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on
Biotechnology in Health Innovation

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Biotechnology Innovations and Institutional Transformations in Health: Issues in Public/Population Health— A Summary and Synthesis with Recommendations

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I. Introduction: An Exercise in Moral Discourse

The purpose of this brief report is to summarize and synthesize some of the ideas, concepts, and issues that were discussed at the CBAC workshop on "Biotechnology in Health Innovation". The particular focus of this document is the impacts and institutional transformations that are already occurring in public health with the advent of new biotech innovations, and/or that are anticipated to occur in the public health sector in the next three to five years and beyond. Some attempt will be made to provide some specific recommendations about how policy and programs might be shaped in the near future to ensure that Canada is able both to preserve and extend its public health care vision well into the future, even as it becomes more economically competitive in the global marketplace.

Public health is only one of the spheres around which this workshop was organized. Health care, regulation, R&D, and commercialization constitute the other specific spheres in which institutional transformations are anticipated. Inasmuch as public health is intimately connected to and affected by the developments that will occur in these related spheres, it will be necessary to situate the discussion of biotech and public health within this broader context.

In many respects this workshop can be viewed as something of a microcosm of the on-going public conversation that serves to define Canada as a nation even as it provides a vision for our future. It is in this respect an exercise in moral discourse in which all of us have a stake, and in which each of us participates either directly or vicariously through those who represent our various interests and concerns. Moral discourse is one way in which to refer to the evolving social contract by which we define ourselves as a moral community, organize our public and private institutions, and manage the activities of our communal existence. The various participants at this workshop represented a variety of perspectives and interests. Indeed the five spheres of influence around which the workshop was organized represent different interests and perspectives as well. Despite these differences, however, the common purpose of providing a collective vision for the future of health biotech in Canada resulted in a degree of convergence and progress.

Whether at the interpersonal, the institutional, or the international levels, however, moral discourse can break down for a variety of reasons. When moral discourse breaks down it leads to disagreement, distrust and conflict, rather than agreement, trust and collaboration. Inasmuch as health biotech is a relatively new and complex phenomenon affecting a broad range of public and private institutions, it can be expected that disagreement and misunderstanding can and will occur. Before attempting to summarize and synthesize the broad range of perspectives and ideas presented at the workshop, then, a brief discussion of where and how moral discourse breaks down could be useful in situating the various tensions that were evident at times even in the discussion that ensued at this workshop. Anticipating and identifying potential tensions and sources of disagreement in advance may enable CBAC to take proactive steps to clarify and

communicate its vision for health biotech in a manner that is sensitive to these various perspectives and associated tensions.

In what follows, the basic levels at which the breakdown of moral discourse can occur is briefly explained and illustrated. These levels will then serve as an organizational framework for the summary and synthesis of the workshop activities that follows.

When analyzing the manner in which moral discourse breaks down, three broad levels of disagreement and/or misunderstanding can be usefully identified. These include the factual level, the level of guiding principles, and the conceptual level. A few words on each will help to situate the general flow of discussion at the CBAC workshop, along with the associated tensions that arose from time to time.

The factual level refers simply to the basic description of the phenomenon under investigation. In the case before us, the phenomenon is health biotech. While basic description may strike some as obvious (and therefore trivial), misinformation, misunderstanding and/or inaccurate assumptions at the factual level are often the source of much disagreement and resultant miscommunication. Accurately describing a rapidly developing and expanding technology and simultaneously anticipating the future trajectory of technological innovation is notoriously difficult in this regard. The advent of the automobile was predicted to all but eliminate pollution as the massive quantities of horse manure in the streets would disappear. Nuclear technology was trumpeted as an inexpensive source of electrical power. Talk of the "paperless office" in the new age of information technology has now all but disappeared. The common lesson here is that what is presented as fact is often mere speculation, and the results are often dramatically different from what was anticipated. The manner in which technological uptake occurs in a society is highly unpredictable and often defies logic.[1]

At this early stage in the development of the biotech industry, when competition for investor dollars and market share is particularly acute, especial caution must be exercised in playing down the hype that will accompany many predictions of our biotech future. Conversely, the recent negative experiences with the "dot com" meltdown could well put potential investors in a defensive mode with regard to these emerging technologies. The predictions that the various workshop participants offered with regard to where biotech would take us in the coming years reflected both the optimistic and pessimistic sides of this equation.[2] The key lesson here in either case is that **careful and measured statements should be the CBAC norm when giving descriptions of what has occurred in the field already, and when anticipating what might occur in the years to come**.

The principled level is a second area in which moral discourse can break down. Disagreement at the level of moral principle is often assumed to represent the source of

[1] Why did VHS supplant BetaMax when the latter was a superior technology? Why hasn't the Mac operating system dominated the market place?

[2] See for example Lynn Curry—"Biometrics busts budgets" vs. Elly Alboim—"Health industries power Canadian economy."

the majority of moral conflicts. In fact, this is generally not the case. Moral principles represent those fundamental normative statements that embody the basic values by which we define ourselves both individually and corporately. "Do no harm," "respect human dignity," "promote sustainable technology for the common good" are just three obvious examples of fundamental moral principles. Each normative statement is an action guiding principle with which virtually everyone will agree. An extensive list of similar norms could be readily produced. While it is at times the case that different individuals and groups will prioritize principles differently, leading to conflict in the manner of application, the mere fact that there is generally a high degree of agreement among stakeholders on what the key principles are should provide a measure of comfort in this regard. For example, while there were clearly different perspectives among the various representatives at the workshop on where biotech priorities should be placed, **the Wednesday morning "visioning" session demonstrated a remarkable convergence around the question of fundamental defining values. CBAC would do well to capitalize on this common base as it advises on future directions for biotech.** We will return to this general point momentarily.

