/alternative therapy used were chiropractic (36 percent), relaxation techniques and massage (both 23 percent), and prayer (21 percent).
- The authors estimated that, during the 1997 calendar year, Canadians spent approximately CDN\$1.8 billion out of pocket on visits to complementary and/or alternative medicine providers and an additional CDN\$2 billion on herbs, vitamins, diet programs, and books.

These studies put to rest any doubt that complementary/alternative medicine is “fringe” in a statistical sense. When a majority, or even a significant minority, of Canadians use these therapies as part of their health care, there can be no doubt of the need for research, patient and provider education, and a consideration of the appropriate regulatory mechanisms to strike the right balance between informed patients’ autonomy in making health-care decisions, the use of public health-care funds, and the protection of the consumer and public health.

## Use of Complementary/Alternative Health Care by People with HIV/AIDS

The limited research on the use of complementary/alternative therapies by people with HIV/AIDS shows patterns and motivations similar in many respects to those of users as a whole. People with HIV/AIDS use

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Studies put to rest any doubt that complementary/alternative medicine is “fringe” in a statistical sense.

<sup>47</sup> Angus Reid Group. Use and Danger of Alternative Medicines and Practice: Parts I and II. Consumer poll conducted by CTV/Angus Reid Group in August 1997. 1998.

<sup>48</sup> Berger E. Standing Committee on Health. *Natural Health Products: A New Vision*. Ottawa, November 1998, at Chapter 1, Part C. According to this report, the Canadian Health Monitor has recently collected, but not yet published, data for the 1997-99 period, including data on the use of complementary/alternative therapies, the reasons for their use, and their possible substitution for conventional care: York University Centre for Health Studies, supra, note 10 at 261, n422.

<sup>49</sup> Cited in: Sibbald B. New federal office will spend millions to regulate herbal remedies, vitamins. *Canadian Medical Association Journal* 1999; 160: 1355-1357.

The limited number of studies available reflect high variation in the overall use of complementary/alternative medicine by people with HIV/AIDS.

Generally, examining physicians will assess the expected demand of the applicant over the first five years following admission.

complementary/alternative medicine for a variety of reasons and with a variety of therapeutic goals in mind. This section reviews the various types of complementary/alternative therapies used by people with HIV/AIDS, as well as the social, personal, and clinical determinants of their use in the context of HIV/AIDS care.

This review is necessarily incomplete. Increasing numbers of alternative therapies are now being researched or tested by university or government researchers. While the results of some of these studies are already available, others will not appear for years. Moreover, a great many of the complementary/alternative therapies actually being used by people with HIV/AIDS are not being tested by researchers, and patterns of use may often change. As several people with HIV/AIDS have recently put it, in the face of rapidly changing treatment information “adaptability has been key to survival for people with HIV, and will be key for providers.”<sup>51</sup>

The goal of this paper is not to provide an overview of the types of therapies available or to analyze the validity of these therapies. But a discussion of ethical issues and regulatory policy must be informed by basic information about the prevalence of their use among people with HIV/AIDS, and why and how they are used.

### Prevalence of Use

There is a handful of studies of the prevalence of complementary and/or alternative medicine use among people with HIV/AIDS. In Canada, reported studies have been done in Ontario, British Columbia, Saskatchewan, and Québec. (Two tables in Appendix C provide a summary overview of both Canadian and other studies of complementary and/or alternative medicine use among people with HIV/AIDS.) Despite the limited number of studies, some conclusions can certainly be drawn from the available research.

### Variation in use

First, the limited number of studies available reflect high variation in the overall use of complementary/alternative medicine by people with HIV/AIDS. Many studies often examine the use of only one particular category of CAM, and studies are often structured differently, making it difficult to draw firm comparisons. With this qualification in mind, the US studies report overall rates of CAM use ranging from 22 percent (looking at the use of herbal products only) to 100 percent of respondents (looking at the use of vitamins and relaxation techniques only); most reported US studies examining use of many CAM forms show that anywhere from 1/4 to 3/4 of respondents use some form of CAM or another (see Table 2, Appendix B).

In the Canadian context, the limited data available suggest a significantly higher proportion of CAM use by people with HIV/AIDS in Ontario as opposed to British Columbia, Saskatchewan, and Québec.

- A 330-person Québec study published in 2000 showed that 34 percent of the HIV-positive study participants used vitamins, 16 percent used dietary supplements, and three percent used homeopathic products.<sup>52</sup> Yet, forthcoming research confirms a surprisingly low percentage of HIV-positive Québecers using complementary/alternative therapies (aside from 18 percent of respondents in one study who reported smoking marijuana for therapeutic reasons).<sup>53</sup>
- In British Columbia, studies over several years among people with HIV/AIDS attending HIV clinics or accessing the provincial HIV drug plan show that between 39 and 42 percent of respondents have used CAM,<sup>54</sup> although it has also been reported that use has been steadily

<sup>50</sup> Ramsay C, Walker M, Alexander J. Alternative medicine in Canada: use and public attitudes. Vancouver, BC: The Fraser Institute, 1999; also reported in *Public Policy Sources* 1999; 21. Available online at [www.fraserinstitute.ca/publications/pps/21](http://www.fraserinstitute.ca/publications/pps/21).

<sup>51</sup> Wellesley Central Hospital, Toronto, Ontario. *A Comprehensive Guide for the Care of Persons with HIV Disease*. 1998 at 11.

<sup>52</sup> Jalbert Y et al. Adherence to HIV antiretroviral therapy among people living with AIDS in Québec. August 2000. Communication with M Hendricks, COCQ-sida, dated 14 February 2001 [on file].

<sup>53</sup> Communications with M Hendricks, COCQ-sida, dated 13 and 14 February 2001, regarding research by Jalbert et al at COCQ-sida. PVVH: Utilisation des traitements alternatifs et complémentaires (TAC) au Québec, 2001.

<sup>54</sup> Meneilly GP, Carr R, Brown L. Alternative Therapy Use in HIV Positive Women [poster]. XI International Conference on AIDS, Vancouver, Canada, 7-12 July 1996: Abstract Mo.B.301; Ostrow MJ et al. Determinants of complementary therapy use in HIV-infected individuals receiving antiretroviral or anti-opportunistic agents. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* 1997; 15: 115-120; Braitstein P et al. Information seeking and health care utilization patterns among people living with HIV/AIDS who currently use both antiretrovirals and complementary therapies in British Columbia, Canada. Poster presentation, 9<sup>th</sup> Annual Canadian Conference on HIV/AIDS Research, 27-30 April 2000, Montréal: Abstract 338P.



increasing in recent years, which is contrary to the trend of decreased CAM use observed in a small sample of people with HIV/AIDS accessing care at a Saskatoon clinic.<sup>55</sup>

- In contrast, the reported prevalence of CAM use is markedly higher in several Ontario studies, ranging from 67 to over 90 percent.<sup>56</sup> The largest study, involving 2400 people recorded in the provincial HIV observational database, found that 81 percent of respondents had used complementary/alternative medicine at some point and 73.6 percent were currently using CAM.<sup>57</sup>

This is surprising, given that among Canadians generally, use of CAM appears to be highest among residents of British Columbia (see above). This suggests that further analysis of the patterns of CAM prevalence among people with HIV/AIDS is required in order to determine whether the existing studies accurately reflect levels of use.

### **Women use CAM more than men**

As in the general population, there is some evidence suggesting that among people with HIV/AIDS, women and men differ somewhat as to which complementary/alternative therapies they use.<sup>58</sup> Overall, HIV-positive women are more likely to use complementary/alternative therapies than men.<sup>59</sup> However, data remain limited, with only a few studies of relatively small sample size having been reported in Canada, so conclusions on this point are tentative.

### **Use of wide range of CAM**

The available research suggests that people with HIV/AIDS generally use the same types of complementary and/or alternative therapies as the population as a whole, with therapies such as massage, acupuncture, vitamins, supplements, and herbal products being most common. In particular, people with HIV/AIDS tend to use many botanicals, nutritional supplements, or other substances that are intended to boost the immune system. Thus, compounds such as N-acetylcysteine (NAC) and dinitrochlorobenzene (DNCB) can be found among the range of therapies used by people with HIV/AIDS.<sup>60</sup>

### **Overall satisfaction with at least some therapies**

Finally, the studies that have examined the effectiveness of complementary/alternative therapies as perceived by people with HIV/AIDS who use them, have often reported high levels of satisfaction. In most of the reported US studies, a majority described their therapy as beneficial, and in a couple of studies between 72 and 100 percent of participants indicated they felt better as a result of the therapy. In Canada, one recent study (with a small sample size) found that 87 percent of respondents “felt good” about their use of CAM; another study reported high levels of overall satisfaction for physical therapies (eg, massage, chiropractic) and plant-based medicines, but overall no single therapy was associated with an identifiable effect on quality-of-life measures or severity of symptoms.<sup>61</sup>

### **How and Why People with HIV/AIDS Use CAM**

There are many reasons for the use of complementary/alternative medicine among people with HIV/AIDS. In identifying specific determinants of CAM use, we do not claim that these hold true for all people with HIV/AIDS or only for such people. Some will have highly idiosyncratic reasons for using alternative therapies, while others will have widely shared reasons for using these therapies. As one group of Canadian researchers has pointed out, based on an in-depth qualitative study discussed below,

**Complementary therapies represent different things for different individuals.**

<sup>55</sup> Heath KV, Gatarick N, Yip B et al. Complementary therapy use in a province-wide HIV/AIDS drug treatment programme. 8<sup>th</sup> Annual Canadian Conference on HIV/AIDS Research, Victoria, British Columbia, May 1999: Abstract C335; Kamyab M et al. Changes in use of complementary and alternative (CAT) among HIV+ patients in Saskatchewan. 10<sup>th</sup> Annual Canadian Conference on HIV Research, Toronto, Ontario, June 2001: Abstract 292P; reported at: *Canadian Journal of Infectious Diseases* 2001; 12 (Supp B): 51B-52B.

<sup>56</sup> Community Research Initiative of Toronto & Canadian AIDS Society. The Complementary Therapies Project: HIV Treatment Survey Project Report. CRIT/CAS, 1995; Furler M et al. Patient reported complementary and alternative medicine (CAM) use – An interim assessment of drug utilization patterns for patients attending Ontario HIV outpatient clinics. Poster presentation, 9<sup>th</sup> Annual Canadian Conference on HIV/AIDS Research, 27-30 April 2000, Montreal: Abstract 340P; Furler M et al. Gender Differences in the Drug Utilization Patterns of HIV Infected Outpatients: An Interim Analysis. Oral presentation and Summary of Proceedings: “Towards Equity in HIV Health Care for Vulnerable Populations,” Ontario HIV Treatment Network Research Day, 27 November 2000, Toronto, Ontario (proceedings available online via [www.ohtn.on.ca](http://www.ohtn.on.ca)); Furler M et al. Physician awareness of complementary and alternative medicine use. 10<sup>th</sup> Annual Canadian Conference on HIV Research, Toronto, Ontario, June 2001: Abstract 363P; reported at: *Canadian Journal of Infectious Diseases* 2001; 12 (Supp B): 72B.

<sup>57</sup> K Leeb et al. An HIV/AIDS Population-Based Report on Complementary Therapy Use. Unpublished manuscript. HOOD Project, Toronto, Ontario, cited in: Pawluch D, Cain R, Gillett J. Approaches to Complementary Therapies: Diverse Perspectives Among People with HIV/AIDS. Health Canada, March 1998.

<sup>58</sup> Meneilly, supra, note 54.

<sup>59</sup> M Furler et al, supra, note 56.

<sup>60</sup> For further information concerning specific alternative medicines, readers should consult the Canadian AIDS Treatment Information Exchange (CATIE) website ([www.catie.ca](http://www.catie.ca)).

<sup>61</sup> Kendall T. Optimal Environments for Integrated Care: Complementary and Alternative Medicine in HIV Management in British Columbia. British Columbia Persons with AIDS Society, March 2001: at 6; CRIT/CAS, supra, note 56.

One reason for the widespread use of complementary and/or alternative therapies may very well be a general dissatisfaction with more technological and impersonal medical care, which has become one of the characteristics of modern-day medicine.

complementary therapies represent different things for these individuals – a health maintenance strategy, a healing strategy, an alternative to Western medicine, a way of mitigating the side-effects of drug therapies, a strategy for maximizing quality of life, a copying strategy, and a form of political resistance.... These meanings are neither mutually exclusive nor fixed. The therapies often appeal to individuals on different levels and their appeal may change over time.<sup>62</sup>

Nonetheless, general claims can be made. A review of the literature indicates that the most common reasons given by people with HIV/AIDS for using complementary/alternative therapies are:

- to take active control over one's own health care;
- to boost immune function;<sup>63</sup>
- to lower viral load and prevent, delay, or treat symptoms of HIV disease progression or opportunistic infections;<sup>64</sup>
- to help with side effects of conventional therapy (antiretroviral drugs and treatments for opportunistic infections), which facilitates adherence to a prescribed drug regimen;
- to help relieve stress, depression<sup>65</sup> and fatigue, and improve general well-being.<sup>66</sup>

### More holistic approach

One reason for the widespread use of complementary and/or alternative therapies may very well be a general dissatisfaction with more technological and impersonal medical care, which has become one of the characteristics of modern-day medicine.<sup>67</sup> Many complementary and/or alternative medicine modalities are perceived to embrace a more holistic approach to health and to health-care delivery. Unlike conventional medicine, which for the most part focuses on treating the underlying cause of the disease with a specific intervention, complementary/alternative medicine often takes a broader perspective, attending to the person's physical, mental, social, and spiritual health. So it is not surprising that many use alternative therapies for symptom control and general mental/spiritual well-being, rather than for cure. Many CAM practices are considered to be more holistic and more "person friendly."<sup>68</sup> It has also been pointed out that many CAM therapies offer "more than physical and mental care"<sup>69</sup> and some comprise "medical systems that dispense heavy doses of unconventional religion."<sup>70</sup> People who use complementary and/or alternative medicine may be searching for a more personal involvement, either by alternative medicine practitioners or by community members who share concerns about their health and who exchange information on available alternatives to standard medicine.

### Exercise control over own health care

Having reviewed numerous studies on CAM use by people with cancer, Truant and McKenzie conclude that "the desire to regain control and to maintain hope are the two most frequently cited reasons for considering and using complementary therapies."<sup>71</sup> These are key reasons for CAM use by many people with HIV/AIDS as well:

Many PHAs use complementary therapies throughout their illness. Although the reason for using these therapies may change as their disease progresses, the high use of complementary therapies could indicate that PHAs have a desire to take some control over their health and well-being and wish to combat some of

<sup>62</sup> Pawluch D, Cain R, Gillett J. Lay constructions of HIV and complementary therapy use. *Social Science and Medicine* 2000; 51 (2): 251-264.

<sup>63</sup> Anderson W, O'Connor BB, MacGregor RR, Schwartz JS. Patient use and assessment of conventional and alternative therapies for HIV infection and AIDS. *AIDS* 1993; 7: 561-566.

<sup>64</sup> Ibid; Kendall, supra, note 61 at 6.

<sup>65</sup> According to some of the literature, depression (not specifically among people with HIV, but generally) is one of the most common reasons for using complementary/alternative therapies. It is reasonable to assume that such a reason is also common among people with HIV/AIDS: Kendall, supra, note 61 at 7. See also: Ernst E. Complementary therapies for depression: an overview. *Archives of General Psychiatry* 1998; 55(11): 1026-1032. For a 1998 review of the medical literature on the use of herbal remedies in psychiatry, see: Wong AHC, Smith M, Boon HS. Herbal remedies in psychiatric practice. *Archives of General Psychiatry* 1998; 55(11): 1033-1044.

<sup>66</sup> Anderson et al, supra, note 64; Bates BR, Kissinger P, Bessinger RE. Complementary therapy use among HIV-infected patients. *AIDS Patient Care and STDs* 1996; 10: 32-36; Carwein VL, Sabo CE. The use of alternative therapies for HIV infection: implications for patient care. *AIDS Patient Care and STDs* 1997; 11: 79-85; Fairfield KM et al. Patterns of use, expenditures, and perceived efficacy of complementary and alternative therapies in HIV-infected patients. *Archives of Internal Medicine* 1998; 158: 2257-2264; and O'Connor BB. *Healing Traditions: Alternative Medicine and the Health Professions*. Philadelphia: University of Pennsylvania Press, 1995; Kendall, supra, note 61 at 6.

<sup>67</sup> On this development in medicine generally, see: Elliott C. *Bioethics, Culture and Identity: A Philosophical Disease*. New York: Routledge, 1999.

<sup>68</sup> Kaptchuk TJ, Eisenberg D. The persuasive appeal of alternative medicine. *Annals of Internal Medicine* 1998; 129:1061-1065.

<sup>69</sup> Ibid.

<sup>70</sup> Fuller RC. *Alternative Medicine and American Religious Life*. New York: Oxford University Press, 1989, cited by Kaptchuk & Eisenberg, supra, note 68.

<sup>71</sup> Truant T, McKenzie M. Discussing complementary therapies: there's more than efficacy to consider. *Canadian Medical Association Journal* 1999; 160: 351-352.

their symptoms without using prescription medication.<sup>72</sup>

Many people with HIV/AIDS who use complementary and/or alternative therapies express the view that when they take an active role in their treatment regime, by educating themselves and seeking out alternative therapies, they are empowered and reclaim the control in their lives they feel they have lost as a result of acquiring HIV and of the social and other barriers that people with HIV/AIDS often experience. The following personal narratives are examples of the proactive attitude current among many people with HIV/AIDS:

With this disease, you have to do it for yourself. You have to be your own doctor. There is so much information out there. You can't count on somebody to get it all for you. Especially when it doesn't matter to them. And with alternatives, so many people don't even bother to learn about them. So that's one more thing. You really have to become your own doctor with AIDS.<sup>73</sup>

I see truth in alternative therapies. They're everything with AIDS. They're an alternative to giving in and a way to fight back. The best defense we have is to stay alive.<sup>74</sup>

While it is a generalization that certainly does not hold true for all people with HIV/AIDS, it is fair to say that the history of treatment activism that has, of necessity, marked the "AIDS movement" has encouraged many people to be more proactive in their health care.<sup>75</sup> As the available data show, many people with HIV/AIDS have turned to alternative therapies as an additional resource in the face of an illness that has so far seen important, but nevertheless limited, successes in the field of conventional medicine. The decision to use alternative therapies is, for some, a reflection of the belief that all treatment avenues should be explored, and often goes hand in hand with an activist ethos that exists within specific (but not all) HIV/AIDS communities.

When you've got something like HIV you want to try for as many lifeboats as possible and tackle the problem in a few different ways. I have been seeing a traditional Chinese medical practitioner and I use other forms of complementary therapy as well. There's no doubt that a good massage makes you feel better and that makes you more able to cope – the psychological aspects are important. The doctors I've talked to have been very dismissive about complementary therapies and so I haven't told mine about the alternative stuff as I want to feel free to make my own choices.<sup>76</sup>

The image of the well-informed, proactive person with HIV/AIDS is certainly not true for all (or even most) of those with the disease. But, insofar as the use of complementary and/or alternative medicine use requires some initiative on the part of the user, it is true to say that those who use alternative therapies (whether HIV-positive or not) are to varying degrees informed and proactive.<sup>77</sup>

This seems to correlate with information about Canadians generally. According to a 1997 NDMAC/ACNielsen survey,<sup>78</sup> alternative remedy users were the most active group when it came to gathering information about their general health, regardless of the source of the information. Users of alternative remedies consulted a wide range of sources for information about natural health products: books/magazines (64 percent), family/friends (63 percent), product literature from health food stores (42 percent) and

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The history of treatment activism that has, of necessity, marked the "AIDS movement" has encouraged many people to be more proactive in their health care.

<sup>72</sup> Millson P, McMurchy D, Leeb K. Complementary Therapies: A HOOD Report on the Cost of HIV in Ontario. *HIV Health Evaluation Update*, June 1999, at 1.

<sup>73</sup> Furin JJ. "You have to be your own doctor": sociocultural influences on alternative therapy use among gay men with AIDS in West Hollywood. *Medical Anthropology Quarterly* 1997; 11: 498-504 at 502.

<sup>74</sup> Ibid.

<sup>75</sup> Bruhn JG. Therapeutic value of hope. *Southern Medical Journal* 1984; 77: 215-219; Ezzy D. Illness narratives: time, hope and HIV. *Social Sciences & Medicine* 2000; 50: 605-617.

<sup>76</sup> McKnight I, Scott M. HIV and complementary medicine. *Medical Journal of Australia* 1996; 165: 143-145 at 143.

<sup>77</sup> One vocal critic of complementary/alternative medicine, Dr Lloyd Oppel of the lobby group Canadians for Rational Health Policy, argues that people using CAM are often urged to use these therapies indefinitely, for "maintenance" or continued wellness. In a recent special investigation into alternative medicine by the *Toronto Star*, he was quoted as saying: "The alternative medicine movement talks about empowering patients but exactly the opposite is true – it tends to make people more dependent on a caregiver or philosophy"; Papp L. Blind Trust – Special Report: An Investigation into Alternative Medicine [last in series]. *Toronto Star* 23 January 2000, page not available. (Series may be purchased online for a fee via [www.torontostar.com](http://www.torontostar.com).) But the same criticism could be leveled against many conventional therapies and practices – particularly for the treatment of chronic conditions such as HIV disease. So is this really a strike against CAM per se except where it is done for unethical, exploitative reasons instead of for the benefit of the patient?

<sup>78</sup> NDMAC/ACNielsen HealthVision'97 survey, summarized in: NDMAC. Seeking Information About Our Health. *Pharmacy Post*, August 1998, available online at [www.ndmac.ca](http://www.ndmac.ca).

pharmacists (40 percent). (But only 27 percent identified product labels and package inserts on natural health products, whereas a 1996 survey showed that 87 percent of Canadians read labels on over-the-counter drugs.)

**To complement conventional therapy**

For many people complementary and/or alternative medicine may be a necessary adjunct to conventional therapy, one that helps them get as much benefit from conventional therapy as possible. For example, in a recent study involving 49 people with HIV/AIDS in British Columbia who use at least one complementary therapy, none of the participants perceived CAM as a cure for HIV infection. Rather they emphasized the benefits to their immune system (81 percent), of lowering their viral load (58 percent), and the general health benefits associated with taking an active role in one’s own health care, and that they used CAM to manage symptoms of HIV disease, the side effects of antiretroviral drugs, substance addiction, hepatitis, and depression.<sup>79</sup>

For many people complementary and/or alternative medicine may be a necessary adjunct to conventional therapy.

One US study done in 1993 found that approximately half of those using complementary/alternative therapies expected them to slow the progression of HIV disease or provide “better immunity,” and roughly one-third of patients believed the complementary therapies would have a positive synergistic effect with antiretroviral drugs or reduce HIV-related symptoms. (Interestingly, 21 percent expected complementary medicine to provide a cure for their HIV disease, an unusual finding that seems at odds with the bulk of the research data – including Canadian data – showing this is not an expectation on the part of many people with HIV/AIDS. It should also be noted that this finding dates back to 1993, before the introduction of protease inhibitors in 1995-96.)<sup>80</sup>

Many people with HIV/AIDS are dissatisfied with the conventional-medicine approach to the illness, either because the present therapies are ineffective, or because they have intolerable side effects, or because CAM practitioners offer a type of care that, in their opinion, they do not receive from physicians practising conventional medicine.

**An in-depth qualitative analysis**

A 1998 research project by Pawluch, Cain, and Gillett provides valuable Canadian data on the perspectives of people with HIV/AIDS with regard to CAM, based on in-depth interviews with a diverse (albeit small) sample of respondents. The authors examined how the social background of people with HIV/AIDS (personal understanding of HIV infection, ethnocultural background, gender, and addiction) shapes their views of their health and the place of complementary approaches in their health care. They also discussed common themes about the use of complementary therapies that cut across differences among the respondents in study.

**Social background and views of complementary therapies**

Individuals’ own view of their HIV infection affected their approach to complementary therapies:

Those who understood themselves as “with HIV/AIDS” were more future oriented, proactive, and purposive in making health care decisions. These respondents tended to select and judge complementary therapies on the basis of their long term health goals. In contrast, others focused more on the realities of being sick with or suffering from HIV-related conditions; these

<sup>79</sup> Kendall, supra, note 61 at 6.

<sup>80</sup> Anderson et al, supra, note 63. See also Manfredi R, Chiodo F. The effects of alternative treatments for HIV disease on recommended pharmacological regimens. *International Journal of Antimicrobial Agents* 2000; 13: 281-285; de Visser R et al. Alternative or complementary: nonallopathic therapies for HIV/AIDS. *Journal of Alternative Therapies in Health & Medicine* 2000; 6: 44-52.

respondents were more present oriented – their decisions to use complementary therapies were framed in terms of how they made them feel in the short term.<sup>81</sup>

The authors also found that the ethnocultural background of respondents shaped their views of complementary therapies in a number of ways:

First, the Aboriginal and Black respondents tended to be more familiar with non-Western forms of medicine and healing traditions than those from European backgrounds, making them more open and knowledgeable about different approaches to health care.

Second, for many respondents the use of complementary therapies had a symbolic or political dimension; complementary approaches help make them less dependent on medical institutions that they perceived to be insensitive and racist. Others were uncertain about embracing complementary therapies because they have been deemed fringe or marginal forms of medicine.

Lastly, many respondents were drawn to complementary therapies because they were compatible with their spiritual or religious values.<sup>82</sup>

For many respondents the use of complementary therapies had a symbolic or political dimension.

A number of gender-specific issues stood out among HIV-positive women:

First, women used complementary therapies in order to keep themselves healthy so that they could look after family or be there for their children – in other words, the reasons for using therapies were framed in terms of their care giving responsibilities.

Second, many women felt that their needs regarding HIV were being neglected, prompting them to take a more active role in their health care and to consider a range of health care options beyond what is offered by Western medicine.

Lastly, in relation to reproductive health, women viewed complementary therapies as less toxic, more natural, more benign, and therefore a safer form of health care.<sup>83</sup>

Finally, the authors examined the perspectives toward complementary therapies of those respondents dealing with addiction:

For those respondents who had a history of drug use, managing their addiction was their primary health concern; dealing with their HIV infection was largely secondary. Respondents felt that complementary therapies, unlike Western medications, provided a nonaddictive means of reducing stress and dealing with pain.<sup>84</sup>

### Common themes

The researchers also identified a number of common themes in participants' use of complementary/alternative medicine that emerged from the interviews.

- People relied primarily on the experiences of friends and family members in deciding which complementary therapies to use.
- Cost was the most significant barrier to the use of complementary therapies. For many, the choice of therapies was largely dictated by what was affordable.
- Other barriers included, for some, a lack of access to particular approaches;

<sup>81</sup> Pawluch et al, supra, note 57 at ii.

<sup>82</sup> Ibid at iii.

<sup>83</sup> Ibid.

<sup>84</sup> Ibid. Similar responses were reported by Kendall in the survey of 49 CAM-using people with HIV/AIDS in British Columbia, supra, note 61 at 8.

Cost was the most significant barrier to the use of complementary therapies.

- for others, an overwhelming degree of choice and information; the rigid scheduling, time, care, energy, and commitment required for some therapies; and the stigma associated with complementary medicine.
- People were open to a range of health-care options, but uncertain about how to integrate complementary therapies and Western medicine.
- Most relied on physician advice and felt their physician was open to the use of complementary therapies, but many wished their physician would provide more guidance and advice in the area of complementary approaches.
- Many were ambivalent about using Western medications, particularly AIDS medications considered experimental, unproven, toxic, and likely to cause long-term health problems.<sup>85</sup>

### Changing reasons for CAM use

The reasons for using CAM may change not only over the course of disease progression, but also with developments in HIV/AIDS research and treatment. For example, Italian researchers examined the use of alternative treatments for HIV disease before and after the introduction of highly active antiretroviral therapy (HAART) in 1996. They found that recourse to alternative treatments rose from 22.8 percent to 35.7 percent between 1996 and 1998, but that unorthodox treatments were used by most patients concurrently with, rather than instead of, conventional antiretroviral medications; and this did not interfere with compliance with recommended regimens of those medications.<sup>86</sup> Abrams and Steinberg have pointed out that

there have been distinct fluctuations in the search for and use of unconventional therapies for HIV disease, which ... reflect the availability of effective conventional drugs. Through the 1980s, limited options and disappointing data from trials of traditional drugs fueled an upward trend in the use of complementary therapies. With an expanded indication for zidovudine [AZT] and the availability of didanosine [ddI] and zalcitabine, interest in alternative compounds leveled off until discouraging results from the Concorde study spurred renewed interest. Now, with the availability of stavudine, lamivudine, and the potent protease inhibitors, the focus in the complementary/alternative therapy movement may be shifting toward investigating therapies for HIV-related symptoms or conditions for which few effective prescription drugs are available.<sup>87</sup>

In the Canadian context, data presented at the 12th International AIDS Conference in 1998 showed changing patterns of complementary therapy use among patients at an HIV clinic in downtown Toronto. With the caveat that the sample was almost entirely men (and the vast majority of them gay men), Waring et al reported that, at the beginning of 1998, 88 percent of respondents were currently using complementary therapies of some sort, as opposed to 63 percent who indicated using it in the past. The researchers concluded that

the frequency and pattern of CT use has changed since the advent of new antiretroviral regimens. More patients are taking a greater number of products now and the primary reason for current CT use is to promote general health rather than to increase immunity.<sup>88</sup>

<sup>85</sup> Ibid at iv-v.

<sup>86</sup> Menniti-Ippolito F, De Mei B. [The characteristics of the use and the levels of use of nonconventional medicine.] *Annali dell'Istituto Superiore Sanità* 1999; 35(4): 489-97. [Italian]

<sup>87</sup> Abrams DI, Steinberg C. Complementary Therapies in HIV Disease. In: International AIDS Society. *Improving the Management of HIV Disease* September 1996; 4(3). Available online via JAMA HIV/AIDS Information Center at [www.ama-assn.org](http://www.ama-assn.org).

<sup>88</sup> Waring V, Tseng A, Salit IE. Complementary Therapy (CT) Changes in patterns of use among HIV clinic patients. 12th International AIDS Conference, Geneva, 28 June - 3 July 1998, Abstract No 42379.

## Conclusion

Although one can discern several reasons that lie behind the use of complementary and/or alternative therapies among people with HIV/AIDS, the determinants of use of such therapies are highly varied and often unknown.

There is a clear information gap between which complementary and/or alternative therapies people with HIV/AIDS are currently using and the reports of complementary/alternative therapy use in the medical literature. This is partly due to the fact that CAM use is rapidly changing, and there is a significant time lag between when research is conducted and its publication in the medical literature. Community-based treatment information organizations have been effective in narrowing this gap. In addition to this time-lag problem, however, complementary and/or alternative medicine use among people with HIV/AIDS is simply under-researched. Information on the determinants of complementary and/or alternative medicine use is currently incomplete. Developing appropriate, ethical policy requires further research into all the social, personal, and cultural aspects of alternative medicine use.

There is a clear information gap between which complementary and/or alternative therapies people with HIV/AIDS are currently using and the reports of complementary/alternative therapy use in the medical literature.

## Recommendation 2

**Research funding bodies (both health-care research funding bodies and bodies funding research in other disciplines), as well as Health Canada under the Canadian Strategy on HIV/AIDS, should fund research that provides up-to-date information about:**

- (1) Use of complementary/alternative therapies by people with HIV/AIDS**
  - (i) the patterns and prevalence of complementary/alternative medicine use among people with HIV/AIDS;**
  - (ii) which therapies are used most commonly by people with HIV/AIDS, how they are used and for what purposes or conditions, and the users' reasons for choosing certain therapies, including the range of beliefs held by people with HIV/AIDS regarding both the merits and demerits of conventional and complementary/alternative therapies;**
  - (iii) which complementary/alternative therapies are commonly used in conjunction with conventional medicine, and the reasons for combining treatment approaches;**
  - (iv) the effectiveness (real and perceived) of various complementary/alternative therapies, and users' satisfaction with them;**
  - (v) profiles of people with HIV/AIDS who use complementary/alternative therapies, including variations across regional, age, gender, socioeconomic, racial/ethnic, and disease/disability/health-condition categories;**
  - (vi) whether special features, patterns, or needs exist among specific subpopulations that use complementary/alternative therapies as part of HIV/AIDS care, such as: Aboriginal people (including those who use both conventional Western medicine and traditional healing practices); women; gay men; drug users; various ethnocultural communities; low-income people; and prisoners (whose access to various kinds of therapies is often limited).**

- (2) Consumer information and knowledge**
  - (i) the sources of information about complementary/alternative products and therapies accessed by people with HIV/AIDS, and consumer satisfaction;**
  - (ii) the accuracy, completeness, and ease of access of sources of treatment information regarding complementary/alternative therapies for people with HIV/AIDS, including such sources as HIV/AIDS-treatment information organizations, buyers' clubs, websites, information pamphlets, and brochures available at community organizations, practitioners' offices, or vendors of natural health products;**
  - (iii) how people with HIV/AIDS would prefer to get information about complementary/alternative therapies, barriers to getting the information they want, the need to make informed treatment choices, and feasible mechanisms for making reliable information accessible;**
  - (iv) what kind of information people with HIV/AIDS use and want to make decisions about their health care, and their level of trust in various sources (such as recommendations from conventional or complementary/alternative practitioners, family, friends or acquaintances; product labels and monographs; promotional material produced by manufacturers or practitioners; professional associations; community organizations; websites; and medical or other literature).**
- (3) Access to complementary/alternative therapies**
  - (i) where, how, and from which sources people with HIV/AIDS access complementary therapies and what barriers to access exist;**
  - (ii) the interface between the use of complementary/alternative therapies and the conventional health-care system, including the degree to which patients are referred to complementary/alternative practitioners by conventional practitioners and vice versa, and the attitudes of conventional practitioners toward complementary/alternative practitioners and vice versa;**
  - (iii) what people with HIV/AIDS spend on complementary/alternative therapies, and on which sorts of therapies;**
  - (iv) the views of people with HIV/AIDS who use complementary/alternative therapies, practitioners (complementary and conventional), government, and private insurers regarding coverage of different kinds of complementary/alternative therapies under private and public health insurance plans.**



## Aboriginal People and Traditional Healing

In its 1996 report, the Royal Commission on Aboriginal Peoples noted that:

Although Aboriginal people have moved far away from the lifestyles of their ancestors, they still see value in the traditions and practices that made them unique – including medical traditions ranging from herbal therapies to forms of psychotherapy. Often, they find that mainstream health services do not understand or fully meet their needs. They want to re-examine practices that were once suppressed or ridiculed for their possible usefulness today.<sup>89</sup>

Many Aboriginal healing practices that non-Aboriginal people would consider “alternative” or “unconventional” are conventional or traditional from the perspective of Aboriginal people. As one Elder put it:

I’d like people to understand and respect the alternative methods. I don’t know why they call it alternative. It’s natural for us. It’s *the* method. I look at western medicine as an alternative for us, as Native people.<sup>90</sup>

To the extent that one can generalize across many peoples and histories, the approach to healing among Aboriginal peoples is “inherently cultural, where definitions of illness and modes of treatment, issues of efficacy, and the transmission of medical knowledge are all culturally determined.”<sup>91</sup> Traditional healing practices are often quite unlike “Western medicine” practices in that conventional medicine is usually a discrete intervention that serves a merely mechanistic function. Many traditional Aboriginal healing practices are often lengthy, holistic processes with a variety of medical, social, and spiritual goals that are fundamentally premised on the view that there are many dimensions to health. The mental, physical, emotional, and spiritual state of a person is affected by their relationship with themselves, their family and community.<sup>92</sup> In Aboriginal philosophies, it is the balance of the elements of mind, body, emotion, and spirit in a person, as well as balance in that person’s relationship with the earth and the natural world, that is necessary for good health. Illness (understood in a broad sense, not simply a mechanistic biomedical sense) can result if there is imbalance in one or more of these elements.<sup>93</sup>

In the First Nation communities, health means balance and harmony within, and among the four aspects of human nature (physical, mental, emotional spiritual). Over-focusing on any one aspect upsets the balance of the four.<sup>94</sup>

Aboriginal concepts of health and wellness involve not only the physical but also the mental, spiritual and emotional aspects of health. This holistic approach to health is widely accepted and practised in Aboriginal communities, through traditional medicine and healing practices such as sweatlodges, sweetgrass ceremonies, smudges, talking circles and teachings from Elders.<sup>95</sup>

Traditional Aboriginal healers include herbalists and *medicine men or medicine women*. “The Medicine Person is a physician, psychiatrist/psychologist, family counsellor and spiritual advisor all in one. S/he is concerned with the balanced relationship between the body, mind and spirit. In treating sick people, s/he helps to restore the individual’s balance.”<sup>96</sup>

Many Aboriginal healing practices that non-Aboriginal people would consider “alternative” or “unconventional” are conventional or traditional from the perspective of Aboriginal people.

<sup>89</sup> Royal Commission on Aboriginal Peoples. *People to People, Nation to Nation: Highlights from the Report of the Royal Commission on Aboriginal Peoples*. (“Culture and traditional healing.”) Ottawa: Supply and Services Canada, 1996. (RCAP Report)

<sup>90</sup> Quoted in: Vanderhoef S, with Gray W (ed). *Nashine Ginwenimawazawin – Constant Care*. 2-Spirited People of the 1<sup>st</sup> Nations. March 1998, at 173.

<sup>91</sup> Waldram JB, Herring DA, Young TK. *Aboriginal Health in Canada: Historical, Cultural, and Epidemiological Perspectives*. University of Toronto Press: Toronto, 1998, at 224.

<sup>92</sup> McLeod A, Peterson T. *Care and Treatment of Aboriginal People with HIV/AIDS: Summary Report*. Manitoba Aboriginal AIDS Task Force, 1993.

<sup>93</sup> Shestowsky B. *Traditional Medicine and Primary Health Care Among Canadian Aboriginal People – A Discussion Paper with Annotated Bibliography*. Ottawa: Aboriginal Nurses Association of Canada, 1993.

<sup>94</sup> National Indian & Inuit Community Health Representatives Organization. *Coping with HIV/AIDS in Aboriginal Communities: A 1998 Resource Manual*. NICCHRO, 1998, at 69.

<sup>95</sup> Ontario Aboriginal Patient Advocacy Initiative. *OAPAI Manual*, 1999, section 10 at 1.

<sup>96</sup> National Indian & Inuit Community Health Representatives Organization, *supra*, note 94 at 70. It would be incorrect to claim that these are entirely distinct: herbalists can make use of spiritual assistance in their work, just as other healers may use herbs in their practices. The point here is simply that there are different types of healers that one may find across many different Aboriginal communities.

In the First Nation communities, health means balance and harmony within, and among the four aspects of human nature (physical, mental, emotional, and spiritual).

There is little research on the experiences of Aboriginal people with HIV/AIDS and their approaches to health care.

Beyond this basic belief in the importance of a holistic approach that addresses the different facets of a person in dealing with illness and wellness, traditional healers will each have their own techniques, tailored to the individual seeking assistance. Traditions vary among different Aboriginal peoples in Canada (although there are some shared features). Aboriginal communities themselves – and individuals within their communities – will be either more or less “traditional” in their approaches to dealing with illness, depending how they have incorporated various elements of “Western” biomedicine. The extent to which traditional knowledge has been preserved will also vary. And Aboriginal people will identify with Aboriginal communities in different ways. Some Aboriginal people have lived on reserve in a close-knit, traditional, predominantly Aboriginal community all of their lives. Other live off reserve in urban centres without ever having lived in a traditional community. Yet others have a lot of contact with both a traditional, on-reserve community and the non-Aboriginal population.

All these factors will affect *why* and *how* Aboriginal people – including those with HIV/AIDS – may access or use traditional healers and healing practices as part of dealing with disease and promoting wellness, and *which* practices they use. Although certainly some will use both conventional medicine and seek out traditional healers and healing practices, there is little (documented) research on the experiences of Aboriginal people with HIV/AIDS and their approaches to health care.

One study conducted by an Aboriginal health centre in the US examined different attitudes between Native Americans on reservations and those living in urban areas with respect to integrating HIV/AIDS services and traditional medicine. Interestingly, the study found that, on the reservation, the use of Native traditional medicine as part of HIV care was not advocated or sought openly. The researcher suggested this was because reservation populations have learned it is often taboo to discuss topics of a “traditional” nature outside the immediate family. In contrast, Native people living in urban areas have often been removed from their traditional roots and seek Native traditional medicine to address HIV/AIDS concerns.<sup>97</sup>

Yet with respect to Aboriginal people generally, based on the available research and their experience, Waldram et al suggest that

it is widely known that some Aboriginal patients will seek treatment simultaneously from a physician and a traditional healer.... It is also known that some Aboriginal people will utilize the two medical systems in a serial fashion, seeking treatment solely from one until a certain subjective point of dissatisfaction is reached, whereupon the services of the other are obtained. In the case of long or problematic illness, this pattern can repeat itself many times over.... Aboriginal people, like all people, want ... a full range of services, and see no incompatibility in using them, regardless of what the various medical practitioners think.<sup>98</sup>

Aboriginal people with HIV/AIDS frequently seek the assistance of traditional healers in their community. Like conventional medical practitioners, traditional Aboriginal healers who are respected in their community have the best interest of the person in mind and will tend only to those aspects of the person’s health that they are able to treat. Thus, much of traditional Aboriginal healing practices for people with HIV/AIDS aim at symptom management and spiritual health.<sup>99</sup> For symptom management, it is more

<sup>97</sup> Lidot T, HIV Director, San Diego American Indian Health Center: HIV/AIDS Services Integrated with Native Traditional Medicine for Urban vs Reservation Native Populations: What’s the Difference? XI International Conference on AIDS, 7-12 July 1996, Vancouver: Abstract Th.D.5127.

<sup>98</sup> Waldram et al, supra, note 91 at 210.

<sup>99</sup> Vanderhoef, supra, note 90.

common for an herbalist to treat persons with HIV/AIDS. Examples include horseradish to promote appetite, or blackberries and raspberries to prevent diarrhea. For spiritual and general well-being, the services of medicine persons are usually used (following the accepted protocol for approaching such persons) and ceremonies may be carried out: examples include sweat lodges and pipe ceremonies.

These practices are of a more traditional kind. However, as noted, while such healing practices are carried out in many Aboriginal communities, there is a degree of integration of conventional medicine and Aboriginal healing practices that occurs as well. This integration of conventional and traditional healing practices can occur in several ways:

- conventional medicine practices find their way into Aboriginal communities;
- members of Aboriginal communities seek the services of conventional medicine practitioners outside the community;
- non-Aboriginal people seek out traditional healing practices in Aboriginal communities; or
- traditional Aboriginal healers practise in conventional hospitals when accommodations have been made for them to attend to the health needs of Aboriginal people.

