Black Holes of Risk:

Collected Papers on Risk Management, 1995-2017

Volume I: The Ubiquity of Risk

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ISBN 978-0-9738283-4-4

COVER ARTWORK:
NASA, ARTIST'S RENDITION OF A SUPERMASSIVE BLACK HOLE
(2017)

Author's Note:

Many of the chapters in this volume were prepared with the collaboration of a number of other authors. Please see the chapter headings for details.

William Leiss is a Fellow and Past-President (1999-2001) of the Royal Society of Canada and an Officer in the Order of Canada.

From 1999 to 2005 he held the NSERC/SSHRC Research Chair in Risk Communication and Public Policy in the Haskayne School of Business, University of Calgary, and from 1994 to 1999 he held the Eco-Research Chair in Environmental Policy at Queen's University. His earlier academic positions were in political science (Regina, York), sociology (Toronto), environmental studies (York), and communication (Simon Fraser). At Simon Fraser he was also Vice President, Research. He is currently a Scientist with the McLaughlin Centre for Population Health Risk Assessment, University of Ottawa. He was a member of the Senior Advisory Panel for the Walkerton Inquiry (2000-2), Chair of the Task Force on Public Participation for Canadian Blood Services (2002), and an advisor on risk management to the Commission of Inquiry into the Investigation of the Bombing of Air India Flight 182 (2008-2010). Over many years he was responsible for organizing expert panel reports on behalf of The Royal Society of Canada.

He is author, collaborator or editor of fifteen books and numerous articles and reports. Three books are made up of case studies dealing with controversies, in Canada and elsewhere, about health and environmental risks: *In the Chamber of Risks: Understanding Risk Controversies* (2001); *Mad Cows and Mother's Milk: The Perils of Poor Risk Communication* (with Douglas Powell, 1997; second, enlarged edition 2004); and *Risk and Responsibility*, 1994 (with Christina Chociolko). Earlier books are *The Domination of Nature* (1972), *The Limits to Satisfaction* (1976), *Social Communication in Advertising* (1986, 1990, 2005), *C. B. Macpherson* (1988, 2009), and *Under Technology's Thumb* (1990), all of which are currently in print. With the exception of *Social Communication in Advertising,* all of these titles are published by McGill-Queen's University Press. His later book, *The Doom Loop in the Financial Sector, and Other Black Holes of Risk*, was published by The University of Ottawa Press in October 2010.

He is also the author of a trilogy written in the genre of utopian and science-based fiction: *Hera, or Empathy* (2006); *The Priesthood of Science* (2008); and *Hera The Buddha* (2017). All are available as E-books on Amazon.

FIGURE 1 NASA, ARTIST'S RENDITION OF A SUPERMASSIVE BLACK HOLE

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PREFACE

The ultimate goal of risk management and risk communication is to assist stakeholders, consumer and the general public in understanding the rationale behind a risk-based decision, so that they may arrive at a balanced judgement that reflects the factual evidence about the matter at hand in relation to their own interests and values. Risk communication should not be seen as an attempt to convince or persuade people to adopt the judgement of the communicator about the tolerability or acceptability of risks. It is rather the attempt to help people to make more informed judgments and enable them to have agency over the risks that they face in their own lives. In addition, effective risk communication is a central prerogative for taking an active part in contemporary discourses about risks, and in particular technological and environmental risks. Being well informed about and aware of risks posed by new technologies and changes in lifestyle is also paramount to all involvement and participation programs that are directed towards more direct codetermination for designing and shaping regulations and standards.

Effective risk communication can make a strong contribution to the success of a comprehensive and responsible risk management programme. Through effective risk communication one can: (1) ensure that society is or becomes aware of the risks associated with new products, technologies and human interventions into nature; (2) build public confidence in appropriate risk assessment and management decisions and the associated risk/benefit considerations; (3) contribute to the public's understanding of the nature of risk, the magnitude of risks in a comparative review of potential threats; and (4) provide fair, accurate, and appropriate information, so that society and its institutions are able to choose among a variety of options that can meet their own "risk acceptance" criteria.

The two volumes written by William Leiss include seminal papers and analyses on the two topics: risk management and risk communication. They are a strong reminder that risks can be managed, governed and communicated. Scientific advances, professional expertise and management skills are key to reducing risks in modern live to a standard that appears acceptable to society. The acceptability level that a society is willing to tolerate is a political decision that requires intensive public discourse and effective democratic institutions for decision making. Informing this discourse and guiding societal actors

through the complex evidence about potential harm is one of the most important tasks for risk scholars and communicators alike.

William Leiss is one of those risk pioneers who has the rare gift of being a highly competent scientist in risk analysis and management and a dedicated and effective communicator. The two volumes that he has authored speak to the comprehensive and interdisciplinary competence in many risk fields but also to his ability to make complicated insights into risk management challenges easily understood by an attentive lay public. His contributions to the field have and continue to have major impacts on risk discourses in the public. In particular, he has pointed out where society has probably spent too much attention and resources on minor risk threat and not enough attention on those systemic risks that pose long-lasting threats to Canada and the rest of the world. When society gets too concerned about marginal risks such as food additives it may be distracted from the larger risk scene where issues such as climate change emerge into potential global disasters.

The author does not convey a pessimistic outlook into our future. On the contrary, he points out that society has been very successful in reducing risks in many domains of life. As a professional in the field, he has also induced and inspired many managerial changes in Canada that helped to improve risk management practices and make governance efforts more effective. Furthermore, he has introduced improved manuals and guidelines for institutions all over the world to be better prepared and skilled to deal with complex risk situations. I myself was privileged to cooperate with William Leiss for initiating and guiding a substantive relaunch of the risk communication program of the German Federal Agency for Risk Assessment. This program is still in place and does what it has been designed for: help people to deal prudently with risk in their daily life.

The two volumes represent a large array of the major accomplishments and ideas of William Leiss over a professional lifespan of many decades. They testify to the author's competence and ability to make a difference in the risk world. Moreover, the book is highly informative, educational and inspiring. It is a "must" for all those who have an interest and/or an obligation to continuously reduce the level of unwanted risks to society.

ORTWIN RENN
Berlin, October 31, 2017

INTRODUCTION

Risks are everywhere, ubiquitous. For the individual, they begin even before conception, in the genetic matchups from one's parents that could presage becoming afflicted with one of the more than ten thousand known inherited diseases, many of which have catastrophic consequences. They carry on throughout pregnancy, with rates of miscarriage and complications exceeding 30%, and into early childhood; before modern public safety and medicine, about half of all newborns died before the age of five. And then throughout life, with premature mortality resulting from accidents, disease, and acts of deliberate malice.

Should a realization about the ubiquity of risk induce in us a state of paralyzing, overwhelming fear? Should it send us into a catatonic state, unable to function at all? Quite the contrary, for it tells us that we are well on our way to *domesticating* risks, to becoming, if not comfortable with them, then at least understanding them far better than we have done before: That we are steadily learning what substances, behaviors, activities and conditions are quite likely to be harmful to us, and which ones are much less likely to do so, enabling us to set priorities for spending time and money on figuring out how to reduce the impact of potential harms on our health, well-being, and longevity.

The great discovery about risk in the modern West was simply that risks are *measurable*, whereas dangers are not. (The early history in this area is wonderfully told by Peter L. Bernstein in his 1998 book, *Against the Gods: The Remarkable Story of Risk*.) In other words, what is really important about the things that may do us harm is just how much harm may be approaching, from a specific source, and how likely it is to strike us. And because risks are measurable, that is, quantifiable, we can rank a collection of them in order of importance, estimating how much more likely one is as

opposed to another, and also how much more harm one may do to us than some other one may.

But there is a downside as well: Because risk is *the chance of harm*, what we can never have is any certainty about who exactly might be harmed – that is, ourselves, our neighbors or distant relations, or complete strangers everywhere on the globe. The apparent randomness of outcomes bedevils the appreciation of risk: For most risks of any importance, every one of us among those in a discrete human community is constantly or sporadically at risk, throughout our lives, but only some few will be struck down from a particular type of threat which hangs over all. Where risks are closely studied on an ongoing basis, as they are in modern societies, the apparent randomness gradually turns out to be an illusion, as the proximate causes for the distribution of risks among populations are better understood and the underlying patterns of outcomes become more predictable. And yet, some pure randomness will always prevail as a result of simple accidents and unforeseeable circumstances.

And then there is uncertainty, which to many persons appears to be the same thing as randomness, that is, the equivalent to something being utterly unknown. Because risk is inherently the *chance* (or the possibility) of harm, it is also inherently uncertain as to either the likelihood, or the consequences, that harm will actually be inflicted in any particular case. But it is not necessarily (thus not inherently) random: There are distinctive patterns to the harms inflicted, although not in all cases. Those patterns can be described and, in fact, when sufficient evidence is available, described quite precisely. A famous definition by Frank Knight referred to risk as "measurable uncertainty." In risk estimation, uncertainty appears in the form of upper and lower ranges around a most-likely number. An example can be drawn from Chapter 3 in this volume.

When one needs a blood transfusion in hospital, the nurse will fill out a requisition drawing on the local blood bank, a supply donated by one's

fellow citizens. The benefits of receiving blood are huge, and sometimes life-saving, but the blood carries risks to the recipient as well, although medical authorities try to reduce those risks to the lowest possible level. Among the risks is the chance of contracting HIV/AIDS, and in Canada it has been quite carefully estimated: About 1 in every 8 million liters of donated blood may be contaminated (that amounts to about ten years of blood donations in this country). It *may* be 1 in 8 million, but the uncertainty is large, ranging from a high of 1 in 3 million to a low of 1 in 20 million. But this is the bottom line: Even if one were to take the highest estimate, 1 in 3 million, what we are told is that *once every decade* there is a 1-in-3-million-chance that one liter of blood administered to a patient in a Canadian hospital may be contaminated with HIV/AIDS. And that is too small a risk to worry about.

The foregoing helps explain why, to many people, risks appear to be black holes for understanding, devouring infinite amounts of information without yielding clear directions for action. And, to be honest, there is some truth in this suspicion. Almost everyone drinks caffeinated beverages and, if one samples the substantial scientific literature on the subject of caffeine, the conclusions therein about benefits and possible harms appear to be about equally distributed. There are many examples of this kind, especially for high-profile issues such as breast-cancer screening or dietary and health-supplement advice, where the average citizen who tries to follow the twists and turns of the newest information might be left depressed. But in fact the scientists are not being deliberately perverse, for the simple reason that risks are tricky; and, to some extent, it is the scientists' continued search for more and better evidence, on which to base advice to the public, that is responsible for the ongoing difficulty with risk information.

Nowhere is the seemingly ambiguous nature of risks more apparent than in the matter of *dose*, as in the famous phrase, "the dose makes the poison." In other words, there are many, many substances for which relatively small amounts are quite beneficial, whereas just a bit more can bring serious harm. Getting the right dose in prescribed medicines, for

example, makes all the difference in the world, sometimes a life-and-death difference. Few substances are more ubiquitous in human life than alcohol, the production and use of which can be traced back as far as 3000 BCE, and here dose is very important. A little, on a regular basis, can be relatively harmless for most people, and may even be beneficial; more consumption, especially regularly, can lead to serious disease, because alcohol is a carcinogen. Women can tolerate quite a bit less than men, adjusted for body weight; and repeated, long-term binge drinking can cause permanent brain damage. Right down to the present day, it remains difficult for public health authorities to communicate convincingly, especially with young people, on this risk issue.

The good news for everyone is that, despite inevitable randomness and uncertainties, most of the lifetime risks we face can be managed. This is becoming increasingly true even of the first-mentioned risk in our list, that of inherited diseases. For example, there is adrenoleukodystrophy (ALD), caused by a single defective gene among the nineteen or twenty thousand that make up the human genome. It affects about one in 20,000 boys, and its effects are truly devastating, turning a bright and healthy youngster, around seven years old, into one who cannot walk, talk, or eat, and later cannot even see, hear, or think, until death intervenes five years later. Now there is both an effective treatment and a cure (involving gene therapy), although both are expensive and not always successful.

Risks are managed through our gaining evidence about their causal factors and the availability of preventative or mitigating strategies to control them. Simple examples abound, such as reducing traffic-accident fatalities by aggressively combatting drunk and distracted-driving behaviors, mandating childhood vaccinations for infectious diseases, or (outside the USA) strictly controlling gun ownership. And yet, the mention of vaccination points to one of the best examples of how the sheer, frustrating perversity of the human intellect erects limits to risk management: In many cases, presenting evidence to people about proven ways to control risks simply causes them to

intensify their efforts to invent more reasons why their contrary views are in fact correct, or to redouble their search for apparently disconfirming evidence, however bizarre or anecdotal. Or even (but only in the USA) to pass laws forbidding the use of public funds to compile evidence about the deleterious consequences of virtually uncontrolled gun proliferation.

On the level of personal risk management, there are actually a few helpful rules that can be followed, provided that one is prepared to put one's trust in evidence-based reasoning. They are just three in number, and one can follow them for all the things that are most worrying: First, be proactive, rather than waiting until harm strikes; second, be precautionary, that is, take some practical steps to reduce the expected harm; third, focus primarily on the potential downside, and ignore the expected benefits. Here's an example for a parent worrying about the risk of alcohol abuse by their teenage children. First, follow the always-developing medical literature on the long-term effects of alcohol abuse, so that you can offer specific reasons for your advice; second, introduce responsible alcohol use in your home, rather than waiting for it to occur first outside the home; third, recognizing how strong the positive socialization benefits of alcohol use are for teenagers, focus your advice only on the most serious deleterious consequences, especially the serious risks associated with binge-drinking.

To take another example, pertinent to North America, consider the case of concussion risk for youngsters who are playing organized sports involving physical contact, such as football and ice hockey. Recent publicity about the long-term physical and mental effects of repeated violent contact have made parents more aware of the severity of this risk. So, what should they do? First, be proactive, paying close attention to developing medical research that better characterizes the true frequency and consequences of the risk. Second, be precautionary, including promoting the development of no-contact sports in your area (such as flag football) and enrolling one's children therein. Third, work with your children to diminish the social prestige aspects of the traditional violent-contact sports and to focus on the

serious downside risks – in terms of potential lifelong adverse health consequences – of those sports.

The paradoxes involved in our experience with risk management in modern times are legion. None is more potentially consequential than the truly desperate urge on the part of many to shield themselves from scientific knowledge about the risks of climate change. To be sure, this is a devilishly complicated business: The risk estimation requires using global models that can only run on the largest supercomputers, synthesizing evidence derived from the work of literally thousands of talented scientists. The conclusion drawn therefrom, considered to be of high likelihood and high confidence, is that we humans are engaged in "dangerous anthropogenic interference" with the global climate system; and the only remedy for this activity is to drastically reduce the emission of greenhouse gases to the atmosphere. But despite the direst warnings about failing to do so, many prefer to take refuge in simple denial, and have done so for so long that it is less and less likely, with each passing year, that any effective measures for avoiding the most serious adverse future consequences will be available.

Half of the world's population currently lives in proximity to oceans. The latest predictions, from the National Oceanographic and Atmospheric Administration (NOAA) – in the United States, where most of the climate-change deniers live – suggest a sea-level rise of up to six feet by 2100. Such predictions have always erred deliberately on the conservative side, so the actual result could be considerably worse. And the prediction points out that the world's oceans will continue to rise, after 2100, *for centuries to come*. Having reached that point, at the turning of a new century, there will no longer be any option left for us to change the coming course of events.

About sixty-five million years ago, a massive asteroid crashed into the sea-bed off the coast of Mexico. To be sure, we are now entitled to regard such an event as a very rare occurrence indeed, to be expected on our planet on average once every 100 million years or so. But after the asteroid gouged

out the Chicxulub crater, the ensuing years of huge volcanic eruptions induced severe climate change that brought the reign of the top predators, the land-based dinosaurs, to an end. At the time the largest mammal was the size of a rat, the evolutionary success of mammals having been kept in check by those predators. The Cretaceous Period ended, to be followed by the Cenozoic Era, the "age of mammals," and ultimately, us. To be sure, the species of modern humans will survive the coming climate change, but it will not be a pretty sight, as billions of people are set in motion by the rising seas. Most of the great achievements of our evidence-based risk management will probably be swept away in the chaos. We in advanced, science-based societies would be well-advised to "eat, drink and be merry" while the good times last.

GUIDE TO THE STUDIES THAT FOLLOW

Following the opening section, entitled "Prelude: A Risk Sampler," Part One of this volume is a compilation of eight studies, either published in peer-review journals or otherwise disseminated in the period 2003-2008, on the risk-based approach to decision-making, which illustrate both the considerable strengths, as well as the persistent weaknesses, in that approach as it is now practiced. These studies deal with issues that range from the safety of blood and drinking water to the risk assessment of climate change. Part Two looks at risk communication practice, which is the aspect of risk management dealing with the need for a sustained, two-way dialogue between risk managers, on the one hand, and stakeholders and the general public, on the other, that is a necessary precondition for building public confidence in the whole risk management enterprise.

Part Three consists of one paper on carbon capture and storage, and two extensive case studies on the management of the prion diseases BSE (mad cow disease, affecting domesticated cattle) and CWD (chronic wasting disease, affecting both wild and farmed deer and other species). These eighteen studies in all make up Volume I. Part Four is a collection of seven

studies, all of which deal with managing radioactive nuclear waste, both high-level as well as low and intermediate-level; they make up the entirety of Volume II. A short introductory note for three of the four parts offers some additional information about the context within which the various studies were researched and written.

With the sole exception of Chapter 2 (where I am the second author), I am either the sole author, or the lead author, for all of the studies collected in Volume I. However, in every one of the multiple-author papers included herein, the designation as lead author is largely an honorific title. In all of them my collaborators, who are without exception distinguished authorities in their own right, provided important and indeed indispensable contributions, drawn from many different specialized academic disciplines, in none of which do I have any expertise. These collaborations have been a source of deep personal satisfaction as well as of academic accomplishment.

My three earlier books in the field of risk management, all of them published by McGill-Queen's University Press (MQUP), contain eighteen additional case studies, many of which are also the result of collaborative efforts. They are:

A. *Risk and Responsibility* (with Christina Chociolko, 1994):
1. Electric and magnetic fields (high-voltage power lines);
2. Alar, a pesticide used on apples;
3. Antisapstain chemicals, pesticides used in the softwood lumber industry.

B. *Mad Cows and Mother's Milk* (with Douglas Powell, 1997), 2nd edition (2004):
1. Government communication on mad-cow disease in the U.K.;
2. Dioxins;
3. The bacterium *E. coli* in hamburger meat;
4. Silicone breast implants (with Conrad Brunk);
5. rBST in milk;

6. Genetically-modified foods;
7. PCBs in mother's milk (with Pascal Milly);
8. BSE in Canadian cattle;
9. A Night at the Climate Casino (with Stephen Hill);
10. Genomics (with Mike Tyshenko).

C. *In the Chamber of Risks* (2001):

1. MMT, A Risk Management Masquerade (with Stephen Hill);
2. Frankenfoods;
3. Radio-frequency fields for cellular telephones (with Greg Paoli);
4. Pulp-mill effluent;
5. Tobacco.

These three volumes are available on the MQUP website:

1) http://www.mqup.ca/risk-and-responsibility-products-9780773511941.php?page_id=73&
2) http://www.mqup.ca/mad-cows-and-mother-s-milk--second-edition-products-9780773528178.php?page_id=73&
3) http://www.mqup.ca/in-the-chamber-of-risks-products-9780773522466.php?page_id=73&

Hamilton, Ontario, Canada
November 2017

Note to the Reader:

Since the individual pieces collected in this Volume were written at different times and for different audiences, there are inevitably some repetitions in them (for example, in the references to BSE, or "mad cow disease," in Canada). Please just skip or skim the material when you encounter any such repetitious passages.

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No. 1: Review of Ulrich Beck, *Risk Society*

(Published in *Canadian Journal of Sociology,* 1993)

Ulrich Beck, *Risk Society, Towards a New Modernity.* Translated from the German by Mark Ritter, and with an Introduction by Scott Lash and Brian Wynne. London: Sage Publications, 1992 [originally published in German in 1986]. 260 pp.

This is three books in one and only the intelligence and courage of the author holds them together, forging them into a single spirited essay on broad themes that has proved to be attractive to readers in its original

language (it qualifies as an academic best-seller in Germany and already has gone through three editions) and will do so, albeit to a lesser extent, to the readers of this translation.

The three books are as follows: (1) a worthy contribution to the theory of industrial society and the concept of "modernity,'' situated within the long tradition that stems from Marx and Weber and runs primarily through Critical Theory; (2) a critique of the role of science and instrumental rationality in modern society that, like so many others, draws its inspiration from those two extraordinary works from the “Frankfurt School,” *Dialectic of Enlightenment* and *Eclipse of Reason* (although the latter is not cited); and (3), a theory about a distinctive form of society, "risk society,'' that includes a specific perspective on the way in which we experience risks to health and the environment today. Given its wide scope Beck's book could only have been written in essay form, as a series of essentially declarative sentences -- *obiter dicta*, as it were -- that requires the reader to fill in the blanks and to accept a good deal on faith. In this style of presentation fragments from the empirical world can intrude only as illustration or example, which is assumed to be representative of the full picture.

Book number one, the theory of industrial society and the concept of "reflexive modernity,'' will have the broadest appeal and indeed, as the authors of the Introduction note, its perspective finds solid support in the analogous but independently formulated views of such a prominent authority as Anthony Giddens. The excellent point it makes is that the first full phase of industrial society (say 1800-1950?), with its radical transformations in so much of everyday life, concealed its heavy dependence on traditional social forms, particularly the maintenance of old gender and family roles. In its newer phase these forms are undergoing equally radical change: For example, as women enter the paid work force in great numbers and challenge the pervasive gender stereotyping still deeply entrenched there, within a larger context in which highly stratified class and status inequalities persist.

Beck names this the progressive "individualization of social inequality.'' Other changes are sketched here which have become more widely noted in the past few years, such as structural unemployment, the shift from full-time to part-time employment, and the erosion of lifetime job security in both blue-collar and white-collar occupations; all observers agree that these are momentous developments for the industrialized world, but like Beck, most are reduced to simple speculating about what it all means for the underlying longer-term economic and political development of these societies.

The second book, which pops up here and there in the text and receives one full chapter entitled "Science beyond Truth and Enlightenment?'' will have a more restricted appeal. The question-mark is well placed and indicative of the tentative nature of Beck's conclusions. For the sake of continuity in his chief thread of argument Beck in fact is required to contend that natural science also becomes "reflexive,'' as it is "dethroned'' because its "monopoly'' on truth is challenged. Here the lack of detail and example begins to tell. If the concern here is to attack (again) the philosophy of "scientism,'' which I understand to be the unsupportable claim made by some advocates of the natural sciences, to the effect that these provide the only solid basis for true knowledge in all domains, then fine, I and others can accept this.

And if the concern is to undermine the practical effect of scientism in society, which is the claim that the practitioners of science ought to occupy a privileged position with respect to political decisions about the management of risks and other things (the contemporary variant of the old technocracy), then fine, I and others can accept this too. Yet in Beck's book, as in others in the same tradition (Jürgen Habermas, too, wrestled with this problem before giving up), there always seems to be more to the questioning of science, and, in the end, the reader is hard-pressed to know what it is. Beck ends by calling for a new "pedagogy of scientific rationality,'' but it is impossible to tell what this would accomplish or even why we need it.

The third book is the most curious but in some ways the most innovative. Beck was well ahead of his time in calling attention to the importance of the concept of risk and the practice of risk management as essential features of modern society, and he is to be congratulated for his foresight. Developments since he first completed his work have confirmed his view of that importance, and there is little doubt that in the future the centrality of risk debates will be amplified steadily. But he wants to do much more, and if there is a failing here, it may be one that is inherent in German social theory, namely to wish to transmute every newly discovered sociological phenomenon into the latest chapter of the world-historical dialectic (the French seem to do the same with psychological phenomena).

Beck writes: "Risk may be defined as a systematic way of dealing with hazards and insecurities induced and introduced by modernization itself'' (21). And: "In contrast to all earlier epochs (including industrial society), the risk society is characterized essentially by a lack: the impossibility of an external attribution of hazards. In other words, risks depend on decisions, they are industrially produced and in this sense politically reflexive'' (183). Now, the very important point here, where we can agree with Beck, is that industrial society marks a transition, a watershed in human history, in fact, from a human condition where naturally occurring hazards (disease, flood, famine, and the like) -- along with socially determined hazards such as invasion and conquest, regressive forms of thought and culture, and rigid class structures – molded the fate of individuals and groups, to one where increasingly our fate is bound up with risks that are deliberately undertaken – for the sake of benefits conceived in advance, by means of our technological mastery over nature. So far so good. Thereafter the argument gets murkier and the reader is never quite sure whether for Beck it is the nature of risk or of society which has undergone the change.

There are a number of specific and very important confusions in the text. (1) "Natural'' versus technological or artificial: Surely in the age of AIDS we must confess that we are still subject to hazards originating in

nature. (2) On the same theme, on a "new'' risk such as "pollutants in foodstuffs'': In industrial society, on the whole and on balance, the food supply is far safer than it was previously, since we are protected against potent, naturally occurring toxins. (3) Still on the same theme, now in terms of the alleged novelty of the global dimension of risk: It is estimated that the volcanic explosion of Mount Pinataubo in the Philippines put an amount of particular matter in the atmosphere equal to that attributable to the entire world history of industrialism to date. So? (4) Risks and benefits: whatever happened to the latter? Did Beck just forget to write about them? (5) The "toxic threat'': average life expectancy in the industrial world continues to increase. There are particular threats, to be sure, but does this rather visible marker of human welfare count for nothing? (6) "Acceptable levels'' of risk: goods such as pesticides and drugs (antibiotics) and many other useful chemicals (e.g., chlorine) are toxic by nature and design and depend for their utility on our being able to specify acceptable levels of exposure to humans, other animals, and the environment (64-9).

There are many other objections which could be made to this whole section, which has all the overtones of an irrational "zero-risk'' mentality that is unworthy of (and probably unintended by) the author. These examples could be multiplied indefinitely.

The main problem is not just sweeping generalizations and a lack of balanced illustrations, but a lack of clarity about the target. I think that Beck wants to write a diatribe against risk management, in particular, against risk management as too many risk experts wish to practice it, namely, as an exercise in bureaucratic rationality, technocracy, and contempt for the public perception of risk. And if this is what he wants to attack, I and others can agree with him (although the situation is changing). But what he actually does is give us a one- sided, highly selective account of the mismanagement of a few technologically induced hazards, an account which simply cannot be generalized. Yet more serious is the fact that Beck overlooks another dimension almost entirely (except for a few passing references without

comment, for example on automobile fatalities), namely, voluntarily induced risks.

There is not a single mention of tobacco use, the single gravest risk to health in the industrialized world and a fast-rising candidate for this status even in "developing'' countries as poor as China. Individuals have become aware of the magnitude of this risk only thanks to the science of epidemiology, which helps us to overcome the intuitive deception induced by the long latency period (20 years or more) for lung cancer and the other fatal diseases caused by tobacco use. (In industrialized countries it accounts for ten times the mortality of the next leading cause of death, which are traffic accidents.) Is this not a "toxic threat'' of massive proportions? And yet this whole category of risk does not fit comfortably into the superstructure of the author's design and indeed threatens to explode it.

We should expect so adept a thinker as Ulrich Becker to seek to persuade the reader that indeed he has written one book and not three, and he does not disappoint us (153-4), for he maintains that both risk and individualization exhibit their unity as dimensions of the "reflexive modernization of industrial society.'' This is the logic: in the second phase of industrial society individuals are freed from their unselfconscious immersion in traditional group determinations and are challenged to come to terms self-consciously with (i.e., reflect on) their unmediated relation to society. At the same time, the formerly latent dimensions of producer-driven industrial risks are brought out into the open and can be apprehended for what they are, that is, as problems that (a) are formally constituted in scientific terms and (b) are a "new source of conflict and social formation'' (99). There is a nice kernel of truth here, but it is insufficient to make anywhere near as sumptuous a meal as Beck would like.

In this book, the whole is less than the sum of its parts: the main reason is, I think, that Beck has not thought through his perspective on risk with sufficient care, nor has he devoted enough time and effort to presenting a balanced account of the trade-offs between risks and benefits in industrial

technologies. (Many of these become enormously complicated affairs, especially when controversies over scientific risk assessments erupt, and they can require elaborate case study treatment.) In view of the power and range of his thinking as it is exhibited in this book, however, we hope that he will return to the se themes again.

No.2: Mr. Bush's Panopticon (2003)

Update 2009:

The program described below no longer exists, as such, for reasons that may be obvious after reading about it. It seems to have been supplanted by the Information Processing Techniques Office (IPTO 2009). The new program is described as follows:

> IPTO programs create the advanced information processing and exploitation science, technologies, and systems for revolutionary improvements in capability across the spectrum of national security needs. The capabilities that IPTO enables will lift the fog of war and increase the speed and accuracy of decision-making for the warfighter. IPTO aims to ensure U.S. superiority in all areas where information can provide a decisive advantage, including:
>
> - Anticipating potential adversary actions in advance of actual hostilities;
> - Shaping the battlespace before and during conflict;
> - Improving the effectiveness of major combat operations; and
> - Providing force multipliers for post-conflict reconstruction and stability operations.

Internet Essay posted in February 2003:

DARPA is the U. S. Defense Advanced Research Projects Agency, legendary for having laid the original foundations for the Internet. Its newest project is called the "Information Awareness Office," described on the home page of the agency's website as follows:

The DARPA Information Awareness Office (IAO) will imagine, develop, apply, integrate, demonstrate and transition information technologies, components and prototype, closed-loop, information systems that will counter asymmetric threats by achieving total information awareness useful for preemption; national security warning; and national security decision making.

IAO Vision

The most serious asymmetric threat facing the United States is terrorism, a threat characterized by collections of people loosely organized in shadowy networks that are difficult to identify and define. IAO plans to develop technology that will allow understanding of the intent of these networks, their plans, and potentially define opportunities for disrupting or eliminating the threats. To effectively and efficiently carry this out, we must promote sharing, collaborating and reasoning to convert nebulous data to knowledge and actionable options. IAO will accomplish this by pursuing the development of technologies, components, and applications to produce a proto-type system. Example technologies include:

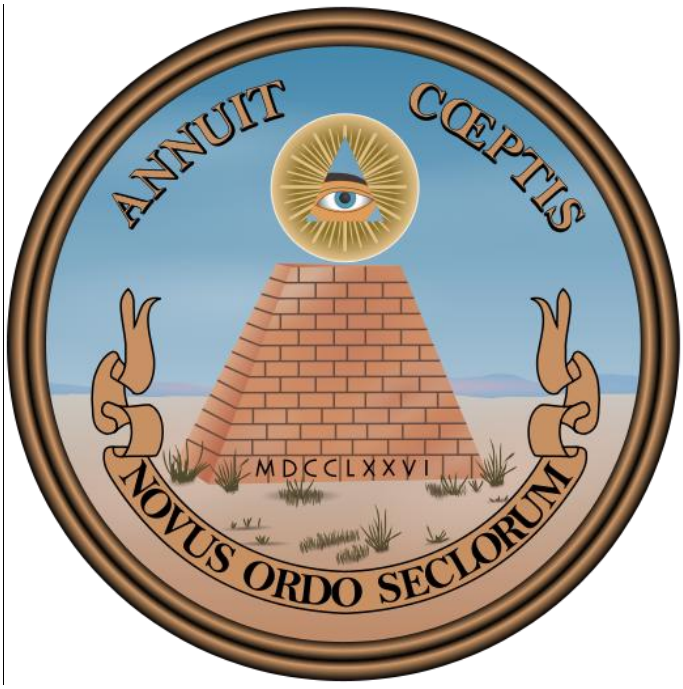
- Collaboration and sharing over TCP/IP networks across agency boundaries
- Large, distributed repositories with dynamic schemas that can be changed interactively by users
- Foreign language machine translation and speech recognition
- Biometric signatures of humans
- Real time learning, pattern matching and anomalous pattern detection
- Entity extraction from natural language text
- Human network analysis and behavior model building engines
- Event prediction and capability development model building engines
- Structured argumentation and evidential reasoning
- Storytelling, change detection, and truth maintenance
- Business rules sub-systems for access control and process management
- Biologically inspired algorithms for agent control
- Other aids for human cognition and human reasoning.

Under “Programs,” there is this list:

- Total Information Awareness (TIA) System

- Babylon
- Bio-Surveillance
- Communicator
- Effective, Affordable, Reusable Speech-to-Text (EARS)
- Evidence Extraction and Link Discovery (EELD)
- FutureMap
- Genisys
- Genoa
- Genoa II
- Human ID at a Distance (HumanID)
- Translingual Information Detection, Extraction and Summarization (TIDES)
- Wargaming the Asymmetric Environment (WAE)

Something of a stir was created when the IAO website was first launched by DARPA in early October 2002, mainly because it carried an extraordinary logo and banner, since removed (Hertzberg 2002). The original banner and logo contained the phrase, "Scientia est Potentia," the famous dictum from the great English seventeenth-century thinker, Francis Bacon, which is usually translated as "Knowledge is Power." The original home page, with its remarkable logo and banner, is now reproduced on a variety of websites maintained by individuals and organizations, whose websites also discuss the political implications of the Information Awareness Office idea.



(Above: the reverse side of the "Great Seal of the United States.")

What is the Panopticon?

The main theme in the logo is the "all-seeing eye" atop a pyramid, which is well-known to Americans because it is on the reverse side of the country's Great Seal. But in the context of information collection and analysis, the reference that springs to mind immediately is the notorious 1791 concept of a "panopticon" by the English thinker Jeremy Bentham. The panopticon was a design for a prison in which the warders could keep the inmates under surveillance, without themselves being seen, so that the inmates would never know just when they were being watched. (See the Wikipedia entry on "Panopticon."}

Of course, the IAO projects, as well as legal authorization for new information collection authority under the pending Homeland Security Act, are said to be a response to the threat of terrorism. The first thing that must be conceded, therefore, is that the risk of further terrorist attacks by al-Qaeda affiliates on Western nations, in North America and Western Europe, is a substantial and ongoing reality. Furthermore, these risks include a

category of possible events I call "catastrophic risks," where the consequences of death and destruction are very large. They include the use of "dirty" nuclear bombs and widespread dispersal of chemical and biological agents, including, most seriously, genetically-engineered bacteria and viruses which might defeat the defensive measures in place now or in the future. Adequate responses to these new perils are absolutely essential. No government can ignore its responsibilities in this domain. No matter what cause is called upon to justify them, terrorist attacks against civilian populations are an unqualified wrong and must be forestalled. However, reasonable people can disagree about which types of measures are or may be necessary in order to provide sufficient deterrence against them.

A Few Questions.

Is a program of "total information awareness" a reasonable and necessary response to the terrorist threat? Such a program proposes, first, to develop and use technologies that will expose every aspect of every individual's life to continuous surveillance, and second, to deposit the information so collected in searchable electronic databases. Is this a reasonable response to the risk of terrorist attack? Or does it simply exchange one existing risk (terrorism) for a new risk of a different sort (the end of individual privacy)? And is it possible that the new risk could be the greater one?

Discussion.

Very few people could be found, I am sure, who would defend such a program on grounds of principle – namely, that democratic governments ought to collect unlimited amounts of information on the private lives of their citizens. So the obvious defense is that it's an unfortunate but necessary weapon in the "war on terrorism." This is a practical justification, and therefore it can be evaluated on its own terms.

First: If one is being attacked, the usual response is to collect as much information as possible on the likely suspects. Many commentators have argued that the intelligence failures prior to the September 11 attacks

were primarily a matter of the declining U.S. capacity for external surveillance, as well as complacency about the threat itself and underestimating the capacity of one's foes. These shortcomings are being corrected, but the litany of vague and useless "credible threat" warnings issued regularly by U. S. authorities since then shows that there is still a long way to go in this regard. The "manhunt" for five suspects at the end of 2002 continues this farcical routine; by early January Canadian police were chalking it up as the result of a "slow news day" in Washington, D. C (Cheney and Malarek 2003).

To be sure, the teams that hijacked four airplanes on September 11 were on U. S. soil prior to the events. However, revelations since that time have shown there were serious failures in traditional intelligence gathering about Zacarias Moussaoui and the flight-training schools (CBS 2002). This, combined with information about the FBI's lack of modern computers and linked databases, provides a *prima facie* case for saying that traditional, competent intelligence gathering might well have been expected to turn up information that could have prevented or mitigated the attacks.

The key question is: Assuming that some terrorists will be operating both outside and within the borders of Western nations, is the best response to that threat the collection of a "total" information profile on *all* of a nation's residents? Second: All databases, including electronic databases, contain a certain percentage of erroneous information. In addition, experience shows that deleting or changing such information is difficult to do, even with electronic databases. The larger the database, the greater is the sheer volume of erroneous or misleading information it will contain. This leads to two possibilities:

(1) The effort to separate correct from incorrect information (and the inferences drawn therefrom) – in technical terms, detecting the percentage of "false positives" in the data – may frustrate the ability to discern a true terrorist threat in time to forestall it.

(2) The consequences for all citizens may include many instances of false arrest or detention, increased prosecution for so-called "victimless" crimes, abuse of private information (blackmail, extortion), and the diminution of political freedom, among other things.

Question.

What is the likelihood that the much-enlarged databases proposed in the DARPA programs will so overwhelm the surveillance system with false positives that there will be a diminished, rather than enhanced, capacity to act on true threats in a timely fashion?

Recommendation.

The scientific search for the "needle in a haystack" occurs daily for the practitioners of risk assessment and risk management. Trying to find the few tracks of true terrorists among the infinite number of innocent footfalls in daily life is not unlike the attempt to detect minute quantities of target chemical compounds in a sample of water, air, or soil.

We should stop and consider this lesson from risk assessment: If one enlarges the size of available databases by many orders of magnitude, as the IAO programs promise to do, one inevitably changes the ratio between any specific "datum of interest" and the total data set. In other words, the data indicating true terrorist activity, considered as a percentage of all data, will fall precipitously to vanishingly small dimensions. Since there are error rates in all data detection, this means – inevitably – that the proportion of "false positives" will rise. (In this context, a false positive is an indication of terrorist activity that turns out to be incorrect upon further analysis.) In fact, that proportion will rise until it is perilously close to 100% of the total number of positive results. All false positives which cannot be resolved by purely analytical means will have to be "chased" in the field by agents assigned to the task. The likely consequences of this activity have already been suggested above.

I conclude with a modest proposal: We would all be better off if governments would apply the robust principles of risk assessment and management to the consideration of policy options – in whatever field of policy we are dealing with. In the present case, this would mean applying the following types of tests:

Risk – Risk Tradeoffs:

1) What new risks arise as a result of this particular attempt (i.e., the IAO mission) to respond to terrorism risk?
2) Has a comparative risk assessment been done on each of these dimensions (i.e., the terrorism risk vs. the new risks)? If so what are the results? If not, why not?

Risk – Benefit Tradeoffs:

1) What *actual* level of benefit (i.e., reduction in terrorism risk) can be expected to be delivered by the new surveillance programs?
2) What level of benefit could be delivered by enhancements to the analysis of information delivered by existing surveillance programs?
3) Has a comparative risk-benefit assessment (existing programs vs. new programs) been done? If so, what are the results? If not, why not?

We await the answers.

No. 3: Elementary, My Dear Watson (2003)

With apologies to Sir Arthur Conan Doyle

The Issue.

Our technological capacity to genetically-engineer human and animal traits is developing rapidly. Do we have the institutional capacities in place to manage the associated risks?

A front-page story in *The Globe and Mail* (Toronto) on 26 October 2002 reported a speech in Toronto by the very famous Dr. John D. Watson

(Abraham 2002). He is, of course, the Nobel laureate and co-discoverer – along with Francis Crick, Rosalind Franklin, and Maurice Wilkins – of the "double helix," the shape representing the structure of the DNA molecule. He is also notorious among his colleagues for provocative musings, inciting controversy over his strong advocacy of gene enhancement.

Some of his colleagues, such as the 2000 Nobel laureate Eric Kandel of Columbia University, a neurobiologist, have called Watson a "precocious adolescent" who is eager to make outrageous remarks. Introducing Watson's speech at the First Annual Neurogenomics Symposium in 2001, Kandel also called him "the biological prophet of the future," a characterization I will comment on later. [Gregg 2001; this is the report of a speech by Watson, along with introductory remarks by Eric Kandel, at the First Annual Neurogenomics Symposium, Research Triangle Park, North Carolina in May 2001.] Other colleagues are not so kind. Watson himself remarked, referring to a similar speech he gave at the University of California, Berkeley in November 2000, that an unnamed fellow of the U. S. National Academy of Sciences told him that he "did not have a right to give that speech" and called the speech "stupid."

The Berkeley speech was reported in the *San Francisco Chronicle*; the article's subtitle was: "Geneticist's views strike many as racist, sexist." (Abate 2000). The biology professor who chaired the session and had studied with Watson, along with other senior members of the Berkeley department, criticized his remarks; another department member walked out during the talk. His Toronto speech, given late last year, showed clearly that Watson remains indifferent to the criticism of colleagues in his profession. I offer below a précis of the main points in the *Globe* article, written by Carolyn Abraham:

> James D. Watson, the grand duke of DNA, described one of his greatest fears yesterday to a packed auditorium: that society will be too scared to use genetics to make people as perfect as they can be.

> Dr. Watson is one of the founding fathers of modern genetics. He was in Toronto for the respected Gairdner Foundation awards, which this year honored the scientists who unraveled the human genome. He said the information will allow society to eradicate and prevent not only diseases but any other traits that might be deemed undesirable.
>
> Watson described the genetics revolution as "an absolute flood that will start to explain everything." And not just explain, but create. Some possibilities mentioned by Watson include:
>
> - Turning the shy into extroverts;
> - Turning "cold fish" into "warm human beings";
> - Making genes to help people succeed in specific professions, such as undertaker or sprinter;
> - Adding genes that will "turn slow learners into whiz kids."
>
> Finally, and most important, Watson "is also a proponent of so-called human-germline engineering, in which doctors could add or delete elements from egg and sperm cells that will be passed down to future generations."

It concerns me greatly that at least some of Watson's most senior and distinguished scientific colleagues are willing to indulge him in this display of provocative nonsense. But most of all it concerns me that referring to him in an offhand way as a "biological prophet" suggests that his "vision" will be realized someday, perhaps sooner than we think, given the mad pace of discovery and innovation in genetics. If Watson is indeed a prophet, it's not too soon to begin worrying about what will happen to individuals and societies when these kinds of visions begin to be realized: As they almost certainly will be, if current conditions, laws, and institutional norms persist.

I have given this article the title, "Elementary, my dear Watson," not just to pay tribute to the great author of the Sherlock Holmes stories. More to the point, the title phrase just seemed to be perfectly apt in light of what Watson said during this speech. What occurred to me immediately is: "Fine, geneticists expect to be able to do all of those things in the future, maybe sooner than many people think. What else will we want them to do, too?"

It's elementary: All kinds of people will want to do all kinds of things, and not all of them will be "cute" or "amusing" by any means.

What is "elementary" about this issue is this: Assuming that Watson's list of possible genetic modifications represents only desirable changes (itself a dubious proposition), who's to say that things will stop there? DNA manipulation is fast becoming what I call a "backyard-garage" type of technology. The technical equipment needed to carry out insertions and deletions in the genome resident in a cell nucleus becomes simpler and more accessible by the day. All graduate students in molecular biology at every respectable university around the world are trained to use such equipment and to carry out these procedures. Biology classes at leading high schools already can offer this training as well.

So, just to be equally provocative and to even the score, so to speak, let me juxtapose to Watson's list a few other trait modifications that some people may want to carry out, both in humans and other animals:

- Breeding young males as killing machines who cannot feel remorse;
- Turning normal people into obedient servants with diminished mental capacities;
- Creating young women who will function as docile sex slaves;
- Breeding a sub-class of manual laborers with distinctive physical traits, such as extra limbs or a tail;
- Developing all kinds of modified animals with special traits, including entirely new types ("chimeras") as pets or domestic slaves;
- Monkeying around with the genomes of the great apes to see if we can get them to reason and talk something like us.

Then what?

Some will say, in response to this list: "Don't be ridiculous. Those kinds of things can't be done! You can't make people with tails!" For these

folks, we can now just refer them to the press release dated 5 December 2002 from The Wellcome Trust Sanger Institute (which includes a beautiful graphic), announcing the sequencing of the complete mouse genome. Dr. Jane Rogers, Head of Sequencing at the Institute, is quoted in the press release: "We have deciphered the mouse book of life. We share 99 percent of our genes with mice, and we even have the genes that could make a tail! (Wellcome 2002)." The exclamation mark at the end of the quotation is in the original. If you wish, have a look at the mouse DNA sequence, which is posted on the Internet (*Mus musculus* 2002).

[The statement that "we share 99% of our genes with mice" is potentially misleading, as my colleague Donal Hickey (University of Ottawa) has explained to me. The 99% in this case, according to Hickey, refers to "the fraction of genes that can be assigned a partner in the other genome" (e-mail message, 3 February 2003). The 99% proportion more accurately reflects the similarities of human and chimp genomes: "My understanding," Hickey writes, "is that if we take a random human gene, its sequence will resemble that of the corresponding chimp gene at about 99% of the sites." On the basis of this criterion, the similarity between human and mouse falls to somewhere between 60% and 80% – which is still an interesting degree of similarity, however!]

Indeed, scientists are well on their way to building a complete organism "from scratch," starting with the set of 300 or so genes which are all that is necessary to create a self-perpetuating entity:

> Scientists in the United States plan to build a tiny new germ from scratch, promising it will be harmless to people and could someday be used to produce new forms of energy.
>
> The scientists … want to keep portions of their work secret to prevent terrorists or hostile nations from using the new organism to make biological weapons. If the experiment works, the synthetic germ would begin to reproduce on its own.
>
> A Stanford University bioethicist was quoted as saying that she wasn't too worried by this project "partly because I have

> a sense that the scientists are aware of the possible risks of what they're doing" (Evenson 2002).

I certainly hope so, but I doubt it.

A Modest Proposal.

We need greatly-enhanced resources for facilitating public debate on managing the risks and trade-offs associated with genetic engineering. The main reason is that this technology confronts us with moral and social issues that go far beyond those raised by any other human technology. These issues reach down into the very foundations upon which human civilization is built – such as personal identity and the family, religion, law, morality, and intergenerational responsibility. And as two recent commentators based at the University of Toronto, Peter Singer and Abdallah Daar, said, "We're not yet set up for the debate" (Singer and Daar 2002).

A public debate about such momentous issues must be conducted in different types of forums. Our national academies provide an ideal setting for at least one of them. Active national academies, such as those in the United States, Britain, France, and Canada, are often called upon by their national governments to provide guidance on issues where scientific and technological matters overlap with public policy choices. The academies have the capacity to appoint highly-credible panels of experts who are charged with developing consensus judgments on contentious issues. Their reports can provide one solid basis on which a broader, informed public debate can occur.

Among those whose participation in all forms of debate is essential are the molecular geneticists themselves. So far this has happened far too little. What the public normally gets is a media report of some new scientific discovery or process, such as the ones recounted above, followed by brief quotations from other people identified as "bioethicists," who comment on its possible implications for society. This nicely divides the world into the innovators and the commentators, those who are forging ahead and those who look on, expressing fond hopes that the innovators know what they're

getting us into and that our society will be able to cope with the consequences.

Some time ago one of Canada's best-known science fiction writers, Robert Sawyer, told a journalist that some molecular biologists had stopped talking to the press about cloning and other matters, because they feared the public would become alarmed and perhaps wish to have certain types of research banned (Stonehouse 2000). More recently some scientists working in nanotechnology expressed the same concerns when Michael Crichton's latest thriller, *Prey,* was published. One said: "If enough senators in the U. S. get phone calls from their constituents saying, 'I just read *Prey* and I'm scared,' it could have a real impact on our funding. Nanoscience is just in its infancy. We can't afford to be cut off" (Buck 2002).

Nanoscience is not the only human endeavor still in its infancy. Our ability to have informed public debate on risky technologies in process of development – *prior to their launching into the world* – is even more undeveloped. Such a debate cannot be held if its leading representatives in the scientific community itself, especially in molecular biology, are unwilling to become fully engaged in our social and ethical discussions, with the full support of the funding agencies for their research. Unfortunately, this will come at a price, in this case, less time in the lab. But not doing so will entail other costs that may turn out to be much higher.

Postscript 2009:

In October 2007 Watson, who was then nearing the age of 80, resigned from his long-held position as Director of Cold Spring Harbor Laboratory, a post he had held since 1968, as a result of some comments he made on race and intelligence. (See the Wikipedia entry, "James D. Watson.")

No. 4: Higher Life-forms before the Law (2003)

Issue.

The Supreme Court of Canada's recent decision on patenting of the "Harvard mouse" raises issues that go far beyond the law's simple categories of life-forms.

Background.

The "Harvard mouse" is genetically engineered to be more likely to develop certain forms of cancer than a normal mouse is (thus it is called an "oncomouse"), a trait that is useful in medical research. Harvard University applied for patents on the process of creation, on the specific gene sequence in the mouse, and on the mouse itself. In a 5-4 decision handed down on 5 December 2002, the Supreme Court of Canada ruled that the mouse could not be patented in Canada (Harvard Mouse 2002). In an opinion piece about the Supreme Court's decision, University of Ottawa law professor Daniel Gervais says that Parliament must now act to set out a pathway for the courts in this area: "Parliament must amend the Patent Act to cover all "higher life-forms – except humans" (Gervais 2002). He proposes:

> First, there should be a broad definition of "higher life-form" that would include any animal, but clearly exclude human beings at any stage of development…. Second, … this should be combined with a provision allowing the patent office to deny a patent where its development has caused suffering to animals without substantial medical benefits to humans or animals….

His third point is that regulations should be in place to enforce these provisions.

Professor Gervais's argument seeks to confine the issue of patenting life-forms within the realm of legal technicalities. But the oncomouse raises questions that go far beyond the framework of law. In fact these little mice bring us face-to-face with the troubling interface of religion, science, and human interest. We shouldn't avoid confronting what lies at this interface,

because molecular biology's growing command over the genomes of all living things represents nothing less than humanity's supreme Faustian bargain. And we all know where that can lead. Writing for the majority in this case, Mr. Justice Bastarache said:

> The distinction between lower and higher life forms, although not explicit in the *Patent Act,* is nonetheless defensible on the basis of common sense differences between the two…. If the line between lower and higher life forms is indefensible and arbitrary, so too is the line between human beings and other life forms. It is now accepted in Canada that lower life forms are patentable, but this does not necessarily lead to the conclusion that higher life forms are patentable, at least in part for the reasons that it is easier to conceptualize a lower life form as a "composition of matter" or "manufacture" than it is to conceptualize a higher life form in these terms.

He then gives us the missing definition: "Higher life-forms are generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which they are composed." Unfortunately, this raises more questions than it solves. When we combine the statements quoted above from Mr. Justice Bastarache and Professor Gervais, we get a fairly traditional picture of the hierarchy of Creation: first, bacteria, viruses, protozoa, and plants; second, animals; third, in a special category all by ourselves, humans (human animals?). The entities in the first category are, apparently, all "lower" life-forms. All animals except humans are "higher" life-forms. And humans are – what? "Very much higher" life-forms? "Special" or "unique" life-forms? Or something a bit more traditional: The only life-form that has a "soul"?

The most fascinating aspect of this whole business is that lawyers and the courts have expostulated at length for years about *the patentability of higher life-forms* without bothering to define the key term, "higher life-form." Obviously, the term presupposes a difference between "lower" and "higher," but in reality, as we have already seen, there is a three-part distinction: lower, higher, and "human." Because the essential differences

are nowhere articulated, it is in fact a pseudo-distinction, one without intellectual substance, resting on some mysterious foundation of logic that is never exhumed and subjected to critical analysis.

This curious anomaly persists in the academic commentary as well. There is a superb review paper, "Ethical Issues associated with the Patenting of Higher Life Forms," prepared for Industry Canada in 1997 by a team led (https://www.iatp.org/files/Ethical_Issues_Associated_with_the_Patenting_o.pdf) by Ted Schrecker. The paper includes useful brief discussions in sections 9-11 that are relevant to the three-part distinction above. But nowhere in its almost 100 pages of text is there a simple definition of "higher life-form"! I believe that there is a good reason for this elaborate dance around the matter at hand: What exactly are we talking about here? It's all about human interests, and about preserving our freedom of action with respect to the rest of nature, our entitlement to use everything else in nature, and not to be used in turn. It's about our being "special."

From the standpoint of monotheistic religions, it's clear that humans are "special." *But they are not special from the standpoint of the molecular biology that is busily creating modified life-forms*! The scientific community told us on 5 December 2002, when announcing the sequencing of the complete mouse genome, that we humans share 99 percent of our genes with mice, although mice have 400 million fewer nucleotide base-pairs than we do (see endnotes 13 and 14). So is it "our" position that the residual difference in the gene complement – even if we don't know what the residue is, exactly –, or the fact that we have more nucleotides in our DNA sequence (although we don't yet know what those extra stretches of DNA actually do for us, if anything – they could be just so-called "junk DNA"), that makes us "special" by comparison with the mouse?