While factual errors, omissions, and exaggerations can be managed simply by being more careful with available data, doing further investigation when necessary, or simply through honest communication of what is and isn't known, and while principled disagreements are often more a matter of priority-setting rather than a fundamental incompatibility of values, the matter of conceptual disagreement is often more difficult to identify and manage. Concepts are those fundamental terms that define the topic or domain under investigation. In the present case "biotechnology," "health," and "the common good" are key representative concepts. Workshop participants used these and related terms and concepts freely during the open discussion and debate. However there was very little opportunity in this forum to clarify what exactly the various discussants meant by the central terms that were employed.

It is sometimes easy to assume that we all know what we mean by biotech, that we share a common understanding of health, and that we agree on the principle that Canada's biotech policy should promote the common good. However there are a variety of ways of defining and employing all the relevant concepts here. For example, the workshop organization included the separation of "health care" from "public health" for the purpose of discussion. This led to some initial musing at the public health table concerning how the two were to be distinguished. The upshot was that we assumed "health care" referred to the hospital based, physician centered care that is generally covered under the *Canada Health Act* (perhaps better described as "sick care"), while public health referred to the broader determinants of health that include social, economic, and environmental concerns among others. Hence **a key component of CBAC's report should include some attempt to clarify some of the key concepts involved**. Again, in what follows, some effort will be made to identify some of these key conceptual matters and to offer some suggestions as to where conceptual differences could arise and how particular understandings might result in fundamentally different policy recommendations.

The foregoing brief overview of the nature of moral discourse has identified some of the crucial points at which policy discussion can go awry. The discussion to follow is organized around these key areas.[3] It begins with a brief overview of the current state of affairs (i.e., the factual situation) as we currently understand it. This section will focus on the key descriptive elements of the current Canadian and global context that could impact the direction of health biotech development, and/or that might provide specific opportunities for Canadian biotech. The "drivers" of biotech innovation that were raised and discussed at the workshop will be summarized, with particular attention to those related to public health. This is followed by a discussion of the common values and guiding principles that appeared to animate the discussion at the CBAC workshop, especially as these arose during the "visioning session" on Wednesday morning. The report goes on to outline some of the major concepts that will need to be clarified as CBAC moves to provide policy recommendations in the area of health biotech. The discussion in the workshop often traded on quite different notions of biotech and health, for example, resulting in quite different visions of our potential biotech future. Key issues and concerns that arise in the area of health biotech and public health applications will be used to illustrate the discussion throughout.

In the remainder of the report, key recommendations will be offered with regard to potential areas of institutional reform affecting health biotech in general, and its application in the area of public health in particular. It should be noted, however, that unless otherwise specified the specific recommendations offered here are those of the author and do not necessarily reflect the views of the participants from the public health discussion group. This is not an attempt on the author's part, however, to co-opt the discussion. It is only that time and organizational constraints of the workshop did not permit a great deal of opportunity for detailed discussion in this regard. Where recommendations flowed from specific comments made by members of the working group on public health, these will be identified in the body of the text.

II. Factual Considerations: Setting the Context—What do we know for sure? What do we think we know?

As mentioned previously, describing the current state of health biotech, and anticipating where it will be in the next few years are no easy tasks. However, several observations can be made about the Canadian context in general, and the health biotech environment in particular, that may help to focus our biotech vision for the future.

Consider first the evolving social-political context in Canada. Since the patriation of the *Canadian Charter of Rights and Freedoms* some 20 years ago, Canadian polity has moved steadily toward a greater concern with issues of individual rights and freedoms. The Supreme Court has taken a more central role in Canadian social policy, as numerous Charter challenges have resulted in the striking down of previous laws (consider Morgenthaler, for example). The advent of NAFTA, coupled with this move toward

[3] While an attempt has been made to organize the discussion around the descriptive, principled, and conceptual matters, the nature of the subject matter is such that there is often considerable overlap between the various sections of the report.