One pressing need identified by the Royal Commission on Aboriginal Peoples is for “people who can apply Aboriginal knowledge to current health problems and combine traditional health and healing practices with mainstream approaches to build distinctive Aboriginal healing systems.”<sup>100</sup> The National Forum on Health has also identified the need to ensure that health practices are sensitive to the needs of Aboriginal peoples, and the benefits that can flow to Aboriginal people from combining traditional healing practices with contemporary approaches.<sup>101</sup> It recognized that there are serious gaps in the information available on Aboriginal health, although the information that is available indicates an ongoing health crisis in most Aboriginal communities.

The Forum recommended the creation of an Aboriginal health institute that would engage in training of Aboriginal health professionals, support health services at regional and community levels, and ensure an agenda for health research that is controlled by Aboriginal people. This has now been realized: the Institute of Aboriginal Peoples’ Health within the Canadian Institutes of Health Research has a mandate to fund and promote research in a variety of areas, including research “to determine the most effective interventions with aboriginal populations in order to address a variety of health needs (e.g. assessment of alternative and complementary medicine)” and “ethics issues related to research, care strategies, and access to care (e.g. community consent, sensitivity to culture).”<sup>102</sup>

Few would disagree on the need for more and better research into Aboriginal health. But as Waldram et al point out:

The scientific study of Aboriginal healing is contentious. There are some Aboriginal people who feel that their medicine is a gift from the Creator, and that as a result there is no need to “prove” its efficacy according to scientific principle. But there are others who believe that limited scientific study is essential to having Aboriginal medicine accepted by Aboriginal and non-Aboriginal patients and by health care administrators and funding agencies.<sup>103</sup>

One pressing need identified by the Royal Commission on Aboriginal Peoples is for “people who can ... combine traditional health and healing practices with mainstream approaches to build distinctive Aboriginal healing systems.”

Few would disagree on the need for more and better research into Aboriginal health.

<sup>100</sup> RCAP Report, supra, note 89.

<sup>101</sup> National Forum on Health. “The Need for an Aboriginal Health Institute” In: Canada Health Action: Building on the Legacy - Synthesis Reports and Issues Papers - Final Report (Vol II). February 1997 (available online via [www.nfhh-sc.gc.ca](http://www.nfhh-sc.gc.ca)).

<sup>102</sup> Canadian Institutes for Health Research – Institute of Aboriginal Peoples’ Health, available online via [www.cihr.ca/institutes/iaph](http://www.cihr.ca/institutes/iaph) (accessed 29 March 2001).

<sup>103</sup> Waldram et al, supra, note 91, at 209.

In light of a history in which Aboriginal knowledge and culture has often been taken and exploited by non-Aboriginal people, a critical issue that must be addressed is the role of the law in protecting the intellectual property of Aboriginal communities.

However this debate may be resolved, it remains important that the principles of Aboriginal peoples' and communities' ownership, control, and access over research methods and results be respected – particularly when it comes to research into traditional healing. Particularly in light of a history in which Aboriginal knowledge and culture has often been taken and exploited (including for commercial purposes) by non-Aboriginal people, a critical issue that must be addressed is the role of the law in protecting the intellectual property of Aboriginal communities. This issue warrants an entire discussion itself. It cannot be explored here in detail other than to highlight the need for effective protection for the traditional knowledge (including healing knowledge) of Aboriginal peoples and communities, as both an ethical matter of respect that needs to find translation into enforceable legal mechanisms,<sup>104</sup> and as a necessary prerequisite to effective and ethical research into the use and benefits of traditional healing practices for Aboriginal people with HIV/AIDS.

<sup>104</sup> For a discussion of some of these issues, see: Brascoupé S, Endemann K (authors), Cassidy M, Langford J (eds). *Intellectual Property and Aboriginal People: A Working Paper*. Industry Canada, Fall 1999 (available online via [www.inac.gc.ca](http://www.inac.gc.ca)), and the resources cited therein. The authors acknowledge that developing legal mechanisms to help indigenous communities protect and preserve traditional knowledge is an ongoing project, but argue that "in the meantime, the use of existing legal tools can be part of a 'web' of strategies" to achieve this goal, including the development of local mechanisms within communities to control and protect traditional knowledge." See also: Rights & Democracy/Indigenous Women's Continental Network. *Protecting Indigenous Women's Intellectual Property*, undated (via [www.ichrdd.ca](http://www.ichrdd.ca)); Nijjar G. In *Defence of Local Community Knowledge and Biodiversity*. Third World Network, 1996.

### Recommendation 3

**Research with and within Aboriginal communities should respect principles of ownership, control, and access over research methods and results. Adequate, enforceable legal protections for the intellectual property of Aboriginal communities (which property includes knowledge of traditional healing practices) need to be guaranteed in the design of such research. Health Canada, the Canadian Institutes for Health Research, and representatives of Aboriginal communities should ensure that protocols are developed to govern the conduct of health research with and within Aboriginal communities that are approved by the communities in question before any such research is undertaken.**



## Ethical Issues

When addressing ethical issues in the context of health-care practice, it is helpful to focus on four basic and frequently invoked ethical principles:

- *Non-maleficence* guides us to do no harm when our actions can affect the welfare or interests of others.
- *Beneficence* directs us to do those actions that bring about the good of others, whenever possible.
- *Respect for personal autonomy* counsels us to respect and honour the choices and actions of autonomous persons, acting voluntarily and with adequately understood information.
- *Justice* requires a fair distribution of resources, or of opportunities to gain access to resources, as well as fair compensation for harms and wrongs done to people.<sup>105</sup>

This chapter applies each of these four principles in the context of the use of complementary/alternative medicine. This ethical analysis yields a number of implications in three areas: research, education/training, and regulation. The principles of non-maleficence and beneficence are closely linked, and have several implications in the area of research. Each of these principles is therefore considered individually, but they jointly yield a series of recommendations for research. Much of this research is necessary for improvements in the area of education/training of health-care professionals and to inform appropriate regulatory policy. The principle of respect for personal autonomy yields a number of recommendations in the area of educating both users and providers of health care aimed at ensuring this respect.

<sup>105</sup> This principled approach to biomedical ethics is advocated in Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*, 4<sup>th</sup> ed. New York: Oxford University Press, 1994.

## A Comment on Risk/Benefit Assessment

We must ask whether and to what extent the complementary and/or alternative therapies most frequently used by persons with HIV/AIDS are both safe and effective.

Many of the ethical concerns we identify and analyze below are concerns that apply equally to conventional medicine.

First, a comment on the nature of risk/benefit assessment is required. An ethical analysis of medical practice considers both its benefits and risks. In any given case, we want to determine if the current use of a therapy is justified based on certain specific outcome measures. Given the widespread use of a great variety of complementary and/or alternative therapies, we must ask whether and to what extent the complementary and/or alternative therapies most frequently used by persons with HIV/AIDS are both safe and effective. It is common practice when doing risk/benefit analysis to catalog both the risks and the benefits of a certain medical procedure, to compare the risks and benefits, and then to determine if the benefits outweigh the risks sufficiently to justify the continued use of the procedure.

In carrying out a risk/benefit analysis, contextual details are of prime importance. For example, increased risks of a therapy *may* be more acceptable in the case of a disease that is uniformly fatal and for which no effective therapy exists. On the other hand, for an illness that is not very serious and for which safe and effective therapy exists, medical procedures that carry very high risks, even if effective, will likely not be ethically justified. It should be acknowledged that risks and benefits may be weighted differently depending on perspective (eg, the person with HIV/AIDS, the conventional practitioner, and the experienced complementary practitioner).

Two points are important to note at the outset. First, many of the ethical concerns we identify and analyze below are concerns that apply equally to conventional medicine. For example, a recent study estimated the incidence of serious and fatal adverse (conventional) drug reactions among hospitalized patients.<sup>106</sup> The authors estimated that, in United States hospitals in 1994 alone, 2,216,000 people suffered serious adverse drug reactions and 106,000 of them died from these adverse drug reactions.<sup>107</sup> Moreover, a recent study from the Institute of Medicine of the US National Academy of Science reports that medical mistakes by conventional medical practitioners cause at least 44,000 and maybe as many as 98,000 deaths per year in hospitals; using the lower figure, this makes death by physician error the eighth leading cause of death in the United States.<sup>108</sup> Extrapolating from US figures, Pomeranz estimated that about 10,000 people might die yearly in Canada due to drug allergies and other reactions to conventional medicine.<sup>109</sup> In January 2000, the *Toronto Star* reported that “more recent work by Kingston researchers, studying Ontario data, concluded that about 680 people die yearly in Ontario after developing bad reactions to conventional drugs. That translates into about 1800 deaths Canada-wide – still a heavy toll.”<sup>110</sup>

Although it is sometimes erroneously presumed that all CAM therapies are necessarily safe(r) because they are more “natural” than conventional drugs, it is likely that most CAM therapies do have fewer potentially severe side effects than many conventional drugs. When we warn about the potential toxicity of CAM and the potential interactions with conventional drugs, and when we recommend that further research be undertaken to analyze these risks, we do not pretend that conventional drugs are necessarily safer, and we should not be taken as singling out CAM for special criticism in this regard. Although we will not discuss the issue further (given the focus in this paper on CAM), it is important to realize that conventional medicine itself can carry great risk and limited benefit.

Second, the discussion below concerns complementary and/or alternative

<sup>106</sup> A serious adverse reaction is defined as an adverse reaction that “requires hospitalization, prolonged hospitalization, is permanently disabling, or results in death.” Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients. *Journal of the American Medical Association* 1998; 279: 1200-1205 at 1201.

<sup>107</sup> Lazarou et al, *ibid*. This study is controversial and has been subject to some criticism that it overstates the magnitude of the problem. For a related editorial, see: Bates DV. Drugs and adverse drug reactions – how worried should we be? *Journal of the American Medical Association* 1998; 279: 1216-1217.

<sup>108</sup> Kohn L, Corrigan J, Donaldson M (eds). Committee on Quality of Health Care in America. Institute of Medicine. *To Err is Human: Building a Safer Health System*. Washington, D.C.: National Academy Press, 1999.

<sup>109</sup> Reported in: Papp, *infra*, note 126, in Part 1: Herbal “cures.” *Toronto Star*, 15 January 2000: A1, A14-A15 at A14.

<sup>110</sup> *Ibid*.

medicine quite *generally*, and no attempt is made to comprehensively cover the details of all such therapies. In what follows, we make use of examples from specific therapies to illustrate certain points. But we do not mean to suggest that a conclusion about *one* therapy holds true for *all* therapies. Rather, our intention is to provide the reader with a set of evaluative tools and with examples of how the four above-mentioned ethical principles are used in practice. Although we note concerns about specific therapies based on the available data (eg, some herbal preparations carry known risks), the important general point is that we must take the principle of non-maleficence seriously by examining risks of harm associated with the use of complementary/alternative medicine. Similarly, we take other therapies as examples to demonstrate the importance in evaluation of the ethical principles of beneficence, respect for personal autonomy, and justice.

## Non-Maleficence

The principle of non-maleficence instructs us to refrain from intentionally harming others. It is the first principle in the Hippocratic oath of physicians to never use their “ability and judgment” in order to “injure or wrong” a patient.<sup>111</sup>

In discussions of biomedical ethics, a harm is often identified *as a setback to a person’s interests*. This is perhaps best shown with an example. Most of us would agree that we have an interest in maintaining a state of good health. So if we engage in practices that tend to bring about a state of bad health, such as heavy smoking or excessive alcohol consumption, then this would constitute a setback to our interest in maintaining good health. We would be harming ourselves.

The question in this context is the following: What harms can occur to those people with HIV/AIDS who make use of complementary and/or alternative therapies? We identify two broad classes of harm.

The first class of harm is *physical harm* and, in particular, the ill health that can occur as a result of using certain complementary and/or alternative therapies, alone or in conjunction with conventional treatment. Physical harm can also occur when people delay or forego conventional therapies that are beneficial on balance because of reliance upon unproven complementary and/or alternative therapies.

The second class of harm is that brought about through the *exploitation* of people with HIV/AIDS. Here we are speaking of both financial exploitation resulting in harm (ie, loss of income) and emotional exploitation resulting in harm (ie, the psychological harm of having been taken advantage of or of having one’s expectations falsely raised and then unmet). Both kinds of harm will be discussed in this section.

## Physical Harms

One of the reasons that complementary and/or alternative medicine use is so prevalent is that many are natural (eg, herbal preparations); that is, they are not manufactured by chemists. This can make people believe that alternative therapies are (1) necessarily safe or harmless and (2) necessarily beneficial. The so-called “myth of beneficent nature” that equates “natural” with “safe,” and “safe” with “beneficial” is false and potentially harmful.<sup>112</sup> Moreover, a belief frequently held about natural products – “if some is good, then more is better” – exacerbates the potential harm. At the same time, even those who are critical of CAM recognize that “most untested herbal remedies are probably harmless.”<sup>113</sup>

It is important to realize that conventional medicine itself can carry great risk and limited benefit.

What harms can occur to those people with HIV/AIDS who make use of complementary and/or alternative therapies?

<sup>111</sup> As quoted in Beauchamp & Childress, *supra*, note 105 at 189.

<sup>112</sup> Huxtable RJ. The myth of beneficent nature: the risks of herbal preparations. *Annals of Internal Medicine* 1992; 117: 165-166.

<sup>113</sup> Angell M, Kassirer JP. Alternative medicine – the risks of untested and unregulated remedies. *New England Journal of Medicine* 1998; 339: 839-841.

## ETHICAL ISSUES

There are many complementary and/or alternative therapies that carry a wide variety of risks, from being harmless when used properly to being very harmful when used inappropriately. No cataloguing of these risks will be attempted here since this would be a monumental task. For example, with approximately 20,000 herbal preparations available,<sup>114</sup> describing the possible herbal toxicities, allergic reactions, and harmful herb–drug interactions would be impossible. However, broadly speaking, there are three ways that a complementary and/or alternative therapy can be physically harmful to the user.

### **Direct physical harm**

The first is by directly harming the individual who uses it. This kind of direct harm is, of course, not an issue with many kinds of complementary and/or alternative therapies used by people with HIV/AIDS. For example, no direct harm can come of prayer, imagery (eg, the visualization of one's immune system riding the body of HIV), or general positive thinking. However, some other therapies do pose a risk of harm if not appropriately used. Taking the example of herbal medicines, we can identify a number of ways in which direct harm may result.

### **Allergic reactions**

One way that direct harm occurs is in an idiosyncratic or unexpected way, such as when a user experiences an allergic reaction to an herbal product.

### **Toxicity and dosage uncertainty**

A potentially more serious way that direct harm results is if a biologically active therapy causes some directly toxic effect or, though safe when used properly, is taken in excess. For example, some herbal medicines contain arsenic or mercury, and popular remedies such as St John's wort, kava kava, aloe vera, henna, and others can cause dermatological side effects.<sup>115</sup>

The issue may also be one of dosage, where the resulting harm is predictable and dose-dependent. People may use too much of an herbal remedy in a short period of time, or they may use it properly but because certain preparations can be stored in body tissue, even chronic low-level intake can lead to harmful exposures of the compound over time. For example, Shiitake mushrooms, ginseng, and traditional Chinese herbs, all of which are used frequently among people with HIV/AIDS, have certain side effects associated with their use. These range from vomiting,<sup>116</sup> nausea, diarrhea, and hypertension among users of ginseng,<sup>117</sup> to the inhibition of platelet aggregation and severe contact dermatitis (skin eruptions) among users of Shiitake mushrooms.<sup>118</sup> Acute liver failure<sup>119</sup> and fatal renal failure<sup>120</sup> have also been reported among users of some traditional Chinese herbs.

What is perhaps more worrying is that these toxicities are reported among people who are, in general, healthier than people with HIV/AIDS. This suggests (1) the possibility that such toxicities and allergies may be more pronounced among persons with HIV/AIDS, and (2) that further toxicities and allergies may occur in persons with HIV/AIDS who use these therapies. Far from being harmless, some herbal or biological complementary/alternative therapies used by people with HIV/AIDS may carry serious risks.

### **Uncertain quality**

Yet another way that a complementary and/or alternative medicine can directly harm its users results from the fact that there is very little quality

<sup>114</sup> Winslow LC, Kroll DJ. Herbs as medicines. *Archives of Internal Medicine* 1998; 158: 2192-2199.

<sup>115</sup> Ernst E. Adverse effects of herbal drugs in dermatology. *British Journal of Dermatology* 2000; 143(5): 923-929.

<sup>116</sup> Miller LG. Herbal medicinals: selected clinical considerations focusing on known or potential drug–herb interactions. *Archives of Internal Medicine* 1998; 158: 2200-2211 at 2203.

<sup>117</sup> Winslow & Kroll, *supra*, note 114 at 2196.

<sup>118</sup> Kassler WJ, Blanc P, Greenblatt R. The use of medicinal herbs by human immunodeficiency virus-infected patients. *Archives of Internal Medicine* 1991; 151: 2281-2288 at 2285.

<sup>119</sup> Perharic L et al. Toxicological problems resulting from exposure to traditional remedies and food supplements. *Drug Safety* 1994; 11: 284-294 at 289.

<sup>120</sup> Ernst E. Harmless herbs? A review of the recent literature. *American Journal of Medicine* 1998; 104: 170-178 at 171.



control involved in the preparation of many widely used herbal preparations. Often this is because of the multi-stage and multi-site processing and manufacturing of herbal medicinals. In most countries, there is no system of oversight and control for herbal preparations. One cannot, therefore, be certain of the initial product's purity.<sup>121</sup> Such a lack of quality control can lead to: (1) inaccurate labeling of the contents of the herbal preparation (eg, a complete misidentification of the product, or an incorrectly labeled dosage), (2) the inclusion in the product of naturally occurring toxic compounds, or (3) contamination of the herbal preparations.

For example, contaminants repeatedly found in herbal remedies include aluminum, arsenic, betamethasone (an anti-inflammatory), diazepam (ie, Valium®), lead, mercury, tin, and zinc.<sup>122</sup> And in some cases, the product may not be contaminated, but may nonetheless contain harmful ingredients. For example, in February 2001, Health Canada released a warning to consumers not to use two herbal products containing compounds considered highly toxic – particularly to children – and known to produce severe allergic reactions and to suppress the immune system.<sup>123</sup>

Due to poor quality control, there are often vast differences in the concentrations of herbal preparations between manufacturers, and between product lots within the same manufacturing company. Given that the potency of many compounds can vary depending upon growing conditions, storage and handling of the compound, and preparation, it has been reported that the potency of different products made from the same plant can vary by as much as 10,000-fold.<sup>124</sup> In one study, the content of ginsenoside was examined in 50 commercial brands of ginseng sold in 11 countries; in 44 of the products, the concentration ranged from 1.9 percent to 9 percent and six products contained no ginsenoside at all. In Germany, often considered to be a leader in quality control standards for herbal medicines, tests on commercial products of devil's claw showed an unacceptable variability in quality.<sup>125</sup>

Such wide differences in an herbal preparation's active compound mean that product labels can often be misleading. Indeed, the *Toronto Star* recently reported that lab tests performed on a variety of herbal remedies commonly sold off the shelf in major drug stores or health food stores showed significant discrepancies from the information provided on the product labels.<sup>126</sup> People can find themselves using mislabeled products such that, even if they are conscientiously following instructions, they might nonetheless put themselves at risk of harm.

### **Harm from interactions with conventional therapy**

The second general way one may be harmed by a complementary/alternative medicine is that although it may be harmless if used properly on its own, it can interact with conventional medicine to produce harmful results. A prime example is the possibility of interactions between herbal products and conventional drugs (or also between different kinds of herbal products, just as different kinds of conventional drugs may harmfully interact).

As noted in the two major studies of complementary/alternative medicine use among the general population in the United States, the use of herbal remedies and megavitamins increased by 380 and 130 percent respectively in the years that elapsed between the two studies (1993 and 1998). The risk of possible harmful interaction between prescription drugs and herbal preparations and/or high-dose vitamins has therefore increased. The authors estimate that because of this, 15 million adults in the United States are at risk for possibly dangerous drug-herb/vitamin interactions.<sup>127</sup>

There is very little quality control involved in the preparation of many widely used herbal preparations.

<sup>121</sup> This issue is currently under review in Canada by the federal government. See the website of the Office of Natural Health Products via [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca) for the current proposals under discussion.

<sup>122</sup> Ernst, supra, note 120 at 175; Kassler et al, supra, note 118 at 2286.

<sup>123</sup> Health Canada. Warning not to consume traditional Chinese medicines containing tricosanthes and indicated for use in children. 28 February 2001 (available via [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)).

<sup>124</sup> Winslow & Kroll, supra, note 114 at 2194.

<sup>125</sup> Chrubasik S et al. Zum Wirkstoffgehalt in Arzneimitteln aus Hapargophytum procumbens. *Forsch Komplementärmed* 1996; 3: 57-63, cited in: Ernst E. Herbal medicines: where is the evidence? *British Medical Journal* 2000; 321: 395-396.

<sup>126</sup> Papp L. Blind trust – special report: an investigation into alternative medicine. *Toronto Star*, 15 January 2000 (A1, A14-A15); 16 January 2000 (A1 etc); 17 January 2000; 22 January 2000 (A1, A14-A15); 23 January 2000. Available (for a fee) via [www.torstar.com](http://www.torstar.com).

<sup>127</sup> Eisenberg DM et al. Trends in alternative medicine use in the United States, 1990-1997: results of a follow-up national survey. *Journal of the American Medical Association* 1998; 280: 1569-1575 at 1574-1575. Concern about possible harm following surgery from pre-surgery use of herbal medicines has also been identified: MK Ang-Lee et al. Herbal medicines and perioperative care. *Journal of the American Medical Association* 2001; 286: 208-216.

## ETHICAL ISSUES

Since many people with HIV/AIDS often take a host of conventional medicines as well as of biologically active alternative medicines, the potential for dangerous drug–herb/vitamin interactions can be great, but is presently unknown. These interactions are under-researched and almost certainly underreported, thus leaving a void when it comes to available evidence regarding actual adverse herb–herb or herb–drug interactions. However, there are some limited data, some of it particularly relevant to people with HIV/AIDS:<sup>128</sup>

- It has been documented that St John’s wort (hypericin), which has been widely used among people with HIV/AIDS for its putative antiretroviral and anti-depressant properties, inhibits iron absorption and thus puts those who have AZT-induced anemia at further risk.<sup>129</sup> More recently, researchers have discovered that St John’s wort affects the body’s ability to metabolize the protease inhibitor indinavir (Crixivan®), dramatically lowering the level of the medication in the blood. This reduces its effectiveness and can have serious clinical implications, such as possible treatment failure and drug resistance, for HIV-positive patients.<sup>130</sup> This prompted both the US Food and Drug Administration<sup>131</sup> and Health Canada to issue a warning to the public.<sup>132</sup> Even more recently, researchers have found that St John’s wort can also reduce levels of another anti-HIV drug, nevirapine (Viramune®).<sup>133</sup>
- Canadian researchers have documented that 12 Chinese herbal products can affect the major human enzymes associated with the disposition of drugs in the body, and have concluded that the suggested daily ingestion of these products could result in clinically significant drug interactions if taken concomitantly with conventional drugs, thereby affecting the latter’s safety and efficacy. They note that this could have serious implications for people with HIV/AIDS, interfering with the bioavailability of antiretroviral drugs, as has been demonstrated with St John’s wort.<sup>134</sup>
- Canadian researchers have also examined 21 selected commercial herbal extracts and tinctures, as well as 13 relevant phytochemicals. They found that roughly 75 percent of the extracts and tinctures and 50 percent of the phytochemicals studied significantly inhibited a key drug-metabolizing enzyme. They cautioned that this could potentially result in adverse drug reactions when taken concomitantly with prescription drugs metabolized by the same enzyme, such as the protease inhibitors ritonavir, saquinavir, nelfinavir, and indinavir. Among the herbal extracts and tinctures studied, goldenseal, St John’s wort, and cat’s claw showed the highest inhibition of enzyme activity.<sup>135</sup>
- In a small-sample study, US researchers found that chronic dosing of garlic supplements (commonly used to lower cholesterol in patients receiving protease inhibitors) significantly decreased plasma concentrations of saquinavir, and recommended that patients use caution when combining garlic supplements with saquinavir used as a sole protease inhibitor.<sup>136</sup>
- Some data suggest the safety of at least short-term use of cannabinoids (marijuana) by people with HIV using the protease inhibitors nelfinavir or indinavir. Researchers recently reported on a 21-day study conducted with 67 people with stable viral load on a stable antiretroviral regimen, randomized to groups smoking THC, taking the substance in capsule form, or placebo (all three times daily). They found no significant

<sup>128</sup> For a recent summary of research data on interactions between drugs and herbal products, see: Fugh-Berman A. Herb–drug interactions. *Lancet* 2000; 355: 134-138.

<sup>129</sup> Miller, supra, note 116 at 2205.

<sup>130</sup> Piscitelli SC et al. Indinavir concentrations and St John’s wort. *Lancet* 2000; 355: 547-548. See also the numerous commentaries and other correspondence in the same issue of the *Lancet* on this topic, with extensive references to a variety of research studies regarding pharmacokinetic interactions involving St John’s wort. Available online via [www.thelancet.com](http://www.thelancet.com).

<sup>131</sup> US Food and Drug Administration (Center for Drug Evaluation and Research). FDA Public Health Advisory: Risk of Drug Interactions with St John’s Wort and Indinavir and Other Drugs. 10 February 2000. Available online via [www.fda.gov/cder/drug/advisory/stjwort.htm](http://www.fda.gov/cder/drug/advisory/stjwort.htm).

<sup>132</sup> Health Canada. Advisory: Potentially harmful drug interaction with St. John’s wort and prescription drugs, 7 April 2000 (available online via [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca)).

<sup>133</sup> de Maat MMR et al. Drug interaction between St John’s wort and nevirapine. *AIDS* 2001; 15(3): 420-421.

<sup>134</sup> Foster BC et al. Effects of Chinese herbal products on cytochrome P-450 drug metabolism. 9<sup>th</sup> Annual Canadian Conference on HIV/AIDS Research, Montreal, 27-30 April 2000 [poster]: Abstract 144P, reported in: *Canadian Journal of Infectious Diseases* 2000; 11 (Suppl B): 23B.

<sup>135</sup> Budzinski JW et al. Effect of commercial herbal extracts and tinctures on cytochrome P450 3A4 drug metabolism. 9<sup>th</sup> Annual Canadian Conference on HIV/AIDS Research, Montreal, 27-30 April 2000 [poster]: Abstract 145P, reported in: *Canadian Journal of Infectious Diseases* 2000; 11 (Suppl B): 23B.

<sup>136</sup> Piscitelli SC et al. Garlic supplements decrease saquinavir plasma concentrations. 8<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, 4-8 February 2001, Chicago: Abstract 743.

changes in viral load or CD4 count in any of the subjects. The long-term clinical impact (if any) of cannabinoid use on antiretroviral drugs is unknown.<sup>137</sup>

### **Indirect harm from “opportunity cost”**

The third way that a complementary/alternative medicine may cause physical harm is indirect. Some people with HIV/AIDS choose to discontinue conventional medical therapies because they find the many side effects intolerable. This is, of course, a legitimate choice (we discuss this below in considering the ethical principle of respect for personal autonomy).<sup>138</sup> Others decide to delay (or forego) conventional therapy because they want to try (or rely exclusively on) alternative therapies. This choice carries the risk of delaying the benefits that could have accumulated for them with conventional medicine, even though the alternative therapy may itself be harmless. Thus, the harm comes as a form of “opportunity cost” – the lost opportunity for more effective treatment. For example, if one relies exclusively on alternative therapies, HIV disease may progress more quickly to a diagnosis of AIDS, at which point conventional therapies may be less effective.

### **Harm from Exploitation**

In addition to such physical harms, there are the further harms associated with financial and emotional exploitation that need to be identified and addressed. Exploitation occurs when someone has taken unfair advantage of another person. The one who exploits gains something from the exploitative transaction, while the exploited person is either made worse off or is (at best) made no better off.<sup>139</sup>

Although the clearest case of exploitation occurs in a transaction between two individuals, elements of exploitation are still present between marketers and distributors of herbal preparations or other health products on the one hand, and people who buy these products from stores on the other. The risk of exploitation is, of course, not exclusive to complementary/alternative medicine by any means. In any domain of human interaction, exploitation and abuse can occur. For example, the pursuit of huge financial profits may push some producers of conventional drugs to promote products that are not efficient or not as efficient as the products of competitors, or products that have not been adequately tested for their safety. Drug-approval systems are a recognition of the fact that there should be some control over the type of products that enter the market. These considerations are equally valid with respect to the sale of natural health products (or the sale of practitioners’ services).

### **Emotional exploitation**

Because hope can figure prominently in the motivations to use complementary/alternative therapies, people with HIV/AIDS may put themselves at risk by trying alternative therapies of unknown benefit. Emotional exploitation can occur in a number of ways.

### **Unethical practitioner**

First, a person with HIV/AIDS may seek the services of an unscrupulous provider of a complementary/alternative therapy. Indeed, such a person could be a product manufacturer or conventional medicine practitioner trying to take financial advantage of patients by relying on the fact that many complementary/alternative products or practices are unregulated. In such a transaction patients may be purposely misled about the complementary/alternative therapy’s effectiveness or safety, and thus find themselves with expectations that

Drug approval systems are a recognition of the fact that there should be some control on the type of products that enter into the market.

<sup>137</sup> Kosel B et al. The pharmacokinetic (PK) effects of marijuana (THC) on nelfinavir (NFV) and indinavir (IDV). 8<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, 4-8 February 2001, Chicago: Abstract 745; Abrams D et al. Short-term safety of cannabinoids in HIV patients. 8<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, 4-8 February 2001, Chicago: Abstract 744.

<sup>138</sup> For the most recent recommendations regarding antiretroviral therapy, see: US Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents, 5 February 2001. Available online via [www.hivatis.org](http://www.hivatis.org).

<sup>139</sup> For an excellent extended philosophical discussion of exploitation see: Wertheimer A. *Exploitation*. Princeton: Princeton University Press, 1996.

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are built up only to be necessarily unmet. In such cases, we would say that the unscrupulous practitioner has taken unfair advantage of a person's vulnerabilities and made them do something they would not do under conditions of full and truthful information. Even if they are not physically harmed, and even if they recover the money they spent, we would still say that emotionally or psychologically they have been exploited. This exploitation counts as a harm.

### **Self-medication with incomplete or inaccurate information**

More common than cases of unscrupulous providers are cases of HIV-positive people seeking self-administering therapies and information on their own. Indeed, the data canvassed above show that many people using CAM do so with little reliable information. Misinformation and misplaced hope is less likely if information is obtained from reputable sources. However, the proliferation of information sources makes quality control extremely difficult. Several factors contribute to the creation of potentially exploitative situations, including:

- the multitude of publications in print and on the Internet;
- the fact that most complementary/alternative therapies are unregulated and easily available (at least for some would-be users), and
- the fact that users of complementary/alternative therapies often self-administer without professional consultation.

In such circumstances, misinformation, incomplete information, and easy availability of some complementary and/or alternative therapies come together to produce a potentially exploitative situation. The hopes of many people with HIV/AIDS who may feel the need to "try anything and everything" are often unjustifiably raised and left unmet. In such cases, the producers, marketers, and providers of therapies or products that they know to be inefficient ought to be collectively held accountable for delivering the exploitative harm. Furthermore, regulatory agencies have a duty to prevent this harm by imposing standards of consumer information or product/practice safety to prevent uninformed access to products or practices about which there is incomplete information. They have a duty to prevent such harm.

The problem is to define what constitutes an ineffective product or practice. Some complementary/alternative therapies may, for example, be defended on the ground of offering a measure of spiritual or emotional well-being, without claiming to heal or ameliorate an illness or condition. If that is the case, it is not clear on what ground society should intervene to avoid exploitation. In other words: what seems to be exploitation for some may very well be an acceptable and worthy healing practice for others.

### **Financial exploitation**

Financial exploitation is perhaps a more tangible harm: we can easily see how being unfairly taken advantage of can set back one's interest in not losing money. Three recent cases in the United States highlight the need for federal regulatory authorities to protect against financial and emotional exploitation of people with HIV/AIDS when they act as consumers. In March 1999, a Florida court sentenced a couple on a variety of charges for selling ozone generators with the claim that the use of generators to oxidize toxins in the body could cure such conditions as gangrene, cancer, or AIDS.<sup>140</sup> In December 1999, the US Department of Justice charged a com-

<sup>140</sup> [US] Food and Drug Administration/State AIDS Health Fraud Task Forces – Evaluating Medical Therapies. News update: Ozone Generator Sentencing. Office of Special Health Issues, April 1999 (available at [www.fda.gov/oashi/aids/eval.html](http://www.fda.gov/oashi/aids/eval.html), accessed 5 April 2001).

pany and its president for illegally marketing products such as shark cartilage as a treatment for cancer, and a rice-bran extract as a treatment for cancer and HIV. The products were not approved for sale in the US, as their safety and effectiveness had not been demonstrated.<sup>141</sup> And most recently, in April 2001, the president of a vitamin manufacturing company was charged in connection with fraudulent claims for its product “T-Factor” (made from freshly slaughtered calves’ organs) that it sold via the Internet with the claim that it has anti-HIV effects.<sup>142</sup>

Complementary/alternative medicine is big business in North America. In Canada, estimates provided to the Standing Committee on Health suggest that the gross income of the natural health products industry ranged between CDN\$1.5 and CDN\$2 billion in 1997.<sup>143</sup> The same source predicts an annual growth of this industry of 10 to 15 percent a year. The Fraser Institute study estimates that Canadians spent approximately CDN\$3.8 billion on alternative medicine in the latter half of 1996 and the first half of 1997.<sup>144</sup> In the United States, it is estimated that consumers spent US\$21.2 billion in 1997 on alternative therapies, including US\$3.3 billion on high-dose vitamins and US\$5.1 billion on herbal products.<sup>145</sup>

Among people with HIV/AIDS, it has been reported that the approximate annual expenditures vary from US\$40 to US\$8000, with a median expenditure of US\$700.<sup>146</sup> The average out-of-pocket expense found in another study (in the early 1990s) was US\$18 a month.<sup>147</sup> Similar figures are found in the few Canadian studies that have looked at this issue:

- A 1995 study by CRIT/CAS that surveyed 200 people with HIV/AIDS in Toronto (185 men, 15 women) found that the majority of them had disability insurance or social assistance as their main source of income. A significantly higher proportion of respondents reported HIV-related symptoms than respondents who were working (68 versus 28 percent). On average, respondents spent 10 to 20 percent of their incomes on complementary therapies – which, as the authors point out – is most significant for people on fixed social assistance incomes. This point was also highlighted in research by Kendall et al among 49 people with HIV/AIDS in British Columbia: the majority were living on less than \$10,000 per year, and of these, 16 percent reported spending between \$200 and \$400 a month on CAM, and many limited their food consumption as a result.<sup>148</sup>
- In a 1996 study by Meneilly et al among HIV-positive women in Vancouver, which found that 42 percent used complementary/alternative therapies, 75 percent spent over \$100 a month on such therapies. The average annual income of the women in the study was in the \$10,000 to 20,000 bracket.<sup>149</sup>
- Finally, data from Ontario finalized in 1999 found that people with HIV/AIDS who used complementary therapies reported spending an average of \$85 a month or \$1020 annually. Based on this data, the study authors estimate that people with HIV/AIDS in Ontario alone spend \$5.5 million annually on complementary therapies.<sup>150</sup>

Such figures may not seem excessive, but people with HIV/AIDS are, collectively and broadly speaking, an at-risk population for unemployment or underemployment, and hence lower income. This can be the result of job discrimination or because their declining health prevents them from working as much as before.<sup>151</sup> In one study, it was found that the loss of earnings as a consequence of having HIV/AIDS reduced monthly income by 75 percent for one in three study participants.<sup>152</sup> In another study, it was reported that 27

## Complementary/alternative medicine is big business in North America.

<sup>141</sup> [US] Food and Drug Administration. DA takes action against firm marketing unapproved drugs: Talk paper, 10 December 1999 (available via [www.fda.gov](http://www.fda.gov)).

<sup>142</sup> Evans D. Ives health president arrested on HIV fraud charges. *Bloomberg*, 5 April 2001.

<sup>143</sup> Standing Committee on Health. *Natural Health Products: A New Vision*. Ottawa, November 1998, Chapter 1. Available online via [www.parl.gc.ca](http://www.parl.gc.ca).

<sup>144</sup> Ramsay et al, *supra*, note 50.

<sup>145</sup> Eisenberg et al, *supra*, note 127 at 1573.

<sup>146</sup> Anderson et al, *supra*, note 63 at 564.

<sup>147</sup> Kassler et al, *supra*, note 118 at 2282.

<sup>148</sup> CRIT/CAS, *supra*, note 56; Kendall et al, *supra*, note 61 at 4, 12-13.

<sup>149</sup> Meneilly et al, *supra*, note 54.

<sup>150</sup> *Supra*, note 72.

<sup>151</sup> Not only does an HIV-positive status increase one's risk for unemployment or underemployment, but those who are already socially and financially marginal tend to be disproportionately at highest risk for contracting HIV in the first place.

<sup>152</sup> Massagli MP et al. Correlates of employment after AIDS diagnosis in the Boston Health Study. *American Journal of Public Health* 1994; 84: 1976-1981 at 1981.

A conventional medical practitioner has an ethical duty to elicit information on whether or not his or her patients are using complementary and/or alternative therapies.

percent of people with HIV/AIDS were having financial difficulties paying for basics (eg, food, rent) as a result of their illness.<sup>153</sup>

Many complementary/alternative therapies (such as herbal preparations or homeopathy) are unregulated, and are often not covered by private or provincial insurance plans. Individuals are therefore paying for many alternative therapies out of pocket (that is, with no help from insurance or employers). Given such clear economic consequences, there is cause for ethical concern if a therapy shows no clear evidence of benefit. Just as with emotional exploitation, it is difficult to locate the source of the harm precisely. It is arguable, however, that the responsibility for preventing the exploitative harm rests ultimately with regulators.

### **Ethical and Policy Implications of the Potential Harms**

Given the various physical harms that may be associated with certain complementary and/or alternative therapies, as well as the harms that may result from emotional and financial exploitation, what is the ethically correct response to the current state of alternative medicine use among people with HIV/AIDS? We will identify three areas of ethical concern.

#### ***The practitioner's duty to elicit information from patients***

Given the possible safety hazards associated with some complementary and/or alternative therapies, the fact that they are so widely used, and the fact that a large proportion of those who use complementary/alternative medicine do not tell their primary care physician about their use, a conventional medical practitioner has an ethical duty to elicit information as to whether or not the practitioner's patients are using complementary and/or alternative therapies as part of the routine taking of medical history and regular patient check-up. "This measure would promote greater patient-physician communication and integration of complementary health care services into patient care."<sup>154</sup> Some regulatory bodies have articulated this professional obligation. For example, in its policy on complementary and alternative therapies, the College of Physicians & Surgeons of British Columbia has stated that:

Physicians must be aware of their patients' use of such therapies, and should ask about alternative remedies in the same way that they ask about non-prescription drugs. Both types of treatment can produce direct toxicity, or interactions with pharmaceutical medications or other accepted treatments.<sup>155</sup>

Nonetheless, this duty is under-recognized. A recent US study found that only 26 percent of physicians caring for people with HIV/AIDS discussed alternative medicine use with their patients at new visits, and only five percent discussed CAM at follow-up visits. A recent Ontario study of 70 people with HIV/AIDS found that, while 93 percent of the women and 70 percent of the men reported CAM use, the HIV physician was aware of only 37 percent of CAM agents used, and that in over half the cases in which the physician was unaware of CAM use, 96 percent of the time the physician had not asked the patient about it.<sup>156</sup> Such lack of communication does not address a risk of harm to the patient that is reasonably foreseeable to the average practitioner.

There are a number of further ethical duties that conventional professionals need to recognize. For instance, if physicians are to be effective in preventing people with HIV/AIDS from being at risk for harm, they must

<sup>153</sup> Kass NE et al and the Multicenter AIDS Cohort Study. Changes in employment, insurance, and income in relation to HIV status and disease progression. *Journal of Acquired Immune Deficiency Syndromes* 1994; 7: 86-91 at 89.

<sup>154</sup> LaValley JW, Verhoef MJ. Integrating complementary medicine and health care services into practice. *Canadian Medical Association Journal* 1995; 153: 45-49.

<sup>155</sup> College of Physicians & Surgeons of British Columbia. Complementary and Alternative Therapies. Policy Manual, Chapter C-12, June 1999 (available via [www.cpsbc.bc.ca](http://www.cpsbc.bc.ca)).

<sup>156</sup> Wynia MK, Eisenberg DM, Wilson IB. Physician-patient communication about complementary and alternative medical therapies: a survey of physicians caring for patients with human immunodeficiency virus infection. *Journal of Alternative and Complementary Medicine* 1999; 5: 447-456; Furler M et al. Physician awareness of complementary and alternative medicine use (2001), *supra*, note 56.

themselves become familiar with: (1) the complementary and/or alternative therapies most often used by those in their medical practice; (2) the possible risks associated with such complementary and/or alternative therapies, including direct toxicities and possible harmful interactions between therapies; and (3) the clinical manifestations of toxicities and allergic reactions from different complementary/alternative therapies, so that these toxicities can quickly be identified and addressed if necessary.<sup>157</sup> With complementary and/or alternative medicine use so prevalent and on the rise, conventional medical practitioners will have to keep up with new information in order to prevent harm from befalling those who are often self-administering alternative therapies.

All these requirements apply equally to complementary/alternative medical practitioners who must elicit information from their patients regarding what conventional medicines they may be using, and who need to become aware of the specific considerations for people with HIV/AIDS in using certain CAM therapies in light of HIV infection.

#### **Recommendation 4**

**Professional practice policies or guidelines on complementary/alternative therapies developed by regulatory bodies for health professionals (eg, Colleges of Physicians and Surgeons) should instruct members to inquire into their patients' use of complementary/alternative medicine. Individual practitioners should consciously make an effort to inquire into their patients' use of complementary/alternative therapies.**

#### **Recommendation 5**

**Practitioner associations in the field of complementary/alternative health care should encourage their members to inquire into their patients' use of other complementary/alternative therapies as well as conventional medical treatments. Individual practitioners should make an effort to inquire into such use.**

#### ***The need for safety research***

Given the widespread use of complementary and/or alternative therapies, it is ethically imperative that safety research be conducted on the most widely used complementary and/or alternative therapies. The state has a duty to protect its citizens, using reasonable means. Although a state does not have a duty to ensure that its citizens live in a risk-free society, it does have a duty to ensure that the choices citizens make that fall under its jurisdiction carry reasonable risk/benefit ratios. For example, the United States Food and Drug Administration and Canada's Health Products and Food Branch do not have the duty to ensure that all licensed drugs are completely safe (ie, riskfree) for their users; rather, they need only ensure that the risks and benefits of these drugs are reasonably balanced. An important part of this process is the determination of the thresholds of safe use for a specific drug (ie, the upper bounds of safe drug dosage).