When we examine Mr. Justice Bastarache's statement a bit more closely, we realize that we should pause a bit before we rush to codify its logic into settled jurisprudence. He wants to define higher life-forms as

things which possess "qualities and characteristics that transcend the particular genetic material of which they are composed." Doesn't that concept cover also the exceptional beauty of the orchid's flower? Or the majesty of an 800-year-old Sitka Spruce tree? Of course it does, in my opinion. But why stop there? From the standpoint of evolutionary success, wouldn't this definition also encompass a quality such as the extraordinarily rapid mutability we associate with the AIDS retrovirus, which so far has defeated all that human ingenuity can throw at it?

So this definition won't work, at least, not for its intended purpose, I'm afraid. But there's a bigger problem here: The court appears to want to include *all* non-human animals (presumably including our cousins, the great apes) in this category – but we aren't given the slightest clue as to why humans shouldn't be included in it as well! [The short answer is that it is all a matter of property rights. See the statement made by Binnie J., for the minority in section 54: "It has been established for over 200 years that people cannot, at common law, own people: *Somerset v. Stewart* (1772), Lofft 10, 98 E.R. 499 (K.B.). The issue of whether a human being is a 'composition of matter' does not, therefore, arise under the *Patent Act*. If further reinforcement is required, ss.7 and 15 of the *Canadian Charter of Rights and Freedoms* would clearly prohibit an individual from being reduced to a chattel of another individual."]

The "special" place of humans in Creation is a proposition of monotheistic religions. But it is most certainly not a proposition of molecular biology. What the book of DNA tells us is that we're composed of the same stuff as every other life-form is – amino acids and proteins that derive from a code that is written in just four "letters" (the letters are chemicals). It's the same type of code for the orchid, the spruce, the mouse, and humans – as well as slugs, worms, rats, bacteria, fish, sloths, and chimps.

There is no place in the book of DNA for such brittle categories as "higher" and "lower" life-forms. This is a metaphysical or religious

distinction, not a scientific one. We impose this distinction on other creatures because we have the power to do so for now. When we erect legal structures that place humans in a special category, we're doing this because we *believe* that we're "special" in a way that no other creature is, and we believe this because our religions tell us so. Our science is completely indifferent to this pseudo-distinction.

And our science soon may give us innovations that explode such neat little distinctions and render them meaningless. Late in 2002 a front-page article in *The Globe and Mail* told the story of Canadian scientists who were invited to a meeting at New York's Rockefeller University. Their U.S. colleagues wanted to get their reactions to a scientific protocol that would inject stem cells from a human embryo into a mouse embryo, thus creating what's called a "chimera" – an animal entity combined of two separate sets of DNA. The Canadian researchers were rather horrified. One of them, Janet Rossant, said: "Do you generate a human brain in a mouse … Where do you draw the line?" Alan Bernstein, president of the Canadian Institutes of Health Research, added: "We don't even really know what happens when you mix two different species like this. Are you now going to have a mouse walking around with human sperm – what would the public reaction be to that?" (Abraham 2002b).

Well, yes, one supposes we might. That would pose an interesting dilemma for Mr. Justice Bastarache and Professor Gervais, wouldn't it? How would they classify such an entity in their neat scheme of life-forms? My point is a rather simple one. If we are going to ask Parliament to revise the Patent Act to permit the patenting of "higher life-forms," let's not confine our debates to technical jargon alone. The science of molecular biology, and the language of DNA, has opened up a fundamental chasm in our society. We now face a divide between traditional norms of religious-based ethics, and the story of divine creation, on the one hand, and the new reality, which tells that humans are simply the result of another random mutation in the four-

billion-year-old saga of DNA, on the other. To be blunt, from this perspective, we're not special at all, so let's stop kidding ourselves.

The innovation promoters tell us that a Paradise of health benefits awaits us in the new reality of DNA. We will have gene enhancement, gene therapy, genetic screening, designer babies, targeted pharmaceuticals, and so much more. In other words, we will have the power in our hands to redo the work of Creation. Are we ready for it?

A Hypothesis.

Our rapidly-developing capacity to engineer the genomes of all living things, including our own, explodes the categories of law, religion, and ethics with which humans have operated in civilization up to now. We cannot respond by seeking to contain this new reality in old and brittle categories of thought and logic.

A fundamental principle in the premises of risk management is that the scope or scale of benefits is commensurable with the risks taken to procure them. As indicated just above, we seek in gene manipulation a scale of health and other benefits undreamed-of in earlier times. But an iron law of commensurability compels us to recognize that the risks of harm and misadventure rise proportionately. As our collective capacity to "do good" through technological innovation grows exponentially, so too does the capacity for evil applications of those very same instruments. But the impact of molecular genetics is unique in this regard, because it goes beyond the realm of the purely technological and threatens to sap the foundations of our ethical and legal systems.

This is what I mean by the question, Are we ready for it? Are the processes of debate and deliberation we have at our disposal, as well as our capacities for policy development and legal innovation, up to the task of managing such risks?

In Kafka's *The Trial,* a priest relates a parable, "Before the Law," to K (Kafka 2009): A man waits for years outside the doorway of the law courts, requesting admittance, until he is near death and gives up. At that point an official tells him: "No one else could ever be admitted here, since this gate was made only for you. I am now going to shut it." There are some questions which the law cannot answer all by itself. How do we propose to answer them?

No. 5: The Risks of Policy Choices: The War in Iraq and the Doctrine of Preemption (2003)

Published in *Policy Options*, vol. 24, no. 05 (May 2003), pp. 41-44

For thirty years the people of Iraq suffered under one of the most brutal and criminal dictatorships on the planet. The crimes to which they were subjected include the following, all on a massive scale over long periods of time: arbitrary arrest, detention, and incarceration without trial, including children and infants; "disappearances" without trace; torture, murder, brutality, and bestiality; theft and confiscation of property; crimes against humanity; production, stockpiling, and use of chemical and biological warfare agents; persecution of minorities; deprivation of the means of livelihood; invasion of privacy; cultural persecution (religion, language, intellectual life). The fact that Iraqis are the process of being liberated from the long nightmare of this oppression and horror is an unambiguous good.

Those soldiers who have died or were injured in this process are honorable warriors, no matter what other agendas they may have been serving. They and their comrades also risked their lives in the service of the policy of minimizing civilian casualties, perhaps the first time in human history where a powerful nation going to war has adopted such a policy. Their medical teams have treated the enemy's wounded. They have done

what they could to deliver humanitarian assistance to the population even while combat still raged. All these things too are unambiguous goods.

Now, here is a partial list of other countries and regimes in the world that have practiced, condoned, sponsored, or facilitated some important subset of those same crimes within living memory, arranged alphabetically:

Argentina	Libya
Belarus	North Korea
Burma	Pakistan
Chile	Russia
China	Saudi Arabia
Columbia	Somalia
Congo	South Africa
Guatemala	Syria
India	Turkey
Indonesia	Ukraine
Kazakhstan	Zimbabwe

I have deliberately excluded Israel, which differs from the above-named in being a nation surrounded by oppositional forces, some of whom deny its very right to exist, although this provides at best a severely limited defense for certain types of actions, and no defense at all for some others. [The 2009 attack on Gaza has raised serious issues about civilian casualties and the use of white phosphorous (Bronner 2009, Human Rights Watch 2009).] Can anyone doubt that many of the citizens of the listed countries devoutly and fervently have prayed for "regime change" – a prayer that for the most part went unanswered? No "coalition of the willing" was ever formed, to my knowledge, with the purpose of terminating the horrors and oppression rampant at times in these and other countries. What is it about Iraq that is so different?

Certainly, the answer cannot be, "its possession of weapons of mass destruction (WMD)," or even the regime's unconscionable use of them against the Kurdish people at Halabja. So far as "possession" is concerned, a goodly number of the nations on my list, and a fair number of others not listed, fall into this category. (I am assuming that WMD refer to those

biological, chemical, and nuclear devices which are capable of inflicting massive numbers of casualties and damage in a single attack, and where in some cases the effects would persist.)

So far as "use" is concerned, this is more ambiguous, because most of the foulest crimes itemized earlier do not require them as instruments, and so the case for "regime change" is independent of this factor. In fact, the total number of cases where such weapons in the strict sense have been used, say during the last fifty years, is quite small. Perhaps the most extensive use of such weapons in this period was by the United States, against the Vietnamese and Cambodian peoples, in the period 1963-1973. The instruments used extensively included high-explosive bombs ("carpet-bombing"), napalm, and, of course, chemical weapons (defoliants) with known human health risks, all of which were deployed indiscriminately against noncombatants as well as combatants. The perpetrators of these crimes against humanity were never arraigned.

When I consider the question of Canada's role I cannot overlook – for biographical reasons – the comparison between today's events and those of the decade during which the United States, the country of my birth, committed atrocious crimes against humanity in waging war against the Vietnamese. I immigrated to Canada in 1968, after a period of years spent on a campus of the University of California where antiwar activities competed equally with the demands of degree completion. I had never before set foot in Canada and was astonished at what I encountered, both at the level of federal government policies and among the attitudes of most citizens here.

Not only was Canadian policy set firmly against that of the United States, not only did Canada welcome the legions of draft resisters who flowed north across its borders, all of whom were violating U. S. laws, but Canada even turned a blind eye when large numbers of deserters from the U. S. armed forces followed in their train! The latter situation is almost without

precedent in the relations among Western nations in the modern world. After those who wished to stay (following the amnesty) had put in their five years of waiting time, they were awarded Canadian citizenship.

What is so different about the times in which we Canadians now live? How is it possible that the federal Official Opposition, as well as many citizens, could portray Canada's decision to opt out of the coalition of the willing – ambiguously, as always with the current government – as some kind of betrayal of principle? Which of the two nations, Canada and the USA, had chosen the honorable course in 1939 and gone to war against the evils of Nazism, and a formidable military machine possessing weapons of mass destruction, even though it had not been attacked? Which has the right to assume the stance of "holier than thou"?

Is it the new reality of terrorism risk that makes the difference? Here too the ambiguities and ironies are plentiful. Although the Bush regime has labored mightily to connect its Iraq policy with the war on terrorism, this is perhaps the most implausible and even farcical aspect of its entire rationale. In saying this I do not for a moment discount either the reality of terrorism risk or the need to confront it resolutely. The September 11 attacks were *casus belli* for the United States and its allies, who reacted instantly and unanimously by invoking (for the first time ever) the collective self-defense provisions in the NATO alliance. The Taliban regime in Afghanistan was at that time self-evidently the protector and enabler of the international criminal conspiracy founded by Osama bin Laden, for whom the lives of innocent civilians are pawns of no value whatsoever in the game of unconventional warfare. The quick demise of that rogue regime, as well as the subsequent crippling of al Qaeda's international network by dedicated police work in many countries, were unambiguous goods.

Yet the awkward truth is that Saddam's regime – included on bin Laden's own long list of rogue states run by "infidels" – was perhaps the last place in the world that al Qaeda's terrorist entrepreneurs would have been

allowed to operate freely. Britain's Prime Minister appears to have been the only person in the world outside Washington, D.C. who professed to believe that the link between Saddam and bin Laden had been proved. For most of the rest of us, the implausibility of this case was matched only by that of the American "evidence" about Iraq's WMD facilities, presented by the U. S. Secretary of State at the UN Security Council.

The lasting effect of the September 11 terrorist assaults on American policy is to be found elsewhere, namely, in the foundations of the policy of preemption. There is currently a lively discussion in the United States around the old doctrine of "just war," originated by Thomas Aquinas and developed by the 17th-century jurists Grotius and Pufendorf. This doctrine includes prescriptions on how war may rightly be fought (and is thus the ultimate source of the Geneva Convention) and when one has the right to initiate war (*jus ad bellum*). The latter includes two-types of actions in self-defense, namely, responding to an actual attack and preemption of one that is anticipated. An example of a justified preemptive attack would be if the Soviet Union had struck first against Germany in June of 1941, before the Nazis had launched against it the massive military formations that had been assembled on its frontiers.

A policy of preemption is at the heart of the Bush administration's rationale for waging war on Iraq. However, only by the most tortuous exercise of logic could this be considered as an application of the ancient doctrine of *jus ad bellum.* It is rather a reckless new version of the gunboat diplomacy – although the preferred circumlocution at present is "muscular diplomacy" – which the United States has practiced for well over a century in Central and South America and now seeks to extend to the entire world.

The current U. S. doctrine on the right of preemptive war was unveiled by President Bush in a speech on June 1, 2002 and was later incorporated into the "National Security Strategy" (NSS 2002). The claim is that the older right of preemptive action must be adapted to the new reality

of "rogue states and terrorists," as follows: "The greater the threat, the greater is the risk of inaction – and the more compelling the case for taking anticipatory action to defend ourselves, even if uncertainty remains as to the time and place of the enemy's attack. To forestall or prevent such hostile acts by our adversaries, the United States will, if necessary, act preemptively … [but] will not use force in all cases to preempt emerging threats, nor should nations use preemption as a pretext for aggression."

Thanks to good investigative reporting by Seymour M. Hersh in *The New Yorker* and Steven R. Weisman in *The New York Times,* we know where and when the current doctrine actually originated – namely, in 1998 among the ranks of a conservative cabal known as the "Project for the New American Century." Among the key players are some now-familiar faces – Donald Rumsfeld, Paul Wolfowitz, and Richard Perle. These three are also among the signatories to an open letter addressed to President Clinton and dated 26 January 1998, which stated that "removing Saddam Hussein and his regime from power" should become "the aim of American foreign policy." The date on this letter, of course, predates September 11, 2001 by almost four years.

It is virtually self-evident that the Bush Doctrine, and its application to Iraq, is a policy choice that entails great risks for the entire world as well as for the United States itself. This is because there is neither an inherent limit nor an inherent rationale in its potential range of application. Bush's June 2002 speech explicitly recognized the limitation that had been built into the earlier concept of *jus ad bellum*: "Legal scholars and international jurists often conditioned the legitimacy of preemption on the existence of an imminent threat – most often a visible mobilization of armies, navies, and air forces preparing for war." The existence of "rogue states and terrorists," it is then argued, means that this "condition" must be repealed. But no other limitation is imposed in its place.

The key phrase is "imminent threat." True, the al Qaeda operatives have no standing armies no mobilize. But there were not only clear threats of imminent actions in the run-up to September 11, there were actions as such – the planning for simultaneous attacks on airliners in the Philippines, the bombing of the World Trade Center (1993) and the Khobar Towers in Saudi Arabia (1996), the horrific blasts at the U. S. embassies in Nairobi and Dar es Salaam (1998), and the attack on the *U.S.S. Cole* in Yemen (2000). At least the last three were definitively linked to al Qaeda. Why would anyone think that bin Laden had called off his jihad after the last one, since all of his utterances delivered exactly the opposite message?

Thus, preemptive action designed to forestall the next strike from al-Qaeda would have been clearly justified by the traditional *jus ad bellum* at any time after 1996. But nothing in those events justified, at any time, action against Iraq. The confusions about the new doctrine's range of application began in the famous and utterly illogical "axis of evil" characterization. "Axis" means in this context an agreement among countries united in a common purpose. At no time in human history have Iraq, North Korea, and Iran ever formed an axis of any sort. The real message in this pronouncement is that the U. S. reserves the right to label unilaterally any nation in the world as a "rogue state." Or not to label them as such, at its sole discretion.

The bottom line for the Bush Doctrine is this: Any nation considered by the United States to be a "rogue state" is at risk of having preemptive action taken against it. The importance of this message has not been missed by some of those so labeled, such as North Korea, which replied, in effect, "what's sauce for the goose is sauce for the gander." And then we were told that North Korea's nuclear-tipped missiles have a range sufficient to reach the west coast of North America.

Little time need be wasted on observing that no country has the right to decide which of its contemporaries is in dire need of regime change

directed from abroad – a Hobbesian world-order if there ever was one. The Bush Doctrine of preemption destroys the meaning of the ancient *jus ad bellum* when it detaches the concept of imminent threat from its essential limitation (location in a *particular* source) and gives it an open-ended and arbitrary application. The Canadian government was clearly justified in announcing its explicit opposition to the former (regime change) and its implicit opposition to the latter (unrestricted preemption). The reason is straightforward, namely, that both expose the world of nations to anarchy and incalculable risk.

No. 6: Mr. Gibson's Mistake – and the Middle East War (2006)

Priests often say that God works in mysterious ways. Was it just a coincidence that the creator of that ardent profession of faith, *The Passion of the Christ,* delivered himself of a vicious anti-Semitic rant just as the Middle East was erupting in a new spasm of violence? [See the Wikipedia entry, "Mel Gibson DUI incident."] Or was Mr. Gibson's drunken tirade in Malibu sent to us as a sign from above, suggesting that we consider more carefully what is happening in the region justly known as the cradle of religion?

The world is full of nations and parts of nations that were stolen from somebody else at some time or another (North Americans especially should appreciate this fact). So what is it about the state of Israel, then, that seems to provoke a persistent and especially inflammatory response to its very existence? The U. S. Secretary of State delays the drafting of a cease-fire agreement because she wants a "sustainable" solution, which seems reasonable. But is there any chance at all that we are likely to see such a thing?

I fear not, because the community of nations is faced not with a political problem, which is hard enough to fix at the best of times, but an essentially different type of dilemma, one that is rooted in endemic religious intolerance. Once such a disorder has become endemic, as it has, it cannot be cured by purely political initiatives, such as introducing new armies and buffer zones. It *might* have been suppressed if Israel's strongest ally, the United States, had insisted, decades ago, that a fair two-state solution, as well as adequate compensation for the Palestinian refugees displaced at Israel's founding, must be achieved as the price of its continued support.

But it's too late for that type of "rational" solution now, for a simple reason: As of now, there are too many other actors in the region who have a real and immediate interest in making sure that no such political solution is ever achieved. Rather, their political interests are now served by fueling a religiously-inspired intolerance until it reaches its own sustainable level – a level of permanent, murderous frenzy.

This is the new reality of the Middle East: Israel is the indispensable symbol for the maintenance of an unlimited, fratricidal conflict for which there is no end in sight. We need to remember that, although the Holocaust was the product of a modern secular state, the idea of holocaust – the extermination of a faith-based collectivity, down to the last remnant of its being – is originally a program of competing religious faiths. And the Middle East is where it all started.

There are no innocents in this present horror. This includes the U. S. evangelical Christians who tour the Holy Land looking for signs of the impending apocalypse Weber 2004). And Shia and Sunni Muslims, who pause in the act of regularly slaughtering each other, in countries such as Pakistan and the newly-liberated Iraq, to pray for the extinction of their common enemy, the Jew; and even at least some of the conservative Jewish sects in Israel, who regard Muslims as *Untermenschen.*

It would be unwise to expect very much good to emerge from the negotiations that will seek a short-term political solution. The prognosis is grim: Even some Israeli military analysts have concluded that their country was sucker-punched by Hezbollah. What Hezbollah feared was that the movement toward a secular democracy in Lebanon would pick up steam; their attack, and Israel's careless response, has finished off that option for the foreseeable future. Whatever else happens, Hezbollah will emerge from this present crisis stronger than ever in terms of popular support, in excellent shape for preparing the next round.

What else is to be done? I suggest that it is time for leaders of all the major sects among the Western religions, Christian, Muslim, and Jewish, to recognize their own responsibilities in the matter. These leaders should convene in a neutral location somewhere in the Middle East (if one can be found!), and begin their own negotiations, pledging not to suspend them until a mode of religious reconciliation has been found. Then they need to persuade their flocks to follow them rather than the prophets of hatred.

The alternative is grim. The bombs now being exchanged across the Lebanese border contain high explosives. But remember, this is not a political conflict where compromise is inevitable; it is one which has the thrill of "final solution" as its underlying motivation. Shall we wait until the high explosives have been replaced with nuclear materials or engineered biological pathogens?

No. 7: Applying Net Present Value Calculations to Long-range Political Promises (2008)

Faced with severe credibility problems on pledges to "take action" on climate change, many national governments—including Canada's—have adopted a new strategy. The new approach is elegant in terms of simplicity:

Push your actual policy deliverables so far into the future that you are virtually assured of being either dead or deranged by the time the policy becomes due and payable.

In one sense, this is an elementary application of the well-established NIMTOF principle, "not in my term of office." But as the time gap between present promises and future deliverables widens, this maneuver threatens to migrate from NIMTOF to "not in my lifetime." So it is with the current round of promises to reduce GHGs. In April 2007, Canada's Environment Minister John Baird promised to reduce Canada's GHG emissions to 20% below the 2006 level by 2020, and to 60-70% below the 2006 level by 2050. My modest proposal is that we should apply the standard economic calculation of the present value of future goods to political promises of this sort. If we did so, what would the result be?

The supposed 2020 target still would leave Canada a bit above its 1990 emissions level, but at least close to its Kyoto commitment. This is awkward, because the Kyoto-level commitments are only a down payment toward the only meaningful objective in climate action, namely, stopping the rise in global GHG emissions and then bringing emissions down to some fraction of its former level.

Let's ignore the 2020 target, then, as being irrelevant to climate action, and focus on the 2050 one. What is the present value (in 2008) of this political promise? If we assume that promise for 2050 has a nominal value of $100 in that year, and that the discount rate is 4%, its value in 2008 dollars is: $2.29. Actually, that seems high. Therefore, I offer to all takers a bet of 10¢ (Canadian), monies to be held in trust and earning interest until 2050 and payable to named beneficiaries, that Canada will not even approach the lower range of its 2050 target in that year.

No. 8: Comprehensive Risk Assessment for Federal Departments:

Design for a Risk Forecasting Exercise (2000)

The basic idea is that an appropriate central agency might exercise some form of oversight on the disparate risk management responsibilities of departments using the "reinsurance" model. The reinsurance industry is the insurer of last resort, backstopping the coverage of primary insurers when the policy limits have been exhausted but residual liabilities remain. Risks are pooled over larger domains and the premiums reflect a variety of factors, including how well the primary insurers have estimated their exposures to loss in the past.

On this model, a central agency (probably Treasury Board: TB) would provide "coverage" for departments from government-wide financial resources, above and beyond departmental budgets, for "catastrophic" losses in their areas of responsibility, or even just for unusual items, as specified in the coverage, that arose from time to time. TB would write this coverage on the basis of audits of their risk forecasting and risk management decision-making [RF-RM] processes. This coverage could be either optional or mandatory for departments. If one wanted to follow this analogy to the limit, departments could be charged an annual dollar premium, based on the level of coverage chosen. Following is a sketch of how this might work. [Thinking outside the box, one could try to come up with an analogy to "catastrophe bonds," which the private sector is now trading as a way of spreading insurance risk for very expensive catastrophic risks, such as earthquakes and hurricanes (Lewis 2007).]

First, a TB template for RF-RM "best practices" would be developed. Then a department would prepare its RM plan for, say, a 3-year cycle. TB would appoint an audit team consisting of its own personnel, people drawn

from other Canadian agencies, some drawn from similar agencies abroad, and some outsiders (consultants, academics). On the basis of the audit results, TB would offer both a premium level and a spectrum of coverage for "specified perils."

This is an artifice, to be sure, because government as a whole will always cover all of its bills in the end. Notwithstanding this caveat, there may be two distinct advantages to this device. First, for individual ministers, the external audit of a department's risk forecasting should both (1) lower the rate of occurrence of unexpected disasters in that portfolio and (2) lessen the "political damage" that does occur from truly unforeseeable events, since the insurance scheme would be a recognized instrument to deal with such. Second, and more important, there should be a real advantage to government as a whole, in that the multiple audits would steer departments towards more realistic risk forecasting, and so the political risk from both simple managerial blunders and major unforeseeable events also would be reduced.

What kinds of responsibilities – which may be insurable -- are being referred to? The best examples are always in the field of health risk management (prescription drugs, blood and organ tissue, radiation, medical devices, and many others), within Health Canada's mandate. Here I should mention that the present and enormous future applications of genetic engineering technologies for medical applications, due to their relatively recent development, present a new and unknown level of risk for the health risk managers. Environmental risk provides another set, especially if weather forecasting is included; but other Environment Canada responsibilities, including the approval of genetic engineering applications for bioremediation, should be mentioned.

Food risk is a very high-profile area in which both the Canadian Food Inspection Agency (CFIA) and Agriculture Canada have wide-ranging responsibilities, and where adverse health effects from foodborne pathogens

are weekly occurrences. Transportation risks are another. As in the case of CFIA, much of the regulatory apparatus in this area is being transferred to crown agencies, which means that those agencies definitely should be required to be a part of this insurance scheme (in the case of crown agencies, it would be advisable for this coverage to be mandatory).

What are others? Regulation of financial institutions (consider the banks' possible exposure to the collapse of Long-Term Capital Management, or the bank failures of the 1980s, and money-laundering today)? [See the Wikipedia entry on "Long Term Capital Management."] Customs and excise (smuggling of people and goods)? Parks Canada (visitor injuries and deaths)? Tax expenditure programs (think of Revenue Canada's notorious SRTC scandal of the early 1980s: Leiss 1988)? [The failed innovation program was replaced in the late 1980s by a more successful one, known as the Scientific Research and Experimental Development (SRED) tax credit: http://www.cra-arc.gc.ca/txcrdt/sred-rsde/menu-eng.html.] Fisheries?! (If a rigorous audit had turned up the existence of the abundant early warning signals of troubles – contained in scientific reports of the late 1980s – in the management of both the East Coast stocks of cod, and the West Coast stocks of salmon, and had resulted in different policy outcomes, think of the cost savings and other benefits that might have been reaped!) There are perhaps few government departments that have no responsibilities that could be subsumed under this scheme.

The political advantage of this scheme is that, even if the coverage is made mandatory, the minister's independence and sway over the management of her or his own department is not compromised. The presentation of the RF-RM scenarios is entirely in the department's own hands, and local control is maintained by the discretionary authority to decide on the level of coverage to be obtained.

In conclusion, rigorous risk forecasting exercises should be mandatory for federal departments and agencies, but they should be done

within the larger context outlined above. Such a larger context would make a risk forecasting exercise truly meaningful, because it would have real consequences for departmental issue management; as a stand-alone exercise it could be a purely intellectual construction which would have no real impact on "business as usual." Indeed, this has been the fate of a few priority-setting exercises to date.

One can always get cheap coverage, in business as in this version, by concealing managerial weakness and the exposures of the entity to risk. However, insurers have well-crafted ways of protecting themselves from such maneuvers.

No. 9: What went wrong in the BSE file? (2005)

Published in the *Edmonton Journal,* March 10, 2005

The informative article by David Staples, "The BSE saga: a long and maddening road" (*Edmonton Journal*, March 6), ends with these remarks from the Canadian Food Inspection Agency's [CFIA] chief vet, Brian Evans: "That, I think, is the ongoing legacy of BSE. In the same way that people have been critical that the government didn't do enough in some people's minds in 1990 and 1993 to prevent BSE from getting into the cattle population, my view is that people will look back in 2020 and say, 'What was the government thinking when it spent all that money on this particular disease?'"

No, Mr. Evans: In my opinion, that is not what we will be asking ourselves in 2010, 2020, and beyond. To say that this is the key question, in a long-term view, to emerge from Canada's BSE crisis is to do a serious disservice to the beef farmers whose lives and livelihoods have been ruined by it. The key question is: Why did Canada's risk manager (CFIA) not do a

proper risk assessment, right after 1997, so that it could communicate the true – catastrophic – risk of impending calamity to Canadian beef farmers? And why do both the Federal and Alberta governments continue to insist that the only solution going forward is to re-establish the practice of shipping millions of live animals per year across the fickle U. S. border?

Here is my bill of indictment. All of the evidence to support the propositions in what follows is in the public domain:

Why was no proper risk assessment of BSE for Canada, using a recognized international standard, ever performed by CFIA, to this day? A standard risk assessment uses the formula R = P x C, where R is risk, P is probability (or expected frequency), and C is consequences or impact. CFIA's so-called risk assessment, dated December 2002, is actually a frequency estimation only, since consequences were not estimated. It was not the expected frequency (7 chances in a thousand, according to CFIA) that was important: It was the consequences of finding even just one case in our herd, at the time when Canada, like other beef-exporting nations, had a policy of "one case and you're out of the beef export business – for seven years."

Why did the CFIA do a quantitative frequency estimation in 2002 only for the period before 1997? Who would care in 2002 what the risk was before 1997? Why not do a quantitative estimation for the really important period, that is, after 1997? And, if CFIA did not have the resources on hand to do so, why didn't it follow the US lead and ask for outside help (the USDA asked the Harvard Centre for Risk Analysis for this type of help in 1998)?

Why did CFIA refuse to collaborate with Health Canada in 2000 and thereafter to complete HC's draft and unpublished risk assessment for BSE in Canada? The never-completed HC study is the only federal document on BSE ever produced which includes a rigorous exposure pathway analysis; certainly, there is no evidence that CFIA itself ever published such an analysis.

Why did CFIA take so long (1994 to early 2003) to produce any risk estimation at all, even a seriously flawed one? During all this time, Canada's beef farmers were building up their export herds. During all this time, they were at catastrophic risk, as we discovered in May 2003. All the evidence needed by CFIA to tell farmers that they were at catastrophic risk was available by 1994 (although the evidence had not been analyzed, of course).

Instead, both Canada's beef farmers and the rest of the world were told something else entirely, as David Staples shows in quoting the 2001 remarks by CFIA's Claude Lavigne: "We are completely free [of BSE]. The risk of transmission in a country where the disease doesn't exist is zero. And that's our situation."

My bill of indictment concludes as follows: Certainly CFIA did not know that such a statement was false at the time when it was made, because the risk estimation had not been completed. But this also means that there could be no justification for Mr. Lavigne's remarks; his statement was irresponsible in the extreme, because it gave Canada's beef farmers a false reassurance which contributed to their ultimate ruin.

What if CFIA had figured out the truth, and then told the truth in clear language? What if the agency, having done what was needed, namely, a post-1997 risk estimation – in, say, 1999 – had then told Canadian beef farmers: "You are at risk of catastrophic economic failure. You should reduce your herds and exports starting immediately, until we have evaluated the risk again at a later time." How would the cattlemen's association and the Alberta government have reacted? Would they have said, "Yes, we agree with this wise advice, and we will work with beef farmers to get this done." Or would they have said: "CFIA is only guessing. We don't have any BSE in Canada. This is a piece of foolish federal meddling in an important provincial industry."

Take your pick. The problem is, risk assessments come with uncertainties, because that's the nature of risk: You can tell your kids not to drink and drive, but you can't prove to them in advance that if they do, they'll wind up dead or injured. But if we're smart, we will try to figure out what disasters might lie ahead, and take the prudent steps needed to reduce the impact they might have on us, if we cannot prevent them from happening altogether.

The economic losses from BSE in Canada exceed $5billion to date (and may be as high as $7-$8b already), and they will continue to increase now that the US has once again "delayed" the opening of its borders. The personal and family costs to Canada's beef farmers are incalculable. We must not allow this to happen again. All of us in Canada need answers to the questions posed above.

No. 10: A Risk Assessment Protocol for analyzing Risk-Based Policy Initiatives

A. Purpose.

This Protocol is designed to assist decision-makers who are (1) faced with choices among policy initiatives and (2) need to assess the various dimensions of risks associated with those choices. The Protocol specifies a step-by-step procedure for carrying out such an assessment.

B. Terminology.

Risk is the chance that an adverse occurrence of some magnitude will occur – in this context, as a direct or indirect result of a policy choice.

Intrinsic risks are those risks which are implicit in the policy choice itself and are a direct result of that choice.

Extrinsic risks are those risks which arise from the reactions of other parties to the policy choice and are an indirect result of that choice.

Political risks are those risks which arise from the fact that public policy choices are ultimately the result of a political process and are the responsibility of the government in power.

Risk Assessment is a procedure for estimating a specific set of risks in the context of other relevant information, such as benefits resulting from the policy choice, other related policies or procedures, established legal and regulatory frameworks, related developments in other jurisdictions, the "political climate," and so forth.

Risk Estimation is a formal procedure using the formula R = P x C (risk equals probability times consequences): See Appendix.

Risk Factors are the specific cause-effect relationships which give rise to the possibility that adverse consequences will occur.

Risk Ranking is a procedure that takes both probability (likelihood) and consequences into consideration in order to classify risks into various categories – for example, acceptable or unacceptable risks. (See Appendix.)

Risk Transfer occurs when, as a result of a policy choice, some element of risk is transferred from one party (e.g., the population as a whole) to another (e.g., a particular neighborhood or community – for example, as a result of siting a hazardous waste facility. (Also *excess risk,* because the affected community now bears a risk greater than that of the general population.)

Benefits arising to specific parties or constituencies as a result of the policy choices may be either monetary or non-monetary in nature. *Nota bene*: There will be great interest in whether any new risks and new benefits are

"matched," namely, that new benefits flow to the same parties which are asked to assume new risks.

Incremental Costs / Cost Savings: Identifications of the incremental costs of the policy initiative itself as well as the cost savings to be realized, if any.

Risk/Benefit Trade-off is the net result of a policy choice for a particular constituency – for example, where an economic and social benefits package is offered to a community in compensation for assuming the excess risk involved in hosting a hazardous waste facility, and where, it is argued, the benefits "outweigh" the excess risks according to some form of measurement.

Risk Control (or Risk Mitigation) refers to the adoption of specific strategies that reduce risk levels. (Purchasing insurance is a familiar form of risk control.)

C. Step-by-Step Procedure.

(1) Identify the policy choice (or set of choices) under consideration.
(2) Specify *all* of the relevant risks and risk factors associated with the choice(s) – including intrinsic risks, extrinsic risks, and political risks – as well as the parties who are expected to bear those risks.
(3) Identify any risk transfers – specifically, where risks formerly borne by one party or constituency are proposed to be transferred to another as a result of a policy choice.
(4) List the benefits arising from the policy choices and the parties who are expected to reap those benefits; list the incremental costs and cost savings.
(5) For all risks, do a qualitative estimation of (a) probability or likelihood, and (b) impact or consequences. Use this scale for likelihood: **Moderate–Low–Very Low–Minimal–Negligible**. Use this scale for consequences: **Catastrophic–High– Medium–Low**. (See Appendix.)

(6) For all the qualitative judgments made in #5, assign a *degree of confidence* in the information base upon which the judgment is made (H – M – L).

(7) Define a risk acceptability threshold for this policy area, using the Risk Rating matrix illustrated in the Appendix.

(8) Screen out all unacceptable risks. (These are the risks for which no amount of benefits would constitute an acceptable trade-off.) Remove for consideration any policy choices which give rise to unacceptable risks. [Policy choices giving rise to unacceptable risks may be brought back to the table *if* risk control or risk mitigation strategies can be specified which, when applied, reduce the risks sufficiently so as to rate them as acceptable.]

(9) For all acceptable risks, match risks and benefits and assess the resulting trade-offs qualitatively (and quantitatively, if desired and possible with the information base).

Finally, implement a data tracking and analysis program for the policy initiatives, so that the outcomes may be assessed against expected results on a regular basis, and also may be applied to improving future use of the Protocol exercise.

Guidelines for the Concluding Section
(Risk/Benefit/Cost "roll-up")

Use a narrative format to summarize the results of the three risk assessment modules (risks, non-monetary benefits, and incremental costs/cost savings). Non-monetary benefits are, for example, quality-of-life improvements to families or communities. Identify any trade-offs and/or risk transfers that will be made. In general, a policy initiative should be able to demonstrate clearly the net benefits to be achieved. However, the net benefits should be examined closely with the following guidelines in mind:

For policy initiatives in sensitive areas (such as the criminal justice system), there should be a set of non-monetary net benefits, rather than cost savings only, which can be clearly identified. In terms of trade-offs and risk transfers, no identifiable segment of the population (such as a community) should be made worse-off as a result of a policy initiative: The analysis should be able to show that there is a negligible chance that there will be any incremental risks of the high-consequence kind (e.g., violent sex offenses) – as a result of more widespread use of screening instruments, for example.

Appendix: Risk Estimation Procedure

The standard formula for risk estimation is R = P x C (risk = probability times consequences). Each of these two sides of risk must be evaluated separately, and then combined. Also, either side may be expressed in either quantitative or qualitative terms, or both. The combined results are normally placed into a risk rating scheme, as illustrated below. The quantitative expression of frequency is, for example, given in the expression "7×10^{-3}" (about 7 chances in a thousand); then it can be turned into some kind of qualitative measure. In 1996 the chief medical officer of health in Great Britain, Sir Kenneth Calman, proposed a five-point risk classification scheme that received much attention:

Moderate risk = less than 1:100 but greater than 1:1,000, e.g., smoking 10 cigarettes a day, parachuting

Low risk = less than 1:1,000 but greater than 1:10,000, e.g., influenza, road accident

Very Low risk = less than 1:10,000 but greater than 1:100,000, e.g., leukaemia, playing soccer, accident at work, murder

Minimal risk = less than 1:100,000 but greater than1:1,000,000, e.g., railway accident, horse riding, fishing

Negligible risk = less than 1:1,000,000, e.g., hit by lightning or radiation leak from nuclear power station

On this scale 7×10^{-3} would be rated as a "low risk."

Consequences can be represented quantitatively as estimated numbers of casualties (deaths and injuries), or the economic costs of such casualties, or both. They can then be turned into a qualitative expression, e.g., Low – Medium – High – Catastrophic. In the risk literature, the most high-profile type of risk is the one known as "low-probability, high-consequence" events – examples are severe earthquakes in populated areas, terrorism attacks, or core-melt incidents at nuclear power plants. In this type there is an extreme sensitivity among the public to the possible occurrence, no matter how low the statistical probability might be. Murders or violent sexual assaults perpetrated by previous offenders released on parole also would fall into this category of risk.

The formula R = P x C is used to generate a formal matrix, where consideration of the *combined* impact of frequency and severity (consequence) generates a "risk rating," as in the example above (System Safety 2009). The roman numerals refer to a series of classes of risk: Class I (intolerable risk), Class II (undesirable risk), Class III (tolerable risk), and Class IV (negligible risk). *The shaded boxes represent unacceptable levels of risk.*

Consequence / Frequency	**Catastrophic**	**High**	**Medium**	**Low**
Moderate	I	I	I	II
Low	I	I	II	III
Very Low	I	II	III	III
Minimal	II	III	III	IV
Negligible	III	III	IV	IV

Risks may be assigned to various classes, representing degrees of urgency for risk control, such as in the following illustrative scheme:

Class I: Calls for urgent attention and significant risk control measures.
Class II: Risk control measures are needed.
Class III: A risk that should be monitored.
Class IV: A risk that does not need to be managed.

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Part One:

Risk Decision-Making

CHAPTER 1:

INTRODUCTORY NOTE TO PART ONE

The case studies dealing with risk management decision making that are presented in this section span only a small fraction of the total, but they do illustrate some important themes in the larger literature. The single most important theme is that trouble usually arises at the interface of science and policy.

> [Some collections of case studies are S. Krimsky & A. Plough, *Environmental Hazards* (Dover, Mass.: Auburn House, 1988); L. Salter, *Mandated Science* (Dordrecht: Kluwer, 1988); J. Linnerooth-Bayer, R. Löfstedt & G. Sjöstedt (eds.), *Transboundary Risk Management* (London: Earthscan, 2001); P. Harremoës et al. (eds.), *The Precautionary Principle in the 20th Century* (London: Earthscan, 2002); Leiss & Chociolko (1994); Leiss (2001); Leiss & Powell (2004); Charles Perrow, *Normal Accidents* (Princeton University Press, 1999).]

The troublesome nature of the science/policy interface was highlighted a quarter-century ago in one of the most influential publications in the field of risk management, the s0-called "Red Book" (named for its cover, not its ideology), *Risk Assessment in the Federal Government: Managing the Process*. On the very first page of this pathbreaking document, prepared under the auspices of the U. S. National Academy of Sciences, two themes are mentioned which continue to characterize this field down to the present day: (1) the domain of risk assessment involves "the intricate relations between science and policy"; (2) regulatory decisions about health hazards can be "bitterly controversial." Another interesting aspect of this document is its statement about the need "to ensure that risk assessments are protected from inappropriate policy influences." [U.S., National Research Council (1983), *Risk Assessment in the Federal Government: Managing the Process*, p. 14; see generally W. Leiss, "Between expertise and bureaucracy:

Trapped at the science-policy interface," chapter 7 in Leiss (2001).] The normal case is that they are not so protected.

In terms of the ultimate stakes in the risk management game, nothing will exceed what has been bet on the outcome of global climate change. Nor is there likely ever to be a more epic battle between science and policy. If the scientific consensus position on climate forcing receives further confirmation during the next two decades, as is very likely to be the case, governments everywhere will face the ugly reality that they may well have already run out of time to constrain the first level of long-term adverse outcomes – and, moreover, that much more serious elevated effects are virtually inevitable. In other words, no ordinary policy measures in their arsenals will be of any use, because the window of opportunity for decisive intervention had closed much more quickly than most people had anticipated.

Chapter 10's comparison between the issues of ozone depletion and climate change tries to identify some of the reasons why the problem structures that are so similar in these two cases of science-policy interaction had such different outcomes. Then Chapter 11 outlines a simplified approach to decision making for climate change, suggesting by implication that we ought to have been able to make more progress, during the last decade, in coming to a policy consensus on climate change. The explanation for why we failed may be as simple as the problem itself is complex: The entrenched economic interests, based on two hundred years of tight coupling between industrialism and fossil fuel use, are just too powerful to be swayed by scientific rationality itself. The upshot is that we are content to carry on as before, rolling the dice in the hope that we will eventually get lucky (i.e., that the issue will miraculously go away of its own accord).

Acting in a precautionary manner has been decisively rejected in the case of climate change; given the long time-frame in which the ultimate results will unfold, "to regret at leisure" will take on a whole new meaning.

Two other chapters in Part Two seek to build support for the precautionary approach by identifying some of its inherent limitations. Chapter 5 ultimately carries the simple message that "the wisest course of action is to avoid trying to be more precautionary than our knowledge enables us to be." Disregarding this advice can lead us to outcomes that are self-defeating. One example of a self-defeating outcome is provided in Chapter 6, where the subject is a risk issue of great sensitivity: Is it appropriate to discriminate against gay men with respect to blood donation?

To put the same question in a different way: Is it possible that being inappropriately precautionary in one respect can lead to potentially adverse outcomes in other respects – and is, in addition, an ethical wrong in itself? This subject turns out to be an especially severe test for the precautionary principle, because blood safety is more than a matter of applying a well-known and purely pragmatic guideline in order to control risks at a level that is "as low as reasonably achievable" (the ALARA principle). The management of risks associated with donated blood also involves a complex set of subtle ethical compacts, and potential risk transfers, between blood donors, regular blood recipients, and the public, which are mediated by blood collection and processing agencies. The discussion illustrates both what place our use of risk estimation itself has in the management of sensitive risk issues as well as what its inherent limitations are in such matters.

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CHAPTER 2

RISK MANAGEMENT AND PRECAUTION
INSIGHTS ON THE CAUTIOUS USE OF EVIDENCE

Original Publication:
Steve E. Hrudey and William Leiss,
"Risk Management and Precaution:
Insights on the Cautious Use of Evidence,"
Environmental Health Perspectives **111** (No. 13, October 2003),
1577-1581

This is an Open Access Publication:

Abstract

Risk management, done well, should be inherently precautionary. Adopting an appropriate degree of precaution with respect to feared health and environmental hazards is fundamental to risk management. The real problem is in deciding how precautionary to be in the face of inevitable uncertainties, demanding that we understand the equally inevitable false positives and false negatives from screening evidence. We consider a framework for detection and judgment of evidence of well-characterized hazards, using the concepts of sensitivity, specificity, positive predictive value, and negative predictive value that are well established for medical diagnosis. Our confidence in predicting the likelihood of a true danger inevitably will be poor for rare hazards because of the predominance of false positives; failing to detect a true danger is less likely because false negatives must be rarer than the danger itself. Because most controversial environmental hazards arise infrequently, this truth poses a dilemma for risk management.

CHAPTER 3

MEN HAVING SEX WITH MEN DONOR DEFERRAL RISK ASSESSMENT:

AN ANALYSIS USING RISK MANAGEMENT PRINCIPLES

Author's Note:
Original publication: William Leiss, Michael Tyshenko, and Daniel Krewski,
Transfusion Medicine Reviews **22** (No. 1, January 2008), 35-57.

Update 2017: See the end of the article.

Abstract

This article discusses issues associated with the lifetime deferral from donating blood of males who have sex with males (MSM), in the context of well-established risk management principles, including ethical considerations associated with the risk-based approach to social policy matters. Specifically, it deals with the questions about the rationale for the existing policy in Canada of lifetime deferral for MSM, a rationale applied in practice by blood-collection agencies and supported by the regulatory authority of Health Canada.

We identify several alternative time frames for MSM deferral: sexual abstinence over either a 10-, 5-, or 1-year period, or no deferral. Two options are selected for more complete discussion, namely, abstinence for a period of either 1 or 5 years prior to donation. The available evidence about

estimated residual risk (RR) – that is, the risk remaining after various safeguards for blood are applied – strongly suggests that choosing a 1-year deferral period for MSM would almost certainly give rise to an incremental risk of transfusion-transmitted infection (TTI), over existing levels of risk, for blood recipients. The article argues that, under these circumstances, such a policy change would represent an unethical type of risk transfer, from one social group to another, and therefore would be unacceptable. The evidence is less clear when it comes to a change to either a 10- or 5-year deferral period. This is the case in part because the current level of residual risk is so low that there are, inevitably, substantial ranges of uncertainties associated with the risk estimation. There is no firm evidence that such a change in the deferral period for MSM would result in an incremental level of risk, although the possibility of a very small increase in risk cannot be entirely ruled out. Under these circumstances, other social policy issues, relevant to the idea of changing the deferral period for MSM, become worthy of additional consideration.

1. INTRODUCTION.

Speaking at a U.S. Food and Drug Administration (FDA) workshop on "Behavior-Based Donor Deferrals in the Nucleic Acid Test (NAT) Era," on 8 March 2006, Jay Epstein, FDA's Director of the Office of Blood Research and Review, stated: "In fact, our current risks are now so low that they cannot be measured directly and, hence, we rely on models to estimate the current residual risk, that is to say the risk after all the safeguards have been followed." In this context, Epstein went on to say, "the question has arisen whether testing has become so effective that some risk-based deferrals no longer provide a significant added safety value." At the same conference, the FDA's Alan Williams reiterated one of the agency's fundamental principles for the blood safety regime: "Ensure that any *changes* in existing policy result in improved or equivalent safety."[1]

Although the blood system uses a suite of behavioral criteria in its deferral program, one criterion in particular has been, for some time now, a

source of protest and controversy. This is men having sex with men (MSM), and the lifetime deferral that is imposed, for even one instance of such activity for the entire period since 1977. Although blood safety regulators in Canada, the United States, and Europe have not announced any plan to change MSM donor deferral policy, there are ongoing discussions about this issue, involving many professionals and stakeholders, at present.

Through a combination of donor selection, screening, and testing, the blood system seeks to reduce the risk of an infectious unit being transmitted to a recipient to the lowest achievable level ("*A*s *L*ow *a*s *R*easonably *A*chievable" [ALARA]). The donor screening process has been described by King et al. as "the first line of defence" in this process.[2] Of course, for some risks the donor screening process is the only line of defence. For example, although it is now established that the infectious agent implicated in variant Creutzfeldt-Jakob disease (vCJD: prions) can be transmitted in blood, there is as yet no test for this agent.

Unreported Deferrable Risks, Testing Error Rates, and Residual Risk.

There are a number of challenges to the efficacy of the donor screening process. One is unreported deferrable risks. Referring to 1998 data from the U. S. Retrovirus Epidemiology Donor Study (REDS), Glynn, in Chiavetta et al.,[3] states: "Overall, the level of unreported deferrable risk (risk that if reported at the time of donation would have resulted in deferral) was about 3.0%." Damesyn et al.[4] remark that donors under 25 "were significantly more likely to report a UDR" than those over age 25. Data from the REDS study indicated that among male blood donors in the sample (25,000 in all), 1.2% acknowledged MSM activity since 1977.[5]

Another challenge includes the ongoing question of the extent to which donors do actually read and understand the screening materials, and whether new forms of information presentation (in addition to standard written formats) could be beneficial, especially for young people. A related study compared the performance of the standard Donor Health Assessment

Questionnaire (DHAQ) with an experimental alternative, using a computerized hand-held tool (HQ), concluding that a "computerized questionnaire may improve the efficiency of the donor screening process."[6] Rugege-Hakiza et al.[7] concluded that, despite these challenges, "the current screening process is actually very effective."

Then there is the challenge posed by testing errors. At the March 2006 FDA Workshop, Michael P. Busch gave an extended presentation on "Window Periods, Errors and Transfusion Risks in the NAT Era." Referring to 2 viruses of special concern (HIV and hepatitis C virus [HCV]), and the 2 types of tests now used (antibody or enzyme-linked immunosorbent assay and NAT), Busch calculated the risk that positive units could evade detection in the event that both tests failed sequentially: "You could then sum all these error relationships up and you are down in the range of 3 per billion for HCV and 0.1 per billion for HIV. So, the probability that errors in routine screening will result in release of a unit in our analysis is so remote as to be inconsequential…. So, from our analysis we believe that errors are really minimally contributing to risk…"[7]

Residual Risk in Canada.

The risk that, despite the application of various safeguards, an infectious unit will escape undetected into the blood supply is known as residual risk (RR). Canadian Blood Services has estimated RR by using what is called the "classic incidence/window-period method." The most recent published data (for the period 2001-2005) is: HIV, 1 in 7.8 million donations; HCV, 1 in 2.3 million; hepatitis B virus (HBV), 1 in 153,000.[8]

In this article, we examine the issue of whether the current MSM donor deferral policy could and should be changed, in the light of both the scientific information we have on the estimation of RR for donated blood, as well as a set of commonly-accepted principles used in risk management practices.

2. RISK MANAGEMENT PRINCIPLES.

Evidence-based Risk Assessment and Risk Estimation.

Risk management begins with the evidence of a hazard and then proceeds to estimate risk, which is an attempt to predict the degree of a health risk resulting from exposure to that hazard.[9] These 2 fundamental aspects of risk management (evidence and estimation) are equally important. Plausible evidence that a hazardous factor, such as virus, can cause an adverse effect on health is the original basis for every further step in the risk management process.

On the other hand, the extent to which those adverse effects will actually manifest themselves, for example in a human population, under specific types and conditions of exposure, cannot be definitively characterized until after the effects have begun to be observed. At that point, risk estimation is used to anticipate and predict the likely range of effects, using a variety of assumptions (such as dose-response rates), so that pro-active risk control measures may be put into place: "Done well, risk management is inherently precautionary, in the sense that it should make use of effective risk assessment to predict, anticipate, and prevent harm, rather than merely reacting when harm arises."[10]

Especially where low-level risks are concerned, evaluation of the evidence base in the process of instituting precautionary risk control measures always presents difficult challenges for risk management. A recent U.S. government document, which proposes to issue technical guidance for the formulation of risk assessments, states: "Every risk assessment should provide a characterization of risk, qualitatively and, whenever possible, quantitatively. When a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided. Expressing multiple estimates of risk (and the limitations associated with these estimates) is necessary in order to convey the precision associated with these estimates."[11]

Specification of Uncertainties.

A famous definition of risk, formulated by the economist Frank Knight in 1921, refers to risk as "measurable uncertainty." In 1994 the U.S. National Research Council issued the first in a series of reports emphasizing the importance of specifying the uncertainties in risk assessments.[12] This theme was reiterated 2 years later, in another report which introduced the consideration of important associated dimensions of the issue of uncertainty while reiterating its main theme: "Uncertainty is a critical dimension in the characterization of risk."[13]

The first new element has to do with the need to specify the full scope of types of uncertainties that are pertinent to a particular risk management problem: "Because risk characterization requires providing information about the full set of factors of concern to the interested parties, it must address uncertainty not only about the physical and biological impacts of the risk, but also about the social and political factors inherent to the risk." It is clear that this directive is applicable to something like the management of blood safety. The second is equally important, especially in contexts where members of the public, and stakeholder groups, need to be intensively involved in risk management decisions. It is derived from the fact that uncertainties are one of the things that worry people most, when they are thinking about risks to health. Therefore, it is advisable to go beyond the quantitative and qualitative representation of existing levels of uncertainty and to discuss how those levels may be reduced, if possible.

Acceptable Risk, especially in cases of Involuntary Risk.

Tyshenko and Krewski argue that the "concept of acceptable risk is tightly linked to perceived risk." Most people use their own reflections on, and intuitive feelings about, their daily experiences to array the risks they perceive into hierarchies of escalating concern: "The experiential system is intuitive, quick and largely inaccessible to conscious awareness, relying on images and associations linked by experience, emotion and affect (in

cognitive science 'affect' is used to mean the conscious subjective aspect of feeling or emotion)."[14]

Risk acceptability – also sometimes referred to as risk tolerance – is also influenced by whether the risk is considered to be a result of "voluntary choice" (smoking) or is involuntarily imposed – and, within the latter category, whether it is a matter of a natural or human-caused hazard (a device). It should occasion no surprise to learn that people have a much higher tolerance for voluntary risk, and, within involuntary risks, for natural as opposed to man-made catastrophes.