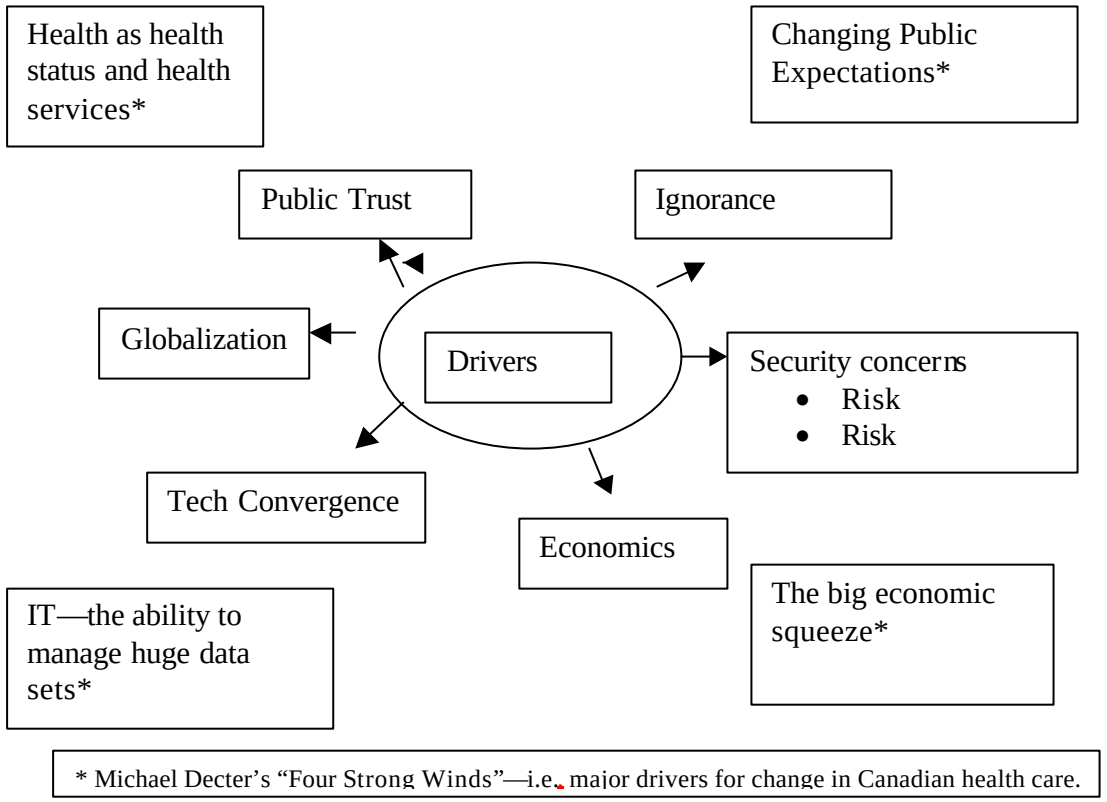
individualism, has resulted in a Canadian culture that is much more consumer-oriented, with a concern for individual rights. Indeed, the recent Senate Committee headed by Michael Kirby anticipates that aspects of the *Canada Health Act* might be struck down under Section 7 of the Charter if access to available medical interventions is not forthcoming on a timely basis.[4] Such considerations could have important implications for health biotech in Canada, both with regard to consumer demand for emerging technologies, and from the perspective of governments (federal and provincial) that may be hesitant to support biotech innovations that could represent significant new costs. Of course the private sector might be more than willing to develop and offer new innovations in the same manner in which diagnostic imaging is now being offered through private clinics across the country. However, each step in this direction represents serious challenges to Canada's public health care system. **As emerging health biotechnologies come on stream the federal and provincial governments will need to consider carefully what is and isn't affordable in this regard, and what the implications will be for the broader publicly run health care system as an increasing number of products and services are offered through the private sector. A systematic review of individual biotech impacts will be required.** Furthermore, while Canadian health care has enjoyed a certain tenuous exemption under NAFTA to this point,[5] **further involvement of the Canadian private biotech sector in providing products and services to Canada's public health care system could lead to challenges from the U.S. biotech industry. ~~under NAFTA.~~**

A related observation with regard to the increased emphasis on individual rights in recent years is that genomic research is by its very nature communal in nature. For example, geneticists speak of studying families, not individuals, and the focus is on populations. One implication here is that health care delivery may need to move beyond the traditional doctor-patient relationship to include care team-family kinds of interactions. Issues related to individual privacy and community consent are already much discussed in the literature in this area.

There was some discussion at the public health table about the public's general willingness to embrace biotech. This is very much an open question. On the one hand there are certainly special interest groups that are lobbying for quicker access to various tests and treatments that are becoming more readily available.[6] Some will be ready and willing to embrace the "technological fix." At the same time, however, we have seen an increased emphasis in recent years on alternative/complementary medicine, and a growing skepticism about what science and technology can provide. **Public opinion in this regard is quite fickle, and caution must be taken in setting a direction based on the most recent opinion polls.**

[4] Standing Senate Committee on Social Affairs, Science and Technology (Senator Micheal Kirby, Chair), *The Health of Canadians—The Federal Role, Volume Six: Recommendations for Reform*.
[5] See Brian Laghi, "NAFTA Could Hike Health Expenses," The *Globe and Mail*, Sept. 28, 2002: A10.
[6] Arthur Allen, "Who Owns My Disease?" *Mother Jones*, Nov-Dec 2001.

With these few general observations to set the broader social-political-economic context, we turn now to some of the specific observations that were generated by the public health working group. Subsequent commentary will expand on these observations:



The "drivers" of biotech innovation represented in the above diagram are intended to convey the multiplicity of social, economic, and political pressures that will influence the future of health biotech both in Canada and globally. At any given time, some will be positive drivers in that they will serve to promote health biotech, while others will be negative drivers that curtail or hamper development. The ability to manage huge data sets, for example, presents an opportunity for population health epidemiological investigations. At the same time, however, concerns about security may hamper advances in this regard. Public trust is closely tied to these drivers and it will be either undermined or buoyed by developments in the months to come. Media coverage, for example, of the death of Jesse Gelsinger as the result of an experimental genetic therapy has led to greater skepticism in some quarters, as has the plethora of more general reports of "medical error" in recent months. Other positive stories regarding advances in remote surgery could have the opposite effect.

Much that occurs in health biotech in the near future will depend upon public perceptions. The public health group spent some time discussing the problems of the general ignorance that obtains with regard to science and technology in society in

general. Such ignorance can manifest itself in a number of ways. Consider the problem of genetic determinism with regard to population screening for potential conditions. There will be a tendency on the part of some/many to view a positive predisposition toward a particular condition as genetic fatalism. That is, since they are genetically predisposed, they are bound to get the condition. This could lead to some taking prophylactic measures that are unwarranted in light of the information (e.g., double breast mastectomy) on the one hand, and others who view their fate as inevitable and hence simply do nothing to change it. The example of a west coast community in Newfoundland comes to mind here. Researchers had discovered a genetic condition that hampered the ability to produce HDL cholesterol (the good stuff). When they counseled the affected individuals to change their diets, they were greeted with a kind of "eat, drink, and be merry, for tomorrow we die" attitude.[7] As the ability to do more population-based screening for a variety of conditions increases, the need for well trained genetic counselors will be great.

RECOMMENDATION—In the face of more population-based screening for a variety of conditions, there will be a need for larger numbers of genetic counselors. At present, there are only three programs in the country, graduating only 14 new counselors each year. This needs to be increased dramatically.