Within some of the more regulated complementary and/or alternative medicine specialties, such as chiropractic, the parameters of safe practice have been largely established.<sup>158</sup> But with certain complementary and/or alternative therapies, notably herbal preparations and biological therapies, where self-administration without "professional" consultation is common, reliable

Given the widespread use of complementary and/or alternative therapies, it is ethically imperative that safety research be conducted on the most widely used complementary and/or alternative therapies.

<sup>157</sup> Eisenberg DM. Advising patients who seek alternative medical therapies. *Annals of Internal Medicine* 1997; 127: 61-69; Wynia et al, supra, note 156.

<sup>158</sup> Chiropractic has become so prevalent and professionalized in the 20<sup>th</sup> century that some think it is contentious to call it an "alternative" medical practice at all. See: Kaptchuk TJ, Eisenberg DM. Chiropractic: origins, controversies, and contributions. *Archives of Internal Medicine* 1998; 158: 2215-2224.

Quality control in the area of many complementary and/or alternative therapies is lacking, but is necessary to protect people with HIV/AIDS from harm.

A policy of consumer protection that imposes certain safety standards focuses on the protection against harm and is minimally paternalistic.

and credible safety information is lacking. Research needs to be conducted in order to fill this information gap and better protect from harm those who use these therapies. Priority should be given to researching those complementary/alternative therapies that are known to be most widely used by people with HIV/AIDS, and/or for which there is some evidence of known or potential significant adverse effects, including if used in conjunction with conventional HIV/AIDS treatments.

### ***The need for quality control measures***

Quality control in the area of many complementary and/or alternative therapies is lacking, but is necessary to protect people with HIV/AIDS from harm. For natural health products, this would include standardized “good manufacturing practices” (GMPs) for the manufacture of products, as well as labeling guidelines that would clearly indicate the safe dose range, contraindications, risks, the kind of benefit that can be expected, and the evidence for this benefit, among other essential pieces of information. Quality control in the context of practices requires different, more varied approaches (see the discussion below about the regulation of practitioners). But the principle remains the same: quality control measures are necessary to ensure that producers of complementary and/or alternative medicine are more accountable for their products.

### **Policy Option: The Example of National Health Products**

Herbal remedy manufacturers, by way of ethical and responsible product promotion, and government organizations, through establishment of proper regulatory standards, have an obligation to protect the public – and vulnerable populations – from undue harm and exploitation.<sup>159</sup>

Many regulations impose safety standards on products. We believe that this form of policy is of prime importance in the context of complementary and/or alternative medicine. As long as a therapy is demonstrably safe, this may be a sufficient safeguard for people with HIV/AIDS. The adoption of a safety-standard policy should involve setting production and quality standards (as noted above); and regulation of product content, including prohibitions on certain ingredients because of toxicity or potential harm to specific categories of consumers for whom the product is being targeted (eg, children, or people with compromised immune systems). Questions relating to such regulations include: What is the likelihood of harm to consumers? Are there any predicted side effects and are these reasonably acceptable? If so, how do we inform consumers?

A policy of consumer protection that imposes certain safety standards focuses on the protection against harm and is therefore minimally paternalistic. The ethical grounding for such a policy is based on the principle of non-maleficence. At the same time, imposing quality control standards still reflects the idea that, although people should reasonably be able to expect certain minimal standards for a given product, they are basically free to choose (within certain limits) what they want to consume and/or use.

For example, the Standing Committee on Health, in the Final Report of the Advisory Panel on Natural Health Products, supported the idea that safety should remain a crucial concern for a new natural health product agency, but accepted the claim by many witnesses that the vast majority of natural health products are safe. It suggested that “regulatory resources would be best directed toward those products that are less safe.”<sup>160</sup> This is

<sup>159</sup> Gold JL, Laxer DA, Rochon PA. Herbal remedies: a critical perspective. *Annals of the Royal College of Physicians and Surgeons of Canada* 2000; 33(8), available online via <http://rcpsc.medical.org>.

<sup>160</sup> Final Report of the Advisory Panel on Natural Health Products: Regulatory Framework for Natural Health Products, May 13, 1998 at 10 (Advisory Panel). Available online at [www.hc-sc.gc.ca/main/drugs/zfiles/english/herbals/finalrpt-e.html](http://www.hc-sc.gc.ca/main/drugs/zfiles/english/herbals/finalrpt-e.html).



an important argument, related to the appropriate allocation of scarce research and regulatory resources. Regulatory agencies have to be able to focus on what is most likely to cause harm.

The Standing Committee recommended that for the safety assessment of natural health products, evidence can “be drawn from a range of sources, historical and recent, traditional knowledge and contemporary science.”<sup>161</sup> While we do not reject the usefulness and value of historical knowledge, we do caution against too much reliance on this type of information. Well-known natural health products with an established safety record may nevertheless be harmful when taken in combination with newly developed drugs, or by people with a particular health condition (eg, HIV/AIDS). More contemporary scientific studies may often be the only way to adequately assess the safety of a given natural health product in the context of, for example, conventional HIV/AIDS treatment. Historical and traditional accounts of a product’s safety can be a first indicator and a basis for further research.

In light of these considerations, the Advisory Panel, followed in this by the Standing Committee, recommended a proportionate approach to safety. It suggests that a review system be constructed around the following three pillars:

- Regulations must require products to adhere to quality and safety standards that may substantially mitigate risk.
- Products with lower safety margins should be held to higher standards within the regulatory process.
- Risk assessments for natural health products may refer to a wider variety of reference sources than conventional pharmaceutical drug evaluations.<sup>162</sup>

## Beneficence

The principle of beneficence counsels one to do those actions that bring about the good of others. Ethical medical practice requires that patients benefit, or that there be a reasonable prospect they will benefit, from a given therapy or practice. The absence of harm is arguably a benefit, of course, but here we mean an actual increase in someone’s well-being, rather than merely avoiding harm, which is required by the principle of non-maleficence. We want available therapies (conventional or unconventional) to be safe (ie, not harmful) within a range of use. But we also want them to be effective in increasing the well-being of their users (ie, beneficial) within such a range.<sup>163</sup>

## Difficulties in Assessing the Benefits of CAM

As is the case with conventional medicine, some complementary and/or alternative therapies carry more or less serious risks. We are ethically required to ask whether or not these risks are adequately balanced by known or reasonably anticipated benefits. There are two issues that make answering this question difficult.

### **Problems with existing data**

#### **Little reliable “scientific” data**

As pointed out by two Canadian experts in the field, in their proposal for the creation of a national office for research into complementary and alternative health care:

The reason most frequently cited in opposition to the integration of CAM into conventional practice is that CAM practices are not

Well-known natural health products with an established safety record may nevertheless be harmful when taken in combination with newly developed drugs.

<sup>161</sup> Ibid at 10.

<sup>162</sup> Ibid.

<sup>163</sup> The term “effectiveness research” will be used in this paper to indicate the testing process that seeks to determine if a therapy is effective; i.e., brings about the well-being of a person relative to some specific outcome measure. This is sometimes referred to as “efficacy research.”

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Ethical medical practice requires that patients benefit, or that there be a reasonable prospect they will benefit, from a given therapy or practice.

evidence based. This perception is not entirely accurate; there is reliable data from clinical trials for some CAM therapies and this knowledge base is growing rapidly. However, the cumulative number of clinical trials is small, and at the moment, consumer demand has outstripped clear evidence of efficacy and safety for many CAM therapies.<sup>164</sup>

It has also been argued that the continued hostility toward many complementary/alternative therapies on the part of many conventional health-care professionals presents an additional barrier to the publication of research in this area (particularly research showing positive outcomes) in “mainstream” medical journals, and that conscious or unconscious bias on the part of mainstream medical reviewers results in an uneven playing field tilted against complementary/alternative medicine. For example, British and German researchers recently published the results of a randomized controlled study examining possible bias against unconventional therapy on the part of experts who undertake peer review of studies submitted for publication in orthodox journals. They found a significant level of reviewer bias against publication of unconventional therapies in the setting they examined. While they concluded that the bias did not create an insurmountable barrier to publication, authors of papers on unconventional therapies were at a disadvantage (see Resch et al in bibliography). This places consumers and practitioners of such therapies in a Catch-22 situation: without published research, the field lacks “legitimacy” in the eyes of many conventional practitioners (and funders and policymakers), but the bias against complementary/alternative therapies as “unscientific” and hence illegitimate presents a challenge to the publication of research in this area.

Answering the question “Is this effective?” is difficult in the case of many complementary/alternative therapies because there are few high-quality and reliable data, especially in the form of randomized controlled trials. Generally, most reports of *highly effective* complementary and/or alternative therapies tend to be anecdotal. Because of this, and because in the case of some CAM the therapy is by its nature individualized, such reports are unreliable as a basis for generalized treatment and offer weak support for generalized claims of efficacy. For example, in testimony before a subcommittee of the United States National Institutes of Health, it was reported that six physicians using ozone therapy (which is purported to selectively destroy anaerobic viruses like HIV, while leaving healthy cells alone) have collectively brought over three hundred AIDS patients from HIV-positive to HIV-negative status.<sup>165</sup> However, no corroborating evidence for such striking anecdotal claims exists.

Formal studies tend to support modest claims on behalf of some complementary/alternative therapies (eg, acupuncture for chronic pain, homeopathy for a variety of ailments, and chiropractic for lower back pain), for which randomized controlled trials and meta-analyses have been conducted showing inconclusive evidence for effectiveness.<sup>166</sup> In some areas, the research is more promising.

For example, in 1997 the US National Institutes of Health produced a “Consensus Statement” on acupuncture, based on extensive review literature and deliberations over several days by experts drawn from numerous disciplines at a conference of over 1200 participants. The consensus was that, whereas many studies provide equivocal results because of factors such as trial design or sample size, promising results have emerged that

<sup>164</sup> Best A, Balon J. Design for a Canadian Office for Complementary and Alternative Health Care: A White Paper for the Interim Governing Committee of the Canadian Institutes of Health Research, 20 December 1999, at 6, citing: Beyerstein BL. Alternative medicine: where's the evidence? *Canadian Journal of Public Health* 1997; 88(3): 149-150; Barnes J, Abbot NC, Harkness EF, Ernst E. Articles on complementary medicine in the mainstream medical literature: an investigation of MEDLINE, 1966 through 1996. *Archives of Internal Medicine* 1999; 159(15): 1721-1725.

<sup>165</sup> McCabe E. Ozone therapies for AIDS. *AIDS Patient Care* 1992; 254-255.

<sup>166</sup> Ernst E. Complementary medicine – is it effective and safe? *Drug Information Journal* 1999; 33: 291-295.

show the efficacy of acupuncture for nausea in adults following surgery and chemotherapy, and for post-surgical dental pain. The NIH also concluded that, for numerous conditions (eg, addiction, headache, menstrual cramps, fibromyalgia, lower back pain, and carpal tunnel syndrome), acupuncture may be a useful adjunct treatment, an acceptable alternative, or included in a comprehensive management program. The NIH indicated that further research is likely to uncover additional areas in which acupuncture will be useful.<sup>167</sup> More recently, some data have indicated positive results in the use of acupuncture to treat cocaine addiction.<sup>168</sup>

For HIV/AIDS and its associated medical conditions systematic and reliable data are limited. For example:

- A recent randomized controlled trial of acupuncture vs amitriptyline vs placebo for the relief of pain caused by HIV-related peripheral neuropathy demonstrated that neither acupuncture nor amitriptyline was more effective compared with placebo for pain relief.<sup>169</sup> However, in a small study of 21 HIV-positive men and women reporting objectively measured sleep disturbance, sleep quality significantly improved following five weeks of individualized acupuncture delivered in a group setting.<sup>170</sup>
- A study of St John's wort as an antiretroviral agent among HIV-infected adults produced significant toxicity (16 of the 30 participants dropped out of the study because of adverse reactions) and no antiretroviral activity was demonstrated in those who could tolerate the herbal preparation.<sup>171</sup> (This study was undertaken before data emerged showing that St John's wort could impair the effectiveness of protease inhibitors, as noted above.)
- A pilot study of a standardized Chinese herbal preparation vs placebo for the treatment of symptoms relating to HIV/AIDS failed to demonstrate any significant differences regarding symptom relief between the study arms.<sup>172</sup> (Again, recent Canadian research raising a concern about the possible adverse effects of many commonly used Chinese herbal treatments for people using conventional anti-HIV therapies due to inhibition of enzyme activity should be noted.)<sup>173</sup>
- On the other hand, researchers at the Harvard School of Public Health report that a number of studies indicate that vitamin treatment has a protective effect against disease progression and vertical transmission of HIV from mother to child.<sup>174</sup>

Obviously, one should not condemn *all* alternative therapies based on the ineffectiveness of a *few*. But poor or mixed therapeutic results in some of the studies mentioned clearly illustrate the need for research into the effectiveness of such therapies.

#### User satisfaction data

Examining user satisfaction with CAM often reveals a different story altogether. Regardless of whether an objective measure of a person's health status (eg, viral load, CD4 cell count, decreased severity of symptoms) changes for the better, many users of complementary/alternative therapies feel better for having used alternative approaches. Among people with HIV/AIDS, many users of complementary/alternative therapies feel empowered by having taken control of their health and health care. They thereby cease being passive recipients of a physician's therapies and actively orchestrate their health care by educating themselves and, in effect, treating themselves. As noted above, this is identified as a primary reason for using CAM. Whether or not this is always a good approach is another question, as the discussion of the risks of

<sup>167</sup> NIH. Acupuncture. Consensus Statement 1997; 15(5): 1-34. Available online via <http://odp.od.nih.gov>. Also summarized at: Acupuncture. *Journal of the American Medical Association* 1998; 280: 1518-1524.

<sup>168</sup> Avants SK et al. A randomized controlled trial of auricular acupuncture for cocaine dependence. *Archives of Internal Medicine* 2000; 160(15): 2305-2312.

<sup>169</sup> Shlay JC et al for the Terry Bein Community Programs for Clinical Research on AIDS. Acupuncture and amitriptyline for pain due to HIV-related peripheral neuropathy. *Journal of the American Medical Association* 1998; 280: 1590-1595.

<sup>170</sup> Phillips KD, Skelton WD. Effects of individualized acupuncture on sleep quality in HIV disease. *Journal of the Association of Nurses in AIDS Care* 2001; 12(1): 27-39.

<sup>171</sup> Gulick RM et al for the AIDS Clinical Trial Group 150 and 258 Protocol Teams. Phase 1 studies of hypericin, the active compound in St. John's wort, as an antiretroviral agent in HIV-infected adults. *Annals of Internal Medicine* 1999; 130: 510-514.

<sup>172</sup> Burack JH et al. Pilot randomized controlled trial of Chinese herbal treatment for HIV-associated symptoms. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* 1996; 12: 386-393.

<sup>173</sup> Foster BC et al. Effects of Chinese Herbal Products on Cytochrome P-450 Drug Metabolism. 9<sup>th</sup> Annual Canadian Conference on HIV/AIDS Research, Montréal, 27-30 April 2000 [poster]; Abstract 144P, reported in: *Canadian Journal of Infectious Diseases* 2000; 11(Suppl B): 23B.

<sup>174</sup> Fawzi WW, Hunter DJ. Vitamins in HIV disease progression and vertical transmission. *Epidemiology* 1998; 9: 457.

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self-medicating above suggests. But the fact remains that personal empowerment is a commonly received benefit and should not be discounted in assessing the benefits of CAM use.

Moreover, general satisfaction levels with complementary and/or alternative medicine have been found to be comparable to the general satisfaction levels obtained with conventional HIV/AIDS medicine,<sup>175</sup> although, not surprisingly, alternative therapies with more severe adverse effects (eg, St John's wort, blue-green algae, pau d'arco and L-lysine) tend to get far lower satisfaction ratings than alternative medicines without such side effects.<sup>176</sup>

### Commentary

The use of most complementary/alternative therapies among people with HIV/AIDS remains unusual when viewed strictly from the standpoint of scientifically measurable "biological effectiveness," because in many cases there seem to be no reliable data indicating that these therapies significantly help bring about the biological therapeutic purposes for which they are often used. In addition, some complementary and/or alternative therapies have side effects that can vary from mildly irritating to severe.

From a broader perspective that includes non-biological factors, such as general feelings of wellness and well-being, it is clear why so many people with HIV/AIDS use complementary/alternative therapies. Therefore, the process of evaluation should consider that, at least among harmless therapies (or therapies carrying a minimal risk of harm), the psychological benefit from the use of CAM could alone justify the use of alternative therapies even in the absence of strict biological effectiveness.

### Methodological problems

Researchers who reviewed the material on CAM published in MEDLINE-listed clinical trial-type articles over the 30-year period 1966 to 1996 found that

interest in and awareness of complementary medicine among orthodox health care professionals has increased in the past 30 years. The increase in the number and proportion of reports of clinical trials indicates an increasing level of original research activity in complementary medicine and suggests a trend toward an evidence-based approach in this discipline. The cumulative number of clinical trial-type articles is small, however, and more high-quality original research in complementary medicine is required.<sup>177</sup>

Regardless of the kind, number, or combination of interventions involved, those who use complementary and/or alternative therapies most often do so in the hope that their physical condition will improve as a result. For that to happen, therapies must be effective. Clinical research techniques in conventional biomedicine are designed to determine whether or not a given intervention is effective and does what it is intended to do. But there are differences between conventional and unconventional therapies that are often thought to make it difficult to determine the effectiveness of complementary/alternative therapies by using conventional scientific methods. As a result, methodological problems in evaluating complementary and/or alternative therapies may (partially) explain the problems with, and inconsistencies of, existing data regarding the effectiveness of many alternative therapies.

<sup>175</sup> CRIT/CAS, supra, note 56; Kendall, supra, note 61 at 6; Langewitz W et al. The integration of alternative treatment modalities in HIV infection – the patient's perspective. *Journal of Psychosomatic Research* 1994; 38: 687-693; Anderson W et al, supra, note 63. Note that both these studies pre-date the advent of protease inhibitors; multiple combination therapy has shown both improved anti-HIV effect in many people with HIV/AIDS, but also often an increase in serious side effects, leading experts to recently advocate a more restrained approach to the use of multiple combination therapy because of such a reassessment of the risk/benefit ratio.

<sup>176</sup> Anderson et al, supra, note 63 at 564.

<sup>177</sup> Barnes et al, supra, note 164.

### Different mechanisms or frameworks

One example is that, as already noted, some complementary/alternative therapies rely on a causal mechanism and/or explanatory framework that differs from conventional biomedicine. It is possible that there is not a mechanism that can be understood or explained in conventional scientific terms. For example, the success of acupuncture in effecting clear clinical outcomes for certain conditions is well documented.<sup>178</sup> However, exactly why and how it works is far from clear in conventional medical terms. Acupuncture functions within, and gets its meaning from, the explanatory framework of traditional Chinese medicine, which is in many respects remarkably dissimilar to Western biomedicine.

A slightly different example is the case of homeopathy. Some studies have shown instances where, as a group, various kinds of homeopathic treatments appear to be more effective than placebo. Yet the exact mechanisms for why this is so in any particular instance are far from understood in terms or concepts accepted in a conventional scientific framework.<sup>179</sup>

### Holistic, individualized interventions

Many conventional therapies are discrete interventions that work only on the physical aspect of a person and are researched and applied in a standardized fashion. In contrast, some, but not all, complementary/alternative therapies are said to be more “holistic” in three senses. First, rather than being discrete interventions, some are more thoroughgoing lifestyle choices involving many health-related activities. Second, they are often thought to work on the mind, which is then presumed to influence the body in certain (unexplained) ways; this can be difficult to measure objectively. Third, complementary/alternative therapies may be more holistic in that they “treat” the whole person, rather than focusing on just one aspect (usually the physical): “CAM treatments may also diverge from conventional medicine in the way they are tailored to individuals so that a patient with identical symptoms and complaints to another may receive entirely different treatments.”<sup>180</sup>

Differences such as these are thought to make it difficult (some say impossible, in certain cases) to evaluate CAM therapies using the same means that scientists evaluate conventional therapies, in which research is designed to isolate as much as possible the measurable and explainable effect of a given therapy on the mechanisms of the body.

Some researchers argue that alternative and complementary medicine requires the development of alternative research methodologies and that the randomised clinical trial (RCT), currently the gold standard for conventional medical research, will not do in all cases. For example, is it possible to double blind acupuncture treatment? What is the appropriate and ethical placebo for chiropractic? Others insist that established methodologies, including RCTs, are quite satisfactory for addressing the majority of study questions. Still others emphasise the fact that many CAM practices have their roots in other times and cultures, and use diagnostic and treatment criteria that differ substantially from those of Western biomedicine. Clinical trials may therefore be inadvertently biased by improper patient selection, variations in practitioner training and experience, and treatment protocols which are too rigid and cannot accommodate the individualised treatment that is the hallmark of so many CAM practices.<sup>181</sup>

<sup>178</sup> NIH Consensus Statement, *supra*, note 167.

<sup>179</sup> Buckman R, Lewith G. What does homeopathy do – and how? *British Medical Journal* 1994; 309: 103-106. See also Eskinazi D. Homeopathy re-visited – is homeopathy compatible with biomedical observations? *Archives of Internal Medicine* 1999; 159: 1981-1987.

<sup>180</sup> Milbank Memorial Fund. *Enhancing the Accountability of Alternative Medicine*. New York: Milbank Memorial Fund, 1998.

<sup>181</sup> Best et al, *supra*, note 164, citing Vickers A. Methodological issues in complementary and alternative medicine research: a personal reflection on 10 years of debate in the United Kingdom. *Journal of Alternative and Complementary Medicine* 1996; 2(4): 515-524 (arguing for alternative methodologies); Levin JS et al. Quantitative methods in research on complementary and alternative medicine: a methodological manifesto. *Medical Care* 1997; 35(11): 1079-1094 (arguing for established methodologies); Hammerschlag RJ. Methodological and ethical issues in clinical trials of acupuncture. *Journal of Alternative and Complementary Medicine* 1998; 4(2): 159-171 (questioning appropriateness of clinical trials for many CAM practices). See also Jacobson JS et al. Research on complementary therapies for cancer: issues and methodological considerations. *Journal of the American Medical Women's Association* 1999; 54(4): 177-181.

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This paper does not attempt to determine which CAM therapies can be assessed using conventional scientific means, or which alternative methodologies may be appropriate for evaluating specific CAM therapies. However, there are a number of general considerations that should inform the development of an approach to CAM research.

There are many differences between complementary and/or alternative medicine and mainstream medicine, but these differences should not be assumed or exaggerated.

First, although there are many differences between complementary and/or alternative medicine and mainstream medicine, these differences should not be assumed or exaggerated and should not be used as an excuse to avoid comparing the two. For example, it is wrong to characterize all complementary and/or alternative therapies as having a more holistic approach to health. Some alternative therapies are part of a more holistic approach to health care, and some are not. In any given instance, researchers must become very familiar with the particular details of an alternative therapy they plan to evaluate. Various complementary/alternative therapies and approaches to health will often aim at different outcomes and may need different assessments. Some are suitable to be submitted to the same evaluations as conventional medicine; others are less so because of their different methods and/or goals. Moreover, some forms of complementary/alternative medicine might be submitted to similar modes of evaluation, either because they share the desired clinical outcome and/or because they function to some extent within the same explanatory framework.

Most interventions, both conventional and complementary, have never been subjected to good-quality randomized controlled trials.

Second, while health-care practices may function within different paradigms (ie, explanatory frameworks), this does not mean there is disagreement on the desired outcomes. While understanding the internal logic of another practice may be difficult, there can be agreement that physical and/or emotional well-being are the final goals of both forms of therapy. This agreement may make it possible to have some uniformity in evaluation by focusing on patient outcomes. Complementary/alternative practitioners and researchers working according to conventional methods should be able to discuss commonalities and differences and should investigate potential ways of conducting research.

The hierarchy of evidence of effectiveness recognises randomised controlled trials as the gold standard. However, most interventions, both conventional and complementary, have never been subjected to good quality randomised controlled trials. Moreover, such trials may not be the best way of assessing whether complementary medicines are effective. The reductionist approach of the randomised controlled trial may fail to allow for the holistic effect that is central to the philosophy of most complementary therapies. Furthermore, the beneficial effects are often so obvious, the side effects so rare and mild, and the duration of effect so variable even after a single exposure that perhaps observational studies may be enough to prove benefit. If not, then randomised controlled trials that compare whole treatments, or packages of care, rather than individual treatments may be a better approach. This would allow inclusion of the things that matter to patients rather than just those that matter to the investigators.<sup>182</sup>

Third, when evaluating a practice, there must be a clear understanding of the desired outcome. It does not make sense to compare the clinical effectiveness of, for example, a spiritual healing practice with chemotherapy for cancer, if the spiritual healing practice aims at some form of holistic well-being and does not claim to be able to cure cancer. In other words, it is

<sup>182</sup> Smith I. Commissioning complementary medicine [editorial]. *British Medical Journal* 1995; 310: 1151-1152 [references omitted].

crucial to say *with respect to what* a practice is effective or not. The specific goals of different products or practices must be considered if a regulator charged with ensuring quality control and minimum standards is to assess the claims made by producers or practitioners.

Finally, as a general rule, complementary and/or alternative medicine and conventional medicine should not be submitted to entirely different modes of evaluation and control if they both claim to focus on the well-being and health of individuals. But as the Association of Complementary Physicians of British Columbia has pointed out, care must be taken to avoid a double standard:

Often when multiple clinical trials are conducted, the results are conflicting, but this does not prevent the continued use of the studied treatment in clinical practice. Much of conventional treatment is not based on definite results from clinical trials, but rather on consensus among physicians with experience in a particular area. To accept nothing but clinical trials as evidence of the effectiveness of a non-conventional therapy is to establish a dangerous double standard which limits access to relatively safe therapies. There are other forms of scientific research and it is necessary to include these when evaluating complementary therapies.... There is no question that further research is needed in the area of complementary medicine but to withhold access to complementary therapies until all the evidence is in is not in the best interest of patients.<sup>183</sup>

Randomized clinical trials can certainly be designed to apply, as one research method, to investigating various complementary/alternative therapies. Such trials could be what researchers from the US NCCAM call “full spectrum” studies that examine a system of traditional medicine as a whole, rather than trying to isolate a single core modality within that system.<sup>184</sup> Alternatively, where appropriate, research could focus on a specific modality for treating a specific disease or condition. Some recent articles also suggest that other research methodologies – such as observational studies – may in some cases be designed to yield research data comparable to randomized, controlled trials.<sup>185</sup>

Designing research protocols that provide reliable information presents a key challenge in developing appropriate regulatory mechanisms, but given the fundamental importance of sound evidence to inform policy, this challenge requires urgent attention by researchers and research funders.

### **Ethical Implications of the Principle of Beneficence**

Many complementary/alternative therapies are being used even though their effectiveness has not yet been shown (or they have been shown to be ineffective). The principle of beneficence leads to two ethical conclusions.

#### ***Ethical duty to research efficacy of various complementary/alternative therapies***

If there are no funds there will be no research. If there is no research, we will be unable to find out whether complementary and alternative medicine does more good than harm. Yet this is the central question destined to determine its role in future health care. Simple answers or broad generalisations are not possible. Each of the numerous techniques has to be evaluated separately and on its own merits. Some forms of complementary and

There is no question that further research is needed in the area of complementary medicine but to withhold access to complementary therapies until all the evidence is in is not in the best interest of patients.

<sup>183</sup> Association of Complementary Physicians of British Columbia, *supra*, note 9 at 3.

<sup>184</sup> Nahin RL, Straus SE. Research into complementary and alternative medicine: problems and potential. *British Medical Journal* 2001; 322: 161-164

<sup>185</sup> *Ibid*; Concato J et al. Randomized, controlled trials, observational studies, and the hierarchy of research designs. *New England Journal of Medicine* 2000; 342: 1887-1892; Benson K, Hartz A. A comparison of observational studies and randomized, controlled clinical trials. *New England Journal of Medicine* 2000; 342: 1878-1886.

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alternative medicine are safe but others aren't; some are effective while others may be pure placebos.<sup>186</sup>

There should be a recognized ethical duty in the scientific and regulatory communities to generate data on the effectiveness of the most frequently used complementary and/or alternative therapies.

The current “free market” that reigns among most complementary and/or alternative therapies, where buyers must beware, is highly problematic because of the unknown safety and efficacy of such therapies. Because complementary and/or alternative medicine use is so prevalent, it is imperative that researchers and regulators determine its effectiveness. Without reliable data, both conventional and complementary/alternative practitioners do not have a stable basis from which to make treatment suggestions. Nor can users exercise their moral (and legal) right to informed decision-making about their health care. Currently, the burden of testing the effectiveness (and safety) of these therapies has largely fallen on people with HIV/AIDS and other users who engage in self-experimentation.

There should, therefore, be a recognized ethical duty in the scientific and regulatory communities to generate data on the effectiveness of the most frequently used complementary and/or alternative therapies. Researchers should begin effectiveness studies for those therapies for which there are

- encouraging, reliable preliminary effectiveness data;
- consistent anecdotal evidence of effectiveness; and/or
- evidence of common use among people with HIV/AIDS.

### ***Erring on the side of caution***

A second point concerns risk/benefit analysis more generally. As we have indicated, some complementary and/or alternative therapies have harmful effects that are inadequately balanced by benefits. But, as we have indicated, the data that are available regarding both safety and effectiveness are sparse and often not of very high quality. We must therefore ask why is it justified to discount (often anecdotal) reports of complementary and/or alternative medicine effectiveness, yet take heed when we hear reports of alternative medicine toxicities.

As a general matter, in evaluating any treatment (conventional or complementary), it is prudent to adopt a more cautious stance toward risk/benefit analysis and to err on the side of caution. The first order of business should always be to ensure that therapies in use are safe. Once safety has been established, the second task is to ensure that therapies in use are effective. This is the position adopted in standard drug testing. The first phase of testing is meant to establish the safety of drug dosages through a small sample, and only after data on effectiveness has been generated should one proceed to a larger trial. This stance is defensible because harms should generally be minimized or avoided, and because harms are often irreversible – that is, a return to the initial state of health is not possible.

Since much of the existing evidence suggesting that complementary and/or alternative therapies are effective is unreliable and unstable across time, researchers and manufacturers/providers should recognize their ethical duty to undertake effectiveness research. Since producers of pharmaceutical products are not likely to be interested in funding this research, more research funding should be made available through public funders, and alternative means of funding (eg, producers of health products) should be explored.

### ***Implications for policy***

The conventional approach toward drug products is to submit them to a tight pre-market control system and to some form of post-market surveil-

<sup>186</sup> Ernst E. The role of complementary and alternative medicine. *British Medical Journal* 2000; 321: 1133-1135 at 1134.



lance. Under such a system, drug products have to be approved by a regulatory agency (eg, Canada's Health Products and Food Branch) *before* they can enter the market, ordinarily after fulfilling strict requirements that demonstrate both safety and effectiveness. Once on the market, the same products are submitted to a post-market control mechanism, under which producers remain obliged to report any adverse reactions to the drug. (The adequacy of Canada's current mechanisms for both pre-market evaluation and post-approval surveillance of conventional drugs is a matter of ongoing debate.)<sup>187</sup>

Regulatory agencies may also be actively involved in the post-marketing testing of the safety of a product, which testing simultaneously focuses on quality and safety. Regulatory agencies rarely require pre-market approval of all food products, but will be involved in random or more systematic control of food products that are on the market. (They may also prohibit the use of certain products in food, or determine a maximum level for a given product. Regulations establish, for example, maximum residue limits for pesticides in foods.)

This shows how important definitions of natural health products can be in a regulatory system. If a certain natural health product is qualified as a drug, it generally will be submitted to more stringent testing and pre-approval requirements than if defined as a food product. Thus, the pre-market approval and post-market control policy option could be considered for those therapies that make claims to effectiveness (ie, treat them more like drugs). For those therapies that make no effectiveness claims, it may be sufficient to ensure that the therapies are safe (ie, treat them more like foods).

The federal government is currently in the process of recognizing, in law, a new intermediate category of "natural health products" that are neither "foods" nor "drugs." Health Canada's new Office of Natural Health Products is currently crafting a proposed regulatory framework that takes into account the sorts of considerations raised here, by tying the strictness of pre-marketing scrutiny to the available evidence regarding both the safety of a product and its efficacy in cases where the manufacturer/vendor wishes to make health claims regarding the product. As for post-approval surveillance of natural health products, the primary focus of which is the safety of a product, there is no reason to subject natural health products to any lesser degree of scrutiny than products legally classified as "drugs."

### **Implications of Principles of Non-Maleficence and Beneficence: Recommendations**

The preceding discussion considered the ethical implications of both the principle of non-maleficence and the principle of beneficence. Some recommendations have already been made regarding the need for practitioners to elicit from patients information about their use of complementary/alternative medicine. Considering these two ethical principles jointly also yields a number of further recommendations for action in the areas of research, education, and regulation in the field of complementary/alternative therapies.

#### **Recommendation 6**

**The Canadian Institutes for Health Research, the Office of Natural Health Products, other health-care research funding agencies, and Health Canada, should participate (or continue participating) in developing, implementing, and funding an agenda for research into the safety and efficacy of complementary/alternative medicine as part of HIV/AIDS health care (both natural**

The federal government is currently in the process of recognizing, in law, a new intermediate category of "natural health products" that are neither "foods" nor "drugs."

<sup>187</sup> For example, see Canadian Treatment Advocates Council. A Pilot Test to Determine the Most Effective Methods of Collecting Information in a Post-Approval Surveillance System of Anti-HIV Treatments, December 1999; Mintzes B. How safe are our medicines? Monitoring the risks of drugs after they are approved for marketing. *DES Action Canada*, March 1999 ([www.web.ca/~desact/anglais/legisl/4safe.html](http://www.web.ca/~desact/anglais/legisl/4safe.html)); and the acknowledgment in a recent CMAJ editorial that "even major pharmaceutical companies, with extraordinary depth of resources, abundant traditional scientific expertise, and extensive premarket evaluation of short-term safety, have a patchy record when it comes to postmarketing surveillance for severe but rare side effects; some natural scepticism about the Natural Health Products Directorate [editorial]. *Canadian Medical Association Journal* 2001; 164(5): 613.

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health products and other therapies). The process of developing and implementing this research agenda should involve people with HIV/AIDS as patients/consumers, those providing services to people with HIV/AIDS (including conventional and complementary/alternative health practitioners, community-based organizations), and relevant and appropriate government regulators (eg, ONHP in the case of research into natural health products).

### **Recommendation 7**

Health Canada, provincial health ministries, the Canadian Institutes for Health Research, the Office of Natural Health Products, and health-care research funding agencies should further investigate the possibility of developing and supporting a “virtual” institute or centre of excellence in complementary/alternative health-care research (to research both natural health products and other complementary/alternative therapies).

### **Recommendation 8**

In funding research in the areas of complementary/alternative medicine, health-care research funding agencies should give priority to research into the safety and effectiveness of those complementary/alternative therapies for which there is:

- (a) encouraging, reliable preliminary effectiveness data,
- (b) consistent anecdotal evidence of effectiveness,
- (c) evidence of common use among people with HIV/AIDS, and/or
- (d) evidence of known or potential significant adverse effects, including where used in conjunction with conventional HIV/AIDS treatments.

### **Recommendation 9**

Health-care research funding agencies should build up a roster of properly trained individual experts in various fields of complementary/alternative therapy practice who can contribute their expertise to panels or committees reviewing proposals for research funding.

### **Recommendation 10**

Health Canada, provincial health ministries, and health-care research funding agencies need to make funds available for – and schools and training programs in complementary/alternative medicine need to include in their curriculum – the development of research skills among practitioners of complementary/alternative therapies, so as to generate more and better-quality research into the safety and efficacy of complementary/alternative therapies.

**Recommendation 11**

Health Canada and health-care research funding agencies should ensure that at least some of their funds used for researching complementary/alternative therapies in HIV/AIDS care is allocated to community-based research projects. Because a significant number of people with HIV/AIDS likely access commonly used complementary/alternative therapies or information about such therapies through community-based organizations, this approach to research could be particularly well-suited to investigating at least some of the key research areas identified above. Furthermore, it offers a way to circumvent resistance to research into complementary/alternative medicine that persists in more institutional research settings, and is consistent with a philosophy of active patient/user involvement in care and treatment decisions common to many people with HIV/AIDS and users of complementary/alternative medicine generally.

**Recommendation 12**

The Canadian Association for HIV Research (CAHR) and similar bodies organized at regional or provincial levels should encourage interest among their members in research into complementary/alternative therapies as a component of health care for people with HIV/AIDS.

**Respect for Personal Autonomy**

The discussion thus far has largely been about protecting people with HIV/AIDS from the harms, or lack of benefit, that may be associated with certain complementary and/or alternative therapies. Such a protective stance toward competent adults may strike some as paternalistic. We must therefore explain the tension that can result between the principles of non-maleficence and beneficence on the one hand, and the principle of respect for personal autonomy on the other – a tension evident in the following view expressed in an editorial in the Canadian Medical Association Journal: “Much as we welcome the extension of food and drug regulation into the nebulous terrain of the natural [health products], we cannot help asking: Safety and efficacy are one thing, but since when have ‘philosophical and cultural diversity’ been a guarantor of either?”<sup>188</sup> Furthermore, we need to consider why this tension is so marked in the case of people with HIV/AIDS using unconventional therapies.

The principle of respect for personal autonomy requires that we respect the choices and actions of those individuals who are competent, act voluntarily, and with sufficient understanding of the existing information relevant to their choice. Clearly, much could be said regarding the proper way to understand the concepts of “competence,” “voluntariness,” and “understanding” (not to mention how one determines what information is “relevant”).<sup>189</sup> But for our purposes, we need only understand such terms in a common-sense fashion. Thus,

- “competence” means something similar to “of sound mind”;
- “voluntariness” means free of internal constraints (eg, compulsions) or

<sup>188</sup> See CMAJ, *ibid.*

<sup>189</sup> For details, see Beauchamp & Childress, *supra*, note 105, chapter 3.

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- external constraints (eg. coercive pressures); and
- “understanding” means that the relevant information has been gathered and processed properly.

Such conditions are met for the most part among people with HIV/AIDS (who are neither minors,<sup>190</sup> nor experiencing impairment of mental function due to HIV or other causes). Decisions taken and actions performed should be respected as being expressions of the will of an autonomous person *unless* there is reason to expect that the decision is not entirely voluntary or is made under conditions of false information.

### Real Autonomy Requires Information

To respect the autonomous actions of people takes on special significance for those with HIV/AIDS because the prevalent self-administration of CAM therapies among this population is often an empowering reclaiming of personal responsibility for health promotion and maintenance. On this basis, some argue that the unrestricted use of alternative therapies should be permitted: the worry over the risks and questionable benefits of many complementary and/or alternative therapies should not matter that much, *provided that* people with HIV/AIDS are making competent, voluntary decisions with sufficient understanding of the relevant information.

But this is precisely the problem. If we are to respect personal autonomy, then reasonable efforts must be made to ensure that people with HIV/AIDS have reliable, truthful information about the risks and benefits of alternative therapies. Research about the risks and benefits of complementary/alternative therapies is dictated not only by the principles of non-maleficence and beneficence, but because of the value we place on respecting personal autonomy. The claim to unconstrained access to any given therapy (conventional or unconventional) on the basis of respecting the individual's autonomy is weakened where that person's autonomy itself is weakened by a lack of information necessary to make an informed choice.

### Difficulty with the Argument for “Unconstrained Autonomy”

One perspective often present in some HIV/AIDS communities (and others dealing with serious illnesses) is the “unconstrained autonomy” viewpoint. This is the view that when one is dealing with so-called “catastrophic” diseases, such as terminal cancers and HIV/AIDS, those who suffer from such illnesses have the right, often called a “catastrophic right,”<sup>191</sup> to engage in any healing practices at all, so long as they are acting autonomously, that is, competently, voluntarily, and with full understanding of the relevant information.

This is the principle of respect for personal autonomy taken to its logical conclusion, and it would sanction the unconstrained use of any and all therapies regardless of the associated high risk, known or unknown. In the context of conventional medicine, this argument has been used to request access to promising new treatments that have not yet been validated in clinical trials. In the context of CAM, the recognition of this principle would mean that there should be no restraint on access to any therapy whatsoever.

However, some take the view that the notion of a “catastrophic right” is not recognized as a legal concept, and that the spirit of any regulatory drug-approval system cannot be reconciled with the extreme vision of such a right.<sup>192</sup> Indeed, while special-access programs have been developed to allow individuals who are terminally ill to obtain access to drugs not legal-

<sup>190</sup> For a discussion of Canadian law about minors and medical decision-making, see: Gilmour J. Minors. In: Downie J, Caulfield T (eds). *Canadian Health Law and Policy*. Toronto: Butterworths, 1999, at 179-215; Elliott R. HIV testing & treatment of children. *Canadian HIV/AIDS Policy & Law Newsletter* 1999; 5(1): 1, 3-8.

<sup>191</sup> See: Dixon J. *Catastrophic Rights: Experimental Drugs & AIDS*. Vancouver: New Star Books, 1990; and Freedman B. Compassionate access to experimental drugs and catastrophic rights. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 3(1): 44-46.

<sup>192</sup> See Lemmens T. Compassionate access to experimental drugs: balancing interests and harms. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 3(1): 43-44; Lemmens T. A response to the Parliamentary Sub-Committee's report and recommendations. *Canadian HIV/AIDS Policy & Law Newsletter* 1997; 3(2/3): 40-43.

ly available for sale in Canada, the fact that there is an exceptional procedure in place affirms the general principle that regulatory agencies are under a general duty to ensure the safety of products.

A paternalistic intervention is an interference with the choice of another person in order to protect them from harm. The justification offered is an appeal to the increased well-being of the person subject to interference. In the current context, paternalism would mean limiting the choices of people with HIV/AIDS, in the interest of preventing harm, so that they may not be able to use all the complementary/alternative therapies they wish.

How can such paternalism be justified? Those who defend paternalistic restrictions on autonomy will generally argue that autonomy is an ideal and that people are subject to many influences that affect their autonomy. One must first recognize that, currently, HIV disease has no cure and is associated with often debilitating symptoms and life-threatening diseases. Moreover, a significant number of people with HIV/AIDS self-administer complementary/alternative therapies, or access CAM practices without the input of conventional physicians. In some cases, the use of such therapies can be based on misinformation or incomplete information, particularly in light of insufficient data regarding safety and efficacy. Anxiety and hopelessness can often set in among people with HIV/AIDS who have received little benefit from conventional therapies and whose health is deteriorating. This could lead to indiscriminate use of complementary and/or alternative medicine (which in many cases is not currently subject to any sort of regulatory, quality control mechanisms) that can result in emotional, financial, and physical harms that are not clearly offset by corresponding benefits. But the hopelessness that could propel a person to seek out possibly harmful and ineffective therapies can act as an internal constraint on voluntariness.