Those who must receive blood or blood products for reasons of medical necessity are bearers of an involuntary risk, with respect to blood safety. And even at the best of times, there is very low public tolerance for involuntary risks of any kind that result from human acts, including policy choices. In a sense, there is almost no lower limit to the "appetite" for risk, or risk tolerance, in this domain, for the public as a whole. (There are always distributions of risk tolerance in populations; in general, for example, women are more risk-averse than men.) For most members of the public, the formulation beloved of experts, *de minimis* risk, simply does not apply, where involuntary risk is concerned. And, if one puts a (very low) number on the risk, it will soon become apparent that no number is low enough.

This absence of a lower threshold for risk acceptability, in matters of involuntary risks, presents many challenges for risk managers. One of the most serious of them is simply trying to conduct a reasoned conversation about very low risks, which are also always in the form of risk estimations. The risk number (or range) itself, combined with both uncertainty ranges and levels of confidence, and all the complicated statistical manipulation that accompanies those numbers, are extremely difficult to communicate.

So far as blood safety is concerned, the (very) good news is that tremendous advances in risk reduction have been made in the past twenty

years. The bad news, in a sense, is that the residual risks are now so low that they can only be expressed as complex estimations. At very low levels the uncertainty ranges can be very broad, so that meaningful comparisons between small changes, one way or another, are difficult to make. As we shall see, at least some aspects of the policy choices relating to MSM donor deferral are in that zone of risk estimation where it is difficult to say whether or not a change in policy would produce a meaningful, measurable change in residual risk.

Risk Tolerance and the "Set-point" for Risk Acceptability.

In his book *Target Risk* Gerald Wilde develops the notion of "risk homeostasis," which is the idea that most people have a "set-point" for risk tolerance that operates very much like a thermostat does.[15] In other words, over time, we try to adjust our exposure to risk so that it falls within certain parameters where we are "comfortable" with the degree of risk we are experiencing. The set-point is another way of expressing the "appetite" for risk which each of us has at any time. The set-point can change over the lifetime of a person – most famously, young males have on average a higher tolerance for risk than do both older males and all females. Quite obviously, the average set-point for a particular risk, in a population or social group, also may change as a result of experiences, especially those which are associated with dramatic (frightening) results. For example, the risk tolerance for civilian nuclear energy changed considerably after the high-profile incidents at Three Mile Island and Chernobyl.

The same is true for donated blood, especially for the groups made up of those who depend on regular transfusions, or blood products. The catastrophic events of the early 1980s, involving large numbers of illnesses and deaths caused by transfusions of infected blood, undoubtedly altered the set-point, or level of risk tolerance, for these groups, and also for society as a whole. Since that time, both society and special groups have become highly sensitized to the issue of blood safety. In other words, there is virtually zero tolerance for any change to the policies regulating blood safety

that would increase, in however small an increment, the risk of transfusion-transmitted infection.

ALARA, or "Continuous Improvement".

As **L**ow **a**s **R**easonably **A**chievable is a risk management principle that has been applied most extensively with respect to radiation risk, although it has many wider applications as well.[16] In a practical sense, it is virtually coterminous with the management principle of continuous improvement. (It is important to recognize, of course, that almost every innovation in risk reduction has some economic cost, and so the principle of relative cost-effectiveness also applies.) Continuous improvement is in the first instance a desirable managerial mind-set for risk managers, but especially for those who manage "public" risks of a highly sensitive kind. Drinking water safety suggests itself immediately, as does blood safety. The mind-set is one of a willingness to go beyond compliance with regulatory standards and continue to search for innovations for additional safety that can be implemented at low cost.

One other point is important here, however. Managers of public risks usually deal with situations where there are multiple sources of risk, and both drinking water and blood donations illustrate this situation well. To some extent, the multiple risks compete with each other for attention and resources. Thus, the calculation of relative cost-benefit and cost-effectiveness for incremental steps in risk reduction, when it has to be arrayed across many different risk factors, is not a simple one. Especially where the threat of new and emerging pathogens is concerned, a delicate balance in the allocation of risk control resources is essential. Thus where a multiplicity of risk factors are being managed simultaneously, it is important to note that the ALARA principle applies in the first instance to the entire set, taken as a whole, and not to its individual members.

Precaution.

As mentioned above, a precautionary approach is inherent in, and integral to, risk management itself. In a sense, it is a response to one of the major types of uncertainty, namely, that which results from incomplete knowledge. More precisely, precaution addresses a certain "zone" within the characterization of a risk where one is unsure about both the efficiency and the efficacy of expending a known amount of resources to achieve a hypothetical increment of risk reduction – without having a guarantee, at the time, that the expenditure is either necessary or sufficient.

There has been a great deal of discussion about precaution in the preceding decades, and during that time many federal authorities, including Canada, have formally incorporated explicit references to a precautionary approach into their risk management strategies. Of course, the basic idea has been around for much longer. For example, an editorial in the *American Journal of Public Health,* May 1984, stated (as cited by Krever[17]): "The incomplete state of our knowledge must not serve as an excuse for failure to take prudent action. Public health has never clung to a principle that complete knowledge about a potential health hazard is a prerequisite for action."

The widespread acceptance of precaution at present, however, has given rise to yet another set of challenges. Simply accepting the view that precaution is an inherent part of good risk management practice is not enough, because the first question is: *How* precautionary should we be in a particular case? There are all-too-many documented instances of insufficient precaution in earlier times.[18] However, it is less well understood that it is also possible to be unwisely and excessively precautionary: "Below a certain low level of hazard frequency, we simply cannot have a reliable idea of whether what we fear is actually there or not, unless we have resources and knowledge to pursue a series of increasingly effective sequential tests to provide meaningful evidence on extremely small risks…. [T]he wisest course of action is to avoid trying to be more precautionary

than our knowledge enables us to be."[10] Later in this paper we shall have occasion to apply this principle to the issue of blood safety.

Equity.

Equity is of course an ethical principle, but it is also a specific concern within the domain of risk management itself. There are 2 aspects in this regard.

Distribution of risk and excess risk. Often, risks are distributed in a population "accidentally," as it were, either by random occurrences (such as many natural hazards) or by inherent differences, such as genetic variation. But they may also be either an indirect or direct result of policy choices. Facilities siting, such as for hazardous waste treatment, is an obvious case: those living in the vicinity bear some amount of excess risk, by comparison with the rest of the population, unless offsetting risk reduction measures were to be implemented (which is rare: where an offset is made, it is usually in the form of compensation). Occupational risk is also a policy area where excess risk is assumed to be tolerable. In general, risk management decisions are always more difficult in those cases where risks are unevenly distributed in a population, and where the risks in question are involuntary. At present, there is increasing recognition of an obligation, in such cases, to give special consideration, in terms of stakeholder relations, to those who bear excess risk. Clearly, blood safety is one of those cases.

Risk transfers. Where there are different or competing interests within the framework of a risk management situation, it is advisable to take note of the possibility that either intended or unintended risk transfers may occur. For example, parents who smoke in the home and car are transferring some health risks (including the higher probability of a child becoming a smoker) to their children. Policy choices may – either directly or indirectly – also transfer a measure of risk from one group to another. For example, the choice to recruit members of the armed forces through volunteers, rather than a universal compulsory draft, will transfer risk from higher-income to lower-income social groups.

Both of these examples show that risk transfers often raise very important ethical issues. In the case of blood safety, it is evident that not all of the interests of donors, for example, are consistent with the interests of blood recipients. (The clearest illustration is the case where a person who suspects that he or she may be HIV-positive seeks to donate blood as a way to be tested for the disease.) Especially in highly sensitive areas of risk management, such as blood safety, policy issues must always be examined carefully in terms of their potential implications for risk transfers.

Trade-offs.

Risk-Benefit. There are many, many instances in which it is highly advantageous, for both individuals and groups, to assume an incremental risk in return for increased benefit where benefits clearly outweigh risks (net benefit). For example, the risk of being trapped, by a seatbelt which cannot be disengaged, in a burning automobile following an accident, is outweighed by a large margin by the benefits of seatbelt use. Likewise, in the case of airbag deployment, where the risk of injury from the airbag itself is outweighed (in most cases) by the benefits to safety in serious accidents. Risk-benefit trade-offs are relatively easy to calculate where it is the same group or individual involved; when this is not the case, it may be a matter of unfair risk transfer.

Risk-benefit trade-offs have been discussed, in the case of blood safety, most recently because of the study of Germain et al,[19] which concluded that the trade-off between benefit (increased donations) and excess risk (in accepting MSM donors abstinent one year) was not advantageous. (Germain et al did a double risk/benefit comparison, estimating the trade-off associated with a change to a 12-month MSM deferral, with that of the current policy of accepting female partners of MSM after 12-month deferral, concluding that the latter was 5 times less risky for the same level of benefit.) [20] However, it is questionable whether this type of issue should be put in risk-benefit terms: Is there *any* level of benefit that

would justify the increased risk of infection? Is it not preferable to assume that Canadians would respond to any emergency involving an imminent blood shortage by mobilizing to increase low-risk donations? This issue should be more properly framed as one of a risk-risk trade-off (see below).

Risk-Risk (Relative Risk). The trade-off discussed in Germain et al could also be arrayed instead as one in which 2 equally serious risks have to be balanced against each other – an estimated increase in transfusion-transmitted infectious disease risk, on the one hand, versus the potential risk of inadequate supplies of blood, on the other. When one arrays the issue in this way, one can see immediately what the initial policy response would be: namely, one would first try to "manage" this set of relative risks by comparing the likelihood of reducing the second of the 2 risks by considering a variety of options, all involving, in the first instance, programs to mobilize additional donations from the set of low-risk donors, both repeat and first-time.

Provided that multiple options were available for reducing the risk in question (inadequate supplies of blood), risk managers would start with the lowest-risk option and proceed, if required to do so, to the relatively riskier ones. In the case discussed here, both risks are borne entirely by the same group of people, namely, those that require blood and blood products for reasons of medical necessity. Relative-risk considerations are, therefore, appropriate in this context. (If this were not the case, the situation would be one of risk transfer, already considered.)

Cost-Benefit. General models for cost-benefit trade-offs, comparing options for ensuring blood safety, have not been well-developed as of this time.

3. Ethical and Legal Principles in Risk Management

Ethical Principles.

It is becoming increasingly common for risk regulators to devote some attention to the formulation of an ethical framework for risk management.[21]

For purposes of illustration, we will discuss briefly here the principles articulated by the World Health Organization in its *World Health Report 2002*, which are 4 in number:[22] (1) autonomy: protecting the rights of the individual and informed choice; (2) nonmaleficence: do no harm or injury; (3) beneficence: produce benefits that far outweigh risks; (4) justice: achieve an equitable distribution of risks and benefits.[23] In the conclusions to this paper we will refer to the values of nonmaleficence, beneficence, justice, and fairness.

Legal Principles.

This section summarizes the analysis of legal principles, relating to donor deferral issues, which was presented at the 2001 Consensus Conference, *Blood-Borne HIV and Hepatitis: Optimizing the Donor Selection Process*.[3]

- Discrimination on the basis of group membership is prohibited in Canada by various statutes and codes, including categories – used in blood donor selection – such as sexual preference, addiction, and place of birth.

- In order to establish a claim of unlawful discrimination, it is necessary to show that there is a stigma attached to being a member of one of these kinds of categories.

- On the basis of court decisions, the donor exclusion of MSM clearly carries such a stigma and thus would fall within the category of a prohibited discrimination, i.e., an abridgement of protected rights and freedoms (Section 15 of the Canadian Charter):

- However, Section 1 of the Charter states that "the rights and freedoms enumerated in the charter can be restricted on the basis that the limit is reasonable and demonstrably justified in a free and democratic society";

- The Supreme Court of Canada promulgated the "Oakes test" in 1986 to set criteria for deciding whether a specific restriction of freedom is or is not reasonable and justified; the three tests are: (1) Sufficient importance of the objective (in this case, blood safety); (2) Rational connection and minimal impairment: the impairment (denial of blood donations by MSM) is rationally connected to the objective, and is the smallest degree of impairment that will safeguard the objective; (3) Proportionate effect: "the risks of infecting patients with HIV are greater than the benefits granted to those who want to give blood."

4. THE CURRENT DONOR DEFERRAL SYSTEM IN CANADA.

Donor deferral refers to the practice of excluding blood donations from specified categories of individuals based on an established set of donor selection criteria. As such it is one of a series of standard procedures that are designed to ensure the safety of blood and blood products, namely:

1. Donor education and voluntary self-deferral (either before or after donating);
2. Health assessment at time of donation;
3. Administration of Donor Health Assessment Questionnaire prior to donating;
4. Application of donor deferral criteria;
5. Testing of donated blood prior to use (individual and batch tests);
6. Quarantine controls prior to distribution;
7. Monitoring and research for emerging blood-borne diseases;
8. Ongoing review of risk management strategies through regular liaison with other domestic and international agencies.

To borrow a term from the drinking water safety area, this may be called a "multi-barrier approach": The high level of safety of the blood supply which has been achieved, in Canada and elsewhere, in recent years is the result of the combined impact of all of these procedures.

Judging the Suitability of Donors.

Application of the management practice of donor deferral is governed by the Donor Selection Criteria Manual (DSCM). The DSCM is a listing of many diseases, medical conditions, behaviors, and drug substances that may provide a basis for deferring a blood donor. (The manual gives guidance on all items in these categories where questions have been raised, and in some cases it instructs personnel to accept the donation.) The manual is continuously updated as new information is acquired by agencies responsible for blood safety. Donors may be deferred because of increased risk to their own health associated with donation (for example, donors with coronary artery disease), or increased risk to recipients (for example, history of hepatitis).

There are 2 basic categories for deferral: "temporary" and "indefinite." The first, "temporary," is a time period that ranges from 1day to 1year, with some specific time frames in between (e.g., 56 days in the case of exposure to West Nile Virus). Many of the deferrals for prescription and nonprescription legal drug use and medical conditions fall into this category; in other words, the deferral is maintained for as long as the condition or drug use persists (there are some drugs with very long half-lives and high teratogenic potential that result in longer deferrals). On the other hand, many diseases and some types of behaviors give rise to an "indefinite" deferral, which is equivalent to a lifetime period.

There are, for example, something on the order of 400 specific diseases and medical conditions listed in the DSCM, which give rise to either temporary or indefinite deferrals. Randomly chosen examples of those designated for indefinite deferral are brucellosis, Chagas disease, cirrhosis of the liver, coronary disease, CJD, Crohn's disease, immune deficiency, multiple sclerosis, and sickle cell anemia.

The questions asked of potential donors are designed to determine whether the donor's blood may itself be unhealthy (e.g., low hemoglobin

level), or could contain an infectious pathogen (e.g., West Nile virus) or harmful substance (e.g., the residue of a prescription drug dangerous to pregnant women), and thus, that the potential donation should not be accepted. More specifically, they are designed to estimate the chance, or likelihood, that this is the case – assuming that all of the prospective donor's answers are truthful, of course. Taken as a whole, the set of questions probes for both direct and indirect markers of the likelihood that one or more factors, in the case of a particular donor, could compromise the safety of the donated blood or the safety of the donor. (Direct markers are evidence of specific disease states in the donor; indirect markers are, for example, "time spent in prison," which is a surrogate measure for the likelihood of exposure to high-risk activities in that environment.) According to one recent estimate from Héma-Québec, 20% of potential donors are excluded at the donor screening stage, including 3.2% who are rejected for high-risk behaviors.

The Basis for Judgment: The Risk Assessment Methodology.

As mentioned earlier, the multi-barrier approach to risk management, which characterizes the field of blood safety, is designed to construct an interlocked series of management strategies that operate simultaneously. For each of these strategies, there are some circumstances under which any particular barrier may fail, for example:

1. Donor education and voluntary self-deferral (either before or after donating): Potential donor is unaware of having a condition that would warrant self-deferral.

2. Health assessment at time of donation: Symptom otherwise justifying deferral unreported or unobserved.

3. Administration of Donor Health Assessment Questionnaire (DHAQ) prior to donating: Potential donor accidentally gives incorrect information that would otherwise justify deferral; or potential donor answers untruthfully on a question that would otherwise justify deferral.

4. Application of donor deferral criteria: Criterion incorrectly interpreted or applied or overlooked.

5. Testing of donated blood prior to use (individual and batch tests); False negative test result; or, operational error in testing procedure.

6. Quarantine controls prior to distribution: Accidental release of unit from unqualified donor.

7. Monitoring and research for emerging blood-borne diseases: New blood-borne pathogen is unrecognized until after first infections occur.
8. Ongoing review of risk management strategies through regular liaison with other domestic and international agencies: Scientific consensus on infectivity by blood of a known disease agent is not reached until after first infections occur.

In the operation of every barrier (except the first: voluntary self-exclusion), and its set of risk control strategies, there is an indispensable element of expert or professional judgment. This is clearest in the case of the administration of the DHAQ, but it is equally important in the others, such as the compilation of the DSCM and the scientific monitoring and consensus-building processes on new and emerging diseases. Errors in judgment are inevitable; they may result, for example, from lack of information (such as about the infectivity of a new pathogen), from an undetected weakness in the established screening procedures (misinterpretation of a question by a donor), or from a simple mistake by someone during a busy day.

Constructed of sequential steps, the multi-barrier approach is designed to be robust in catching inevitable errors in judgment, but it cannot promise perfection in this regard. In other words, the blood safety system, like all other domains of risk management, cannot achieve a state of zero risk, that is, complete safety. Another reason is that all procedures come with an economic cost, which is ultimate reflected in the monetary price of a unit of blood, which in Canada is a cost to the provincially funded health care system. Each of the barriers represents an investment of a certain level of funding in the blood safety system, and there is not an unlimited supply of such funding for any specific purpose; each must ultimately be judged on its cost-effectiveness for the purpose it serves.[24]

On the other hand, the blood system today in Canada and elsewhere has achieved a level of safety that is, almost certainly, unprecedented in the period since blood transfusions have been generally available. (There are of course many different types of risks associated with blood transfusion, most of which are not discussed here; for a comprehensive analysis, see the 2003 review by Kleinman et al[25].) Moreover, there is clear evidence of the application of a continuous-improvement ethos in this system – which is consistent with the risk management principle known as ALARA – to operate with a level of risk that is "as low as reasonably achievable."

"Behavioral" Risk Factors in the Donor Screening Strategy.

As indicated earlier, there are four primary categories of concerns in the blood donor assessment profile: diseases, medical conditions, behaviors, and drugs. Of the 4, the act of probing the category of behaviors stands out from the rest, for a number of reasons, for example: (1) it seeks to elicit a type of information about the donor that is essentially different from what is sought in the others; (2) it explicitly probes the types of social and personal judgments made by the donor in some very sensitive areas (sex, prostitution, illegal drug activity) which are regarded, by many, as giving rise to "moral" issues; (3) it implicitly calls attention to differences in lifestyles among the population; (4) it deals with activities of groups which represent minorities in the population; (5) and, with respect to male sexual activity, it confronts a "zone" in society that is traditionally been the subject of highly-charged emotional confrontation, in social, family, political, and religious domains.

In this context, there is no reason to think that judgments about the evaluation of behavioral risk factors in blood donations could avoid controversy.

A noteworthy feature of the general category of deferrals for behavioral risk factors is the "even one time" provision, with or without mention a specific year in which the type of activity was initiated. This

feature appears in the following 5 instances of specifically behavioral risk: (1) having engaged in injection drug use; (2) having taken money or drugs for sex since 1977; (3) being a male who has had sex with a male since 1977; (4) having had sex with a person with AIDS or testing positive for HIV; (5) having had sex, since 1977, with a person who was born in, or has lived in, 1of 8 named African countries.

The risk assessment basis for the geographical exclusion in this list (8 African countries), namely, the prevalence of a type of HIV that may be undetectable in testing, is different from all the others. For the other 3 categories (MSM, injection drug users, and prostitutes), the risk assessment is based on evidence about the increased prevalence of disease that is in turn related to certain types of behaviors: In all 3 cases, the prevalent infection rate for HIV, for example, has been and remains significantly higher than it is in the Canadian population generally. Thus the basis for donor deferment in these cases is regarded as being a matter of "participating in high-risk activities."

5. MSM DONOR DEFERRAL: HISTORY AND ISSUES.

The first transfusion-associated case of HIV in Canada was officially reported in May of 1985, by which time hundreds of Canadians had already been infected with HIV through blood donations. Testing of blood donations began in November 1985. In January 1986 the Red Cross first began distributing a pamphlet about AIDS "to define unequivocally the largest group at high risk of contracting AIDS as 'any male who has had sex with another male since 1977.'"[15] The pamphlet was part of a strategy to encourage voluntary self-exclusion, however, and it did not form the basis of an active donor screening at the time of donation.

Although questions about risk factors for AIDS were being asked of potential blood donors for a number of years prior to 1989, it was only in 1989 that the Donor Health Assessment Questionnaire became an "official" document whose content was regulated by Health Canada, however. And

only starting in 1989 was the following – rather incoherent – statement added to the DHAQ: "The following activities put you at risk for AIDS: intravenous drug use, living in an area where AIDS is common, regular treatment with blood and clotting factors, men who have sex with men, and sex with any of the above." Potential donors were asked if any of these activities pertained to them, and if the answer was in the affirmative, they were deferred. In 1997 the more specific question ("Male donors: Have you had sex with a man, even once, since 1977?") was separated from this list, and the wording of this question has remained unchanged since that time. In 2004 the requirement for mandatory deferral on this basis was incorporated into CSA Standard Z902-04, "Blood and Blood Components," clause 5.3.9.2. Table 1 compares Canada's practice in this regard with some other countries.

Table 1 – International Deferral Criteria, MSM, 2005

Criteria	Countries
Deferral based on specific activities	Italy ("risky activities")
1-year deferral since last exposure	Argentina Australia Japan Hungary
5-year deferral since last exposure	South Africa
10-year deferral since last exposure	New Zealand
Indefinite deferral, exposure since 1977 or lifetime exposure	Canada US UK France Switzerland Holland Norway Denmark Sweden Germany Finland Iceland Hong Kong

Challenges to MSM Donor Deferral Policy

The beginnings of a challenge to the lifetime deferral for MSM, made from within the blood industry itself, began in the U.S. in 1997. The American Association of Blood Banks stated in 2002: "Since 1997, the AABB has advocated that the deferral period for male to male sex be changed to 12 months." This statement was amplified in March of 2006:

> "AABB, ABC [America's Blood Centers] and ARC [American Red Cross] believe that the current lifetime deferral for men who have had sex with other men is medically and scientifically unwarranted and recommend that deferral criteria be modified and made comparable with criteria for other groups at increased risk for sexual transmission of transfusion-transmitted infections. Presenting blood donors judged to be at risk of exposure via heterosexual routes are deferred for one year….
>
> "It does not appear rational to broadly differentiate sexual transmission via male-to-male sexual activity from that via heterosexual activity on scientific grounds…. We think the FDA should consider that the continued requirement for a deferral standard seen as scientifically marginal and unfair or discriminatory by individuals with the identified characteristic may motivate them to actively ignore the prohibition and provide blood collection facilities with less accurate information."[26]

An extensive public discussion of these issues took place in the U.S. on March 8, 2006 at the FDA Workshop on Behavior-Based Donor Deferrals in the NAT Era. The current clash of expert opinion in this area is nicely illustrated by the sharply divergent positions in 2 back-to-back presentations at the Workshop. The first was articulated by Cees van der Poel of Sanquin, the Dutch blood-collection agency, speaking on behalf of the European Blood Alliance, who referred to the report of a Dutch government committee on the issue of whether the MSM exclusion was a violation of the anti-discrimination provisions of the Equal Treatment Act: "The verdict of that committee … is that … the purpose of the donor selection was not to discriminate but to prevent transmission of HIV and other infections. Homosexual men are disproportionately affected by the selection. That is true. But there is an indirect discriminatory distinction, however,

objectively justified and not disproportional, in the interest of the recipient's blood."

Immediately thereafter Dr. Ronald Bayer, a bioethicist at Columbia University, made the following remarks:* "Given the current testing technology, there is clearly a public health rationale for jettisoning the 29-year exclusion for men who have sex with men…. Indeed, it is hard to understand, given the goal of safety and the commitment to precaution that is embedded in public health practice, why anything more than a one-year exclusion is justified…. What we cannot do as a result of this discussion is take refuge in science when, in fact, what we are responding to is political pressure."[1]

The Current Position of Blood Regulators.

A representative of the European Blood Alliance (EBA), speaking at a March 2006 FDA meeting, stated that no changes to the MSM policy were being contemplated by the EU, because MSM continues to represent a high-risk activity. Although the U. S. FDA apparently will be listening to ongoing discussion of this issue at meetings of its Blood Products Advisory Committee, there is as yet no indication that the current policy will be changed.

Canada's federal regulator, Health Canada, was not officially represented at the FDA Workshop. The Health Canada website does not appear to contain any commentary on the reasons for the current regulations on MSM donors. However, the department's Biologics and Genetic Therapies Directorate (BGTD) presented a document on this matter for discussion at the May 5-6, 2004 meeting of its Expert Advisory Committee. The Expert Advisory Committee's Record of Meeting for its meeting of 12 May 2005 contains the following statement: "MSM: As a follow-up to the May 5-6, 2004 Meeting where this issue was discussed, referenced publications were reviewed by all Committee members and the

consensus was to maintain the status quo, i.e., a lifetime exclusion of MSM, as is the case in Europe and the USA."

6. RISK PROFILE – MSM.

Epidemiology – Canada. The latest figures on HIV prevalence and incidence in Canada, for the period up to the end of 2005, were released in the August 2006 issue of *Canada Communicable Disease Report.*[27]

HIV Prevalence (range of uncertainty given in brackets). At the end of 2005, 58 000 [48 000 to 68 000] were living with HIV/AIDS, a 16% increase over 2002. Percentages in the various exposure categories are the following: MSM, 29 600 (51%); MSM – injection drug use (IDU), 2250 (4%)*;* IDU, 9860 (17%)*;* heterosexual/nonendemic, 8,620 (15%)*;* heterosexual /endemic (origin in a country where HIV is endemic), 7050 (12%)*;* Others, 400 (1%).

HIV Incidence (numerical range of uncertainty given). In 2005, the estimated number of new infections was 2300 to 4500, slightly higher than in 2002 (by exposure category, MSM: 1100–2000 [45%] [42% in 2002]; MSM–IDU, 70–150 [3%]*;* IDU, 350 - 650 [14%]*;* heterosexual/nonendemic: 550 - 950 [21%]*;* heterosexual/endemic: 400-700 [16%]; others: <20 [1%]).

Awareness: "… [W]e estimate that [in 2005] about 15 800 people (11 500-19 500) or 27% were unaware of their HIV infection."

Trends: "The proportion of MSM among new infections steadily declined until 1996 and has increased since then…. The proportions of new infections attributed to the heterosexual/endemic and non-endemic exposure categories have increased steadily since the beginning of the epidemic." Further, "this recent trend among MSM and MSM-IDU is associated with increases in risky sexual behaviour…. Among the heterosexual exposure category, the observed trend is likely a result of the general evolution and spread of the epidemic as well as a recent change in

the Citizenship and Immigration Canada policy on testing immigrants and refugees, which has resulted in more diagnoses."

Statistics: Percentage of Homosexuals in Population and Relative Prevalence of HIV/AIDS: "Among Canadians aged 18 to 59, 1% reported that they consider themselves to be homosexual and 0.7% considered themselves bisexual" (among males the total for bisexual and homosexual combined is 1.8%).* The total Canadian population as of mid-2005 was about 32,800,000. Using epidemiological data (above), the prevalence rate for HIV/ AIDS in male homosexuals/bisexuals in Canada is estimated to be 5.4%, and in the general population, 0.08%, for a ratio of 67:1. [Statistics Canada, 2003 data, reported 15 June 2004; this is the first Statistics Canada survey to collect information on sexual orientation and it is the latest data of this type that is available.] The total Canadian population as of mid-2005 was about 32,800,000. Using epidemiological data (above), the prevalence rate for HIV/ AIDS in male homosexuals/bisexuals in Canada is estimated to be 5.4%, and in the general population, 0.08%, for a ratio of 67:1.

[The calculation first subtracts the HIV/AIDS attributable to MSM (55%) from the total number of estimated cases before figuring the percentage for the general population; the method is similar to that used by Dayton for the U. S. The data is presented by Statistics Canada in terms of homosexuality, which is different from the categories used in the immediately preceding sections, which refer to "MSM." As a category of sexual behavior, "MSM" refers to any male who has ever had sex with another male, even once, since 1977. It is likely that those individuals who are or have been exclusively male homosexuals (gay males), or male bisexuals, and have been sexually active in the period since 1977, make up the largest proportion of those who are classified as MSM in the blood donor system. There are at least two other sets of persons which may be included in the MSM category: (1) male individuals who have, at one time or another, engaged voluntarily in homosexual acts but who do not consider themselves to be homosexuals;

and (2) those males who were involuntarily subjected to homosexual acts by another male (and thus are among the victims of sexual abuse).]

Behavioral Studies. In "The Ontario Men's Survey," using data collected in 2002 from 5000 gay and bisexual men, some of the findings relating to forms of high-risk activity are: (1) In the preceding twelve months, 75% had more than one male sex partner and 45% had more than four; (2) 57% reported sex with at least one casual male partner in the preceding three months; (3) 40% had at least one event of unprotected anal intercourse in the preceding year.[28]

7. RISK ESTIMATION OF TIME-FRAME OPTIONS FOR MSM DEFERRAL POLICY.

The following analysis accepts, as the basis of the discussion of donor deferral issues, the two fundamental principles that provide the foundations of the current system of blood safety: (1) The primary basis for donor deferral rests on the assessment and estimation of the various types of risks to health associated with donated blood; (2) Any changes to existing policies on donor deferral must result in an improved or equivalent level of safety by comparison to what now exists. In evaluating the acceptability of changes to the existing donor deferral policy, we refer to any change that meets these 2 criteria as having "passed the risk hurdle."

<u>Option 1. Change to a 10-year exclusion period.</u>
Reference is to the idea of accepting donors who report no MSM activity for the preceding 10 years or more. No data or studies have been found that are relevant to this time-frame, so this option is not considered here, except in so far as a 10-year exclusion period would give an additional margin of safety by comparison with the 5-year period discussed below.

<u>Option 2. Change to a 5-year exclusion period.</u>
Reference is to the idea of accepting donors who report no MSM activity for the preceding 5 years or more. Since there is some evidence in published

studies relevant to this option, it will be considered in detail in the following sections.

Option 3. Change to a 1-year exclusion period.

Reference is to the idea of accepting donors who report no MSM activity for the preceding 1 year or more. As noted above, this option has been the subject of much discussion and research, and it is considered further in the following sections.

Option 4. Change to no MSM exclusion.

This option refers specifically to MSM, as defined; it does not necessarily rule out self-exclusion or exclusion on other criteria (IDU, etc.). This option has been promoted by some advocacy groups, and has been justified on the grounds that testing is so nearly error-free that there is virtually no chance that an infectious unit of donated blood will enter the blood supply.

Comment on Option 4:

Without donor screening in place, the incremental change in risk, for donated blood prior to testing, would be proportional to the ratio between the increased prevalence of these diseases in whatever population sub-group was no longer screened out, in this case MSM, and the population as a whole. As noted above, this ratio is estimated at 67:1 for Canada; in the U. S., the estimated ratio is 60:1 (Andrew Dayton, 2006 FDA Workshop[1]).

However, two other ratios show that the incremental risk would be much higher, because both current repeat donors, as well as current first-time donors, in fact have lower risk profiles than does the population as a whole. U.S. data (from the American Red Cross) for HIV prevalence in these 2 groups of donors has been compared with HIV prevalence in MSM "likely to donate," which is estimated by Dayton as follows: "We know that about 75 percent of MSM know their serostatus, and it is likely that these people will self-defer so we assume that the effective prevalence of likely MSM donors is approximately 2%." The ratio between HIV in MSM in comparison to

current first-time donors is 200:1; in comparison with current repeat donors, the ratio is 2000:1 (Dayton[1]). This same source gives the latest calculations for testing and operational errors (window-period, false negatives, and quarantine release), none of which is zero. [We acknowledge that there is a range of estimates for the sources of residual risk, such as testing errors. On this point, see also the presentations by Celso Bianco and Sharon O'Callaghan at the March 2006 FDA Workshop.] Therefore, it is impossible to avoid the conclusion that the elimination of all MSM screening would result in some increase, however small, in the risk of transfusion-transmitted infection.

This option does not pass the risk hurdle and thus is not further considered.

Option 5. Change to "identifying risky sexual behaviors."

Some of those opposed to the policy of MSM donor deferral have argued that the blood collection system should be using a set of specified "high-risk" behaviors, rather than social groupings, as the basis of the donor screening process. There are some apparently plausible aspects to this argument, because on its face it seems to be consistent with the basic objective of donor screening, which is to identify individuals, wishing to donate blood, who are at high risk of being infectious. However, its advocates rarely make the effort to state the objections that can be made to this proposal, and to provide a reasoned response to them. Two of the primary objections are:

1. The questions asked during screening procedures would have to focus directly and in detail on certain highly sensitive and intimate areas of actual sexual behavior. It is well-known that many individuals find it awkward to answer truthfully these types of questions. Second, nurses would be required to make a series of difficult, individual judgments in interpreting the prospective donor's answers. And finally, this procedure would raise serious practical issues in the administration of questionnaires in the settings of blood donor clinics, on account of the degree of intrusiveness involved in a more detailed probing of sexual behaviors.

2. The behaviors of individuals can and do change over time, sometimes more than once. Relying on a strategy for identifying risky behaviors, as the basis for donor screening, would inevitably give rise to difficult challenges, including ethical and policy dilemmas, for administrators of blood collection agencies. For example, suppose that an individual who had been accepted in the recent past as a blood donor then, at the next occasion, acknowledged participation in a high-risk activity that would lead to deferral. Would the agency not have a reasonable concern that this same type of deferrable behavior might have occurred earlier as well?

As noted above, the existing system of donor screening has succeeded in producing a supply of donated blood which, upon being tested, is known to have a very low risk of being infectious. There would be, understandably, great reluctance on the part of blood collection agencies, and of blood and blood product recipients, to take part in an experiment to see whether a radically different form of donor screening could yield a comparable or better level of safety.

Current blood donor deferral policy, like all public policy choices in all dimensions of social life, represents an inheritance from the past. It is possible to imagine that a different path might have been chosen in some earlier period. For example, at the time when dramatic changes were being introduced into the blood safety system, in Canada and elsewhere, in the mid to late 1980s, officials might have chosen to institute a donor screening system based on identifying risky sexual behaviors. (This is only a hypothetical situation; we must also recall the tremendous pressure that the blood safety system was under during that time.) Had they done so, they *might* have found that, over time, and in conjunction with the introduction of new testing regimes, these innovations had resulted in an acceptable level of risk for blood recipients.

However, officials did not make such a choice at that time. And the evidence we have now is that the choices they did make have resulted in a very low (albeit nonzero) level of such risk. This is so even though new challenges, such as those represented by West Nile Virus and vCJD, continue to arise. As a result of this "inheritance," it is difficult to imagine that the public would consent to engaging in a new experiment with blood safety, by changing the basis of all forms of donor deferral to the identification of risky sexual behaviors in individuals. Such a wholesale change could entail – at the very least, in the initial phases – significant incremental risks to the blood supply, simply as a result of the complex operational changes which would be required in order to implement it. Therefore, this proposal does not appear to pass the "risk hurdle." On the other hand, it may be possible, at some future time, to assemble more complete evidence about the degree of risk associated with making this type of change to the system.

Option 6: Change to relying exclusively on testing for assuring blood safety.

As testing procedures for blood safety become progressively better, in terms of sensitivity and specificity, it may seem that testing alone would provide an acceptable margin of safety, and thus that all donor screening could be eliminated. However, this proposition overlooks the fact that blood must be drawn from donors, packaged, and handled by a variety of personnel, prior to testing. There are a number of well-described risks (such as needle-stick injuries) of being accidentally exposed to contaminated blood that are inherent in these procedures. Consideration of employee safety (for blood services employees) alone is sufficient to rule out such an option.

8. Further Consideration of Two Change Options.

First Option: Change to a 1-year MSM donor deferral policy.

Many of those who advocate changing the blood donor policy of lifetime deferral for MSM have pointed to a specific kind of allegedly pernicious effect resulting from it: "Many have expressed the view that such a policy [lifetime deferral for MSM], while it may have been justified in the early days

of the HIV epidemic, is now overly cautious and has the unfortunate effect of stigmatizing gay men who would donate blood."[29]

A social stigma may be defined as a "mark," either a physical sign or a symbolic identifier, which is attached to a specific category of persons, within society as a whole; this type of "marking" almost always is associated with a pattern of unjust discrimination, and often persecution, against those persons.[30] Thus the fact of being stigmatized carries with it the risk of being subjected to a hierarchy of adverse consequences, on a scale that runs from merely being shunned in social relations all the way to the horrors of violence and murder.

We accept the notion that both male and female homosexuality (and, to a lesser extent, bisexuality) has been stigmatized to varying degrees in Canadian society, although recently, important changes also have been occurring that have reduced this stigma significantly. And we recognize that in the opinion of many within the gay community – as well as to others in Canada – the perpetuation of the lifetime deferral for MSM is a form of stigma (that is, unjust or unreasonable discrimination) for male homosexuals. Finally, we accept the idea that reducing all forms of stigma – unjust and unreasonable discrimination against specific groups of persons – is a *general benefit* to Canadian society as a whole.

However, we are not fully persuaded that – at the present time in Canada – there is good evidence to show that the lifetime MSM deferral for blood donation is an important contributing factor in whatever stigmatization of gay men remains in our society. Nevertheless, to the extent to which the contrary view prevails among certain individuals and organizations, we recognize that they could reasonably regard a shortening of the deferral period for blood donation as representing a reduction, or even the elimination, of part of the stigma against homosexuality, which still exists within Canadian society. Therefore, in the discussion that follows we accept, for the sake of argument, the proposition that a shortening of the

MSM deferral period would represent a benefit to a specific set of persons, namely, male homosexuals and bisexuals.

In the foregoing discussion we reserved 2 options, with respect to changing the MSM deferral policy, for further discussion. Here we take up the proposed changing of the deferral period to 1-year (i.e., MSM who have been sexually abstinent for at least one year prior to donating). The principal reasons for *not* making this change to the current donor deferral policy are as follows: First, risk estimations in published studies show some very low incremental risk of additional units of infected blood entering the system, if MSM deferral periods were to be changed to 1 year (see further the discussion in the following section on the second option); therefore, this proposal does not pass the risk hurdle. Second, subsequent to any such policy change, all of the incremental risk would be borne by a single group, namely, those who require transfusions of blood for urgent medical reasons. Third, there is no reasonable justification for acceding to *any* increased avoidable risk of life-threatening illness to blood recipients.

On the basis of these considerations, it can be said that there is no reasonable way to balance the increased risk of illness to blood recipients, on the one hand, against the benefit to an entirely different set of persons, on the other (namely, reducing the possible stigma imposed on male homosexuals by the current policy). Furthermore, there is no reasonable way to balance the increased risk of illness to blood recipients, on the one hand, against the general benefit, to Canadian society as a whole, from reducing the apparent stigma imposed on another identifiable set of persons by the current policy.

<u>Further Discussion: First Option.</u>

Changing the existing MSM donor deferral policy to a 1-year period would be, in effect, a "rebalancing" of the existing, net risk-benefit calculus between 2 quite different sets of persons within Canadian society: the set of those who are, in any one period, the recipients of donated blood for health

reasons, on the one hand, and the set of all men who have had sex with other men, even one time, since 1977, on the other. The result of this rebalancing would be as follows: (1) For recipients of blood, there is a small net increase in risk, with no increase in benefit (since there is no deficiency in the supply of blood); (2) Both for prospective MSM blood donors, and by extension for all gay men, there is a benefit in possibly reducing a social stigma, without any corresponding incremental risk.

The hypothetical benefit to gay men, above, may also be called a reduced risk of stigma, and when formulated in this way, one can see that changing the MSM donor rule in order to achieve this purpose would be, in effect, a covert risk transfer, i.e., a transfer of risk from male homosexuals to recipients of blood. As stated above, we agree that reducing the stigma associated with homosexuality is an incremental social good, but we also maintain that it is a good that more properly should be achieved in some other way, rather than through the specific change to blood donor policy under discussion here.

In this case the possible benefit to one set of persons can only be obtained by imposing an increase in risk upon an entirely different set. Moreover, the benefit in question is of a qualitatively different kind from that of the risk; the 2 are incommensurable. It would be a violation of very important ethical principles to create such a benefit for the one by imposing a cost of this kind on the other. Moreover, there is another, entirely different set of persons which would be a very small elevated risk under this policy change, namely, blood services employees (risks of needle-stick injuries and blood splashes). Thus there would be a second type of covert risk transfer.

In saying this we do not dispute the charge that the current policy is *prima facie* discriminatory. We also do not dispute the fact that the deferral period has the appearance of being arbitrary, since what was once a deferral, relating to specific behaviors, for ten years has now become one of

thirty years. Moreover, it is conceded that the huge advances in testing regimes during this period have changed the risk profile of donated blood.

On the other hand, the existing policy was originally adopted for good and sufficient reasons, based on urgent health protection objectives. In the intervening years many changes and improvements have been made in the combination of donor deferral policy and testing regimes; the net result is that the risk of transfusion-transmitted infection (TTI) has dropped considerably in the 20 years between 1987 and 2007. At this point the decisive question is whether the remaining residual risk at this time is so small that some very low additional risk to blood recipients, resulting from a change to MSM donor deferral policy, could be regarded as acceptable. In view of the fact that receiving blood for health reasons is an involuntary risk, incurred by individuals as a result of medical necessity, it is difficult to understand how the imposition of additional risk could be justified.

The episode of transfusion-transmitted HIV and hepatitis C in Canada was rightly regarded by those who suffered the severe effects as a betrayal of their trust in the blood system. Organizations representing regular recipients of blood products are on record as strongly opposing any change to MSM donor deferral policy that represents any avoidable increase in residual risk of TTI. In such circumstances, were the change to be imposed on blood recipients without their consent, it would almost certainly be interpreted by them as a second betrayal of trust.

<u>Conclusion – First Option.</u>

Taken by itself, and in the absence of any other changes to donor deferral policy, a shortening of the current MSM donor deferral period to 1 year would constitute a covert and unacceptable risk transfer *from* the male homosexual and bisexual community *to* the community of blood recipients. Such a transfer would be both unreasonable and unfair. The blood system can acknowledge the unfairness of the apparent stigma associated with homosexuality, but this is a broader social issue and must be dealt with in

other arenas; responsibility for dealing with this broader issue cannot be imposed on the blood system.

Second Option: Change to a 5-year MSM donor deferral policy.

We refer here to a set of hypothetical blood donors who would report no MSM activity for a period of 5 years prior to donation. Judged on the basis of the scientific studies completed to date, there is no clear evidence of an increased risk of transfusion-transmitted infection with a MSM deferral period of 5 years or more (although a very small increase in risk cannot be ruled out). In addition, a 5-year MSM deferral period represents a reasonable time-frame, according to expert opinion, within which to detect any novel pathogens that may be especially relevant to the MSM group (recent novel pathogens, including vCJD and West Nile virus, are not of this kind).

[It has been suggested that the case of human herpesvirus 8 may be relevant here, since a period of twenty years elapsed between identification of the virus (1986) and the first "compelling evidence" of its transmissibility in blood (2006).[31-33] There are four separate issues at stake here: (1) how long it takes for scientists to identify a previously-unrecognized infectious agent; (2) whether and in what way this new agent is capable of causing harm to health ("novel pathogen"); (3) whether the new agent is transmissible in blood *and* may lead to transfusion-acquired disease; (4) with respect to the specific topic of discussion in this paper, whether the nature of the new agent and its transmissibility in blood is relevant to the policy of MSM donor deferral. All of these considerations, taken together, do not appear to suggest that the case of human herpesvirus 8 would cause us to qualify the statement in the text about the reasonableness of a 5-year "precautionary deferral" to take into account the matter of novel pathogens.]

Therefore, this proposal appears to pass the risk hurdle.

Further Discussion: Second Option.

There are also reasons in ethics and law for changing the policy in accordance with the most up-to-date risk estimations, in that not to do so might be considered to be "unreasonably" discriminatory. Further, there could be significant long-term benefits, resulting from this policy change, both to blood recipients and to Canadian society in general, in that there is a potential for a small, but non-trivial, increase in the repeat blood donor cohort in the short term. And, in the longer term, removing what is perceived, by increasing numbers of people, as an unreasonable discriminatory barrier to donation, may increase the level of overall public confidence and willingness to participate in the blood system. Thus this policy change, if it is adequately supported by the current risk estimations, could be perceived as being appropriate in the light of changing public values and attitudes, as well as legal frameworks, with respect to homosexuality and the remaining stigma associated with it.

Analysis: "Passing the Risk Hurdle."

The decisive question is, do we have any clear evidence that there would be an increase in residual risk, if the deferral period for MSM donors were to be moved from the current thirty-year period to a five-year exclusion period?

The actual level of residual risk is difficult to determine precisely. However, current measures to reduce the risk of transfusion transmitted infection, including the use of sensitive chemiluminescent serological tests coupled with nucleic acid amplification testing, have resulted in enhanced safety of the Canadian blood supply. Chiavetta and colleagues estimated the transmission rate for HIV to be about 1 in 10 million donations in Canada in the year 2000.[34] This is similar to estimates reported in the United Kingdom and lower than estimates from the United States.[35-37] More recent findings by O'Brien et al, based on a comparison of predicted versus actual contaminated units suggest a slightly higher risk (1 in 7.8 million) than that estimated by Chiavetti.[8] However, within the limits of uncertainty, these two estimates are indistinguishable.

Germain et al calculated the incremental risk if a 1-year donor deferral policy for MSM would be implemented. They estimated 1 additional HIV-contaminated unit for every 136 000 new MSM donations, representing an overall 8% increase in HIV risk (a change from 1:1 million to 1:925,000 U).[19] Soldan and Sinka estimated the increased risk of a 1-year donor deferral policy to be approximately 60% in England.[38] These results suggest that a revised policy for MSM donors with a less than 5-year deferral period may be expected to lead to some increased risk of transfusion-transmitted HIV infection.

Using REDS data, Sanchez and colleagues recently estimated that the prevalence of reactive infectious screening tests among MSM donors who reported the practice within the last year to be 5-fold higher than among non-MSM donors in the United States. Although a similar increase in prevalence was seen among MSM donors who reported the practice within the last 1 to 5 years, there was no significant difference for donors who reported the practice more than 5 years ago. Sanchez et al came to the following conclusions: "Unlike men with recent male-to-male sex experiences, screening test results for donors who last engaged in male-to-male sex more than 5 years ago were comparable to those of male donors not reporting male-to-male sex, although the prevalence of UDRs was significantly higher [2-6 times higher]."[5] At the 2006 meeting of the FDA's Blood Products Advisory Committee, Andrew Dayton commented: "For MSMs who have abstained for more than five years, they basically had an odds ratio of one, suggesting that there may be something identifiable about a 5-year abstention that identifies a safe subset."[26]

Both the screening and testing regimes now in place for known pathogens, as well as the enhanced epidemiological surveillance for new and emerging pathogens, provide robust barriers against the chance that infectious agents will enter the blood supply. The residual risks now present in the blood supply are extremely low. (Residual risks of transfusion-transmitted infection are already so low in Canada that they cannot be

measured directly, but can only be estimated using mathematical models. See further the Appendix: What is Risk Estimation?) Although there is no clear evidence of an increased risk with a deferral period of 5 years or more, a small increase in risk cannot be ruled out. However, any incremental risk due to changing the MSM deferral period to 5 years could very well be so small as to have, in a statistical sense, no measurable impact on the current level of risk.

Therefore, would the policy change discussed here (changing the MSM deferral period to 5 years) pass the risk hurdle successfully? In the end, this is a matter of judgment, that is, a matter on which reasonable people may disagree. What we can say with some assurance is that, at the very least, it may provisionally pass the risk hurdle. [As the foregoing discussion seeks to point out, what is at issue here is a double risk hurdle: first, residual risk for currently known infectious diseases of concern; second, the risk of encountering novel pathogens. The conclusion – namely, that the 5-year exclusion period for MSM appears to "provisionally" pass the risk hurdle – applies to both.] In other words, it may be regarded as being "within the ballpark" for discussion. As a result, it is fair to ask if there may be other types of benefits that are likely to flow from making this policy change. These potential benefits are of 2 types: (1) a utilitarian benefit, namely, the possible impact on the size of the future donor pool, and (2) a non-utilitarian benefit, namely, the potential social benefit attendant upon reducing the perceived stigma associated with homosexuality.

<u>The Future Donor Pool.</u>

Some blood collection agencies, notably in the United States, have identified a concern that many persons among the next generation of prospective donors might be unwilling to donate because of a belief that current policy discriminates unfairly against MSM. On the basis of existing evidence, it does not seem possible to estimate either how likely it is that this attitude will be a factor in future behavior, or how large the pool of potential donors who fail to volunteer could be. What one can say is that the trajectory of

events, especially the growing protests on U.S. and Canadian college campuses, appears to be strengthening this concern.

Although Canadians are on the whole less likely to mount protests and legal challenges than their U.S. counterparts, there is more than enough reason to be concerned here as well. This is because, although the Canadian currents are more subdued, they may well run stronger and deeper than the U.S. trends. The best indicator is, of course, the state of the homosexual marriage issue as between the 2 countries. Whereas the individual-rights-based legal system in the U.S. would seem to give the advantage to that country, the social consensus in favour of this practice – especially among young people – developed more quickly, and solidified more quickly (into the "let's move on, it's no longer an issue for us" phase), in Canada. This is consistent with the more general values of tolerance, avoidance of "moralizing" about health issues (abortion is the best example), respect for multicultural diversity, and fairness, all of which have strong bases across the entire Canadian population.[39]

Also, it is just these types of values that are held most strongly by younger people. This is why the concern for what might happen in the next generation, including the willingness to donate blood, is a legitimate and appropriate one for blood collection agencies and governments. This is a matter of utilitarian benefit: Everyone who might need blood at some point in time in the future has an interest in the outcome. The prevailing MSM donor deferral policy can only survive the test of these Canadian values so long as the "risk hurdle" appears to represent an unchallengeable trump card in the argument. Indeed, this does appear to be the case, up to now. How long it will remain so is open to question.

<u>Perception of Stigma.</u>

There are very few rules involving non-criminal personal choices in our society that carry, as a penalty for violating them, a lifetime ban on being able to perform one of the noblest of acts, namely, donating blood freely and without recompense. That the 30-year rule (and counting) should seem to

many to be unjust and blatantly discriminatory should occasion little surprise. For is it conceivable that someone infected with HIV in 1977, as a result of a single act involving MSM, and still infected today, would be undiagnosed, would show no symptoms of AIDS and, in fact, would be still alive without the help of antiretroviral drug therapies? It seems impossible that such could be the case (although there may be rare exceptions). And then we could go on to ask: What if the year were 1978? 1979? And so forth.

The charge (or imputation) of engaging in immoral behavior – and the social stigma that almost always accompanies it – is a powerful and dangerous remedy for deviance in human societies. All too often in human history, murder and mayhem have been its accompaniment. The social values that counteract it – tolerance, respect for others, the individual rights philosophy, privacy – are still frail almost everywhere on earth, and even in our own country are not always secure.

Here we accept the premise that these social values are legitimate and that all individuals in society are better off where they are respected. We regard them as intrinsic goods that are intended to protect the dignity and worth of every person; they are among the preconditions for the maintenance of a good society and for individual self-fulfillment. We think that society and its agencies, including the blood collection system, should be always on guard against adopting rules that embody any kind of unreasonable discrimination, however unintentional, against allegedly deviant behaviors. The 30-year rule appears to fall into this category, and there are good reasons for thinking it should be changed. (One of the strongest ethical imperatives for changing the current policy exists with reference to a specific social group, namely, individuals who have a remote history of sexual abuse.)

This perspective compels us to conclude that, with respect to MSM deferral for blood donation, *we ought to accept no longer a period of deferral*

than what the risk hurdle can clearly support, using an evidence-based argument with a little help from the precautionary principle. In other words, we should "avoid trying to be more precautionary than our knowledge enables us to be."[10]

Earlier we cited the "2004 Ontario Men's Survey" to support the view that MSM remains a relatively high-risk activity, in general, and by comparison with what we know about heterosexual behavior. This justifies a choice of a 5-year deferral period, as opposed to a 1-year period, due to a reasonable apprehension about the possibility of the emergence of new pathogens, undetectable at first, which may circulate in blood and may, like HIV, be introduced and become established first in the male homosexual community.

We accept the view that current health surveillance methods make it unlikely that such a new pathogen would remain undetected for very long. We accept the views of qualified experts that a 5-year deferral period may provide sufficient protection against this threat, and thus may be an appropriate precautionary barrier against the possibility of a new round of transfusion-transmitted infection.

<u>Conclusion – Second Option.</u>

Thus, if it can be fairly said that there is no clear evidence of an increase in residual risk, then moving the MSM deferral period deserves further consideration by those who regulate and administer the blood collection system in Canada. It is possible that it may be determined, after such further consideration, which might include a wide public and stakeholder discussion, that changing the MSM deferral policy to a 5-year, or possibly 10-year, exclusion period, would be regarded as satisfying the criteria for risk tolerance, or risk acceptability, in Canada.