Similarly, at the policy level, it might be both prudent and ethically sound to insist that **no population-based screening programs will be conducted without ensuring that there are adequate human resources available to provide the kind of counseling required.** That is, no results should be shared without appropriate counseling about what this all means. Also, there is no point in screening for a condition if there aren't reasonably effective and affordable interventions available. The relative utility of population-based screening for a variety of disorders is still very much debated.[8] More research needs to be done in this area before any such programs are implemented.

This general ignorance about biotechnology in general and genetic testing/screening in particular may manifest itself in other areas as well. Consumers will be more vulnerable to commercial interests that misrepresent both the need to access certain biotech applications, as well as anticipated benefits of doing so. Greater emphasis needs to be put on public education that fairly represents the pros and cons of various biotech innovations. In the face of increased direct-to-consumer marketing of pharmaceuticals and biotech applications (more on this below), it may be prudent for the federal government to implement a public education campaign of its own.

RECOMMENDATION: The federal government should mount a public education campaign similar to those regarding Canadian heritage and "Participaction" that

[7] Charlie Gillis, "'Doomed' Newfoundlanders Opt to Eat, Drink and Be Merry," *National Post*, April 12, 1999: A1-2.

[8] H. M. Malm, "Medical Screening and the Value of Early Detection: When Unwarranted Faith Leads to Unethical Recommendations," *Hastings Center Report*, Jan-Feb 1999: 26-37. Also, D.J. Watmough et al., "Does Breast Cancer Screening Rest on a Wobbly Hypothesis?" *Journal of Public Health Medicine*, 19, 4 (1997): 375-379.

aims to educate Canadians on various elements of our potential biotechnological future.

The other side of technological ignorance includes those who are well trained in the sciences and well versed in the technical aspects of emerging technologies, but who fail to understand the broader social, cultural, and environmental determinants of health. Medical training devolved in the past century into a highly specialized, science-centred, technologically driven exercise. Many physicians have little or no training in the social sciences and humanities and hence little appreciation for the broader determinants of health that are so central to a progressive public health agenda. Yet physicians are often a key source of the public understanding of health and health care, even as they represent the interface between industry and the health care consumer. **More needs to be done to ensure medical professionals have a broader knowledge base with adequate preparation in the social sciences and humanities.[9] This may require a change of entry requirements for medical school (i.e., greater emphasis on a broadly humanistic education as an undergraduate), and a major overhaul of the medical school curriculum to adopt a public health care paradigm as primary care.**

Further to the previous points, there may be a tendency to believe that a technological innovation will provide better management of some conditions. Again, this is sometimes referred to as the "technological fix."[10] For example, it was suggested that nanosensors would make it possible to monitor certain conditions more effectively by tracking blood sugars, lipid levels, and other metabolic functions continuously. Many of the nanotech applications that might have some utility for limited kinds of conditions are not really relevant to the larger population. The ability, for example, to track certain blood sugar levels and related metabolic processes in order to recommend specific diet and exercise regimens is not really all that important for the broader population. We know already what kind of diet we should have and the need for exercise, etc. A high tech device that can give us this information in more precise terms will not translate into better health outcomes if people don't have the will power to follow through.

On the other hand, nanotech may be important for population health applications in monitoring water and air quality and in increasing our ability to respond quickly in these areas. **Walkerton is not too far removed from our public consciousness, and the**

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[9] The reference escapes me at the moment, but I recall a recent (i.e., past two years) missive from one of the organizing medical bodies (Medical Council of Canada, or perhaps the Royal College) that called for more specialized training of medical practitioners in emerging biotech applications. It strikes me that this would be exactly the wrong thing to do. The medical school at Brown University, for example, offers a new clinical clerkship in biotechnology that "links business and medical education like never before" (see http://www.brown.edu/Administration/George_Street_Journal/vol27/27GSJ16b.html). This is a most disturbing precedent and should be resisted in Canadian medical schools. The recent *Health Canada* document titled "Social Accountability: A Vision for Canadian Medical Schools" seems to set a more appropriate agenda. See http://www.hc-sc.gc.ca/hppb/healthcare/pdf/socialaccountability.pdf.

[10] A naïve faith in this regard can at times lead to premature conclusions. Consider, for example, this statement from a recent paper in a journal of cardiology: "We are beginning to track the actual chemical, mechanical, and electrical pathways by which the heart is damaged or dies. When we can interfere with those pathways and stop the events, we will have defeated heart disease." J. Flower et al. "Technological advances and the next 50 years of cardiology, *J Am Coll Cardiol* 2000 Apr, 35 (5 Suppl B): 81B-90B.

requirements of Kyoto are ever more pressing. There may be significant opportunities for the Canadian biotech industry to capitalize on these developments from a public health perspective. With the emerging concerns regarding global terrorism there may be important applications here as well. There may also be important opportunities to monitor common food borne pathogens more directly to control instances of bacterial infection (e.g., nanosensors on food wrap).[11]

Pharmacogenomics promises to provide individualized medicines as our knowledge of the human genome allows the production of pharmaceuticals that are designed with fewer side affects and for specific populations within sub-classes of diseases. The potential in this regard creates a number of areas of concern. First, given that these new products are targeted at smaller populations, one wonders whether it will be economically feasible to pursue the development of such designer products. This economic reality could lead to more special interest groups that seek to raise their own funding to encourage research on specific drugs. It could also be the case that some conditions will simply go unstudied because of the limited commercial value involved. **Canada may need to consider some means of encouraging research into so-called "orphan diseases", ~~either~~ through special legislation such as has been instituted in the U.S. [12], through other economic means such as tax incentives, or perhaps through a system of benefit-sharing whereby some of the profits that come from blockbuster drugs are cycled back into the public R&D to either support research into rare conditions or at least support the care for those who suffer from such maladies**.[13]