As Freedman noted in his discussion of access to non-validated therapies for HIV/AIDS, even when a person with HIV/AIDS “is beyond help, it does not follow that he or she is beyond being hurt as well. . . . The death of an AIDS patient is not so imminent that it cannot be hastened by misguided treatment, nor is the disease so dreadful that the quality of life . . . cannot be worsened by inappropriate treatment.”<sup>193</sup> Although the non-validated pharmaceutical therapies of which Freedman spoke carried more toxic side effects, the general point is applicable here: though people with HIV/AIDS may sometimes be in a situation of despair because they have no treatment available, it does not thereby follow that they are beyond harm. Situations of catastrophic illness warrant special care, in that promising treatments, including CAM, should be made available as soon as reasonably possible. Special-access programs are appropriate and society may want to offer people with terminal illness the option of taking higher risks. However, terminal illness also increases vulnerability to exploitation, based on the creation of false hope. A higher risk can only be justified if there is a stronger likelihood of benefit. Basic safety standards ought not to be ignored.

This sort of reasoning was adopted by the US Supreme Court in the early case of *US v Rutherford*, in which terminally ill cancer patients and their spouses sought an injunction preventing the government from interfering with the interstate shipment and sale of Laetrile, a drug that was not approved for distribution under US law. The Court rejected their attempt to preserve their access to Laetrile, ruling that:

For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.... Even critically ill individuals

Even when a person with HIV/AIDS “is beyond help, it does not follow that he or she is beyond being hurt as well.”

<sup>193</sup> Freedman B and the McGill/Boston Research Group. Nonvalidated therapies and HIV disease. *Hastings Center Report*. 1989; 19: 14-20 at 16.

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Terminal illness also increases vulnerability to exploitation, based on the creation of false hope.

may have unexpected remissions and may respond to conventional treatment. Thus, as the [Food and Drug Administration] Commissioner concluded, to exempt from the Act drugs with no proved effectiveness in the treatment of cancer “would lead to needless deaths and suffering among ... patients characterized as “terminal” who could actually be helped by legitimate therapy.... To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner’s authority over all drugs, however toxic or ineffectual, for such individuals. If history is any guide, this new market would not be long overlooked. Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer... [H]istorical experience does suggest why Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise. We note finally that [this conclusion] does not foreclose all resort to experimental cancer drugs by patients for whom conventional therapy is unavailing. [The Act] exempts from premarketing approval drugs intended solely for investigative use if they satisfy certain preclinical testing and other criteria.<sup>194</sup>

However, other courts have taken a less paternalistic approach. For example, in *Schneider v Revici*, in which a woman with breast cancer sued a doctor for treating her with “non-toxic,” non-invasive methods such as selenium and dietary modifications, the US Court of Appeals for the 2nd Circuit ruled that

we see no reason why a patient should not be allowed to make an informed decision to go outside currently approved medical methods in search of an unconventional treatment. While a patient should be encouraged to exercise care for his own safety, we believe that an informed decision to avoid surgery and conventional chemotherapy is within the patient’s right “to determine what shall be done with his own body.”<sup>195</sup>

The Court reiterated this approach in another case involving the same practitioner a few years later. In *Boyle v Revici*, the Court again stressed that, while patients should be encouraged to exercise care for their own safety, they have the right to make an informed decision to “expressly assume the risk of malpractice and dissolve the physician’s duty to treat a patient according to the medical community’s accepted standards.”<sup>196</sup> And in a more recent US case, *Charrell v Gonzalez*, a patient with cancer decided to forgo conventional chemotherapy/radiation treatments for her cancer and to follow her practitioner’s alternative nutritional regimen instead. When she sued him, the jury found her partly responsible for her own injuries, apportioning 51 percent of the liability to the practitioner and 49 percent to her. It found that she had implicitly assumed some of the risk of injury when she decided to undergo the alternative therapy. The New York Supreme Court upheld this as a reasonable jury finding.<sup>197</sup>

A key difference should be noted between the *Rutherford* case on the one hand, and the *Revici* and *Charrell* cases on the other, which likely explains the different approaches taken. In *Rutherford*, the patients were trying to

<sup>194</sup> *United States v Rutherford*, 442 US 544, 99 S Ct 2470; 61 L Ed 2<sup>nd</sup> 68 (1979).

<sup>195</sup> *Schneider v Revici*, 817 F.2d 987 (2<sup>nd</sup> Cir 1987); [1987] CA2-QL 414 (QL), also citing: *Schloendorff v Society of the New York Hospital*, 211 NY 125 (1914).

<sup>196</sup> *Boyle v Revici*, 961 F.2d 1060 (2<sup>nd</sup> Cir 1992); [1992] CA2-QL 476 (QL).

<sup>197</sup> *Charrell v Gonzalez*, 660 NYS.2d 665 (1997, Sup Ct), affirmed [1998] NY-QL 3146 (App Div) (QL).

prevent the government from exercising its regulatory authority in a way that would hinder their access to an unproven (and, as it turned out, ineffective) therapy that had not been approved for sale. It therefore directly raised the question of the appropriate balance between the ethical principles of non-maleficence, beneficence, and respect for autonomy. In contrast, the *Revici* and *Charrell* cases did not raise the issue of the government's role in regulating health products in the public interest; rather, they dealt with the question whether a patient, informed of the risks and acting autonomously, could decide to bypass approved medical methods in search of CAM treatment.

The acceptability of paternalist intervention should depend on the degree of risk, on a careful assessment of the potential benefit, and on a careful analysis of the level of knowledge of risks and benefits among users of CAM. As Cohen, a leading US expert on the legal dimensions of complementary and alternative medicine argues:

The paternalistic approach measures patient well-being solely through the biomedical model. It defines, adjudicates, and resolves legal dilemmas by adopting the opinions of biomedical experts, remote insurance adjusters, judges, and other parties – opinions that are based on purportedly objective criteria such as certain levels of acceptance, forms of documentation, and judgments about medical necessity.... The paternalistic approach assumes that patients are dependent children who cannot be trusted to make appropriate health care choices.... Integral health care entrusts the patient with greater responsibility for prevention and self-care.... The legal framework [for integrated health care] will protect such freedom by recognizing that the choice of treatment and responsibility for the body ultimately lies with the individual, not the state.

Weak paternalism protects persons against substantially nonvoluntary conduct, such as conduct by an addict, while strong paternalism violates informed, voluntary, and autonomous choice. Strong paternalism is justified only if the following conditions are satisfied: (1) the patient is at risk of a significant preventable harm; (2) the paternalistic action will probably prevent the harm; (3) the projected benefits to the patient of the paternalistic action outweigh its risks to the patient; and (4) the least autonomy-restrictive alternative that will secure the benefits and reduce the risks is selected. With regard to these conditions, many complementary and alternative treatments, such as chiropractic, massage therapy, and highly diluted homeopathic remedies, are generally safe and non-toxic, when provided within appropriate professional parameters, and relative to comparable conventional treatments. Prohibiting or controlling the voluntary, informed choice of patients, particularly terminally ill patients, to access such treatments is a highly restrictive means of protecting patients from therapeutic choices that medical orthodoxy finds objectionable. Clear informed consent forms, disclaimers, mandatory referrals to and consultations with medical doctors, and good communication between providers and patients manage the risks of such treatments in ways that more fully respect patient autonomy.<sup>198</sup>

<sup>198</sup> Cohen MH. *Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives*. Baltimore: Johns Hopkins University Press: 1998: at 115-117.

### **Ethical Implications of Respecting Personal Autonomy**

Once safety and effectiveness information has been generated, one must determine how best to use and distribute it, in order to further the goal of personal autonomy.

#### **Educate patients/users**

First, information about the risks and benefits of complementary and/or alternative therapies can be given directly to people. This would imply different strategies depending upon the therapy under consideration. For complementary and/or alternative therapies such as herbal preparations that are self-administered and freely available, a minimum ethical requirement is that the products themselves be labeled with the correct information in order to help users make informed choices. For example, a label may contain information such as: “This herbal preparation must not be taken in conjunction with the following medications...”; “No reliable scientific data exist showing effectiveness of this product for ...”; “Do not exceed X capsules a day...” As long as people with HIV/AIDS have reliable and up-to-date information, those in the scientific and regulatory communities are carrying out their minimal duties to respect the personal autonomy of health-care consumers.

Similarly, for those therapies for which one must seek a practitioner (eg, chiropractic), the practitioner should be under a duty to disclose how much evidence exists for the safety and effectiveness of the techniques they are practicing, and the nature and reliability of such evidence. Users, for their part, should not simply assume that someone who practises a complementary/alternative therapy bases their practice on reliable, current, and truthful evidence.

#### **Educate practitioners (conventional and complementary)**

The principle of respect for personal autonomy has additional implications for health-care practice as it relates to CAM. As previously noted, the principles of non-maleficence and beneficence require both conventional and CAM practitioners to elicit information from their patients in order to determine which therapies they may be using, and make as informed a judgment as possible regarding overall treatment strategies. In order to be effective in their role as information providers, practitioners need to attempt to be as up to date as possible with the various complementary/alternative therapies in use, along with their respective risks and benefits.<sup>199</sup> Not only are practitioners under a duty to refrain from doing harm and to attempt to bring about benefit for their patients; they are also under an ethical duty to nurture the personal autonomy of their patients by providing them with up-to-date information about frequently used complementary/alternative therapies.

Considerable work remains to be done in this regard, as is illustrated by a few Canadian studies that specifically examine the knowledge base of conventional medical practitioners regarding complementary/alternative medicine.

In 1995, a random sample of 200 general practitioners in Québec found that 83 percent of them regarded at least one of the following – acupuncture, chiropractic, and hypnosis – as being of some clinical use. Of the respondents, 60 percent knew at least one practitioner of a complementary health service for referral purposes, and 59 percent had referred patients to physicians practicing such a service, while 68 percent had referred patients to non-medical practitioners of complementary services.<sup>200</sup> Although 15

A minimum ethical requirement is that the products themselves be labeled with the correct information in order to help users make informed choices.

<sup>199</sup> Eisenberg, *supra*, note 157.

<sup>200</sup> Goldszmidt M, Levitt C, Duarte-Franco E, Kaczorowski J. Complementary health care services: a survey of general practitioners' views. *Canadian Medical Association Journal* 1995; 153: 29-35.



percent said they currently provided one of these services, their overall self-reported knowledge of CAM was poor: 11 percent reported knowing a lot about acupuncture, 10 percent felt they knew a lot about chiropractic, and eight percent said they knew a lot about hypnosis. Only eight percent reported receiving any previous training in acupuncture; two and three percent had received training in chiropractic and hypnosis, while 48 percent said they would like further training in at least one of these services.

Another survey, undertaken at a single medical school in Alberta in 1999, found that 52 percent of first-year students had used some form of CAM, and 74 percent of these felt they had benefited from it. All the respondents felt that physicians should have some knowledge about common complementary therapies, and 84 percent wanted further education themselves. Their self-reported knowledge about CAM was low and generally derived from friends, relatives, personal experience, or the media. 65 percent of first-year students wanted a course in complementary and alternative medicine, and the researchers recommended that evidence-based, non-judgmental education about CAM be a required component of undergraduate medical education.<sup>201</sup>

More extensive research examined the current state of CAM within the curriculum of all medical schools in Canada. In 1999, researchers surveyed all 16 Canadian medical schools to determine what education is being provided about complementary and alternative medicine in the undergraduate curriculum. The survey covered 18 complementary therapies selected from the list generated by the National Center for Complementary and Alternative Medicine at the US National Institutes of Health, ranging from acupuncture to reflexology. The survey showed that:

- Acupuncture and homeopathy were the CAM therapies most often included in course material.
- Only two schools reported that they provide instruction on the actual practice of one or more complementary therapies.
- Faculty at Canadian medical schools believe that they should provide a general conceptual overview of alternative medicine, and that it is acceptable to deal with the various therapies as a group.

The authors note the contrast with the situation in the UK and the US. A 1997 survey of British medical schools found there was little education on complementary and alternative medicine, although it was an area of active curriculum development at that time.<sup>202</sup> A recent survey of all 125 medical schools in the US reported that 67 percent of them offered stand-alone courses in various topics related to CAM, and nearly all of the other schools (30 percent) incorporated these topics as part of required courses.<sup>203</sup>

### Recommendation 13

**Health Canada, provincial ministries of health, and health-care research funding bodies should fund the development of (a) curricular materials on complementary/alternative therapies that can be incorporated into the core curriculum of conventional health-care practitioners, and (b) curricular materials in basic areas of conventional biomedical practice that should be incorporated into the core training of complementary/alternative practitioners. Developing such curricular materials should involve existing schools and training programs (conventional and complementary/alternative) that have developed educational/training**

**Non-judgmental education about CAM should be a required component of undergraduate medical education.**

<sup>201</sup> Duggan K, Verhoef MJ, Hilsden RJ. First-year medical students and complementary and alternative medicine: attitudes, knowledge and experiences. *Annals of the Royal College of Physicians and Surgeons of Canada* 1999; 32: 157-160.

<sup>202</sup> Rampes H, Sharples F, Maragh S, Fisher P. Introducing complementary medicine into the medical curriculum. *Journal of the Royal Society of Medicine* 1997; 90: 19-22.

<sup>203</sup> Wetzel MS, Eisenberg DM, Kaptchuk TJ. Courses involving complementary and alternative medicine at US medical schools. *Journal of the American Medical Association* 1998; 280(9): 784-787.

standards in their respective fields, those acting in the field, and should also take into account the input of consumers.

### **Recommendation 14**

Curricular material developed for both conventional and complementary/alternative health-care practitioners needs to include basic education about HIV/AIDS, HIV/AIDS-specific considerations in the delivery of complementary/alternative therapies, and possibly clinically important interactions between conventional treatments and complementary/alternative therapies in people with HIV/AIDS.

### **Recommendation 15**

Educational institutions training conventional health-care professionals should encourage the development and introduction into their core curriculum of basic training in fields of complementary/alternative medicine that is sufficient to equip all conventional health-care professionals with the basic understanding necessary to recognize the potential benefits and disadvantages of complementary/alternative medicine and to adequately care for patients who may be using, or who may benefit from, complementary/alternative therapies or practitioners.

### **Recommendation 16**

Educational institutions or programs providing training to complementary/alternative health-care practitioners should encourage the development and introduction into their core curriculum of basic training in biomedical health sciences that is sufficient to equip complementary/alternative practitioners with the basic understanding necessary to recognize the potential benefits and disadvantages of conventional biomedicine and to adequately care for patients who may be using, or who may benefit from, conventional biomedical care.

## **Policy Options**

Given the current incomplete state of our knowledge regarding the harms and benefits of complementary and/or alternative therapies, together with concerns about respect for autonomy, several overall policy options will need to be explored in further detail. Here we merely describe the basics of three options.

First, we could adopt a strict policy regarding complementary and/or alternative therapies and practices, such that there could be no marketing of such therapies until they were proven to be both safe and effective. In effect, this would apply the current conventional drug approval system to unconventional products, and would involve prohibitions on the delivery of some CAM services by practitioners in the absence of the necessary evidence of safety and efficacy. This would represent a dramatic, conservative shift from the current state of affairs in Canada, at least with respect to natural health products. Whether it would be a significant change for practitioners providing CAM services would depend in part on their field of practice and the

degree to which their practice is already recognized as “legitimate” in their jurisdiction, including the question whether their practice is reflected in any applicable legislation or professional regulatory scheme.

A second option would be to have virtually no restrictions or regulation on the provision of CAM products or services. In the UK, for example, there is a recognized right at common law for anyone to practise medicine regardless of their training or lack thereof, as long as the individual treated gives informed consent.<sup>204</sup> This approach would represent a dramatic shift from the current state of affairs in Canada for many health-care practitioners, where there is a long-established tradition of professional regulation (described in more detail below). It would represent a modest liberalizing of the current state of regulation of natural health products, which are largely unregulated under current federal law, although still subject to some guidelines and oversight in some cases by Health Canada.

Third, as a more middle-of-the-road approach, we could adopt a more permissive policy regarding (some) complementary and/or alternative products or practices, such that marketing would be allowed, provided that people with HIV/AIDS are informed of all risks and benefits. Mere reliance on the provision of information may be an imperfect approach, but could be improved somewhat by requiring that safety and effectiveness testing is carried out so that no *excessively* risky therapies are made available. In other words, a zone of tolerance for certain levels of risk would be set; beyond a certain threshold of potential risk exceeding uncertain benefit, a product or practice would not be permitted unless and until safety and efficacy data were available. This option represents a more balanced approach that seeks to appropriately reflect the ethical principles of non-maleficence, beneficence, and respect for autonomy.

As an adjunct to either the first or third options, one could require that some therapies could be accessed only through a practitioner who meets certain qualifications with regard to conventional or complementary/alternative therapies, in which case an even greater reliance would be placed upon regulatory efforts to set standards of acceptable practice.

Key to any policy (and especially a more “hands-off” approach to pre-marketing approval by government) is providing high-quality, up-to-date information as a means of promoting the autonomy of people with HIV/AIDS. A consumer protection policy should aim at requiring manufacturers/vendors to provide detailed information on the content and the quality of a product, and should prohibit false or misleading advertising. Similar considerations regarding the promotion and practice of health-care services should be reflected in the policy approach toward practitioners.

This approach should also be accompanied by adequate provisions that protect consumers against false publicity. If the provision of adequate information is stressed to enhance autonomy, appropriate regulatory intervention has to be developed to counter false claims. This is particularly important in the context of health care, where, as we discussed, people can be vulnerable as a result of their illness and therefore sometimes more easily exploited.

The goal is to ensure the quality of health-care practice and to promote transparency in the contract between provider and patient. A policy approach that promotes informed choice and protects the reasonable expectation people have when they use a certain product or practice, strives to ensure autonomous decision-making. Even if there are no significant known health risks associated with using a given therapy, it would be unethical to allow producers to abuse patients’ expectations about the health benefits of complementary and/or alternative therapies.

The goal is to ensure the quality of health-care practice and to promote transparency in the contract between provider and patient.

<sup>204</sup> United Kingdom House of Lords. *Complementary and Alternative Medicine*. Sixth Report of the House of Lords Select Committee on Science and Technology (HL 123), 21 November 2000, at para 5.9. Available online via [www.parliament.the-stationery-office.co.uk](http://www.parliament.the-stationery-office.co.uk).

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This approach recognizes that there are limits to contractual freedom, in particular when people are in an unequal bargaining position, but focuses on reinforcing autonomous choice rather than on unduly limiting choice through protective measures. The reinforcement of autonomy takes place under such a policy, by ensuring that information relevant for making an informed decision is being provided. This approach is likely to find much support among people with HIV/AIDS. It is in line with the attempt to empower people with HIV/AIDS to control their own health and well-being, which is one of the underlying reasons for many to use CAM in the first place. The active involvement in decisions related to their own health care is a means of asserting personal autonomy that deserves respect.

### Justice

Debates about the proper understanding of justice are among the most contentious in modern ethics. Here, we discuss justice broadly and with a focus on practical concerns. Two elements of justice are important in the context of complementary and/or alternative medicine use among people with HIV/AIDS: distributive justice and compensatory justice.

Distributive justice requires a fair distribution of burdens and benefits in society.

### Distributive Justice

Broadly construed, distributive justice requires a fair distribution of burdens and benefits in society. As applied to the issue of complementary/alternative medicine, the principle has implications in two areas: (i) coverage under health insurance plans, and (ii) distribution of health-care research funds. As noted earlier, the focus of this paper is on the appropriate approach to the regulation of complementary/alternative medicine. Therefore, these concerns are only addressed briefly here.

### Insurance coverage for CAM

Researchers, providers, and patients have raised concerns about access to complementary and/or alternative therapies. One significant constraint on access is the requirement that people pay for many complementary/alternative therapies out of their personal funds, rather than having such health-care expenses covered through a public or private insurance plan – even, in some cases, where there is substantial support for the benefit of such therapies. Among people with HIV/AIDS, for whom unemployment or underemployment is a significant problem, the question of cost is even more important.

The coverage provided by private insurers is largely a function of what the purchaser of the coverage will pay; practically any form of health-care coverage could be purchased if the price paid were high enough. There are numerous questions to be explored regarding whether the current regulation (or lack thereof) of the private health insurance industry in Canada is ethical from the perspective of distributive justice as concerns people with HIV/AIDS; these questions require a separate, detailed analysis. However, because there is no single standard regarding the minimum scope of coverage of health benefits applicable in the private sector, the question of distributive justice for people with HIV/AIDS who use, or would benefit from, complementary/alternative therapies is a more complicated question than can be addressed here.

In contrast, in the public sector, there is (at least in theory) a minimum scope of coverage that is to benefit all eligible citizens and permanent residents; in essence, there is a public standard set out in law that represents the health-care coverage Canadians are willing to collectively purchase through

the pooling of public funds. The *Canada Health Act* requires that, in order to receive federal contributions, the public-health insurance plan of each province/territory must cover “medically necessary” services provided by “hospitals, medical practitioners or dentists, and where the law of the province so permits, similar or additional services rendered by other health care practitioners.”<sup>205</sup> To deny public-health insurance coverage of such services would breach the *Canada Health Act*, the possible penalty for which would be the withholding of federal funds to the province/territory in question.

In addition, if a province/territory were to disproportionately disadvantage a particular group of people in their access to medically necessary services, there could well be a constitutional claim of discrimination, contrary to the equality guarantees in the Charter (section 15), if such disadvantage were directly or indirectly related to one of the prohibited grounds of discrimination.

For example, the Supreme Court of Canada has ruled that a province’s failure to cover the costs of sign language interpretation for deaf patients accessing hospital services constitutes prohibited discrimination on the basis of disability, in that it denies deaf people the same access to health-care services as hearing patients.<sup>206</sup> Justice similarly requires that people with HIV/AIDS do not disproportionately bear the burden of health-care expenses by being denied public health insurance coverage of medically necessary care.

The key question is thus: Which services are “medically necessary”? There is no clear, principled definition of medically necessary services in Canadian law. It certainly means more than the bare minimum necessary to preserve life, given the current extent of coverage in every jurisdiction. These include many procedures and therapies that are not essential to life but are widely accepted as required to meet the minimum standards of care we would expect as patients/consumers in preventing and treating illness and disease. But exactly what is covered by public health insurance as “medically necessary” has, in practice, been determined largely by the requests of recognized health professions in negotiation with the provincial/territorial health ministries that pay these costs, and has been influenced by political negotiations between the federal and provincial/territorial governments over their respective contributions.<sup>207</sup>

The crucial question is the extent to which public health insurance schemes should cover complementary/alternative therapies. In order to justify the expenditure of public funds through public health systems that covers “medically necessary” health care, it is unavoidable that access be at least partly contingent on the basis of proven effectiveness. For example, if it is shown that a complementary therapy is effective in treating the effects of HIV disease or reducing the side effects of conventional HIV/AIDS therapies, then a case can be made that people with HIV/AIDS should have access through a public health insurance scheme, just as a heart bypass operation and the necessary anesthetic for such surgery are covered where medically necessary for heart disease. Although demonstrated effectiveness will be a necessary condition for coverage, it may not be sufficient, because considerations of cost-effectiveness also face governments with rising health-care costs. But without convincing evidence of benefit, it will be difficult to make the case that distributive justice requires coverage of a therapy – either conventional or unconventional – from the public purse. Some form of access should be established for those complementary/alternative therapies that are demonstrated to be an aspect of health care on par with other “medically necessary” services already covered.

Justice requires that people with HIV/AIDS do not disproportionately bear the burden of health-care expenses by being denied public health insurance coverage of medically necessary care.

The crucial question here is the extent to which public health insurance schemes should cover complementary/alternative therapies.

<sup>205</sup> *Canada Health Act*, RSC 1985, c C-6, s 9. Note that only “services” are covered, not products. In practice this means that there is no national coverage of individuals’ expenditures on drugs or devices (although some provinces provide “pharmacare” to varying degrees) except for those provided in conjunction with hospital services.

<sup>206</sup> *Eldridge v British Columbia (Attorney General)*, [1997] 3 SCR 624.

<sup>207</sup> Caulfield TA. Wishful thinking: defining “medically necessary” in Canada. *Health Law Journal* 1996; 4: 63-85; Flood C, Archibald T. Legal Constraints on Privately-Financed Health Care in Canada: A Review of the Ten Provinces. April 2000 [on file].

Without convincing evidence of benefit, it will be difficult to make the case that distributive justice requires coverage of a therapy – either conventional or unconventional – from the public purse.

A systemic bias against research into complementary/alternative therapies on the part of health-care research funding agencies is unjust.

### ***Distribution of health-care research funds***

The preceding observations on coverage under health insurance plans highlight yet again that one of the most fundamental needs in the area of complementary/alternative therapies is research. The principle of distributive justice also carries another implication for health care research that is relevant to complementary/alternative medicine. Distributive justice requires that funds for health-care research be distributed so that they stand the best chance of equitably benefiting those in need of care and treatment. Research funding should be biased in favour of research concerning treatments that address the real health-care needs and wants of patients/consumers. This method of selective research is preferable to a haphazard approach that may require potentially limitless resources and is arguably wasteful and ultimately unproductive. In determining the best use of research funds, there must be due consideration of the needs and desires of those whom the research is ultimately intended to benefit. Such a distribution of limited research resources is just because an equitable distribution of benefits is guided by respect for the autonomy of patients/consumers who articulate their health-care needs (and thereby help identify priorities for research), as well as a genuine commitment to their well-being (ie, the principle of beneficence).

The principle of distributive justice leads to two conclusions in the area of health-care research. First, a systemic bias against research into complementary/alternative therapies on the part of health-care research funding agencies (or other institutions playing a critical role in conducting or facilitating health-care research, such as hospitals and universities) is unjust. The bias in allocating limited research funds should favour research, whether conventional or unconventional, that can reasonably be expected to yield information that could improve the overall health and well-being of patients/consumers, rather than favour conventional medical practices over unconventional practices. To dismiss or marginalize research simply on the basis that it investigates unconventional therapies, and to privilege research simply because it fits within the framework of conventional medicine, is to allocate limited funds based on ideological grounds rather than on reasoned assessment of the merits or demerits of a given proposal in light of the currently available evidence and knowledge of patient/consumer needs.

Second, the principle of distributive justice should apply equally to research into complementary/alternative therapies used in HIV/AIDS care. Identified above were the priorities for research required by the principles of non-maleficence and beneficence. Considerations of distributive justice reinforce the conclusion (see Recommendation 8 above) that limited research funds be prioritized for those complementary and/or alternative therapies for which there are encouraging, reliable preliminary data of effectiveness; where there is consistent anecdotal evidence to suggest effectiveness; where there is evidence of known or potentially significant side effects, including where used in conjunction with conventional HIV/AIDS treatments; and/or where the therapy is commonly used among people with HIV/AIDS. If none of these conditions are met, then it would be a misuse of limited resources to invest in the expensive research of such complementary/alternative therapies.

### **Compensatory Justice**

Compensatory justice, broadly construed, requires that people be compensated for the wrongs done to them. One background factor in the recent

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increase in interest in complementary/alternative therapies is that producers of some therapies (eg, herbal preparations) seek to increase their share of the health-care market. Similarly, some practitioners of complementary/alternative therapies seek public recognition of their practices. The principle of compensatory justice requires that providers of health-care products and practices (whether conventional or unconventional) be accountable to patients/consumers. This principle is key to the legal/policy framework for regulating health-care products and practices, as will be discussed in the next chapter.

As a matter of compensatory justice, producers of natural health products must demonstrate that their products (1) meet quality control standards, (2) are safe, and if health claims are made and/or insurance coverage of these products is sought, (3) are effective. This means that the state, given its responsibility to protect the public interest, must ensure that mechanisms are in place that will guarantee the accountability of producers. Similarly, CAM practitioners are ethically required to demonstrate the safety of their practices, and if health claims are made and/or insurance coverage for those practices is sought, their effectiveness.

At the centre of this issue is the health and well-being of those who use these therapies. Those who care about the best interests of the people whom they are committed to help will agree to be accountable for the products and services they provide.<sup>208</sup> Some express legitimate concerns, based on the history of conventional medicine's attitude toward, and treatment of, complementary/alternative medicine and its practitioners, that in law and practice there has been or could be a double standard of accountability, with different, higher standards applied to CAM practitioners than are required of conventional medical professionals. But any practitioner with a commitment to the well-being of patients, be it a conventional or complementary/alternative practitioner, should be committed to the principle of accountability, and should welcome laws and policies that equitably make providers accountable.

Compensatory justice, broadly construed, requires that people be compensated for the wrongs done to them.

<sup>208</sup> Milbank Memorial Fund, *supra*, note 180.







## Legal and Policy Issues

The preceding chapter applied four basic principles to identify and analyze ethical issues related to the use of complementary/alternative medicine. This chapter draws upon the preceding ethical analysis in commenting on existing and proposed legal frameworks in Canada that govern or influence the use of complementary/alternative medicine. How do, and should, those ethical principles inform law and policy? In particular, this chapter looks at legal issues in three areas relevant to complementary/alternative medicine:

- (1) the regulation of natural health products;
- (2) the direct regulation of practitioners; and
- (3) the application of common law principles to practitioners.

Before we look at each of these, it should be understood that legislative authority regarding health care is divided under Canada's constitutional scheme between the federal and provincial/territorial governments. In particular, the federal government has jurisdiction over the licensing and monitoring of products such as drugs, foods, medical devices and, now, the category of "natural health products" that has been created in Canadian law. The provinces and territories have legislative jurisdiction over, and responsibility for, the delivery of health care, and this includes the authority to license and regulate health-care practitioners and other service providers.<sup>209</sup> The common law, as developed by the courts, complements the statutes enacted by the federal and provincial/territorial legislatures, and governs the conduct of product manufacturers or health-care practitioners largely by imposing liability for negligent or otherwise unacceptable conduct. These three components shape

<sup>209</sup> For a good overview, see: Flood CM. The Structure and Dynamics of Canada's Health Care System. Chapter 1 in Downie & Caulfield, *supra*, note 190.

Regulation and labeling alone cannot ensure safety. Safety requires informed consumers who have access to reliable and objective information.

the legal/policy environment in which complementary/alternative health care is provided and used. Each should reflect the ethical principles outlined in the previous chapter.

## Natural Health Products: Laws, Policies, and Practices to Govern Their Use

Until recently, natural health products were classified as either “foods” or “drugs” under federal law.<sup>210</sup> The designation determined the degree of scrutiny a product received before it could be legally sold in Canada, as well as the kinds of claims that could be made about the product by the manufacturer/vendor, and the rigour with which the safety of the product was monitored after it was on the market: drugs receive far stricter scrutiny than food products. With respect to what are now called “natural health products,” Health Canada had developed policies on:

- the use of herbals as non-medicinal ingredients in non-prescription drugs;<sup>211</sup> and
- a special subclass of “drugs” called “traditional herbal medicines” to which less stringent evidentiary standards would be applied than to regular “drugs” in reviewing the product for sale in Canada.<sup>212</sup> (This policy will likely no longer be necessary with a new regulatory framework on natural health products, including herbals that are intended for use as health products.)

In January 2000, the Office of Natural Health Products came into existence as a new regulatory body within Health Canada, on a par with the existing directorate responsible for the regulation of pharmaceutical drugs. In mid-2000, the ONHP carried out a consultation process across the country, seeking input on a proposed new regulatory framework to govern the approval for sale in Canada of a new legal category of “natural health products,” which until now have been classified as either “foods” or “drugs,” often with inappropriate results. In March 2001, as Phase 2 of its consultations, the ONHP released a draft of its proposed regulatory framework for public comment until the end of May 2001, indicating that a second draft would be released in late autumn 2001 for final comments.<sup>213</sup>

Several organizations working in the field of HIV/AIDS prepared a joint submission during the first phase of consultation. Some of these comments have been reflected in the draft of the proposed regulatory framework. These organizations stressed, as a general point, that “regulation and labelling alone cannot assure safety. Safety can only result from informed consumers who have access to reliable and objective information from practitioners who are trained, licensed and regulated as well.”<sup>214</sup> The organizations also made several points with regard to specific issues to be considered in the design and implementation of a new regulatory framework for natural health products. Some of these points and accompanying recommendations are outlined below.

### Product Licensing: Degree of Risk and Nature of Health Claim

Organizations working in the field of HIV/AIDS agree with others such as the Canadian Medical Association<sup>215</sup> and the Nonprescription Drug Manufacturers Association of Canada (NDMAC)<sup>216</sup> on the basic principle that the regulatory system for natural health products should be risk-based, both at the stage of regulatory review and of post-marketing surveillance.

<sup>210</sup> *Food and Drugs Act*, RSC 1985, c F-27.

<sup>211</sup> Health Canada (Drugs Directorate, Therapeutic Products Programme). Drugs Directorate Policy on Herbals Used as Non-medicinal Ingredients in Nonprescription Drugs in Human Use. 22 September 1995. Available online via [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca).

<sup>212</sup> Health Canada (Drugs Directorate, Therapeutic Products Programme). Drugs Directorate Guideline – Traditional Herbal Medicines. 16 November 1995. Available online via [www.hc-sc.gc.ca](http://www.hc-sc.gc.ca).

<sup>213</sup> Health Canada, Natural Health Products Directorate. Proposed Regulatory Framework for Natural Health Products, March 2001; Building Together: Phase 2 in Developing a Proposed Regulatory Framework for Natural Health Products – NHPD Public Consultation, March 2001 (both available via [www.hc-sc.gc.ca/hpb/onhp](http://www.hc-sc.gc.ca/hpb/onhp)).

<sup>214</sup> Letter to ONHP dated 30 September 2000 from Canadian AIDS Society, Canadian HIV/AIDS Legal Network, British Columbia Persons with AIDS Society, Community AIDS Treatment Information Exchange, and Canadian Treatment Advocates Council [on file].

<sup>215</sup> Canadian Medical Association. CMA Policy: Natural health products (update 2000). Available online via [www.cma.ca](http://www.cma.ca).

<sup>216</sup> NDMAC is the national association representing manufacturers, marketers, and distributors of self-care products, including nonprescription medications, herbal remedies/natural health products, and nutritional supplements. It includes major pharmaceutical companies among its members. For a list of active and associate members, see the NDMAC website at [www.ndmac.ca](http://www.ndmac.ca).

For example, in its submission to the Standing Committee on Health in 1998, the NDMAC advocated a flexible approach:

The proposed regulatory framework recognizes that health products fall into a continuum of relative risk. That is, not all products carry the same level of risk nor do all products require the same level of control. Regulatory requirements, therefore, should be based on the relative risk of the product.<sup>217</sup>

Similarly, the stringency of regulatory review should also partly depend on the strength of the health claims made with respect to a product. Given that natural health products are used by consumers for the purpose of improving their health and well-being, it is acceptable to allow a manufacturer to make claims about the benefits of a product (including vitamins and minerals), as long as those claims are substantiated. The stronger the claim, the stronger must be the evidence to support it. Otherwise, only generalized claims should be permitted. It would be unjustifiably paternalistic and unnecessarily restrictive of consumers' access to natural health products to insist that, even if no health claims are made about a product and it carries a relatively low risk of harm, the product cannot be licensed for sale in Canada. Rather, the twin goals of protecting consumers and respecting autonomy are adequately served by requiring that a product label carry a disclaimer, where appropriate, that no specific health claims have been approved for the product (see the next section on labeling requirements).

The stringency of regulatory review should depend on the relative risk of the product and the strength of the health claims made about a product.

### Recommendation 17

**The strictness of regulatory review for pre-marketing approval of natural health products for sale in Canada should correlate with (a) the known or reasonably foreseeable risk of harm from the product, and (b) the strength of the health claim made for the product.**

### Labeling Requirements

Labeling requirements for natural health products, as with pharmaceuticals, are a key legal mechanism for avoiding harm to users, and promoting their well-being and informed decision-making in the use of natural health products. As such, minimum labeling standards are required by the principles of non-maleficence, beneficence, and respect for autonomy.

A recent survey by the NDMAC found that users of natural health products get most of their information from family and friends (30 percent), health books (18 percent) and other health professionals, print articles, and product literature (7 percent). In the NDMAC's view, "this makes it even more important to have proper labelling."<sup>218</sup> Research conducted by NDMAC showed that 87 percent of Canadians read the labels of non-prescription products.<sup>219</sup> Based on further research assessing consumer comprehension using different label models, NDMAC has put forward several recommendations for improving readability and understanding of labels on non-prescription drugs that could easily be applied to labeling of natural health products.<sup>220</sup> (As demonstrated by current federal guidelines applicable to medical devices, under current federal law, the term "label" is sufficiently flexible to include not only the label affixed to a package but also to any material provided with the product, such as package inserts with information about the product, instructions for

<sup>217</sup> NDMAC. Proposed Regulatory Framework for Natural Health Products. Submission to the Standing Committee on Health. 18 February 1998. Available online via [www.ndmac.ca](http://www.ndmac.ca).

<sup>218</sup> G Harrington, NDMAC Director of Public & Professional Affairs, quoted in: Sibbald B. New federal office will spend millions to regulate herbal remedies, vitamins. *Canadian Medical Association Journal* 1999; 160: 1355-1357.

<sup>219</sup> NDMAC. Improving label comprehension. *Pharmacy Post*, March 1999, available online via [www.ndmac.ca](http://www.ndmac.ca).

<sup>220</sup> NDMAC. Technical Research Paper for Improving Label Comprehension, 1999. Available online via [www.ndmac.ca](http://www.ndmac.ca).

use, etc.<sup>221</sup>) The Canadian Medical Association has also recommended that labels on natural health products should advise consumers to inform their health-care provider of their use of the product, even if it may not seem relevant at the time.<sup>222</sup>

The working group of HIV/AIDS organizations noted above identified a number of minimum labeling requirements that should form part of the federal government's new regulatory framework for natural health products. The following recommendations are adapted from that original consensus.

### Recommendation 18

**The federal government should require the following in the labeling of natural health products as a condition of licensing for sale in Canada:**

- **Labels should conform to a standardized format that is accessible to a wide audience (plain language, multiple languages, large print, inclusion of key information on the package itself, and inclusion of other information in large print on package inserts).**
- **Labels should indicate the quantities of all contents, and there should be minimum specified quantities of a vitamin, mineral, or other substance in the product in order for it to be labeled for sale as such.**
- **Labels should indicate whether the product is synthetic or natural, including whether it uses animal sources, and whether it incorporates genetically modified organisms.**
- **Labels should include directions for use, warnings, recommended dosage, and possible interactions with drugs or other natural health products, where known.**
- **Labels should advise consumers to inform their health-care provider of their use of the product, even if it may not seem relevant at the time.**
- **Labels should indicate a toll-free phone number and website for information on how consumers can report an adverse reaction (if and when such a mechanism for post-marketing monitoring is created).**
- **In those cases where the physical packaging of a product does not allow for the inclusion of the above information on or in the package itself, vendors of natural health products should be required to have product monographs including this information available for consumers at the point of sale.**

<sup>221</sup> *Food and Drugs Act*, supra, note 210 at s 2 ("label"); Health Canada (Medical Devices Bureau). Guidance for the Labelling of Medical Devices, Sections 21 to 23 of the *Medical Devices Regulations* (draft), available at [www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmd.html](http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmd.html), at 4.

<sup>222</sup> Canadian Medical Association. CMA Policy: Natural health products (update 2000). Available online via [www.cma.ca](http://www.cma.ca). It should be noted that, as a result of concern over medication errors by conventional health-care practitioners using pharmaceutical products, in 1999 the Canadian Standards Association International published a voluntary standard for labeling, and there have been calls to the Minister of Health for the federal government to adopt it as a regulation that would legally bind manufacturers: Orser B. Reducing medication errors. *Canadian Medical Association Journal* 2000; 162: 1150-51, referencing *Labelling of drug ampoules, vials, and prefilled syringes*. CAN/CSA Z264.2-99. Toronto: CSA International, 1999.

### Post-Approval Surveillance and Other Safety Monitoring Mechanisms

#### *Post-approval surveillance by regulators*

A system for reporting adverse events linked to the use of natural health products would enable consumers and practitioners to provide input regarding their observations and experiences using natural health products. It would also ensure that consumers have easy access to information regarding known adverse reactions (for example, access through a toll-free telephone number) in addition to the disclosure of such confirmed information on product labels (including package inserts).

Under existing law applicable to “drugs,” there are specific obligations on holders of a product licence to report adverse events in relation to a drug to Health Canada, so that it may take any necessary steps (including, possibly, removing the drug from the market) to safeguard the health of consumers. A similar reporting scheme has been proposed for the post-approval surveillance of natural health products.<sup>223</sup>

However, there are two concerns with the proposed requirements for post-approval surveillance, both dealing with the extent of obligations to report adverse reactions to a product.

### **Reporting all serious adverse reactions**

First, the Office of Natural Health Products has proposed that product licence holders be required, within a set period of time (eg, 15 days), to report to the ONHP information regarding *any* “serious adverse reaction” that occurs in Canada in relation to their specific product (as opposed to the medicinal ingredient in it). This would include “unexpected” adverse reactions (defined as adverse reactions that are not identified in nature, or the severity or frequency in the risk information set out on the label). However, in the case of serious adverse reactions that occur *outside* Canada, under the ONHP’s proposals the product licence holder only needs to report those adverse reactions that are “unexpected.”

However, this limitation that requires the reporting of adverse reactions outside Canada only if they are “unexpected” is unwarranted. If the product licence holder is aware of serious adverse reactions in relation to its product, whether expected or “unexpected,” that have occurred outside Canada, it can play a useful role in assisting Canadian regulators in protecting the health of Canadians by notifying the regulator of such events. Whether the adverse reaction happens within Canada or outside Canada should not affect the degree of the reporting obligations: all serious adverse reactions to a licence holder’s product should be reported to Canadian regulators. Keeping Canadian regulators informed about experience elsewhere with the use of a product licensed in Canada is not particularly onerous and is a reasonable condition of receiving a licence to sell a product for profit in the Canadian market.

### **Reporting mechanisms to capture all adverse reactions, serious or otherwise**

Second, given the proposed definition of “serious adverse reaction,” this term would only encompass those noxious and unintended responses to a natural health product that require hospitalization or cause persistent or significant disability, or death. This is an under-inclusive definition that would inadequately protect the health of Canadians: individual adverse events that do not meet this definition of “serious” may, in the longer term, accumulate and have serious effects. (One example in the realm of pharmaceutical products is that reports of lipodystrophy, bone-density loss, and other serious side effects of protease inhibitors among people with HIV/AIDS only began to emerge after several years of use of these products, highlighting the importance of continuing to monitor health products after they enter the market.) Furthermore, tracking a broader range of adverse events (and not limiting monitoring to “serious” events) can provide important information about the safe and effective use of a natural health product beyond that needed to avoid the most extreme unsafe uses that could cause disability, hospitalization, or death.