If this were to take place, such a change in MSM deferral policy could be said to give rise to at least some of the attributes of "Pareto optimality"

(also known as a "win-win" solution): Considered over a period of time that stretches into the near future, the members of each of the 2 social sets of persons most immediately affected by this set of issues (MSM, blood recipients) would be better off, as would Canadian society as a whole, and no individual or group would be worse off.

We acknowledge that this is, quite obviously, a matter of judgment. First, we arrive at the conclusion that, on balance, blood recipients will be at least no worse off as a result of this change, and may in fact be better off, because (1) there is no clear evidence of increased risk, and (2) there would be a lower risk that perception of unreasonable discrimination would result in a decrease in the pool of available, healthy donors over the long term.

Second, we arrive at the conclusion that male homosexuals and bisexuals would be better off because the new exclusion period (5 or 10 years sexually abstinent) is based squarely – and exclusively – on the results of a careful review of the scientific evidence, which is made up of studies of disease prevalence and of up-to-date estimations of the risks of infectious diseases in donated blood. Similarly, we argued against any shorter period of exclusion on the grounds that those other options did not satisfy either the demands of the risk hurdle or the ethical principles that ought to guide the formation of risk management policy.

9. GENERAL CONCLUSIONS.

The 2 fundamental principles, relating to donor deferral, according to which the current system of blood safety is administered are: (1) The primary basis for donor deferral rests on the assessment and estimation of the various types of risks associated with donated blood; (2) Any changes to existing policies on donor deferral must result in an improved or equivalent level of safety by comparison to what now exists. These principles apply equally to all donors and donor behaviors, including MSM. They are well-supported both by established risk management procedures and by important ethical considerations. [Many of the risk management principles,

discussed in this article, for donor deferral policies to reduce the risk of transmission of HIV and other infectious diseases via blood transfusions may also be relevant for other risks, including prion diseases.[40,41]]

The specific risk management issues considered in this paper, in the context of the 2 principles stated above, are: (a) What is the basis in risk estimation for the current MSM donor deferral policy, taking into account the MSM risk profile? (b) On the basis of risk estimation, what would be the net impact on residual risk, for transfusion-transmitted infection, if the lifetime MSM deferral period were to be changed to some specified, shorter period?

The foregoing discussion suggests the following summary response to these 2 questions. The risk estimation for the current MSM deferral policy is arrived at in 2 steps. Step 1 is a calculation derived from two primary sources of evidence: (*a*) Epidemiological data, for extended time periods, on HIV prevalence and incidence rates in male homosexuals, and a comparison of those rates with rates for other demographic groups; (*b*) Data from behavioral studies of MSM, indicating persistence of certain types of high-risk sexual activities. The inference drawn from this data is that there would be a higher risk of blood infected with HIV and HBV, and a comparatively lower incremental risk for HCV, from donations of MSM, by comparison with the current risk profile of both repeat and first-time donors.

Step 2 calculates, using 1 or more methods, the estimated residual risk after screening and testing. The estimation of residual risk, therefore, takes into account the possibility of one or more types of errors, such as: (i) window period; (ii) false-negative results; (iii) quarantine release of an infected unit (operational error).

Residual risk refers to various ways of estimating the risk that remains after the various types of protective barriers have been employed. Using the window-period method, RRs in Canada are currently estimated as

follows: HIV, 1 in 7.8 million donations; HCV, 1 in 2.3 million; HBV, 1 in 153 000. To be sure, there are uncertainty ranges in these estimations, but there is also clear evidence – based on the true positive results in tests – that there are a very small number of infectious donations which can escape the screening process and which are subsequently detected in testing. Since no technology or operational procedure performs perfectly at all times, it may be fairly concluded that, whatever the uncertainties, these RRs, although very small, are nonzero.

Changing the current MSM donor deferral policy in either of 2 ways – to no deferral at all, or to a 12-month deferral – is estimated to increase the residual risk of transfusion-transmitted infection for blood recipients. To accept a change of either type would be a clear violation of the following ethical principles: (1) nonmaleficence: there is a reasonable chance that harm could be done; (2) beneficence: any benefits do not outweigh the incremental risks; (3) justice: these changes would not be equitable, as between 2 social groups; (4) fairness: these changes fail the test of fairness because a benefit to one specific set of persons would be purchased at the cost of transferring incremental risk to another, quite different set.

Based on the evidence and risk estimations reviewed in this paper, it is not possible to state with assurance that changing the MSM deferral period to 5 years (sexually abstinent ≥ 5 years) would result in a measurable, incremental risk of transfusion-transmitted infection. The following points are relevant: (*a*) in the two published studies, normally cited during discussions about changing MSM deferral policy, Germain et al. and Soldan only calculate residual risk with respect to a hypothetical 12-month deferral; (*b*) the only published study of 5-year deferral (Sanchez et al) suggests that there may be no incremental risk in this case; (*c*) A 5-year deferral period may provide sufficient protection against the risk associated with new and emerging pathogens, although a further review of the consensus of expert opinion on this point may be needed. Quite obviously,

using a 10-year, rather than a 5-year, MSM exclusion period would provide an additional margin of safety.

If it were to be agreed that, for example, change to either a 10- or 5-year deferral period would pass the "risk hurdle," as defined above, then it would be reasonable to consider the possible, longer-term social benefits that may result from making such a change, including the lower risk that perceptions of unreasonable discrimination may compromise the continued availability of a sufficient pool of healthy blood donors in Canada. In addition, the change to either a 10- or 5-year exclusion period would provide a basis for collecting actual evidence of any changes to residual risk, as opposed to relying solely on the calculation of estimated risks.

APPENDIX: WHAT IS RISK ESTIMATION?

Risk is the combined product of the expected frequency of an event as well as the expected consequences, in terms of harm, that will occur if the event takes place. Each of the two dimensions of risk can be framed in terms of either quantitative or qualitative expressions, or both. For example, frequency can be expressed as chance, say, one-in-a-thousand or one-in-a-million; and consequences can be formulated as deaths, injuries, or property damage, which then can be converted into economic terms, such as dollar costs (in the form of insurance payouts, for example).

For the purposes of effective risk communication, qualitative expressions are often preferable. Table 2 gives an illustrative list of such expressions for both terms, and – in the form of a matrix – allows people to see how frequency and consequence can be combined into an overall judgment about relative risk.

Consequence / **Frequency**	**Catastrophic**	**High**	**Medium**	**Low**
Moderate	I	I	I	II
Low	I	I	II	III
Very Low	I	II	III	III
Minimal	II	III	III	IV
Negligible	III	III	IV	IV

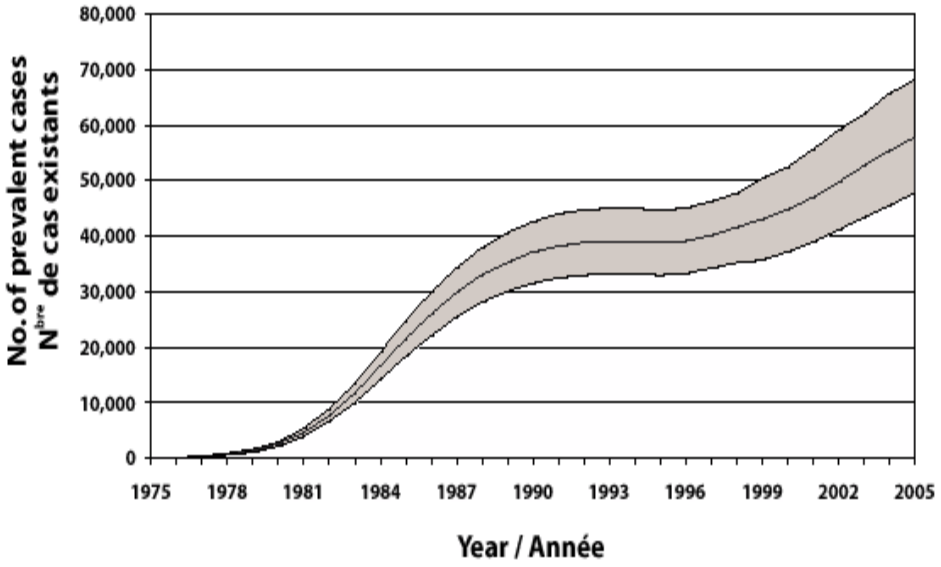
Risks may be assigned to various classes, representing degrees of urgency for risk control, such as in the following illustrative scheme:

Class I: Calls for urgent attention and significant risk control measures.
Class II: Risk control measures are needed.
Class III: A risk that should be monitored.
Class IV: A risk that does not need to be managed.

However, when risk is expressed in quantitative terms, risk estimates may be expressed not as single numerical values, but as ranges of values. This practice reflects that fact that risk estimates, by their very nature, are subject to a number of uncertainties.[40]

As noted above, the current expert estimates of transfusion-transmitted blood risks are normally framed in quantitative terms. These estimates are "residual risks," that is, risks that remain after safeguards such as donor screening and testing have been applied. For the three most serious infectious diseases, the most recent figures are: HIV, 1 in 7.8 million; HCV, 1 in 2.3 million; HBV, 1 in 153 000. In other words, for HIV, there is one chance in 7.8 million that a unit of blood transfused to a blood recipient will be infected with this virus.

Figure 1: Estimated number of prevalent HIV infections in Canada, including range of uncertainty, by year (Boulos et al[27])



But these numbers alone do not tell the whole story. The expert estimations are usually accompanied by "confidence intervals" (CIs), which is one of the ways in which the range of uncertainty associated with a risk estimate is conventionally expressed. To illustrate this point, consider the prevalence of HIV in the Canadian population as a whole referred to earlier. At the end of 2005, it is estimated that there were about 58 000 Canadians

living with HIV/AIDS, with an uncertainty range of 48 000 to 68 000. These estimates are shown at the extreme right edge of the diagram in Figure 1.

How are these figures determined? In this case, the experts (epidemiologists) start with reports of diagnoses made by physicians across Canada. HIV/AIDS is a "notifiable" disease in Canada, that is, a "disease deemed of sufficient importance to public health to require that its occurrence be reported to public health officials." Estimation of HIV risk starts with a compilation of actual cases, as reported by physicians. However, this may not represent the "true prevalence" of the disease, for a number of reasons – for example, those living with HIV, a disease with a long incubation period, who are not yet symptomatic or diagnosed will not be included in this compilation; as a consequence, the actual prevalence may be higher.

Because of these and other sources of uncertainty, epidemiologists must use a variety of statistical techniques in order to estimate the true prevalence; the specific techniques that are used are referred to in technical publications.[27] This is where the confidence interval is relevant: How certain can we be that the "true" number of cases has been indicated? In terms of our example, the range of uncertainty (48 000 to 68 000) is the 95% CI, meaning that we are 95% confident that the "true" number is neither higher that 68 000 nor lower than 48 000. (The numbers have been rounded to the nearest 1000; since the CI is not specified, it is assumed to be 95%.[27] The more confident we wish to be, the wider will be the range of uncertainty; for example, if we thought we wanted to be 99% certain about our result, the range of uncertainty would be wider than that stated here.) Another way of stating this point is to say that we can be a great deal more confident that the true number of people living with HIV/AIDS in Canada is somewhere in the range between 48 000 to 68 000, than we can be that the number is precisely 57 780.

With this background on uncertainties in risk estimation, we now return to the residual risk number for donated blood in Canada, using just the HIV number: Our best estimate is that there is a 1-in-7.8 million-chance that a

unit of blood will be infected with HIV. The 95% confidence interval gives us the following range of uncertainty: The chance in Canada that, at the time of transfusion, a unit of blood will be infected with HIV is about 1 in 20 million at the lower end, and about 1 in 3.6 million at the upper.[8] In other words, we can be very much more confident that the true residual risk number is somewhere between 1 in 3.6 million and 1 in 20 million, than we can be that the number is precisely 1 in 7.8 million.

Table 3 (O'Brien et al[8]): Residual Risk and Uncertainty Range Calculated by Two Different Methods

Method	**Residual Risk per Million**	**Uncertainty Range (95% CI)**
A. Incidence/ Window-Period	0.13 (1 in 7.8 million)	0.28, 0.05 (1 in 3.6 million to 1 in 20 million)
B. NAT-reactive, Antibody -negative	0.20 (1 in 5 million)	1.04, 0.03 (1 in 1 million to1 in 33 million)

Where estimates of risk are given for risks that are known to be very low, and especially when two estimates are compared, there is an inherent difficulty in giving a simple answer to the question as to whether or not one represents an incremental risk in comparison with the other. This point is illustrated in Table 3, which gives side-by-side estimates of the residual risks per million donations, for HIV in donated blood, calculated by two different methods.[8]

If one looks just as the single risk number itself, it appears that Method B yields a "higher" risk than does Method A. However, when the uncertainty ranges are specified, it can be noted that the range under Method A fits within the range under Method B: The two ranges overlap.

Therefore, within the limits of uncertainty about these two estimates, it is difficult to conclude which risk is higher or lower than the other.

What is the "bottom line" here? Currently, the residual risks for transfusion-transmitted infectious diseases in Canada are extremely low. As the risk becomes smaller and smaller, incremental risk becomes increasingly difficult to estimate. As is argued in the Chapter 2 paper in this volume, in any particular case where very low risks are concerned, we should not try to be more precise than the available evidence allows us to be.

ACKNOWLEDGMENTS

The authors thank Judie Leach Bennett, Mindy Goldman, and Sheila O'Brien, all of Canadian Blood Services, Ottawa, for insightful discussions. Professor Kevin Brand, Faculty of Management, University of Ottawa, provided valuable assistance for the Appendix. We also acknowledge the helpful comments of two reviewers.

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UPDATE 2017

The period since this article was published (2008) has been one of dramatic changes in policy about MSM blood donation in many places across the globe. And these changes are most relevant to the detailed discussion of risk control options in the latter part of that paper.

Donated blood holds a special place in civilized societies, and also a special place in risk calculus. In most of those countries, where donation is voluntary and unpaid, this act is regarded as the highest form of personal generosity and responsibility. But, at the same time, donated blood carries literally hundreds of risks for its recipients, and, if those risks are not adequately controlled, great tragedies can result, as was proved in the 1970s through 1990s in many countries, when two life-threatening illnesses, HIV/AIDS and Hepatitis C, were contracted by hundreds of people, including infants, from infected blood. Although the risks related to HIV and Hepatitis C are obvious, less well-known is the fact that agencies must address literally hundreds of medical and behavioral conditions for the possibility of serious risks to blood safety. In the current (2017) list of reasons for deferral published by Canadian Blood Services, there are about 50 *categories* of reasons; major categories include drugs, diseases, health, and viral infections.

In this context, the well-known high prevalence of HIV/AIDS among gay men presented a severe challenge to regulators and agencies which dealt with blood donations. Here robust evidence intersected with ancient, deep, and widespread prejudices against same-sex activity; but it was unsurprising that regulators responded with blanket, lifetime bans against gay men donating blood, since available risk control options were quite limited then. This policy choice was always controversial to some extent, but gradually became increasingly so due to changing attitudes, government policies, laws, and regulations regarding homosexuality, gay marriage, discrimination, and related issues. It was in this context that Canadian Blood

Services commissioned the study, by the McLaughlin Centre for Population Health Risk Assessment at the University of Ottawa, which was published shortly thereafter as the 2008 paper by Leiss, Tyshenko, and Krewski.

The key development was the emphasis in the 2008 paper, and in related publications in preceding years, on using *evidence-based reasoning* as the most important criterion for setting blood donor acceptability policies. Once this criterion was fully accepted and promoted by both government regulators and blood distribution agencies, significant policy changes were in store. Then the period after 2008 was marked by a flurry of supporting studies on MSM and blood donation, among them (full citations appear at the end of this section: note that is by no means a complete list):

1. Anderson et al. (2009), emphasizing the search for reliable and up-to-date quantitative estimates of risk;
2. Vamvakas (2009), demonstrating serious inconsistencies in blood agency risk control strategies;
3. Seed et al. (2010), presenting hard evidence of MSM risk based on Australia's 10-year experience of a 1-year deferral policy;
4. Wainberg (2010), arguing for the need to reconsider the lifetime ban;
5. Galarneau (2010), making the case that existing policy by the FDA in the U.S. was unjustly discriminatory;
6. Vamvakas (2011), strengthening the case for greater across-the-board consistency in risk control strategies;
7. Goldman et al. (2014), a Canadian publication by blood agency representatives giving reasons for the first change in Canadian policy on this issue;
8. Canadian Blood Services (2015), an important general review on this issue for the public; and
9. Borra et al. (2016), a strong European viewpoint, focused on the importance of evidence-based analysis.

Of the items on this list, it was Seed et al. (2010) which decisively broke the logjam on this issue which for decades previously had paralyzed the capacities of both regulators and agencies to consider significant policy changes in this area. And, of course, the great strength of Seed et al.'s contribution was that it was evidence-based. Their conclusion stated: "Notwithstanding these limitations there is no evidence that the implementation of the 12-month MSM deferral resulted in an increased recipient risk for HIV in Australia."

As these study findings were being disseminated and discussed, blood agencies began to undertake stakeholder consultations about changing their policies on the duration of deferral, including countries such as Canada which had (effectively) a lifetime ban for MSM. For example, Goldman et al. (2014) describes a stakeholder consultation process leading up to 2013 change by Canadian Blood Services to 5-year deferral. And by 2016, further examination of evidence-based findings, and additional consultations, reduced the deferral period to one-year sexual abstinence. As of the time of writing (late 2017), the current policy of Canadian Blood Services is as follows

There is no international consensus on an optimal deferral period for men who have sex with men, since the patterns, causes and effects of HIV infection differ by country. Currently many large blood suppliers such as the United States, the United Kingdom, Australia and the Netherlands have or are implementing a one-year deferral. In 2014, Australia's health regulator denied a proposal to move from a one-year, men who have sex with men deferral period, to six months. Men who have sex with men account for the largest proportion of new HIV infections reported in Canada. A one-year deferral period, which was implemented in 2016, was chosen as a safe incremental step forward in updating our blood donation criteria based on the latest scientific evidence.

In 2013, the ineligibility period was reduced to five years, replacing a previous regulation which affected men who had sexual contact with another man even once since 1977. Canadian Blood Services is exploring the possibility of moving toward a behavior-based screening criterion (https://blood.ca/en/media/msm). The last sentence is also important, as it refers back to the discussion in the 2008 paper about risk control options other than the so-called blanket deferral. Beginning in early 2017, Canadian Blood services and Héma-Québec announced funding for a new national research program, designed *inter alia* "to inform the development of an individual risk assessment donor policy (behavioral based) or to strengthen the existing policy (population based)." It is clear that the policy framework will continue to evolve on the basis of new findings in evidence-based research.

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CHAPTER 4

EXPERT WITNESS STATEMENT FOR THE AIR INDIA INQUIRY

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Prepared for the
Commission of Inquiry into the Investigation
of the Bombing of Air India Flight 182
December 5, 2007

Purpose of this Statement.

I will undertake an evaluation of the representations concerning risk assessment and risk-based decision making with respect to civil aviation security, as they have appeared in witness statements and documents submitted to this Commission of Inquiry. (See Appendix A for a list of transcripts and documents reviewed.)

General Summary of Findings.

There are numerous references to risks, risk assessment, and risk-based approaches in the documents I have reviewed. In general, it is safe to say, virtually all parties who have ongoing responsibilities for civil aviation security have affirmed to the Commissioner that they, and the organizations they represent, are using a risk-based approach and have been doing so for some time.

In not a single instance, however, has any one of these persons stated what he or she means by the phrase "risk assessment" or "risk-based approach." It is possible, of course, that each of them knows exactly in what sense he or she is using these phrases; it is also possible that each of them

knows full well what all the others mean when they use those phrases; and finally, it is also possible that all of them attach pretty much the same meanings to this terminology. On the other hand, it would be unwise to assume that such is the case in the absence of further evidence. The two outstanding issues are:

(a) Do all of these parties employ *methods* in risk-based approaches that are appropriate according to today's prevailing professional standards?

(b) Do all of these parties set *objectives and targets* for risk control and measure performance regularly against those targets?

Any agency that claims to be employing a risk-based approach should be able to provide to the public ready answers to these questions. These questions can be posed as well as answered without compromising in any respect the secrecy that is required for agencies whose mandate it is to provide an appropriate level of civil aviation security.

The fields of risk assessment and management are intended to represent an approach that

(1) is based on many different and specific inputs, using scientific and statistical analysis, and

(2) relies on a rigorous decision-making framework which only yields reliable results if it is complete.

All government agencies and large business entities in developed economies represent themselves as using risk-based approaches today. Indeed, this has become something of a "profession of faith." However, we have abundant proof that major institutions often fail to manage risks effectively, resulting in devastating consequences for individuals and entities that are affected by these failures. One example in recent years is Canada's failure to properly manage the risk of BSE (mad cow disease) in its national herd. A more recent example is the failure of major financial institutions, around the globe, to properly assess and manage the risks associated with certain types of debt instruments, where losses may eventually total hundreds of billions of dollars. All this means that assertions to the effect that some agency is

following a risk-based approach in discharging its responsibilities cannot always be taken at face value.

The Different Domains of Risk.

Risk is "the chance of harm." (In a business sense risk is also, of course, the chance of gaining an incremental benefit; this other meaning is not relevant in the present discussion.) As such, there are, quite literally, an incalculable number of discrete risks facing each of us in everyday life. These encompass our health, our financial well-being, the physical environment, personal and family security, our hopes for the future, and many other domains. In today's society many individuals as well as institutions attempt to bring to bear a disciplined perspective on risk, so as to control, at least to some extent, such key factors as lifetime health outcomes.

One of the main purposes of risk assessment and management is to provide reliable guidance as to which current risks are of the highest priority for risk control measures, as well as to how to allocate risk control budgets in the most cost-effective manner possible.

Overview of the fields of Risk Assessment and Risk Management.

The purpose of risk management is to *anticipate and prevent or mitigate serious harms that may be avoidable*. Each of the principal components of this definition requires a brief commentary:

1. "Anticipate" means developing the capacity to amass evidence in a timely manner so as to take proactive, cost-effective measures for risk control when the level of risk appears to be excessive (by some standard).

2. "Prevent": By removing a substance from further use, for example lead in gasoline or PCBs, we seek to eliminate all of the potential harms that continued use would have caused.

3. Through "mitigation," and by using the precautionary approach, we seek to reduce a substantial amount of the anticipated harms, even when the cause of the harm itself cannot be eliminated. (A good example is pandemic influenza advance planning.) The word "mitigation" is not always used consistently. This word has a variety of meanings, e.g., as referring to extenuating circumstances. But in the phrase "risk mitigation," it properly means actions "resulting in a lessening of severity or intensity." In practice risk mitigation means the same thing as risk reduction. Terminological precision is very important in risk management.

4. "May be avoidable": Most of the risks we face cannot be avoided entirely; however, it is possible that many of the more serious consequences from encountering them may be reduced, sometimes substantially.

Risk assessment [RA].

RA is always the first step in risk management. RA attempts to give a clear picture of the *likelihood* (or estimated frequency) and *consequences* of becoming exposed to a specific hazard. The level of assessed risk is the combined product of the estimated probability of an occurrence and its estimated consequences: The combined product is expressed as R = P x C and can be shown in a "risk matrix" (see Appendix D).

The seriousness of a risk issue can be a function either of its level of likelihood, or the level of consequences, or both. For example, there is a well-known class of risks known as "low probability, high consequence"; an example is a serious earthquake or a catastrophic failure at a nuclear power plant.

When reasonably good data is available, risks can be estimated in quantitative terms, e.g.: "In Canada today, the chance that a unit of donated blood will be infected with the HIV virus and escape detection is 1 in 7.8 million donations." (This is known as a *risk estimation*; sometimes it is necessary to specify which particular method has been used to estimate a

risk.) Where sufficient data is unavailable at a time when a decision is thought to be necessary, qualitative judgment may be used (e.g., elicitation of expert opinion from a panel of qualified experts).

All quantitative risk estimations have *uncertainty ranges* attached to them. For the statement about risk of donated blood given above, the uncertainty range – at the 95% confidence interval – is: 1 in 3.6 million (maximum) and 1 in 20 million (minimum). In ordinary language, this means that we can be 95% certain that the true risk is neither higher nor lower than the given range.

In this case the "bottom line" is that the residual risk of finding an infectious pathogen in donated blood, after screening and testing, is very low – but it is not zero. The "public message" based on this analysis is that the Canadian blood supply almost certainly has never been safer than it is now, but the responsible authorities remain very vigilant in this regard; their objective is to manage the full set of risks to a level that is "as low as reasonably achievable [ALARA]."

Risk Management [RM].

In RM the results of a risk assessment are fed into a decision process in which a number of other inputs are considered. Some of these are: risk control options analysis; legal, regulatory, and policy framework (domestic and international); cost-benefit analysis; public perception of risk; sharing of responsibility among agencies and other actors; and acceptable level of risk. (See illustration in Appendix E.) The relative importance of any of these factors, with respect to a particular risk, timeframe, and special circumstances, will vary, sometimes greatly.

Good risk management means adherence to a set of principles that reflect the "state-of-the-art" in this area. Some important principles are:

1. Risk managers must utilize RM methods and protocols (sequential steps) that are widely recognized by professional practitioners in the field.

2. Organizations responsible for managing multiple risks, of the same or different types, must have robust procedures for ranking risks and allocating risk control resources across the range of risks effectively.

3. Since risk is often a "dynamic environment," risk managers must have robust procedures in place to scan the environment for novel threats (anticipation of harms).

4. Even for threats that are well-known, risk managers must continually update their risk assessments and risk ranking based on new information.

5. Risk managers should be working to an explicit performance standard and be held accountable for achieving it (for example, a "continuous improvement" standard).

6. Organizations with responsibilities for managing serious risks should be able to report regularly, both to their stakeholders and to the public, on their performance with respect to risk assessment and management. [There are ways of imparting this information that do not compromise security.]

Application of the foregoing to the materials before the Commission.

As detailed in Appendix B, many of the reports and statement submitted to this Commission of Inquiry make explicit reference to the need to utilize both risk assessment and a "risk-based approach" to civil aviation security. The same is true about the testimony of many witnesses who have appeared before the Commission. Unfortunately, in none of the documents examined by me did I find any elaboration of what those who used this terminology think that it means, or any details about how this method and approach is actually used within any of the organizations which have responsibilities for managing the risks to civil aviation in Canada.

[The Special Examination Report on CATSA by the Auditor General (15 December 2006), pp. 22-3, discusses a 2006-7 "risk profile" prepared by CATSA and makes the following recommendation: "CATSA needs to better operationalize its risk management strategies by ensuring clear accountability for results, by ensuring all high- and medium-risk areas are addressed, and by providing more training to managers." CATSA replied as follows: "CATSA has an integrated risk management action plan in place for 2006-7…. A corporate process for tracking risk management is in development."]

At only one single point in the testimony I have reviewed was a witness asked specific questions in this regard. The following exchange occurs in Vol. 66, pp. 8241-2:

> MS. GRAHAM [IATA]: Again, I refer back to our risk-based approach to the screening of – to aviation security generally, and this also applies to the screening of airline and airport staff….
>
> MR. GOVER: And when we speak of a risk-based approach what tools do you advocate being used in assessing risk? How do we – how do we gauge this question of what the risk is?
>
> MS. GRAHAM: Again, this goes back to the regulator and to the governments and to the geopolitical aspect. There are many, many different layers of assessing risk and there is, again, no one-size-fits-all solution for assessment of risk because, depending on where you are, which airline you are, which government, which airports you're flying to, this all has to be included in your risk assessment. And your risk may be different depending on, as I say, the geopolitical aspects of the government that you are regulated by, the places that you fly to. And all of these things have to be taken into account when assessing risk.

The politest comment one could make is that the witness did not know the answers to the two questions. However, a short, informative, and perfectly satisfactory answer to these questions could have been provided in the following way: "My organization has adopted the tools and procedures for undertaking risk assessment and management from the [select from the following list]":

- Australian Standard 4360 Risk Management;

- Canadian Standards Association CAN/CSA-Q850-97 (R2007), "Risk Management: Guideline for Decision Makers" [available since October 1997];

- UK, HM Treasury, *The Orange Book: Management of Risk – Principles and Concepts* (2004);

- The Institute of Risk Management, London, UK, of which we are a member, and whose materials and training resources we rely on;

- Any of the above, "and incidentally we will be moving to the ISO Risk Management Standard, which is expected to be released in 2008";

- The Wikipedia articles on risk assessment and risk management.

From such an opening answer, an interesting follow-up dialogue might have ensued, dealing with how the methods and protocols were applied by the organization to actual cases, either real or hypothetical. And from such a dialogue, carried out with the representatives of a number of organizations concerned with civil aviation security, a reliable profile of the sector as a whole could be constructed, especially with respect to the existence of a shared knowledge base on how risk assessment and risk management is currently practiced.

A Note on shared oversight.

Issues of special concern are raised in any domain of risk management where responsibility is shared among two or more agencies or entities. This is because of the risk that something important may "fall between the cracks." In civil aviation security in Canada, legal and regulatory authority for all matters of safety rests with Transport Canada, but in practice the immediate responsibilities are shared between a number of different parties: Transport Canada, CATSA, airport operators, air carriers, and local police. [*Flight Plan: Managing the Risks in Aviation Security,* Sect. 2.4, pages 26-31.] In addition, intelligence information relevant to civil aviation security is provided to Transport Canada and CATSA by the RCMP and CSIS.

Civil aviation security is a prime example of an intensely dynamic environment of risk. This is not primarily due to the fact that there are

multiple categories of risk (e.g., passengers, non-passengers, cargo). Rather, it is because the risk sources include those terrorist groups that are presumed to be actively, and continuously, probing the international aviation system for areas of weakness in the risk control systems that can then be exploited to their advantage.

This means that the agencies that share the risk control responsibilities must be, to the greatest extent possible, "on the same page" when it comes to the methods and protocols they use for risk management. It means that each of those agencies must be capable of presenting the structure and protocols of its "risk-based approach" to its partners – clearly, completely, and updated on a regular basis. It means that those agencies must have addressed and overcome, at this point in time, any discrepancies in that set of protocols as a whole. It means that all of the partners know exactly what each of them is doing and that they can rely on the information and analysis that is provided to them by all concerned. ["The Auditor General is equally insistent that a risk-based approach is required, and has indicated her disappointment that Transport Canada 'has not fully implemented formal risk management.'" *Flight Plan,* p. 32 and footnote 32. Further: "We note with approval that Transport Canada has conducted at least one exercise in which aviation threats were assessed according to risk, measured quantitatively, and ranked. We also note that this has yet to occasion further exercises along these lines. *Flight Plan,* p. 33, footnote 33.]

This objective of seamless coordination can only be achieved if *all of them* are in the same room together, face to face, both on a regular and a when-needed basis.

"Roll-up" of shared risk management responsibilities.

Managing the risks for which one is responsible costs money. Since resources are always constrained, an institution's "risk budget" must be allocated across the full set of risks in some defensible scheme. The principle of cost-effectiveness (maximum benefit per unit of expenditure) can be used here, with the proviso that no important risk can be short-

changed: In other words, both public expectations and good business practices demand that corporations and governments should control specified risks to a level that is regarded as "acceptable."

There are at least four general domains of risk in civil aviation security: passengers, non-passengers, cargo, and fixed based operations (obviously, these categories can be further subdivided). Good risk management practices dictate that, so far as risk control objectives are concerned, *there must be no gaps in the system*: The whole set of risk domains must be managed so as to achieve performance outcomes according to a predetermined level of acceptable risk. "Air cargo operations represent a major security gap, perhaps the single most significant gap that has been brought to our attention." *Flight Plan: Managing the Risks in Aviation Security,* p. 48. And testimony of R. Whitaker, Public Hearing, 1 June 2007 (vol. 38, p. 4329): "Okay, among other gaps and vulnerabilities which we addressed and this is a very serious one and it was raised at the time of Air India, it was raised by Seaborn, and it's still being raised. And that has to do with air cargo and the inadequate, to put it mildly, the inadequate screening of air cargo."

If this cannot be accomplished in any one domain, either risk control resources must be rebalanced across those domains, or additional resources must be allocated. As the senior government authority with overall responsibility for civil aviation security, the Minister of Transport should receive from his or her department, on an annual basis, a certification to the effect that the resources allocated to each domain of risk are adequate to achieve an acceptable level of risk control objectives.

Recommendation.

The Commissioner should make a set of recommendations to the Minister of Transport to the following effect: that the Minister be able to satisfy himself or herself that all of the parties who share responsibility for civil aviation security in Canada:

(a) have a common set of protocols for carrying out risk assessment and risk management,

(b) are using risk management protocols and methods that are based on current best practices in these fields,

(c) are operating under a performance standard of continuous improvement, delivering levels of risk in all relevant areas that are as low as reasonably achievable, and

(d) have achieved acceptable levels of risk control in all of the domains of risk pertinent to civil aviation security.

APPENDIX A: LIST OF DOCUMENTS AND HEARINGS TRANSCRIPTS REVIEWED FOR THIS REPORT

Documents:

- Submission of the Air Line Pilots Association International to the CATSA Advisory Review Panel
- Submission of the Air Canada Pilots Association to the CATSA Advisory Review Panel
- Submission of the Canadian Airports Council to the CATSA Advisory Review Panel:
- Treasury Board Secretariat, Government of Canada Risk Management Policy
- Terms of Reference, Commission of Inquiry, 2006
- Transport Canada, "Aviation Security Technology Status," 2007
- "Flight Plan: Managing the Risks in Aviation Security," 2006
- The Auditor General's Special Examination Report of CATSA, 2006
- CATSA, 2007 Annual Report
- Seaborn Report, 24 September 1985
- Kirpal Report on Air India Flight 182
- Canadian Aviation Safety Board Report on Air India Flight 182

Transcripts:

Volumes 37, 38, 39, 40, 41, 42, 43, 65, 66, 72

APPENDIX B: LIST OF BRIEF CITATIONS FROM THE HEARINGS TRANSCRIPTS

Vol. 41, pp. 4946-7 (K. Sweet): "They use the term risk assessment, but how every airline implements that term, how every freight carrier implements that term, how every truck driver that carries the cargo to the airport defines that term, it all goes into the mix."
Vol. 42, p. 5085 (N. Cartwright, Transport): "… it's primarily a risk-based approach that we try and take."
Vol. 42, p. 5185 (S. Conrad, Transport): "… ensuring that we had a risk-based approach."
Vol. 42, p. 5208 (S. Conrad, Transport): MR. GOVER: "I suppose the point is you need to use a risk based approach. Is that right?" MR. CONRAD: "We certainly do."
Vol. 43, p. 5287 (Y. Duguay, Air Canada): "We need to look at standards, and we need to look at a different way to do the work that we do, ideally through a risk-based approach, where you have a security management system that is based on standards."
Vol. 65, p. 8115 (J. Bertram, RCMP): MR. GOVER: "And I take it, Mr. Bertram, that it's essential that you use a risk-based approach to security, is that right?" MR. BERTRAM: "… and so the risk-based approach to security we feel is the only long-term sustainable approach to dealing with security."
Vol. 66, p. 8219 (G. Graham, IATA): "… we do have and we do try to have a risk-based approach to security."
Vol. 72, p. 9017 (L. Scotton, Office of the Privacy Commissioner): MR. GOVER: "Is the Office of the Privacy Commissioner aware of any risk-based assessment conducted by Transport Canada to justify the implementation of this program [no-fly list]?" MS. SCOTTON. "We haven't received such a study, so the answer to that is no."

APPENDIX C: RISK MATRIX

Consequence / Frequency	**Catastrophic**	**High**	**Medium**	**Low**
Moderate	I	I	I	II
Low	I	I	II	III
Very Low	I	II	III	III
Minimal	II	III	III	IV
Negligible	III	III	IV	IV

Risks may be assigned to various classes, representing degrees of urgency for risk control, such as in the following illustrative scheme:

Class I: Calls for urgent attention and significant risk control measures.
Class II: Risk control measures are needed.
Class III: A risk that should be monitored.
Class IV: A risk that does not need to be managed.

UPDATE 2017

Report of the Commission of Inquiry into the Investigation of the Bombing of Air India Flight 182 (2010)

John C. Major, C.C., Q. C., Commissioner

Volume 1: Overview

http://publications.gc.ca/collections/collection_2010/bcp-pco/CP32-89-4-2010-eng.pdf

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EXCERPTS:

5.10 Risk Management [Pages 179-180]

Risk has been defined as the "chance of loss or harm" or the "probability that some discrete type of adverse effect will occur." Threat, which is present in security-related risk, is an expression of intention to inflict evil, injury or damage. A proactive approach to risk management is essential for a robust civil aviation security regime. The object of risk management is to reduce risk to a predetermined and acceptable level (often described as "as low as reasonably achievable" or ALARA). This object is attained by applying a reliable method for identifying the highest priority risks in order to determine appropriate risk control measures. This in turn assists in allocating resources in a cost-effective manner.

In 1985, the risk of sabotage against Air India would have ranked highly in a risk matrix. Moreover, risk management processes used at the time should have identified the June 1st Telex as having a significant impact on the perceived risk. The telex, sent to all Air India stations on June 1, 1985, contained a threat advisory from Air India's Chief of Vigilance and Security Manager. It was based on intelligence obtained by the government of India and reported that Sikh extremists were likely to sabotage Air India aircraft by means of time-delayed explosives being placed in the cabin or in checked baggage. It directed all Air India stations to implement counter-sabotage measures for flights at all airports. However, this telex was not shared with Transport Canada, and decisions were made to employ methods that were known to be of questionable value for the risk faced, or to waive protective measures where there should have been no
discretion.

The terms "risk-based approach" and "risk assessment" were used liberally throughout the Commission's hearings, but at times, those who used these phrases offered little explanation or had little apparent regard for their precise meaning. This may have created an illusion of rigor where the evidence may, in some instances, suggest otherwise. When pressed,

Transport Canada officials were unable to articulate a consistent means by which that Department manages risk in civil aviation security. Public confidence in civil aviation security demands that institutions with responsibility in this area provide adequate disclosure of the methods they use to manage risk. In addition, although civil aviation security is a shared responsibility amongst numerous stakeholders, there was little evidence of a coordinated, system-wide risk management strategy.

The Commission has concluded that, in the absence of a systematic approach to risk management, there is cause for concern that significant risks in civil aviation security may go unnoticed.

II. Risk Management [Pages 204-206]

Recommendation 6

6. Transport Canada should ensure that acceptable levels of risk control have been achieved in all areas of risk pertinent to civil aviation security in Canada. In doing so, it should adopt a national risk management protocol based on best practices and using a performance standard of continuous improvement, delivering levels of risk in all relevant areas that are as low as reasonably achievable. Where acceptable levels have not been achieved, resources must be allocated on a priority basis to address the risk appropriately.

6.1 To facilitate clear communication and understanding, Transport Canada should require those responsible for aviation security to follow a common set of risk management protocols consistent with the national protocol. Transport Canada should require all stakeholders to:

a. Provide a detailed description, in their respective security programs that are submitted to Transport Canada for acceptance or approval, of the risk management protocol employed for their operations;
b. Systematically employ these risk management protocols in the development and implementation of aviation security measures, policies, practices and procedures for their operations; and
c. Promote coordinated risk management decision-making by engaging in ongoing dialogue with Transport Canada and other stakeholders through participation in AGAS and its technical committees, and elsewhere as necessary, to ensure clarity, precision and a shared understanding of terminology and methodologies.

6.2 Each year, the Minister of Transport should certify that the civil aviation security regime in Canada possesses:

a. A common set of protocols for carrying out risk management, based on current best practices;
b. A performance standard of continuous improvement, delivering levels of risk in all relevant areas that are as low as reasonably achievable; and
c. Acceptable levels of risk control in all domains of risk.

6.3 Periodic assessment of Transport Canada's risk management protocol by the Auditor General is encouraged.

Recommendation 7

7. There should be no significant gaps in civil aviation security. When a significant deficiency is identified, the best interim measures must be implemented to address the risk while more permanent measures, including technological solutions, are developed.

7.1 The civil aviation security regime must be capable of redeploying resources so that all significant threats are adequately addressed and measures do not disproportionately emphasize a particular threat, such as the threat posed by passengers and baggage.

7.2 As soon as improved equipment and measures become available, they should be deployed.

7.3 If, after a systematic risk management process, a decision is made not to implement measures that address a given threat, measures should nonetheless be designed for emergency implementation if the threat subsequently becomes imminent.

7.4 Legislative initiatives to improve civil aviation security should not be subject to unreasonable delay.

CHAPTER 5

THE INTERFACE OF SCIENCE AND POLICY:
THE CASES OF OZONE DEPLETION AND CLIMATE CHANGE

Prepared for the Canadian Foundation for Climate and
Atmospheric Sciences,
"Symposium: From Research to Action," Ottawa, November 2005

Overview.

In contemporary industrial societies, there is an increasing degree of interdependence between scientific and public policy development. This is especially true in the broad area of global health and environmental risks. This interdependence suggests that we should be concerned about how to make the interplay of science and policy as "efficient" and "effective" as possible. In practical terms this means, for example, identifying specific obstacles to the attainment of a desired level of efficiency and productivity, as well as means of overcoming them. This paper uses the cases of ozone depletion and climate change in order to explore this subject. It sets up a simplified schematic diagram, describing stages in the pathways of both scientific and policy development, as well as specific feedback loops between the two domains. It raises two major questions for debate: (1) Is there an "ideal state" for science/policy interaction – using the area of climate change issues as the main case? If so, what are its characteristics? (2) Considering the situation in Canada at present, in terms of moving forward with the climate change file, what may be specified in terms of best practices for this interaction?

Introduction.

In contemporary industrial societies, there is an increasing degree of interdependence between scientific and public policy development. This is especially true in the broad area of global health and environmental risks: We cannot assess risks without scientific characterizations of the hazards,

and we cannot hope to manage and mitigate risks without having risk assessments in place. [Both health and social policy are other areas in which there is strong interest in what is called "evidence-based policy." For a good review and list of citations see Nutley 2003.] Managing and mitigating environmental risks occurs largely in the domain of public policy, because due to externalities, extended cause – effect connections, lag effects, and other reasons, individual actions alone inevitably are insufficient to address such risks.

This necessary interdependence of science and policy immediately gives rise to questions about the desirable or "ideal" state of the relationship between the two – as a practical, rather than theoretical, matter. Let us say that we wish to have a relation between science and policy that is "productive." What concrete objectives do we have in mind in this context? I propose that there are two sets of objectives:

"efficiency," including factors such as

- timeliness and ease of information flow;
- early uptake of novel research results;
- maintaining the requisite level of scientific competence;
- ability to set priorities;
- capacity for consensus-building in both domains.

"effectiveness," including

- development of robust policy options for risk management;
- ability to handle inevitable uncertainties;
- promoting public understanding of science;
- creating meaningful stakeholder engagement with industry and ENGOs;
- securing intergovernmental cooperation, both domestically and internationally.

[It is no accident that efficiency and effectiveness are regarded as the hallmarks of what is known as "smart regulation." There are many other ways of expressing the desired criteria for the characteristics of knowledge that is useful for policy. Haas 2004, p. 574 offers several lists from the

literature, including credibility, legitimacy, and saliency; or adequacy, value, legitimacy, and effectiveness.]

I hypothesize that the characteristics of a productive relationship, as specified in the criteria of efficiency and effectiveness listed above, would, if operative, create an ideal state of robustness at the interface of science and policy. However, taken together, they represent a necessary, but not necessarily sufficient, basis for the achievement of appropriate risk mitigation solutions. This will become apparent in the discussion of the comparative case studies of ozone and climate – in relation to which some commentators have raised very serious issues about what I may call the "forms of engagement" of climate scientists in the policy arena.

Two Key Case Studies: Ozone and Climate.

There is a considerable literature in the field of policy studies on the science-and-policy interaction in the case of ozone-depleting substances – and its relevance to the climate issue. R. Grundmann and others claim that leading climate scientists consciously chose the path to success laid down by their predecessors on the ozone file (Grundmann 1998, p. 36):

> The IPCC is modeled precisely after the WMO-UNEP assessment reports in the ozone case. In both cases, a standardization of scientific knowledge is seen as instrumental to get to the right policy decisions. This follows a linear or 'technocratic' policy model according to which first a scientific consensus has to be reached which then is transformed into political decisions.

Such a view has been described – in the policy community – as "naïve." And perhaps ozone was the exception, not the rule. [Indeed, as Haas 2004, p. 580 suggests, perhaps IPCC was formed precisely in an effort to re-establish the political control over the science/policy process which had been lost during the ozone years: "The IPCC was established in 1988 as the principal international science policy advisory body for global warming, but it is widely believed to have also been formed politically in order for governments to reassert control over the science process in an issue which was accelerating on the policy agenda more rapidly than most leaders in the North were comfortable with."] Grundmann adds: "In very many cases no

political action follows from conclusive scientific knowledge or consensus expert opinion because economic and political factors are much more influential." Let us first review the key milestones to date in those two cases, and then see what lessons might be drawn from the two taken together. Appendix I contains a highly selective chronology of key milestones in the two cases. These are some of the observations on the cases that are pertinent to the lessons I wish to draw from them:

A. The Ozone Case:

(1) A rapid formation of science consensus following the initial path-breaking publications (5 years);

(2) Formation of an early international policy consensus against determined political and economic opposition (U. K. government, DuPont);

(3) Formation of an international policy consensus during the time when the "science action" leaders were hesitating to draw policy-relevant conclusions. [The "science action" phase (see Appendix II) occurs when leading scientists become strong advocates of policy prescriptions; for the hesitancy in this case (Rowland), see the ozone file in Appendix I (1986 entry).]

(4) An environmental risk issue with limited impact on established lifestyles and seamless product substitutions (from a consumer perspective);

(5) A risk issue with dramatic "presence" (the ozone hole) and immediate and personal consequences of concern (skin cancer rates).

B. The Climate Case:

(1) A much slower formation of initial science consensus (1955? to 1985/1990);

(2) A "policy interruption" phase in the 1970s, freezing the early momentum in the policy arena on the issue;

(3) Much more limited international policy consensus [by comparison with ozone] for ratified and enforceable emissions reductions;

(4) Formation of a strong "science action" voice *against* a determined political and economic opposition;

(5) An environmental risk issue with profound potential impacts on established lifestyles, in terms of energy use patterns and other socio-economic and health impacts;

(6) A risk issue with limited personal "presence" in the short term (episodic extreme weather events) and remote consequences of concern (future rising sea levels, other vague and remote impacts); also, apparently contradictory types of impacts (cooling and warming).

For many commentators, item B (4) is a key factor in the comparison, and is the proof that a "science action" movement – where leading scientists act as spokespersons for dramatic policy-type actions – cannot triumph, at least in the short run, against opposition from powerful political and economic actors. But all of the differences listed above, as well as other salient ones, are relevant to the way in which the two issues have played out.

Commentary on the Ozone – Climate Comparison.

Reiner Grundmann of Aston University is one of the leading academic researchers on the relation between the cases of ozone and climate. What he calls "the technocratic policy model" is the idea that a scientific consensus can and should lead, relatively smoothly, to a policy consensus and, presumably, onward to policy action. In his view it is climate change that shows the limits of that model: scientific consensus is not the driving force of the policy process. However, his other point about the climate file is the more serious one (Grundmann 2002, pp. 412-413):

> In order to preserve a consensus (of which too much was expected politically), the scientific controversy was silenced…. The construction of the IPCC as an international epistemic community committed to a scientific consensus has proven, on this view, to be somewhat counterproductive. The drive to establish a scientific consensus robbed the controversy of an essential dynamic. ["Epistemic community," a term coined by Peter M. Haas (2001), is defined as "a network of knowledge-based experts or groups with an authoritative claim to policy-relevant knowledge within the domain of their expertise."]

Whether or not one agrees with this judgment, it has the virtue of forcing us to state a clear position on the issues at hand here: What do we mean by a productive relationship between science and policy in the case of climate change?

To answer this question, we may regard Grundmann's technocratic policy model as a useful foil. Its chief error is that it focuses on an outcome rather than a process. [There is much useful discussion, with many examples, related to this process-orientation in Haas 2004, who states that, as a rule, "science is seldom directly converted to policy."] A focus on process, on the other hand, would define a productive relationship between science and policy as one in which an elaborate series of feedback loops between the two domains are operating well. (See Appendix II for examples of feedback loops.) In other words, it is a relationship where the various outputs of scientists, from novel research results all the way through the statements of clear scientific consensus – which are recognized *on both sides* as having policy relevance – are taken up and evaluated seriously in policy deliberations.

The criteria of efficiency and effectiveness provide some benchmarks to ascertain whether that process is working as well as it should. But nothing in this conception implies that there can or should be any kind of direct chain from scientific consensus to policy consensus. Or, to use the words from the title of this Symposium, "[directly] from research to action." In the domain of environmental risks, risk assessments that are ultimately derived from basic science should be seen – by the policy community – as an indispensable and necessary ingredient in good risk management. But they are never sufficient, in and of themselves; they may be trumped by political and economic forces, which means simply that societies will have to live with the choices they make.

The science/policy interaction in the climate case has been strongly marked by such forces, which play these games by their own rules. The controversies stirred up by the community of "climate change skeptics" would never have reached the level of public attention they did, were it not for the financial backing of certain corporate and other interests. This has represented a strong influence in the U. S., where there continues to be an insistence that a full global policy consensus, including China, must come into being before that nation will agree to emissions-reductions targets (Stewart and Wiener 2003). In Canada, during the long run-up to Kyoto

ratification, and continuing thereafter, there has been strong and determined opposition to mandatory emissions-reductions targets from powerful economic and political sectors. These are realities against which even the strongest scientific consensus is powerless – at least, in the (relatively) short run.

Those of us – including myself – on the policy side of this equation ought to acknowledge other truths as well. The scientific consensus tells us that 60% reductions in anthropogenic emissions from 1990 levels are needed for the stabilization scenario for GHG concentrations. Is it not prudent to confess that we cannot now even imagine a "stabilized" policy scenario in which this is remotely possible? That we may be confronting a form of global environmental risk that we cannot manage? (Some have predicted that the level of "dangerous" climate impacts may occur at the 450 parts per million (ppm) threshold, and that the year 2010 is the date when the window for constraining climate forcing around that level will start to close: Speth calls attention to the 2002 O'Neill and Oppenheimer paper in *Science* where this prediction was first made.) Nevertheless, we are morally obliged to try!

Some perspective from other cases – which cannot be elaborated here – is helpful in this regard. Selecting a few from a longer list, one can say that the cases of tobacco, asbestos, and persistent organic pollutants illustrate well the dictum that the passage from scientific knowledge to appropriate policy action is often a long, troubled, and contentious one. These cases and others demonstrate that this troubled history can and does include episodes of bitter conflict over the meaning and application of knowledge, conflict which is sometimes exhibited in courtroom battles, often in intense lobbyist pressure on politicians, and occasionally even in deliberate attempts – undertaken by those with a claim to scientific credibility, and funded by economic interests – to obfuscate the scientific record and confuse the public.

The social, political, and economic stakes in the struggle over climate science and climate policy are so immense that no one should be surprise

that trouble has developed in the zone of the science / policy interface in this case. And it will get worse – indeed, much worse – before any definitive resolution of this tension is arrived at. The key question is what we should be doing in the meantime. And, I believe, our experiences with the climate file to date can allow us to draw some lessons, in the form of best practices, from what has happened so far. First, however, I would like to address briefly the contentious point, raised by Grundmann and others, about the "advocacy engagement" of leading scientists associated with IPCC. It may very well be true that experience with the ozone file led some scientists to exaggerate their expectations about the policy influence of science consensus.

Note that one can support this contention without accepting the legitimacy of any of the claims made by the so-called "skeptics" that the way in which the IPCC scientific consensus was forged was politically motivated and manipulated by certain scientific leaders. Haas, a reliable authority in these matters, affirms (2004, p. 582) that "there is no strong evidence that the state of knowledge about the phenomenon [of climate change] is directly biased or controlled by political influences." That said, he also argues that the IPCC outputs have very strong deficiencies as providers of "usable knowledge" for the policy process; his important argument may be found on pp. 581-4 of his 2004 publication. So what? Surely, the important issues are ones such as the following:

(a) Was the credibility of the overall climate science research effort – represented collectively in the peer-reviewed literature – significantly damaged as a result?

(b) Would the fierce opposition to mandatory emissions-control measures for GHGs, organized by powerful economic and political interests, have been less forceful or successful (to date) if those scientists had kept a lower profile?

(c) Would the majority of citizens, especially in North America, have supported necessary policy measures – especially the carbon (dioxide) tax, which will have to be implemented sooner or later – if these scientists had kept a lower profile?

In my opinion, the answer to every one of these questions is: No.

Let us move on. As I mentioned earlier, my own forecast is that the degree of contentiousness in this file will get worse, not better, as time passes. In other words, the climate file will represent a severe test for efforts by governments, all over the world, to maintain a productive relationship between science and policy. All, including Canada, will require both an appropriate set of principles, and a robust set of good practices, in order to survive this test.

Principles and Practices: Suggestions.