Finally, as we consider the current state of health biotech in Canada and speculate about its future, we must remind ourselves of one clear fact from the public health sector that is often overlooked. This is the simple observation that **the major advances that have occurred in population health in the past century had more to do with improved diet, access to clean water, and better sewage systems than with more specialized technological interventions.** It is somewhat disconcerting in this regard that the Joint Centre for Bioethics "Top 10" report begins with the observation that "Over one billion people entered the 21st century unaffected by the previous century's health revolution that contributed to dramatic improvements in the quality and length of life of people in the developed world."[14] The assumption appears to be that the health revolution that occurred in the developed world had come about because of access to new technologies, and if we can only get new biotech into the developing world we'll be able to solve their health problems. While there are doubtless many biotech innovations that would benefit the developing world (as the report goes on to relate), there are probably many "low tech"

[11] As mentioned elsewhere in this report, however, the tendency will always be there to develop a false sense of security for the technological fix. Public education about how to store and prepare foods is a lower tech solution to this generalized problem.

[12] "Rare Diseases Orphan Product Development Act of 2002," One hundredth and seventh Congress of the United States of America.

[13] Newfoundland and Labrador is currently considering instituting a benefit-sharing policy that will provide for such contingencies. See D. Pullman and A. Latus, *Policy Implications for Commercial Human Genetic Research in Newfoundland and Labrador*, Jan. 2003.

[14] Joint Centre for Bioethics, Top 10 Biotechnologies for Improving Global Health, p. 1.

interventions relating to access to better diets, clean water, and decent waste management that will do more to enhance public health.[15]

III. Shared Values, Principles and a Common Vision

Clearly this workshop was designed to bring together experts who represent a variety of stakeholder perspectives in order to generate discussion and debate regarding emerging concerns and issues in health biotech. Predictably, this resulted in some animated discussion as the various parties involved engaged in often heated debate. While there is always a danger that such a forum will generate only heat but little light, this was not so in this case. The defining moment in this regard occurred in the Wednesday morning open discussion. Although a variety of perspectives were advanced once again, revolving around the common tension between economic opportunism and the most appropriate means for health promotion (both domestically and internationally), the discussion moved eventually to the question of how Canada wants to define itself within the global community. Here it was both comforting and inspiring to see some convergence on the role Canada can play as an international leader in developing a world standard of health for both Canada and the rest of the world. In the later discussion, this general vision was reiterated by a number of the smaller groups, and was articulated most succinctly perhaps in **the vision statement: "Canada will lead the world in developing and marketing technologies for the environment and for human health."**

This vision statement brings together a number of important elements. First, it builds upon a vision (and defining mythology) of Canada that has evolved over previous decades. This mythology includes reference to our multicultural heritage, our view of health as a common good, and our collective sense of our self (since the Pearson era) as international peacekeepers who look after the needs of both our own citizens and those of the international community. This is an important mythology that has been under some strain in recent years.[16] Hence it was somewhat reassuring to be in a room full of individuals, many of whom represent quite different interests, but who nevertheless spoke sincerely about a common vision for Canada and health biotech that sought to build upon and extend these commonly shared values and meanings. It is worth noting, in this regard, that Canada's current non-involvement in the Iraqi conflict has positioned it well to retain a certain distance from its powerful neighbour (and competitor) to the south. As the U.S. becomes more insular and isolationist in both its domestic and foreign policies, Canada should aim to be more active internationally. **With the current global interest in peace and security at an unprecedented high, Canada's biotech vision should build upon both its history and current international position and reputation as a global peace maker/keeper.** While Canada may not provide the troops that enforce the peace, it can provide the biotechnological means to contribute to more stable and

[15] Technologies for environmental improvement rank fourth on the Top 10 list, with the top three all aimed at diagnosing and treating infectious disease. If number four became the top priority perhaps the top three would become less urgent.

[16] Consider the *Canadian Charter of Rights and Freedoms* and *NAFTA* as discussed in a previous section

sustainable communities in the developing world, thus helping to ensure that peace breaks out.[17]

Previously mentioned reservations aside, the recent report of the Joint Centre for Bioethics on the "Top 10 Biotechnologies for Improving Health in Developing Countries"[18] is particularly important in this regard. **The fact that a Canadian team took the lead in identifying these health biotech needs and in preparing this report should be exploited as a means for positioning Canada as the country to take the lead in developing and implementing these products. Key collaborations between the academic and private sectors should be encouraged that focus specifically on these issues. These partnerships should in turn be coordinated with appropriate federal government and international agencies (e.g., UNESCO) from the beginning in order to ensure a seamless transition from concept to research and development to market and delivery.** Perhaps the sequencing of the malaria genome that occurred some time ago in B.C., but seems not yet to have gained either the political will or economic impetus to move it into the international scene, could serve as a test case for the federal government's international biotech initiative.

A second key element of the proposed visioning statement is this: it presupposes that economic and health values need not be incompatible, and that economic prosperity can be a means of health promotion. **The key here, however, is to ensure that health promotion is seen always as the goal and economic development as the means.** This will be especially crucial in Canada's domestic market, in which the idea of health as a public good has been under some pressure of late, with an increased emphasis on the introduction of market-based solutions to health care delivery.[19] As health biotech applications come on stream with the promise of faster and more effective diagnostics, we can anticipate a greater pressure to allow more applications to be provided in the private sector, which could result in a further erosion of the value of health as a public good. **Innovative means of reorganizing Canada's health care system in order to utilize market based solutions to the problem of access to emerging technologies, while preserving the fundamentals of a publicly administered health care system, will need to be explored.**[20]

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[17] See, for example, Robert Kaplan, "The Coming Anarchy," *Atlantic Monthly*, Feb. 1994: 44-76. Kaplan observes: "Saddam Husseins of the future will have more, not fewer, opportunities. In addition to engendering tribal strife, scarcer resources will place a great strain on many peoples who never had much of a democratic or institutional tradition to begin with." He goes on to note: "where there has always been mass poverty, people find liberation in violence." And further: "a large number of people on this planet, to whom the comfort and stability of a middle-class life is utterly unknown, find war and a barracks existence a step up rather than a step down." This in itself might provide a manifesto for Canada's biotech future.