It is therefore proposed that a post-approval surveillance system should be

<sup>223</sup> Proposed Regulatory Framework, *supra*, note 213.

designed not only to capture *serious* adverse events, but adverse events generally. However, it is important that a reporting system not be overwhelmed with reports of non-serious events, thereby impeding its ability to monitor and respond to serious events. One possibility would be to require of product licence holders and practitioners that they only report “serious” adverse events (to one particular designated recipient of such reports), while at the same time ensuring the accessibility of the reporting system to consumers and health-care practitioners so that they may report non-serious events as well. Such an approach would capture more data regarding both serious and non-serious adverse events over time, but would preserve the ability of federal regulators to concentrate their resources on responding quickly and effectively to reports of the most serious adverse events. One model is the Special Nutritionals Adverse Event Monitoring System (SN/AEMS) operated by the US Food and Drug Administration, which receives reports from consumers, health professionals, public health agencies, and others about adverse events involving “dietary supplements” (defined broadly in federal US law to include what are called “natural health products” in Canada). Reports can be made to federal regulators not only by phone or letter, but also through the FDA’s MedWatch program online, and the system of reports is searchable by members of the public.<sup>224</sup>

Indeed, such a system is really a more formalized mechanism for capturing some of the data about the use, safety, and efficacy of a product that is currently often referred to as “historical knowledge” or “traditional knowledge” – that is, the knowledge base about a natural health product (or practice or system of medicine) that has been built up over decades or centuries by healers and patients. Such information provides “warning signals” to regulators about emerging safety concerns, provides information for consumers, and also helps identify priorities for research in the field of complementary/alternative medicine.

### **Recommendation 19**

**In consultation with consumer groups, manufacturers, health-care practitioners, and manufacturers, the Office of Natural Health Products should establish a post-approval surveillance system to collect the following information about natural health products approved for sale in Canada: adverse events of varying degree; short-term side effects and long-term cumulative effects; and independent data regarding consumer use (eg, prevalence and frequency of use, conditions for which product used, etc).**

### **Recommendation 20**

**Product licence holders should be required by law to report *any* “serious adverse event” relating to the use of their licensed product, whether inside or outside Canada, and whether anticipated or “unexpected,” to the Office of Natural Health Products within a set, short number of days after receiving information about such an event.**

### **Recommendation 21**

**Health-care practitioners should be required by law to report to the Office of Natural Health Products any serious adverse event**

<sup>224</sup> US Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Special Nutritionals. The Special Nutritionals Adverse Event Monitoring System (via [www.fda.gov/medwatch](http://www.fda.gov/medwatch)).

**relating to the use of a natural health product (whether or not licensed for sale in Canada) occurring in Canada or in a patient under their care and of which they have personal knowledge, within a set, short number of days after learning this information.**

### **Other safety monitoring mechanisms**

Post-marketing monitoring of the safety of drugs need not be the responsibility of government alone. Manufacturers and vendors of health products can demonstrate good corporate behaviour and a commitment to quality health care by doing more than simply the reporting that is required by law. Indeed, larger vendors can make their own contribution to protecting consumers of their products through proactive initiatives to monitor the use and safety of products.

Good examples can already be found in both Canada and the United States. The HealthWatch program of Shoppers Drug Mart, one of the largest Canadian drugstores with in-store pharmacies, seeks to provide information to consumers about the uses, contraindications, and possible side effects of both prescription and non-prescription medications, as well as possible combinations of medications to avoid.<sup>225</sup> It also makes this information available online via its website. In the United States, CVS Corporation, the largest drug-store chain in the country, has done its own research indicating that almost 40 percent of people in the US do not advise their doctors when they self-medicate with herbal remedies. In response, in January 2000 it implemented a nationwide “voluntary disclosure” program that encourages customers to complete a form listing all non-prescription pharmaceuticals, vitamins, supplements, and herbal products they use. The pharmacy enters that information into a confidential patient profile, which is then used to generate a warning of possible interactions with the prescription medication being purchased, which information is provided to the customer. The program is operating in every store, and patients can also access the relevant information via the company’s website (although the information is not always presented in a way that is accessible to many consumers).<sup>226</sup>

With due protections for confidentiality (eg, aggregating data with consumer identifiers stripped), such programs could provide a highly useful source of data on patterns and prevalence of the use of natural health products in Canada. They could, however, be even more useful if large pharmacy chains were to assist with implementing a computerized system for the reporting of adverse events in the use of medications (prescription drugs or natural health products). This could provide “flags” for pharmacists and federal regulators as to potential harmful side effects from a product, or the interaction of products, that can then be subject to further investigation in order to protect consumers.

### **Recommendation 22**

**The Office of Natural Health Products, Colleges of Pharmacists, pharmacists’ professional associations, and manufacturers of natural health products should, with the input of consumer groups, collaborate to develop a protocol for pharmacists to encourage patients purchasing prescription drugs to voluntarily disclose which natural health products and non-prescription medications they are using. That information must be kept confidential, and should be tracked by pharmacies so that possible interactions**

<sup>225</sup> See the HealthWatch Medication Library at [www.shoppersdrugmart.ca/en\\_CA/healthwatch/drug\\_index.html](http://www.shoppersdrugmart.ca/en_CA/healthwatch/drug_index.html).

<sup>226</sup> CVS first to launch program to assist customers who use herbal products [media release], 20 January 2000 ([www.CVS.com](http://www.CVS.com)); Helwig D. US pharmacy chain tracks customer’s use of herbals. *Canadian Medical Association Journal* 2000; 162: 852.

**between natural health products and pharmaceutical drugs, or between different natural health products, can be identified to inform consumers about possible safety concerns with the use of a product, or the interaction of products, and to draw these concerns to the attention of Health Canada for further investigation.**

### **Enforcement of Regulatory Standards**

Adequate deterrents and effective enforcement of a regulatory framework are required if the goal of protecting the public is to be realized. The ONHP Transition Team noted in its final report that

under the present system ... compliance to [sic] current regulations is very low. This is partially the result of common knowledge that regulatory enforcement has been, at best, sporadic and weak. In addition, if one is found to be in non-compliance, the probability of prosecution is low. If a charge is laid, the penalty is minimal and is considered by many to be merely the cost of doing business.<sup>227</sup>

The lessons learned from experience with the current system applicable to “drugs” should inform the development of an improved regulatory framework for natural health products (and for drugs). It has been highlighted earlier that, from the perspective of the ethical principles of non-maleficence, beneficence, and respect for autonomy, it is of particular concern that currently the quality of natural health products sold to consumers is often uncertain and highly variable. Quality control mechanisms (eg, good manufacturing practices, standardized labeling requirements, etc) have been identified above as ways of enhancing consumer protection and autonomy.

But quality standards are meaningless unless observed and enforced. To rely solely on voluntary compliance by product manufacturers would be naive, particularly in light of past experience with the regulatory system for drugs and the demonstrated current lack of quality standards prevalent in the natural health products market. Deterrents against non-compliance with regulatory standards need to be established by, among other things, setting appropriate penalties in the regulations.

### **Recommendation 23**

**To protect consumers, the federal government should ensure that penalties established for breach of regulatory requirements regarding the manufacture, licensing, labeling, and distribution and sale of natural health products should be sufficiently strong, and their enforcement sufficiently vigorous, to ensure compliance with those regulatory requirements.**

### **Cost Recovery**

During the transition process of establishing the ONHP, it was suggested by the ONHP Transition Team that in providing “services” to its industry “clients,” the government as regulator of health products should develop its regulatory system (including fees charged) in consultation with industry, so as to ensure that industry “has a voice in the design and delivery of such service”<sup>228</sup> and to avoid over-burdening applicants for product licences.

<sup>227</sup> *A Fresh Start*. Final Report of the ONHP Transition Team. May 2000, at 34 (available via [www.hc-sc.gc.ca/hpb/onhp](http://www.hc-sc.gc.ca/hpb/onhp)).

<sup>228</sup> *Ibid* at 38.



Clearly, an overly cumbersome process is not ultimately in consumers' interests because it unnecessarily creates barriers to accessing health care. However, a caution must be sounded here. The rigour of the regulatory process cannot be weakened as a result of allowing holders/applicants for product licences to exercise any significant influence on the fees charged for regulatory review and approval or the design and implementation of the regulatory system. To do otherwise would be detrimental to both public health and to public confidence in the regulatory system. It is consumers who ultimately ingest, apply, or otherwise use industry's products and generate industry's profits – and it is to consumers that the Office of Natural Health Products owes its ethical and legal duty of care.

### **Recommendation 24**

**The Office of Natural Health Products must ensure that, in designing the regulatory system applicable to natural health products, the public interest remains paramount and must always supersede the interests of industry, where these are in conflict. Safeguards have to be put in place to ensure that the Office remains fully independent from the industry it purports to regulate.**

## **Regulating Practitioners Who Deliver Complementary/Alternative Health Care**

In light of the conspicuous increase in popularity currently being enjoyed by alternative therapies, it is clearly cause for concern that the vast majority of these therapies are not regulated in any significant way. Two potentially important consequences of this lack of regulation are: (1) that it is difficult for the public to distinguish among therapies and among practitioners of these therapies; and (2) that there is a potential for harm to the public as a result of unregulated practice.<sup>229</sup>

The preceding section examined specific aspects of direct, statutory regulation of natural health products in Canada. This section examines issues related to directly regulating complementary/alternative health-care practices and practitioners. (The next section deals with issues raised by indirectly regulating practice through the application of common law doctrines.) In this section, the paper:

- (1) describes the primary models for statutory professional regulation;
- (2) discusses practitioner views of regulation and identifies voluntary self-regulation as a suitable approach for complementary/alternative practitioners not already regulated by statute as health professionals;
- (3) discusses the regulation of conventional health-care professionals who incorporate complementary/alternative therapies into their practice; and
- (4) notes the special position of traditional Aboriginal healers vis-à-vis regulatory authority.

### **Statutory Approaches to Regulating Health-Care Practitioners**

The principal purpose of regulation of any healthcare profession is to protect the public from unqualified or inadequately trained practitioners. The effective regulation of a therapy thus allows the

<sup>229</sup> McNamara L, Nelson E. Regulation of Health Care Professionals. Chapter 2 in: Downie & Caulfield, supra, note 190, 51-81 at 79.

public to understand where to look in order to get safe treatment from well-trained practitioners in an environment where their rights are protected.<sup>230</sup>

The regulation of occupations and professions (including health-care practitioners) is a provincial/territorial responsibility. However, provincial/territorial governments have largely delegated regulatory responsibility to (recognized) health-care professions themselves by statute. Professional regulatory bodies (eg, “colleges,” “boards,” etc) are delegated the power to establish standards of practice and codes of conduct for their members by enacting regulations, by-laws, and policies.<sup>231</sup>

There are three principal forms of regulation of health care providers, listed here from most to least restrictive:

- (1) a licensure model;
- (2) a certification model; and
- (3) a registration model.

Until recently the first two of these have been the principal models adopted in Canada, although, as described below, several jurisdictions have now moved to reform their licensure models (moving from a system of “exclusive scopes of practice” for each profession to a “controlled acts” model with overlapping scopes of practice). As each province and territory in Canada has its own legislation – in many cases, numerous statutes and regulations – governing a variety of health-care providers, it is not possible to canvass them all here.<sup>232</sup> Instead, examples of the various models will be used where necessary to illustrate the implications for the practice of complementary/alternative medicine.

### Licensure

“A licensure or exclusive scope of practice regime means that only licenced members of those professions can do things considered to be ‘medicine’ or ‘dentistry’ or whatever other services fall within the scope of practice of the particular profession. The governing legislation defines the scope of practice of each regulated profession with varying degrees of specificity (medicine generally being the broadest), effectively granting members of the profession a monopoly over the provision of those services.... Providing services considered to constitute practising medicine or one of the other regulated professions without the authorization of a licence to practice or a proper delegation of authority is an offence.”<sup>233</sup> Licensing regimes usually also involve the ongoing regulation of professional practice, and discipline for those who fail to meet the standard set by the profession through its regulatory body.

Québec offers a good example of the licensure model. The *Medical Act*<sup>234</sup> contains a very broad definition of the “practice of medicine” and excludes all except physicians from engaging in such practice:

s. 31 Every act having as its object to diagnose or treat any deficiency in the health of a human being constitutes the practice of medicine. The practice of medicine shall comprise, in particular, medical consultation, prescribing of medication or treatment, radiotherapy, attendance at confinements, establishing and controlling diagnosis and treatment of illnesses or diseases.

s. 43 Subject to the rights and privileges expressly granted by law to other professionals, no person may perform any of the acts described in section 31, unless he is a physician.

<sup>230</sup> UK House of Lords, *supra*, note 204 at para 5.1

<sup>231</sup> McNamara & Nelson, *supra*, note 229 at 69-70.

<sup>232</sup> For a recent, comprehensive overview of the status of statutory regulation of various health-care practitioners in the field of complementary/alternative medicine, see *Canadian Overview*, *supra*, note 10. Note that this 1999 report is now slightly out of date, as there have been developments since its publication (eg, the recognition of practitioners of traditional Chinese medicine and acupuncture as regulated health professionals in British Columbia in December 2000). See also Casey JT, Status Report and Analysis of Health Professional Regulations in Canada. Prepared for the Federal/Provincial/Territorial Advisory Committee on Health and Human Resources, March 1999.

<sup>233</sup> *Canadian Overview*, *supra*, note 10 at 93.

<sup>234</sup> RSQ, c M-9.

Those not licensed in Québec as physicians, but whose services fall within this very broad definition of practising medicine, are technically breaking the law. The practice of complementary/alternative medicine is not per se illegal in Québec, but only a licensed physician who is subject to professional codes – which greatly restrict the freedom of practice – may practise such therapies legally. The broad definition of practising “medicine” noted above makes it clear “that non-physicians may practise neither conventional nor alternative forms of healing.”<sup>235</sup>

### **Certification**

Under a certification system, the use of a designated professional title is restricted to practitioners who have qualified by meeting certain educational and training requirements. Other practitioners may offer a given service, but they cannot use the title. (For this reason, a certification system is sometimes referred to as a “right to title” system.)<sup>236</sup> Certification is therefore meant to serve as a form of quality assurance, signaling to the consumer/patient that a certified practitioner meets certain minimum standards.

Certification is not as strict as licensing in the sense of creating a monopoly over the occupation as a whole.... The certification is a form of shorthand or credentialing signal for the public, indicating a certain background or educational level. The public is still free to choose to use a certified or uncertified supplier of services, but is given more information on which to base a choice.... Because certification does not restrict the number of practitioners in the market, it does not have the same anticompetitive problems as licensing. Certification, however, may also have its disadvantages. Consumers may not be aware of what is implied by certification and fail to make informed decisions regarding the qualifications of practitioners. Certification does not protect against third-party harm or mitigate the risk of severe harm. Certification may be also only a step on the way to the more restrictive regime of licensing.<sup>237</sup>

Unlike a licensure system, a certification regime generally does not involve an ongoing system of professional accountability, such as mechanisms for disciplinary proceedings against certified practitioners.

It is possible for a jurisdiction to have both licensure and certification approaches for different fields of practice or groups of practitioners. Some professionals (eg, physicians) could be granted a licence and with it an exclusive right to practise that profession; practising without a licence would be prohibited. Other practitioners (eg, massage therapists) could be granted a right to use a particular professional title upon being certified, but non-certified practitioners could still offer the service.

### **Registration**

The least restrictive regulatory model is a registration model, which simply requires that every practitioner providing the service must register their name and address on some sort of official registry. From a strict legal perspective, a registration model can barely be considered a form of “regulation,” since it imposes no particular training standards or other qualification requirements, and involves no legally binding professional standards or mechanism for investigating and disciplining practitioners who do not meet established standards. “As such, registration schemes are not necessarily found in legislation. Rather, a registration model would likely be the initial step taken by a

<sup>235</sup> Blanc MT. Health and multiculturalism: an inquiry into the juridical limits of medical pluralism in Quebec. *Ottawa Law Review* 1997-98; 29: 335-367 at paras 15-16 (QL).

<sup>236</sup> It should be noted that matters are made even more confused by the fact that some certified practitioners under a certification system are entitled to refer to themselves as “registered” practitioners (eg, “registered massage therapist”), and sometimes certification systems are referred to as “registration” systems. However, this is not only confusing but is inaccurate, as should be evident from the comments that follow about the registration model. Certified practitioners must do more than simply register the fact of their practice with some registering body; they must meet specified standards of training.

<sup>237</sup> Priest M. The privatization of regulation: five models of self-regulation. *Ottawa Law Review* 1997-98; 29: 233-302 at paras 53-54, 63 (QL).

professional organization in its quest for certification or licensing and, ultimately, [statutory] self-regulation.”<sup>238</sup> (The next subsection looks at the issue of voluntary self-regulation by complementary/alternative practitioners, which could, outside a statutory scheme, complement a registration system with more substantial, private regulation of practitioners.)

### **Reforming the licensure model: “controlled acts” and overlapping areas of practice**

In recent years, some provinces have introduced significant reforms to their regulatory regimes that more directly flow (at least in theory) from the policy objective of protecting the public. Rather than focus principally on licensing professions and establishing “scope of practice” monopolies on expansively defined disciplines such as “medicine,” this new model focuses on identifying acts or practices that pose a risk of harm to patients and authorizes only certain practitioners to provide or perform them.

Ontario was the first Canadian jurisdiction to adopt this new “controlled acts” model. The *Regulated Health Professions Act, 1991*<sup>239</sup> eliminated exclusive licences to practise, and instead introduced a new regime that:

- (1) describes the scope of practice for each of the twenty-four regulated health professions, setting out which practices members of the profession may perform;
- (2) lists a number of “controlled acts” that may only be performed by members of specific professions because specialized knowledge and expertise are required to avoid unacceptable risks to public safety;
- (3) prohibits any person (including health professionals acting outside the permissible scope of their practice) from treating or advising people about health matters if it is foreseeable that serious harm may be the result; and
- (4) regulates the titles that members of various health professions may legally use in providing services, and prohibits unregulated practitioners from holding themselves out as qualified to practise a regulated profession.

The statute also sets out a mechanism for considering requests by other groups of practitioners for recognition as statutorily recognized, self-regulating health professionals.

Some other jurisdictions have also moved, or are moving, to reform their licensure systems away from an “exclusive scope of practice” model to a “controlled acts” model with shared scopes of practice. For example, at the end of March 2001, the BC Health Professions Council produced a report recommending such a revision of that province’s system for regulating health professions.<sup>240</sup>

### **Should Complementary/Alternative Practitioners Be Regulated, and How?**

Whether the professionalization of complementary/alternative medicine is desirable and warrants support by the state is an issue for further debate. It can be seen as protection of the public or as the furthering of self interests for complementary/alternative therapists. Much depends on the form in which professionalization is implemented. The outcome will hinge not only on the state and the medical profession, but also on the position taken by complementary/alternative medicine organizations themselves on the most appropriate way to professionalize.<sup>241</sup>

<sup>238</sup> McNamara & Nelson, *supra*, note 229 at 59 n37.

<sup>239</sup> *Regulated Health Professions Act, 1991*, SO 1991, c 18. It should be noted that while chiropractors, midwives, and massage therapists are “regulated health professionals” subject to the “controlled acts” legislation (and specific regulations in the case of massage therapists), acupuncturists are not recognized health professionals in Ontario, and naturopathic physicians are not licensed, regulated health professionals but rather are governed by a “right to title” (ie, certification) scheme under the *Drugless Practitioners Act*, RSO 1990, c D18.

<sup>240</sup> See BC Health Professions Council. *Safe Choices: A New Model for Regulating Health Professions in British Columbia*. March 2001 (available via [www.hlth.gov.bc.ca](http://www.hlth.gov.bc.ca)); BC Ministry of Health news release. Revamp of Health Professions Regulation Recommended, 26 March 2001 ([www.hlth.gov.bc.ca](http://www.hlth.gov.bc.ca)).

<sup>241</sup> Summary of remarks by Saks M. Professionalization, Politics and Alternative Medicine. In: Summary Report of an International Symposium on “Why People Use Complementary and Alternative Medicine: Social Science Perspectives,” 16-18 April 1998, Toronto.

**Practitioners' views of practice regulation**

In its recent report on complementary/alternative medicine, the UK House of Lords reported that all witnesses appearing before it (including numerous complementary/alternative practitioners) “saw that some form of regulation was important; there was widespread consensus that regulation, handled appropriately, had many benefits for the public and the professions.”<sup>242</sup> Furthermore, it noted the position of the Foundation for Integrated Medicine that effective regulation of complementary/alternative therapies is central to development in many areas of complementary/alternative medicine.<sup>243</sup>

Cain et al have reported similar findings from in-depth interviews with Canadian practitioners who provide complementary therapies to people with HIV/AIDS. Their literature review suggested that most practitioners were “ambivalent about state intervention and regulation.” But in fact, among the practitioners they interviewed “there was little ambivalence. The complementary therapy practitioners interviewed were by and large unanimous in their support for state regulation of both therapists and products (herbs and supplements).”<sup>244</sup> Practitioners interviewed by Cain et al saw regulation as desirable for a number of reasons:

- the symbolic value of being recognized as legitimate practitioners;
- the protection against possible charges of practising medicine without a licence that could come with such recognition;
- the ability to set standards and “weed out” unqualified practitioners “whose incompetence jeopardizes the health of patients and at the same time reflects badly on the entire profession”; and
- greater integration into the health-care system, with consequent benefit to patients, such as ease of referral between conventional and complementary/alternative practitioners, improved access to diagnostic services, greater likelihood of access to government funding for services, and reduction of financial barriers for patients to access therapies.

Cain et al reported that:

We had expected to hear an underlying critique of the state and of governmental control.... Yet, when practitioners discussed the role of government, it was almost always to mention how they wished the state would regulate their practice (or, in the case of chiropractors and naturopaths, how glad they were they were regulated). Rather than being seen as a mechanism by which Western medicine could control and restrict their practices, state regulation was welcomed as an important element in the achievement of recognition and legitimacy, and in protecting them from accusations of practicing medicine without a licence. Practitioners themselves cited the important role of the state in monitoring and disciplining “the quacks” among them, partly to protect patients and partly to protect the reputation of their approach.

Our initial expectations [of practitioners' ambivalence toward regulation] were, perhaps, most supported by the statements of the Aboriginal healers. They expressed a more serious critique of Western medicine, and distrust of governments which they felt reflected the interests of the dominant white culture in Canada. Their approach to healing was firmly grounded in a spiritual/philosophical belief system or cosmology. In a variety of ways, they represented a more clear cut alternative not only to Western

<sup>242</sup> UK House of Lords, *supra*, note 204 at para 5.2

<sup>243</sup> Foundation for Integrated Medicine. *Integrated Healthcare: A Way Forward for the Next Five Years?* London: FIM, 1998 (available via [www.fimed.org](http://www.fimed.org)).

<sup>244</sup> Cain R, Pawluch D, Gillett J. Practitioner Perspectives on Complementary Therapy Use Among People Living with HIV. Health Canada, March 1999: 17-19, 22-23.

treatments, but to the mainstream, Western understanding of what illness and healing are fundamentally about.<sup>245</sup>

There is a wide range of opinion among CAM practitioners as to the value of regulation.

There is a lack of reported research on the views of practitioners in various complementary/alternative health-care fields. Furthermore, it has been noted that there is a wide range of opinion among complementary/alternative practitioners generally, both in different areas of practice and within specific fields, as to the value of regulation. Some practitioners already have the experience of both the benefits and drawbacks of direct, statutory regulation (eg, chiropractors being the most widely recognized, in almost every province/territory), while others are only just beginning to be recognized as health-care professionals (eg, acupuncturists, Traditional Chinese Medicine practitioners, naturopaths, massage therapists).

***Is a licensure model appropriate?***

Cohen has identified a number of possible benefits and concerns about moves toward professional regulation on a licensure model<sup>246</sup> for complementary/alternative practitioners. Possible benefits include the following: (1) minimum competence criteria help establish the legitimacy of a profession by reassuring the public and regulators about quality of practice; (2) independent professional licensing helps preclude other professionals (eg, physicians, nurses) from taking over the profession; and (3) licensure encourages and facilitates the development of the profession through opportunities for insurance coverage, hospital privileges, and the like.

However, not all complementary/alternative practitioners favour this approach. Some are concerned that it may lead to more, rather than fewer, restrictions on the practice of complementary/alternative medicine.<sup>247</sup>

Further, some providers prefer to remain outside the regulatory system, finding regulation inappropriate or reductionistic and arguing that modalities such as skilled touch cannot be tested by uniform, written examinations. Finally, some fear “the heart and art of the profession will be lost,” as licensure increases bureaucratic control and brings subjective or intuitive modalities into the biomedical model.<sup>248</sup>

Another consideration is the financial cost of professional regulation. Members of regulated professions bear the principal cost of supporting a regulatory body that administers the regime of training, examining, and licensing members and maintaining malpractice insurance. This cost, some of which may be passed on to consumers, also needs to be considered in determining whether, and to what degree, a professional regulatory system is feasible or desirable.<sup>249</sup>

In the abstract, it is difficult to say whether, at the end of the day, moving to a professional licensure model would increase access to complementary/alternative health-care practices. It may restrict access in the sense of imposing some additional cost on practitioners that will be reflected in the cost of their services to patients, but at the same time it will increase the chances of public and private health insurance plans covering such treatments; the net result could be increased access for patients. It may restrict access in the sense of excluding from legal practice those who do not meet the criteria for being licensed, but at the same time it will improve access to practitioners who the consumer can feel confident have met at least some minimum qualifications, are bound by professional standards and obliga-

<sup>245</sup> Ibid at 17.

<sup>246</sup> Cohen, supra, note 198. Cohen’s observations apply equally to an “exclusive scope of practice” form of licensure and to a more flexible “controlled acts” form.

<sup>247</sup> For a Canadian example of this phenomenon, see by-laws adopted by Toronto that have attracted considerable criticism from local massage therapists: City of Toronto By-Laws Nos. 806-1998 and 737-1999.

<sup>248</sup> Cohen, supra, note 198 at 35.

<sup>249</sup> Milbank Memorial Fund, supra, note 180 at 6.

tions, and carry malpractice insurance. The most contentious issues will be determining the appropriate qualifications and standards of practice for various complementary/alternative modalities. Raising (or establishing) the bar will necessarily exclude some practitioners, but at least theoretically ensures a more reliable, acceptable quality of service in more cases. It may be possible to strike a balance between, on the one hand, preserving access for patients and the freedom of qualified practitioners and, on the other, protecting the public's interest in receiving quality services when they seek out complementary/alternative therapies.

### **Voluntary self-regulation as the initial step**

A statute-based regulatory model of licensing with a defined scope of practice has been achieved in some jurisdictions by some practitioners who were (at least at one time) considered "alternative" or "complementary." For example, osteopathy is incorporated (in different ways) into the legislation of several provinces; chiropractors are regulated by legislation in all provinces and in Yukon (although the defined scope of practice varies somewhat); and naturopaths are regulated by legislation in four provinces.<sup>250</sup> But, even if practitioners felt it desirable, this most extensive model of statute-based professional regulation is not necessarily feasible for many complementary/alternative practitioners at this time, and alternatives such as voluntary self-regulation might be considered.

Over the years, [the] system of state-sanctioned self-regulation has been extended to an increasing number of health professions. In practical terms, this means that the rules governing the practice of the profession and the institutions that formulate and implement them have the imprimatur of the state, and that the state will support both the enforcement of those rules and sanctions imposed for their breach. This is to be contrasted with systems of voluntary self-regulation that prevail among providers of some types of health care services, where entry [into practice] and activities are controlled and standards imposed independently of the state, and the state does not lend its weight to sanctions such an independent group may impose.<sup>251</sup>

Voluntary self-regulation may be the first step in a process of eventual professionalization with statutorily-sanctioned self-regulation, which process may be described as follows:

A voluntary group of practitioners bands together to raise the standards of the profession. Efforts are made to establish a university program of training and continuing education programs are offered. A code of conduct is written and members are expected to adhere to it. Membership in the organization may become prestigious and an important asset in job-hunting. The members begin to lobby for regulation and self-government.... "It [the organization] emphasizes that, unlike other occupations, its members act on the basis of a body of knowledge which has been organized into a systematic theory and is taught at a university.<sup>[252]</sup> It also stresses its members' commitment to high standards of competence and ethics and points to its own efforts in this regard. In other words, it makes the case that it is similar to other groups which have already been given professional status and is dissimilar to mere occupations."<sup>253</sup>

Voluntary self-regulation may be the first step toward eventual statutory self-regulation as health professionals for many complementary/alternative practitioners.

<sup>250</sup> *Canadian Overview*, supra, note 10 at s III(D).

<sup>251</sup> *Ibid* at 92.

<sup>252</sup> It should be queried, however, whether university-based training should be thought of as necessarily a prerequisite, or whether other educational/training avenues could serve the purpose just as well – particularly since there are few university-level educational opportunities in Canada in most fields of complementary/alternative medicine.

<sup>253</sup> Priest, supra, note 237 at para 64, citing Manitoba Law Reform Commission, *Regulating Professions and Occupations* (Report 84). Winnipeg: Queen's Printer, 1994, at 5-6.

Recommendations have certainly been made in the UK for pursuing this route among complementary/alternative health-care practitioners. In 1997, researchers with the University of Exeter's Centre of Complementary Health surveyed all regulatory and professional registering bodies in the field of complementary/alternative medicine, which included representation from the vast majority of various complementary/alternative medicine therapies and professions. The researchers concluded that statutory regulation is "not a realistic option" for most complementary/alternative practitioners in the near future, due to lack of government willingness and the high administrative costs. However, they also suggested that complementary/alternative practitioners

would need to demonstrate a sound record of voluntary self-regulation before moving to statutory regulation.... For the majority of CAM professions, the establishment of a credible and effective self-regulatory system is practical, achievable and desirable. This should be done without delay. The challenge is for groups within each profession to put aside past differences and unite around agreed standards of training, competence and ethical practice.<sup>254</sup>

After hearing from numerous witnesses, the UK House of Lords Committee reached a similar conclusion in its 2000 report on complementary and alternative medicine.<sup>255</sup> The Committee outlined the features of a good voluntary self-regulatory body:

- maintains a register of individual members or member organisations;
- sets educational standards and runs an accreditation system for training establishments;
- maintains professional competence among its members with an adequate programme of continuing professional development;
- provides codes of conduct, ethics and practice;
- has in place a complaints mechanism for members of the public;
- has in place a disciplinary procedure that is accessible to the public;
- requires members to have adequate professional indemnity insurance;
- has the capacity to represent the whole profession;
- includes external representation on executive councils to represent patients or clients and the wider public interest.<sup>256</sup>

Implementing a regulatory scheme (whether statutory or voluntary) requires resources, which many groups of complementary/alternative practitioners will not necessarily be able to pool to support the necessary infrastructure, given the small numbers of practitioners in some disciplines (particularly if groups on a regional or provincial level are contemplated, as opposed to drawing upon a larger field of practitioners from across the country). Furthermore, practitioners need support in organizing professionally so as to implement self-regulation in the public interest. Participants at the January 2001 national planning workshop on issues related to complementary therapies and HIV/AIDS in Canada identified the need for this support in the form of concrete resources, and we reiterate that recommendation here.

## Recommendation 25

**Recognizing that different fields of complementary/alternative practice are at different stages of professional organization,**

<sup>254</sup> Kelner M. Presentation to the Advisory Group on Complementary and Alternative Practices and Therapies, Health Canada (Health Systems Division, HPPB): Report on Regulation and Coverage, based on: Discussion Document on Integrated Health Care (1997, UK), 7 June 1999, at 2-3, summarizing Mills S, Peacock W. *Professional Organisation of Complementary and Alternative Medicine in the UK 1997: A Report to the Department of Health*. University of Exeter, 1997.

<sup>255</sup> UK House of Lords, *supra*, note 204, paras 5.17, 5.23.

<sup>256</sup> Budd S, Mills S. *Professional Organisation of Complementary and Alternative Medicine in the United Kingdom 2000: A Second Report to the Department of Health*. University of Exeter, 2000, cited in: UK House of Lords, *supra*, note 204 at para 5.16.



practitioners should: organize themselves into practitioner associations; via such associations, consider the costs and benefits of establishing professional standards of qualification, ongoing competence, and acceptable practice as conditions of membership; and establish a mechanism for ensuring accountability of members for caring for patients in accordance with those standards.

### **Recommendation 26**

Health Canada should facilitate the creation of a working group, including representatives of newly or recently regulated complementary/alternative medicine practitioner groups, to produce and disseminate a resource tool (a “how to” guide) on developing mechanisms for voluntary self-regulation as a profession.

### **Recommendation 27**

Research funding agencies (both health-care research funding agencies and agencies funding research in other disciplines), as well as Health Canada under the Canadian Strategy on HIV/AIDS, should fund research that provides up-to-date information about:

- the views of people with HIV/AIDS who use complementary/alternative therapies, practitioners (complementary and conventional), manufacturers of natural health products, government, and private insurers, regarding the necessity for regulation in the fields of complementary/alternative health care, the role of government in regulation, and different models for regulating products and practitioners;
- a review of legal cases that (i) assesses the treatment of complementary/alternative medicine and practitioners using complementary/alternative medicine by professional regulatory bodies and before the courts; and (ii) explores the ethical and legal obligations of both conventional and complementary/alternative practitioners in the use of complementary/alternative medicine, as well as providing guidance for community-based organizations serving people with HIV/AIDS about the legal and ethical obligations governing the provision of complementary/alternative services and information; and
- the financial and other costs and benefits of different models of regulating practitioners in the health-care field, to inform decisions about which regulatory models are best suited for the regulation of practitioners in different fields of complementary/alternative medicine (if any regulation is found to be necessary).

### **Regulation of Conventional Practitioners Who Use Complementary/Alternative Medicine**

The preceding section examined the sentiments expressed by “complementary/alternative practitioners,” referring to those whose sole or principal practice is in a field or discipline of complementary/alternative medicine. But the use of complementary/alternative therapies or practices is not limited solely to these providers. Some “conventional practitioners” – meaning those who are trained and qualified within a conventional, biomedical model – are dual

practitioners with training in one or more fields of complementary/alternative medicine (with varying degrees of emphasis between conventional and complementary/alternative practice). Others, while not properly characterized as dual practitioners, incorporate some complementary/alternative therapies into their predominantly conventional medical practices. And an increasing number of conventional practitioners are expressing an interest in improved professional education regarding complementary/alternative therapies, either out of personal conviction that such therapies are or may be an important aspect of improved health care, or simply out of a recognition that the use of complementary/alternative therapies is common among patients and better knowledge of these therapies is required as part of better practice.

But conventional practitioners generally operate in a different regulatory environment than most complementary/alternative practitioners. Conventional practitioners are subject to statute-based regulatory regimes implemented by a professional regulatory body with professional codes and standards of practice that affect practitioners' freedom to refer patients to complementary/alternative practitioners and/or the use of complementary/alternative therapies by a conventional practitioner. Of course, some "complementary" disciplines, such as chiropractic, are subject to regulatory regimes very similar to those of conventional practitioners such as physicians or nurses. But for our purposes, a general distinction can be drawn to illustrate that practitioners who are members of regulated conventional health professions often face specific considerations in incorporating complementary/alternative therapies into their practices.

According to the recent review conducted by the York University Centre for Health Studies:

Currently, six of the ten provinces and one territory have formal statements [by professional colleges] regarding the practice *by physicians* of complementary/alternative medicine: British Columbia, Alberta, Saskatchewan, Ontario, Quebec and the Yukon. New Brunswick has not yet adopted a general policy on the topic, but endorses national statements that have been produced and responds to ancillary issues that arise using its professional misconduct rules. Newfoundland is in the process of developing guidelines. The remaining two provinces, Nova Scotia and Prince Edward Island, have not adopted specific policies. In addition, the Federation of Medical Licensing Authorities of Canada (FMLAC), an umbrella organization of the various self-governing bodies, has issued a position statement on alternative therapies and practices. Five of the six provincial policy statements on the topic are in general terms. The sixth, Saskatchewan's, and the Yukon's are specific to particular forms of alternative treatment. While all give primacy of place to conventional, scientifically recognized treatment, the emphasis and regulatory approach varies considerably.<sup>257</sup>

### **Restrictive approaches**

The historical tension between the medical profession as a whole and practitioners of complementary/alternative therapies is often reflected in the policies governing the conduct of physicians. For example, in Québec, although physicians (and only physicians, as noted above) can legally practise complementary/alternative medicine, they are bound by strictly worded

<sup>257</sup> *Canadian Overview*, supra, note 10 at 103. See this document for a review of the substance of each of the policies (where adopted). These include: College of Physicians & Surgeons of British Columbia. Acupuncture. Policy Manual, Chapter A-2 (February 1997); Complementary and Alternative Therapies. Policy Manual, Chapter C-12 (June 1999); Unproven and Unconventional Treatment. Policy Manual, Chapter U-2 (June 1995), all online via [www.cpsbc.bc.ca](http://www.cpsbc.bc.ca); College of Physicians & Surgeons of Manitoba. Scientific Acceptability – Procedure Approval. Statement No. 153 (revised 1998); College of Physicians & Surgeons of Ontario. Complementary Medicine: Policy #1-00 (approved November 1997, February 2000), available online via [www.cpso.on.ca](http://www.cpso.on.ca); College of Physicians & Surgeons of Manitoba. Unproven Therapies. Statement No. 149. (revised 1999); College of Physicians & Surgeons of Alberta. Complementary Health Care Therapy Provided by Medical Practitioners (1996); College of Physicians & Surgeons of Saskatchewan. Standards for Performance of Chelation Therapy (By-law 52); Corporation professionnelle des médecins du Québec. Professional Practice and Alternative Therapies (June 1994); Yukon Medical Council. Acupuncture Guidelines (6 May 1986); Yukon Medical Council. Position Statement: Chelation Therapy (undated); Federation of Medical Licensing Authorities of Canada. Considerations for the Regulation of Physicians Who Use "Complementary Therapies" by Licensing Authorities in Canada, 3 September 1998.

policies that in effect prevent most use of such therapies (or at least cast the pall of possible professional discipline over their use). As Blanc points out,

physicians who hold a valid provincial licence may resort to alternative therapies, but are limited by sections 2.03.14 and 2.03.17 of the Code of Ethics, which provide, respectively, that physicians must adhere to “scientific principles” and refrain from acting in a way that contradicts “current medical science.” Thus, Quebec physicians must refuse to administer an alternative form of treatment where recognized therapies exist. Alternative medicine may be resorted to only where no treatment is specifically recognized by current medical science. The physician must then justify his or her choice of therapies and obtain the patient’s free and informed consent pursuant to articles 11 to 25 of the Civil Code of Quebec and section 2.03.28 of the Code of Ethics. Again, “scientific principles” and “current medical science” are not defined in ... the Code of Ethics. It is therefore far from certain that physicians may practise alternative medicine freely.<sup>258</sup>

British Columbia policy – at least at the level of the professional regulatory body – is in some respects similar in its view of physician involvement with complementary/alternative therapies. The College of Physicians & Surgeons has issued policies that make it very difficult for a physician to provide any sort of complementary/alternative therapy to a patient without breaching College policy. Even though informed consent of a patient to any procedure is always required as a matter of ethical practice, official College policy states that “the ethical physician ... must not expose the patient to *any* degree of risk from a complementary or alternative therapy of no proven benefit.”<sup>259</sup> The College’s guideline even goes so far as to prohibit physicians from associating with health professionals who offer complementary/alternative therapies:

the ethical physician ... must not associate with, or refer patients to, alternative practitioners who recommend unproven over proven therapies. By doing so, the physician assumes a degree of responsibility for the outcome of the treatment.<sup>260</sup>

It should be queried whether such prohibitions are truly in the best interest of patients – they reinforce patients’ concern that patients cannot disclose their use of complementary/alternative therapy to their physician, and they ignore the wishes of patients rather than assist them in making informed decisions about their treatment choices. It also prevents or at least inhibits interdisciplinary or “integrated” approaches to health care in which there is proper communication and consultation between conventional physicians and complementary/alternative practitioners sought out by a patient.

This suggests a double standard that violates respect for the autonomy of patients. Conventional therapies may often carry well-documented, significant risks of harm in addition to their benefits, yet would be considered perfectly appropriate prescriptions. The key point is that it should be the patient who decides, based on the available information, what treatment they wish to pursue. Even if there is no benefit of a particular therapy that has been “proven,” if the benefit and the risk have been thoroughly explained to a patient and upon adequate reflection the patient feels the risk is worth taking, it goes too far to discipline the physician who chooses to accede to the patient’s wishes. This is not to argue that a physician must always agree to a patient’s request. But the issue here is whether the physician who does so,

<sup>258</sup> Blanc, *supra*, note 235 at paras 15-16.

<sup>259</sup> Policy Manual, *supra*, note 155.

<sup>260</sup> *Ibid.*

It is too restrictive to professionally discipline the physician who accedes to the informed wishes of the patient to use an unconventional treatment.

with the informed consent of the patient, should face accusations of professional misconduct and negligence. (It should be remembered that complementary/alternative therapies have suffered from a lack of quality research, and may well face systemic biases in obtaining research funding and in the evaluation of results from a biomedical model. Whether a benefit is “proven” may depend in part on who is assessing the evidence.)

The BC College, while stating that the ethical physician “must respect the autonomy of the patient in choosing from available treatment options,” then immediately states that:

If the patient’s choice of a complementary or alternative therapy has made it impossible for the physician to discharge his or her ethical responsibilities, it is acceptable for the physician to terminate the doctor–patient relationship.<sup>261</sup>

Given that physicians have just been instructed that their ethical responsibilities include not exposing the patient to *any* risk of harm from a therapy of unproven benefit, and not associating with or referring patients to practitioners who do expose patients to such therapy, the policies of the BC College of Physicians & Surgeons present a significant barrier to the careful and sensible practice of medicine with patients who seek care from complementary/alternative practitioners.

### **Less restrictive approaches**

More liberal approaches have been advocated or adopted in some jurisdictions. In some cases, a College has asserted that it does not consider the mere fact of using an unconventional therapy as evidence of professional misconduct for falling below the acceptable standard of care. For example, this was the position articulated by the College of Physicians & Surgeons of Ontario in the *Krop* case, in which a physician practising “environmental medicine” faced disciplinary charges (not as a result of patient complaints). The College argued that, given his particular mode of treatment, his practice had been substandard, and that it was not targeting him because of his unconventional approach.<sup>262</sup> Critics dispute this claim, and unfortunately the case has done little to diminish mistrust of the College on the part of some complementary/alternative medicine practitioners and patients. Since the *Krop* decision, the Ontario College has adopted a policy that states:

In treating patients, physicians should ... provide sufficient information to allow patients to make informed choices, and to refer to, or consult with, others when the practitioner requires assistance or when the standard of practice requires it. It should not be misconduct to refer a patient, honestly and without conflict of interest, to unconventional or complementary practitioners when appropriate and when there is no reason to believe such a referral would expose the patient to harm.<sup>263</sup>

Furthermore, the Ontario legislature has enacted a private member’s bill that clarifies in law that a physician

shall not be found guilty of professional misconduct or of incompetence under ... the Health Professions Procedural Code solely on the basis that the member practises a therapy that is non-traditional or that departs from the prevailing medical practice unless there is evidence that proves that the therapy poses a greater risk to a

<sup>261</sup> Ibid.