The key principles identified in the May 1999 report from the Council of Science and Technology Advisors, "Science Advice for Government Effectiveness," remain, in my opinion, an appropriate set of principles for this relationship. They are:

- Early identification of those issues for which science advice will be required;
- Inclusiveness;
- Sound science and science advice;
- Considerations of uncertainty and risk;
- Openness; and
- Review, which includes two principles: (1) subsequent review of science-based decisions; and (2) evaluation of the decision-making process.

On the other hand, "best practices" should provide concrete and practical guidance to departments, as adapted to particular policy files and to the current state of affairs. It is timely for us to consider such matters on the eve of the first Meeting of the Parties under the Kyoto Protocol, especially since Canada is the host (UNFCCC 2005). What follows is a first cut at specifying the most important best practices, and the issues that such practices should be capable of addressing, at the present time.

1. Review and modify, as required, and on a regular basis, the criteria for "efficiency" and "effectiveness" and evaluate performance on this basis.

Rationale: Specific criteria are needed in any framework dealing with the practical or applied aspects of a broadly-framed objective (here, seeking a productive relationship between science and policy). The criteria specified on page 2 above may be taken as a starting-point for an exercise of this nature.

2. Examine the key feedback loops at regular intervals and ascertain whether they are working well, or alternatively identify what improvements are needed.

   Rationale: See Appendix II for a schematic diagram of the science/policy interface. This diagram is intended to enable one to specify the types of feedback loops between the two domains that are needed in order to operationalize the objectives listed under efficiency and effectiveness.

3. Reaffirm commitments to providing adequate funding levels for both curiosity-driven and targeted research in climate change science.

   Rationale: Despite the significant level of investments in research of both types that has already been made, there is good reason – from a public policy perspective – to intensify this effort in the coming years. The basic reason for this is a simple one. As the reality about what is required for the GHG "stabilization scenario" to succeed gradually penetrates the public mind, the first (and most natural) reaction of citizens will be to question the science consensus. ("Why should we believe it, since it's mostly based on modeled data? Let's wait a while longer until we're really convinced." Et cetera.) The needed types of policy actions can gain public confidence only if new levels of research efforts are made, especially in targeted areas where – for example – results may be influential in increasing public confidence in the reality of "threshold zones" constraining the increase in GHG concentrations.

4. Greatly enhance the scope and content of public engagement efforts for climate issues.

   Rationale: The complexity of climate science is a significant barrier to public understanding of the issues and need for action. There are, to be sure, some good products to meet this need; for example, there is Environment Canada's (2002) web page, "Frequently Asked Questions about the Science of Climate Change." But a much larger effort is needed – not necessarily including the indulgence in expensive television advertising. Both the scope of the engagement itself, and the types of issues presented for public debate, must be significantly expanded.

So far as issues are concerned:

- Citizens need to understand the full scope of the challenge inherent in the stabilization scenario (it is not ethically appropriate to postpone this discussion);
- Citizens need to understand better the type of tradeoffs inherent in the strategies of mitigation and adaptation – especially for Canada, with its huge northern-latitude territory;
- Citizens need complex climate information (including the models) to be represented in sophisticated animated graphics;
- Citizens need to better understand the range of policy options for controlling GHG emissions.

On engagements: For all contentious issues of environmental science and policy, direct initiatives by governments should be complemented with third-party activities – which, in Canada, often must be funded by governments.

In these contexts, I usually recommend spending at least 50 cents in public engagement for every dollar invested in primary research. The research community reacts with alarm to this proposal, since many in that community see this as a zero-sum game, in which monies allocated for the public engagement exercises are "withdrawn" from research budgets. I cannot agree, of course. From a public policy perspective, unless public understanding of, and confidence in, the climate science consensus can be greatly enhanced in the coming years, there will be little or no support for the needed policy actions that will reallocate considerable sums within the family budgets of Canadian citizens. Should this come to pass, these same citizens will not wish to be presented with fresh scientific results purporting to show that they are being extremely unwise and short-sighted in their desire to wait and see what happens to the climate.

5. Use national-academy mechanisms for periodic review of "contentious" science issues.

> *Rationale:* The U. S. National Academies' 2001 response to questions raised by the Bush administration about the IPCC3 report was a key milestone in the simmering controversy over policy interventions by climate scientists. National academies in both the U. S. and the U. K. have been very active on this file for many years. Canada will soon have, for the first time, a similar capacity, and I hope that the federal

government will take advantage of this to request that certain specific topics be addressed by independent panels.

Concluding Comments.

- The nature of environmental risks – and especially, given its special complexity as a risk issue, climate change risk – reveals the close interdependence of science and policy;
- It is necessary to define what we mean by a "productive" relationship between the domains of science and policy;
- The comparison of the ozone and climate cases (in the record to date) displays both similarities and differences between them – but drawing the correct conclusions from the comparison requires due care;
- Given the scope of the social, political, and economic stakes in the climate change issue, no one should be surprised at the troubles that have developed so far, in so far as the relation of science and policy is concerned (and there is worse to come);
- Best practices for improvements in the science / policy interface, in the current context, include:
    - re-examining the key feedback loops to ensure that they are working well;
    - targeting new scientific research efforts, both inside and outside government, at the policy-relevant aspects of science that are especially pertinent to the new phase of international negotiation now starting;
    - enhancing the scope and content of the public engagement efforts for climate change issues.

Appendix I: Ozone / Climate Case Comparisons

A. Ozone Science/Policy Timeline (based on Benedick)**:**

1974: Stolarski/Cicerone and Molina/Rowland papers

1975: WMO, "Statement on Modification of Ozone Layer due to Human Activities"

1976 U. S. National Academy of Sciences, *Halocarbons: Effects on Stratospheric Ozone.*

1977: UNEP, "World Plan of Action on the Ozone Layer"

1978: (March) U. S. – followed by Canada, Norway, Sweden – bans CFCs in all nonessential applications

1979: U. S. National Academy of Sciences, *Stratospheric Ozone Depletion by Halocarbons.* (Updates 1982, 1984)

1981: UNEP Governing Council, resolution on working toward an international agreement on protecting the ozone layer

1982: UNEP, Stockholm meeting of 24 countries, Ad Hoc Working Group … for the Preparation of a Global Framework Convention for the Protection of the Ozone Layer

1983: First meeting of the Toronto Group: first discussion of reducing CFC emissions

1985: (March) Vienna Convention. Benedick, p. 45: "The Vienna Convention was itself a considerable accomplishment. It represented the first effort of the international community formally to deal with an environmental danger before it erupted." [U. K. leads opposition to any control protocol; no policy goal or methods on reductions are stated.]

(May) "Ozone hole" discovered (publication in *Nature*)

1986: WMO/UNEP assessment published (150 scientists, 3 volumes);

Rowland (writing in 1989): "… statistical evidence through 1986 gave no indication of any trend in global ozone significantly different from no trend at all."

Rowland (in 1986): "… the causes of the massive seasonal loss of ozone over Antarctica are not yet fully understood, and its implications for the ozone layer above the rest of the earth are also uncertain."

1986: (December) Beginning of negotiations on protocol. Countries having ratified Vienna Convention at that point: Canada, Finland, Norway, Sweden, U. S., Soviet Union.

1987: (July) NOAA: "… the scientific community currently is divided as to whether existing data on ozone trends provide sufficient evidence … that a chlorine-induced ozone destruction is occurring now."

(September) Montreal Protocol adopted

1988: (March) Report of the Ozone Trends Panel: the "definitive proof" of the effect, as well as projections of much greater ozone losses than previously estimated; call for phase-outs

(September) Vienna Convention in force

1989: (January 1) Montreal Protocol in force

(May) Reports from international scientific expedition to the Arctic, and Helsinki Declaration on the Protection of the Ozone Layer: new calls for additional controls and accelerated phase-outs

1990: (June) London Agreement on phase-outs (in force August 1992)

B. Climate Change Science/Policy Timeline (based on Fleming and Weart):

To 1925: Fourier, Tyndall, Arrhenius, Chamberlin

1950s: H. Suess, G. S. Plass, C. S. Callendar, C. D. Keeling: CO_2 measurements

1963: Conservation Foundation conference, New York: possible doubling of CO_2, impact on global temperatures, impacts on glaciers and sea levels

1965: First major scientific conference, "Causes of Climate Change," Boulder;
First U. S. National Academy of Sciences report, *Weather and Climate Modification,* 2 vols., on possibility of human influence on climate

1970s: the global cooling vs. warming conundrum: policy confusion

1979: U. S. National Academy of Sciences, *Carbon Dioxide and Climate* (effect on temperature of doubling of CO_2);
World Climate Conference and WCRP, Geneva

1981: James Hansen, article in *Science,* "Climate Impact of Increasing Atmospheric Carbon Dioxide"

1983: U. S. National Academy of Sciences, *Changing Climate*

1985: Villach Conference, "international consensus"

1988: James Hansen, statement to the U. S. Congress;
Toronto conference (limit GHG emissions);
IPCC formed by WMO/UNEP

1990: First IPCC report (identifies the need for 60% reduction in global emissions for GHG concentration stabilization scenario)

1991: U. S. National Academy of Sciences, *Policy Implications of Greenhouse Warming*

1992: UN Framework Convention on Climate Change (in force March 1994):

- Policy goal in Article 2: "stabilization of greenhouse gas concentrations in the atmosphere at a level that would prevent dangerous anthropogenic interference with the climate system."

- Policy directive (for industrialized nations) in article 4: GHG emissions to be rolled back to 1990 levels by 2000.

1995: IPCC2: "balance of evidence suggests a discernible human influence on climate"
Berlin Mandate (COP2), targeted reductions in various time-frames

1997: Kyoto Protocol adopted

2001: IPCC3

2002: U. S. National Academy of Sciences, *Abrupt Climate Change*

2005: (February) Kyoto in force

(February) Marc Jaccard, SFU, article in *Vancouver Sun:* policy recommendations for Canada (carbon dioxide tax)

(May) James Hansen, article in *Science* (empirical confirmation of model predictions, and thermal inertia and lag effect – with policy implications)

Appendix II:
List of Key Elements or Stages in the Science / Policy Interface

Science and Policy Elements:

S1 = First publications in top journals of new scientific results relevant to potential policy concerns

S2 = Additional peer-reviewed publications confirming, replicating, extending initial results

S3 = Major conference publications, NAS panel reports, expert committees, etc.

S4 = Scientific leaders urge policy action based on implications of science consensus

P1 = Early confidential discussions about potential policy implications, "watching brief"

P2 = Responsibilities assigned in agencies for policy analysis and development; early public communications

P3 = Announcements of policy directions, engagement of stakeholders and other nations, international bodies

P4 = International agreement and treaty development; national laws, regulations, policies, budgets

Illustrative Feedback Loops:

(1) Targeted research funding; sponsorship of conferences and workshops

(2) "Pressure" by scientific leaders / researches on the policy development process

(3) Regular interactions between scientists in government, industry, academia, including lobbying; battles over choices in policies and implementation strategies, both open and behind closed doors

(4) Regular interactions as commitments and policy options are finalized and research continues; or, negative feedbacks and calls for corrective action, targeted research, policy adjustment, etc.

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CHAPTER 6

RISK MANAGEMENT: WHY AND WHEN DECISIONS FAIL

Written October 2005 for:
American Waterworks Association Research Foundation, Project 2939:
"Risk Analysis Strategies for more Credible and Defensible Decisions"

We have had and continue to have serious outbreaks of waterborne disease in affluent nations. These outbreaks were preventable….
Safe drinking water is one of our best bargains.
(Hrudey & Hrudey 2004, pp. 3, xvii)

Abstract

Over the past thirty years governments and industry have created a paradigm for health and environmental risk management that is now widely accepted. This paradigm is incorporated into regulatory decision making as well as into standards and codes. It is designed to assist risk managers in reaching a threshold of "acceptable risk" (however defined) in all types of challenges, both in everyday routines and in crisis situations. And yet, all too often, the system breaks down, often in the most elementary ways. This paper examines some of the reasons for these breakdowns; one overriding cause of failure, it argues, is rooted in a failure to cut through complexity and focus on the "bottom line" – namely, the demand for continuous improvement in risk mitigation. This demand applies in all cases, even where attained organizational performance in risk management is at a very high level, because the strict focus on this goal at all times is the best guarantee against the subtle accumulation of seemingly trivial lapses that can accumulate and be transformed into catastrophic but preventable events.

Overview.

Decision making in the areas of health and environmental risks has become effectively standardized, in industrialized nations over the course of the last

forty years or so, with the use of a risk management [RM] approach. The institutionalization of RM in regulatory practice, and its expression in explicit, detailed, step-by-step manuals of procedure, means that there is no excuse for managers who fail to discharge their responsibilities in this regard. And yet high-profile failures abound, often with truly disastrous and avoidable consequences. There are of course many reasons for these failures. This paper will concentrate on explicating the following types of failures:

- *Type 1: Decisions fail because many organizations, in dealing with risk issues that develop slowly, do not pay attention to important changes over time in the risk profile, thus neglecting to notice that risk is not stable, but escalating.*
- *Type 2: Decisions fail because practitioners have not been taught to look for the bottom line in risk management: the daily delivery of incremental improvements in risk reduction and risk mitigation.*
- *Type 3: Decisions fail because practitioners do not realize that true public engagement in the work of risk management is a necessity, rather than something to be avoided or provided for in cursory fashion.*

A clear recognition of the seriousness of these types of failures and the severity of their potential consequences, and the development of a willingness within an organization to confront and overcome them, are the difficult steps. Actually, taking the actions needed to surmount them is the easy part.

The Risk Management Paradigm.

The "conventional paradigm" for health and environmental risk management in a regulatory setting evolved in Western nations over the preceding forty years. This was a linear, step-wise process having the following components, among others:

- Hazard characterization,
- Exposure assessment,
- Risk characterization and estimation,
- Management Options Analysis,
- Risk Management decision,

- [Risk Communication].

Typically, this procedure separated risk assessment from risk management: The former was regarded as a strictly scientific and technical procedure (the first three steps in the list above), whereas the latter (the last three steps) incorporates social, economic, political, and policy considerations. (The last step is put in brackets, both because it was often an afterthought and, in any case, was either left undone or done poorly.) Over the course of the past forty years governments and industry gradually became committed to this approach, and both accepted its application in a wide range of formal regulatory settings and for a broad range of risks – chemicals, radioactive substances, food- and water-borne pathogens, environmental contaminants, and so forth. The concepts, methods, and quantitative techniques are well established; they are summarized in many manuals of procedure as well as in national standards and in a major international standard that is soon to be issued (ISO31000).

The risk management approach has enormous advantages – for the public as well as for the institutions of business and governments – in economic, social, health, and policy dimensions. In essence, what RM allows us to do – when it is done well – is to manage our exposures to hazardous substances in a way that is both "acceptably safe" and cost-effective at the same time. And since everything we encounter is hazardous at some dose, this is a proposition with very broad application indeed. But it is not an unproblematic proposition.

Managing risk cost-effectively means to find the least-cost mechanisms for reducing risk to the level that is acceptable, and putting control measures in place to achieve this goal that are reliable. There are, to be sure, difficult challenges in actually carrying out this mandate, but the mandate itself is unproblematic. The problematic character of the proposition given above lies in its other dimension: The level where "acceptably safe" is set is always potentially controversial, by its very nature – which means that the element of controversy has to be recognized and "managed." The most important reasons why this is so are: first, since our

knowledge about risk changes over time, expert determination of acceptable risk also will vary, usually in the direction of lowering allowable exposures. [There is an abundance of such cases: For example, what are considered to be "safe" or acceptable levels of exposure to radiation (such as X-rays), lead (especially for infants), and fetal exposure to alcohol have been steadily reduced over many decades as a result of newer risk assessments.]

Second, as society changes, new values will change public attitudes towards acceptable risk, especially for infants and children. Third, well-publicized incidents of harm (such as the Walkerton tragedy) will also strongly affect the regulatory environment in specific areas.

The Three Key Failures.

As of now we know a fair amount about how to execute risk management decision making – and yet all too often we fail at it, and fail egregiously. For in many high-profile cases, the well-known procedures mentioned above are simply ignored. Some examples, the first two of which are discussed in the following sections, are:

- BSE in Canada (2003): The probability of BSE was quantitatively estimated, but the consequences were not (no agency in Canada is responsible for doing this); the result was a disaster waiting to happen.
- Walkerton, Ontario (2000): The most elementary rule of precautionary action in drinking water protection – maintaining the chlorine residual – was violated.
- Hurricane Katrina (New Orleans, 2005): Detailed studies after the fact show that proper engineering guidance based on risk estimations were ignored for decades, making this another colossal disaster waiting to happen (Team Louisiana 2006).

Many of these high-profile cases, of course, involve multiple types of failures in good risk management. In the discussion that follows, the three types of failure singled out in this paper are presented as "ideal types," with illustrations.

Type 1 Failure: Ignoring Changes in the Risk Profile.

The underlying objective of risk management is to (1) *anticipate* potential threats to health and to (2) *implement proactive mitigation measures* to reduce [sometimes: eliminate] their consequences. Sometimes, when these principles are ignored, the outcomes are much worse than anticipated, because the profile of the risk has been changing over time – in other words, what was assumed to be a static situation turned out to be a very dynamic one. This is what happened to Canada during its BSE crisis.

The zoonotic disease, BSE (bovine spongiform encephalopathy), better known as "mad-cow disease," has had devastating impacts around the world as it spread from its country of origin, the United Kingdom, to more than twenty other nations. The class of diseases to which it belongs, called TSEs (transmissible spongiform encephalopathies), has always presented a challenge due to their long latency or incubation period, during which infected individuals display no symptoms of the disease. First scientifically characterized as a novel spongiform disease in 1986, British scientists knew by 1988 that BSE was likely transmitted through infected cattle feed and took the first steps to controlling this route of exposure. But the political system in the U. K., seeking to protect its domestic and export markets for beef and beef products, resisted demands for full disclosure to both the British public and its trading partners of what was scientifically known, and estimated, for a full eight years thereafter. A meticulous book-length study by Van Zwanenberg and Millstone, as well as the record of a major public inquiry, fully documents the supporting evidence of catastrophic policy failure (Van Zwanenberg and Millstone 2005; BSE Inquiry 2000).

As the infection spread from one country to another over a period of decades, a number of those countries experienced especially severe impacts from BSE, but none more so than Canada, based on the ratio between the number of discovered cases of the animal disease and the sum total of economic and social impacts attributable to them. But, as is so often the case, the larger dimensions of this risk management disaster were entirely of our own making. Our federal scientists were aware that there was a "very high probability" that BSE was incubating in the domestic herd as of 1994, but the political-bureaucratic system chose to conceal its knowledge of this

risk estimation from the beef farmers, who in the period after 1994 were industriously enlarging the size of the herds in response to new opportunities in export markets. When the federal government analysts finally published their formal risk estimation, fully eight years later, they wrote it up in such as way as to discount the underlying risk. This was a disaster waiting to happen, and when it finally did, in May 2003, Canadian beef farmers were totally unprepared for it. There can be no doubt that serious deficiencies in Canada's risk assessment and management processes, then in place, were a significant contributing factor to the full scope of the adverse consequences that followed upon the first and succeeding cases of BSE (see Section 4 of W. Leiss et al., 2009).

Indeed, there is something tragicomic about the use of a formal risk estimation algorithm for BSE by CFIA. The original 1994 estimation has the look of a "back-of-the envelope" calculation, whereas the 2002 one took dozens of pages, in the form of a quantitative risk assessment (QRA) to explain in detail how all of the possible exposure pathways were combined in order to give a numerical probability of the risk of finding a single case of BSE in the domestic herd: 7.3×10^{-3}, with an uncertainty range falling between 2.2×10^{-2} and 3.7×10^{-4} (APFRAN 1994 and CFIA 2002). The 1994 document translated the risk into plain English in easily understood terms, referring to a "very high probability," but the later, far more elaborate, document downplayed the problem. The numerical probability mentioned above pertained only to the period prior to 1997, when a specific risk control measure (banning the use of ruminant material in cattle feed) was introduced, and the 2002 document concluded: "The risk was even further reduced by the mitigating measures in place since 1997."

This, however, was simply an arbitrary and unwarranted assumption, entirely unsupported by argument or evidence, which stands in stark contrast to the detailed QRA; it also turned out to be wrong, because a majority of the cases of BSE occurring in Canada are "BABs," cattle born after the feed ban was introduced. The tragicomic aspect of all this is that the earlier and simpler risk estimation was a far more reliable guide to the

actual risk, whereas the later one used complex modeling to – in effect – disguise it. But the earlier one was buried by the bureaucratic system and never publicly released thereafter, and thus could not be of help to the beef farmers who were later ruined by the loss of their export markets after Canada announced its first domestic case of BSE in May of 2003. [I have been working and publishing intermittently since 2003 on the BSE file, especially on the risk assessment and management performance of the Canadian Food Inspection Agency and other parties. On various occasions during that time suggestions have been made that my criticisms of CFIA's performance have been unhelpful and unnecessary, an experience which prompted a recall from memory of some maxims from my childhood: Everyone makes mistakes, including the critic; the relevant point is that, unless one acknowledges one's mistakes, opening the way to figuring out how and why they happened, one cannot learn from them and thus avoid repeating them.]

During all the time that elapsed between 1994 and 2003, no one appeared to notice that the risk to Canadian beef farmers, and by extension to the larger Canadian farm economy, had been escalating dramatically with each passing year. As the infection spread from country to country, nations importing beef became increasingly nervous, since anything that seems to compromise food safety is a highly sensitive matter. Although it had been a major beef-exporting country for some time, Canada displayed its own nervousness by shutting its borders to small imports from elsewhere (Japan, Brazil) on a number of occasions prior to 2003. Nevertheless, Canadian federal and provincial governments rolled out new economic development programs in the same period (1994 to 2003) to encourage beef farmers to expand the herds destined to be sold on export markets.

At the same time, the percentage of its beef destined for export, as opposed to that consumed within the domestic market, steadily increased. This was the basis of the dramatic, and unanalyzed, steady escalation in Canada's risk profile – the fact that, if BSE struck, and export markets were closed, the consequences would be worse with each passing year. When the decisive events occurred, and the borders were shut, Canadian politicians

and industry spokespersons first reacted with anger and then assured beef farmers that it was all a mistake and that the borders would quickly reopen. Alas, they were wrong, although why any of them honestly would have been surprised at what happened is the only real mystery in the affair (Leiss 2004, pp. 229-261 and 387-396).

Type 2 Failure: Missing the Bottom Line.

A hypothesis that cannot be proved, strictly speaking, but one that is supported by much case-study evidence, is this: Decisions in a risk management context – and disproportionately, the ones that have the most severe consequences – fail for the most trivial of reasons. This hypothesis is, of course, a variant of the thesis made famous by Charles Perrow in his book, *Normal Accidents* (Perrow 1999). Waterborne disease outbreaks around the world provide the best evidence in support of this hypothesis – in part because they have been so intensively studied.

According to the report of the Commissioner for the inquiry into the North Battleford, Saskatchewan episode in April 2001, which was occasioned by an outbreak of *Cryptosporidium parvum,* the city had no manual for the operation of its water treatment plants. No manual whatsoever. Period. Moreover, the group of senior city management personnel testified that *none* of them had any idea how the foreman of the plants department was carrying out his responsibilities. Furthermore, the city managers simply ignored requests from the provincial government department to have a performance evaluation done on its surface water treatment plant after a coliform event in 2000. The Commissioner concluded (Laing 2002, Part 6, pp. 196-8):

> There was a systematic failure on the part of the City of North Battleford to recognize its responsibility to produce safe drinking water. This failure was brought about by the City's collective lack of knowledge about what it takes to produce safe drinking water, and policies that discouraged the possibility it might acquire such knowledge.

The failure in North Battleford was not the result of a safety system defeated by a set of complex and mysterious challenges. The failure was that of a

managerial system marked by incompetence and ignorance of the most elementary kind.

About a year earlier (May 2000) another outbreak – in this case, of the pathogens *Escherichia coli* O157:H7 and *Campylobacter jejuni* – in the town of Walkerton, Ontario had left seven dead and over 2,300 ill, including many burdened with the prospect of lifelong disabilities. A list of the most egregious failures in this case would include (Hrudey et al., 2003):

- Knowledge by the provincial regulator *beginning in 1978* that a well through which the pathogens reached drinking water was vulnerable to surface water contamination – and yet no special operating conditions were ever imposed;

- Failure by the operator to monitor turbidity and maintain the chlorine residual (which would have prevented the tragedy);

- Deliberate concealment of the possible contamination by the operator (so that a boil water advisory was not issued until 10 days later), preventing other health authorities from being able to take earlier action that would have reduced the consequences of the contamination.

A unique aspect of the fallout from this case was the ability of inquiry leader Justice Dennis O'Connor to examine under oath both officials and political leaders in the province of Ontario – and, in this way, to determine what role politically-driven policy choices may have played in bringing about this tragedy (O'Connor 2001). Over the course of the previous decade, the Ontario Ministry of Environment's budget had been halved and its personnel reduced by 40% (Hrudey & Hrudey 2004, p. 120). This ministry was, among other responsibilities, the regulator for drinking water safety. The former premier of the province, Mike Harris, who had presided over the last stages of this *reductio ad absurdum* exercise, commented as follows during cross-examination on the witness stand (Walkerton Inquiry 2001, pp. 82:20-23, 247:8-11):

> Well certainly we weren't given any advice that any of the reductions and the actual dollar expenditures led to any increase in risk to health by any Ministry, including Environment … What is also clear is that that had any of those risks been felt to have -- or potential risks, been felt to have been real, we would not have proceeded [verbatim transcript].

As in the case of North Battleford, in the lead-up to the Walkerton tragedy the failures of the provincial government (to see any connection between drastic budget and personnel reductions and the risk profile of the drinking water system); of the regulator (to impose appropriate operating conditions on a risky well; to ensure adequate training of water system operators); and of the operator (to monitor turbidity and maintain the chlorine residual; to inform health authorities of an imminent danger) – were not precipitated by mysterious or complex challenges. Rather, they resulted from willful blindness, simple carelessness, and errors in procedure of a type that had been fully documented a century beforehand.

The North Battleford and Walkerton cases are exhaustively and incisively studied in the volume by Steve and Elizabeth Hrudey, *Safe Drinking Water: Lessons from Recent Outbreaks in Affluent Nations* (2004). Some comfort could be taken from these cases, were they shown to be exceptions. However, this does not appear to be the case. ["These high-profile incidents held much in common with previous waterborne outbreaks elsewhere in the developed world (Hrudey and Hrudey 2004). Most notable was the reality that the failures leading to this disaster and many others were failures to implement sound water treatment practices that were well known and established" (Hrudey 2004, p. 1555).]

The occurrence of basic failures in managerial oversight and staff performance has been extensively documented in other industries, notably the nuclear power stations operated by Ontario Hydro (now Ontario Power Generation). In 1997 an external audit by the Nuclear Performance Advisory Group (NPAG) rated the performance of the entire group of three nuclear stations – Pickering, Darlington, and Bruce – on ten different criteria: training, maintenance, engineering, emergency preparedness, operations, quality, radiation protection, chemistry, organizational effectiveness, and security (the security rating was classified). On *all nine* of the publicly-reported criteria, all stations were rated as either "below standard" or "minimally acceptable."

As a result, the group recommended that seven out of a total of nineteen reactors should be shut down and withdrawn from service. Their analysis of failure, contained in a report entitled "Nuclear Report Card: Ontario's Reactors are Minimally Acceptable" (July 1997), includes the following indictments (Nuclear Report Card 1997):

> There are significant numbers of managers at all levels of the nuclear organization who lack the basic management and leadership skills to be successful. They lack a fundamental understanding of the need for and value of a consistent, integrated managerial system.
>
> Employees lack a questioning attitude; deficiencies with safety systems are tolerated at all levels of the organization; procedures are violated and management is tolerant; justifying that "that is OK"; managers, staff and suppliers are not accountable for timeliness or meeting quality and safety standards. Staff are in effect rewarded for poor performance; training in safety and job-related accountabilities and authorities, procedures and tasks is insufficient or ineffective.

What I referred to earlier as the "bottom line" in risk management – the daily delivery of incremental improvements in risk reduction and risk mitigation – has been expanded by Hrudey into a more specific set of "principles" for total quality management in the drinking water industry. These include (Hrudey 2004, pp. 1559ff.):

- Anticipate and prevent harm rather than just reacting to problems;
- Set priorities;
- Seek actions that will achieve the greatest overall reduction of risk;
- Maintain vigilance and fight complacency.

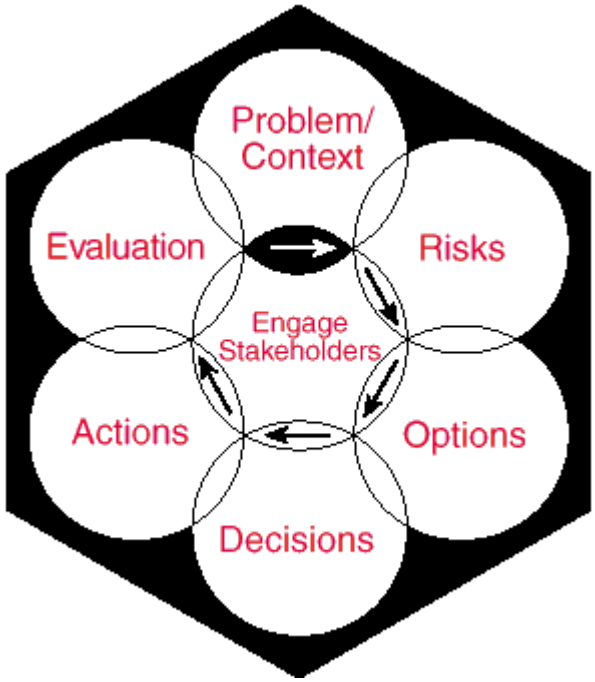
Although there are cases where failures are attributable to simple ignorance of accepted risk management approaches, failures also can and do arise from focusing on rote obedience to manuals of procedure – or from assuming that the successful achievement of regulatory benchmarks is an occasion for celebration and relaxation. For manuals reflect the "state-of-the-art" of best practices on the day they were written, and regulatory benchmarks enshrine (at least ideally) the state of scientific knowledge on the day when some

bureaucratic apparatus brought to a close its long, slow process of turning reliable knowledge into enforceable law. But when was the manual last updated? And how much time has elapsed (during which scientific knowledge has advanced) since the benchmarks were re-evaluated?

For effective risk managers, there is no appropriate end-state except that of daily vigilance and continuous improvement. Compliance with standards and regulations is a minimal, not maximal, achievement – a necessary, but not sufficient, basis for preventing the next tragedy.

Type 3 Failure: Undervaluing Public Engagement.

Every good RM plan, when carried through to the risk mitigation point, inevitably has implications for other agencies, businesses, and other external stakeholders. Therefore, a timely and open engagement with other stakeholders is an essential part of the plan – since it cannot be carried out successfully without their willing cooperation. It is fair to say that this element was entirely absent in the first phases of the development of the conventional paradigm of risk management.



But there was an entirely new turn in this conception in 1997, with the appearance of the two-volume report of the U. S. Presidential Commission (1997) on Risk Assessment and Risk Management. Its logo is shown just above.

Every aspect of this diagram marked a sea-change in the conception of the RM process. Notable features are its starting-point, in "context," and its representation of the overall process as an interconnect series of circles. But the most dramatic feature is the centrality of the "engage stakeholders" circle as well as its connection with every one of the other stages in the process as a whole.

The "separation" of risk assessment and risk management, which had been the hallmark of the earlier phase, was effectively undermined in the new conception. It had been challenged more and more frequently by groups outside of the formal regulatory framework – public-interest groups, community-based associations, and citizens among the general public. Certainly this challenge had a basis in resistance against the frequent use of complex technical jargon and statistical expressions in the risk assessment exercises, and also in the common failures of risk managers to make any decent effort to communicate effectively with the public (Leiss and Powell 2004).

Second, risk managers failed to realize that their decision-making exercises had the characteristics of a "black box": the decision inputs may have been described in detail, but all too often the logical connections between the inputs and the output (the decision) were not at all self-evident. Finally, this resistance had another, more general grounding in the decreasing level of trust on the public's part towards the institutions of industry and government. The result has been that risk managers regularly face the threat that the public will disavow or resist their elaborate attempts to rationalize regulatory decisions by using the language of risk assessment and management.

Examples abound. Quite recently, Health Canada's reassessment of the health risks of the pesticide 2,4-D, some fifteen years in the works, has been largely ignored by municipal officials and citizens who are determined to banish lawn pesticides from their cities (PMRA 2005, Flora 2009, Healthy Lawns 2009). There are long-running controversies about what experts believe are small risks, such as those arising from dioxins or endocrine disruptors, a belief that is not shared by many citizens (Emcom 2009). Public health officials in many countries face tremendous challenges in the face of widespread public skepticism about the safety of vaccines, where the societal risk/benefit calculus appears to greatly outweigh the small individual risks of adverse effects (Vaccination 2009). And large segments of the public in Canada and elsewhere – as well as a fair number of people with some expertise in risk matters – do not appear to accept the case for the safety and operational integrity of nuclear energy plants which is presented by the nuclear industry and the many governments which have supported that industry for decades (Nuclear Safety 2009).

Increasingly, therefore, risk managers in government and industry are faced with public reactions to the risk management approach which are far more complex than has been generally imagined. They are obliged by regulatory requirements to carry out risk assessments within a standard risk management framework, but more and more they must also be prepared to engage the public directly on a larger set of issues surrounding the risk-based approach, issues that are framed by types of concerns that are deeply rooted in popular opinion.

In more technical terms, risk managers face the situation where the public perceptions about risks can deviate substantially from their own – and, increasingly, risk managers are unable to simply take refuge in their expertise and remain indifferent, or hostile, to those public perceptions. Competence in risk management must be complemented, these days, with a very different type of expertise – namely, competence in engaging stakeholders and the public on matters of risk acceptability. [Stakeholders are individuals, informal groups, communities, corporate entities, and organized interest groups who have a *prima facie* entitlement to be involved

in public decision-making processes. Normally, some agency of government, or a body otherwise authorized by government, will have the responsibility for the liaison function with stakeholders, for any specific decision process. Also, the "rules of engagement" are almost always informal ones, although in some cases there are formal administrative-law procedures in place for such events.

Stakeholder engagement is one of the commonest forms of the more general process, "public participation in decision-making"; the latter is enshrined as a fundamental right of all peoples in the United Nations' "Aarhus Convention" (1998). Since effective participation depends in the first instance on adequate provision of information to the public about environmental matters, this Convention enshrines a presumption in favor of public release, putting the onus on authorities to justify any restrictions and establishing a specific list of exemptions where withholding information is justified.

The Risk Calculus in the Context of Stakeholder and Public Engagement.

Risk managers will always have to do their work while being aware of certain parameters of uncertainty so far as the determination of acceptable risk – at any particular point in time, and with respect to their specific type of business – is concerned. In layman's terms acceptable risk is "safety," and there is an excellent formulation of what this means (Hrudey & Hrudey 2004, p. 4):

> A pragmatic notion of safety is a level of risk so small that a reasonable, well-informed individual need not be concerned about it, nor find any rational basis to change his/her behavior to avoid a negligible but non-zero risk.

This is an eminently sane proposition. But every risk manager needs to be fully aware that here he or she is in what may be called a "permanently contestable zone." In other words, both what is or should be a matter of "concern" to anyone, and what a "reasonable" response – especially by someone in a position of responsibility – is to that concern, are always

disputable. Only by keeping this elementary fact always uppermost in mind can risk managers hope to succeed in their difficult endeavor.

What the risk manager knows – or should know, in someone else's opinion – at any particular point in time, about all the risks pertinent to his or her area of business, as well as what management decisions are taken (or not) based on that knowledge, goes to the heart of the risk management enterprise. This can be well illustrated by the recent controversies surrounding the risks associated with the class of drugs known as cox-2 inhibitors (Vioxx, Celebrex, Bextra and others). Here is one commentary on the situation:

> Internal company documents show that Merck employees were debating the safety of the drug [Vioxx] for years before the recall. From a scientific perspective, this is hardly damning. The internal debates about the drug's safety were just that – debates, with different scientists arguing for and against the drug…. And there's no clear evidence that Merck kept selling Vioxx after it decided that the drug's dangers outweighed its benefits. While that kind of weighing of risk and benefit may be medically rational, in the legal arena it's poison. Nothing infuriates juries like finding out that companies knew about dangers and then "balanced" them away (Surowiecki 2005, p. 38).

The lesson – and the dilemma – here is a simple one: No risk manager can avoid making judgments about both the acceptable level of risk, because risk is never non-zero, or about what the right balancing of risk, cost, and benefit is at any time. And these are just the kind of judgments that can get one in serious trouble when things go wrong, as they will.

One of the greatest difficulties in this dilemma is what to tell your stakeholders and your public about what you know, when you gained this knowledge, what in that knowledge may be relevant to their concerns about risks, and what decisions you made (or not) based on it – including decisions about what you decided to share with them. This is one of the primary *organizational risks* associated with the practice of good risk management. There is no perfect solution to this dilemma. The main point here is that an organization should be aware of this "double layer" of potential responsibility (and, of course, liability): The duty to conform to regulatory

and/or ethical standards of good risk management practice, on the one hand, and the need to manage the organizational risk of doing effective risk management, on the other.

I shall make only one type of recommendation here. In general, and "all other things being equal," I believe that a strong case can be made for full and timely disclosure to the public of all risk information relevant to the organization's line of business, including disclosure of the management decisions made on the basis of current information. That said, there is a necessary precondition, namely, making an effort on an ongoing basis – which means investing time and resources – to enlarge the public's understanding of the language of risk itself.

The reason is that risk is a devilishly tricky language, for so many reasons – the essential difference between hazard and risk, the differential level of consequences for exactly the same level of exposure (as influenced by age, gender, genetic factors, etc.), the mysteries of statistical expression, the inevitability of uncertainties, and so forth. The public needs help in this regard, help from sources whom they can trust. "Raw" risk data is almost never helpful, but on the other hand, interpreting the data fairly and honestly can sometimes get one into trouble. A lot of practice helps, as it usually does for difficult tasks of all types. So the sooner one starts, the better off one will be.

By and large, I think it is fair to say that the basic logic of the Presidential Commission logo – putting the "engage stakeholders" theme at the center of all risk management activities – is a long way from being implemented in most organizations that manage risk. Rhetorical obeisance to this paradigm is common, but rarely is it matched with the one thing that could turn it into reality, namely, an appropriate allocation of the organization's resources and commitments. And yet, as citizens become more adept at accessing pertinent information (using the Internet) and at confronting organizations with different perceptions of risks, decisions that essentially pay lip service to the "engage stakeholders" mantra increasingly will fail.

Conclusions.

The established practices in risk management have proved their usefulness in controlling within acceptable levels risks in a countless range of practical applications. However, these practices are not without their own challenging complexities, especially when it comes to the technical side of the business, namely, quantitative risk assessments. These complexities do not only bedevil many members of the public, who can react badly when risk managers fall back on technical jargon, such as probabilistic expressions, in an effort to explain what they are doing and why the public should trust them.

This much is fairly well known by now. Less well known is the challenges faced by organizations in training their personnel to zero in on the most essential requirements of the risk management approach – as opposed to, for example, focusing only on completing the steps in the manual of procedures. These essential requirements may be summarized as follows:

1. Complete – and continuously update – the risk profile pertinent to the organization and allocate resources in proportion to the results of the risk ranking matrix.
2. Mandate continuous improvement in risk reduction and mitigation for all of the most highly-ranked risks that are to be managed.
3. Make stakeholder engagement the real and vital center of the risk management enterprise.

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CHAPTER 7:

SMART REGULATION AND RISK MANAGEMENT

Written November 2003
At the request of the Government of Canada, Privy Council Office,
External Advisory Committee on Smart Regulation (EACSR)

Overview.

This paper places the discussion of "smart regulation" in historical context – first, the history of controlling health and environmental risks in modern economies, second, the more recent history of the preceding decade, during which reviews of regulatory effectiveness have taken place. The history of risk regulation itself is the story of how modern societies constructed an "invisible shield" around individuals and social groups, in areas such as finance and markets, criminal behavior, family and child welfare, public health, and industrial workplaces. Taken as a whole, these protective measures have become a dense structure of overlapping provisions for personal security, or what is referred to as a "risk regulation regime." This structure is dynamic and not static and is in fact changing constantly. It is also a dense and complex structure, and so any attempt to revitalize it (in terms of effectiveness and efficiency) must be done with due care and attention to public expectations.

This is followed by a short explanation of the "risk-based approach," which lies at the heart of any risk regulation regime. Then we turn to the more recent history of regulatory review, which has taken us through concepts such as regulatory efficiency, regulatory effectiveness, and regulatory burden; "instrument mix" (referring to the array of policy instruments through which we seek to implement regulatory objectives); and the optimal policy mix. Each of these concepts is briefly explored.

The paper includes a proposal for "a way forward," in which it is suggested that we should develop the capability to conduct controlled experiments with regulatory structures. This paper makes the following specific recommendations:

1. Central agencies should establish an Office of Integrated Risk Management to oversee and assess the risk/risk tradeoffs that occur as a matter of course.

2. The Government of Canada should create and implement a wider set of policy instruments for risk regulation than what now exists.

3. A credible and transparent methodology for assessing the comparative efficiency and effectiveness of policy instruments for risk regulation should be developed.

4. The federal government should design and implement a robust method for risk forecasting.

5. Canada should be in the forefront of the creation of additional international assessment organizations to assist our national risk regulation regime.

6. Canada should undertake controlled experiments, using a transparent evaluation methodology, in seeking to improve the efficiency and effectiveness of our risk protection structures.

Introduction.

Health and environmental risk management – and the subset of that activity which may be called risk regulation – has been an active area of public policy debate, in Canada and elsewhere, during the past decade or more. Very active debates have occurred in both the United States and Australia during this period, for example (Executive Order 1993, Grabosky & Braithwaite 1993). In Canada, these debates have been oriented around such episodes (at the federal level) as the introduction of the "Regulatory Efficiency Act"

(Bill C-62, 1994); the renewal of the *Canadian Environmental Protection Act* (1999); and Health Canada's proposals for "renewal" of the traditional basis of its legal and regulatory authority, the *Food and Drug Act* (Health Canada 2003; Canadian Health Coalition 2009; Picard 2003a).

Along the way, a good deal has been written about such concepts as "regulatory burden," "voluntary initiatives," an "optimal policy mix" for environmental policy, and others. I take the view that the present discussion about "smart regulation" ought to be understood as another step in this broader discussion, and what I have to say in this paper is framed accordingly. The second consideration, which also frames my analysis, is the need for an awareness of the long history of health and environmental risk management in Western democracies, stretching back over more than a century and a half. Again, in my view, no current discussion which ignores that history – and the challenges which are still presented to us, as recent episodes (such as SARS and BSE) illustrate well – will prove to be either relevant or enduring.

That said, it must be recognized that these present-day challenges have been severe and unrelenting – and there will be more of them. They are also very expensive, in terms of economic impacts. All of which means that Canada must re-examine, on an ongoing basis, the way it conducts the business of risk regulation. There *must be* a way forward, in the sense of – at the very least – devising practical, real-life experiments in finding ways to achieve our collective objectives in health and environmental protection both more efficiently and more effectively.

The single most important caveat to be added here is, these are areas of great public sensitivity, in part because the public is aware of terrible tragedies – notably in the blood system and at Walkerton, Ontario – which are the direct outcome of *mistakes in regulatory policy and practice*. [These mistakes include making changes to the existing regime that were precipitous and thoughtless, and made without having in place a mechanism for the prediction of expected outcomes. See below, Section F.]

In my view, the mistake that has been made so far in Canada, among those desirous of effecting changes in risk regulation, is to want to run before they have learned to walk. In other words, as indicated in the sections that follow, in some cases the proposed changes to established policy and practices have been far too sweeping and indiscriminate, having been based on either a superficial analysis – counting costs while ignoring benefits – or on an ignorance of the scope of the possible costs (human and economic) of the mistakes that have been made. The appropriate course of action, in finding a way forward is to:

(a) Identify a number of well-defined and limited areas of risk regulation where change might be desirable;
(b) Apply a robust methodology for comparative assessment;
(c) Design experiments *based on predicted outcomes*;
(d) Evaluate the results – under full public disclosure and transparency, and without ideological preconceptions – as to their degree of success or failure.

In the risk analysis literature of the last decade a huge amount of attention has been devoted to the issue of trust and credibility (Poortinga and Pidgeon 2003). Anyone who works in this area, either as an academic analyst or as a practitioner in government or industry, ignores the dimension of public trust at his or her peril. In the general area of risk management, the factor of public trust grows in importance with each passing year. Finding a viable way forward should be done with the objective of retaining public trust uppermost in mind.

Historical Overview: Risk and Regulation.

Seen from the angle of public policy, health and environmental risk regulation in Western democracies may be said to have begun with the episode of the "Broad Street pump (2009)." In 1854 a physician, John Snow, investigating another in a series of cholera outbreaks in London, England, associated excess mortality with a specific source of contaminated water; his findings not only launched the discipline of epidemiology but also the practice of science-based public health strategies. The victories won since that time, especially in the control of infectious disease through sanitary

measures and surveillance, are the enduring foundations for the entire edifice of risk management.

The later phases of risk regulation include: occupational health and safety regulation and workers' compensation schemes (late nineteenth and early twentieth century); consumer protection legislation (food, drugs, and product safety), dating from the first quarter of the twentieth century; and comprehensive environmental protection legislation, starting in the 1970s. In all these areas, of course, there is lively and ongoing debate about what works and what doesn't, and why.

Over a period of more than 150 years, therefore, modern society has constructed what may be called an "invisible shield" of protection for individuals and collectivities, embracing many and diverse types of risks. The major categories of protection include:

1. Health and environmental risks;
2. Markets, banking, insurance, finance, contracts, business practices;
3. Regulation of labor and professions (medicine, law, accounting);
4. Public safety and security (criminal code);
5. Family life and child protection;
6. Industrial standards (products, processes);
7. Animal welfare.

The areas of life that are regulated or controlled include many aspects of individual and collective behavior; tens of thousands of industrial and consumer products, processes, and services; workplaces; and thousands of specific chemicals, minerals, and metals, as well as biological agents (plants and pathogens).

There is a very broad variety of policy instruments through which these controls may be exercised, either through consensus or directive processes:

1. Explicit statutory authority (police, public health);
2. Regulation;
3. Compensation for injury or accidental death;
4. Voluntary standards (CSA, CGSB);

5. Market-based instruments (taxes, incentives);
6. Social-welfare support structures;
7. Legal liability (class-action lawsuits);
8. Insurance;
9. International conventions (Law of the Sea, etc.).
10. Information dissemination.

As can be seen, domestic regulation *per se* is only one of a number of instruments, perhaps not even the most important one, for risk regulation in the broad sense. What this list also indicates is that regulation is a part of a large and dynamic structure of social institutions in the modern state. Because all these instruments are part of an interconnected whole, changes to any important part of the risk regulation framework can have unintended or spillover effects, which ought to be taken into consideration.

The Risk-based Approach.

There is clearly an imperative to explain what meaning we assign to risk for the purposes of managing risk. Kaplan and Garrick proposed that risk is a multi-dimensional entity comprising the answers to three questions:

- What can go wrong?
- How likely is it?
- What are the consequences?

The answers to these questions effectively amount to an assessment of risk (Kaplan and Garrick 1981; Kaplan 1997; Renn 1992).

Risk situations form part of a seamless continuity bounded by *what is known with a reasonable degree of certainty*, on one side, and *the sphere of the (currently) unknown*, on the other. A risky situation as such is one that is expressed as a range of probabilities, within which there are one or more aspects of uncertainty, low or high. This is a continuum, not an array of three independent categories. At the border where the category of the known shades into that of the "at risk," a physical process has been described and validated: A single particle of alpha radiation *can* initiate the long process resulting in a fully-developed case of lung cancer, by causing unrepaired

genetic damage in a single cell of lung tissue in an organism. (In other words, this is a well-characterized hazard.)

Now, let us say, we encounter the case of a person who *may have been* exposed – with a high degree of probability – to some amount of alpha radiation. What cannot be known, but only estimated (with varying degrees of uncertainty), is the probability that this particular person will go on to develop lung cancer. We can reduce, but not eliminate, some of these uncertainties if we know something about the genetic variability of the whole population, the genetic profile of the individual in question, and the relationship between genetic variation and the toxic dose of alpha radiation. But some uncertainties will always remain, because that is the very essence of risk itself.

On the other side of this border, "what is (now) unknown," reside the basic physical, chemical, and biological processes which remain undiscovered at present. For example, before 1984 the existence of the so-called "prion particle" (an infectious protein) was not known, and therefore the risk of prion disease, such as contracting the neurological disorder known as Creutzfeldt-Jakob Disease from transmission of infected tissue, could not even be estimated, as it now can be (Ridley and Baker 1998). Since the process of scientific discovery is ongoing, we can expect that in the future a continuous stream of entirely new risks (or risk factors) will be uncovered and characterized – and that existing risk factors will be re-evaluated through new studies. But in all of the risk characterizations some uncertainties will remain, because uncertainty is an integral part of risk itself.

There are a number of problematic areas for public policy choices within the risk-based approach. One that requires careful attention is known as *risk-risk tradeoffs.* An important study was published on this subject some years ago, Jonathan Wiener and John Graham's *Risk vs. Risk* (1995). I will summarize some of their main points here:

1. Virtually all decisions taken to reduce health and environmental risks (called the "target risk") involve some kind of tradeoffs whereby other ("countervailing") risks are affected; it is advisable to make a dedicated effort to assess whether those tradeoffs are *advantageous* or *disadvantageous* (i.e., whether they result in clear net benefits once the offsetting impacts are taken into account).

2. There are many reasons why the need for these comparative assessments is rarely recognized, and why disadvantageous tradeoffs occur, the most significant of which are jurisdictional divides between both levels of governments as well as between the many separate agencies at senior levels of government. Another important reason is that some "voices" among social interests are much more influential than others, in lobbying both governments and industry and in monopolizing public attention; this too can be a source of disadvantageous tradeoffs.

3. *Inadvertent risk transfers* are one of the most serious consequences of failing to assess risk/risk tradeoffs. For example, in a publicly-funded health care system, insufficient attention to children's health programs (and in Canada, especially for aboriginal children) can result in vastly increased incidence of illness and medical costs in later life – as well as premature morbidity – for individuals at special risk. Or, the public may be unaware that a process of "downloading" responsibility from one level of government to another may represent an unarticulated risk transfer – as happened in Ontario during the 1990s in the case of drinking water protection.

4. When the need for risk/risk tradeoffs is clearly recognized, carefully assessed, and competently communicated to the public, risk managers are doing their job. For example, Canadian Blood Services has had to undertake these tradeoffs, imposing a donor deferral program in parts of Canada to control the risk of spreading West Nile virus infection, thereby exacerbating the risk of inadequate supply of blood for medical treatment (CBS 2009). In my opinion they have assessed and communicated the need for these tradeoffs competently.

5. Proposed solutions to the serious problem of disadvantageous tradeoffs tend to focus on various strategies for centralizing risk management, by a combination of administrative changes (central agency control), judicial oversight (this applies only to the U.S. system), and greater reliance on international institutions.

6. My own assessment: There is a serious issue here that should be addressed. In terms of the Canadian governance system, by far the best option for introducing changes lies in establishing some form of central agency oversight (an "Office of Integrated Risk Management") in both federal and provincial governments. This Office would be charged with (1) developing and applying protocols for (a) identifying when risk/risk tradeoffs are occurring and (b) assessing whether they are either advantageous or disadvantageous, and (2) communicating effectively the methods and results both to risk managers and the public, so that social learning in this area can be advanced. This forms *Recommendation 1* in my paper.

Regulatory Burden and Regulatory Efficiency.

1. The Concept of "Regulatory Burden."

In Canada, this concept has been promoted largely by the Fraser Institute (2001), notably in a report entitled "Canada's Regulatory Burden," issued in 2001. The wording chosen for the concept is itself provocative, and almost certainly was designed to be so. However, it was the mode of exposition chosen by the authors that is probably responsible for the limited attention bestowed on the report since its publication. The contention is that the direct costs of regulation (expenditures by federal and provincial governments) amounted to $5.2 billion in 2001; at the same time, the indirect economic costs of regulation to Canadians – in the form of costs of compliance born by firms – was $103 billion.

These are substantial sums, to be sure. What one needs to know, however, is the other side of the coin – namely, the benefits derived by

Canadians from these expenditures. The Fraser Institute report acknowledges that such benefits do exist (such as law enforcement), but immediately adds: "It is beyond the scope of this study to measure the benefits of regulation." For all we know, therefore, this level of expenditure (assuming that it is correctly tabulated) may be a genuine bargain, in that it might yield – if we did the appropriate calculation – a level of benefits considerably in excess of these costs. What is the value of the high degree of public safety and security we Canadians enjoy, for example? Whatever the answer might be, this one-sided analysis focusing on the costs of regulation alone, even assuming they are fairly tabulated, sheds no light whatsoever on either the efficiency or the efficacy of Canada's existing regulatory structures.

2. "Regulatory Efficiency."