[18] Daar, A.S. et al, *Top 10 Biotechnologies for Improving Health in Developing Countries*. University of Toronto Joint Centre for Bioethics, 2003.

[19] Alberta's *Bill 11* is one example, but the recommendations of the Kirby Commission include many others. The whole issue of consumerism in health care is implicated here and needs to be examined more carefully. See: Herzlinger, R. E. *Market Driven Health Care*, Reading, MA: Addison-Wesley, 1997. Also, the review of Herzlinger's book by Alexander Wyke, "Can patients drive the future of health care?" *Harvard Business Review*, July-August 1997: 146-150.

[20] See, for example, D. Pullman and L. Twells, "Pareto Optimal User Fees: A Canadian Case Study in Ideological Compromise," currently under review by the *International Journal of Health Services*.

While the foregoing has demonstrated that health and economic values need not conflict, the reality is that they often do. Most often this occurs when economic self-interest either supplants broader public health interests, or else exploits health concerns. Emerging biotech means to conduct broad-based population screening will provide many opportunities for such exploitation in this regard. As the capacity to screen for genetically based disorders increases, and as other tests become more readily available, we can anticipate greater public concern and demand for access to these products. Pharmaceutical and biotech companies that develop these products will have a major economic interest in seeing that a demand is created. Direct to consumer marketing is one means by which this occurs already in the U.S. For example, Myriad has a well polished ad campaign in some states that promotes BRCA and testing for all middle-aged women. A recent report in the British Medical Journal reports that pharmaceutical companies provide significant funding for so-called public interest groups that advocate for such things as PSA screening for prostate cancer.[21] **While the genie is already out of the bottle on this one, in that the U.S. is unlikely to reverse itself on direct-to-consumer marketing, Canada should maintain a strong stand against any regulatory changes in this regard within our own borders, and should lead international regulators in setting appropriate standards for marketing and appropriate penalties for abusers**. As industry develops novel health products, new models of collaboration between private providers of products and services and public funders may need to be explored. Consider this recent novel example of "pharmaceutical accountability" as a case in point: "One way of achieving maximum benefit could be to set up an 'outcomes guarantee,' in which a pharmaceutical company and prescribing stakeholders (such as health authorities and primary care or hospital trusts) agree on the outcomes that they would expect from a drug in a given indication. If the drug fails to fulfil expectations, the pharmaceutical company refunds the health service for the cost of the drug."[22]

Finally, two other values that often conflict are respect for individual privacy on the one hand and the need to promote the greater public good on the other. This point came up often in the workshop and has especially momentous implications for population health.

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[21] Jeanne Lenzer, "Lay campaigners for prostate screening are funded by industry," *BMJ* 326 (March 29, 2003): 680.

"A lay men's group which campaigns for men to take the prostate specific antigen screening test for prostate cancer gets 95% of its funding from the pharmaceutical industry, its chief executive officer admitted last week.

"The group, called Us Too! International, also led the attack on two doctors who wrote articles in the San Francisco Chronicle (2002 Jan 18;A:29) and the BMJ (2002;324:431)[Free Full Text] arguing that routine screening for prostate cancer was not supported by the evidence. Us Too! International claims to be the world's largest "grassroots, independent, patient-focused charitable organisation" and has 380 chapters in nine countries, including the United States, Canada, Australia, and the United Kingdom. The group emphasises its independence, saying it is "not beholden to any ... company" and that it offers "discussion of medical alternatives without bias."

[22] S. Chapman et al, Setting up an outcome guarantee for pharmaceuticals: new approach to risk sharing in primary care, BMJ 236 (29 March 2003): 707-709.

While there is a growing public concern about privacy of genetic information, which is leading to stricter standards about access to health information generally, this has potentially devastating implications for broad-based epidemiological research. The current push in both the USA (*HIPPA*)[23] and Canada (*PIPEDA*)[24] is toward individual privacy. However, **there needs to be more discussion about appropriate regulations that allow for the kind of access to health records necessary to do surveillance studies, while ensuring that personal identifiers are removed and privacy is protected**. CIHR released a document recently that deals with these concerns.[25] It is an excellent resource.[26]

IV. Some Conceptual Considerations:

This section considers the various ways some of the key concepts that are invoked when discussing health biotech are either defined or else interpreted when they are mentioned. In some respects this discussion should have come at the outset, as various crucial concepts have been utilized throughout this document. However, this is not the place to stipulate in any normative sense how a term will be used. Rather, the purpose here is to demonstrate that key concepts can convey quite different meanings. As CBAC makes recommendations about health biotech policy, it will be important to keep some of these distinctions in mind.