<sup>262</sup> College of Physicians and Surgeons of Ontario. News release re Dr Jozef Krop, 20 January 1999 (available via [www.cpsso.on.ca](http://www.cpsso.on.ca)).

<sup>263</sup> College of Physicians and Surgeons of Ontario. Policy Statement: Complementary Medicine, Policy No. 1-00, approved by Council February 2000 (available via [www.cpsso.on.ca](http://www.cpsso.on.ca)).

patient's health than the traditional or prevailing practice.<sup>264</sup>

This new Ontario provision is almost identical to the provision that has existed in Alberta law for several years which, as a result of a 1996 amendment, now provides that a registered physician or osteopath:

shall not be found guilty of unbecoming conduct or be found to be incapable or unfit to practice medicine or osteopathy solely on the basis that the registered practitioner employs a therapy that is non-traditional or departs from the prevailing medical practices, unless it can be demonstrated that the therapy has a safety risk for that patient unreasonably greater than the prevailing treatment.<sup>265</sup>

Finally, in sharp contrast to policy at the College level, at the legislative level British Columbia has recently adopted an even more far-reaching stance than Alberta and Ontario. In April 2001, despite strong opposition from the provincial College of Physicians & Surgeons, the legislature enacted Bill M202, a private member's bill that amended several sections of the province's *Medical Practitioners Act*. As amended, the statute now defines "complementary medicine," with reference to a medical condition of a patient, as "a diagnostic or therapeutic measure" that (a) "would not customarily be used ... by most other medical practitioners," (b) poses "no greater risk" to the patient than a measure in general use by most other medical practitioners, and (c) "presents a reasonable prospect" for alleviating the suffering or improving the health of that patient in relation to the condition. The statute further provides that:

- a qualified medical graduate cannot be denied registration as a physician "solely because he or she supports complementary medicine or expresses a desire to use non-traditional therapies";
- the entitlement to practise medicine includes "the option to use any complementary medicine or any diagnostic or therapeutic measure if, in the judgment of the medical practitioner, it offers the reasonable hope of saving life, alleviating suffering or improving health";
- college rules must not "unreasonably interfere" with the option of a medical practitioner to practise complementary medicine (this calls into question the continued validity of some aspects of the College's policy statements);
- a committee to investigate a physician's skill may not be appointed "solely on the grounds that such a medical practitioner practises complementary medicine or uses non-traditional therapies";
- a physician cannot be professionally disciplined by the College solely on the basis that he or she practices complementary medicine or uses non-traditional therapies.<sup>266</sup>

Another example of a more permissive approach comes from the United Kingdom. Rather than calling for prohibitions on the use of complementary/alternative therapies by physicians, or their involvement in some fashion with practitioners who do provide such therapies to their patients, the British Medical Association has recognized that an increasing number of conventional physicians often use complementary/alternative therapies in their practices. In the interests of patient/consumer protection, the BMA has urged that "Medically qualified practitioners wishing to practise any form of non-conventional therapy should take recognised training in the field approved by the appropriate regulatory body, and should only practise the therapies after registration."<sup>267</sup> While this is not currently practicable in many cases, given the

In some jurisdictions, it has been recognized that using an unconventional therapy does not amount to professional wrongdoing per se.

<sup>264</sup> *Medicine Amendment Act, 2000*, SO 2000, c 28, s 1 (amending the *Medicine Act, 1991* by adding section 5.1 to this effect). This private member's bill came into force on 21 December 2000.

<sup>265</sup> *Medical Profession Act*, RSA 1980, c M-12, s 34(3).

<sup>266</sup> *Medical Practitioners Act*, RSBC 1996, c 285, as amended by the *Medical Practitioners Amendment Act, 2001*, SBC 2001, c 16 (in force 20 April 2001); see sections 1 ("complementary medicine"), 5(1.1), 34(1.1), 51(1.1), 60(1.1), and 80(2). For the position of the College of Physicians & Surgeons of British Columbia objecting "in the strongest possible terms" to these amendments, see the College's two releases to the media dated 6 April 2001, available online via [www.cpsbc.bc.ca](http://www.cpsbc.bc.ca).

<sup>267</sup> British Medical Association. *Complementary Medicine: New Approaches to Good Practice*. Oxford University Press, 1993.

lack of professionalized development in many fields of complementary/alternative health-care practice, and hence the lack of established, quality training programs and mechanisms for professional regulation, the BMA position nonetheless reflects a less restrictive approach to the incorporation of complementary/alternative therapies into practice by conventional physicians that should be considered as more appropriately striking the balance between non-maleficence/beneficence and respect for patient's autonomy.

This requirement has been established by some Colleges in Canada as well, even while existing alongside more restrictive policies. For example, the College of Physicians & Surgeons of BC, in its policy on acupuncture, has recognized that acupuncture has a "valid role in the management of patients with selected pain syndromes," and is of the opinion that physicians who face a complaint or lawsuit alleging malpractice will be required to demonstrate that they have documented evidence of having taken acceptable courses of study in acupuncture, and either that they have passed the Acupuncture Foundation of Canada examination or have been certified by the University of Alberta Programme on Medical Acupuncture.<sup>268</sup>

### **Recommendation 28**

**Colleges of Physicians and Surgeons, and other health professional regulatory bodies, should solicit the views of their members, of complementary/alternative practitioners, and especially of patients as to how restrictive current professional guidelines, codes, or policies are regarding physicians' involvement in providing complementary/alternative therapies or referring patients to providers of such therapies. The results of such consultation should inform a possible review of existing policies, if and where indicated.**

### **Recommendation 29**

**As a matter of policy, regulatory bodies for conventional health-care professionals should include a requirement that those members who wish to practise unconventional therapies should, where possible, take training in the relevant field in a form that has been approved by a regulatory body or professional association of practitioners specializing in that field.**

### **Recommendation 30**

**Provincial health ministries should, in collaboration with professional associations of both conventional and complementary/alternative practitioners and health professional regulatory bodies, identify those legislative or regulatory changes necessary to enable multidisciplinary practices that could facilitate the integration of care between conventional and complementary/alternative practitioners for patients who seek such care.**

## **Aboriginal Healers**

The idea of identifying who is a Traditional Elder, Healer or Medicine Person and committing this information to paper is a prospect many Aboriginal people would not even speak about.

<sup>268</sup> College of Physicians & Surgeons of British Columbia. Acupuncture. Policy Manual, Chapter A-2. February 1997, available via [www.cpsbc.bc.ca](http://www.cpsbc.bc.ca).

Aboriginal traditions and culture have witnessed a continual aggressive assault in this country from government and religious leaders. Aboriginal people, especially within traditional circles, are skeptical that Canada's desire to assimilate Aboriginal people and destroy Aboriginal culture is over. With the increase of traditional healing programs and public utilization of Elders, Healers and Medicine People off-reserve, however, the risk of misuse and abuse of traditional healing knowledge and practice is increasing. Aboriginal service providers are saying that the time has come to consult with the traditional people and determine whether or not it is appropriate for the Aboriginal community to formalize the recognition of Traditional Elders, Healers or Medicine People, like that of other health professionals. Should this be done? If so, how can this be done in a culturally appropriate manner?<sup>269</sup>

As the above passage indicates, there is an ongoing discussion within Aboriginal communities about the appropriateness of regulating (understood in a broad sense) healing practices and those who provide them. There are, however, few firm data to inform the discussion (partly for some of the reasons just noted). One relevant initiative, however, illustrates that regulation in the context of the relationship between Aboriginal peoples and the federal/provincial/territorial governments is a complicated and sensitive issue.

### ***Consultations regarding occupational standards for Aboriginal health workers***

A lengthy consultation process undertaken by ten national Aboriginal organizations and the Canadian Public Health Association examined the issue of developing occupational standards for Aboriginal health workers. The process revealed that a majority genuinely desired some sort of occupational standards for Aboriginal health workers, but that this was conditional upon Aboriginal people developing, implementing, and maintaining those standards, and the commitment of sufficient and sustained resources to support such standards. It should also be noted that this study focused on the question of standards for community health representatives, addiction workers, and mental health workers; it was *not* a study of the use of traditional healing practices by Aboriginal people per se or assistance sought from traditional healers.<sup>270</sup> In particular:

Although some participants expressed support for occupational standards in the strongest possible terms, many were much more guarded in their reaction, recognizing the possible benefits to be derived from occupational standards while at the same time fearful that they might negatively affect Aboriginal workers and communities.... Several participants ... expressed concern that standards would be imposed and that they would be either unwanted by particular communities or out of touch with their needs and priorities.... At the very least it was emphasized that standards should be measurable, dynamic and practical, as well as being based upon tradition, experience and the cultural rules that govern how people live and behave.... Throughout..., participants emphasized again and again that any move to develop occupational standards must give sufficient recognition to traditional Aboriginal values, arguing that these have for generations served to define relationships, to demonstrate rights and responsibilities and to show there are consequences to any action.

<sup>269</sup> Noojimawin Health Authority. *Aboriginal Traditional Healing in Ontario: Issues and Concerns*. Draft paper, April 1999, at 2.

<sup>270</sup> Canadian Public Health Association. *Exploring Occupational Standards for Aboriginal Health Workers: Final Report*. Ottawa: Canadian Public Health Association, March 1997, at xvi, 35-38.

With respect to the question of occupational standards in particular, several participants argued for traditional approaches to be incorporated into any standards that might be developed, for example, by involving Elders in training initiatives. Others called upon communities to spend some time thinking about ethics and examining the nature of the roles of Aboriginal health workers in order to identify the ethics, values and principles that underlie them. In this way, a “code of ethics” might be developed alongside occupational standards, the former being a potentially valuable tool for the protection of confidentiality and for the encouragement of positive role models... [But] several leaders commented that occupational standards were likely to promote further division and specialization within the health care system, while moving away from a holistic and flexible model of care.<sup>271</sup>

As already noted, the Aboriginal healers interviewed by Cain et al in their survey of practitioners working with people with HIV/AIDS were the respondents who expressed the strongest distrust of government regulation. Such mistrust is not surprising, given the history of racism experienced by Aboriginal peoples at the hands of non-Aboriginal governments in Canada – including the criminalization of Aboriginal cultural and spiritual practices (including healing practices). At many points, this has reflected a deliberate policy of assimilation of Aboriginal people. In more recent times, it has been born less of such overtly and deliberately racist objectives, but continues to reflect a clash of cultural values.

#### **Individual rights vs traditional practices: *Thomas v Norris***

This is illustrated in the case of *Thomas v Norris*.<sup>272</sup> In this case, a BC trial court heard a lawsuit by an Aboriginal man alleging assault, battery, and false imprisonment against several other Aboriginal people (including elders) who initiated him against his will into the Spirit Dance tradition of the Coast Salish. Thomas had lived off reserve for many years and did not identify with Coast Salish culture, according to the court’s findings. His wife, believing that initiation would heal his alcoholism and repair their marriage, requested that he be initiated. Thomas was “grabbed” by the defendants and forcibly taken to a long house of the Cowichan Indian Band where, over a four-day period, he was deprived of food (but received water), forced under water, whipped with cedar branches, and repeatedly lifted up by several men who dug their fingers into his sides and bit him. His pre-existing ulcer was exacerbated and he was hospitalized for treatment; the attending physician testified that he was suffering from dehydration and multiple contusions as well.

The court found that, according to Coast Salish custom, the community was entitled to submit an individual such as Thomas to Spirit Dancing in the interests of the community. However, the court disagreed that this collective right could supersede Thomas’s individual rights: “No group of persons, Indian or non-Indian, has the collective right to subject an individual to assault, battery or false imprisonment.”<sup>273</sup> The court did not accept the argument that submitting an individual against their will to the Spirit Dancing tradition was an “aboriginal right” protected by s. 35 of the Constitution. It awarded Thomas damages against the defendants, two of whom were elders who supervised the initiation. As Waldram points out:

<sup>271</sup> Ibid at 36-43.

<sup>272</sup> [1992] 2 CNLR 139 (BCSC). This decision was also applied in *R v Paul*, [2000] 3 CNLR 262, a case about Aboriginal hunting rights in which the Québec Superior Court held that Aboriginal practices that are known to risk harm to other people must be subject to “the principles of fundamental justice” as required by the Constitution.

<sup>273</sup> Ibid at para 6 of headnote.



Spirit Dancing is easily misunderstood when stripped of the proper cultural context as described in the judgment (as any biomedical practice or European religious service would be). A proper understanding of this cultural context, as expressed by the elders, provides a very different view of the process of initiation into the dance which Mr. Thomas underwent. But, as was pointed out, Mr. Thomas did not believe in this aspect of Coast Salish culture, and the courts supported his assertions that the initiation was nothing more than a kind of torture.<sup>274</sup>

Although *Thomas v Norris* is the only reported Canadian case specifically addressing the issue of traditional Aboriginal healing practices in Canadian law, it is of limited application to most circumstances in which a claim to the use or provision of traditional healing practices might conflict with existing legislation regulating health-care practitioners. It is limited for one very important reason: in *Thomas v Norris*, the practice in question had been administered *without the consent* of the “patient.” Therefore, as reflected in the judgment, the claim to a constitutional Aboriginal right to engage in this practice was set squarely against other, competing rights of the individual not to be subjected to the practice against his will.

But such a situation would be rare because, as with other healing practices, most practices by traditional Aboriginal healers would only be done with the consent of the person seeking the healer’s assistance. Therefore, were such practice by a traditional healer to fall afoul of other legislation (such as that restricting the practice of a particular act to a conventional, regulated health professional such as a physician or nurse), there would likely be a much stronger constitutional claim to an Aboriginal right to engage in that practice and be exempt from the requirements of other legislation governing registered health-care professionals.

### **Accountability of traditional healers**

The issue of accountability to patients raises an important and sensitive question when one considers the relationship between Aboriginal peoples and non-Aboriginal governments in Canada. It is widely accepted that conventional, biomedical physicians and other health-care professionals should be held accountable via formalized regulatory bodies (eg, Colleges of Physicians and Surgeons) that hold practitioners to certain standards of professional practice that are to be met across the board.

Yet the issue of accountability may be approached somewhat differently in the context of a traditional healer in an Aboriginal community. Traditional healers are generally seen to be accountable to the people they assist, but also to the Creator from whom they receive their gifts, to be shared when appropriate.<sup>275</sup> Mechanisms or processes for accountability to the community more generally are not as defined or formalized as a system of professional regulatory bodies, although this is not to say that there is no such accountability; it is simply more diffuse and does not give rise to discernible legal remedies such as suits for malpractice or disciplinary proceedings that are applicable to regulated practitioners of Western biomedicine.

There are ongoing discussions within Aboriginal communities about how to deal with individuals who may claim to be traditional healers but who are not aware of, or who do not follow, such teachings.<sup>276</sup> Waldram et al explain the difference from a “Western” approach to regulation, and the issues prompting concern within Aboriginal communities:

<sup>274</sup> Waldram et al, *supra*, note 91 at 223.

<sup>275</sup> Commentary from A. Zoccolle, Canadian Aboriginal AIDS Network, 12 February 2001.

<sup>276</sup> Eg, see Noojimawin Health Authority, Aboriginal Traditional Healing in Ontario, *supra*, note 269; LaBillois V. Horn M. Development of Occupational Standards for Health Workers Panel. In *Touch Magazine* 1997; 8(1): no page; *Exploring Occupational Standards for Aboriginal Health*, *supra*, note 270.

The biomedical and traditional Aboriginal systems are in conflict with respect to methods of validating healing knowledge and practitioners. With biomedicine, practitioners receive formal education, must pass rigorous exams, and must continue to practise efficiently while under the scrutiny of licensing and professional associations. Canadian law protects the patient from exposure to unqualified medical practitioners, and will assist patients who are harmed as a result of medical incompetence. In contrast, Aboriginal medical knowledge is often handed down from generation to generation to individuals selected by existing healers. Ultimately ... the power to heal comes from the Creator. Healers in the Aboriginal tradition are culturally validated; they are accepted by community members as healers, and those who wish to avail themselves of a healer's services follow the culturally prescribed method of requesting assistance. There are no licences, and no regulating bodies. In general, people know who the good healers are, and will attempt to avoid those who are considered to be incompetent or are known to deal in "bad medicine." [...]

From a purely cultural perspective, the validation of Aboriginal healers is generally effective, though not unproblematic. Once we begin to talk about making Aboriginal medicine more formal and more readily available, and about developing collaborative programs, then the question of validation becomes more difficult. It is not easy for most non-Aboriginal people, and even many Aboriginal people who have little traditional cultural knowledge, to distinguish between true traditional healers from others whose knowledge lacks cultural or community validation. Indeed, there is a whole growth industry, related to current "New Age" trends, in promoting and selling Aboriginal medicine and philosophies. It is so serious, in fact, that the Traditional Elders Circle of the Indigenous Nations of North America passed a resolution in 1988 warning that many so-called "medicine people" lack the proper knowledge and authority to heal and to carry sacred objects.... A key issue was the use of traditional medicine for profit, often involving non-Aboriginal clients....

True Aboriginal healers, those with cultural validation, are most likely to speak their Aboriginal language and be, at the most, bilingual. They are also humble about their abilities. One would not normally hear a healer pronounce that he or she is in fact a healer; this is a status that is ascribed to them by others. Some are also still afraid of legal prosecution, a legacy of the past. Furthermore, many operate under constraints preventing them from disclosing fully their medical traditions, for fear of losing their powers.<sup>277</sup>

But there is also very real concern with any attempts to "formalize" (in a Western regulatory perspective) traditional health-care practices. That discussion is a sensitive one for both Aboriginal and non-Aboriginal people:

<sup>277</sup> Waldram et al, *supra*, note 91 at 218-219.

It seems as though very few observers wish to tackle openly the legal aspects of formalizing Aboriginal medicine, perhaps because they are complex and pose a direct threat to the integrity of the Aboriginal cultures themselves. Certainly a central question in any discussion of legal aspects is, “Does Aboriginal medicine work?,” a question whose corollary, “Can Aboriginal medicine do harm?,” no one seems to want to discuss. Related to these questions is another one which is linked more directly to the legal framework of the country: “Do Aboriginal healers practise medicine without a licence?” In terms of the Constitution, we could ask, “Is Aboriginal medicine an Aboriginal right under section 35?” The answers to these questions will not come easily, but we believe they must be addressed.

These issues are complex and cannot be satisfactorily answered here. Nor should they be without the participation and direction of Aboriginal people themselves. For the present purposes, however, it should be noted that it is certainly possible to recognize the distinct status of Aboriginal peoples and Aboriginal healing practices in provincial laws regulating health-care practitioners, whether a certification system or a licensure model (either in its “exclusive scope of practice” or “controlled acts” form) is followed. For example, in 1994 Ontario announced a province-wide Aboriginal Health and Wellness Strategy (AHWS), a fundamental principle of which is that

traditional Aboriginal approaches to wellness, including the use of traditional resources, traditional healers, medicine people, midwives and elders, are recognized, respected and protected from government regulation. They enhance and complement healing, as well as programs and services throughout the health system.<sup>278</sup>

This policy approach of protecting traditional Aboriginal healing practices from government control was reflected in the new regulatory framework for health professionals implemented in Ontario in the same year. The province’s *Regulated Health Professions Act* (RHPA) expressly states that it does not apply to (a) Aboriginal healers providing traditional healing services or (b) Aboriginal midwives providing traditional midwifery services to Aboriginal persons or to members of an Aboriginal community.<sup>279</sup> While an Aboriginal healer or Aboriginal midwife who is a member of a College is subject to the jurisdiction of the College, membership in the College is not required in order to practice traditional healing or midwifery. In addition, although the *Midwifery Act, 1991* restricts the use of the title “midwife” to members of the College of Midwives, an Aboriginal person who provides traditional midwifery services is exempt from this requirement,<sup>280</sup> meaning that she need not be a member of the College in order to practise under the title of “midwife,” nor is she subject to investigation and discipline by the College in the event of a public complaint about quality of care. Finally, in a provision that is not specific to Aboriginal people but has obvious implications for at least some Aboriginal healers, the RHPA states that a person does not break the law by doing a “controlled act” if the act is done in the course of “treating a person by prayer or spiritual means in accordance with the tenets of the religion of the person giving the treatment.”<sup>281</sup>

<sup>278</sup> Ontario Ministry of Health. *New Directions: Aboriginal Health Policy for Ontario*. Toronto, 1994: at 15.

<sup>279</sup> SO 1991, c 18, s 35.

<sup>280</sup> *Midwifery Act, 1991*, SO 1991, c 31, s 8.

<sup>281</sup> RHPA, supra, note 279 at s 29(1)(c).

***Integrated approaches for Aboriginal people***

The integration of conventional and traditional Aboriginal healing practices is an issue that will need to be addressed further because Aboriginal people living with HIV/AIDS will continue to rely on both approaches:

The significance of medical pluralism as a treatment strategy needs to be drawn out. From the patient's perspective, it actually empowers the patient who, though the choice of medical system and practitioner, has a measure of control over his or her own health. Likewise, the availability of significantly different alternatives further provides for choice should the encounter with one system prove unsatisfactory. Cultural understandings of illness and treatment are validated, since Aboriginal medicine can be sought, yet the patient can also use biomedical services to treat the same problem, or a component of that problem. In effect, medical pluralism allows the patient to retain both control and the cultural context of healing.<sup>282</sup>

However, it is not only because Aboriginal people use both conventional and traditional healing that these issues need to be addressed. There is also an ongoing movement toward Aboriginal peoples and communities exercising more control over health-care funds and strategies. Both the Royal Commission on Aboriginal Peoples (1996) and the National Forum on Health (1998) identified the need for Aboriginal peoples to take control of their health and health services, which necessarily means involvement in the design, development, delivery, and evaluation of health services in their communities. One aspect of this will be a push for increased collaboration between biomedical and Aboriginal healers:

Various initiatives to make Aboriginal medicine more formally available, including the development of models of collaboration, will likely continue. These issues are best left with the Aboriginal community to determine, since any change in the current situation of traditional Aboriginal medicine will result in other, broader cultural changes. However, it is incumbent upon biomedical practitioners and researchers to learn more about traditional medicine, and for Aboriginal healers to overcome their reluctance to discuss their medical approaches, so that the best interests of those who are ill can be served. The current movement towards self-determination in health provides perhaps the greatest opportunity to resolve some of these complex issues.<sup>283</sup>

**Recommendation 31**

**Health Canada, provincial ministries of health, and health-research funding agencies should support research by Aboriginal people into the issues related to ensuring proper qualifications and practices by traditional healers.**

**Practitioners' Liability for Malpractice**

Aside from statutory regulation of practitioners (where it exists), all practitioners – regulated or unregulated – are subject to basic common law principles. Thus, apart from disciplinary proceedings, regulation of the conduct

<sup>282</sup> Waldram et al, *supra*, note 91 at 211.

<sup>283</sup> *Ibid* at 226-227.

of health-care professionals is achieved principally through the ostensible deterrent effect of possible civil liability for *negligence* (for practice falling below the acceptable standard of conduct), or *battery* (for performing procedures without a patient's informed consent), or other possible common law causes of action (eg, breach of fiduciary duty to the patient).<sup>284</sup> This section examines the issue of actions for malpractice in the use of complementary/alternative medicine, structured as follows:

- (1) the law establishing a practitioner's *duties of care* with respect to both
  - (i) obtaining informed consent through disclosure of risks and alternatives; and
  - (ii) administering actual treatment;
- (2) determining the *standard of care* applicable in the use of complementary/alternative therapies to treat patients, with respect to:
  - (i) complementary/alternative practitioners; and
  - (ii) conventional practitioners who integrate complementary/alternative therapies into their practice.

It should be noted that there appear to have been very few malpractice claims brought against practitioners of complementary/alternative medicine in Canada, the United States or the United Kingdom. There are only a few cases in Canada in which patients have sued complementary/alternative practitioners alleging malpractice. The UK saw its first case of this sort only recently. Even the US has not seen very many such cases, considering its population, the number of practitioners, and the frequency with which complementary/alternative practitioners are consulted.

Available [US] data suggest that alternative medicine practitioners are sued relatively infrequently, although there is no standardized reporting of claims, and little research on claims rates has been done. In a previous study we examined claims data from leading insurers covering chiropractors, acupuncturists, and massage therapists – the three licensed alternative medicine groups with the largest market shares in the United States – and found relatively low claims rates. Rates of claims against chiropractors through the 1990s were approximately one-third of those against primary care physicians, while rates of claims against massage therapists were approximately one-fiftieth. Average payments among successful claims against chiropractors and massage therapists were also relatively small, suggesting that less severe injuries were at issue.<sup>285</sup>

The researchers offer a number of possible explanations for this lower frequency and severity of claims.<sup>286</sup> First, as complementary/alternative therapies tend to be less invasive, fewer injuries are likely to arise. Second, malpractice doctrine may still be in its infancy as it relates to practitioners of alternative medicine. Third, many complementary/alternative practices stress the “collaborative” aspect of the patient–provider relationship, so there may be less likelihood of resorting to litigation to settle disputes, even where injuries may occur. Finally, as suggested by Cohen,<sup>287</sup> given the diffuse and subjective nature of many alternative medicine practices, patients may not be able to prove that practitioners have departed from a coherent, identifiable standard of care.

<sup>284</sup> Particularly egregious conduct by a health-care provider may also result in criminal charges, such as *assault* or *criminal negligence causing bodily harm*, but these issues are not dealt with here.

<sup>285</sup> Studdert DM. Legal issues in the delivery of alternative medicine. *Journal of the American Medical Women's Association* 1999; 54(4): 173-176 at 174, with reference to Studdert DM et al. Medical malpractice implications of alternative medicine. *Journal of the American Medical Association* 1998; 280: 1610-1615.

<sup>286</sup> *Ibid* at 174.

<sup>287</sup> Cohen, *supra*, note 198.

## The Practitioner's Duty of Care: Two Aspects

### *Duty of care in providing treatment*

The basic principles regarding liability of a health-care practitioner for negligence have been well established in Canadian law for some time, and reflect the ethical principles of non-maleficence and beneficence. In the leading Canadian case, the court held:

If a person holds himself out as possessing special skill and knowledge and he is consulted, as possessing such skill and knowledge, by or on behalf of a patient, he owes a duty to the patient to use due caution in undertaking the treatment.... [H]e owes a duty to the patient to use diligence, care, knowledge, skill and caution in administering the treatment.... The law requires a fair and reasonable standard of care and competence.<sup>288</sup>

There appear to have been very few malpractice claims against complementary/alternative practitioners.

Affirming this decision, the Supreme Court of Canada has ruled that doctors “have a duty to conduct their practice in accordance with the conduct of a prudent and diligent doctor in the same circumstances” and specialists have a duty to exercise “the degree of skill and knowledge of an average specialist in his field.”<sup>289</sup>

In determining what the professional standard of care is, courts will look to legislation and regulations governing such practitioners, and to guidelines, policies, and statements issued by that profession's regulatory body or professional associations. For example, as previously noted, in Ontario, British Columbia, and Alberta, there is legislation expressly stating that a physician is not guilty of professional misconduct or negligence simply by virtue of having provided non-conventional care unless that practice poses a greater risk to patients' health than the commonly accepted, prevailing practice.<sup>290</sup>

In addition, courts will receive into evidence the opinions of experts in the field as to what the reasonably knowledgeable and competent practitioner would have done in the circumstances. The Supreme Court has cautioned, however, that such evidence is only part of the overall assessment that: “The fact that a professional has followed the practice of his or her peers may be strong evidence of reasonable and diligent conduct, but it is not determinative.”<sup>291</sup>

### *Duty of care in obtaining informed consent*

The legal requirement to exercise due care and skill in administering treatment to a patient reflects the ethical principles of non-maleficence and beneficence. But another aspect of the practitioner's duty of care also reflects the principle of respect for autonomy. As affirmed most clearly in the leading Supreme Court decisions in *Reibl v Hughes*<sup>292</sup> and *Hopp v Lepp*,<sup>293</sup> a physician's duty of care to a patient does not mean only a duty to exercise reasonable skill in actually treating a patient, but also to disclose all material information about the risks of a treatment and its alternatives in order to obtain informed consent from a patient. As explained by Picard and Robertson,

it is now well established that the duty of disclosure is not confined to risks, but extends to other material information which a reasonable patient would want to have. In particular, the patient must be informed of any available alternatives to the treatment

<sup>288</sup> *Crits and Crits v Sylvester*, [1956] OR 132, affirmed [1956] SCR 991, citing with approval *Rex v Bateman* (1925), 41 TLR 557 at 559.

<sup>289</sup> *ter Neuzen v Korn*, [1995] 3 SCR 674; *Lapointe v Chevette* (sub nom *Lapointe v Hopital Le Gardeur*), 90 DLR (4th) 7 (SCC).

<sup>290</sup> *Medicine Amendment Act, 2000*, supra, note 265; *Medical Profession Act*, supra, note 264; *Medical Practitioners Amendment Act, 2001*, supra, note 266 at s 60(1.1).

<sup>291</sup> *Roberge v Bolduc* (1991), 78 DLR (4th) 666 at 710 (SCC).

<sup>292</sup> [1980] 2 SCR 880.

<sup>293</sup> [1980] 2 SCR 192.

being proposed, as well as the material risks associated with those alternatives.<sup>294</sup>

Furthermore, the standard for disclosure is a high one, and distinct from the standard for treatment. As the BC Court of Appeal has explained,

the standard set by a reasonable practitioner in the field has been retained as a measure of the extent of the duty of the doctor to the patient for such matters as diagnosis and the carrying out of treatment or surgery, but the standard for gauging the extent of the duty of the doctor to the patient in matters to do with ... decisions about treatment and about all other matters requiring the understanding and knowing cooperation of the patient is not the standard of the reasonable practitioner, set by medical considerations alone, but rather the standard of disclosing all material risks and all special or unusual risks, and answering the patient's questions fully and frankly.<sup>295</sup>

As the Supreme Court stated in *Reibl v Hughes*, the basic question is: would a reasonable person in the patient's position probably have gone ahead with the procedure if there had been proper disclosure?<sup>296</sup>

There is no reason why complementary/alternative practitioners should not be subject to the same duty as conventional physicians to disclose the risks of a proposed treatment in order to obtain the patient's informed consent. In *Forgie v Mason*, the New Brunswick Court of Appeal applied the test of consent to treatment from *Reibl* and *Hopp* to chiropractors, saying they were to be treated like other "medical practitioners."<sup>297</sup> The ethical principle of respect for a patient's autonomy should bind both conventional and complementary/alternative practitioners equally.

But how far does the duty of a practitioner to discuss *alternative* courses of treatment extend? In this area, what little law there is reflects the primacy of conventional biomedicine. Courts have clarified that the patient need not be informed of merely *any* available alternative to conventional treatment. In the case of *Santos v Traff*, an Alberta trial court cautioned that

this characterization is too wide if taken literally and absent the connection to the reasonable patient. In fact, there is no duty to advise of fringe or dangerous alternatives. Common sense suggests that the failure to advise of alternatives might be applied most successfully against the doctor who uses the fringe alternative, or one not generally accepted by the medical profession as within the standard of care, and fails to inform of the medically mainstream alternative.<sup>298</sup>

Another Alberta case demonstrates a similar reluctance to overextend a conventional physician's duty to discuss unconventional treatment options, but again offers little guidance beyond simply saying that "fringe" alternatives need not be considered with the patient. In *Seney v Crooks*,<sup>299</sup> a physician was sued by a patient for malpractice. While the case itself did not involve the use of any complementary/alternative therapy, the issue that arose was the extent of the physician's duty to inform a patient of modes of treatment alternative to the one proposed, in order to ensure that a patient can make an informed decision about which treatment option to pursue. The Alberta Court of Appeal was clear that "the duty to inform a patient includes the duty to inform of alternative treatments as well as the risks of treatment."<sup>300</sup> But the physician argued against expanding such a duty too far:

A physician's duty of care to a patient does not mean only a duty to exercise reasonable skill in actually treating a patient, but also to disclose all material information about the risks of a treatment and its alternatives in order to obtain informed consent from a patient.

<sup>294</sup> Picard EI, Robertson GB. *Legal Liability of Doctors and Hospitals in Canada*. Carswell: Toronto, 1996, at 129-130.

<sup>295</sup> *Arndt v Smith* (1995), 6 BCLR (3d) 201 at 212 (CA), affirmed by SCC, [1997] 2 SCR 539; followed in *Seney v Crooks*, 1998 ABCA 316, [1998] AJ No 1060 at para 71 (QL).

<sup>296</sup> *Reibl v Hughes*, supra, note 292; *Arndt v Smith*, supra, note 295; *Barber v Wilson* [1996] OJ No 2531 (Gen Div) (QL); *LH v Sheppard*, [2000] OJ No 2188 (Ont Sup Ct) (QL).

<sup>297</sup> (1986), 30 DLR (4th) 548 (NBCA), appeal to SCC dismissed without reasons, applied in *LH v Sheppard*, supra, note 296.

<sup>298</sup> *Santos v Traff*, 1999 ABQB 630, [1999] AJ No 931 (QL) at para 49.

<sup>299</sup> 1998 ABCA 316, [1998] AJ No 1060 (CA) (QL).

<sup>300</sup> *Ibid* at para 55 (QL).

There is no reason why complementary/alternative practitioners should not be subject to the same duty as conventional physicians to disclose the risks of a proposed treatment in order to obtain the patient's informed consent. The ethical principle of respect for a patient's autonomy should bind both conventional and complementary/alternative practitioners equally.

to overextend the duty to inform of alternative treatments places an unpredictable and monumental responsibility upon the medical profession and one that is much too onerous. For instance, would it be necessary to inform of every possible alternative available, whether or not generally considered reliable by the profession? Would each professional need to become knowledgeable on, and inform patients of, alternative medicine practices such as chiropractic treatment or holistic medicine treatments? If the treatment performed complies with the local standard, why should it be negligence to fail to inform of another?<sup>301</sup>

While the court ultimately ruled against the physician on the facts of the case, it was sympathetic to this argument:

That is a critical question and the arguments against overextending the limit are compelling. The scope of the duty to inform must be approached carefully. However, while the breadth of that duty is important, this case does not compel a demarcation of its boundaries. The alternate medical procedure in this case was not a fringe alternative. It was not an alternative offered outside the specialty of orthopaedics or by some other form of health care.<sup>302</sup>

Broadly interpreted, these cases suggest that a conventional practitioner might have a duty to advise of an unconventional alternative therapy as long as it is not “fringe” or “dangerous.” Yet this is a lot to read into only two cases, particularly when there is little developed jurisprudence on this point. There is no reported case in Canada of a conventional health-care professional found liable for not advising a patient of an unconventional or alternative form of treatment. This is not surprising: unconventional therapies would by definition fall outside the ordinary range of treatment options and, as suggested by the comments in *Seney v Crooks*, courts are likely to give short shrift to an argument that a physician (or other conventional biomedical professional) is negligent for not raising and discussing options outside the ordinary scope of practice. This highlights the need for greater, improved research into the safety and efficacy of various complementary/alternative therapies, so that practitioners (conventional and complementary) and patients can make more informed treatment decisions, with adequate information about the range of treatment options.

### **Standard of Care for Treatment with Complementary/Alternative Therapies**

The preceding section identified the basic common law principles governing conventional practice by health-care professionals. This section examines how these principles apply to determining the legal standard of care in the practice of complementary/alternative medicine. First, it looks at the regulation of complementary/alternative practitioners; second, it looks at the possible standards to which conventional practitioners may be held when incorporating complementary/alternative therapies into their practice. As Feasby points out, this discussion illustrates that “Alternative medicine and malpractice law are an awkward fit. The issues of what the appropriate standard of care in alternative contexts is, and how to determine it, go to the heart of this question.”<sup>303</sup>

<sup>301</sup> Ibid at paras 57-58 (QL).

<sup>302</sup> Ibid at paras 60, 64 (QL).

<sup>303</sup> Feasby, *supra*, note 19 at para 2.



### ***CAM practitioners of a recognized “profession” or “school” of practice***

A review of US cases indicates that “malpractice claims brought against practitioners of alternative medicine are broadly similar to those brought against physicians. No dramatically new or expanded theories of liability appear to have emerged.”<sup>304</sup> In particular, one of the basic principles in the law of malpractice is the “same school” rule.

#### **“Same school” rule**

It is generally accepted that health care practitioners are entitled to have their treatment of patients tested by rules and principles that conform to their training and to standards set by their immediate professional peers, not by those of some other school. This rule is not confined to generalist, specialist, and subspecialist disciplines within conventional medical practice; courts have also applied it when evaluating the conduct of a wide range of schools of alternative medicine.

School-specific standards have several rationales. Courts have considered it unfair to judge a defendant practitioner by standards that do not conform to her education, training, and peer expectations. Moreover, when a patient knowingly chooses or consents to treatment from a given practitioner, she may expect the skills, but must assume the risks that are common to that practitioner’s healing method. In addition, courts and juries can have a difficult time deciding the negligence question when experts from a range of backgrounds offer testimony about different standards.<sup>305</sup>

This means that, as a general rule, in assessing whether a practitioner has failed to meet the required standard of care, a court will not accept the evidence of a practitioner from a different school of thought about the appropriate method of treatment, but will hear from the practitioner’s own peers from within that practitioner’s own school of thought.

This “same school” rule appears to be the state of Canadian law as well. In the handful of relevant cases in Canada (all dealing with chiropractic), the courts have taken the same approach in cases of alleged malpractice by complementary/alternative practitioners as in cases of conventional physicians. Although there are some possible qualifications or exceptions, the weight of Canadian case law indicates that non-conventional practitioners will be held to a standard appropriate to their discipline.

In the early case of *Gibbons v Harris*,<sup>306</sup> often cited in subsequent cases, a chiropractor failed to diagnose a child with a condition affecting the spine and causing degeneration of several vertebrae, and performed spinal manipulation that worsened the condition. The Alberta appellate court accepted the general rule that treatment offered by one school of practice should not be judged by practitioners of another – meaning that opinions about the appropriate standard of care for a chiropractor should not ordinarily be received from a conventional physician who is not trained in, or familiar with, the theory and practice of chiropractic.<sup>307</sup> On numerous subsequent occasions, Canadian trial and appellate courts have reiterated that, in the case of a chiropractor facing allegations of negligence, “the standard by which he is to be judged is not that of the merely reasonable man but the standard of what may reasonably be expected of the ordinary, careful, competent chiropractor.”<sup>308</sup>

As a general rule, health-care practitioners are to be held to the standards of their own “school” of practice, rather than standards set by some other school.

<sup>304</sup> Studdert, *supra*, note 285 at 173.

<sup>305</sup> *Ibid* at 174.

<sup>306</sup> *Gibbons v Harris*, [1924] 1 DLR 923 (Alta SC App Div).

<sup>307</sup> *Ibid* at 925.

<sup>308</sup> *Penner v Theobald* (1962), 35 DLR (2d) 700 (CA) at 704. See also *Shepherd v Knight*, [1985] OJ No 508 (HCJ) (QL); *Hicks v Schwab* [1993] OJ No 1275 (Gen Div) (QL) at para 75; *Barber v Wilson*, *supra*, note 296 at paras 5, 8 (QL); *LH v Sheppard* *supra*, note 296.

A similar approach was taken most recently in a negligence action in the United Kingdom, in what is apparently the first case in that country to have considered the issue. In *Shakoov v Situ*,<sup>309</sup> in determining whether the practitioner had breached his professional duty to exercise reasonable care and skill in treating the patient, the court considered the issue of whether the practitioner was to be judged by the standards of the reasonably careful practitioner of Chinese herbal medicine, or according to the standards applicable to orthodox medical practitioners. Although it did not say so expressly, the court seems to have accepted, as a general proposition, that the standard of care should be that of the ordinary practitioner of TCM. However, it qualified this by then ruling

that when a court had to adjudicate on the standard of care given by an alternative medical practitioner it would often, perhaps invariably, not be enough to judge him by the standard of the ordinary practitioner “skilled in that particular art”; it would often be necessary to have regard to the fact that the practitioner was practising his art alongside orthodox medicine; and the court would need to consider whether the standard of care adopted by the alternative practitioner had taken account of the implications of that fact.<sup>310</sup>

The implications of this might vary depending on the area of expertise and the specific act or omission on the part of the alternative practitioner that was at issue. However, in the court’s view in this particular case, the fact that the Traditional Chinese Medicine practitioner was practising alongside orthodox medicine led to a number of conclusions:

First, the practitioner had to recognise that he was holding himself out as competent to practise within a system of law and medicine which would review the standard of care he had given to a patient. Secondly, where he prescribed a remedy which was taken by a patient, it was not enough to say that the remedy was traditional and believed not to be harmful; the practitioner had a duty to ensure that it was not actually or potentially harmful. Thirdly, he had to recognise the probability that any person suffering an adverse reaction to such a remedy was quite likely to find his way into an orthodox hospital and that the incident might well be “written up” in an orthodox medical journal. [Therefore,] he should take steps to satisfy himself that there had not been any adverse report in any such journal on the remedy which ought to affect its use.<sup>311</sup>

The court’s approach in *Shakoov* reflects that it was grappling with the reality of patients themselves combining different modalities. Furthermore, the court’s conclusions also highlight the importance of practitioners eliciting information about patients’ use of other therapies, as well as the need for greater practitioner understanding of how different forms of care must be more coordinated so as to complement one another. Finally, the duty on the practitioner to ensure that a remedy is not actually or potentially harmful throws into stark relief the urgent need for more, improved research into the safety and efficacy of complementary/alternative therapies.

### Exceptions to the “same school” rule

The decided cases indicate there are a number of (ill-defined) exceptions to the general rule that only an expert of the same school as the practitioner

<sup>309</sup> [2000] INLR No 137 (QB) (QL).

<sup>310</sup> *Ibid.*

<sup>311</sup> *Ibid.*

accused of malpractice should be able to give an opinion as to the acceptable standard of practice. The exceptions are:

- (1) where a complementary/alternative practitioner strays outside the scope of permissible practice;
- (2) where there is an “overlap” between standards at issue between schools of practice;
- (3) where the alleged malpractice relates to diagnosis as opposed to treatment; or
- (4) where there is no coherent school of practice.

**Practising outside permitted scope:** While practising within the accepted parameters of a particular field, complementary/alternative practitioners accused of malpractice are more likely to be judged by the courts according to the standards of competent practitioners in their field. However, practitioners (conventional or unconventional) who venture beyond the scope of practice that is legally permitted (where the jurisdiction’s legislation contains such parameters) or that is generally accepted by other peer practitioners are not likely to receive the same kind of deference, because there is no claim to be made that they have special expertise or training in such an area. In such cases, should practitioners venture into a realm of practice that is reserved for professionals of a different school or having substantially different qualifications, they will likely be held to the standard of that school, and would therefore be more likely to be judged as having acted negligently by not meeting the standards of that school.