This notion became part of what can only be described as a curious episode in the field of public administration in Canada. Very few Canadians had even encountered the concept before having it sprung on them in the title of a proposed piece of federal legislation, Bill C-62, tabled for first reading in 1994, presented as part of one of many different incarnations of a federal "innovation agenda." Both the bill itself, as well as the manner of its birth, elicited a strenuous response, little of which was favorable. The bill died on the order paper in 1995 and was never re-introduced. One of the reasons, surely, is the poor choice of label; the bill's authors would have been wiser to baptize it the "regulatory effectiveness act."

Todd Weiler, a lawyer who worked on the bill as a consultant with the Regulatory Affairs Office of Treasury Board Secretariat, provided in 1995 one of the few rationales for it that can still be accessed today: "Far from representing an assault on the rule of law, *Bill C-62*, *The Regulatory Efficiency Act*, is really a process-oriented bill designed to improve the way in which Canada regulates risk" (Weiler 1995). (The first part of his sentence gives some indication of its reception.) He wrote:

> Compliance plans – the meat of the bill – would be proposed by a regulated party in order to vary the prescriptive details of an existing, designated regulation. In this way, the regulation and its purpose – some form of risk reduction –

> remain of general application, but the means of compliance would be varied to suit different regulatory environments. Presented with a proposed compliance plan, the regulator would be under a duty to listen to and consider the party's ideas for an alternative to the existing regulation.

The concept behind the bill, at least in this formulation of its intent, was a distinction between means and ends, specifically, between a regulatory objective (in risk reduction) and the range of instrumentalities available to achieve it. This concept survives in the idea of smart regulation, as we shall see. The rest of Bill C-62 perished without a trace.

3. Voluntary Instruments and the "Optimal Policy Mix."

The so-called "CEPA review" process – the renewal of the *Canadian Environmental Protection Act,* 1988 – took, incredibly, a full six years from 1993 to 1999 (Leiss 2001, chapter 8, "The CEPA Soap Opera"). Although the final result was an act pretty much like its predecessor, the review period had witnessed an extensive discussion of policy instruments, particularly the notion of "voluntary instruments" as a mechanism for regulatory compliance. One reason for this was the existence of an actual case of a voluntary (more precisely: "proactive") initiative, undertaken by the Canadian chemical industry, known as "ARET" – the "accelerated reduction and elimination of toxic substances." A broader conception, known as the "optimal policy mix," emerged out of these discussions; the Conference Board of Canada (2000) sponsored a multi-year project on this theme. Its overall thrust can be summarized as follows:

1. Develop environmental objective/policy goal (end);
2. Select policy instruments (means); and
3. Evaluate impacts of alternatives and select preferred approach.

In the Conference Board document policy instruments ("means") include the following:

a) Regulatory (bans, limits, standards);
b) Economic (taxes, depreciation, tradable permits);
c) Voluntary, non-regulatory (negotiated agreements, voluntary codes);
d) Information (technical assistance, public information campaigns).

These were presented in the form of a menu, arranged along a continuum, with "formal structures" (equivalent to command-and-control measures) on one end and "informal structures" (equivalent to "flexible, voluntary" measures), on the other. As we shall see, the core concepts developed in this phase of the risk regulation discussion are carried over intact into the concept of smart regulation.

The Concepts of Smart Regulation and Risk Regulation Regimes.

The most detailed study ever written on smart regulation will be found in the volume published in 1998 by Neil Gunningham and Peter Grabosky, *Smart Regulation: Designing Environmental Policy.* One notes immediately its self-imposed limitation, namely, to environmental policy; thus it does not provide coverage for the broader domain discussed in this paper – health and environmental risk management. Nevertheless, it provides the only systematic thinking published to date on the concept of smart regulation itself. In the "Introduction" we read (p. 4):

> The central argument will be that, in the majority of circumstances, the use of multiple rather than single policy instruments, and a broader range of regulatory actors, will produce better regulation. Further, that this will allow the implementation of complementary combinations of instruments and participants tailored to meet the imperatives of specific environmental issues. By implication, this means a far more imaginative, flexible, and pluralistic approach to environmental regulation that has so far been adopted in most jurisdictions: the essence of "smart" regulation.

The authors also endorse the concept of "optimal policy mix" (pp. 25-31).

One can see immediately the congruence between this perspective and the earlier Canadian discussion. What both do is first, to explicitly set aside the evaluation of regulatory objectives; second, to focus on the efficacy of the policy instrument mix in reaching those objectives; third, to endorse the idea of a flexible mix of instruments as the "optimal" path to the

achieving such objectives. They adopt the economists' terms of "efficiency" and "effectiveness" for seeking optimality:

> By efficiency is meant the static aspects (i.e., what levels of administrative costs are associated with the instruments) and the dynamic ones (e.g., to what extent will the various instruments induce technological innovation or diffusion). By effectiveness is meant the degree to which the determined environmental objectives are achieved through the use of certain instruments. In other words, "smart" means, essentially, (a) having a wide range of policy instruments available for use, (b) being flexible in choosing various mixes, depending on specific situations, and (c) being able to evaluate the comparative efficiency and effectiveness of different instruments objectively and fairly. [H. Opschoor *et al., Economic Incentives and Environmental Policies* (1994), cited by Gunningham & Grabosky (1998, p. 27). Note that they do not refer to "cost-effectiveness."]

It may be objected at once that this conception of smart regulation can appear to be trivial. However, in my opinion this is not the case. For one thing, the definition italicized above reflects a measured approach to the task of changing regulatory structures, rather than one driven by ideological perspectives. [Gunningham and Grabosky (1998, p. 24) advocate "a pragmatic approach to regulatory design, where government is relatively unencumbered by the ideological baggage of the regulation versus deregulation debate…."]

Thus, Gunningham and Grabosky emphasize (p. 6), for example, the point that the "critique of command and control legislation can be seriously overstated." Second, just having a wide range of policy instruments available for use is no trivial task. The Government of Canada, for example, has carried on endless discussions about how to design, create, and manage markets for tradable emissions permits, but so far has failed to actually do anything along these lines. And European governments, led by the Dutch, have spent considerable time and effort in designing an appropriately robust legal framework for negotiated compliance agreements between government and industry, whereas in Canada ours are still too unstructured. [For these two cases see Leiss 2001, pp. 171-2, 221-2 and the references cited.]

Thus *Recommendation 2* in this report: The Government of Canada needs to create and implement a well-designed set of wider policy instruments for risk regulation.

Third, without a credible methodology in place for the evaluation of the key criteria (efficiency and effectiveness), we are unable to make defensible judgments about optimal policy mixes for realizing specific objectives. Advocating the changing of regulatory structures in the absence of such a methodology is a case of the blind leading the blind. Needless to say, given the degree of controversy which can be, and has been, elicited by discussions about changing regulatory approaches, this methodology must have a high degree of transparency and public disclosure. Thus *Recommendation 3* in this report: A credible and transparent methodology for assessing the comparative efficiency and effectiveness of policy instruments for risk regulation should be developed forthwith.

The volume by Gunningham and Grabosky is a long and dense text, with detailed chapters on "varieties of regulatory instruments" and "instrument mixes," as well as elaborate case studies of certain industry sectors (chemicals, agriculture). These chapters cannot be summarized here; suffice it to say that a close examination of this text is a prerequisite for anyone who wishes to take up the challenges posed by the first two recommendations. A second study, published in 2001, *The Government of Risk: Understanding Risk Regulation Regimes,* is less directly useful for these purposes, but is still worthy of study and application in this same context (Hood et al., 2001).

The Legacy of Regulatory Failure: Blood and Walkerton.

To restate here the basic premises of this paper: First, the fundamental objectives of Canada's risk regulation regime, for the management of health and environmental risks, is not in question: Canadians expect a high level of protection from risks to health and the environment, and they expect major institutions (governments and business) to collaborate effectively in

delivering such protection. Second, given the sheer size and complexity of our risk regulation regime in Canada, as well as its importance and sensitivity to our citizens, the condition of our contemporary risk regulation regime needs to be intensively examined, on an ongoing basis. Third, given the length of its history and evolution, our risk regulation regime most certainly can be improved, in terms of efficiency and effectiveness – but only if a fully transparent methodology for the comparative evaluation of instruments is designed and implemented.

Canadians are well aware that public policy and regulatory choices made by both governments and industry can lead to catastrophic regulatory failure. The two most serious cases of such failure in living memory are those of the blood system and the protection of drinking water in Ontario. With respect to the first, the detailed review conducted by Mr. Justice Horace Krever, and reported in his three-volume study in 1997, revealed massive fault lines in the existing risk regulation regime for blood safety, due to (among other things) gaps between the responsibilities of various parties, namely the federal government, the blood products industry, and the Canadian Red Cross (Krever 1997, Picard 1997). Incredibly, the nature of some of those fault lines, which extent back in time to 1981, were still being revealed many years later (Picard 2003b).

In the case of the tragedy at Walkerton, Ontario, where seven deaths and hundreds of serious injuries resulted from failures to control *E. coli* contamination in drinking water in May 2000, the inquiry conducted by Mr. Justice Dennis O'Connor identified specific policy and program choices in the Ministry of Environment's risk regulation regime that played a determining role in bringing about this tragedy. These program choices affected, among other things, the policy instrument mix though which drinking water protection was supposed to be delivered. [O'Connor 2002: See especially pp. 23ff of the *Summary* of Part One. A unique feature of this inquiry was that Justice O'Connor's terms of reference specifically directed him to identify whether government policy choices played a role in the origins of this tragedy; he answered in the affirmative.]

In general, for the whole range of risk regulation regimes in Canada (for environmental and health risks), Canadians do enjoy a comparatively high level of protection. However, they are keenly aware that these regimes have a certain fragility and may be compromised, inadvertently, through changes in policy choices and the instrument mix.

Contemporary Challenges: SARS and BSE.

Only brief mention of these two cases will be made here, for the purpose of indicating that Canada still today experiences shortfalls in its risk regulation regimes – shortfalls that can have, in addition to their human casualties, huge economic costs. In the case of SARS, a disease causing a relatively few cases of serious illness and death brought about, as well, enormous collateral damage to Ontario's health care system (closure of hospitals and cancellation of essential surgery), about $1 billion in excess health care costs, and perhaps as much as $2 billion in direct economic costs (Naylor 2003). Clearly our infectious diseases surveillance system was not ready for this novel virus, even though expert forecasts of new and emerging infectious diseases, originating elsewhere in the world, have been made for some time already.

In the case of BSE, the discovery of a single case of mad cow disease has cost the Canadian economy in excess of $3 billion as of September 2003 (the costs are still rising). Analysis has shown that there was a serious policy failure in the risk regulation regime: Whereas the probabilistic risk assessment ought to have predicted the non-zero chance of a small number of cases of BSE occurring in Canada, Canadian regulators asserted that the risk was "negligible," implying that no case would occur. (The risk assessment would show also a vanishingly small probability of any human cases of human disease occurring as a result of having a small number of BSE cases in Canadian cattle herds.) They also implemented a policy of shutting Canada's borders to other countries which had even a single case of BSE in their cattle herds. Policy choices on animal feed and disease surveillance also were inadequate to control the risk of BSE (Leiss 2004b, pp. 229-261 and 387-396).

In principle, it might be said, a robust system of risk forecasting might have predicted the likelihood of both of these occurrences – and enabled us to make changes in the inadequate risk regulation regimes *before* the incidents of SARS and BSE occurred. These changes, if they had proven to be correct responses to the actual risks, and had they been carried out in a timely fashion, might have reduced, perhaps considerably, the subsequent human and economic costs. However, a robust system of risk forecasting must be carried out in a central agency of government, because it has to be insulated from the commitments of departments to their existing choices of risk regulation regimes. Thus *Recommendation 4* in this report: The federal government should design and implement a robust method of risk forecasting, to be housed in a central agency.

A Way Forward.

In Canada and elsewhere national risk regulation regimes change all the time, and so it is never a question of whether or not change is necessary. The following types of changes occur as a matter of course in such regimes:

1. Entire new domains of social life may be either brought into, or taken out of, regulation regimes (firearms; abortion; marijuana possession);
2. Existing regimes may be altered with respect to an increase or decrease in the degree of control ("stringency") – in terms of penalties, for example (tobacco use, marijuana possession);
3. Alterations in the policy instrument mix;
4. Decisions to adhere or not to international conventions (Kyoto Protocol, International Criminal Court);
5. Impacts of budgetary allocations;
6. Availability of avenues of redress for citizens (class-action lawsuits);
7. Changes in democratic institutions for participation, access, etc.

Some of these changes are the result of explicit choices, for reasons articulated in the policy process; some are intended but implicit; some are inadvertent; and some may be purely accidental consequences of unrelated choices. [Justice O'Connor (2002) specifically identified budgetary changes as a factor in the weakening of

Ontario's risk regulation regime for drinking water protection: *Summary,* Part One, pp. 34-5.]

The purpose of moving towards smart regulation is to bring a higher degree of awareness, explicit design, and coherence to the process of change in risk regulation regimes. The element of awareness refers to reflection on both what is happening in Canadian society generally, and what is happening in the changing international scene which has a bearing on our situation. For example, in risk regulation these days, there is far more activity occurring in international institutions than there used to be. To mention only food safety and animal health regulation as an example, there are very new institutions recently created in the European Union (now the world's largest economic bloc), the European Food Safety Authority and related national agencies, as well as very active agendas at multi-national bodies (the Codex Alimentarius Commission, FAO, WHO, OIE, etc.). The issues addressed by these bodies are international in scope, and thus there is a pressing need to develop modes of higher integration and coordination – while acknowledging, of course, that disputes between nations on these matters will not disappear anytime soon.

But more generally, for many health and environmental risks, where a strong expert scientific consensus is required to underpin credible risk assessments, a higher level of integration for national bodies within international assessment organizations must be achieved. One thinks of prescription drug and toxic chemicals evaluation, for example, substances in common use around the world which could be evaluated for safety using international panels. Thus *Recommendation 5:* Canada should be in the forefront – as it has been in the case of Intergovernmental Panel on Climate Change – of a drive to create additional, credible international institutions for undertaking the scientific assessments necessary in risk regulation regimes.

And finally, *Recommendation 6:* At the domestic level, Canada should undertake specific, "controlled" experiments – in a small number of key domains – for improving the efficiency and effectiveness of its own overall risk regulation regime. (By controlled experiment I mean a proposal for change which specifies in detail and in advance the desired outcomes as well as the method of evaluation.) As

indicated above, one of the reasons for the failure of earlier initiatives along these lines has been the tendency to propose sweeping changes on the basis of rudimentary analyses. Unless this tendency is discouraged, citizens will resist those initiatives – as they have done. A new approach is needed, consisting of the following steps:

1. Develop a credible and transparent methodology for the comparative assessment of efficiency and effectiveness in policy instruments;

2. Choose a small number of specific cases, where changes are thought to be desirable, and specify the desired outcomes of the proposed changes;

3. Conduct the experiment and evaluate it fairly, including the use of independent third-party experts drawn from both within and outside Canada;

4. Fine-tune the methodology and reapply it to new cases.

   One might choose the "change cases" for the first round through a consensus exercise involving a number of federal departments and managed by a central agency.

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CHAPTER 8

SEARCHING FOR THE PUBLIC POLICY RELEVANCE OF THE RISK AMPLIFICATION FRAMEWORK

Original Publication:
Chapter 15 in N. Pidgeon, R. Kasperson & P. Slovic (eds.),
The Social Amplification of Risk
(Cambridge University Press, 2003), 355-73:
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Introduction.

The richness and indeed boldness of the concept of risk amplification has yielded to date both interesting theoretical discussions as well as applications to case materials. But as a concept it is sufficiently rich to encourage us to look further, to see what else it can yield: In particular, we should try to ascertain and extend the scope and possibilities for its relevance to risk management and in particular to public policy decision-making.

Asking this in the context of a review of the risk amplification concept is particularly appropriate. For this concept is premised on a very good core idea, namely, that risk issues – considered as a problematic for public policy and decision-making – are an indissoluble unity of a hazard domain and a socially-constructed process of concern about that domain. I propose the use of a shorthand, hyphenated phrase, "hazard-plus-concern," to express this unity. It differs from the well-known "hazard *versus* outrage" in at least two ways: one, most risk issues evoke concern, whereas true outrage is a relatively rare phenomenon; two, "plus" is very different from "versus." To be sure, an emphasis on addressing concerns is to be found relatively early in the development of the field of risk communication. However, as that phase of risk communication began to be oriented to practitioners, it

sometimes quickly degenerated into lessons on creating manipulative and soothing verbiage devoid of any substantive content; in other word, the need for a fair and balanced discourse about the hazard was forgotten. The most important thing is to preserve the unity of hazard-plus-concern. This concept faithfully represents the reality that confronts public-sector risk managers on virtually every working day: For the hazard and the concern almost always present themselves to managers in unison, not separately; moreover, even though such issues sometimes linger over long periods, the double-sided unity within them rarely decomposes.

The evolution of research in this area has singled out "managerial (in)competence" as a significant variable in determining the impact of risk events. This might be regarded as troubling, but it is actually good news, because – at least in theory – the level of managerial competence within organizations (including those charged with health and environmental risk issue management) ought to be amenable to improvement. From a public policy standpoint, therefore, this is the decisive question: What guidance does the risk amplification concept offer towards improving managerial competence for risk issue management?

There is a sense in which public policy decision-making appears to be inherently incompatible with any risk management approach. This is because policy urgently seeks a "yes/no" answer to public concerns, which further incorporates in Canada a resolve that the word "uncertainty" – much less its statistical expression – shall never pass the lips of a Minister of the Crown. It is doubtful that there is any more disastrous or expensive example of this futile and wrong-headed orientation than the politicians' line about British beef being "perfectly safe" during the run-up to the explosion of the BSE crisis in 1996, but Canada and other countries have plenty of their own sins to confess in this regard.

The originators of the risk amplification concept framed it explicitly and broadly in a decision-making context about five years after it had originally appeared (Burns *et al.* 1993). Operating within this general context, my paper takes as a starting point the idea of "providing tools for policy" found in the Phase I Scoping Study provided as background documentation for this Workshop (Pidgeon 1997, ¶5.8). In particular, I want to take up the question posed there, as to whether "knowledge of the factors likely to lead to amplification effects, and the UK contexts in which they might operate, could possibly be used as a *screening device* for evaluating the potential for such effects."

In the "Phase I Scoping Study" (Pidgeon 1997) this core idea was explicated in such a way as to suggest that there could be four potential outcomes derived from the course of risk issues: appropriate or inappropriate intensification, on the one side, and appropriate or inappropriate attenuation, on the other. (The third, "appropriate attenuation," has no example specified or suggested.) It appears that only two of the four possible placements of issues in the matrix will be of interest to risk managers and policy makers: (1) "Inappropriate intensification," because this can lead to wasting resources on unneeded risk reduction, setting improper priorities for institutional agendas, causing unnecessary public concerns, getting politicians upset or in trouble, etc. (2) "Inappropriate attenuation," because this can lead to very real avoidable suffering (illness and death), avoidable economic costs imposed on various parties, and under-investment in risk reduction (relative to other risks) due to inadequate public support.

Indeed, this may be a trivial point, because, considered from either a theoretical or a practical standpoint, the remaining two (that is, "appropriate intensification" and "appropriate attenuation") are both good things by definition.

In addition, for public-sector risk managers with broad mandates there is a "holding" category, filled with an indeterminate number of potential issues, some of which may lie dormant forever, others of which

may erupt at unexpected times (the bureaucratic equivalent of dread risk). While they are in the holding pattern there is no *issue* to be managed, although risk assessments may be under way or completed, with respect to the particular risk factors related to the nature of the hazards. The absence of "issue" may be due to many reasons, perhaps even because, however unlikely it may seem, the expert risk construction and the public risk construction are roughly in agreement, either by accident or by design (e.g., the existence of a healthy public risk dialogue). One question to be considered is whether or not there is a screening procedure that could be used to "scan" periodically at least the most volatile layers in the basket of hazards making up the holding category, in order to decide whether prophylactic measures are called for with respect to any of them. I shall return to this point.

Again, for public-sector risk managers this is the stuff of everyday life: A good deal of ongoing scientific review is mixed with some low-level issue management, but the organization never seems to know when something is going to erupt into a high-profile controversy. Can the risk amplification concept help risk managers at, say, Health Canada or the UK's Health and Safety Executive, and other such agencies, better meet their responsibilities?

The single most notable aspect of the risk amplification concept, without a doubt, is its attempt to synthesize otherwise fundamentally dichotomous aspects of risk issues, represented variously by the difference between (1) the [objective] hazard-risk characteristics of the "risk event" and (2) what may be called "the social construction of risk." This core idea has been put succinctly as follows (Renn et al. 1992, p. 140): "In the social amplification framework, risk is conceptualized partly as a social construct and partly as an objective property of a hazard or event."

[The language here runs counter to one of my mantras, drawn from the "Sayings of P. Slovic," to the effect that "there is no such thing as real risk or objective risk." There is no really satisfactory short-hand

terminology for the contrast; the closest I can come is "expert construction of risk" *versus* "intuitive construction of risk," although this is still unsatisfactory because it appears to deny the role of intuition in disciplined thought processes.]

Public-sector agencies with risk management responsibilities are *ideal test-beds* for exploring the potential practical efficacy of the risk amplification concept! This is because they have no choice but to accept the twin responsibilities of doing both technical risk assessments, in the accepted sense, and also what I call "responsible risk issue management." (Some industrial firms, particularly in the chemical sector, have been moving in this direction as well.) Responsible risk issue management is primarily an exercise in good risk communication practice, or what I call taking responsibility for the creation and maintenance of a "fair risk dialogue."

II. Risk Management versus Risk Issue Management.

Behind many public controversies over risks there is a significant public policy failure, and the source of that failure lies in the inability of some of those in government and industry to see the difference between risk management and risk issue management (as derived from the approach taken in Heath 1997). *Risk management* relies on scientific risk assessment to estimate the probable harm to persons and environments resulting from specific types of substances or activities. As such, even when risk managers seek honestly to take into account varying perceptions of the risk in question among different sectors of the public, they are necessarily and properly constrained by the scope and limitations of their scientific assessment in recommending specific courses of action. This is an inescapable part of their duty to protect public health to the best of their ability, taking into account the uncertainties that are always a factor in risk estimates. Mistakes can and will be made in this regard for a whole host of reasons; the public only has a right to expect that the risk management protocols will be sufficient self-critical and iterative so that serious mistakes are discovered and corrected in the shortest possible time-frame.

Risk issue management is fundamentally different from risk management. (Here it is important to specify at the outset what risk issue management is *not*: It is not seeking to control the information flow about an issue, which is what "issue management" has come to mean in some quarters.) The most important difference is that risk issues, as they play out in society at large, are not primarily driven by the state of scientific risk assessments. Rather, such assessments are just one of a series of "contested" domains within the issue. Risk issues are configured by the competing attempts of various stakeholder interests to define or control the course of social action with respect to health and environmental hazards.

Issue management by refers to the relation between an organization and its larger social "environment," where reigning public policy provides the basic "rules of the game"; and it is inherently governed by *strategic* considerations as developed by an organization or even a loose collection of individuals. All those who wish to become skilled interveners in risk controversies, such as ENGOs, as well as those who will inevitably be caught up in them, namely industry and governments, become issue managers (by choice or default). To do so entails understanding the internal dynamics of risk controversies and seeking to influence them towards some final resolution; in most cases this will be called the "public interest," although inevitably there will be diverse definitions of what this means in practice. These resolutions may be, for example, introducing a new substance or activity or banning an existing one; changing laws or the regulatory environment; adopting new principles, such as the precautionary approach; introducing changes in business practices; approving a new economic development project or creating wilderness preservation zones; and so forth.

To put the main point a bit differently: Whereas risk management seeks to assess and control a *risk domain*, risk issue management responds to a *risk controversy*. A risk domain is a collection of risk factors associated with a specific activity or technology, such as smoking, biotechnology, or radio-frequency fields; the risk factors as assessed or perceived by various

parties over time, quantitatively and qualitatively, become the subject of risk management decision making, which may lead to risk reduction strategies or other action options. A risk controversy, on the other hand, is a risk domain which becomes the subject of a protracted battle among stakeholder interest groups, the outcome of which may or may not be consistent with any set of decision options preferred by the risk managers (in government or industry) who have "official" responsibility for the file in question.

The evolution of a risk controversy is determined primarily by the competing strategies of whatever groups or organizations choose to, or are compelled to, enter into it; as mentioned earlier, the objective of these strategies is to steer the outcome of the controversy towards some preferred risk management option. Since by definition a risk controversy is an area of competing visions about where an optimal resolution lies, competence in risk issue management should not be understood as seeking to "control" the outcome. Rather, it means in general being able to compete successfully with other influential stakeholders within the zone of controversy, *in a way that is appropriate to the specific positioning of an organization and its lines of accountability within the larger social matrix*. Industry, ENGOs, and governments all have quite diverse positioning in this regard. Governments' positioning is defined primarily by its responsibility to define and defend "the public interest" as such, for example, to seek to be as "inclusive" as possible in relation to the spectrum of social interests.

Risk assessment and management is strictly a subordinate activity within the field of risk issues: Sometimes the scientific assessment is definitive for the issue resolution and sometimes it is not; the outcome is often impossible to predict, and in any case depends primarily, in my view, on the specific pathway along which the issue evolves. It is possible that the former (i.e., where the scientific assessment is definitive) predominates, over the whole range of issues, although the most high-profile cases may be those that fall into the latter camp. Where broad stakeholder consensus emerges, as it has now with a group of chemicals called "persistent organic pollutants," the consensus is the product of a long and tortuous pathway filled with recriminations directed at some parties by others.

In other cases (such as Alar and apples or saccharin, for example) some of those affected directly by the outcome remain convinced, years or decades later, that the wrong resolution occurred. In still others, such as BSE and British beef or health risks associated with radio-frequency fields, the weight of massive and irresolvable uncertainties about the scope of exposure and potential harm hangs like a dark cloud over both the issue and its resolution to date. In all such cases, scientific assessment played or plays some role in the issue evolution, but only as one factor among many. What issue managers most need to know is how scientific assessment will "play" at different times in the evolution of risk issues, especially those (like dioxin or now endocrine modulators) that have a very long life-span.

The divide between risk management and risk issue management affects none more seriously than governments. They must do both. Over the past thirty years, coincident with the rise of the modern specialized field of health and environmental risk management, many governments, including Canada's, have developed outstanding expertise in risk assessment. They are not as good, by and large, at risk management, mainly because they experience difficulties (just as citizens do) in integrating multiple decision inputs of qualitatively different sorts into a coherent framework within and across issue types. (Comparative risk management is a radically underdeveloped field of practice.) And unfamiliarity with how risk issue management differs from risk management has hampered the ability of governments to deal at all adequately with risk controversies.

Stages in Risk Issue Development

Competence in risk issue management starts with an ability to understand that risk controversies have common structures and evolve over time in distinctive stages. The particular type of risk issue that becomes controversial is of fundamental importance to risk managers, because it determines which industrial sector and government agency is answerable to the public. But, although controversies originate with the products and processes of many different industrial technologies (chemicals, tobacco,

nuclear energy, forestry, telecommunications, petroleum, food processing, to name but a few), the risk controversies themselves have many features in common.

The Early Stage

The early stage of every risk controversy has the following features. *First*, there is an incomplete hazard characterization, because scientific studies are inadequate, and sometimes scientists do not know at that point even what types of studies will clarify the concerns. At this stage it is not clear what is the range of adverse effects the public should be worried about, or sometimes whether anyone should be worried at all. These large unknowns are compounded by the propensity of spokespersons for industry, often seconded by their government counterparts, either to downplay or deny the scope of the hazards, to be reluctant to initiate adequate funding programs for the science that needs to be done, and to make soothing noises to dampen public concerns.

Second, there is poor or nonexistent exposure assessment: It is not clear who (if anyone) is at risk of harm from many of the suspected effects, nor is it readily apparent how to resolve this question. Providing an answer necessitates being able to separate out specific sets of factors from the entire gamut of the hundreds or indeed thousands of relevant risk factors impinging upon the lives of individuals in modern societies. Epidemiological studies that attempt to do this are notoriously hard to construct and carry out, and the results from such studies are fought over by specialists sometimes for decades. Compounding these intrinsic difficulties is the reluctance of industry and governments to provide early funding for these studies, which are often inconclusive and always expensive.

Third, in the early stage the industrial and government institutions which eventually will be answerable for the issue have a strong desire to avoid calling attention to it, in the hope that there will never be a major controversy. Their motto for this stage is: "Let sleeping dogs lie." Their fear is that, if they take the initiative to call attention to the newly-suspected but poorly understood risk factors, they will raise alarms that might be

unfounded and cause unnecessary worry in a population perhaps predisposed to worry needlessly about certain types of hazards. So, typically, little or no effort is made in risk communication, that is, explaining the nature of the hazards and the scientific studies being done to clarify them. *Fourth*, and following directly from the third, throughout the early stage there is the possibility of "issue capture" and "stigma."

Issue capture refers to the process whereby one party seizes the initiative and succeeds in raising the profile of an issue, to the point where others can no longer pretend it is unimportant and are required to respond. Since there are tremendous advantages to be reaped by the party which succeeds in this endeavor, this is where the strategic competence of ENGOs is put to the test. And one of the most potent devices for issue capture is to find a way to brand the risk source with a stigma, that is, an image with strongly negative connotations and having dramatic power to call attention to a risk; examples abound, in ranging from dioxins in the 1970s ("the deadliest chemical known to mankind") to today's "Frankenfoods" label for genetically-modified crops (Flynn et al. 2001; Leiss and Powell 2004, chapter 3; Leiss 2001, chapter 2).

The early stage of a risk controversy can last for ten or fifteen years, as was the case with dioxins (*ca*1970-85); endocrine disruptors (*ca*1990-present), wireless telecommunications, global climate change, and food biotechnology are still in this formative period. It is possible to say for certain that many other applications of genetic engineering, especially as they apply to human health (xenotransplantation) and manipulations of the human genome (gene therapy, genetic screening, enhanced reproductive success) will generate significant risk controversies. In addition, there will be efforts to win support for the intensive engineering of plants and trees both for enhanced carbon sequestration (to offset greenhouse gas emissions) and to provide chemical feedstocks which promise far lower environmental impacts than conventional products have ("cleaner production"), and this too can be expected to be controversial.

The Middle Stage

The middle stage of every risk controversy has the following features. *First,* large-scale scientific research programs designed to produce a definitive hazard or risk characterization are well under way but remain incomplete, and early epidemiology studies (if they exist) are likely to be inconclusive as well. Typically, there is little, if any, effective communication to the public of the research program objectives, the reasons why certain programs and not others are under way, or how the results are expected to be applied to a surer understanding of the hazards. *Second,* there are initial risk assessments, giving some quantitative expression to the magnitude of the hazard (e.g., "excessive daily alcohol consumption [as defined] is estimated to represent an annual incremental risk of breast cancer on the order of 2×10^{-5} in the exposed population").

But often the uncertainties, which may or may not be specified clearly, remain rather large, or the initial estimates are challenged by subsequent findings. Typically, no effort is made to explain clearly to the public either the great complexities in the risk assessment exercises, or the strengths and weaknesses of competing assumptions and approaches. With respect to both the scientific programs and the risk assessments, the strongest inclination of industry and government, in most cases, is to continue to downplay concerns, to keep a low profile, and to pray that the issue just goes away of its own accord.

Third, the risk information vacuum usually subsisting in the second stage helps to keep an issue "in play," as it were, with various stakeholders jockeying for position and leverage during the ebb and flow of events such as the publication of key studies, calls for regulatory action, protests, closed-door negotiations, and lobbying. There is an inherent volatility in this stage which rules out reliable predictions about the future course of the issue agenda. For example, the release of a long-awaited major scientific study can generate competing efforts by opposed factions to provide the "spin" (interpretive context) that will define the public attitudes of the great majority of the population who will never see the study itself; for example, this happened a number of times during 1999 in the risk issue domain of radio-frequency fields used in wireless telecommunications.

Fourth, and increasingly, an issue will be "bounced" around the globe as the contending parties (industry, governments, ENGOs, academics) find different venues in which to mount their campaigns in strategic issue management. Globalized business strategies mean that the same technologies are deployed around the world and, in reaction to this, many ENGOs have become highly adept at internationalizing their own operations and matching the capacities of multinational firms to operate on a world scale. Electronic mass communications and above all the Internet promote the increasingly sophisticated coordination of marketing campaigns for both products and issues.

Dioxins passed through the middle stage of controversy in the period 1985-99, as did the issues of risks associated with high-voltage transmission lines and household electricity supply (extremely low frequency electric and magnetic fields: ELF-EMF) during the decade of the 1990s. The intense international controversies over forestry practices, involving clear-cutting and the logging of old-growth forests, also seemed to enter this stage in the late 1990s.

The Mature Stage

The mature stage of every risk controversy has the following features. *First,* scientific research programs are scaled back to a "maintenance" state, although they never stop entirely for major risk domains, as the full hazard characterization is increasingly well-understood. *Second*, exposure measures become more and more sophisticated, and therefore the quantitative risk assessments are correspondingly well-defined and the uncertainties are reduced to acceptable levels. As a result, the public can expect few great surprises from the ongoing scientific programs in these areas, although essential new knowledge is gained all the time, some of which leads to important modifications in risk assessments even for relatively well-described risks. For example, both geological radon and food- and water-borne pathogens appear to be more serious hazards than they were thought to be until quite recently.

Third, in most case the longstanding inadequacies in risk communication typically are never repaired and therefore continue to take their toll, in that the framing of issues is frozen in time and cannot respond to changing circumstances. For example, there are those in Canada and elsewhere who now would like to see nuclear generation of electricity as a newly-desirable option in an era of concern about lowering atmospheric greenhouse gas emissions; but there is an enormous weight of resistance to this option in public opinion to be dealt with, the legacy of decades of appallingly inadequate risk communication from the nuclear industry. *Fourth,* there is a shifting stakeholder interest profile in the mature stage, as businesses, governments, and non-governmental organizations make strategic choices about allocations of time and resources to a variety of risk issues.

Among major risk controversies reviewed in this and earlier volumes tobacco use and nuclear power probably entered the mature stage first (of course these two are among the oldest contemporary risk controversies), sometime in the 1980s. Asbestos risk – still an issue around the world and of great interest to Canada, as a large producer – also appeared to enter a mature phase of controversy in the 1990s, as did most aspects of pesticides use in agriculture. And it seems likely that both dioxins and most ELF-EMF issues have now entered this stage.

Conclusion: The underlying common structure of risk controversies and their evolution through distinct stages has considerable significance for defining competence in risk issue management. At one time or another, intense and persistent risk controversies have affected, or are likely to affect, most major industrial sectors and many different government agencies. The "instinctive" response of managers within those organizations, when a brewing risk controversy first threatens to engulf them, is one of denial: Denial, that the *issues* as represented by other interested parties are at all significant – and that those parties have any business meddling in such matters anyway; that the management of the risk factors in question is or should be open to dispute by those who are not "experts" in the relevant scientific disciplines; and that "the public" really needs to be involved in the

intricacies of evaluating scientific research results, assessing the credibility of experts, figuring out exposures and uncertainties, doing quantitative risk estimates, and exploring risk-benefit trade-offs among the decision options for risk control. Certainly, no sector could ever match the tobacco industry for turning its denial phase into the longest-running and most absurd charade ever staged — fully fifty years in duration, extending from the 1950s until late 1999, when a major firm first explicitly conceded some elements of the truths about the risk factors associated with smoking conceded earlier by almost everyone else on the planet.

The case studies of risk controversies to date show, alas, that those instincts are unreliable guides to effective risk issue management. In all cases the opposite propositions are the better guides – namely, that public perceptions of risk are legitimate and must be treated as such, that risk management subsists in an inherently disputable zone, and that the public ought always to be involved (through good risk communication practices) in discussions about the nature of risk evaluation by scientists and risk managers.

III. A Managerial Approach derived from Risk Amplification

What are here called "risk controversies" all illustrate the process of risk amplification. What the perspective outlined above indicates, however, is that *risk controversies – and thus the process of risk amplification – are normal events in contemporary society.* In other words, risk controversies arise out of two independent sources: first, the inherent features of risk issues themselves, especially irreducible uncertainty; second, structural defects in risk management processes which have plagued risk managers in industry and government for a long time. Neither of these sources are about to dry up anytime soon; in any case, only the latter is amenable to correction through improved practices in risk management and risk communication.

So far as I know, only two published pieces in the risk amplification literature (Renn et al. 1992, Burns et al. 1993) explicitly have raised the issue of managerial factors in this process, by identifying a variable called "perceived managerial incompetence"; the variable is defined as the "degree to which the public believes that a hazard implies that similar risks are being managed incompetently." The key finding is stated as follows (Burns et al. 1993, p. 621): "Perceptions of managerial incompetence influence the public's response to a hazard to a degree approaching the scale of the event."

Here is a finding, derived from the risk amplification concept, that is of direct relevance to the mission of public-sector risk managers. Should this be regarded as a plausible finding, it means quite simply that managers have a lever with which they can influence the outcomes of risk issues – so long as they are in a position to operate the lever. The critical question becomes: How can the perception of managerial competence for risk issues be influenced? Before suggesting a route towards an answer to this question I would like to expand on its description in the published study. This is where the perceived managerial incompetence variable seems to stand within the larger picture of the risk amplification concept:

> "Future risk" is defined as the "degree to which other people are at risk of experiencing harm from future hazards of this type"; this variable is linked to the other and important key finding from this set of two studies (Renn et al. 1992, p. 151): "It was not the magnitude of a risk that was most influential in shaping the individual and social experience of risk, but the exposure to risk." It was further hypothesized that the two well-known factors elucidated in risk perception research, namely dread and familiarity, will combine with the "exposure" variable to influence public response (Renn et al. 1992, pp. 154-6).

Neither the perception factors of dread and familiarity, nor the perceived exposure variable, are directly amenable to managerial control during the active phases of a risk issue, certainly not in the short- to medium-term, which is the conventional horizon for decision-

making. And the extent and type of media coverage, driven as it is largely by accidental circumstances, rests almost entirely outside of the managerial domain. (It can be affected marginally by good risk communication practice, I believe, but pretty much has a life of its own, because journalists simply will not accept someone else's agenda for the development of a story line, especially if that person works for an organization which is caught up in the story.)

"Managerial Competence" remains as a domain where improvement in risk issue management is or ought to be possible, at least in theory. My own conviction that such improvements are possible, and that the attempt to find a promising path to improvement ought to be made, stems in part from some fifteen years of involvement with personnel in Canadian federal government departments charged with environmental and health risk management over a broad range of hazards. It also stems in part from work on academic case studies of almost twenty major risk issues occurring in the period 1970-present (and ongoing), and a more casual acquaintance with a few dozen more.

IV. Managerial Competence for Risk Issues.

I think it could be quite useful if we were to look back sometime at the history of risk controversies over the last thirty years or so (the list in Appendix I, or any other similar list) in order to see if we could derive screening criteria from them that might be then used in a forecasting mode. In other words, if, for the sake of argument, we say that two risk issue outcomes pose potential problems, of quite different types, for risk managers – namely, inappropriate intensification or attenuation -, can we forge the tools that would enable us to screen the holding basket of risk issues, so as to predict which ones are likely to be most salient of each type (or if already so, to persist in being so) in the near future?

I cannot answer this question here. But I want to raise it in order to make another point, namely, that if it were indeed possible to forge and deploy such tools, *the screening exercise itself would be only a*

preliminary step towards the real goal, which is improved managerial competence in risk issue management. Without the latter, the former would simply furnish astute managers with enough advance warning of emerging intractable problems to seek reassignment to a less personally damaging zone in the civil service. (I have met some persons, for example on the tobacco control file, who have done so for just such reasons.)

So, what are the prospects for improved managerial competence? I begin with a speculative diagnosis of the causes of perceived managerial incompetence here, because so far as I know it has not yet been presented in the literature. I believe that at least some primary sources of this perception are to be found in a faulty self-assessment and self-representation, by the agencies charged with health and environmental risk management, of their basic mission. To put the point succinctly, they have conceived themselves (over a long period of time) as experts in hazard characterization, and to a lesser extent in risk assessment, whereas what is needed from them above all is expertise in risk issue management. Those agencies naturally also configured their professional staff complement in line with this conception. The commonest example of these faults can be found in the responses of such agencies over the years to public expressions of concern about hazards that fall under their mandates: All too often the representatives of those agencies addressed the hazard characterization (and done so quite fairly, on the whole), but not the concern.

What is needed above all is competence in addressing the unity of hazard-plus-concern. In terms of professional complement, this means that such agencies should be staffed primarily by specialists in risk issue management, who are assisted by risk assessors, and only secondarily by scientists who have been trained in specialized fields of chemistry, biology, toxicology, and so forth.

The Golden Rule for risk managers is: Always focus on the linked hazard-plus-concern. Their credo might be formed from the following propositions:

1. With an awareness of the stations of risk amplification, anticipate the evolution of risk issue development;
2. Use screening criteria on the holding issue basket to do forecasts and to set priorities for agency resource allocation;
3. Ensure the existence of a healthy public risk dialogue (as the agency's primary mission);
4. Clearly concede the existence of uncertainties and discuss the implications of this uncertainty for the individual's personal safety and well-being
5. Where final responsibility for risk management falls squarely on government, advocate strongly for the filling of key scientific knowledge gaps and the reduction of unacceptable levels of uncertainties;
6. Assume responsibility for ensuring that some credible party is charged with periodic scientific review;
7. Promote clarity of public communication about the nature of the hazards and always address the specific concerns that are expressed.

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Part Two:

Risk Communication

CHAPTER 9

INTRODUCTORY NOTE TO PART TWO

Most of us regard ourselves as being good communicators on the grounds that we all have a fair amount of everyday practice in the art. Because risks are inherently complex and tricky, however, good risk communication invariably turns out to be harder than it seems at first glance. From its origins in the mid-1980s, this field has been bedeviled by an underlying inconsistency in its objectives. On the one hand, there is the idealistic motivation to present to the educated and interested public, fairly and without bias, the formidable complexities in risk estimations in a language that is understandable to those who are not expert in the basic sciences or statistics. On the other hand, there is a persuasive bent, at odds with the other impulse, and more akin to the hope of every monotheist to convert the unbelievers, under which it is assumed to be in the public interest for risk analysts to convince citizens that, all too often in matters of risk, they believe things they should not and do not believe what they should.

No matter which of these two missionary programs they represent, too many risk experts prefer to ignore the real-world context in which they operate, namely, the harsh reality of differentiated social, economic and political interests. As Chapter 10 argues, risk management is a strategic game and one that is often played for high stakes, involving long and bitter struggles over accounting and compensation for unhealthy and unsafe working conditions, harmful consumer products, cover-ups, environmental pollution, lax regulation, and externalities on a massive scale (consider just the cases of stratospheric ozone and greenhouse gases). In *this* context, there is precious little motivation for any of the parties to tell the whole truth and nothing but the truth in matters of risk. While this trait is hardly peculiar to the risk field alone, the inherent nature of risk, in being a matter of a probability of harm, where in quantitative terms the range of uncertainty around the "most likely" number – say, "1 chance in 8 million" –

can be quite large, can and often does provide much material for mischief, as well as, of course, quite honest confusion. In other words, it is possible to hide in the swamp amongst the uncertainties, especially when one is denying culpability in a court of law.

Politicians in charge of government departments have a more straightforward reaction to the inevitable uncertainties that come with risks: They loathe and fear them in equal measure. The fact of frequent elections acts as an independent variable in their reckoning with risk management issues. The quantitative risk estimation seeks to answer the question, "How likely is it that the bad event will happen within a certain period of time?" The government minister wants to know: "How does the estimated timing map against my term of office?" Where long latency is involved, the politician's dilemmas are compounded. Slowly-developing disorders such as asbestosis, smoking-related diseases, and transmissible spongiform encephalopathies (TSEs) only very gradually reveal their true toll in population-health terms, but some environmental risks are far more challenging in this regard.

Imagine the hapless environment minister who is being briefed by her scientists about the time-lags involved in climate change, learning in the process that human-caused emissions released on the day of this briefing will be integrated into cause-and-effect chains that result in cumulative impacts over centuries. In a moment of boredom, the minister unexpectedly looks at the briefing book and notes the following statement from IPCC 2007: "Earth System Models of Intermediate Complexity with coupled carbon cycle model components show that for a reduction to zero [GHG] emissions at year 2100 the climate would take of the order of 1 kyr to stabilize." Ignoring the reference to models, she asks what "1 kyr" means, and is told that it's a millennium.

The aide helpfully points out that the scenario is based on the model assumption that all new human emissions would have ceased at year 2100 and that, therefore, all of the expected impacts on temperature, sea levels, and so forth for the next thousand years are "locked-in" effects based on

accumulated emissions up to 2100. Is it any wonder that political promises about taking "decisive actions" to reduce the risk of global warming, by constraining human-caused GHG emissions, are now routinely put in terms of reductions targets that are more than a decade into the future (year 2020), *with no interim targets whatsoever*? And as for the much more dramatic targets promised for the year 2050, these not only qualify for the "not in my term of office" pledge, but also for the much more comforting "not in my lifetime" one.

The greatest outstanding risk communication challenge for public officials and industry spokespersons is not, as so much of the recent academic literature would have it, "building trust" among one's audiences for whatever one might say in the future, but rather figuring out how to respond honestly to the need to inform the public that we need to inform the public that we must take essential precautionary actions on certain risk files *now*, not at some hypothetical future date, despite the fact that there are uncertainties about outcomes that cannot be reduced.

CHAPTER 10

'DOWN AND DIRTY': THE USE AND ABUSE OF PUBLIC TRUST IN RISK COMMUNICATION

Author's Note:
First published in *Risk Analysis,* vol. 15, no. 6 (1995), pp. 685-692;
some minor revisions to the text and notes have been made.
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Introduction.

When I played low-stakes poker with family and friends long ago the dealer in a game of five-card stud (where the sequence of cards is first card face-down, the next three face-up, and the last one face down again) always prefaced the deal of the final card with the phrase "down and dirty." We understood this warning to meant that the last card down, delivered after a series which were visible to all players, had injected a suddenly elevated level of risk into the hands: Since the unknown card could change the configuration of possibly winning hands represented by the cards that were showing, each player's risk of being bluffed successfully had increased dramatically. In recent years, I have often thought that the phrase "down and dirty" makes not a bad metaphor for the equally tense games that stakeholders in matters of health and environmental risks can play with each other, where what is at stake in the end is nothing less than the determination of what is in the "public interest" in managing those risks.

In this paper, I will explore the usefulness of this metaphor for testing the appropriateness of the risk communication strategies that various stakeholders may use, in their interactions with each other and the

public, when engaging in controversies over environmental and health risks. (Stakeholder is used here as a "neutral" term: A stakeholder is any individual or group who can demonstrate, for any particular "game of risk," that he or she, or that group, can affect the outcome. As a practical matter, the various stakeholders for any issue can recognize readily who the set of relevant stakeholders are.) In other words, starting from the presuppositions that all participants in these controversies have particular interests to advance and that each will employ tactics and strategies (including "dirty" ones) calculated to maximize its own interest, I want to see whether we can define the boundary between the use and abuse of public trust in those settings. After developing this central theme a bit, and exploring the concept of interest-based participation in risk controversies, I shall offer one detailed case study to show how the metaphor works.

Kraus et al. comment, "the controversies over chemical risks in our society may be fueled as much by weaknesses in the science of risk assessment as by misconceptions by the public." [N. Kraus, T. Malmfors, and P. Slovic, "Intuitive toxicology: Expert and lay judgments of chemical risks," *Risk Analysis* **12** (1992), p. 230.] I agree, except that I would use the term "inherent limitations," rather than "weaknesses," and emphasize the fact that, no matter further scientific refinements in risk assessment methods are made, these assessments will *always* be a field of contention. Both anonymous readers of an earlier version of this paper objected strongly to my references to the "risk assessments" of various stakeholders, in a context where (in the opinion of those readers) a purely tactical position on risk was being advanced. In their view, the term "risk assessment" should be reserved for procedures that are commonly adhered to by scientific and technical experts. I emphatically disagree, but by doing so I do not suggest that all risk assessments are "equivalent" in any sense.

I prefer to distinguish between "scientific (or expert) risk assessments" and "intuitive risk assessments" (corresponding to the concept of "intuitive toxicology"), following the usage of Paul Slovic and his colleagues. In my paper, the context makes it apparent which of the two types is being referred to. This is a "value-neutral" distinction, with no

presumption *a priori* about "good" or "bad," "right" or "wrong": The difference is essentially based on what mental or logical procedure is employed in order to come to a risk assessment judgment. Any stakeholder may, in principle, be found on either side of the divide; for example, environmental organizations more and more use references to studies in the scientific literature, or engage their own qualified scientific experts, when engaging in risk controversies. Finally – and this is my key presupposition – in a regulatory negotiation context all stakeholders are presumed to have *some* tactical or strategic interest in the way in which they assess risks. The conclusions I draw from our experience with these risk controversies to date are:

(1) The adequacy of risk assessment results, including lack of vital data (at the time when a decision is called for), as well as the inherent uncertainties, is the core element in stakeholder interests in risk management decision making *and will remain so*;

(2) The very nature of risk assessments makes protracted and often bitter stakeholder disagreement inevitable;

(3) Stakeholder involvement is on the whole a healthy process that can lead to acceptable and legitimate risk management decisions, so long as the game is played within the terms or rules that protect the larger framework of public trust from abuse.

Despite its apparent "messiness," this process can lead to outcomes that are at least as reliable and enduring as are others based solely on a consensus of allegedly disinterested experts or a quasi-autonomous bureaucratic process. [M. G. Morgan, "Risk analysis and management," *Scientific American* **269** (July 1993), pp. 32-41.] I do not claim that the outcomes are "better" on average in some absolute sense; given the inherent uncertainties in risk assessments, it is doubtful whether it would be meaningful to attempt such a judgment, at least in many cases.

Risk controversies as a domain of interest-based politics.

Recently there has been a good deal of emphasis on the element of "trust" in the context of controversies over risks. [S. Krimsky & D. Golding (eds.), *Social Theories of Risk* (Praeger, Westport, Connecticut, 1992), chapters 4, 5,

and 12, at pp. 95, 152, 277-8.] Since bluffing is a deliberate and calculated exercise in deceit it would appear to be the opposite of trustworthy behavior. This stricture does not apply to poker because bluffing is an inherent element of the game itself. But risk management is likewise a "game of chance" in view of the inherent and irreducible uncertainties that are part of the nature of risk, and so, I content, bluffing is a legitimate tactic here too. Just as in poker, the level of tension created by bluffing will be especially high during the period when new players are being admitted for the first time, because the opportunities for successful bluffing are in part a function of the relative unfamiliarity among the players with each other's style, mannerisms, skill, and coolness under pressure. [W. Leiss, "Three stages in the evolution of risk communication practice," in H. Kunreuther and P. Slovic (eds.), "New Directions in Risk Management," *The Annals of the American Academy of Political and Social Science* **545** (May 1996), 85-94.]

Ironically, even that phase in the evolution of risk communication practice which was focused on how to create trust and credibility provides proof of the strategic orientation of players in the game of risk. Training manuals for industry and government managers emphasized becoming skill in the external manifestations of sincerity (through body stance and gestures, style of dress, expressions of empathy, and so on); yet all of this *could* be nothing more than putting on a good act for the audience.

I believe that reflecting on the act of bluffing can be useful for us when we consider how best to manage risks to life and health "in the public interest." It encourages us to acknowledge the fact that, in a society which promotes the interplay of structurally differentiated social interests (as a democratic society with a market-based economy ought to do), players representing different interests will bring to the negotiating table, in risk matters as in others, sharply conflicting evaluations of the same situation. Furthermore, it helps us to understand that in this setting no adept player will reveal prematurely all of her cards, or even her knowledge of the relevant data set (which may be done in poker by keeping track of the cards already played as the deck is exhausted and so being able to better predict the set of cards yet to be played). Furthermore, every player will try t cause

as may others as possible to fold – that is, to become passive observers rather than shapers of the final outcome – before the final cards are dealt, so as to reduce the number of variables in the decisive rounds of play.

The metaphor could be extended but the point ought to be clear by now. By means of this comparison I am suggesting that risk controversies are strategic contests involving social groups with differentiated interests and that the parties are inclined to perceive the outcomes in terms of winning and losing. [J. Flynn, P. Slovic, and C. K. Mertz, "The Nevada initiative: A risk communication fiasco," *Risk Analysis* **13** (1993), pp. 497-502.] (Indeed, failure of parties to reveal or acknowledge that they have approached a risk controversy with a strategic intent can itself become a factor in the outcome.) From the standpoint of interest-based politics, the views of parties to risk controversies reflect their distinctive position in society's matrix of differentiated interests, as well as the boundaries within which each party can accommodate the views of others in negotiated compromises. [L. Clark, "Politics and bias in risk assessment," *Social Science Journal* **25** (1988), 155-165.]

Each will expect the others to seek to advance their own interests, but in a mature pluralist society all will agree that this legitimate pursuit of self-interest must occur within a set of rules on fairness and due process. Given the provisional nature of all risk assessment data and the irreducible uncertainties therein, a form of decision making based on negotiated consensus among interested parties may be regarded as an appropriate type of society risk management. [R. L. Keeney and T. L. McDaniels, "Value-focused thinking about strategic decisions at BC Hydro," *Interfaces* **22** (1992), pp. 94-109.]