Consider first the term "biotechnology." What does the term convey? Is biotech simply a generic term for a certain class of value-neutral tools, or do biotech products and devices convey their own value priorities? There has been much discussion in the philosophy of technology in general over the past century on the nature of technology. French theologian/philosopher Jacques Ellul, for example, speaks of "autonomous technology."[27] Ellul argues that, while we assume naively that we control our technologies for our own ends, in fact it is technology that controls us. Physicians today cannot imagine practicing without access to high-tech imaging and, when these are not available, the health care system is slowed to a snail's pace. Many of the major bottle-necks in our current system revolve around diagnostic imaging as the public has come to expect it, and physicians believe they can't practice without it, often out of fear of litigation. Clearly there are distinct advantages in some cases to using advanced imaging, but one wonders how we practiced medicine only 10-15 years ago without these technologies. **Technological dependency undermines physicians' diagnostic skills and creates a new layer of litigious opportunism.** We should be cognizant of these possibilities as we explore our biotech future. It is the rare exception when physicians resist the technological juggernaut

[23] *Health Insurance Portability and Accountability Act.*
[24] *Personal Information and Electronic Documents Act.*
[25] CIHR, *Secondary Use of Personal Information in Health Research: Case Studies*, November 2002.
[26] See also the UK Human Genetics Commission, *Inside Information: Balancing interests in the use of personal genetic information*, May 2002.
[27] J. Ellul, *The Technological Society*, New York: Random House, 1964.

and resort to low-tech interventions. The Ottawa Ankle Rules developed for the purpose of avoiding needless x-rays of ankle injuries are one refreshing exception in this regard.[28]

Philosopher Albert Borgmann offers further insights into the nature of technology through what he calls "The Device Paradigm."[29] Borgmann maintains that it is the nature of contemporary technology to reduce complex phenomena into discrete problems that technological devices are designed to solve. Devices, in Borgmann's terminology, deliver commodities. In so doing, the context in which the so-called problem developed is often lost. Think of a wood stove, for example. When viewed in terms of the device paradigm, a wood stove is a technological device designed to produce a particular commodity (heat). Given that wood stoves are labour-intensive to operate, are not all that safe, and only heat a limited area, they are inefficient technologies. Central heating produces heat (the commodity) much more efficiently. However, Borgmann asks us to consider what else a wood stove might represent in a home that relied upon it as its main source of heat. First, it would represent a set of chores and related responsibilities that family members would need to cooperate in performing. Someone would need to be skilled with an axe, and perhaps someone else in lighting a fire. On cold evenings, the family would gather in the room with the stove and engage in communal practices rather than scattering to various separate rooms to pursue activities independently. In short, far from being a simple device to produce a discrete commodity, the wood stove becomes the focal point for a variety of social practices.

Although Borgmann may have a rather romantic sense of what it is like to live in a low tech world, his general point is well worth pondering as we consider our biotech future. The history of technology has been dominated by the search for the technological fix. Again, certain health biotechnologies may reduce complex social phenomena to simple commodities, eliminating~~losing~~ opportunities for social engagement in the process. One of the presenters at the workshop, for example, alluded to "ethical computers" that might visit the lonely elderly. If "companionship" is reduced to a commodity that can be produced technologically, then perhaps computers can solve the problem of loneliness. However, one suspects that the need for human companionship is somewhat more complex. Another example can be found in the JCB's Top 10 list that includes "female-controlled protection against sexually transmitted disease." While this is certainly a valid concern and such biotech innovations could well have positive outcomes in the short term, we should guard against the allure of the technological fix. In this case, it may lead us to avoid dealing with the challenges of more complex social transformations that are required to make women safe from male dominance in every aspect of their lives, of which sexual behavior is only a part.[30]

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[28] LM Bachmann, et al., Accuracy of Ottawa ankle rules to exclude fractures of the ankle and mid-foot: systemic review, *BMJ* 326 (2003): 417.

[29] Albert Borgmann, *Technology and the Character of Contemporary Life*, Chicago: U of Chicago Press, 1984.

[30] The current issue of Health Canada's *Health Policy Research* discusses the importance of culture to aboriginal health and health care. Technologies tend to create their own cultures, and important dimensions of human culture are often displaced in the process.

Jeremy Rifkin offers an interesting antidote to the technological reductionism which Borgmann critiques in what he describes as an ecological approach to technological development.[31] Rather than viewing nature in the Baconian sense as something to be harnessed and/or dominated through "divide and conquer" scientific and technological means, "ecologists favor more subtle forms of manipulation designed to enhance rather than overpower and sever existing relationships, always with an eye to preserving ecological diversity and maintaining community bonds."[32] **While the reductionist model has well served both industry and the acute care model of health services delivery to this point, an ecological model is more conducive to biotech developments and applications in the public health sector.**

The upshot of this rather long digression is that technological transformations are deceptively complex. As Canada contemplates its biotech future, extensive technological impact assessments at every level will be required. CBAC might recommend that more interdisciplinary programs be developed across the country to encourage closer collaboration among researchers from a variety of fields in assessing the long-range impacts in this regard. The University of Waterloo, for example, established a Centre for Society, Technology and Values almost 15 years ago with the founding vision of engaging in this kind of work. However, the centre has never realized that vision because current institutional structures for funding, faculty appointments, and related matters of infrastructure simply are not conducive to sustaining long-term interdisciplinary work of this nature. In short, everybody's baby is nobody's responsibility (the tragedy of the commons). The U of T JCB seems to have made some inroads in this regard. In any case, it is worth exploring what does and doesn't work, and in developing sustained sources of funding over the long term that will encourage institutions (both universities and funding agencies) to change their internal structures and to create new models for inter-disciplinary work that will encourage more collaboration in this regard. Some of the recent faculty renewal opportunities provided through current programs are a step in the right direction. We could certainly use more steps along this path.

RECOMMENDATION: Develop Centres of Excellence in Biotech R&D and global commercialization. Utilize a well funded model for cross disciplinary programs that requires partnerships domestically (e.g., Northern Health Unit University of Manitoba; Community Health, Memorial University; University of Northern British Columbia Prince George) and internationally with institutions in the developing world to provide sustainable development solutions for local needs. The partnership requirement of this recommendation flows from the observation that economies of scale and the necessary critical mass of expertise required for such centres generally results in establishing them in major universities in major urban centres. If partnerships with remote institutions are required (as opposed to encouraged), and if a significant percentage of the research budget must be dedicated to addressing needs of these local communities, the probability of knowledge transfer and endogenous technology will increase dramatically.