**Overlap:** In the US, courts have ruled that where the expertise of one school overlaps or converges with that of another, an expert from a different school than that of the practitioner accused of malpractice can testify as to the appropriate standard of practice. For example, in the leading case of *Rosenberg v Cahill*,<sup>312</sup> a chiropractor failed to recognize tumours on an x-ray and prescribed a regimen of manipulation. The patient sued, alleging the misdiagnosis resulted in delay in obtaining a proper diagnosis and treatment. The chiropractor argued that the patient could not have a medical doctor testify as to the appropriate standard of care expected of chiropractors. However, the New Jersey Supreme Court accepted that an exception to the “same school” rule should be made – the overlap of the two professions in using x-rays and diagnosing conditions requiring conventional medical treatment was sufficient for a doctor to give evidence about the care that should be taken by the chiropractor.

**Diagnosis/treatment distinction:** Feasby’s review of Canadian cases indicates that this “overlap” exception has not been considered by Canadian courts (although he suggests that it could very well be recognized where the medical profession is given jurisdiction over some alternative therapy, such as osteopaths being supervised in Alberta by the College of Physicians & Surgeons).<sup>313</sup> However, he suggests that this “overlap” exception may not be adopted in Canadian law because some courts here have already drawn a distinction between taking adequate care in *diagnosis* and taking adequate care in *treatment*, and that this distinction may be similar in its effect to the “overlap” rule in US case law.

As noted above, in the first Canadian case on the standard of care for an “alternative” practitioner, *Gibbons v Harris* (1924), the Alberta appellate court affirmed the general “same school” rule. However, it added a significant caveat to this rule. In the court’s view, such a rule only applied to *treatment*, and not to *diagnosis*:

<sup>312</sup> *Rosenberg v Cahill*, 492 A 2d 271 (NJ 1985).

<sup>313</sup> Feasby, *supra*, note 19 at para 36.

Upon this question there is an obvious distinction between diagnosis and treatment. Diagnosis is the process of discovering what is actually in real truth the exact physical nature of the trouble. Upon this question there cannot be any question of different schools of opinion.... [I]t is contended [by the defendant chiropractor] that he did exercise reasonable skill and care in the treatment given according to the methods of his school and that practitioners of other schools cannot be admitted as witnesses to shew that this treatment was wrong. But surely this rule can only apply where the diagnosis has been correct. If the diagnosis was wrong and was wrong through culpable lack of skill and care it is difficult to see how the defendant can still say that his treatment was reasonably skilful and careful.<sup>314</sup>

This approach was followed in the more recent (1996) case of *Barber v Wilson* (also noted above), in which an Ontario trial court ruled that:

Defence counsel has submitted that I should not rely on the evidence of [the medical doctor specializing in physical medicine and rehabilitation] as he is not an expert in the field of chiropractic and therefore cannot comment on whether the defendants met the standard of a reasonable chiropractor in their care of the plaintiff. Under these circumstances I find that the principles set out in *Gibbons v Harris* ... are applicable, that is, [the physician's] evidence was not an opinion on the standard of chiropractic care but rather a more general opinion that any health care professional should take care before manipulating the plaintiff's spine, given his complaints at the time.<sup>315</sup>

Yet there is also an appellate court decision directly rejecting such a treatment/diagnosis distinction in deciding which experts can testify as to standards of care. In *Penner v Theobald* (1962), the Manitoba Court of Appeal heard a case alleging malpractice against a chiropractor, and the issue of the appropriate standard to be applied at the stage of diagnosis was directly addressed:

it should be noted that types of diagnosis may vary with different systems of health care; the type of diagnosis is naturally founded on the basic principles of each particular system. For that reason diagnosis by a medical doctor or an osteopath or a chiropractor may differ in some respects; but of the necessity for some type of diagnosis, or, as the chiropractors prefer to call it, analysis, I do not think there is any doubt.... [T]he only question to be considered in the instant case is whether or not the diagnosis or analysis carried out by the defendant in regard to the plaintiff was sufficient by chiropractic standards.... What is important ... is whether or not the diagnostician succeeds in ascertaining the source and nature of the illness or injury from which the patient suffers. In doing so a practitioner naturally and properly follows the methods characteristic of the school of health care of which he is a member; therefore, it is by the methods and practices which characterize his school that he must be judged in determining whether or not he was negligent in his diagnosis.<sup>316</sup>

<sup>314</sup> Supra, note 306 at 925, 929 (Alta SC App Div).

<sup>315</sup> Supra, note 296 at paras 5, 8.

<sup>316</sup> *Penner v Theobald*, supra, note 308 at 706, 708.

The reasoning in *Penner v Theobald* is certainly more respectful of differing schools of thought; it recognizes that systems of health-care practice do not differ merely at the stage of *treatment*, but in some cases operate within entirely different paradigms and understandings of illness and disease, with unavoidable implications for *diagnosis* of ill-health as well. This approach demonstrates a much less pronounced bias in favour of the dominant biomedical model than is reflected in the *Gibbons* and *Barber* cases.

Given this conflict in Canadian case law, it may still be possible that the “overlap” exception adopted in US law could be incorporated into Canadian law as a more rational and principled approach. This approach would allow for overlapping standards in both diagnosis and treatment in those cases where a complementary/alternative system of practice shares a basic degree of common understanding about the mechanisms of human illness and injury, or techniques in assessing patient condition, with conventional biomedicine. For example, chiropractors and osteopaths share with conventional medical doctors the same basic concepts of anatomy in their understanding of disease, and sometimes use similar diagnostic techniques (eg, x-rays). But the approach would also recognize that, where the explanatory framework or diagnostic and treatment techniques of a traditional practice are fundamentally alternative to biomedicine’s concepts of disease or injury – such as an imbalance of *qi* – it would be nonsensical to expect the practitioner of traditional Chinese medicine to be held to the same diagnostic standards as the conventional medical doctor. Such an “overlap” approach would thus better reflect medical pluralism and the autonomy of patients to determine which systems of health-care practice they choose to use, in the knowledge that different systems will approach diagnosis and treatment differently.

**No coherent standard of care:** As Cohen points out, “it is often difficult to determine exactly what protocols or procedures are within the standard of care for complementary and alternative medicine. Outside of biomedicine, standards of care are more fluid, because treatments involve widely varying schools of thought and techniques, and highly individualized or nonstandardized methods. Many treatments, such as massage therapy, draw on the provider’s intuitive or subjective faculties as much as on uniform, professionally prescribed practices.... [But] despite the less formalized agreement around standards of care, some professions have established guidelines for practice which could serve as the basis for standards of care in malpractice actions.”<sup>317</sup>

However, practitioners of some complementary/alternative therapies may not be recognized as belonging to a “profession” – in part because such standards of care have not been identified. Reviewing US and Canadian law, Feasby suggests that

there are three indicia of a health profession: (1) statutory recognition; (2) specialized education; and (3) substantially different treatment. Statutory recognition is in some respects an anomalous indicator as it can be considered to be a legislative recognition that (2) and (3) have been satisfied. If the first marker (statutory recognition) is present, in most cases a court would hold that a school of medicine was, indeed, a profession without further inquiry. If there was no statutory recognition, however, I suggest that it would still be open for a court to find that an alternative school of medicine was in fact a profession, based on the fact that it was

<sup>317</sup> Cohen, *supra*, note 198 at 45.

characterized by both specialized education and substantially different treatment.<sup>318</sup>

In cases where there is no recognizable profession, it will not be possible to identify a professional standard of care. In such cases, courts faced with malpractice suits against a practitioner who provides unconventional treatment will be left to apply basic principles of negligence law – the same standards that would be applied to any person. There is no professional standard to which the practitioner can be held, but at the same time there will be no special deference accorded to practitioners’ “professional” explanations of their conduct as situated within, and informed by, their school of thought regarding diagnosing and treating ill-health.

### **Standard of care for conventional practitioners using complementary/alternative medicine**

The preceding discussion identified that complementary/alternative practitioners are, generally speaking, to be held to a standard of care appropriate to their profession, school, or discipline. But the legal situation of conventional practitioners (eg, physicians) who utilize complementary/alternative medicine is likely somewhat different. After all, as noted above, they are already licensed within a biomedical regulatory framework, bound by policies and guidelines issued by their professional regulatory bodies, and are expected to approach the practice of health care within the biomedical model of diagnosing and treating illness and disease.<sup>319</sup>

Where they exist, such guidelines, policies, and practice directives from professional associations and professional regulatory bodies are key in determining the common law standard of care to which courts will hold practitioners. But there is still the legal issue of the appropriate standard to be applied. There are three possible standards of care to which the “dual practitioner” may be held.<sup>320</sup>

#### **Alternative medicine standard**

One option is to hold the physician to the standards set by complementary/alternative practitioners who regularly deliver the therapy in question. This makes sense if the issue is the care taken in the actual use or implementation of the therapy, because other regular practitioners of that school are best suited to judge whether the practitioner has acted with the requisite degree of skill and care for that practice. However, as Studdert notes:

The logical appeal of this approach does not extend to all situations. A relatively common allegation in claims against alternative medicine practitioners is failure to refer patients in need of medical treatment to an appropriate form of conventional medical treatment; other suits allege the use of alternative therapies that eliminate or reduce a patient’s chance at better recovery by conventional treatments. When these types of claims are brought against dual practitioners, application of alternative medicine standards is problematic. Courts are unlikely to consider that dual practitioners are somehow “blinded” to the medical knowledge they possess or are reasonably expected to possess. Thus, while arguments for application of alternative medicine standards may have some force in cases where physicians are alleged to have been negligent in administering techniques

<sup>318</sup> Feasby, *supra*, note 19 at para 26. For example, in *Penner v Theobald*, *supra*, note 308, the court stated that chiropractic was a recognized system or school of health care in Manitoba, as a result of the provincial *Chiropractic Act*.

<sup>319</sup> *Canadian Overview*, *supra*, note 10 for a review of policies on complementary/alternative therapies adopted by bodies such as colleges of physicians and surgeons.

<sup>320</sup> Studdert, *supra*, note 285.

that are foreign to medicine, a medical standard of care probably better reflects the dual practitioner's duty in clinical situations that implicate knowledge of both alternative and conventional medicine.<sup>321</sup>

Although it involved a professional disciplinary hearing and not a malpractice suit brought by a patient, the high-profile *Krop* case in Ontario seemed, on the surface at least, to adopt the approach of holding a conventional doctor practising “environmental medicine” to the standard of the reasonably competent practitioner in that field. The College of Physicians and Surgeons of Ontario was at considerable pains to clarify that *Krop* was not found guilty of practising “environmental” or complementary medicine, and that neither of these is prohibited by Ontario law or College regulations.<sup>322</sup>

Instead, it found *Krop* guilty of professional misconduct for failing to maintain a professional standard of practice in the care of six patients (none of whom had complained to the College), because his methods differed significantly from the majority of practitioners whom he called in his defence as experts in this field. The College discipline committee issued a reprimand and imposed a number of conditions on *Krop*'s registration as a physician, including adherence to the recommendations in the Report of the College's Ad Hoc Committee on Complementary Medicine; providing a patient with sufficient information to make informed choices, including not misrepresenting information or opinion before carrying out certain diagnostic or therapeutic procedures; and advising the patient of the usual and conventional treatment options (and their risks, benefits, and efficacy as reflected by current knowledge).<sup>323</sup> (*Krop* sought judicial review of the College's decision on technical grounds relating to the composition of the discipline panel, but was unsuccessful.<sup>324</sup>)

#### Mixed practice standard

A second option is that, in the spirit of the “same school” rule, courts faced with malpractice allegations against dual practitioners that relate to the use of complementary/alternative therapies will, in trying to determine the appropriate professional standard, seek the expert opinions of other dual practitioners – that is, other conventional practitioners who incorporate unconventional therapies into their practice of medicine. However, this may prove difficult in practice, given (a) the limited (albeit growing) number of conventional practitioners who practise “integrative” medicine, and (b) “the court may still have trouble discerning a coherent standard of care – one that is somehow distinct from either conventional or alternative medicine – against which to judge the defendant's conduct.”<sup>325</sup>

#### Conventional medical standard

Finally, the most likely outcome is that a court will hold a dual practitioner to a professional standard of care strictly articulated by conventional physicians. This poses a particular problem for the integration of complementary/alternative therapies into conventional medical practice: unless there is express legislation to the contrary (as exists in Ontario, British Columbia and Alberta, for example), the practitioner might be considered negligent simply on the basis of using an unconventional therapy, since to do so would, by definition, not meet the standard of care generally accepted by conventional practitioners. This was highlighted in the recent decision of a New York trial court in the case of *Charell v Gonzales*:

In judging malpractice claims, courts are unlikely to consider that dual practitioners are somehow “blinded” to the medical knowledge they possess or ought to possess.

<sup>321</sup> *Ibid* at 175.

<sup>322</sup> CPSO news release, *supra*, note 262.

<sup>323</sup> CPSO, Discipline Committee Decisions – Case Summaries: Dr. Jozef Krop, 1 January 2000. Available online via [www.cpso.on.ca](http://www.cpso.on.ca).

<sup>324</sup> *Krop v College of Physicians and Surgeons of Ontario*, [1997] OJ No 1950 (Div Ct) (QL).

<sup>325</sup> *Ibid*.

A court is most likely to hold a dual practitioner to a professional standard of care established by conventional practitioners.

The standard for proving negligence in a malpractice case is whether the treatment deviates from accepted medical standards.... [I]t would seem that no practitioner of alternative medicine could prevail on such a question[,] as the ... term “non-conventional” may well necessitate a finding that the doctor who practices such medicine deviates from “accepted” medical standards. This indeed creates a problem for such physicians which perhaps can only be solved by having the patient execute a comprehensive consent containing appropriate information as to the risks involved.<sup>326</sup>

In suggesting that comprehensive consent forms may be a sufficient defence for the practitioner, the court in *Charell* found support in the two *Revici* decisions already mentioned, in which a US appellate court affirmed the right of patients to choose which treatments to follow – provided that they are fully informed of the risks involved with a particular unconventional treatment, including the risk associated with forgoing conventional treatment.<sup>327</sup>

Another disciplinary (not malpractice) case from Ontario demonstrates how a conventional physician using unconventional therapies might be held to the standard of professional care expected of the conventional physician, without going so far as to make the use of an unconventional treatment negligent in itself. In *Ravikovich*, the defendant physician faced charges of professional misconduct for failing to maintain the standard of practice of the profession by employing diagnostic and therapeutic practices with no scientific or medical validity. He was also charged with incompetence for displaying a lack of knowledge, skill or judgment, or disregard for his patients’ welfare, because of his use of histamine injections for the purposes of diagnosis and treatment. Finally, he was charged with professional misconduct for making misrepresentations regarding a remedy or treatment – specifically that histamine injections could be used for diagnosis and for therapeutic purposes for a variety of conditions when the efficacy of this treatment is unproven.

The College’s Discipline Committee reaffirmed the principle (recognized in Ontario law) that using or recommending a non-traditional treatment is not in itself proof of deficient clinical ability.<sup>328</sup> But it also ruled that

there are certain obligations which a physician must accept if he or she employs a drug for a new or non-traditional treatment. The drug must be proven safe. The physician must record in considerable detail the clinical state of the patient and the changes in this state, both good and bad, that are produced by the medication. The physician should be aware of all of the pertinent publications that bear on the clinical problem as well as on the proposed treatment.<sup>329</sup>

The College’s Discipline Committee found *Ravikovich* guilty of professional misconduct; it reprimanded him, placed restrictions on his practice, and suspended his licence for three months. *Ravikovich*’s appeal to the courts was dismissed.<sup>330</sup>

### **The importance of informed consent**

The law on the issue of malpractice and professional standards for treatment remains uncertain – particularly with respect to conventional medical prac-

<sup>326</sup> *Charell v Gonzalez*, supra, note 197.

<sup>327</sup> *Schneider v Revici*, supra, note 195; *Boyle v Revici*, supra, note 196.

<sup>328</sup> O. Reg 52/95, made under the *Medicine Act*, 1991.

<sup>329</sup> College of Physicians and Surgeons of Ontario, Discipline Committee Decisions: Dr Felix Ravikovich (undated) ([www.cpso.on.ca/drravikovich.htm](http://www.cpso.on.ca/drravikovich.htm)). Reported in: CPSO, Member’s Dialogue, January 1996: Case #4.

<sup>330</sup> *Ravikovich v College of Physicians and Surgeons of Ontario*, application for leave to appeal dismissed [1997] OJ No 1625 (CA) (QL).



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tioners who incorporate the use of complementary/alternative therapies into their practice. But while the law struggles to achieve the right balance between protecting patients and ensuring freedom of choice, there is at least one ethical imperative that must bind practitioners of all schools and fields, and provides at least some guidance for sound (and legal) practice. The principle of respect for personal autonomy certainly requires of all practitioners, as both a moral and a legal duty, that they ensure “their patients are fully informed about any therapies they elect to receive, as well as any treatment they may forgo as a result of their decisions. In addition, dual practitioners should keep up to date with available evidence on the safety and efficacy of various alternative therapies.”<sup>331</sup>

<sup>331</sup> Studdert, *supra*, note 285 at 176.





## Conclusion

We should not tolerate adding to the misery of patients by placing them in conflict between alternative medicines. Good medicine is indivisible.... The resolution we should seek is to combine all that is beneficial.... We need new knowledge, but we also need to utilize effectively existing knowledge.<sup>332</sup>

As reflected in the above passage, what underlies the practice of good medicine is the pursuit of patient well-being. This paper has explored the implications of the imperative of practising good medicine, by identifying and applying key principles that are often used in bioethics, and by analyzing three key aspects of the legal framework governing complementary/alternative medicine in Canada. Three themes have repeatedly emerged from this discussion.

First is the critical need for additional and better research on complementary/alternative therapies. This need has been identified over and over as fundamental to ensuring informed access to a range of safe and effective treatment options – from the perspective of the consumer/patient who needs information to make health-care decisions; from the perspective of both conventional and complementary/alternative practitioners who need it to improve the quality of practice and advice to patients; and from the perspective of regulators who need this information to shape a regulatory environment that balances the interest of consumer/patient protection with the interest of consumer/patient freedom in health-care choices.

Building on the need for research, the second theme is the need for improved education and training of health-care practitioners as a key prerequisite for developing models and approaches to health care that recognize the benefits and disadvantages of both conventional biomedicine and a range of complementary/alternative therapies. Informed decision-making by patients

<sup>332</sup> Wall PD. Introduction. In: Wall PD, Melzak R (eds). *Textbook of Pain*, 1989, cited by the Association of Complementary Physicians of British Columbia. Consensus Paper on Complementary Medicine – November 1999 ([www.ccmadoctors.ca/acp\\_consensus.htm](http://www.ccmadoctors.ca/acp_consensus.htm)).

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rests not only on the data available, but also on the advice of trained, knowledgeable, and ethical practitioners whose overriding duty is to maximize patient well-being and minimize patient harm, unhindered by prejudices or ideology, with a critical but open mindset.

Finally, and facilitating achievement of the first two, the third theme is the need for regulation that strikes the right balance between the ethical imperatives of maximizing patient well-being, respecting patients' autonomy in making health-care decisions, protecting patients against harm, being equitable in the allocation of resources, and ensuring the accountability of health-care providers.

While this paper cannot cover the whole gamut of legal and ethical issues related to complementary/alternative health care and HIV/AIDS in Canada, the hope is that it will assist us in moving forward on these themes of research, education, and appropriate regulation to ensure that providers of both products and practices deliver safe and effective therapies to informed patients.



# Summary of Recommendations

## **Recommendation 1: Defining and Understanding the Field of Complementary/Alternative Health Care**

The Canadian Institutes for Health Research (CIHR), the Office of Natural Health Products (ONHP), and other research funding agencies should fund further research into clarifying appropriate definitions and key characteristics of “complementary/alternative health care,” as well as developing an appropriate conceptual framework for organizing the wide range of therapies and practices that fit within this category in order to guide consumers, providers, and regulators.

## **Recommendation 2: Key Areas for Research regarding CAM and HIV/AIDS**

Research funding bodies (both health-care research funding bodies and bodies funding research in other disciplines), as well as Health Canada under the Canadian Strategy on HIV/AIDS, should fund research that provides up-to-date information about:

- (1) Use of complementary/alternative therapies by people with HIV/AIDS
  - (i) the patterns and prevalence of complementary/alternative medicine use among people with HIV/AIDS;
  - (ii) which therapies are used most commonly by people with HIV/AIDS, how they are used and for what purposes or conditions, and the users’ reasons for choosing certain therapies,

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including the range of beliefs held by people with HIV/AIDS regarding both the merits and demerits of conventional and complementary/alternative therapies;

- (iii) which complementary/alternative therapies are commonly used in conjunction with conventional medicine, and the reasons for combining treatment approaches;
- (iv) the effectiveness (real and perceived) of various complementary/alternative therapies, and users' satisfaction with them;
- (v) profiles of people with HIV/AIDS who use complementary/alternative therapies, including variations across regional, age, gender, socioeconomic, racial/ethnic, and disease/disability/health-condition categories;
- (vi) whether special features, patterns, or needs exist among specific subpopulations that use complementary/alternative therapies as part of HIV/AIDS care, such as: Aboriginal people (including those who use both conventional Western medicine and traditional healing practices); women; gay men; drug users; various ethnocultural communities; low-income people; and prisoners (whose access to various kinds of therapies is often limited).

### (2) Consumer information and knowledge

- (i) the sources of information about complementary/alternative products and therapies accessed by people with HIV/AIDS, and consumer satisfaction;
- (ii) the accuracy, completeness, and ease of access of sources of treatment information regarding complementary/alternative therapies for people with HIV/AIDS, including such sources as HIV/AIDS-treatment information organizations, buyers' clubs, websites, information pamphlets, and brochures available at community organizations, practitioners' offices, or vendors of natural health products;
- (iii) how people with HIV/AIDS would prefer to get information about complementary/alternative therapies, barriers to getting the information they want, the need to make informed treatment choices, and feasible mechanisms for making reliable information accessible;
- (iv) what kind of information people with HIV/AIDS use and want to make decisions about their health care, and their level of trust in various sources (such as recommendations from conventional or complementary/alternative practitioners, family, friends or acquaintances; product labels and monographs; promotional material produced by manufacturers or practitioners; professional associations; community organizations; websites; and medical or other literature).

### (3) Access to complementary/alternative therapies

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- (i) where, how, and from which sources people with HIV/AIDS access complementary therapies and what barriers to access exist;
- (ii) the interface between the use of complementary/alternative therapies and the conventional health-care system, including the degree to which patients are referred to complementary/alternative practitioners by conventional practitioners and vice versa, and the attitudes of conventional practitioners toward complementary/alternative practitioners and vice versa;
- (iii) what people with HIV/AIDS spend on complementary/alternative therapies, and on which sorts of therapies;
- (iv) the views of people with HIV/AIDS who use complementary/alternative therapies, practitioners (complementary and conventional), government, and private insurers regarding coverage of different kinds of complementary/alternative therapies under private and public health insurance plans.

### **Recommendation 3: Principles and Protocols for Research with and within Aboriginal Communities**

Research with and within Aboriginal communities should respect principles of ownership, control, and access over research methods and results. Adequate, enforceable legal protections for the intellectual property of Aboriginal communities (which property includes knowledge of traditional healing practices) need to be guaranteed in the design of such research. Health Canada, the Canadian Institutes for Health Research, and representatives of Aboriginal communities should ensure that protocols are developed to govern the conduct of health research with and within Aboriginal communities that are approved by the communities in question before any such research is undertaken.

### **Recommendation 4: Conventional Practitioners Should Ask about Patients' CAM Use**

Professional practice policies or guidelines on complementary/alternative therapies developed by regulatory bodies for health professionals (eg, Colleges of Physicians and Surgeons) should instruct members to inquire into their patients' use of complementary/alternative medicine. Individual practitioners should consciously make an effort to inquire into their patients' use of complementary/alternative therapies.

### **Recommendation 5: CAM Practitioners Should Ask about Patients' Use of Other CAM or Conventional Treatments**

Practitioner associations in the field of complementary/alternative health care should encourage their members to inquire into their patients' use of other complementary/alternative therapies as well as

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conventional medical treatments. Individual practitioners should make an effort to inquire into such use.

### **Recommendation 6: A Research Agenda for CAM and HIV**

The Canadian Institutes for Health Research, the Office of Natural Health Products, other health-care research funding agencies, and Health Canada, should participate (or continue participating) in developing, implementing, and funding an agenda for research into the safety and efficacy of complementary/alternative medicine as part of HIV/AIDS health care (both natural health products and other therapies). The process of developing and implementing this research agenda should involve people with HIV/AIDS as patients/consumers, those providing services to people with HIV/AIDS (including conventional and complementary/alternative health practitioners, community-based organizations), and relevant and appropriate government regulators (eg, ONHP in the case of research into natural health products).

### **Recommendation 7: Support a Centre of Excellence in CAM research**

Health Canada, provincial health ministries, the Canadian Institutes for Health Research, the Office of Natural Health Products, and health-care research funding agencies should further investigate the possibility of developing and supporting a “virtual” institute or centre of excellence in complementary/alternative health-care research (to research both natural health products and other complementary/alternative therapies).

### **Recommendation 8: Priorities for Research in CAM and HIV/AIDS**

In funding research in the areas of complementary/alternative medicine, health-care research funding agencies should give priority to research into the safety and effectiveness of those complementary/alternative therapies for which there is:

- (a) encouraging, reliable preliminary effectiveness data,
- (b) consistent anecdotal evidence of effectiveness,
- (c) evidence of common use among people with HIV/AIDS, and/or
- (d) evidence of known or potential significant adverse effects, including where used in conjunction with conventional HIV/AIDS treatments.

### **Recommendation 9: Roster of CAM Experts for Reviewing Research Proposals**

Health-care research funding agencies should build up a roster of properly trained individual experts in various fields of complementary/alternative therapy practice who can contribute their expertise to panels or committees reviewing proposals for research funding.



**Recommendation 10: Developing Research Skills among CAM Practitioners**

Health Canada, provincial health ministries, and health-care research funding agencies need to make funds available for – and schools and training programs in complementary/alternative medicine need to include in their curriculum – the development of research skills among practitioners of complementary/alternative therapies, so as to generate more and better-quality research into the safety and efficacy of complementary/alternative therapies.

**Recommendation 11: Community-Based Research into CAM**

Health Canada and health-care research funding agencies should ensure that at least some of their funds used for researching complementary/alternative therapies in HIV/AIDS care is allocated to community-based research projects. Because a significant number of people with HIV/AIDS likely access commonly used complementary/alternative therapies or information about such therapies through community-based organizations, this approach to research could be particularly well-suited to investigating at least some of the key research areas identified above. Furthermore, it offers a way to circumvent resistance to research into complementary/alternative medicine that persists in more institutional research settings, and is consistent with a philosophy of active patient/user involvement in care and treatment decisions common to many people with HIV/AIDS and users of complementary/alternative medicine generally.

**Recommendation 12: Encourage Interest in CAM Research among HIV Researchers**

The Canadian Association for HIV Research (CAHR) and similar bodies organized at regional or provincial levels should encourage interest among their members in research into complementary/alternative therapies as a component of health care for people with HIV/AIDS.

**Recommendation 13: Funding curriculum development for training of conventional and CAM practitioners**

Health Canada, provincial ministries of health, and health-care research funding bodies should fund the development of (a) curricular materials on complementary/alternative therapies that can be incorporated into the core curriculum of conventional health-care practitioners, and (b) curricular materials in basic areas of conventional biomedical practice that should be incorporated into the core training of complementary/alternative practitioners. Developing such curricular materials should involve existing schools and training programs (conventional and complementary/alternative) that have developed educational/training standards in their respective fields, those acting in the field, and should also take into account the input of consumers.

### **Recommendation 14: Include HIV/AIDS-specific information in curriculum**

Curricular material developed for both conventional and complementary/alternative health-care practitioners needs to include basic education about HIV/AIDS, HIV/AIDS-specific considerations in the delivery of complementary/alternative therapies, and possibly clinically important interactions between conventional treatments and complementary/alternative therapies in people with HIV/AIDS.

### **Recommendation 15: Include CAM basics in training for conventional health care practitioners**

Educational institutions training conventional health-care professionals should encourage the development and introduction into their core curriculum of basic training in fields of complementary/alternative medicine that is sufficient to equip all conventional health-care professionals with the basic understanding necessary to recognize the potential benefits and disadvantages of complementary/alternative medicine and to adequately care for patients who may be using, or who may benefit from, complementary/alternative therapies or practitioners.

### **Recommendation 16: Include basics of conventional medicine in training for CAM practitioners**

Educational institutions or programs providing training to complementary/alternative health-care practitioners should encourage the development and introduction into their core curriculum of basic training in biomedical health sciences that is sufficient to equip complementary/alternative practitioners with the basic understanding necessary to recognize the potential benefits and disadvantages of conventional biomedicine and to adequately care for patients who may be using, or who may benefit from, conventional biomedical care.

### **Recommendation 17: Stringency of pre-marketing approval of natural health products**

The strictness of regulatory review for pre-marketing approval of natural health products for sale in Canada should correlate with (a) the known or reasonably foreseeable risk of harm from the product, and (b) the strength of the health claim made for the product.

### **Recommendation 18: Labelling requirements for natural health products**

The federal government should require the following in the labeling of natural health products as a condition of licensing for sale in Canada:

- Labels should conform to a standardized format that is accessible to a wide audience (plain language, multiple languages, large print, inclusion of key information on the package itself, and inclusion of other information in large print on package inserts).

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- Labels should indicate the quantities of all contents, and there should be minimum specified quantities of a vitamin, mineral, or other substance in the product in order for it to be labeled for sale as such.
- Labels should indicate whether the product is synthetic or natural, including whether it uses animal sources, and whether it incorporates genetically modified organisms.
- Labels should include directions for use, warnings, recommended dosage, and possible interactions with drugs or other natural health products, where known.
- Labels should advise consumers to inform their health-care provider of their use of the product, even if it may not seem relevant at the time.
- Labels should indicate a toll-free phone number and website for information on how consumers can report an adverse reaction (if and when such a mechanism for post-marketing monitoring is created).
- In those cases where the physical packaging of a product does not allow for the inclusion of the above information on or in the package itself, vendors of natural health products should be required to have product monographs including this information available for consumers at the point of sale.

### **Recommendation 19: Establish a post-approval surveillance system for natural health products**

In consultation with consumer groups, manufacturers, health-care practitioners, and manufacturers, the Office of Natural Health Products should establish a post-approval surveillance system to collect the following information about natural health products approved for sale in Canada: adverse events of varying degree; short-term side effects and long-term cumulative effects; and independent data regarding consumer use (eg, prevalence and frequency of use, conditions for which product used, etc).

### **Recommendation 20: Requirements for product licence holders to report adverse reactions**

Product licence holders should be required by law to report *any* “serious adverse event” relating to the use of their licensed product, whether inside or outside Canada, and whether anticipated or “unexpected,” to the Office of Natural Health Products within a set, short number of days after receiving information about such an event.

### **Recommendation 21: Requirements for health care practitioners to report adverse reactions**

Health-care practitioners should be required by law to report to the Office of Natural Health Products any serious adverse event relating to the use of a natural health product (whether or not licensed for sale in

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Canada) occurring in Canada or in a patient under their care and of which they have personal knowledge, within a set, short number of days after learning this information.

### **Recommendation 22: Collaboration with pharmacists to prevent and track product interactions**

The Office of Natural Health Products, Colleges of Pharmacists, pharmacists' professional associations, and manufacturers of natural health products should, with the input of consumer groups, collaborate to develop a protocol for pharmacists to encourage patients purchasing prescription drugs to voluntarily disclose which natural health products and non-prescription medications they are using. That information must be kept confidential, and should be tracked by pharmacies so that possible interactions between natural health products and pharmaceutical drugs, or between different natural health products, can be identified to inform consumers about possible safety concerns with the use of a product, or the interaction of products, and to draw these concerns to the attention of Health Canada for further investigation.

### **Recommendation 23: Enforcement of adequate penalties for breaching regulatory requirements**

To protect consumers, the federal government should ensure that penalties established for breach of regulatory requirements regarding the manufacture, licensing, labeling, and distribution and sale of natural health products should be sufficiently strong, and their enforcement sufficiently vigorous, to ensure compliance with those regulatory requirements.

### **Recommendation 24: Independence of government regulator from industry**

The Office of Natural Health Products must ensure that, in designing the regulatory system applicable to natural health products, the public interest remains paramount and must always supersede the interests of industry, where these are in conflict. Safeguards have to be put in place to ensure that the Office remains fully independent from the industry it purports to regulate.

### **Recommendation 25: Initiatives toward voluntary self-regulation by unregulated CAM practitioners**

Recognizing that different fields of complementary/alternative practice are at different stages of professional organization, practitioners should: organize themselves into practitioner associations; via such associations, consider the costs and benefits of establishing professional standards of qualification, ongoing competence, and acceptable practice as conditions of membership; and establish a mechanism for ensuring accountability of members for caring for patients in accordance with those standards.

### **Recommendation 26: Developing a resource guide for CAM practitioners to voluntarily self-regulate**

Health Canada should facilitate the creation of a working group, including representatives of newly or recently regulated complementary/alternative medicine practitioner groups, to produce and disseminate a resource tool (a “how to” guide) on developing mechanisms for voluntary self-regulation as a profession.

### **Recommendation 27: Funding research into models and legal parameters of regulating CAM practitioners**

Research funding agencies (both health-care research funding agencies and agencies funding research in other disciplines), as well as Health Canada under the Canadian Strategy on HIV/AIDS, should fund research that provides up-to-date information about:

- the views of people with HIV/AIDS who use complementary/alternative therapies, practitioners (complementary and conventional), manufacturers of natural health products, government, and private insurers, regarding the necessity for regulation in the fields of complementary/alternative health care, the role of government in regulation, and different models for regulating products and practitioners;
- a review of legal cases that (i) assesses the treatment of complementary/alternative medicine and practitioners using complementary/alternative medicine by professional regulatory bodies and before the courts; and (ii) explores the ethical and legal obligations of both conventional and complementary/alternative practitioners in the use of complementary/alternative medicine, as well as providing guidance for community-based organizations serving people with HIV/AIDS about the legal and ethical obligations governing the provision of complementary/alternative services and information; and
- the financial and other costs and benefits of different models of regulating practitioners in the health-care field, to inform decisions about which regulatory models are best suited for the regulation of practitioners in different fields of complementary/alternative medicine (if any regulation is found to be necessary).

### **Recommendation 28: Review of policies by conventional health professionals' regulatory bodies**

Colleges of Physicians and Surgeons, and other health professional regulatory bodies, should solicit the views of their members, of complementary/alternative practitioners, and especially of patients as to how restrictive current professional guidelines, codes, or policies are regarding physicians' involvement in providing complementary/alternative therapies or referring patients to providers of such therapies. The results of such consultation should inform a possible review of existing policies, if and where indicated.

**Recommendation 29: Requiring conventional health professionals to seek appropriate training before practising CAM**

As a matter of policy, regulatory bodies for conventional health-care professionals should include a requirement that those members who wish to practise unconventional therapies should, where possible, take training in the relevant field in a form that has been approved by a regulatory body or professional association of practitioners specializing in that field.

**Recommendation 30: Legislative review to facilitate safe integration of CAM and conventional treatments by patients**

Provincial health ministries should, in collaboration with professional associations of both conventional and complementary/alternative practitioners and health professional regulatory bodies, identify those legislative or regulatory changes necessary to enable multidisciplinary practices that could facilitate the integration of care between conventional and complementary/alternative practitioners for patients who seek such care.

**Recommendation 31: Funding Aboriginal research into traditional healing practices and practitioner**

Health Canada, provincial ministries of health, and health-research funding agencies should support research by Aboriginal people into the issues related to ensuring proper qualifications and practices by traditional healers.



## Appendix A: Use of Complementary/Alternative Medicine

For data about the use of complementary/alternative medicine in Canada, see pages 11 to 26 above. This appendix contains data from selected other countries.

### United States

Results similar to the prevalence of complementary/ alternative medicine use in Canada have been reported in two widely cited United States studies by Eisenberg et al. In the first study (1993) they found:

- If prayer and exercise were excluded (since one cannot visit a practitioner for these practices), 34 percent of respondents had used at least one complementary and/or alternative medicine during the previous 12 months.
- Among those who reported using complementary and/or alternative medicine, 64 percent did so without visiting a complementary and/or alternative medicine practitioner. In addition to this, 89 percent of respondents used complementary and/or alternative medicines without the recommendation of their conventional medical doctor, while 72 percent of complementary and/or alternative medicine users did not tell their conventional medical practitioners that they had used complementary and/or alternative medicine.

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- And, perhaps surprisingly, the estimated number of visits to complementary and/or alternative medicine providers (425 million) far exceeded the estimated number of visits to conventional medical practitioners (388 million) during the study year.<sup>333</sup>

The follow-up study by Eisenberg et al (1998) showed a significant increase in the use of complementary/ alternative medicine (again excluding prayer and exercise):

- Most notable in this study was that 42 percent of respondents reported using complementary and/or alternative medicine during the study year (up from 34 percent in the previous study), while the total number of visits to complementary and/or alternative medicine providers increased by 47 percent, thus attesting to the ever-increasing popularity of complementary and/or alternative medicine in the general population.<sup>334</sup>
- Similar to the situation in Canada: relaxation techniques (16.3 percent), herbal medicines (12.1), massage (11.1), and chiropractic (11.0) were among the most common complementary and/or alternative therapies used.<sup>335</sup>

The most recent data from a large-scale research effort in the United States were published in May 2000 by *Consumer Reports*, which reported the results of a survey to which 46,000 of its readers responded. Respondents provided information regarding their CAM use in the preceding two years.<sup>336</sup>

- Almost 35 percent of respondents had used megavitamins and other nutritional supplements; deep-tissue massage; chiropractic manipulation and acupressure; and mind–body treatments such as meditation and relaxation therapy. Some got these treatments through their regular doctors or an alternative practitioner. Nearly half tried new remedies on their own – most often herbals.
- Overall, 58 percent of conditions were treated with conventional – not complementary – treatments. However, readers report that 25 percent of conditions were treated with both conventional and complementary therapies. Just nine percent used alternatives only. The remaining conditions were treated primarily with over-the-counter drugs or lifestyle changes (exercise and diet).
- The 35 percent of readers who did turn to alternatives were looking mainly for relief from troublesome symptoms that had not yielded to conventional treatments. Those who said they were in severe pain or stress were more likely to try alternatives.
- For most medical conditions, the majority who tried alternatives found them very or somewhat helpful. But some highly touted alternatives – melatonin for insomnia, saw palmetto for prostate problems, magnets for pain – scored poorly. For nearly all medical conditions, readers said they got the best results from prescription drugs, and from surgery when it was recommended. Even among people who tried herbal therapies, prescription drugs won higher marks for all medical conditions.
- When readers felt comfortable enough to tell their doctors about their alternative choices – and 60 percent did – most doctors expressed approval (55 percent) or at least neutrality (40 percent), according to patients' assessment of doctors' responses. Only five percent said their doctor disapproved.

<sup>333</sup> Eisenberg DM et al, supra, note 25.

<sup>334</sup> Eisenberg DM et al, supra, note 127.

<sup>335</sup> Ibid at 1572.

<sup>336</sup> The mainstreaming of alternative medicine. *Consumer Reports* May 2000: 17-25 at 17-18.



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- Nearly one in four readers who tried an alternative did so on the recommendation of a doctor or nurse. More than half such recommendations were for herbals and other supplements, most typically for arthritis and prostate problems.

Some recent studies in the United States have questioned the popular belief that there is limited use of complementary/alternative medicine within poor and underserved populations. In 2000, Wolsko et al reported the results of a survey administered to 93 percent of patients (536 people) seen consecutively over a five-day period in December 1998 at three general medical clinics in Denver, Colorado, each serving distinctly different socioeconomic segments of the area's population. Respondents were asked to complete a brief, self-administered questionnaire involving five of the modalities reported in previous research as more commonly visited: acupuncture, chiropractic, herbal medicine/dietary or vitamin supplements, meditation/relaxation, and massage. Researchers reported two major findings:

First, use of and interest in future use of practitioners of alternative medicine did not differ substantially when three diverse patient populations were compared. These clinic populations comprised markedly divergent socioeconomic groups as assessed by race, insurance status, and self-reported annual income. We found no relationship between annual income and complementary medicine usage on multi-variable analysis. Other recent studies support our observations [references omitted].... Taken together, our and other observations clearly emphasize that alternative/complementary medicine usage is not confined to any well-circumscribed socioeconomic group.<sup>337</sup>

A second noteworthy finding of our study is that low self-perceived health status is a major, independent significant predictor of the use of an alternative medicine provider. We found that users of alternative/complementary medicine were more than twice as likely to have low self-perceived health status than nonusers.... Together our results and those of others support that poor health status is another significant, independent determinant of alternative medicine usage.<sup>338</sup>

Wolsko's questioning of assumptions about the economic status of those who use complementary/alternative medicine may be bolstered by a study published in 1998 that looked at the use of CAM by over 96 percent of homeless youth receiving care at a street-clinic youth program in Seattle, Washington. In that study, Breuner et al found that:

- CAM was used by over 70 percent of the youth.
- Referrals to CAM came most often from friends (52.7 percent).
- The most common reason given for using CAM was because it was "natural" (43.9 percent).
- Most of those who used CAM (87.3 percent) believed they had been helped "some" or "a lot."
- Given their choice of providers to visit when ill, 51.7 percent would seek care from a physician, 36.9 percent from a CAM provider, and 11.4 percent would self-treat.<sup>339</sup>

Breuner et al concluded that care with complementary/alternative medicine is frequently used and accepted by homeless youth (at least this population

<sup>337</sup> Wolsko P et al. Alternative/complementary medicine: wider usage than generally appreciated. *Journal of Alternative and Complementary Medicine* 2000; 6(4): 321-326 at 324-325.

<sup>338</sup> *Ibid* at 325.

<sup>339</sup> Breuner CC, Barry PJ, Kemper KJ. Alternative medicine use by homeless youth. *Archives of Pediatrics & Adolescent Medicine* 1998; 152: 1071-1075.

accessing a health clinic), and suggested that integrating CAM into allopathic health centres may serve as an incentive to entice youth into mainstream health care.