In this setting, each party will have a healthy mistrust of the motives and behavior of others as all advance various positions on how to manage risks in general or what stance to take on a particular element in a risk-management scenario. In a strategic context each will be motivated to supply information and reasons supportive of its own perceived self-interest, to conceal or downplay that which is not so supportive, to conduct

smokescreens that obscure areas of uncertainty, to probe for weaknesses in the standpoints of others, and generally to seek to weaken the credibility of their strongest opponents.

This is all perfectly sensible utility-maximizing behavior and indeed the past record of events provides complete justification for all of the parties to proceed on this basis. This viewpoint echoes what Luther Gerlach said about social movements in general: "Their presence in a socio-cultural system, a way of life, should be considered quite natural and ordinary, not something so unusual that specialists take it as a sign that the system is in extreme crisis." [L. P. Gerlach, "Protest movements and the construction of risk," in B. B. Johnson & V. T. Covello (eds.), *The Social and Cultural Construction of Risk* (Dordrecht, D. Riedel Publishing Co., 1987), p. 140.] On the other hand, when things are going smoothly, the parties themselves can choose to utilize techniques of analysis that provide a common information base, that clarify the consequences of different decision options or trade-offs, that suggest how to structure the multi-stakeholder negotiations themselves, and so on.

I will offer only a few examples of what I mean. If we start with what might be called a typical "environmentalist" organization, we expect to find a risk-averse standpoint including a blanket rejection of most industrial chemicals and large-scale development projects. (By virtue of their placement within the range of interest groups these organizations are arrayed against the traditional promoters of industrial development strategies, notably industry and governments.) [M. Douglas & A. Wildavsky, *Risk and Culture* (University of California Press, Berkeley, CA, 1982).] So, in the first instance, other parties should regard any claim that a particular chemical or project represents unacceptable risk for what it actually is: namely, a bluff. For example, I know a member of one such organization who has been searching for years in the scientific literature for evidence damaging to glyphosate, a widely-used herbicide; having failed to find anything sufficiently dramatic about this active ingredient, she has turned to the inert ingredients used in the spray mixture, and is still searching: In the

meantime the claim is advanced that there is "evidence" of unacceptable risk.

A high-profile campaign by Greenpeace and other organizations, which began in the late 1980s with a focus on dioxins and other compounds in pulp mill effluent, demanded a complete phase-out of chlorine-based compounds. [J. Thornton, *The product is the poison: The case for a chlorine phase-out* and J. Thornton, J. Weinberg, and J. Palter, *Transition planning for the chlorine phase-out* (Greenpeace USA, Washington, D.C., 1991, 1993); "The crusade against chlorine," *Science* **261** (July 9, 1993), pp. 152-154; B. Hileman, "Concerns broaden over chlorine and chlorinated hydrocarbons," *Chemical and Engineering News* (November 1, 1993), pp. 28-41.] The campaign was based in part on allegations of associations between organochlorines (in particular, organochlorine pesticides) and adverse human health effects in some very sensitive areas of public health concerns, especially breast cancer rates and the possible role of "estrogenic activity" or so-called "estrogen mimicking"; disruption of immune, endocrine and hormonal systems; and reproductive system effects in humans and wildlife species, especially alleged declines in male sperm counts. [J. Thornton, *Chlorine, human health and the environment: The breast cancer warning* (Greenpeace USA, Washington, D.C., 1993). These arguments about breast cancer in particular were picked up in women's magazines; they are nicely summarized by D. Marshall, "Breast cancer: The toxic trail," *Lear's Magazine* (April 1994), pp. 36-7.]

The plausibility of these assertions was enhanced by the U.S.-Canada International Joint Commission, which wrote in its *Seventh Biennial Report* that "[f]or the Commission … there is sufficient evidence now to infer a real risk of serious impacts in humans," stemming from industrially-produced organochlorine compounds in the environment, in the areas of breast cancer, the "startling decrease" in male sperm counts, the "alarming increase in male genital tract disorders," as well as the "declining learning performance and increasing incidence of problem behavior in school children." The conclusion is: "It is the conviction of the International Joint Commission that the risk of such damage exists, and that virtually any level

of risk of this type should be considered too high to accept." [International Joint Commission [IJC], *Seventh Biennial Report under the Great Lakes Water Quality Agreement of 1978 to the governments of the United States and Canada and the state and provincial governments of the Great Lakes Basin* (Windsor, Ontario, 1994), p. 5.] The alarmist tone of this document, emanating from a government-sponsored body, its acceptance of unconfirmed adverse health impacts as well as unproven cause-and-effect scenarios, and its general risk-averse orientation, represented at least a temporary strategic advantage for the "environmentalist" cause.

While the "estrogen activity" of organochlorine compounds is well-recognized, as is the occurrence of residues of such compounds in human tissues, a recent literature review found that the studies to date do not indicate an association between breast cancer and serum organochlorines. [L. Ritter & D. Houghton, "Organochlorine residues and risk of breast cancer," *Public Health Epidemiological Reports Ontario* **5** (No. 8, August 26, 1994), pp. 176-83; D. L. Davis & H. L. Bradlow, "Can environmental estrogens cause breast cancer?" *Scientific American* **273** (October 1995), pp. 166-72.] The recent discussion in the medical and scientific literature, with respect to the alleged significant declines in male sperm counts in industrialized countries in the last 50 years, suggests that this matter is being taken seriously, although it is too early to draw definitive conclusions, either about the phenomenon itself or (if it exists) its probable causes. Such continuous re-evaluation of prior research is, of course, essential to the scientific enterprise; but in the dirty business of risk controversies, exacerbation of public fears based on provisional research findings is just part of the game.

Thus, there are good grounds for others to mistrust the information and arguments presented by risk-averse "environmentalists." The same goes for their own mistrust of those whom environmental activists regard as their chief opponents, notably the dominant industries. Here we have a lot more "hard" evidence, simply because the risk promoters (industry and governments) have been in this business much longer. Many people have a vague intuitive familiarity with the long history (stretching back to the origins of the industrial revolution) of the *calculated under-assessment of risk*

by their risk promoters, in particular the willful neglect of worker exposure to hazardous substances and processes.

Studies in labor history and the development of occupational health and safety legislation have documented the devastating effects of worker exposure to toxic levels of hazardous minerals, metals and chemicals throughout the history of industrialism, beginning with coal and running virtually the entire gamut of economically useful substances such as asbestos, benzidine and beta-naphthylamine (used to make synthetic dyes), feldspar, lead, mercury, phosphorus, radium, and many others. [Bruce Ames, "Six common errors relating to environmental pollution," *Regulatory Toxicology and Pharmacology* **7** (1987), p. 381, contrasting environmental and worker exposures: "For example, I testified in 1981 in California that the EDB [ethylene dibromide] levels that workers were allowed to be exposed to were shockingly high…."]

The initial response to worker complaints almost always was a denial that there was any identifiable risk from the specific substance (with the observed effects attributed to more familiar causes) and, all too often, a blanket assertion that the "carelessness" of the workers themselves was at the root of the problem. With advances in scientific knowledge making the existence of specific occupational disease impossible to deny, leading to employer liability and worker compensation schemes, a determined effort was made to control the production and distribution of such knowledge by industry (much of which they generated as sponsored research) for as long as it was possible to do so (see the cases of beryllium, lead, radium, and byssinosis). [D. Rosner & G. Markowitz (eds.), *Dying for Work* (Indiana University Press, Bloomington, 1987); D. Michaels, "Waiting for the body count: Corporate decision making and bladder cancer in the U. S. dye industry," *Medical Anthropology Quarterly* N. S. **2** (1988), pp. 215-232; E. Leyton, *Dying Hard* (McClelland & Stewart, Toronto, 1977); R. Rabin, "Warnings unheeded: A history of child lead poisoning," *American Journal of Public Health* **79** (1989), 1668-74.]

We need not revisit these tragedies except to say that the systematic nature of the responses from industry and governments, which often collaborated on these deceptions, is the historical basis for a justifiable mistrust by other stakeholders of risk assessment data generated from these sources. Certainly, the best-known case is that of asbestos, because extensive litigation brought to light an enormous body of documentation on the systematic effort to suppress knowledge about occupational diseases associated with asbestos. [D. E. Lilienfeld, "The silence: The asbestos industry and early occupational cancer research – a case study," *American Journal of Public Health* **81** (1991), 791-800; "Corruption of occupational medicine literature: The asbestos example," *American Journal of Industrial Medicine* **20** (1991), pp. 127-9 and **22** (1992), pp. 609-611, 613.]

It goes on: The government of Nova Scotia file charges of criminal negligence against the operators of the Westray mine in the deaths of 26 coal miners in May of 1992, based on evidence of the willful neglect of elementary occupational safety rules. There is one notorious case of widespread fraud in toxicology testing within the last 20 years (the IBT affair) and some others where a suspicion of mischief may have hindered our understanding of health and environmental risks. [See the Wikipedia entry on "Westray Mine"; IBT: *Science,* **251** (February 8, 1991), p. 626; C. Van Strum & P. Merrill, "Dioxin human health damage studies: Damaged studies?" *Journal of Pesticide Reform* **10** (Spring 1991), pp. 8-12.]

I do not wish to grind any specific axes here: The point is *only* that risk assessment, communication, and management can be – and often is – a very dirty business. In particular, we know that major players in the game of environmental and health risks controversies, when they are communicating with other parties, have made use of the inherent uncertainties in risk estimates, and the frequent lack of complete databases for full risk analyses, to advance what they perceive to be their own interests, and that sometimes they will take steps to conceal what they do know (or suspect). It is unwise to hope that these proclivities will disappear anytime soon.

An illustration from the real world.

In the real world of risk management, the various parties seek to advance their own interests by whatever legal means and natural advantages are available to them. One detailed account of an actual case is offered below; two others may be mentioned briefly here. First, there is the notorious "Alar and apples" episode from the late 1980s, during which there was a long-running struggle between industry and the U. S. federal government over the validity of toxicology studies, using laboratory animals, which were used in the risk assessment for a pesticide product. The protracted battles over the minutiae in the scientific procedures used by the researcher in a few key studies, which included detailed examination of his lab notebooks, provides the unedifying spectacle of laboratory science as it is being filtered through the minds of lawyers.

All of this wasted effort could have been short-circuited by simple replication of the studies; why neither side saw the adoption of that elegant solution as being in its own strategic interest is crucial to the meaning of the story. [W. Leiss and C. Chociolko, *Risk and Responsibility* (McGill-Queen's University Press, Montreal, 1994), chapter 6, esp. pp. 160-75.] The case of another chemical (Alachlor) with different uses unfolded at about the same time. In this one Monsanto Canada and the Government of Canada advanced competing health risk assessments for this herbicide, and Canada ultimately cancelled its registration on the grounds of unacceptable risk for applicators (whereas the U. S., acting on the same database, did not). This risk assessment controversy was examined carefully in a published book-length study, and it is not hard to draw from the authors' account the conclusion that both sides played elaborate games with their assessments. [C. G. Brunk, L. Haworth, and B. Lee, *Value assumptions in risk assessment* (Wilfred Laurier University Press, Waterloo, Ontario, 1991).]

The case I wish to describe at greater length involved antisapstains, which are pesticides (fungicides) used to control the growth of a mold on freshly-sawn softwood lumber that otherwise will produce highly noticeable stains on the lumber surface that will make it difficult or impossible to sell. [A much longer account of this case will be found in *Risk and Responsibility,*

chapter 8.] The events to be recounted, which occurred in the years 1989-90, were the result of the lumber industry's decision to discontinue its use of chlorophenate compounds as antisapstain agents, despite the fact that they had given excellent results at a relatively low cost for about forty years in Canada and elsewhere, due to determined pressure from labor unions concerned about both long-term occupational health effects and environmental impacts (dioxin contamination and persistence in soil and water).

Alternative registered products had been introduced in the late 1980s, but the most common of these also gave rise to strenuous union protests, due in this case to acute health effects (skin irritation), and a call for its elimination as an option in the mills. The industry replied that no other efficacious registered products were available for use; the federal regulatory agency, Agriculture Canada, added that no new antisapstain products were likely to be registered for quite a number of years, due to serious gaps in the required toxicology databases. At the same time, the British Columbia (B. C.) provincial government was warning that existing uses probably would not meet its new effluent regulations for allowable concentrations of chemicals in stormwater runoff from the mill sites.

Thus, there was a stand-off with a highly uncertain outcome for an industry of great economic importance to Canada, which supplied as of 1989 about 40% of the world's softwood lumber market, and especially to B. C. as a major producer within Canada. Many of the parties had met continuously for more than five years to find a way out of the impasse that had been developing slowly, to no avail. In the meantime, the exchanges among all of them had grown increasingly bitter. Most expected Agriculture Canada to take some action that would resolve the matter, but when that agency stated firmly in late 1989 that it saw no way of doing so, the parties realized that they had no alternative but to explore the one option that the agency was prepared to leave open: The B. C. stakeholders should meet together to see if they could agree to support some solution to the impasse, including a recommendation that the agency should register one or more chemicals that did not have adequate databases; If they did so, Agriculture Canada

"probably" would take regulatory action consistent with those recommendations.

In the first half of 1990 eleven organizations sent representatives to the table: four labor unions, three industry sectors, two provincial government departments, and two environmental organizations (the federal agencies maintained an arm's-length stance so as to keep their own options open). The first round of meetings in early 1990 was not at all friendly: All of the following moves were made in an atmosphere of considerable hostility and tension. (I participated as the "neutral" chair for these meetings. In the discussion that follows, it is important to note that the representation of the strategies employed by the various parties is based entirely on my own interpretation and reconstruction of events and not on any self-reports of the participants.)

1. *Agriculture Canada's (Apparent) Bluff.* Nothing will be done to resolve the impasse unless there is a "consensus" among a group of B. C. stakeholders – which would have no legal standing in the regulatory process, by the way – to support a specific course of action.

   Comment. As it happened the major stakeholders were unwilling to call it, so one cannot tell whether it was a bluff or not. However, given the importance of the industry, it is hard to believe that the situation would have been allowed to drift slowly into chaos, so there was probably an element of bluff in Agriculture Canada's stated position.

2. *The B. C. Ministry of Environment's Bluff.* The new stormwater effluent regulations will come into effect in 9 months' time. We are aware that (1) the lumber industry says it cannot satisfy those regulations with available technologies for the chemicals it is now using, (2) there are no alternative chemicals available, and (3) there are no alternatives to chemical treatment at the moment. However, none of this is sufficient to justify our amending or postponing the new regulations.

Comment. Again, this was not called because a new chemical was introduced for which effluent regulations could be met. However, it was almost certainly a bluff.

3. *The Lumber Industry's Bluff.* There are only three other options if this stakeholder negotiation process fails: (i) We will get new chemicals (which have incomplete databases) registered, without the consent of the unions or anybody else around the table, despite the statements from federal regulatory officials that they will not do this, by putting pressure on politicians; (ii) we will return to using the chlorophenates; (iii) we will be forced out of the business and close a lot of mills.

   Comment. The second was a bluff; the first was not, and given the economic importance of the industry, it may have succeeded; as the third, who knows?

4. *The Labour Unions' Bluff.* It is the responsibility of the federal government to come up with a solution to the problem of having an adequate technology to deal with sapstain on sawn softwood lumber; if it is a solution that involves chemicals, then we are confident that some compound can be registered that is both efficacious and represents acceptable worker and environmental risk. Therefore, we should not be asked to find the solution.

   Comment. This was a bluff. The unions knew that there was no such compound.

5. *The Environmentalists' Two Bluffs (Addressed to the Union Representatives). First.* By bringing in our own experts, we will show you that *all* of the chemical technologies represent unacceptable cancer risk. If we don't budge from this position, together we can force the industry to come up with a non-chemical technology. *Second.* If the industry insists that a chemical technology is inevitable, then neither you nor we should get into the game of giving our explicit consent to these risk-benefit tradeoffs. For what if, acting on behalf of your members in the mills, you consent to the use of a new chemical with an incomplete toxicology database, and later find out that it is extremely hazardous?

Let the governments (and industry) come up with a solution that is acceptable to us; if they don't, and the industry is damaged, it will be on their heads.

Comment. The first was a bluff, the second probably was not.

Of all the people in the room, the labor union representatives face by far the most agonizing choices, for the real consequences of the risk-benefit tradeoffs being discussed fell squarely on their shoulders. The dilemmas they faced were as follows:

Health Risks (1). Giving their explicit consent to the use of a new chemical with an incomplete toxicology database, whose use later might be proved damaging to the health of the people they were representing, was something that had not been done before. [The mammalian and environmental toxicology databases for a large number of endpoints and impacts, for eight antisapstain chemical formulations, are summarized in two charts in *Risk and Responsibility*, pp. 238-9; the majority of boxes in the charts are labeled "ND" (no data).] What was the probability of this outcome?

Health Risks (2). If there was no agreement on a new chemical, Agriculture Canada's *status quo* option meant that the existing chemicals, to which their members objected and at least one of which had known adverse acute effects, would continue to be used. What was the probability that this was a worse option than agreeing to the use of a new chemical in the mills?

Health Risks (3). What was the probability that the industry was serious about the option of reinstating use of the chlorophenates – about which there were fears of long-term chronic adverse effects, especially excess cancer mortality?

Economic Risks. At the same time, they had to consider the adverse economic consequences to their members of a failure to find any solution, namely the risk to their jobs. What was the probability, first, that there really was no viable non-chemical technology, and second, that a failure to find any solution could result in significant job loss? Thus, they were caught

between the bluffs by the industry on the one side and the environmentalists on the other. In deciding whether or not to join the environmentalists in the second bluff they had to assess the probabilities of all the scenarios listed above, *and in the end, they decided not to do so*.

After some difficult meetings, an agreement was signed by a majority of the parties which was accepted by Agriculture Canada as a stakeholder "consensus," and the federal agency implemented all recommended actions in the agreement, including permitting the introduction of a chemical not previously authorized for use in Canada. The stakeholder group continued to meet periodically for many years after the initial agreement was signed, in order to monitor progress toward objectives and consider new issues. This group, called the B. C. Stakeholder Forum on Sapstain Control, faced a particular difficult new challenge in 1992. The issue was triggered by the circulation (to union members in sawmills) of what proved to be highly misleading information on the health hazards of certain chemical products in use in the mills. This turned out to be a deliberate attempt, on the part of a company which manufactured antisapstains, to seek to discredit a competitor's product by referring to alleged scientific and regulatory information that turned out upon examination to be patently false. The Stakeholder Forum representatives were able to get expert advice in a timely fashion in order to expose this "strategic" risk assessment.

Conclusions.

When the parties to controversies over health and environmental risks confront each other with their respective views, either face to face in stakeholder negotiations or indirectly through the media and in other ways, almost always the single most contentious item each seeks to communicate to the others is its interpretation of risk assessment methods and results. And, whereas much of the recent literature has emphasized the importance of trust among social actors as a necessary basis for effective communication, and properly so, this factor must be balanced against the recognition that all of the parties have very good reasons for mistrusting what the others will say.

I have suggested that, in this setting of permanent tension, we can at least define the boundary conditions for what separates the use of public trust from its abuse. Bluff and other forms of dissimulation ought to be expected and can be tolerated so long as there are effective procedural safeguards against such practices as concealing relevant information (or failing to disclose it promptly), on the one hand, or excessively alarming the public about not fully confirmed scientific research findings, on the other. These safeguards consist essentially in finding ways to put pressure on all stakeholders to be accountable for their actions and viewpoints in some common public forum, such as a stakeholder negotiation, expert panel, or public hearing process.

In the context of the inherent uncertainties associated with risk management, a form of decision making based on a poker-playing analogy featuring a group of social actors with strongly differentiated interests very well may lead to acceptable risk management outcomes for society as a whole. There is a caveat, however, namely that there must be a setting in which the various players can call each other's bluffs in a timely way, to "clear the air" of the various strategic bargaining positions and prepare the way for a fair resolution of an issue at a particular point in time. If such a setting is available, when various stakeholders are communicating their interpretations of risk to each other, we have some hope that abuses of public trust can be minimized.

Acknowledgments.
The author is grateful for the comments of two anonymous reviewers and for additional comments provided by R. Gregory and T. McDaniels.

CHAPTER 11

THREE PHASES IN THE EVOLUTION OF RISK COMMUNICATION PRACTICE

Originally Published in

The ANNALS of the American Academy of Political and Social Science

Volume 545, May 1996, Pages 85-94

Abstract

Effective communication between interested parties is widely held to be a vital element in health and environmental risk management decision-mak ing. There have been three phases in the evolution of risk communication during the last twenty years. Phase I emphasized risk: in a modem industrial economy, we must have the capacity to manage risks at a very exacting level of detail. Phase II stresses communication: statements about risk situations are best regarded as acts of persuasive communication, that is, as messages intended to persuade a listener of the correctness of a point of view. Now, in Phase III, public and private sector institutions increasingly are recognizing their responsibility to deal adequately with both dimensions and carry out sound risk communication as a matter of good business practice.

Introduction.

Risk communication may be defined as the flow of information and risk evaluations back and forth between academic experts, regulatory practitioners, interest groups, and the general public. The sharp disagreements that can occur between members of these constituencies over the best ways to assess or manage risks sometimes are based on disagreements over principles or approaches, sometimes on differences

in the information base avail- able to various parties, and sometimes on a failure to consider carefully each other's position.

In such situations, the risk communication process itself often becomes an explicit focus of controversy. Charges of media bias or sensationalism, of distorted or selective use of information by advocates, of hidden agendas or irrational standpoints, and of the inability or unwillingness of regulatory agencies to communicate vital information in a language the public can understand are common. Such charges are traded frequently at public hearings, judicial proceedings, and conferences, expressing the general and pervasive sense of mistrust felt by many participants toward others. Of course, there are also genuine differences in principle, outlook, and values in the citizenry; disagreements will persist even with the most complete and dis- passion ate knowledge of others' views. Perhaps the most contentious area of all is that of risk-benefit trade-offs, especially where different types (or distributions) of risk are at stake, or where there is no consensus on acceptable risk, thus preventing trade-offs.

Risk communication research, which seeks to clarify our understanding of the processes just described briefly, is the newest of the four risk subfields; the phrase itself appears to have been coined during 1984. [This .is the year of the earliest uses of the phrase "risk communication," according to the references listed in Bernd Rohrmann, Peter M. Wiedemann, and Helmut U. Stegelmann, eds., *Risk Communication: An Interdisciplinary Bibliography,* 4th ed. (Research Center Jülich GmbH, Germany, 1990), pp. 26, 56, 111.] It arose out of the problems being investigated in the risk perception area, which since its inception had concentrated on the disparities between risks as assessed by experts, on the one hand, and as understood by the general public, on the other. Risk perception studies have been concerned with explaining those disparities.

The interest in risk communication, however, has from the beginning had a practical intent: given that these disparities exist, are deeply entrenched in human awareness, and form the basis of strongly held attitudes and behavior, how can we improve the quality of the dialogue about risk across the gap that separates experts from the general public? Second, how can we apply this improved dialogue to achieving a higher degree of social consensus on the inherently controversial aspects of managing environmental and health risks?

In seeking to answer these questions, risk communication researchers have married their knowledge about risk assessment and management issues with the approaches used in the field of modern communication theory and practice. Statements about risk by various parties are treated as messages intended to persuade others to believe or do something. Like all such messages circulating among persons, their effectiveness as acts of persuasive communication can be evaluated according to well-established criteria: whether they gain attention, are understood, are believed, are acted upon, and so forth. This paradigm of communication research has become very well established since 1945 and has an enormous published literature to support it. [William Leiss, "On the Vitality of Our Discipline: New Applications of Communications Theory," *Canadian Journal of Communication,* 16:291-305 (1991).] Risk communication research has been able to draw on this resource and adapt its findings to the particular concerns of the risk studies area, and as a result it has made substantial progress in a relatively short time.

THE THREE PHASES

There are three phases in the evolution of risk communication, occurring over the past 15 years, and each of the later stages has emerged **in** response to the earlier ones. The earlier ones do not become irrelevant; rather, they are incorporated into the later phases, for each has contributed something of lasting value to the present. [In Phase I, the wide purview enjoyed by the risk approach stemmed from a few early sources, including W. W. Lowrance, *Of Acceptable Risk* (Los Altos, CA: Wm.

Kaufmann, 1976); William D. Rowe, *An Anatomy of Risk* (New York: John Wiley, 19 77).] Any such separation of a dynamic process into phases and dates is somewhat arbitrary; the activities in each phase overlap.

Phase I (about 1975-1984) stressed the quantitative expressions of risk estimates and argued that priorities for regulatory actions and public concerns should be established on the basis of comparative risk estimates. Phase II (about 1985-1994) stressed the characteristics of successful communications: source credibility, message clarity, effective use of channels, and, above all, a focus on the needs and perceived reality of the audiences. The seminal work here was Vincent T. Covello, Detlof von Winterfeldt, and Paul Slovic, *Risk Communication: Background Report for the National Conference on Risk Communication* (Washington, DC: Conservation Foundation, 1986). Around 1995, we entered a new phase, which will be described briefly later.

One of the leading authorities in the risk studies field, Baruch Fischhoff of Carnegie-Mellon University, recently presented a somewhat different account of the developmental stages in risk communication. [Baruch Fischhoff, "Risk Perception and Communication Unplugged: Twenty Years of Process, " *Risk Analysis,* 15:137-45 (1995).] He used colloquial expressions to identify seven such stages:

1. "All we have to do is get the numbers right."
2. "All we have to do is tell them the numbers."
3. "All we have to do is explain what we mean by the numbers."
4. "All we have to do is show them that they've accepted similar risks in the past."
5. "All we have to do is to show them that it's a good deal for them."
6. "All we have to do is treat them nice."
7. "All we have to do is make them partners."

The first two correspond roughly to my Phase I, the next four to my Phase II, and the last one to the current phase. Any such typology is arbitrary. The one I have devised highlights the radical nature of the transition from Phase I to Phase II, and in my view, the field of risk

communication as we know it today was formed by this wrenching transition.

Phase I (1975-84)

The enduring strength of what was accomplished in Phase I is captured in the following statement: In order to function sensibly in a world of expanding opportunity, we must have the capacity to assess and manage risks at a very exacting level of detail; the scientific approach to risk management offers us an imperfect but indispensable tool for doing so. Although risk is conventionally understood as "exposure to the chance of loss," we derive enormous benefits from judicious risk-taking behavior, so long as we are clever enough to know where to draw the line. For example, industrial chemicals are the basis of most consumer goods today, but all of them are also dangerous in certain doses; we have to know what the doses are that are likely to produce adverse effects on human health and the environment, and we must have institutional mechanisms in place to ensure that we do not exceed those doses.

Some serious weaknesses emerged in this phase, the worst of which could be labeled the "arrogance of technical expertise." Faced with public opposition to the results of risk-based decision-making, many experts responded with open contempt to- ward the public perception of risk. [See, for example, Ernest Siddall and Carl R. Bennett, "A People-Centered Concept of Society-Wide Risk Management," in *Environmental Health Risks: Assessment and Management,* ed. R. Stephen McColl (Waterloo, ON: University of Waterloo Press, 1987), p. 272.] For them, perceived risk is correlated with false understanding and is further contrasted with real risk, which is allegedly an objective, that is, "true," account of reality. Fortunately, one encounters this invidious distinction less and less now, since there is a greater appreciation of the errors in judgment that experts are prone to making. [A good summary of the errors in judgment to which experts are prone is National Research Council, *Improving Risk Communication* (Washington, DC: National Academy Press, 1989), pp. 44-47.]

Partly as a result of the arrogance of expertise, there exists on the part of the public a profound distrust of experts and the institutions they represent, which weakens the force of the quite sensible contributions that technical experts can make to the public discourse on risk taking. Another weakness is that critical data gaps and ever changing scientific research results are common in all significant risk management areas; the uncertainties introduced thereby produce legitimate concerns when yes/no decisions must be made.

The underlying message of permanent value in Phase I is that, for individuals as well as societies, man- aging opportunities and dangers on the basis of comparative risk information is an inescapable duty of intelligent life. However, this message could not be communicated effectively to a wide range of public audiences, partly because its authors were often so openly contemptuous of the fundamental beliefs about risk taking that were held by the very audiences whom they were addressing.

Phase II (1985-94)

The radical break that defines the transition from Phase I to Phase II was the realization that statements about risk situations ought to be regarded as acts of persuasive communication, that is, as messages intended to persuade a listener of the correctness of a point of view. Another way of putting this point is to say that "risk is a construct," that is, an understanding of a risk-type situation that is related to the situation of each participant. [Bayerische Ruck, ed., *Risk Is a Construct* (Munich: Knesebeck, 1993).] This transition represents a complete change of emphasis within the components of the phrase "risk communication": in Phase I, the emphasis is on the adjective; in Phase II, on the noun.]

Guidance for this new approach was found in the history of twentieth-century marketing communications, which had demonstrated-

first in commercial advertising, then more broadly- the effectiveness of a strategy that takes into account two key factors: the characteristics of the audience itself, and the intrinsic legitimacy of the audience's perception of the situation. The coinage of good communication is trust in the message source ("Will you believe me when I tell you something?"), and this is the under- pinning for credibility, which is a perception of the intrinsic honesty of the whole process.

The great strength of this new approach was that the formulae of good communication practices adapted from modern marketing had been tested and refined in minute detail over a long period and, for some purposes at least, were known to be highly successful. But there proved to be severe difficulties in adapting this marketing communication paradigm to risk issues. Slovic and MacGregor have diagnosed the main problem well:

> Although attention to communication can prevent blunders that exacerbate conflict, there is rather little evidence that risk communication has made any significant contribution to reducing the gap between technical risk assessments and public perceptions or to facilitating decisions about nuclear waste or. any other major sources of risk conflict. The limited effectiveness of risk communication efforts can be attributed to the lack of trust. [Paul Slovic and Donald J. MacGregor, "The Social Context of Risk Communication" (Paper, Decision Research, Eugene, OR, 5 May 1994), p. 17.]

The paradigm of persuasion in the marketing communication approach had identified a broad range of techniques for enhancing trust and credibility for messages. The early studies on propaganda already had recognized, however, that too strong a focus on the persuasive techniques themselves, especially those that seek to manipulate audiences' emotions, is potentially dangerous, for it could result in any rational content in the message being subordinated or even dissolved by those excessively clever techniques. In the more prosaic world of risk issues, therefore, emotive techniques of effective persuasive communication – that is, techniques for convincing that audience that a

particular person is a credible spokesperson on risk issues – could take precedence over the informational content of the risk message itself. [In this period, institutional risk managers (government and industry) were often told that up to 75 percent of message content-as received by audiences-was based on the non-verbal dimensions of the message delivery format itself: body posture, hand gestures, style of dress, facial expression, and so forth.]

The underlying message of permanent value in Phase II may be stated as follows: There is an obligation on the part of major institutional actors in society to communicate effectively about risks, not by simply touting the superiority of their own technical risk assessments, but rather by making an honest effort to understand the bases of public risk perceptions and by experimenting with ways of constructing a reasoned dialogue around different stakeholder assessments of risk situations. [William Leiss, "'Down and Dirty': The Use and Abuse of Public Trust in Risk Communication, "*Risk Analysis* 15:685-92 (1995).] The residual weakness here is that trust is often far too low for these experiments to succeed.

Phase III (current)

Phase III starts with the recognition that that lack of trust is pervasive in risk issues and that, because of this, risk communication practice must move away from a focus on purely instrumental techniques of persuasive communication. Phase III is characterized by an emphasis on social context, that is, on the social interrelations between the players in the game of risk management. It is based on the presumption that, despite the controversial nature of many risk management issues, there are forces at work also that favor consensus building, meaningful stakeholder interaction, and acceptance of reasonable government regulatory frameworks. Should those forces turn out to be relatively weak, both public sector fiscal constraint and the current delegitim1zation of government may leave the field of risk management exposed to wide-open confrontation between stakeholder interests.

As noted earlier, Phase II remained incomplete because the key ingredient of successful persuasive communication (trust) cannot be manufactured by the use of techniques alone, no matter how artful the practitioners are. A working hypothesis is that trust in institutional risk actors (governments and industry) can accumulate, slowly, through the commitments by those institutions – as demonstrated by deeds, not words – to carry out responsible risk communication; and, furthermore, to do so consistently, as a matter of daily practice over the long term, not just in response to crisis events. At the moment, there is no code of good practice in this area that might pro- vide some benchmarks for determining what is and what is not responsible risk communication, although I suspect that events during Phase III will lead in that direction. For now, we will have to make do with case study examples, two of which follow below.

Thus, the underlying message of permanent value in Phase III may be stated as follows: A demonstrated commitment to responsible risk communication by major organizational actors can put pressure on all players in risk management to act responsibly.

PHASE III CASE STUDIES

A typical Phase III case involves a company that has a sensitive issue, as well as one or more documents in highly technical language, that must be discussed with nonexpert stakeholders (employees, community associations). [The only published case study of this type of which I am aware is Caron Chess et al., "The Organizational Links between Risk Communication and Risk Management: The Case of Sybron Chemicals, Inc.," *Risk Analysis,* 12:431-38 (1992). The two cases that will be identified here occurred in Canada during 1995. Responsible risk communication practice suggests that it is unacceptable to simply distribute the relevant document or documents to the public with a cover note saying, "Here it is; you figure out what it's supposed to mean to you." The risk

communication challenge takes this form: the documents provide the information, but what is the message?

Case study 1: Dow Chemical Canada Inc., report on dioxin emissions from vinyl plant stacks

Dow Chemical Canada voluntarily took responsibility to develop, in co-operation with government agencies, a protocol to measure dioxin emissions from the stacks at its vinyl plant in Fort Saskatchewan, Alberta. Then the company commissioned an independent, university-based expert group to do an exposure assessment for areas within a certain radius of the plant. The expert group's report contains various figures for "incremental" additions to "background" dioxin levels, with the estimated human intakes expressed as picograms per kilogram of body weight per day (the relevant Canadian guideline is 10 pg/kg/d). [John Hicks and Stephen McColl, "Final Report: Exposure Assessment of Airborne Dioxins and Furans Emitted from the *EDCNCM* Facility at the Dow Chemical Canada Fort Saskatchewan Site" (Report, Institute for Risk Research, University of Waterloo, ON, 31 Mar. 1995).]

Prior to communicating publicly about this exposure assessment, the company undertook a series of internal meetings to discuss the most effective way of communicating this in- formation to the community. All of the following statements, as well as many variants that were considered, had to pass a "threshold criterion," namely, each one had to be believed to be a factually truthful statement by everyone who participated in these exercises. With this criterion in place, and recognizing the considerable challenge in the technical description of exposure assessment contained in the report, the objective of the company's ''key messages" was to convey its own understanding of the ''bottom-line" conclusions that it contained. The first two statements in the following list were selected as the bases for framing the communication message:

''The [Institute for Risk Research] Report results show that

- "dioxin emissions from our vinyl plant do not add significantly to the existing 'background exposure' level for dioxins";
- "all together, dioxin levels at and nearby the plant site are well within the current Health Canada guidelines";
- "the incremental contribution to background levels from the vinyl plant is exceedingly small";
- "the incremental contribution ... is insignificant";
- "the incremental contribution . . . is very small, that is, less than [a small percentage of background levels and of the Health Canada guideline]";
- "in assessing total human expo- sure to dioxins, an insignificant portion is attributable to the emissions from Dow sources";
- "current background levels of dioxins in Fort Saskatchewan, and virtually everywhere in North America, are known to be about 3.2 pg/kg/day. The vinyl plant stacks at the Dow site add [a small] additional exposure to the background level. All together, these numbers are still well below the current Health Canada guideline of 10 pg/ kg/day."

It is important to note as well that the formulation of these key messages, considered as an exercise in responsible risk communication, occurred in the context of a broader risk communication strategy. This broader strategy included, first and foremost, the decision to commission an independent group to undertake the study, which, of course, also entailed making it public in exactly the form in which it was written. Second, the company undertook to bring the study's principal author to a meeting of its Citizen Advisory Panel in Fort Saskatchewan, where a face-to-face discussion of the report's findings could take place.

Case study 2: CXY Chemicals (North Vancouver plant), worst-case scenario at a chlorine plant located in an urban area

A quantitative risk assessment (QRA) of the public safety risk associated with the plant was undertaken by an independent consulting firm. The QRA report concluded that the worst case was a possible breach of all of the plant's pressurized storage tanks, containing a maximum total of 1500

tonnes of chlorine, as a result of a severe earthquake (a 1-in-475-year event); a second scenario assumed the possibility of a much reduced chlorine inventory. Air movement (wind speed and direction) at the site was a prime factor in the "risk contours" that were developed in the QRA; the contours are expressed as elongated circles showing varying probabilities of fatalities as a result of the hypothesized event. [Ertugrul Alp et al., "CanadianOxy North Vancouver Plant: Quantitative Assessment of Safety Risks" (Report, Bovar-Concord Environmental, Downsview, Ontario, Aug. 1994); CanadianOxy changed its name to CXY Chemicals in 1995.] The results showed that, under conditions of operation prevailing at the time of the study, the plant would not meet criteria established by the Major Industrial Accidents Council of Canada (MIACC) for acceptable risk for land uses in urban areas.

Prior to communicating publicly about the QRA report, the company undertook a series of internal meetings, evaluating a variety of options, in order to choose how to respond to its findings and to formulate the company's ''key messages" at the time when the QRA report would be publicly released. A particularly difficult challenge was in choosing a method for the communication process about the QRA methodology itself, with the need to explain how such a scenario is constructed, including the use of worst-case assumptions for every relevant risk parameter, without regard to *probability* of occurrence. However successful this communication effort might hope to be, though, the bottom line was that the current plant inventory, as a result of the study findings, would be perceived to be beyond a reasonable contemporary standard for acceptable risk. The company could only respond to this challenge by first making a series of management decisions to reduce the risks associated with plant operations.

The QRA report contained a number of recommendations for immediate risk reduction, in areas peripheral to the main plant operation itself; these were all implemented. The most significant recommendation, also implemented, was to change the plant's inventory management, so that no more than 300 tonnes of chlorine – one-fifth of

the level assumed for the worst-case scenario – would be stored at any time. When the risk contours were recalculated using this operational directive, the plant operations fell within the MIACC criteria for acceptable risk.

The risk communication process associated with the QRA study then came to be viewed as an integral part of the risk management decision making that had led to significant risk reduction. The company had al- ways been committed to commissioning an independent group to under- take the study, which, of course, also entailed making the study public. Second, the company has undertaken to hold face-to-face discussions on the original QRA report's findings with any individuals or local groups who request such a meeting. The company's key messages focus on what it regards as that part of the entire story that is of immediate and practical relevance to its employees and to residents of surrounding communities, namely, the company's ongoing commitment to risk management, which had resulted in significant risk reduction. Thosekey messages were that

- "CXY Chemicals has safely manufactured, stored and transported chlorine and related products from the North Vancouver plant for 37 years."
- "CXY Chemicals, as an industrial chemical manufacturer, is proud of its safety record and continues to take steps to re- duce exposure to risk."

CONCLUSION AND EXPECTED FURTHER DEVELOPMENTS

The perspective taken in this article is that the specific features of each phase in the evolution of risk communication strategies set the challenges for the period to follow. The weaknesses in each phase drive this evolution further, and in this process, we strive to preserve the strengths of each (see Figure 1 at the end). The three-phase evolution A good theoretical framework for Phase III may be found by

extending the “strategic environmental audit: and “environmental responsibility” approach. [Grant Ledgerwood et al., *Implementing an Environmental Audit: How to Gain Competitive Advantage Using Quality and Environmental Responsibility* (Homewood, IL: Irwin, 1994).] This could be operationalized by the formulation of a "code of good risk communication practice," and compliance with the code could be verified through a "risk communication audit" designed to meet the test of public credibility. Some of the much-needed foundations of trust might be laid in this manner.

FIGURE 1

OVERVIEW OF THE THREE PHASES

PHASE I

EXPERTISE (NOT VIABLE IN COMMUNICATIONS WITHOUT TRUST)

PHASE II

TRUST (NOT VIABLE WITHOUT EVIDENCE OF CHANGES IN LONG-TERM ORGANIZATIONAL BEHAVIOR)

PHASE III

ORGANIZATIONAL COMMITMENT (REQUIRES CRITERIA OR CODE FOR “BEST PRACTICES)”

Chapter 12

Effective Risk Communication Practice

Original Publication:
Toxicology Letters **149** (2004), 399-404
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Abstract

Major public controversies over the management of health and environmental risks have been ongoing since the 1970s, starting with chemicals (pesticides and dioxins) and running through risks associated with many other industrial technologies. We can find in those controversies many common features, which cut across differences in both the technologies themselves and the types of risks they engender. This understanding also enables us to propose strategies to organizations to help them better respond to the public's needs (and the public interest) when concerns over risks arise. Effective risk communication practices are among the most important responsibilities for industry and governments in this regard. Since its origins in the late 1980s, risk communication practice has achieved a better understanding both of its goals and of how to achieve them. We are now in a position to specify with some precision what the fundamental requirements of good risk communication are, and they fall into three basic areas: (1) undertaking "science translation," (2) addressing uncertainties, and (3) dealing with the science/policy interface. Within these three areas there are a set of ten specific tasks, representing what may be called the minimum essential content requirements for every effective risk communication effort.

The Concept of Risk.

"Risk" is best described as "the chance of loss (or gain)." I put the aspect of "gain" in parentheses for the simple reason that, when most people think of

risks “off the top of their heads,” so to speak, they think of what worries them most. That is, they think about the bad things that might happen to them, especially to their children, as a result of health problems or environmental pollution. But above all risk is “chance”: Asked whether an uncertain outcome is going to happen or not, the risk expert must reply: “Maybe.”

If people are engaged more fully on this subject, most of them will also readily acknowledge that they willingly participate in risk-taking activities, not just to prevent losses, but to achieve gains. For most this involves buying lottery tickets or spending limited amounts of their money playing various games of chance at casinos, the race track, or in friendly games of poker at home. In fact, playing games of chance is where most people actually encounter the concept of probability or chance in their daily lives. Most will also be aware that they purchase insurance as a hedge against the chance that many bad events which occur randomly in the population may happen to them: Even the most cautious (risk-averse) homeowners or vehicle drivers can wind up inadvertently causing a fire in their home or an accident on the road.

The “language of risk” is, however, gradually spreading throughout various domains of our everyday life, and this is because it is such a useful language. Think about weather forecasts, which are now given in probability terms (“There is a 50% chance of showers today”). This is a relatively recent development. It’s likely that, if asked, many people would still struggle to articulate what a “chance of rain” really means. But using this language competently expands as a result of repeated usage, and we can expect many more such uses in the future, simply because it is the best way to express the fact that reality is made up of a range of possibilities at any moment in time (Ropeik & Gray 2003).

Because the language of risk is spreading, more and more people also are becoming aware that their country depends on an economy which has entrepreneurial risk-taking at its heart. Obviously, in this domain the "chance of gain" predominates and is the main motivator of behavior; great economic wealth has been created under its aegis. Alas, more recent news from financial markets has made many aware that there can be large downsides to entrepreneurial activity as well, and that this is an aspect of the system that can affect them directly. The largest headlines have been devoted to the shenanigans of corrupt and unprincipled corporate executives, but the reality is that, behind the headlines, tens of thousands of employees have lost well-paying jobs and, in some cases, their entire pension assets as well. Yet this too is a consequence of working in an economy founded on risk-taking.

In part this has happened because risk-taking activity itself gets more complicated every day – thus, at the same time as the citizen becomes more educated, the subject becomes harder to understand, requiring continuous attentiveness. I will give two examples. In financial risk management, new devices for hedging risks have been invented, but they are poorly understood even by market regulators, so that, in the case of the Enron collapse, it became clear after the fact that what appear to be very clever and sophisticated financial instruments were shown to be just elaborately-masked frauds. In the case of the earlier collapse of Long-Term Capital Management, it emerged too late that market regulators, as well as the very intelligent investment bankers who had lent vast sums to this firm, had no idea that the firm had found ways to increase the leverage on its capital far beyond any definition of "rational" risk-taking.

In an entirely different domain, that of the regulation of the environmental and health risks associated with chemicals, continuous improvement in detection methods means that scientists can find traces of many substances at minute concentrations. Indeed, it is safe to say that we will continue to detect them, no matter how small the concentrations

become. But should we worry about that? What it means is that the citizen has to be able to trust in the credibility of some very complex statistical manipulations done by the practitioners of risk assessment, who try to figure out whether it makes sense to require some party to spend money to make certain small concentrations even smaller. The problem is, trust is in short supply these days.

The paucity of trust makes risk assessment controversial. Also, many citizens look at risk rather differently than professional risk managers do (Leiss 2001). Many feel much more comfortable with the hazards that are familiar to them, such as car accidents on roads, as opposed to unfamiliar things, such as radiation, and they appear willing to tolerate much higher risks for the former than for the latter. Many do not react in the same way to all consequences, such as fatalities: Deaths of children seem particularly troublesome, for example, as do deaths of large numbers of people simultaneously, as in airplane crashes.

Not all ways of dying or falling ill are regarded as equal, with cancer or slow neurodegenerative disease being more dreaded than sudden accidental death. Many are offended if, in response to an expression of concern about a particular hazard, such as radiation from nuclear power plants, they are told that, by comparison with many other things that people cheerfully indulge in daily, that one is nothing to worry about. And generally many do not understand why, with all the resources of modern science at their disposal, risk managers cannot give clear and unequivocal responses to their concerns, but instead are wont to couch their answers in terms of probabilities, that is, the chances that something bad may or may not happen.

And so, despite the fact that citizens are becoming more and more educated about risk, they also have a long way to go, both in understanding the nature of risk and in deciding how their governments should regulate or

control risk-taking activity. For while it is true that there are significant and demonstrable probabilities of reaping benefits (the "upside") from basing our economy and policy on a risk-based approach, there are equally demonstrable chances of experiencing harms (the "downside"). In fact, if we imagine this as a "game of life," with the aggregate size of the benefits and losses as the stakes on the table, it is clear that the stakes on both sides (upside and downside) increase as we get wealthier. Simply put, we have more to gain if we play the game well, but we also have much more to lose if we play it poorly.

I will make brief comments on two cases to illustrate these difficulties. The first is climate change risk (Leiss, Dowlatabadi & Paoli 2001). The risk itself is characterized by the highly-probable impact of human emissions of greenhouse gases (GHGs) on the climate system, including long-term temperature trends (especially where we live, in northern latitudes) and many other impacts. GHGs are produced by our uses of fossil fuels and other activities, and we are very dependent on these fuels, for our cars and many other things. If we need to reduce climate change risk by limiting our uses of fossil fuels, as climate scientists strongly urge, we will have to make some important changes in the way we live. But do we *really* need to do so? The assessment of climate change risk is a very difficult and complex business, with difficult uncertainties that are hard to communicate to non-experts, and with probabilities of outcomes that extend forward many centuries in time (Kandlikar et al., 2005). We are not very good at managing risks that have such characteristics. As so, as our governments dither about whether or not to ratify the Kyoto Protocol, a very small first step in addressing this risk, many citizens are unsure about what to think and what to do.

The other is genetic engineering, especially of the human genome. When we contemplate such things as gene therapy, gene enhancement, and cloning, we come face to face with moral issues we have never confronted before, about whether we should even be contemplating such radical steps.

At the same time, biotechnology companies and scientists tell us it would be unthinkable to pass up the benefits that could flow from manipulations of our DNA, including the eradication of inherited disease and effective treatments for many other feared diseases. The temptation has been laid before us. How do we even begin to assess the risks, especially if we only discover what they are once we are already well down that path (Tyshenko & Leiss 2004)?

The very nature of risk forces us to balance competing types of uncertainties. This can be a difficult and even unpleasant business, but it seems that we are well along the path anyway, so we shall just have to make the best of it.

Effective Risk Communication Practice.

Risk Communication is the process of communicating responsibly and effectively about the risk factors associated with industrial technologies, natural hazards, and human activities (Leiss & Powell 2004). These communication responsibilities arise for all those who are developers and managers of industrial technologies, as well as for those who have public health and environmental management oversight for technologies, natural hazards (including diseases), wildlife and natural habitat management, and public health.

All industrial sectors involved in chemicals issues must be prepared, in my opinion, to make major investments in good risk communication practice. New types of expenditure are hard to justify for any organization these days, to be sure. I advocate the reallocation of part of the huge, ongoing investments made in primary scientific research and in risk assessment exercises to the area of risk communication. The reason is simple, especially for industry: Science and risk characterization are never-ending quests, and more science will not solve the essential problem, which is public distrust of the risk assessments. We knew enough about dioxin risk by about 1985, for example, to make an educated guess that exposure to dioxins is not, and is highly unlikely to become, a significant risk factor –

relative to many other factors – in the lives of people in Western industrial societies. Yet the science goes on, and the controversy persists, because insufficient attention has been paid to the need for conducting a fair and prolonged risk dialogue with the public about dioxins – and now, about endocrine-modulating substances (see www.emcom.ca).

This situation must change. The primary reason why we ought to spend far more attention and resources in the future on good risk communication practice is this: There is a fundamental and *permanent* divide between the way in which risk assessment experts present risk information, on the one hand, and the way in which most members of the public think about risk issues, on the other. *And this divide is not going to go away.*

All good risk assessments strive for some quantitative expression of the hazard characterization and the exposures of different populations, even if large uncertainties in the estimates must be acknowledged. All of this is summed up as a calculated probability for various outcomes. The "competing" risk assessments made by the public – and I use the word assessment here deliberately, reflecting the fact that judgments are made – are almost always framed in *qualitative* terms, on the other hand. Typical expressions are: "Is it safe to do this – yes or no?" "Will my children be harmed if they are exposed to this?" "That is a horrible way to die." "No one should be exposed at all to cancer-causing substances." Therefore, whereas under certain circumstances some expert assessors may regard low-level exposure to a known carcinogen as an insignificant (*de minimis*) threat to public health, the public's perception of the *meaning* of this information could be quite different, and legitimately so, since different judgmental criteria are being applied to the same set of "facts."

The other, and equally serious permanent divide between experts and the public has to do with relative risk trade-offs and relative cost-benefit ratios for risk reduction expenditures. In fact, everyone in a market-oriented society makes such trade-offs every day, in deciding how much to

spend to protect themselves against various outcomes, what to worry about in the almost infinite array of risk factors in everyday life, and what information to pay attention to or ignore. But mostly this is done subconsciously, and people understandably have a great aversion to admitting to themselves that they do indeed tolerate various levels of risk for themselves and their children. In addition, the public is firmly convinced that it matters greatly whether one is exposed "voluntarily" or "involuntarily" to risks, even if the consequences of the former (such as smoking) should exceed most of the latter by a wide margin. This belief appears to be rooted in the importance of the values of personal choice and individual autonomy.

This is the bottom line: These and other divisions between experts and the public are permanent and will not disappear, although they may be reduced over time. Good risk communication practice seeks to address those divisions, and to facilitate an informed understanding of the risks and benefits associated with the use of industrial chemicals, but it cannot overcome those divisions and, indeed, should not try to do so.

Then why bother spending much more time and resources on good risk communication? Because not doing so represents a business risk which may grow to significant proportions for a sector. In my opinion, a large share of the reasons why these controversies are so intractable lies in the fact that they were allowed to fester unattended for so long (especially with respect to dioxins, which is the principal issue driver here), through the nineteen-seventies and nineteen-eighties and on into the nineteen-nineties. Industry and governments poured huge resources into scientific research and risk assessment, but throughout this long period – alas, it must be said -- *no organization except Greenpeace took seriously the communications challenge!* The results are there for all to see.

Risk communication practitioners should promote, in their areas of responsibility, a reasoned dialogue among stakeholders on the nature of the relevant risk factors and on acceptable risk management strategies. In doing

so they should seek to carry out the following tasks, among others: (1) interpret the results of scientific risk assessments in terms that are appropriate for non-expert audiences; (2) understand the basis of public risk perceptions; (3) work with interested parties towards a shared understanding of the risk factors.

From the standpoint of public policy, risk assessments are a means to the ultimate goal of reasoned public dialogue, wise risk management, and sensible priority-setting in the allocation of resources to risk control and reduction. Given both the inherent limitations of risk assessments, especially the irreducible uncertainties usually associated with them, as well as legitimate differences in society over how to assign priorities for risk reduction, however, even the best risk assessments cannot lead automatically to wise risk management decisions.

Informed public understanding of risk factors is the key to achieving broad support for and trust in risk management strategies, and this in turn depends upon an abundance of good risk communication practice. The present imbalance in resources devoted to risk assessment, on the one hand, and risk communication, on the other, must be overcome if society is to realize the value of its investments in scientific risk assessment. A good shorthand rule would be to invest one dollar of risk communication effort for every dollar devoted to risk assessment.

The responsibility to carry out good risk communication practice is a matter of creating specialized professional skills and an appropriate level of organizational commitment. It is emphatically not a matter of finding a way to emerge unscathed from some community meeting where outraged citizens voice their grievances. Rather, it can only be discharged through activities that go on every day and which endure as long as do the risk factors themselves for which the organization is responsible.

The OECD Guidance Document (2002).