[31] J. Rifkin, *The Biotech Century*, New York: Putnam, 1998.
[32] Rifkin, 228.

Health is another key concept that admits of a variety of interpretations. The distinction between "health care" and "public health" has already been mentioned. Given the manner in which health has been interpreted under the *Canada Health Act* (i.e., primarily hospital-based, physician-delivered services), it is clear that the dominant understanding of health in the Canadian psyche fits more closely with the divide and conquer mentality Rifkin associates with a Baconian view of science and technological reductionism (consider the "war on disease"). Again, public health trades on a broader ecological conception ~~of health~~ that includes a greater emphasis on social, cultural and environmental determinants of health that may not be conducive to device paradigm-type applications. However, **if Canada sets its vision for the biotech future now within a broader ecological paradigm, it could well situate itself globally to be a key health biotech broker for international peace and security.**

Health status[33] is another defining concept that is changing in the wake of the biotech revolution. With the advent of population screening technologies and the identification of an increasing number of "disease genes," a new diagnostic category is emerging. This is the "at risk" health status.[34] As further advances are forthcoming, there will be increased public pressure to assess relative risks. More will need to be done to educate the public on the nature of risk in this regard, in order to ensure the appropriate expenditure of scarce health care resources.

V. Additional Summary Notes: The foregoing has attempted to anticipate some key institutional transformations that emerging biotechnologies may precipitate. While these comments build upon the discussions that took place at the March 25-26, 2003 Ottawa workshop, they have emphasized points on which the author felt relatively better prepared to comment. It could well be the case that key insights and concerns of the public health working group have been overlooked here. In a passing effort to at least acknowledge those concerns, this document concludes with the summary notes prepared by the author after the first day's session (See Appendix 1).

[33] One of Michael Decter's "Four Strong Winds."
[34] R.H. Keenan, "The at-risk health status and technology: A diagnostic invitation and the 'gift' of knowing," *Soc Sci Med* 42, 11 (1996): 1545-1553.

Appendix I--Day One Public Health Table Discussion Summary

I. Top Pop Health Biotech Impacts

- Pharmacogenomics
- Diagnostic Screening
    - Disease prevention
    - Prophylactic intervention
        - Potential health care savings in some cases
- Bioremediation
    - Consider low tech solutions in a variety of areas based on JCB top ten list

- Nanotech
    - Biosensors
    - Monitoring and Surveillance

II. Transformative Institutions (Need some good examples here)

- Change organizational structures
    - For priority setting
    - For flexibility

- Information Access
    - Need for better interface between researchers and practitioners
    - Knowledge translation from what we know to how it is implemented will need to be streamlined

- Tension between individual privacy and public need to know will be exacerbated
    - Legitimate concerns about open health records and privacy issues around genetic discrimination etc. are leading to stricter privacy regimes around the world
    - The foregoing has tremendous implications for epidemiological research if the requirement will be for direct consent before general health information can be accessed
    - Policy: in some cases an opt-out strategy might be most appropriate

III. Links to other areas

- How the regulatory environments develop in this regard will impact developments in this area
- Consumerism will lead to greater public demand to access technologies that are available elsewhere. A caution in this regard once again is that market drivers will

shape the way much of the information about developing technologies is framed and presented. Public education will be a key in this area. We don't need to be technophobes (Luddites), but neither should we be technophiles or technomorons.

- The rapid way in which emerging pathogens etc. and related genetic technologies are transmitted around the world will require greater collaboration at the international level on issues of risk assessment and risk management
    - Again, market drivers tend to force greater collaboration internationally (e.g. TRIPS etc.) than do health-related drivers.

- Population health at a global level will require international cooperation and collaboration in order to ensure that emerging biotech is transferred to the developing world expeditiously
    - This has implications for global security—consider Kaplan's *The Coming Anarchy*

- There is the potential here to make public health primary care in the sense that prevention is practiced more systematically through various public health programs such that physician-delivered care is seen only as secondary. Here it might be important to change the rhetoric around health care to talk about primary care as public health and prevention, to talk about stewardship of our health resources in terms of personal and community responsibility, etc.

Ideas and Visions

- See health as a continuum with no firm divisions between public health and individual health care—individual, family, community, public, global. Thinking ecologically—c.f. Rifkin
- More emphasis on prevention and lifestyle management—we need to be thinking here of marketable products that can be developed and implemented at the broad population health level. Perhaps industry in Canada should be looking specifically at the kinds of biotech innovations anticipated by the JCB report and finding means by which to get involved at that level
- Need considerable structural changes away from the MD as the primary health care provider. Population health requires broader population based solutions aimed beyond the one MD-one patient interaction.

Key Risks to be Managed

- False positives/false negatives
- Genetic determinism/ reductionism
    - Potential discrimination
    - Eugenics

- Data management
    - Private control versus public access for epidemiological purposes

- False steps—bad experiences at this early stage will lead to a public loss of confidence
    - Unrealistic expectations/ unrealized hopes—Need for careful public education to counter the genohype

- High commercial involvement could lead to further erosion of the idea of health as a public good

Biotech Vision

- Participatory approach as opposed to individual client/consumer
    - Better sharing of information
    - Better risk communication

- Target populations in terms of positive interventions that can be delivered, not simply in terms of problem identification
    - Need an improved public health infrastructure—Public health nurses and public health genetic counselors

- Continuing Education
    - Public education—need to be more scientifically literate
    - Medical professionals—need to be more humanistically literate. Offer more than simple technological fixes whether they be pills, new genetic interventions, or whatever.

A key insight here is that the basic things we already know about lifestyle management in terms of lower stress, better diets, exercise, etc. are the same today as they have been for centuries. This emerging area will not change those elements. Indeed we know from previous so-called transformative technologies that life is often more complicated in their wake. The need to guard against technological reductionism and fixism is continual.