## Australia

In 1996, Australian researchers reported the results of research into the use of alternative medicine and alternative practitioners among 3000 respondents (age 15 or older) living in South Australia in 1993. They found:

- Among respondents, 48.5 percent had used at least one alternative *therapy* in the previous year, with women using significantly more therapies than men. Use of therapies was highest among those aged 15 to 34, those with higher socioeconomic status, higher levels of education, and higher household incomes.
- Furthermore, 20 percent had visited at least one alternative health-care *provider* during the previous year. There was no significant difference between men and women regarding the use of such providers, but use was greatest among younger age groups, those born in Australia, those who were employed, and those with higher incomes.<sup>340</sup>

In 1994, a smaller survey among 325 patients attending an urban teaching hospital's emergency department yielded "remarkably similar results in a predominantly white middle-class population."<sup>341</sup> The researchers noted that "the high usage in generally 'healthy' populations could not be attributed to desperation about an incurable disease or to reliance on traditional remedies by certain ethnic groups."<sup>342</sup> They reported that only 35 percent of users had informed their medical practitioner about any use of complementary/ alternative medicine, and noted the main reasons given were patients' perception that doctors would reject these therapies, and a belief that the patient was "in charge" of their health. Research released in 1998 showed that Australians consume as much in the way of "non-traditional" medicine, and in vitamin and mineral supplements, as they do prescription drugs.<sup>343</sup> Furthermore, research into the attitudes of Australian general practitioners toward the use of complementary therapies found that over 80 percent have referred patients to CAM practitioners, and nearly half have considered using them; furthermore, 93 percent of respondents who are general practitioners agreed that core medical undergraduate curricula should include some education on complementary therapies, and there was strong support for public insurance coverage of specific therapies (acupuncture, hypnosis, meditation, and chiropractic).<sup>344</sup> In 1999, researchers concluded that acupuncture has become a well-established complementary practice chosen by Australians, with women more likely than men to submit claims for acupuncture to the public health insurance scheme.<sup>345</sup>

## United Kingdom

The UK House of Lords' Science and Technology Committee recently published an extensive report on *Complementary and Alternative Medicine*, which includes an up-to-date review of the "rather limited data" available on the use of CAM in the UK, and concludes that CAM use is high and increasing.<sup>346</sup> A 1999 study of professional CAM bodies in the UK suggested that up to five million patients have consulted a CAM practitioner in the last year.<sup>347</sup> In 1999, a telephone survey of 1204 randomly selected adults conducted by the BBC found that 20 percent of respondents had used

<sup>340</sup> MacLennan AH, Wilson DH, Taylor AW. Prevalence and cost of alternative medicine in Australia. *Lancet* 1996; 37: 569-573; discussed in: York University Centre for Health Studies, *Canadian Overview* at 257, 260. See also: Shenfield GM, Atkin PA, Kristofferson SS. Alternative medicine: an expanding health industry. *Medical Journal of Australia* 1997; 166: 516; Drew AK, Myers SP. Safety issues in herbal medicine: implications for the health professions. *Medical Journal of Australia* 1997; 166: 538.

<sup>341</sup> Shenfield et al, supra, note 340, referencing Kristofferson SS, Atkin PA, Shenfield GM. Uptake of alternative medicine [letter]. *Lancet* 1996; 347: 972.

<sup>342</sup> Shenfield et al, supra, note 340.

<sup>343</sup> Pirotta MV et al. Complementary therapies: have they become accepted in general practice? *Medical Journal of Australia* 2000; 172: 105-109 at 105, citing Australian Bureau of Statistics. Australian Social Trends 1998. Canberra: ABS, 1998 (Catalogue No 4102.0).

<sup>344</sup> Ibid.

<sup>345</sup> Easthope G et al. Acupuncture in Australian general practice: patient characteristics. *Medical Journal of Australia* 1999; 170: 259-262.

<sup>346</sup> UK House of Lords, supra, note 204.

<sup>347</sup> Mills S, Peacock W. *Professional Organisation of Complementary and Alternative Medicine in the UK 1997: A Report to the Department of Health*. University of Exeter, 1997.

an alternative or complementary medicine or therapy within the previous year. Of these, 34 percent had used herbal medicine, 21 percent had used aromatherapy, 17 percent had used homeopathy, and 14 percent had used acupuncture or acupressure. Extrapolation from the results suggests that people in the UK spend around £1.6 billion annually on complementary/alternative medicine.<sup>348</sup>

### Other European countries

In 1994, Fisher and Ward prepared an overview of research from a variety of European countries regarding the use of complementary/alternative medicine.<sup>349</sup> They reported that in the countries for which statistics were available, between 20 and 50 percent of the population had used complementary/alternative medicine, and that popularity was growing rapidly. They noted that approximately 60 percent of the public in the Netherlands and Belgium were willing to pay additional health insurance premiums for complementary medicine, and 74 percent of the British public favoured it being paid for by the National Health Service. In 1999, Italian researchers noted that national trends showed that an increasing number of patients employ remedies outside the mainstream of conventional Western medicine.<sup>350</sup>

<sup>348</sup> Ernst E, White A. The BBC survey of complementary medicine use in the UK. *Complementary Therapies in Medicine* 2000; 8: 32-36.

<sup>349</sup> Fisher Ward, *supra*, note 30.

<sup>350</sup> Menniti-Ippolito De Mei, *supra*, note 86.



# Appendix B: Complementary/ Alternative Medicine Use by People with HIV/AIDS – Summary of Canadian and Other Studies

TABLE I  
*Overview of Canadian Studies of Complementary/Alternative Medicine Use among People with HIV/AIDS*

Author (Year)	Sample	Overall Prevalence of CAM Use	Most Popular CAM	Comments
Ontario Ministry of Health (1995) <sup>351</sup>	n/a	n/a	n/a	Community AIDS workers and HIV physicians reported an increase in complementary therapy use among clients. Increase appeared most pronounced among those living in large urban areas.

<sup>351</sup> Ontario Ministry of Health. Complementary therapies in HIV. *HIV Update* 1995; 2(3): 9-10.

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TABLE I (continued...)

Author (Year)	Sample	Overall Prevalence of CAM Use	Most Popular CAM	Comments
Community Research Initiative of Toronto & Canadian AIDS Society (1995) <sup>352</sup>	200 (185 men, 15 women in Toronto)	78.5%	Nutritional and other supplements (85%) Physical therapies (59%) Plant-based medicines (55%) Mind-body therapies (46%)	On average, respondents more satisfied with every category of CAM therapy than with drugs. Physical therapies had highest overall satisfaction rating of any category (4.27 out of 5). Over 90% of participants rated their experience with Swedish massage, chiropractic, active exercise, Shiatsu massage, and diet/nutrition as positive or very positive. Participants gave medicines from plants an overall average satisfaction rating of 3.75 out of 5. Fewer than 10% reported any negative experiences with plant-based medicines. Overall, no single therapy associated with identifiable effect on quality-of-life measures or severity of symptoms.
Meneilly et al (1996) <sup>353</sup>	62 women attending HIV clinic (98% Caucasian, mean age over 35)	42%	Herbal remedies (38%) Vitamins & minerals (29%) Relaxation techniques & massage (9%) Acupuncture (2%)	"In comparison to previous studies in homosexual men with similar demographics, women with HIV are more likely to use a wide variety of herbal remedies and less likely to use acupuncture.... HIV positive women appear to have a different pattern on alternative therapy use compared to men."
Ostrow et al (1997) <sup>354</sup>	657 PHAs accessing British Columbia provincial HIV drug plan	39%	Dietary supplements (30%) Herbal & other medicinal therapies (22%) Tactile therapies (22%) Mental relaxation techniques (20%)	Complementary therapy use was associated with younger age, income > US \$7300, having greater physical pain, and university education.
McMurchy et al (1998) <sup>355</sup>	387 PHAs recruited through HIV Ontario Observational Database	77%	Nutritional supplements	On average, respondents used 4 CAM therapies. Average reported monthly expenditure was \$53 per PHA, for an estimated annual expenditure of \$639 per PHA.

<sup>352</sup> CRIT/CAS, supra, note 56.

<sup>353</sup> Meneilly et al, supra, note 54.

<sup>354</sup> Ostrow et al, supra, note 54.

<sup>355</sup> McMurchy D., Leeb K., Millson P. The Utilization and Cost of Complementary Therapies in the Province of Ontario. HIV Ontario Observational Database, 1998. It should be noted that these figures, and those reported in the next two rows (Leeb et al 1998, Millson 1999), are all derived from the same study, although seemingly at different stages in the research process. The information noted under Millson 1999 represents the final figures for the study.

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TABLE I (continued...)

Author (Year)	Sample	Overall Prevalence of CAM Use	Most Popular CAM	Comments
				Total annual expenditure on CAM therapies by PHAs seeking care in Ontario is estimated to be approximately \$5.1 million.  Expenditure appears to increase with age, education level, and income; only income was an independent predictor of expenditure.
Leeb et al (1998) <sup>356</sup>	PHAs with data recorded in provincial HIV observational database (HOOD)	81% (at some point) 73.6% currently using CAM	Dietary supplements (61.7%) Physical therapies (33.5%) Medicinal plants (21.6%) Mind/body therapies (17.9%)	Half of those using CAM used two or more therapies, and a quarter used more than six therapies.
Waring et al (1998) <sup>357</sup>	96 clinic patients at Toronto Hospital (88% gay men)	88% currently using CAM 63% had used CAM in past	Multivitamins Marijuana Chiropractic	86% take 1 or more vitamin products. 60% take 1 or more herbal products. 35% consult a complementary therapies practitioner. General health and well-being most common reason for current CAM use (37%), whereas in past CAM most often used to increase immunity and prevent HIV progression (32%). 43% rate their CAM as “very effective.” 60% spend less than \$100/month on CAM, while 15% spend more than this.
Millson et al (1999) <sup>358</sup>	386 PHAs recruited through HIV Ontario Observational Database	approx 75%		Half of PHAs using CAM used 2 or more therapies, and a quarter used more than 6 therapies.  Those who use CAM report spending average of •85 month (•1016 annually).  Overall estimate that PHAs in Ontario spend •5.5 million annually on CAM.

<sup>356</sup> Leeb et al, supra, note 57.

<sup>357</sup> Waring et al, supra, note 88.

<sup>358</sup> Millson et al, supra, note 72.

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TABLE I (continued...)

Author (Year)	Sample	Overall Prevalence of CAM Use	Most Popular CAM	Comments
Heath et al (1999) <sup>359</sup>	PHAs accessing BC provincial HIV drug plan	n/a	n/a	Annual questionnaire showed increase over 4 years in the use of each category of CAM: 50% increase for dietary supplements; 32% increase for herbal and medicinal therapies; 27% increase for tactile therapies; 23% increase for relaxation therapies.  The use of complementary therapies among PHAs in British Columbia has doubled between 1995 and 1998.
Kendall et al (2000) <sup>360</sup>	979 PHAs receiving anti-HIV ARVs through BC provincial drug plan	n/a	11.6% used meditation	
Braitstein (2000) <sup>361</sup>	977 PHAs receiving ARVs through BC provincial drug plan	n/a	14.7% reported medical use of marijuana	
Braitstein (2000) <sup>362</sup>	1008 PHAs receiving ARVs through BC provincial drug plan	42.1%	n/a	
Furler (2000) <sup>363</sup>	48 PHAs recruited through Ontario HIV Observational Database (HOOD)	96% of women  67% of men	<u>Women</u> Mind-body therapies (86%) Herbal therapies (56%) Supplements (43%) Massage (43%) Chiropractic (39%) Aromatherapy (39%)  <u>Men</u> Mind-body therapies (88%) Herbal therapies (25%) Massage (25%)	“Use of CAM in patients with HIV is relatively common, with a higher proportion of female patients seeking alternative therapies, independent of prescription medication use, income, education, or employment status.”

<sup>359</sup> Heath et al, supra, note 55.

<sup>360</sup> Kendall TR et al. Mind and body: Sociodemographic and clinical characteristics of HIV+ individuals using meditation as a complementary therapy while on antiretrovirals in British Columbia, Canada. Poster, 9<sup>th</sup> CAHR, 27-30 April 2000, Montreal: Abstract 233P.

<sup>361</sup> Braitstein P. Mary-Jane and her patients: Socio-demographic and clinical characteristics of HIV+ individuals using medicinal marijuana and antiretrovirals in British Columbia, Canada. Oral presentation, 9<sup>th</sup> CAHR, 27-30 April 2000, Montreal: Abstract 315.

<sup>362</sup> Braitstein P et al. Information seeking and health care utilization patterns among people living with HIV/AIDS who currently use both antiretrovirals and complementary therapies in British Columbia, Canada. Poster presentation, 9<sup>th</sup> CAHR, 27-30 April 2000, Montreal: Abstract 338P.

<sup>363</sup> Furler et al, supra, note 56; reported in the *Canadian Journal of Infectious Diseases* 2000; 11 (Suppl B): 65B. Note that this report is based on interim data from the same study by Furler et al referred to infra as Furler (2000b) and Furler (2001).

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TABLE I (continued...)

Author (Year)	Sample	Overall Prevalence of CAM Use	Most Popular CAM	Comments
Jalbert (2000) <sup>364</sup>	330	n/a	Vitamins (34%) Supplements (16%) Homeopathic products (3%)	
				Comments
Furler (2000b) <sup>365</sup>	70 (40 men, 30 women) recruited through 9 HIV outpatient clinics in 7 Ontario cities	> 90% (women) 80% (men)		In every category of CAM included, women used such therapy more than men, and a greater proportion of HIV-positive women than HIV-positive men use complementary and alternative medicine.
Furler (2001) <sup>366</sup>	70 (40 men, 30 women) recruited through 9 HIV outpatient clinics in 7 Ontario cities	93% of women 70% of men		<p>Researchers noted a trend to an increased number of therapies reported by women.</p> <p>In patients using CAM, the HIV physician was aware of only 37% of CAM agents used; this value did not differ significantly between men and women.</p> <p>In 55% of cases where the physician was unaware of CAM use, 96% of the time the physician had not inquired about its use.</p>
Kendall (2001) <sup>367</sup>	49 HIV-positive people participating in focus groups	100% (study specifically selected PHAs who confirmed using CAM)		<p>Roughly half the respondents were taking ARVs at time of study, and half were not.</p> <p>Half the participants had used CAM before being diagnosed with HIV. Median number of CAM therapies currently being used was 6; median number ever used was 10.</p> <p>67% were men, 33% were women; 92% had secondary or post-secondary education; 71% were Caucasian, 17% were Aboriginal; 3% were Hispanic; 3% reported some other ethnicity.</p> <p>Reasons for using CAM (from highest to lowest): to improve energy level (93%); to have greater control over health (86%); "I feel good about using CAM" (86%); to enhance immune response (79%); to prevent infections (74%); to supplement dietary intake (74%); to manage side effects (60%); to lower viral load (58%); "CAM won't do any harm" (49%).</p>
Kamyab et al (2001) <sup>368</sup>	68 consecutive HIV+ attendees of immunodeficiency clinic in Saskatoon in 1996 and 58 (out of intended 100) in 2001	In 1996: 78% In 2001: 32.75%		Between 1996 and 2001: percentage of Aboriginal patients increased (15% to 24%) and percentage of female patients increased (23.5% to 34.5%); income and average years of education decreased. Data show, from 1996 to 2001: decreased use of CAT (62.5% to 44%), and increased use of antiretrovirals (72% to 78%). Average confidence in conventional/alternative therapy for slowing HIV progression decreased, while confidence in conventional medical therapy increased.

<sup>364</sup> Jalbert et al, supra, note 52.

<sup>365</sup> Furler S et al. Gender Differences in the Drug Utilization Patterns of HIV Infected Outpatients: An Interim Analysis. See Oral Presentation and Summary of Proceedings: Towards Equity in HIV Health Care for Vulnerable Populations. Ontario HIV Treatment Network Research Day, 27 November 2000, Toronto, Ontario (available online via www.ohtn.on.ca).

<sup>366</sup> Furler et al, supra, note 56.

<sup>367</sup> Kendall et al, supra, note 61.

<sup>368</sup> Kamyab et al, supra, note 55.



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TABLE I (continued...)

Author (Year)	Sample	Overall Prevalence of CAM Use	Comments
Kendall (2001) <sup>369</sup>	survey of 1009 individuals enrolled in BC provincial drug treatment program, plus qualitative interviews with 36 HIV-positive people using CAM from 3 urban clinics and 5 rural family practices	43.3%	<p>Having hepatitis B was associated with CAM use.</p> <p>CAM use associated with higher income, self-identifying route of HIV infection as male–male sex, and not currently using injection drugs.</p> <p>Neither HIV/hepatitis coinfection nor use of CAM was associated with discontinuing antiretrovirals.</p> <p>Reasons for using CAM: enhance immune function (HIV-positive only: 76.3%; coinfecting: 66.8%); reduce viral load (HIV-positive only: 28.7%; coinfecting: 24.6%); manage side effects of conventional therapies (HIV-positive only: 45.6%; coinfecting: 42.3%); supplement dietary intake (HIV-positive only: 72.6%; coinfecting: 70.1%); greater control over health (HIV-positive only: 57.9%; coinfecting: 55.6%); prevent infections (HIV-positive only 33.8%, coinfecting:35.3%); increase energy (HIV-positive only: 72.6%; coinfecting: 69.5%).</p>

<sup>369</sup> Kendall et al, supra, note 55.

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TABLE 2

Overview of Canadian Studies of Complementary/Alternative Medicine Use among People with HIV/AIDS

Author (Year)	Sample Size	Most Popular CAM	Overall Prevalence of CAM Use	Comments
Barton (1989)	190	Massage (20%)	38%	Benefit was attributed to 81% of treatments used.
Hand (1989)	50	Acupuncture (30%)	36%	All users of CAM thought it was of value.
Cohen (1990)	172	Acupuncture (40%)	73%	n/a
Greenblatt (1991)	197	n/a	29%	n/a
Rowlands (1991)	79	Vitamins (46%) Herbal Remedies (16%)	56%	72% felt improvement.
Kassler (1991)	114	n/a	22% (herbals only)	n/a
Stine (1993)	n/a	30-60%	n/a	n/a
Anderson (1993, US)	184 people recruited through 3 HIV clinics in Philadelphia, US area	Immunostimulants (83%) Diet (42%) Vitamins (30%) Healing (39%) Imagery (41%) Bodywork (41%)	40%	On a 1 (best) to 5 (worst) scale, complementary and/or alternative medicine received an overall rating of effectiveness of 1.67. Of respondents, 10% expected unconventional treatment to be a cure for HIV infection; 36% expected it to delay onset of symptoms.
Wolffers (1994, Netherlands)	206	Vitamins (51%) Psychotherapies (46%)* Homeopathy (40%)*	30.6% used alternative treatments. 24% had used CAM before HIV diagnosis; 27% started after diagnosis; 13% started when CD4+ T cells began to decrease.	37% felt better for using complementary and/or alternative medicine; 34% felt they were increasing their resistance. Half the patients used CAM with support of family physician.
Langewitz (1994, Switzerland)	100	Homeopathy (22%) Vitamins (13%)	56% used alternative therapy and/or psychotherapy.	Alleviation of symptoms was slightly better than with conventional medicine.
Barton (1994)	159	Massage (42%) Dietary Treatments (39%)	44%	Majority of treatments were described as beneficial.
Nokes (1995, USA)	145	Vitamins Relaxation	100%	n/a
Singh (1996, USA)	56 PHAs at HIV-clinic in Pittsburgh, PA	n/a	30%	No beneficial effect of non-traditional therapy use on CD4+ cell count, disease progression, or mortality compared to patients receiving only conventional medical therapy.

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TABLE 2 (continued...)

Author (Year)	Sample Size	Most Popular CAM	Overall Prevalence of CAM Use	Comments
Brauchli (1996)	129 PHAs accessed through Swiss hospital and community AIDS organizations	Following were used by > 25% of respondents: vitamins, special diets, food supplements, physical exercise, meditation, phytotherapy, homeopathy, psychotherapy.	> 80%	47% of respondents were also taking antiretroviral medication, prophylaxis against opportunistic infections, or both.
Suarez (1996, USA)	76 Hispanic PHAs at New Jersey inner-city HIV clinic (58 men, 18 women)		2/3 engaged in "folk healing" (spiritualism and/or Santería)	Main desired outcomes included physical relief, spiritual relief, and protection from evil. Nine respondents hoped to effect a cure for HIV infection.
Fairfield (1998)	180 HIV-positive patients	n/a	68%	n/a
Smith (1999, USA)	Analysis of data from 7887 interviews with PHAs as part of larger study on costs and use of AIDS services	n/a	n/a	African-Americans less likely to use nonprescription drugs, vitamins, and herbs than non-Hispanic whites. People with college education more likely to use vitamins and herbs.
Greene (1999, USA)	Review of data in peer-reviewed journals re 1016 PHAs in AMCOA study.	Aerobic exercise (64%) Prayer (56%) Massage (54%) Acupuncture (48%) Meditation (46%)	n/a	n/a
Knippels (2000, Netherlands)	70 HIV-positive gay men	n/a	71%	Typical user was symptomatic, reported little or no pain, and actively tried to cope with disease-specific problems.
Sparber (2000, USA)	99 PHAs involved in clinical research protocols at NIH	Imagery High-dose vitamins Weight gain Massage Relaxation Herbal Spiritual Acupuncture	91% had used at least one CAM therapy at some time.	84% had used at least one CAM following HIV diagnosis (with average of just fewer than 5), which was a significant increase from 64% pre-diagnosis.  High level of agreement that CAM carried following benefits: feeling better (98.1%), increased coping (100%), feeling in control (88.5%), and enhanced treatment outcome (94.2%).  61% stated CAM was as, or more, effective than conventional treatment.  53% were asked by physicians whether adjunct therapies were used.

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TABLE 2 (continued...)

Author (Year)	Sample Size	Most Popular CAM	Overall Prevalence of CAM Use	Comments
de Visser (2000, Australia)	925 HIV-positive men and women in Australia	n/a	56%	Choice of allopathic and/or alternative therapies was related to disease progression, and to attitudes toward these therapies. Many users of CAM believe they can alleviate side effects of antiretroviral drugs.
Southwell (2001)	324	Dietary supplements	82%	59% of CAM users told physicians, but this info was charted by physicians only 13% of the time.
Duggan (2001)	191 HIV-positive outpatients	Exercise “Lifestyle changes” Dietary supplements Counseling Herbal medications Megavitamins Prayer therapy	67% at some point 40% currently using CAM	74% also taking a protease inhibitor. 15% on a protease inhibitor-sparing regimen. 11% did not use any antiretroviral drugs. < 50% said their physician knew of their CAM use. 29% reported receiving CAM info from doctor or other health-care professional. 70% of those using CAM felt it improved quality of life.
Chakraborty et al (2000)	191 HIV-positive patients in the US (88% men; 65% Caucasian; 70% gay men; 80% diagnosed with HIV before 1996)	40% currently using CAM	exercise (43%), lifestyle changes (38%), dietary supplements (37%), counseling (27%), herbal medicine (26%), megavitamins (24%), massage (24%), prayer (23%), yoga (19%), acupuncture (18%)	* 63% used CAM to control HIV, and 47% felt CAM improved their quality of life. Trend toward CAM use by patients with income > US \$15,000 or by those who had previously discontinued medications, but CAM use not related to age, sex, education or CD4 count. 56% had discontinued some form of conventional medication. Reasons for discontinuation: medication failure (55%), difficulty adhering to schedule (8%). 63% said their physician was aware of their CAM use; 25% said physician not aware; only 3 had been told by a physician to discontinue CAM.

\* Percent figures refer to percentages of complementary and/or alternative medicine users using this treatment; all other figures refer to total study population; n/a = not applicable, in some cases simply because there are no data. See bibliography for full citation information for studies summarized in this table.

<sup>370</sup> Adapted (and updated) from: Ernst E. Complementary AIDS therapies: the good, the bad and the ugly. *International Journal of STD & AIDS* 1997; 8: 281-285.



## Appendix C: Canadian Prosecutions for Unauthorized Health-Care Practice – A Chronological Overview

In the 1943 case of *Lesage*,<sup>371</sup> a Québec chiropractor was charged with unlawfully practising medicine. The court ruled that adjustments and manipulations of the spine performed by a chiropractor for the purpose of restoring a patient's health constituted the treatment of disease within the meaning of the *Medical Act* (as it then read). It cited an earlier case (coincidentally of the same name) that had found the accused chiropractor guilty of “an invasion of the rights and privileges alone accorded to the medical profession,”<sup>372</sup> leaving no doubt as to the expansive scope of physicians' monopoly on medical practice. In addition, another case had also clearly established that the practice of chiropractic is the practice of medicine:

No person other than a doctor, that is to say, a doctor of medicine, may practise medicine. The practice of medicine constitutes the profession of caring for the sick by any treatment whatever. Consultations, advice, administration of remedies, the use of physical or mechanical or other processes constitutes the treatment of disease.... But the

<sup>371</sup> *College of Physicians and Surgeons v Lesage* (1943), 80 CCC 139, [1943] RL 363 (QL) (Que Ct of Sessions).

<sup>372</sup> *College of Physicians and Surgeons v Hebert* (1936), 65 Can CC 285 at 288, [1936] 2 DLR 729, 74 Que SC 1.

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defendant pleads that the chiropractor does not mean to practise medicine, that he does not do so at all, because his treatments are not accepted by doctors of medicine. The argument does not seem well rounded [*sic*] to me. The law prohibits everyone who is not a doctor of medicine from attending the sick – the excellence of the remedies, the value of the processes, the extent of his science matter little – and the chiropractor violates the law if he attends the sick.<sup>373</sup>

The court reasoned that to accept the argument that the defendant does not practise medicine because physicians do not recognize the treatment as legitimate would mean “that even the most injurious treatment of sick persons would not be prohibited because that treatment would be foreign to medical science; this would be ignoring the purpose of the *Medical Act* which was enacted to protect the public health.”<sup>374</sup>

A few years later, another Québec court took the same approach. In *Hurtubise*,<sup>375</sup> the accused chiropractor charged with illegally practising medicine argued that giving massage treatments was not practising medicine. The court held that, under the *Medical Act*, massage treatments given after consultations and diagnosis are “medical treatments”; the practice of medicine is not confined to customary methods of treatment (eg, drugs or surgery) but, insofar as the Act is concerned, the prohibitions on practice extend to any form of treatment, including manipulations of the spine, and any form of medical treatment is forbidden unless done by or under the direction of a licensed physician.

A rather different approach was taken in Ontario thirty years later. In *Gaulin*,<sup>376</sup> an acupuncturist was charged under Ontario law with “engaging in the practice of medicine” without a licence and with unlawfully using the title of doctor. He was acquitted, and the acquittal was upheld on appeal. Citing a Supreme Court of Canada decision that statutes creating professional monopolies should be strictly interpreted,<sup>377</sup> the appellate court ruled that:

While medicine considered in its widest sense as a science concerned with human health would include acupuncture, if medicine is defined as the treatment of illness by means of medication then acupuncture is a totally different discipline. Where a statute creates a professional monopoly its terms must be strictly construed so as to permit every act which is not clearly forbidden. The acupuncturist’s methods of diagnosis and treatment differ radically from those of the licensed physician, and thus do not come within the restricted meaning given to “medicine” by the jurisprudence. In addition, the acupuncturist’s advice to his patients to eat and drink in moderation, to rest properly and to exercise, could not in itself be called medical advice.... [And] as to the charge of [illegally using the title “doctor”] the defendant represented only that he was a practitioner of Chinese medicine. He did not claim to be a licensed physician or a graduate of a recognized medical school, and expressly denied such status to his patients. [The Act] forbids usage of the title

<sup>373</sup> *College of Physicians and Surgeons v Lesage* (1933), 71 Que SC 338, aff’d [1936] 3 DLR 71, 65 Can CC 392, 60 Que KB 1.

<sup>374</sup> *Lesage*, supra, note 371, at 149 CCC.

<sup>375</sup> *Collège des médecins et chirurgiens de la Province de Québec v Hurtubise*, [1948] CS 886, [1948] RL 26 (Que Ct of Sessions).

<sup>376</sup> *R v Gaulin* (1982), 35 OR (2d) 195 (Co Ct).

<sup>377</sup> *Pauzé v Gauvin*, [1954] SCR 15. This decision has been subsequently reaffirmed by the Supreme Court in *Laporte v College of Pharmacists of Quebec* (1974), [1976] 1 SCR 101.

“Doctor” only where it leads the public to believe that the user is licensed under [the Act].<sup>378</sup>

In *Sandhar*,<sup>379</sup> the accused was charged with unlawfully practising medicine for operating an Edmonton homeopathy clinic. Although he was acquitted at trial, the acquittal was overturned on appeal. The first appellate court found it unnecessary to decide whether or not homeopathy is the practice of medicine. Instead it noted that the statute sets out acts that may only be done by a licensed medical practitioners, and that Sandhar had engaged in “diagnosis” and had “prescribed” treatment in contravention of the Act. On a further appeal, the Alberta Court of Appeal noted that, even on a strict interpretation required by the Supreme Court of a statute creating a professional monopoly,<sup>380</sup> it was clear that Sandhar’s acts were ones that were reserved for licensed medical practitioners.

In *Cheung*,<sup>381</sup> the College of Physicians and Surgeons sought an order directing Cheung to refrain from using the title of doctor. Cheung argued that he held himself out to be a doctor of traditional Chinese medicine and a specialist in acupuncture, not a medical doctor. Under the *Health Disciplines Act*<sup>382</sup> then in force in Ontario, it was an offence for any person not licensed as such to use any title or description that implies that they are licensed medical practitioners. The court granted the College’s request, ordering Cheung to cease calling himself a doctor.

In *Kish*,<sup>383</sup> a couple practising what they claimed to be “phytotherapy,” which in this case purportedly combined spiritualism and certain nutritional requirements with a program of vitamins, minerals, and the use of hydrogen peroxide for a patient diagnosed with terminal lung cancer. The court found that this constituted “treating” the patient, which could only be done by a properly licensed medical practitioner under the *Medical Profession Act*. The court rejected the argument that, because licensed physicians would not undertake this kind of treatment, it did not constitute the practice of medicine, and so was not reserved to licensed physicians. The Act then in force provided that a person “practises” medicine if he or she “prescribes or administers any treatment for the prevention, alleviation or cure of any human disease, ailment, deformity, defect or injury” (s 77).

In *Lamontagne*,<sup>384</sup> a Montréal homeopath was convicted of illegally practising medicine. She challenged the provision in the Québec *Medical Act*<sup>385</sup> that prohibits anyone other than physicians from engaging in diagnosis and treatment, arguing that this monopoly deprived patients of access to homeopathic treatment, particularly because the professional code applicable to licensed physicians prevents them practising in a way that contradicts “current medical science” (Code of Ethics, Art 2.03.17). She argued that the effect of the law was to violate rights guaranteed by the *Canadian Charter of Rights and Freedoms* – specifically, the right to freedom of conscience (s 2(a)) and the right to liberty and security of the person (s 7). She also argued that it violated the Québec *Charter of Human Rights and Freedoms* – specifically, the right to freedom of conscience (s 1), the right to life, liberty and security of the person (s 3), and the right to privacy (s 5).

The court of first instance was eloquent in declaring that both the Canadian and Québec Charters afforded constitutional protection to the right to make choices about medical care, without state interference. Yet the court dismissed, on purely technical grounds, Lamontagne’s claim that the right to security of the person had been infringed, on the ground that, as there were 200 physicians in Québec practising homeopathy, there was no factual basis

<sup>378</sup> *Gaulin*, supra, note 376 at headnote [translation]: “First, the acupuncturist treats patients in a totally different manner than do licensed physicians, and almost all licensed physicians know nothing about acupuncture. Second, acupuncture is not taught in faculties of medicine, the only courses being given by the Acupuncture Foundation of Canada. Third, a medical diagnosis in no way resembles that of an acupuncturist... Moreover, an acupuncturist’s advice to eat and drink in moderation, to relax, and to exercise, cannot in itself be considered as medical advice... Finally, the health insurance plan of Ontario does not reimburse any expenses incurred for acupuncture.”

<sup>379</sup> (1988), 86 AR 241, [1987] AJ No 149 (QB) (QL), affirmed [1988] AJ No 20 (CA) (QL).

<sup>380</sup> *Pauzé*, supra, note, 377; *Laporte*, supra, note 377.

<sup>381</sup> *College of Physicians and Surgeons of Ontario v Cheung*, [1992] OJ No 2421 (Gen Div) (QL).

<sup>382</sup> RSO 1980, c 196, s 67(2).

<sup>383</sup> *R v Kish* (1993), 12 Alta LR (3d) 185 (Prov Ct), 143 AR 65, [1993] AJ No 559 (QL).

<sup>384</sup> *Corporation professionnelle des médecins du Québec v Lamontagne*, [1998] AQ No 692 (CA) (QL).

<sup>385</sup> RSO, c C-26.

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for her claim that the law restricted a patient's access to this form of treatment. It also rejected, without analysis, the argument that the right to liberty had been infringed; the court merely stated that restricting the practice of homeopathy to licensed physicians was reasonable in light of the goal of protecting the public. Two appeals failed to yield any more substantial analysis of these points; ultimately, the Québec Court of Appeal simply reiterated the earlier conclusions. Unfortunately, the Supreme Court of Canada also refused to hear the constitutional arguments.<sup>386</sup>

<sup>386</sup> [1998] SCCA No 217 (QL). One commentator has argued that such arguments should be bolstered by an appeal to the multiculturalism clause (s 27) of the Charter: Blanc, *supra*, note 235.





## Appendix D: Workshop Participants and Other Commentators

Numerous people provided comments on various drafts of this paper, and several of them participated in a workshop to discuss these issues. Their affiliations are included below for information only. The views presented in the paper are not necessarily those of the workshop participants and other commentators.

Rona Achilles	Independent health policy consultant
Reeta Bhatia	Health Canada
Heather Boon	University of Toronto, Faculty of Medicine (Department of Health Administration)
Evan Collins	Ministerial Council on HIV/AIDS; AIDS Committee of Toronto; Toronto Western Hospital
Robert Crouch	University of Virginia, Department of Philosophy
Elizabeth Czyziw	Consultant
Jessica Daniels	Canadian AIDS Society
Richard Elliott	Canadian HIV/AIDS Legal Network
Michael Hendricks	Coalition des organismes communautaires québécois de lutte contre le sida
David Hoe	Health Canada
Sean Hosein	Canadian AIDS Treatment Information Exchange

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Ralf Jürgens	Canadian HIV/AIDS Legal Network
Laurette Lévy	Voices of Positive Women
Trudo Lemmens	University of Toronto, Faculty of Law and Joint Centre for Bioethics
Nora Morcos	Canadian Complementary Medicine Association, Association of Complementary Physicians of British Columbia
Bob Mills	Canadian Treatment Advocates Council
Devan Nambiar	Canadian AIDS Treatment Information Exchange; St Michael's Hospital, Toronto
Denis O'Hara	Canadian College of Naturopathic Medicine
Alita Sauvé	2-Spirited People of the 1st Nations, Toronto
Joan Simpson	Health Canada
Michael Smith	Health Canada
Art Zoccole	Canadian Aboriginal AIDS Network



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*College of Physicians and Surgeons v Lesage* (1943), 80 CCC 139, [1943] RL 363 (Que Ct of Sessions of Peace).

*College of Physicians and Surgeons of Ontario v Cheung*, [1992] OJ No 2421 (Gen Div) (QL).

*Collège des médecins et chirurgiens de la Province de Québec v Hurtubise*, [1948] CS 886, [1948] RL 26 (Que Ct of Sessions of Peace).

*Corporation professionnelle des médecins du Québec v Lamontagne* (26 January 1994), Montreal 500-27-016575-914 (CQ), affirmed (sub nom. *Lamontagne Corporation professionnelle des médecins du Québec*) (28 March 1995), Montreal 500-36-000042-948, JE 95-1015 (CS), affirmed [1998] AQ No 692 (QL), leave to appeal refused, [1998] SCCA 217.

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## Net Links

British Columbia Persons with AIDS Society  
(Complementary and Alternative Therapies Project, Treatment Information Program)

**[www.bcpwa.org](http://www.bcpwa.org)**

CAMline

**<http://camline.org>**

CAMline is a recently launched database on complementary/alternative medicine (CAM), designed as an information resource to support health-care professionals in their day-to-day practice, aid the drafting of effective health-care policy, and empower consumers in making informed decisions about their health. It includes information on various natural health products, CAM therapies, and health conditions; a list of “best practice” protocols or guidelines from institutions regarding CAM; and offers a facility for submitting reports of adverse reactions involving CAM and searching the database for case reports. It is a partnership between the Ontario College of Family Physicians, the University of Toronto’s Department of Family and Community Medicine, the Ontario Branch of the Canadian Society of Hospital Pharmacists, the Michener Institute for Applied Health Sciences, and the Friends of Alternative and Complementary Therapies Society.

Canadian AIDS Treatment Information Exchange

**[www.catie.ca](http://www.catie.ca)**

CATIE is a national, non-profit organization committed to improving the health and quality of life of all Canadians living with HIV/AIDS. It provides treatment information for persons with HIV/AIDS, their families, care providers, and service organizations, through a comprehensive website, electronic mailing lists, several print publications, and a bilingual, toll-free phone service. Its resources include numerous info sheets on complementary/alternative therapies and “practical guides” on complementary therapies and herbal products.

Canadian College of Naturopathic Medicine

**[www.ccnm.edu](http://www.ccnm.edu)**

A non-profit educational institution “committed to being the profession’s college in Canada, producing excellence in naturopathic medical education, clinical practice and research.” The College’s Learning Resources Centre has an online library catalogue.

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Canadian Health Network – Alternative Health Centre

**[www.canadian\\_health\\_network.ca/1alternative\\_health.html](http://www.canadian_health_network.ca/1alternative_health.html)**

A web-based source of information within the Canadian Health Network, funded by Health Canada and created in partnership with two affiliates, the Tzu-Chi Institute for Complementary and Alternative Medicine (Vancouver), and the Consumer Health Information Service (Toronto Public Library).

Centre for Complementary Health Studies, University of Exeter

**[www.ex.ac.uk/chs](http://www.ex.ac.uk/chs)**

Has information about courses, research and staff at the Centre, and general information about complementary and alternative medicine in the UK and Europe. Publishes the journal *FACT – Focus on Alternative and Complementary Therapies: An evidence-based approach* (**[www.ex.ac.uk/FACT/index.htm](http://www.ex.ac.uk/FACT/index.htm)**).

Cochrane Collaboration

**[www.cochrane.dk](http://www.cochrane.dk)**

An international non-profit organization emphasizing the need to rely on the systematic review of scientific evidence. Its mission is to prepare, maintain, and disseminate systematic, up-to-date reviews of randomized controlled clinical trials across all areas of health care. Field groups work with numerous research groups, arranged by disease specialty, to carry out these systematic reviews. A complementary medicine field was added in 1996 ([www.compmc.ummc.umaryland.edu](http://www.compmc.ummc.umaryland.edu)) and has produced the Cochrane Registry of Randomized Controlled Trials in Complementary Medicine.

EMBASE (Excerpta Medica database)

Available via **[www3.healthgate.com](http://www3.healthgate.com)**

This database, produced by Elsevier Science, indexes over 2500 international journals, including several in the area of complementary/alternative medicine.

Foundation for the Advancement of Innovative Medicine

**[www.faim.org/states.htm](http://www.faim.org/states.htm)**

A non-profit organization founded in 1991 by health-care consumers “to increase public awareness of safe and effective treatment options.” The site includes regularly updated information on laws in various US states governing patient access to complementary/alternative therapies, and news of advocacy initiatives to increase access to “innovative medicine” in the US.

Foundation for Integrated Medicine

**[www.fimed.org](http://www.fimed.org)**

This UK foundation produces policy documents relating to the integration of conventional and complementary/alternative medicine, and includes news updates on its website as well.

National Center for Complementary & Alternative Medicine

formerly the Office of Alternative Medicine, US National Institutes of Health

**<http://nccam.nih.gov/fcp/clearinghouse/index.html>**

The Clearinghouse disseminates information to the public and healthcare providers about the Center’s program and research findings through fact sheets, information packages, publications and a quarterly newsletter distributed to public subscribers.

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CAM on PubMed

via <http://nccam.nih.gov> or at

[www.nlm.nih.gov/nccam/camonpubmed.html](http://www.nlm.nih.gov/nccam/camonpubmed.html)

A partnership between NCCAM and the US National Library of Medicine, CAM on PubMed allows the user free access to a database of journal citations on complementary/alternative medicine.

Combined Health Information Database (CHID)

<http://chid.nih.gov>

A combined effort of several US federal agencies, this database consolidates information related to health and disease in individual US government databases. It contains a variety of records regarding CAM assembled by the NCCAM Clearinghouse that are not publicly available elsewhere.

FACT – Friends of Alternative and Complementary Therapies Society

[www.thefacts.org](http://www.thefacts.org)

A non-profit community organization that includes over three hundred members, representing a broad range of consumers, physicians, nurses, alternative/complementary practitioners, and academics. The Society believes in the democratization of health information by promoting credible and practical information about various types of health practices between cultures. FACT is particularly interested in how alternative and complementary therapies can be integrated with mainstream medicine. The Society's purpose is education for its members and the public as well as the sharing of information with others.

Direct Access Alternative Information Resources

[www.daair.org](http://www.daair.org)

Health Canada (Office of Natural Health Products)

[www.hc-sc.gc.ca/hpb/onhp](http://www.hc-sc.gc.ca/hpb/onhp)

Tzu-Chi Institute for Complementary and Alternative Medicine

[www.tzu-chi.bc.ca](http://www.tzu-chi.bc.ca)

Includes links to websites of various health professionals groups in the area of CAM.

Research Council on Complementary Medicine

[www.rccm.org.uk](http://www.rccm.org.uk)

A charitable organization in the UK “carrying out, promoting and facilitating rigorous research in complementary medicine to encourage safe and effective practice and improved patient care.” The website includes information on recent research, an information database with thousands of references for published and unpublished research in complementary medicine (searchable for a fee), and a list of publications on CAM research.

Rosenthal Center for Complementary and Alternative Medicine – Columbia University

<http://cpmcnet.columbia.edu/dept/rosenthal>

Includes links to complementary medicine Internet resources, factsheets and databases, as well as information about the Center for Complementary & Alternative Medicine Research in Women's Health.

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[US] Food and Drug Administration

**[www.fda.org](http://www.fda.org)**

This site includes both the FDA's Guide to Choosing Medical Treatments (**[www.fda.gov/oashi/aids/fdaguide.html](http://www.fda.gov/oashi/aids/fdaguide.html)**) and links to the FDA's MedWatch program (**[www.fda.gov/medwatch](http://www.fda.gov/medwatch)**) for reporting adverse events, including the Special Nutritionals Adverse Event Monitoring System (SN/AEMS) at **<http://vm.cfsan.fda.gov>**.

United Kingdom House of Lords

**[www.parliament.the-stationery-office.co.uk](http://www.parliament.the-stationery-office.co.uk)**

The report on Complementary and Alternative Medicine of the House of Lords Science and Technology Committee, with an overview of the status of CAM in the UK, including the legal/policy environment, can be found on this site.

White House Commission on Complementary and Alternative Medicine Policy

**[www.whccamp.hhs.gov](http://www.whccamp.hhs.gov)**

The website of the Commission charged by the US President with investigating and reporting back on policy issues relating to CAM will include information about the work of the Commission over the coming year (it is to report back by March 2002).