For the first time ever, this document provides a checklist of "minimum necessary content" for any effective risk communication exercise where substantial issues of public concern are present (OECD 2002, 23):

1. Begin with a statement of commitment to maintaining a communications flow of information *pertinent to public concerns* about the case at hand;
2. Distinguish clearly between hazard (the types of possible harms) and risk (the likelihood for individuals or populations to suffer those harms);
3. If the type of possible harms has special qualities, eliciting feelings of "dread" or heightened fears, be aware of them and acknowledge them in the communications;
4. Specify what is known about exposures and whether it is likely that sensitive populations (especially children) are likely to be exposed;
5. Indicate the quality of the knowledge base, how it is expected to improve through further research, and who is responsible for improving it;
6. Describe qualitatively the uncertainties in the knowledge base and what further steps might reduce these uncertainties, and when;
7. Describe both quantitatively and qualitatively the estimates of probability that have been made, if available, or if not available when they might be expected;
8. Provide a justification for what is thought to be a tolerable or acceptable level of risk in this case, using either risk/risk or risk/benefit trade-offs, or both;
9. Provide a clear and compelling justification for the type of action response that has been chosen or recommended in this case,
10. Provide contact information where responses to questions may be obtained.

4. Applied Risk Communication: The Case of Endocrine Disruptors.

My colleagues and I are developing in Internet-based public information resource for the issue of endocrine disruptors (or modulators): www.emcom.ca. The material on this website seeks to address the three

most important and substantial types of requirements for a risk communication program:

- "Science translation" from technical terminology into user-friendly language, also using animations and graphics to illustrate scientific concepts;
- A fair treatment of the uncertainties and knowledge gaps in the risk assessment;
- An explicit commitment to dealing with the "science/policy interface," that is, the demand by citizens that governments regulate risks appropriately.

I encourage those who are interested in a practical application of the principles of good risk communication practice to visit this website and explore its various sections.

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CHAPTER 13

A TALE OF TWO FOOD RISKS:
BSE AND FARMED SALMON IN CANADA

Original Publication:
W. Leiss & A.-M. Nicol, "A Tale of Two Food Risks,"
Journal of Risk Research **9** (2006), 891-910.
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Taylor & Francis

Abstract

Today the public has access to enhanced resources for interpreting the technical basis of risk communication messages, emanating from government and industry, dealing with food risk issues. These resources include extensive media reporting on key scientific studies as well as Internet sites, hosted by many different players, where the scientific and statistical basis for risk assessments are presented, debated, and criticized. In this information-rich context risk managers are challenged to present a clear, forthright, and honest account of the scientific and statistical underpinnings – including uncertainties – for their risk estimations. We discuss these issues in the context of two recent Canadian food risk cases, BSE in cattle and farmed salmon. In the BSE case the government's risk communications failed to accurately express the nature and scope of the risk as it had been evaluated by government officials in technical documentation; specifically, the complex statistical manipulations served as a smokescreen behind which was hidden the true – catastrophic – risk, namely, that the discovery of even a single case of BSE in the Canadian herd would have "extreme" consequences for the entire group of small, independent beef producers. In the case of farmed salmon, our study shows that the contaminant numbers are open to differences in interpretation among

government agencies, and that understanding the level of risk is no simple business. The industry should have acted years ago to ensure that the public was provided with reliable resources for understanding the nature of chemical contaminants in fish and the risk assessment methodologies used for determining safe levels of consumption.

Introduction.

Risk issues generally, and food risk issues in particular, pose a number of challenges for the interested public (Leiss, 2001). Without a doubt one of the most severe challenges is in understanding and appreciating the scientific research and statistical analysis that lies behind, and supports, the technical risk assessment. Quite often, the body of prior research and analysis is vast and complex – and, in some cases, it is still evolving toward a more complete picture of the risk. In stark contrast to this complexity, however, stands the usual simplistic response of government officials to a potentially worried public: "Trust me, this food is safe to eat." Few among them may know how unstable the feeling of trust is when it comes to food (Frewer et al., 1996; Lang and Hallman, 2005; Poortinga and Pidgeon, 2005).

In the age of the Internet and expanded scientific literacy this standard response becomes increasingly problematic. For example, both print and electronic media now routinely include discussions of new scientific research findings in daily newscasts, especially for risk issues that are likely to be salient in the public mind. Often, when this occurs, the reporting will include interviews with persons who appear to be equally reputable but who interpret the scientific findings in different – or opposite – ways (Schütz and Wiedemann, 2005). Second, for the large segment of the public which has access to high-speed Internet connections, some initial acquaintance with a risk issue can easily open a whole world of information, expert and non-expert opinion, and, arguably, misinformation. A notorious case in point is the alleged link between MMR vaccine and the risk of autism and other diseases. And there can be second-order consequences that flow from these new developments: As is well-known, the alleged MMR/autism

link led to a significant drop in childhood vaccinations in the U. K., requiring public health authorities to mount a campaign to reverse the trend.

There is every reason to believe that these tendencies – where science and risk assessments become a matter of public debate – will strengthen with each passing year. We suggest that these tendencies impose new requirements on government officials and others who must communicate with the public about risk factors, namely, to be more forthcoming and explicit about the scientific and statistical complexities inherent in technical risk assessments. For example, in the case of the MMR vaccine, the "enhanced" discussion, resulting directly from the controversy, necessarily expanded to include elaborate relative-risk estimates (since vaccination is itself not risk-free) and risk-benefit discussions. We believe that those who – in industry and government – bear risk communication responsibilities, and who wish to be regarded as trustworthy, must get themselves prepared to engage in these more elaborate interchanges about risk assessment.

What is true of risk issues generally is doubly the case for food risk issues, which are especially sensitive for the public. Looked at from the other side, in matters of food both governments and industrial firms face having even a risk classified as negligible "blow up in their faces." In the following pages, we present two cases of recent food risk issues in Canada, in both of which events unfolded with startling rapidity. Both illustrate the need to engage the public more fully with respect to the inherent complexities of food risk assessments. In our conclusions, we seek to draw these two lessons for effective risk communication (RC), which go beyond the standard "trust" doctrine: (1) risk managers need to be able to craft RC messages which transcend the level of "formulaic" responses ("food is safe") and address the unique features of a specific controversy; (2) in an age when the public has access to varied information sources, RC messages must strive to embrace adequately both the rich complexity and the uncertainties in the scientific and statistical-analysis basis of the risk assessment.

BSE comes to North America.

In the period between May 2003 and January 2006, five cases of bovine spongiform encephalopathy (BSE) were discovered in the Canadian herd, an episode that has had devastating impacts on Canadian farm families and the country's farm economy. [For a fuller account, see Chapter 17 in this volume.] By November 2003 – a mere seven months after the initial case – the estimated negative economic impact (direct and indirect economic costs) from a single case of BSE had already exceeded $5 billion. The personal and family costs among farm families are incalculable. How could this have happened, as a result of one or two sick cows? How could this have happened, since no one thinks – on a comparative-risk assessment – that the health of Canadians is seriously compromised if meat from a few cattle infected with BSE had entered the domestic food supply over a period of years?

First, BSE did indeed have catastrophic consequences in Canada, but not as a result of issues linked directly to the safety of food. Second, governments in Canada brought on this catastrophe by mismanaging the risk of BSE. Specifically, government officials failed to identify and manage the single most serious risk to a specific segment of the Canadian public, namely, the risk of economic catastrophe – and its attendant social consequences – to the independent beef producers in farm communities. They failed to communicate to beef farmers and the larger agricultural industry the true risk, that is, the best estimate of the likelihood that BSE would show up in the Canadian herd – and, if it did, what the consequences would be. The truth is, there was always a fair likelihood that North America would see a few cases of BSE in its herds. There is still a fair likelihood that one or more additional cases will appear in the coming years.

There are terrible ironies in this whole episode. The normal excuses given by governments for failing to communicate risks effectively is that "the public may panic." With respect to BSE, public panic can be reflected in sharp drops in beef sales, as happened in Japan (which was in fact a collapse in the public's trust in government as regulator of food safety). In the case of

Canada's troubles with beef, however, this excuse is unavailable: Canadians responded to the terror of BSE by *increasing* their consumption of beef, which – since prices did not drop – probably reflects both the public's love of beef and its desire to make a generous gesture of support to the ever-struggling farm sector (cf. Raude *et al.*, 2005).

BSE – bovine spongiform encephalopathy or "mad cow disease" – is one of a larger class of animal diseases called transmissible spongiform encephalopathies (TSEs). They may arise spontaneously (sporadic cases) and can also be acquired by transmission; they can also cross the species barrier. The best-known member of this class is scrapie, which affects sheep (BSE may have originated as a mutation of scrapie); others include CWD (chronic wasting disease) in deer and elk, and feline spongiform encephalopathy (seen in both domestic and wild cats). A number of the cases, such as those in mink, cats, and a wide variety of hoofed animals kept in zoos, are attributable to the feeding of animal protein infected with scrapie and BSE. CWD still presents challenges to science in terms of its origins and mode of transmission. The human form of sporadic TSE is Creutzfeldt-Jakob Disease (CJD), which is transmissible through direct contact with infected nerve or pituitary gland tissue (corneal transplants, growth hormone implants). Another acquired form, caused by infection from BSE, is known as variant CJD (vCJD).

BSE has been one of the highest-profile issues in animal health and food safety around the world for over fifteen years now. The early history of the issue is well known. First, the British beef industry was decimated, giving rise to countless tragedies among farm families and running up costs against the public treasury in excess of four billion pounds sterling. Next, it spread to over twenty other countries, including most of the European continent and as far away as Japan, where the dual difficulties of farmers and public costs have been repeated. The most plausible explanation for the global spread of BSE is that it resulted from the exporting of infected feed, live cattle and other bovine materials from Britain. The feed exports were the worst of these: The official report of *The BSE Inquiry* (Philips *et al*., 2000,

p. 70) in Britain confirmed that British officials permitted these exports to continue in full knowledge that some portion of the feed certainly was infected. As the issue evolved over the course of the decade 1986-1996, there were major failings in risk communication (Leiss and Powell, 2004, chapter 1; Wiedemann *et al.*, 2005).

BSE came to Canada and to the United States as well initially through imports from Britain of small numbers of live animals that were infected, which were rendered following slaughter and subsequently contaminated the domestic animal feed supply in both countries. What follows is a quotation from a draft risk assessment document prepared by a Canadian federal department in mid-2000 but never either completed or publicly released: "Therefore, live cattle and sheep imported from the UK during the early 1980s, and possibly before this, up until the time of import bans could have served as a vector for the introduction of BSE to Canadian livestock either through direct animal contact or through consumption of animal feeds produced with rendered materials of imported animals" (Orr and Starodub, 2000).

And yet the nature of this risk was known to Canada's national risk regulator for animal health at least as early as May 1994, when an internal report – entitled "Risk Assessment on Past Importations of Cattle from France, Switzerland and the U. K." – was prepared, *but never released to the public*. The report (Animal, Plant and Food Risk Analysis Network [APFRAN], 1994) states:

- "The probability of entry of BSE infected cattle through the 1982-89 importation of 183 cattle from the U.K. appears to be very high";

- "Further cases of BSE [in addition to the one found to date in this cohort] would likely prompt a trade embargo against Canadian exports of cattle, beef and dairy products for an indefinite period of time by some or all importing countries"; "domestic consumption of beef and dairy products could diminish considerably … [and] necessitate changes in rendering policies."

- "The economic impact including foreign trade losses and domestic public reaction gives this disease a high impact rating."

We are aware of no evidence that there was any direct and public communication of the nature of this (economic) risk, from the national risk regulator to the beef-producer industry – which as of May 2003 consisted of 90,000 small producers – *at any time* between May 1994 and May 2003, a period of nine years. Instead, for next nine years the risk regulator labored in private on an elaborate quantitative risk assessment. When it finally appeared, in December 2002, Canada was a mere five months away from the discovery of its first indigenous case in May 2003. The following statement is found in the Executive Summary (Canadian Food Inspection Agency [CFIA], 2002a):

> "The estimated probability of at least one infection of BSE occurring prior to 1997 was 7.3×10^{-3} and therefore the likelihood of establishment of BSE in Canada was negligible. The risk was even further reduced by the mitigating measures in place since 1997."

But buried deep in the third section, positioned almost as an afterthought following a recitation of extremely complicated statistical analysis, is another exceedingly simple, but utterly devastating judgment (CFIA, 2002b): "*If BSE was introduced, the consequences would be extreme*" (our italics). [See Appendix I at the end of this chapter.] This statement was never extracted from its hiding-place in this technical document and communicated directly to the beef producers. It is almost impossible to imagine that the ordinary beef farmer would have had the time or patience or skill, between bouts of caring for his herd, to wade through the pages of mathematical expression to find what he needed to know – and to find it in time to digest its meaning and consider his options.

Note also that the Executive Summary – which might have attracted some notice on the farm – CFIA (2002a) describes "the likelihood of establishment of BSE in Canada *prior to 1997* as "negligible." The dictionary definition of the word "negligible" is, "so small or unimportant or of so little consequence as to warrant little or no attention: TRIFLING." How did the "very high probability" of the entry of BSE into the herd – as of the internal document of May 1994, cited earlier – become the "negligible likelihood" of BSE being "established" in the herd as of 2002? This appears to be a

linguistic sleight of hand: If "established" – a word not further explained in the document – meant "similar to what happened in the U.K.," where the disease was spreading quickly through the national herd for some years, then it is true that BSE was unlikely to become endemic in the Canadian herd, since after the early 1990s officials in other countries, including Canada, were on the lookout for the disease.

But that is not what Canadian beef producers most needed to know as of December 2002, when CFIA's Risk Estimation document was finally released. What they most needed to know was that the occurrence of even a single case would have devastating consequences for them – because they were exporting 75% of their cattle by 2003, and their export markets would close instantly if a single case were to be found. Indeed, this is exactly what occurred: Canada's BSE crisis of 2003 was a disaster waiting to happen.

In its evaluation of the period after 1997, the Agency simply asserted – *without any supporting argument whatsoever* – that, in view of policy choices made in 1997, namely, the partial ban on feeding ruminant material to ruminants – the risk thereafter was "further reduced" from "negligible." It is hard to say what the phrase "further reduced from negligible" actually means: "Infinitesimally small"? "Too small to measure"? In any event, no statistical calculations at all were adduced in defense of this judgment. And yet, if you were a Canadian beef farmer in, say, December 2002, what would you care about the risk as it was before 1997? What you needed at that point in time, and should have had in hand from your government, was some solid estimate of the risk you were facing at that moment.

Why were the consequences of finding a single case of BSE in a national herd in 2003 so catastrophic? The reason is, during this time, Canada and many other nations subscribed to an international policy on BSE which is straightforward and brutal in its consequences: If you are a country exporting beef, and you have just one indigenous case of BSE in your herd, you're out of the beef export game *for seven years*.

The standard formula for risk estimation is: R = P x C (risk equals probability times consequences). The consequences of finding only one case in the Canadian herd were qualitatively assessed as "extreme," *but this judgment was never factored into the overall risk assessment*. In other words, CFIA's risk assessment actually amounted to the formula R = P: The frequency estimation alone was allowed to stand as a proxy for the risk assessment, which is contrary to the most basic principles of standard practice, where R = P x C. When consequences are factored in, as they always should be, the risk ranking level for BSE in Canada as of late 2002 – as assessed by CFIA – was in fact a state of "intolerable" or "catastrophic" risk. What they should have said to farmers, in language that could not be misunderstood, was something like this:

- "There's a fair likelihood that anywhere from one to a few indigenous cases of BSE will show up in the Canadian herd;"

- "Since Canada and other countries subscribe to a policy of 'one cow and you're out,' beef producers in Canada should be fully aware of the reality that others will shut their borders *immediately* to our beef if even one indigenous case of BSE is discovered here."

- "You should also be aware that, in the event even one indigenous case of BSE is found in our herd, international trade agreements to which Canada is a party provide that we will not be allowed to resume exports of beef and beef products until a full seven years have passed following the last case."

What would beef producers in Canada have done, in the years between 1997 and 2003, if they had received these three messages, loud and clear, from their industry and their governments? Would they have continued building up a huge beef herd, 75% of which was destined for export after slaughter? Or would at least some have concluded that this was an utterly unreasonable risk for producers to take – *provided that* they had been informed in clear language about this risk by the federal regulator, as they should have been, but were not. Beef producers in Canada were not told the truth about either

the actual risk or the devastating long-term consequences that might follow therefrom.

The lingering tragedy still unfolding around us on Canada's farms arose in large part because the people who speak on behalf of our institutions, principally those in the federal and provincial governments, have never learned how to use the language of risk appropriately. Instead of telling Canadian beef producers – in effect – that BSE wouldn't happen here, they ought to have said, "Yes, it could very well happen, and if it does, the economic consequences will be devastating."

These officials knew that the first case (called the "index case") would bring an economic disaster to Canada's beef producers – because this fact is clearly acknowledged in a CFIA technical publication published, ironically, shortly before May 2003 (Morley *et al.,* 2003, p.178): "The risk estimate … indicates a negligible probability that BSE was introduced and established in Canada; nevertheless, the economic consequences would have been extreme." Subsequent events have shown that the second part of that statement, at least, was brutally accurate. In the light of this knowledge, the appropriate risk management strategy – the one that should have been strongly recommended to Canadian beef producers for the entire period between 1997 and 2003 – would have been, to restrict the growth of the national herd until the risk had diminished (as it will with time).

[Note that the authors – who were the CFIA employees in charge of the Risk Estimation exercise – here refer to the "negligible probability that BSE was *introduced* and established in Canada" (our italics). We have discussed earlier (page 11 above) what the word "established" probably meant. But "introduced" is very different. The "introduction" of BSE into Canada is what the May 1994 document (APFRAN, 1994) was referring to, in the statement quoted above on pages 9-10: "The probability of entry of BSE infected cattle through the 1982-89 importation of 183 cattle from the U.K. appears to be very high." In this published article of 2003 Morley et al. – on the basis of no new evidence or argument – convert the earlier "very high

probability" estimate to a "negligible probability" one. We apologize for taking the reader through this tedious argument about how arbitrary changes in qualitative measures may stand side-by-side with the most exacting quantitative risk assessments. (For another notorious example – the infamous "Alar" episode – see Leiss and Chociolko [1994], chapter 6.) But these qualitative expressions are the words that form the basis of risk communication messages.]

Repeated and longstanding failures in the accurate communication of risk are at the heart of what went wrong in the mismanagement of BSE risk in Canada. These failures occurred in the entire period after 1997, when Canada and the United States adopted a set of policy choices about BSE risk in response to the belated acknowledgment by the government of the UK, in 1996, about its own catastrophic failings in this regard.

Farmed Salmon.

On 9 January 2004 Ronald Hites (Indiana University) and David O. Carpenter (State University of New York at Albany), along with others, published an article in the prestigious scientific journal *Science.* This study was the most comprehensive to date to explore the issue of chemical contamination in farmed salmon on a global scale. The research found significantly elevated levels of chemical contaminants and insecticides such as PCBs, dioxin, dieldrin and toxaphene in farmed salmon as compared to wild salmon. These contaminants have been associated with a range of health problems including cancer and immunological, endocrine and developmental problems.

The article recommended that consumers limit their consumption of farmed salmon from less than one to up to eight meals per month, depending on where in the world the salmon was raised. This was because the degree of contamination varied by country, with European farmed fish containing higher levels of these contaminants than those from Chile or North America. The salmon farmed in British Columbia and Nova Scotia were some of the least contaminated in this report, although the researchers

recommended that people consume less than 10 meals per month of any of the salmon farmed in Canada. Less than one meal per month was the recommended limit for salmon farmed in Scotland and the Faroe Islands (Hites *et al.*, 2004). The authors used the U.S. Environmental Protection Agency's (U.S. EPA) risk assessment protocol to determine the acceptable number of meals that consumers could eat. This protocol is used across the United States to develop advisories for consumption levels for non-commercial (recreational or locally-caught) fish.

Response to the article was swift: Newspapers and electronic media across Canada picked up the story and within days, grocery stores across the country were reporting decreases (anywhere from 20% to 70%) in the sales of farmed salmon ("Salmon Report," 2004; "Salmon Sales," 2004; "Bad Fish," 2004). Stores and fine-dining restaurants increased the profile of their wild salmon selections. This decrease in farmed salmon's popularity was bad news for Canadian fish farmers in provinces like British Columbia and New Brunswick, who had recently contended with significant financial losses due to disease outbreaks in their fish as well as falling prices across the global markets (Statistics Canada, 2005).

By 12 January 2004, as consumers were exercising their choices at grocery stores and restaurants, officials from the Canadian Food Inspection Agency (CFIA) and Health Canada were stating that salmon was still safe to eat at the levels of contamination found in the Hites report. These agencies did not dispute the levels of toxins found in the fish, but rather emphasized that the levels were still below Canada's maximum level of contamination: "According to the CFIA, there are no concerns over eating farmed salmon…especially in regard to contaminants. We feel the product is safe" (Bouzane, 2004). Health Canada's fish and seafood survey, which has not been updated since 2002, recommends that Canadians continue to eat both farmed and wild fish, including salmon, emphasizing that these foods are a good source of healthy oils, and states: "Differences in total PCB levels between farmed and wild species were not statistically significant" (Health Canada, 2002).

Fish farmers around the globe fought the Hites report with their own press releases heralding the continued benefits of farmed fish for a healthy diet and dismissing the study's recommendations. The organization "Salmon of the Americas" (2003) even developed a press kit for retail outlets that provided hand-outs and other materials for consumers concerned about the issue. Pro-farming agencies such as Positive Aquaculture Awareness (PAA) accused the report of being misinterpreted by activists, even though the Hites article itself actually made the recommendations about the number of meals that people could safely consume ("Activists Use," 2004). Salmon farming groups were quick to respond to the bad press by extolling the heart-healthy virtues of eating salmon. These groups' arguments focused on the message that not eating farmed salmon would be more detrimental to people's health from a nutritional point of view than eating salmon that had low levels of contamination with PCBs and other contaminants.

This risk/benefit message further complicated the issue for consumers. Farmed salmon is generally cheaper and more available year-round than wild salmon, making it an easy and healthy protein source. Should consumers stop purchasing this product? To this charge one of the authors, David Carpenter, responded that their study didn't suggest that people shouldn't eat farmed salmon, but rather that they should reduce the amount of farmed salmon that they eat until contamination levels decreased (Pianin, 2004). However, how consumers might find out when levels were decreasing was not clear, particularly when government agencies were stating that salmon was currently safe to eat.

The controversy over farmed salmon should not have surprised the government or the fish farming industry, since the Hites study was not the first to find chemical contaminants in farmed salmon. Three previous studies, all published in scientific journals in 2002, had also reported elevated pollutants in farmed fish compared to wild salmon, although those studies had been conducted with relatively few fish samples (Easton and Luszniak, 2002; Jacobs *et al*., 2002a; Jacobs *et al*., 2002b). These studies

formed the basis of activist campaigns against farmed salmon by U. S. organizations such as the Environmental Working Group (2006). The Hites study was the most comprehensive so far, testing over 200 pounds of fish tissues, and these results confirmed what earlier researchers had suggested about contamination levels. The Hites report was also not new information for the Canadian government agencies responsible for farmed salmon. In fact, Health Canada has been monitoring the levels of PCBs in retail foods yearly since 1992. Within these reports, fish samples in general (marine and freshwater) have consistently had higher levels of PCBs than most other food products (Health Canada, 2003). Additionally, the Canadian Food Inspection Agency (CFIA) routinely monitors contaminant levels in both fish and fish feed (Health Canada, 2001). Scientists in these agencies acknowledge that the numbers in the Hites report are similar to those of their own, in-house programs (personal conversation, Glen McGregor, 7 May 2004).

So, if the science is sound and the government agencies responsible for the health and safety of food in Canada are in agreement with the science on farmed salmon, then why were there conflicting messages about the safety of consuming farmed salmon? The difference in these risk management messages centers on the way that "acceptable levels" of toxins in food are determined. The discrepancy between Health Canada's safety message about farmed salmon and that from the Hites report stems from the different approaches taken to the assessment of human health risks. The Hites study used the U.S. EPA's method to assess risk and determine a safe consumption level. This approach differs somewhat from how acceptable food residue levels are determined by Health Canada and the U.S. Food and Drug Administration (U.S. FDA).

The U.S. EPA method of determining safe fish consumption is used to develop advisories for recreational (locally caught) fish consumption in areas where there is environmental contamination. As of 2004, the US EPA had produced over 3000 such advisories for a range of fish species and contaminants. The U.S. EPA risk assessment approach determines the

number of fish meals that can be safely eaten per month that will not exceed a lifetime (70-year) cancer risk of 1 in 100,000. Each advisory is specific to a fish and contamination problem. The U.S. EPA's fish advisories clearly state how much of a certain type of fish can be eaten and also provides recommendations for groups of people such as pregnant women or infants who may be more at risk than the general population.

Health Canada's approach to setting a safe level of PCBs intake is based, in part, on a total diet approach (Health Canada, 2009). Health Canada examines both the benefits and risks from foods as well as looking at contaminants and average consumption levels. Maximum levels of contaminants are set for food groups rather than for specific foods like salmon. Health Canada had set its guideline for PCBs in fish at 2 parts per million (Health Canada, 2008; these maximum levels are currently under review). This is the level that is also used by the U.S. FDA. Comparing the results from the Hites report to Health Canada's maximum level at the time, the results indicated that the level of PCBs found in farmed salmon was below the 2ppm regulatory guideline.

Yet, regardless of the assurance by Health Canada and other governmental food regulatory agencies, salmon sales decreased both domestically and around the globe (Norwegian Salmon, 2004). This drop is sales provide evidence that the Hites report had captured the public's attention and that government assurances about the safety of farmed salmon were not working. Why? At its fundamental level, this debate about PCBs in farmed salmon is a product and a problem of risk communication. What was so compelling about Hites study was the clear and prescriptive narrative that told consumers how much and which type of fish they could safely consume. Newspaper reports across North American re-created these data in either text or graphical formats; in these formats, they represented an actionable message that people could use to help reduce their exposure to a known toxicant. Additionally, the U.S. EPA's methodology, used by the Hites report, is also very clearly described and is available in detail on websites and in print publications that are geared to the general public.

These documents include information about the assumptions that went into developing risk estimates, including portion sizes and body weights.

By way of contrast, Health Canada's response to the Hites report, dated 12 January 2004, stated: "Based on Health Canada's risk assessment, consuming farmed salmon does not pose a health risk to consumers" (Health Canada, 2004a). Nowhere in the press release or in supporting links and documents does Health Canada indicate *how* it determined that farmed salmon was safe, nor is there readily available information on how much salmon a person could eat that would keep them under the 2ppm maximum level. Health Canada's press release was essentially stating, "Trust us, farmed salmon is safe," without offering an overview of what safe levels of consumption were or how the safety levels were derived. This paternalistic approach is contrary to much of the advice generated by risk communication research (Sandman, 2001).

The effectiveness of the Hites report lay, in part, in its clear message and its prescriptive approach to personal risk management: Consumers were given information about the risk, the approach used, and what options they had to manage their risk. Health Canada's message did not couch its risk/safety message in this manner, nor did it provide consumers with a basic understanding of how its "maximum level" was derived. As a result, Health Canada's safety message was much less resonant with consumers than the recommendations from the Hites study.

Beyond the issue of paternalism, Health Canada's farmed salmon safety message also suffered from the scope of the Canadian government's risk communication efforts, which has, to date, not been very broad. Historically, Health Canada has not aggressively disseminated risk information to the public and there has been insufficient work done to understand the Canadian public's perception of risks (see Krewski *et al.*, 1995a, 1995b). As a result, Canadian consumers are not used to engaging with the government regarding these types of risk issues. This lack of communication can lead to problems of trust and may not give the public

much confidence that the government is managing risks in a way that reflect their priorities. As authors such as Slovic (1993) suggest, trust is a key component for successful risk communication. This problem has not gone unnoticed in government, and very recently, in May of 2006, Health Canada added new Risk Communication tools to its website. These tools range from urgent warnings to information updates that help inform Canadians about potential health risks (Health Canada, 2006b). Whether or not these advisories will help to engage Canadians in discussing risk issues with policy makers remains to be seen. Citizens want to be involved, or at least have the opportunity to be involved, in decisions about risks to which they are involuntarily exposed (Foster, n.d.). Simply adding more warnings without addressing the problems of transparency and allowing for public input or comment may not be what Canadians need to engage in risk debates with the government.

The fish farming controversy also clearly illustrates the problems that result from not anticipating risk controversies. Both the Canadian government and the fish farming industry were put on the defensive regarding the Hites report, even though both acknowledge having known for some time that there are relatively high (compared to other food groups) levels of PCBs in fish tissues. This problem could have proactively been acknowledged and contextualized for consumers (i.e. explaining dietary contributions of PCBs from all foods, discussing the evidence for PCB toxicity, etc.). Public concern about PCBs is not a new phenomenon, and exposure to these chemicals is well known to increase public anxiety. The government and fish farmers' failure to appropriately address the problem of toxins in fish tissues left them open to having others set the risk agenda for them. The public's reaction to the Hites report may have been different had the government or the industry had a history of communicating with consumers and health professionals about the levels of contamination in Canadian fish products and the implications of this for public health.

Other, peripheral issues also helped to ignite ire in the farmed salmon risk debate. Beyond the government's lack of ongoing and engaging

risk communication, the farmed fish industry's profile aggravated the PCB controversy. Problems of disease outbreaks such as sea lice (Krkosek *et al.*, 2005) and Infectious Hematopoietic Necrosis Virus (IHNV), which require massive culls of farmed fish, as well as issues of environmental contamination (Debruyn *et al*., 2006), have been on the Canadian news agenda for quite some time and have resulted in a generally poor media climate for the aquaculture industry. Additionally, unlike cattle ranchers, fish farmers cannot necessarily rely upon grass-roots public support during difficult times, because many of the salmon farms are in relatively remote coastal areas and are foreign-owned operations. Challenges to the local wild salmon also generate opposition both from First Nations people and from those who based their livelihood on the more established ocean-caught salmon industry.

Ultimately, the salmon farming industry has had numerous strikes against it, the majority of which have captured media attention both in Canada and around the world. In an already poor public relations environment, the news that farmed fish may also be bad for human health may convince consumers to no longer buy farmed products. Given that other options exist, such as buying the somewhat more expensive wild salmon, or buying other fish species, it is relatively straightforward for consumers to register their discontent with the industry. Even before the Hites report, fine-dining establishments and high-profile restaurants on the west coast of Canada had already made the switch from farmed to wild salmon due to the perceived negative public reaction to farmed salmon.

The Canadian government's relationship with the fish farming industry may also detract from its ability to send safety messages to the public concerning farmed fish products. Across Canada, aquaculture has grown at an annual rate of 19% between 1996-2001, with support from both provincial and federal government bodies. However, some groups have criticized the government for being too close to the fish farming industry, and one British Columbia fisheries minister resigned as a result of a police investigation of his handling of the aquaculture file in 2001 (Jang, 2003).

Suspected political interference with fish farming organizations, particularly in the province of British Columbia, has made national headlines (Lee, 2004). Organizations such as the David Suzuki Foundation have criticized the federal Department of Fisheries and Oceans for promoting fish farming at the expense of the environment that they are entrusted to protect (Peterson *et al.*, 2005). Such interaction between the government and the industry makes it harder for consumers to trust that the government is prioritizing human and environmental health over the rapid development of this industry.

The story of the farmed salmon controversy illustrates the problems that emerge when communication failures exist between the government and the public; it is also a story about the hazards encountered by companies that do not openly address the problems represented by their industry's development. Fish farming has evolved in Canada with a fairly small amount of public consultation or involvement while being supported and promoted by government agencies and off-shore companies. Scientists and environmental groups have raised a broad spectrum of concerns, many which have not been adequately addressed by those responsible for regulating aquaculture or human health. Such an environment does not breed trust or allow citizens to be confident that risk management decisions are being made in their best interests. This very public debate also illustrates the limitations of risk assessment and the confusion that arises from not clearly outlining how "safe" levels are determined. Although such processes are often complex and filled with uncertainty and assumptions, there is little excuse for the lack of transparency in how regulatory bodies approach and assess risk.

Conclusion.

Quite different dimensions of the complex challenges in food risk communication are revealed by the two Canadian cases reported here. In the case of BSE, the sudden appearance of a "dread-risk" source did not lead to a crisis of consumer confidence or cause a fall in beef consumption. There was still major risk communication failures of a different sort, however: A

failure of federal authorities to properly assess and communicate the risk of BSE and to a specific group within the Canadian public, namely, small independent beef producers. Whereas this would normally be classified as an "economic risk," such risks also have social and health consequences – in this case, for farm families. There is much anecdotal evidence about adverse health consequences and other outcomes, such as suicide, among farm families, resulting from the sudden collapse of the export market for beef and the decline in farm incomes (even after offsetting by government support payments). However, to date it has been difficult to document these important impacts; the report entitled "Farmers, Farm Workers and Work-Related Stress," commissioned by the U.K. Health and Safety Executive and released in 2005, is one of the first to do so, and more are needed (Health and Safety Executive, 2005).

In this case the risk communications failed to accurately express the nature and scope of the risk as it had been evaluated by government officials in technical documentation (some of which was never publicly released). We have tried to demonstrate that, in fact, the complex statistical manipulations served as a smokescreen behind which was hidden the true – catastrophic – risk, namely, that the discovery of even a single case of BSE in the Canadian herd would have "extreme" consequences for the entire group of small, independent beef producers. They were never told, in plain and simple language, by those whose responsibility it was to assess this risk, what was facing them.

In the case of farmed salmon, a high-profile scientific study on chemical contaminants led to a significant adverse reaction on the part of consumers – who were then blamed by some for not understanding that the numbers were non-threatening. They were also blamed for not understanding that the risk/risk or risk/benefit trade-off (risks posed by the contaminants vs. health benefits from eating fatty fish) was overwhelming in favor of continued fish consumption. However, our study shows that the contaminant numbers are open to differences in interpretation among

government agencies, and that understanding the level of risk is no simple business.

In this case the farmed salmon industry should have been alerted to the issue by a series of studies in 2002 that indicate the presence of contaminants in farmed fish tissues. The fish farming industry should have acted years ago to ensure that the public was provided with reliable resources for understanding the nature of chemical contaminants in fish and the risk assessment methodologies used for determining safe levels of consumption. (At the moment the only user-friendly information, replete with good graphics and references to the scientific studies, is provided by environmental organizations.) A template has been developed for a web-based public information resource, operated by a disinterested third party, to assist the public in understanding complex scientific information on issues of concern (Emcom, n.d.). The farmed salmon industry would be wise to move in a similar direction, for there are surely more studies such as the one conducted by Hites *et al.* (2004) now being done.

Appendix A

The point being made here (page 10 above) can only be fully appreciated if we show the full context in which the short, quoted sentence appears (CFIA, 2002a):

The mathematical model used to estimate the probability of at least one infection by oral transmission for *n* imported animals is as follows:

$$P(I\$1) = 1-((1-f_1)+f_1*((1-f_2)*((1-f_3)+f_3*((1-f_4)+f_4*(1-f_5)))+f_2*((1-f_6)+f_6*((1-f_7)+f_7*(1-f_8)))))^n$$

The estimated probability of at least one infection of BSE occurring prior to 1997 was 7.3×10^{-3} with a 95% confidence level of 2.0×10^{-2}. This estimate was based on the expected number of BSE-infected animals that may have been imported, then were slaughtered or died, with their carcasses subsequently rendered between 1979 and 1997. Therefore, the likelihood of establishment of BSE in Canada was negligible. If BSE was introduced, the consequences would be extreme.

The sensitivity analysis (Figure 6) identified the most critical inputs for the model. With the rank order correlation sensitivity analysis, the coefficient is calculated between the selected output variable and the samples for each of the input distributions. The higher the correlation between the input and the output, the more significant the input is in determining the output's value. The tornado graph (Figure 6) indicates that the "age in months," showing the longest bar and a positive coefficient of 0.368, was the most important input for the estimate of the probability of at least one infection. "Pf1," which represented the function assimilating the prevalence of infection by country and year of birth, was second in importance with a positive coefficient of 0.76. The input variable "ncoid50," representing the number of cattle oral ID_{50}s, revealed a correlation coefficient of 0.023.

To the best of our knowledge, the key sentence – "If BSE was introduced, the consequences would be extreme" – occurs nowhere else in this long Risk Estimation document itself or in any other public communications by the Agency either then or later.

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CHAPTER 14

WHO'S AFRAID OF CLIMATE CHANGE? A GUIDE FOR THE PERPLEXED

Original Publication:
William Leiss, Hadi Dowlatabadi and Greg Paoli,
Isuma: Canadian Journal of Policy Research **2** (No. 4, Winter 2001),
Pages 95-103

Abstract

Climate change issues are looked at from the standpoint of the ordinary citizen who is asked to support or oppose government policies, or the actions of corporations and other actors, undertaken in response to those issues. What is it necessary for the citizen to believe, about both the science of climate change and the policy responses to it, in order that she may advocate one of two positions: "Take some action now" or "Do not take action now." Citizens, it is argued, need some special-purpose tools for the occasion, due to the sheer number and complexity of the decision inputs and to the magnitude of the uncertainties that surround so many of the cause-and-effect hypotheses. The authors describe decision support software, which breaks down complex problems into discrete units and supplies information aids along the way. They then outline how the software would be applied to climate change issues, proposing a scheme that identifies 12 such decision units, called "stations," which are the minimally necessary number of steps that could lead one from "concern" about those issues to a menu of action responses (including no action).

Introduction.

As a public policy issue climate change represents a viper's nest of conundrums, paradoxes and no-win options. Are inhabitants of cold countries, many of whom are fond of escaping to tropical beaches when

winter hits, supposed to be afraid of warmer climes? Are politicians, whose ordinary response to health and environmental risk issues is to pray "may nothing happen during my term of office," supposed to take unpopular measures to head off something that may or may not happen a century hence? Are bureaucrats who were reared under the sensible maxim "let sleeping dogs lie," supposed to warn their ministers that the proactive measures now recommended by some are — on the balance of probabilities, with very large uncertainty parameters — actually far too modest to make any difference at all? It would be foolhardy in the extreme for any sane person to stick a good hand into such a black box as this.

And yet: Suppose that key aspects of the climate models are correct. Suppose that the fossil fuel use that powered the West's drive to economic wealth through industrial revolution, a pattern that everyone else in the world now intends to follow, is the main culprit in an environmental disaster about to unfold. Suppose that the relentless climb in anthropogenic atmospheric greenhouse gas concentrations is the primary agent in a "climate forcing" process which will wreak havoc on the lives of huge populations of humans and other species. And suppose that, because of the sheer scale and rate of change induced by human impacts, this climate forcing process can be slowed or reversed only by the most drastic reductions in GHG emissions, on the order of two-thirds below current levels, that must be implemented starting as soon as possible. What would we as citizens say and do, and demand that our politicians say and do, if we came to believe strongly that these were suppositions that reasonable persons ought to make?

In truth neither most citizens of Canada, nor those of most other countries for that matter, are ready to entertain these suppositions — at least not at the level of conviction where they would be ready to pay the price for their belief. Faced with the prospects not only of redesigning the entire basis of our own industrially generated wealth, but also of discovering and transferring the technologies to enable developing nations to become wealthy while using fossil fuel energy only sparingly, the sanest course

surely is to take refuge in denial. We can all join former U. S. President George W. Bush in muttering about "flawed science" and the "need for more research." [In 2001 the Committee on the Science of Climate Change, U. S. National Academy of Sciences, published a short booklet, *Climate Change Science: An Analysis of Some Key Questions* (Washington, DC: National Academy Press, 2001), which put to rest these politically-motivated "doubts" (US NAS 2001).] All politicians in North America know that their constituents keep a watch on fossil fuel energy prices (especially gasoline prices for their trucks and SUVs) and that they will not be fooled into thinking that there are any "solutions" to climate change issues that would not cause those prices to rise. All politicians not suicidal by nature know what they have to do: Get more of the stuff out of the ground and into the pipelines, as quickly and as cheaply as possible.

We Canadians talk a good line, in contrast to our American cousins, about the importance of "upholding" the Kyoto Protocol (which we have not yet ratified, of course) and all that, but in the time that it takes for us authors to write this essay Canada's GHG emissions will have risen. There are economic estimates of the costs of Kyoto compliance, but these have not been effectively brought to the attention of citizens, so at this point we simply do not know if the majority of Canadians would support our politicians' taking the actions that would bring our country into compliance with our Kyoto commitments some years hence. In other words, almost certainly we citizens (most of us, at any rate) are not quite ready to "act on climate change" — at least, not quite yet. So what should we be doing while we wait and see how the winds are blowing?

What should we do while waiting for "more science"?

Most citizens *should* expect to be perplexed by the climate change issue: There is nothing comparable to it in terms of sheer overall complexity, in the number of relevant dimensions, and in the fact that the scale of the possible bad things that could happen to us is matched by the scale of the uncertainties in most of those dimensions — uncertainties likely to persist

for decades to come. That most citizens are unprepared to support the taking of serious actions to "address" the climate change issue by curtailing GHG emissions is not only unsurprising, it is also sane and reasonable, by any conventional standard of such behavior.

The main caveat to be advanced here is whether the "watch and wait for more science" attitude, which we acknowledge to be sane and reasonable by conventional standards, is appropriately "precautionary." The word "appropriately" is important here because what is meant by "being precautionary" is always contextual, that is, to be judged as a function of such criteria as the type and scale of the hazards, the economic and social costs of precautionary measures and, above all, by whether or not the processes leading to the estimated effects are reversible. Think of this as a problem about deciding how much we should spend as a country to "take action now" to reduce the risk of experiencing adverse effects from climate change sometime in the future. Given the scope of the uncertainties as to whether or not we even need to do anything about climate change risk at all, our decision is likely to be influenced heavily by considerations of the reversibility both of the processes of global climate and the adverse effects that may cause serious disruptions to the functioning natural ecosystems to which our social systems have become adapted.

If we think that we can wait for greater certainty before deciding on what actions to take, we must believe (on the balance of probabilities) that actions taken later will slow, stop or reverse the process of climate forcing to an extent sufficient to either avoid the feared adverse effects entirely or at least confine them within "acceptable" limits. On the other hand, if we doubt this (i.e., think that it is more probable that the processes and effects may be becoming irreversible), we are more likely to advocate taking action now, which means committing to expenditures to reduce GHG emissions.

Because of uncertainties about the possible economic costs of action on climate change, most citizens will opt (sensibly, perhaps) to be less precautionary about climate change risk now than they otherwise might be.

To put it bluntly, there is in the climate change policy issue a close and sinister connection between what we are prepared to believe about the nature of the risk itself, on the one hand, and what a specific degree of belief would end up costing us in our pocketbooks, on the other. What we have to guard against, therefore, is a casual willingness to suspend belief, as the results from the climate models and the science supporting them accumulate, if it should turn out to be the case that our less precautionary attitudes are severely challenged in the future.

On the other hand, it is a mistake to assume that higher energy prices in the future inevitably will result in economic crisis, such as what followed OPEC's unexpected oil embargo in 1973. A planned policy for controlling CO_2 emissions, through efficiency measures, wider use of renewable energy and introduction of capture and sequestration efforts will not lead to the same impacts as suffered in the early 1970s. Careful analysis has shown the crises of 1973 and 1978 were mostly due to poor management of the macro-economy, not higher energy prices. Just consider the fact that oil prices rose 100 percent in 1999: The economy was growing strongly and hardly noticed the event. The connection between energy prices and economic well-being is more complex than often assumed, but concern about substantially higher energy prices certainly clouds the consideration of climate change issues in the public mind (Dowlatabadi 1998, 2000).

One of the most effective measures we can take while waiting for the science to grow clearer is to launch policy experiments that help us determine what the real costs and bottlenecks to implementation of strong climate policies might be. In a sense, with our emissions still rising we are engaging in an experiment on a planetary scale, to see if current predictions about climate change will be borne out by the earth system over the next decade. We are as uncertain about economic and social forecasting as we are about forecasting climate change. So why should we not design and launch experiments that would shed light on the real challenges we need to face in order to control CO_2 emissions if and when needed?

All of us need more help in the meantime. In this paper, we present in outline some tools for understanding climate change as a decision problem. The second tool represents our initial attempt to show what "stations" (stages of analysis) an informed citizen would have to pass through on a journey starting with simple "concern" and ending with one of two decision options: (1) the No Option, meaning "do nothing now," or (2) the Yes Option, meaning "take some action now." If the "Yes" Option is chosen, the citizen proceeds to the next layer of the issue; choosing the "No" Option means that the citizen, unpersuaded there is anything to worry about, at least for now, sees no need to investigate further. (For example, if one decides there are no adverse effects from climate change worth worrying about, one does not have to bother with figuring out what their causes might be.)

Climate change is an issue of many-layered dimensions, which have to be separated and considered one by one; we describe this as a process of "peeling the onion" of climate change. There is a specific sequence, we argue, in the ordering of these layers as a decision problem in a policy context; the later stations are encountered only as the earlier ones are peeled away. As each layer is uncovered, the citizen is presented with the option of "terminating" the policy exercise by deciding that there is *not* enough to worry about to "take significant action now."

Our first tool is composed of a variety of "decision-support" software programs, which are designed in different ways to assist people in making decisions under uncertainty.

Decision-support tools.

Societal debate (and the subordinate task of individual decision-making) can be facilitated in a number of ways. The Internet has facilitated the explosion and sustenance of societal debates in several human and environmental risk domains. As such, there may now be a previously unrealized opportunity to engage broad public debate via interactive and computerized resources.

Increasingly, decision-support tools are including within them the capacity to be delivered over the Web. In fact, the business-to-consumer use of the Internet has spurred the development of interactive techniques designed to elicit consumer values and to present interactive information to facilitate consumer's product selection from a catalogue of options. An individual's response to the current state of the climate change debate can be characterized as coming from a catalogue of available actions which must be searched and evaluated according to his or her values and beliefs. This process can be greatly facilitated by a process that directs the consumer through the relevant stages of this decision-making process while providing background information in an impartial manner.

The climate change problem requires that a great deal of qualitative "framing" of the problem be performed before we can reasonably present quantitative information to the user. In addition, there is a significant number of users for whom quantitative information, however carefully and simply presented, will not be the most appropriate means of facilitating their decisions. This paper discusses the problem of a decision-support tool for qualitative framing of the decision problem (Morgan and Henrion 1990). Once qualitative framing is achieved, and if the user is so disposed, quantitative decision support can also be implemented. An excellent tool for quantitative decision support is "Analytica," which was designed for quantitative public policy analysis with a strong emphasis on the communication goals of policy analysis; a quantitative climate change policy model has been implemented in "Analytica" by Dowlatabadi. An ideal qualitative public decision-support tool would have the following characteristics:

1. Dynamic information resource:

It should be easily updated with new research, policy options and new perspectives. This updating requirement would also imply delivery over the Internet so that the most up-to-date version is universally available.

2. Interactive and flexible:

It would need to strike a balance between a) directing the user through some required stations of decision making and b) allowing the user to navigate extensive supporting information, iteratively address issues and focus on areas that they think are most important for them to better understand.

3. Algorithmic and transparent:

The workings of the decision-support model should be transparent and auditable. Since such a tool has the potential to manipulate public opinion, its assumptions and its algorithms should be transparent, at least to a reasonable level. This transparency should allow a full audit-trail that explains the advice given to the user by connection to their own expressed values and beliefs as well as the assumptions and algorithms of the decision-support tool itself.

4. Value-neutral:

The system must query the user to understand their value system and should avoid imposition of a worldview (though it is probably fair to say that this is impossible to do perfectly). A good test of this attribute would be whether the system would allow someone who really doesn't care about impacts (or doesn't believe any scientists) to say so, and to be supported in making the types of decisions which follow from these values and/or beliefs.

5. Flexible scope:

Allow the user to limit the scope of the problem that they will consider. Since users will have highly variable levels of patience for a decision-support tool, it must be flexible to accommodate those who want a quick exchange with the system and those who want to be fully engaged for an extended session of reflection, reasoning and knowledge acquisition. One size will clearly not fit all.

6. Present a variety of alternatives:

This is an extension of being value-neutral. The system should present a variety of explanations for whatever phenomena are considered to be uncertain, a variety of forecasts of the future and should present a variety of perspectives from which to consider the problem. If the user does not wish to choose among, or assign weight to, these alternatives, he might be allowed to choose from among a few recognized "baseline explanations" or "consensus opinions" which have some validity and credibility external to the decision-support system. This functionality would be an obvious candidate for multi-media presentation and linkages to supporting documentation that has come to be expected through popular use of the Internet.

7. Propagate and utilize uncertainty:

The decision-support system must be reasonably fluent in managing uncertainty in multiple dimensions so that this important dimension is not suppressed and can be an active component of the decision-making process.

8. Personalized exchange:

The system should present the user with somewhat personalized descriptions of impacts, adaptations and mitigations. As discussed above, the system needs to descend from the abstract to the concrete in order to allow for any substantive personal decisions to be influenced.

Many of the requirements above have some potential to be met by the current generation of expert system development tools. Clearly the extent to which each of the above ideals can be pursued will be a practical matter of software design, availability of resources and experiences with potential users. The extent of the compatibility of these requirements with any particular decision-support development tool is beyond the scope of this paper. The climate change problem is sufficiently complicated that it is reasonable to expect that public decision making will require facilitation. Decision-support tools (both qualitative and quantitative) are good candidates to facilitate the decision-making process of individuals and subsequently of society as a whole.

While the list of ideal attributes of a qualitative decision-support tool for climate change is somewhat daunting, recent developments in tools for interactive exchange with citizens on the Internet greatly increase the feasibility and suitability of this approach to qualitative (and subsequently quantitative) climate change decision-making.

Peeling the onion of climate change as a policy-relevant decision problem.

Citizens have heard a great deal about climate change and its implications for their lives over the last decade and will hear much more in the present one. But this news strikes their ears randomly, in the form of results from a new scientific study, or a new round of international negotiation, or a new argument about the economic impacts of taking action on climate. Under such conditions, with a decision problem of such complexity, it is difficult to hold the pieces together into a coherent whole. Among all the scientific evidence accumulated so far and still to come, what among it is relevant to the answering the questions: "Should we do something now to change our behavior?" "And if so, what and how much should we do?"

Our method proposes to help the citizen in this regard by structuring her decision problem as a logical sequence of questions, where the provisional answer to each leads either to a (temporary) resolution or to further steps. The entire structure is designed so as to include the minimally necessary number of steps, consistent with both the scientific and policy-relevant complexities of the climate change issue, that one is required to transit in order to be comfortable with a conclusion, namely, "Take action (of some kind) now" or "Do nothing now."

We present this as a process of peeling an onion: As each layer of the onion is peeled away to reveal the succeeding one, we encounter a new layer of complexity in the issues around climate change. Each layer is called a "Station," that is, a stage in the entire decision process that must be passed through in order to get to the next one. At each Station the caution, "revisit when new information becomes available or backtrack," is represented by

the following symbol: (↺). Of course, new information will steadily accumulate. However, (↺) also advises the user that, as he or she passes the various Stations in succession, there may be a need to backtrack to earlier ones, because information gleaned later appears to be relevant to provisional decisions taken earlier.

In the consolidated public information resource (assisted by decision-support software) we envision, the interested citizen will be able to access a suite of information resources, starting with a synopsis of relevant scientific information and proceeding to greater depth on particular aspects, including such resources as "scientific consensus and dissent," "scientific debates," "current research," "bibliography," "websites and Internet resources," etc. The nature and uses of the large "coupled" (atmosphere – ocean) computer-simulation models, will be featured extensively. Pictures, animated graphics and video sequences will be provided where possible.

One of the two decision options allows the participant to say, in effect, "We just don't know enough right now," or alternatively "There are a lot of other world problems that deserve our money and attention first." However, this way of representing the issue has, we hope, other benefits besides helping citizens make up their minds about what their governments should or should not do "about" climate change — namely, the benefit of being able to track the process of interaction between highly complex scientific analyses, probabilistic reasoning, risk management strategies and public policy formation.

First Round (no weights assigned to specific decision factors).

[Note that our context is Canada; citizens in other nations and regions may have different decision situations. (For example, countries in the northern hemisphere are expected to be affected differently from those in the South.]

[See the Appendix at the end for explanatory remarks on Probability, etc.]

The Stations of Climate Change:	The Decision Options:
Probability: L / M / H	Y ⇓ = Go to the next Station
Confidence level: H / M / L	N ⇒ = Exit decision problem:
Significance: H / M / L	[Stop worrying and wait for more science]
	↺ = Revisit or backtrack

Start: "Concern" ⇓

→ A. Evaluating the science of climate change:

1. Effects. (↺)

The effects of global climate change are something to be concerned about and could have major impacts on our lives.

(Y ⇓ N ⇓)

Comment: We begin with effects because, from a policy perspective, one cannot expect citizens to be prepared to do anything about climate change risk if they are not first convinced that there are, or will be in the future, effects worth worrying about. (At this point, moreover, it is immaterial whether natural or human aspects of climate variation are involved as putative causes.) We assume that change, especially large-scale change, from well-established patterns of weather and climate would be worrisome in themselves, quite apart from specific effects. We have, however, shown both arrows pointing downwards, because citizens need to know that, due to lag effects only understood subsequently, it is possible that effects could become obvious only at a time when it had become much more difficult to do anything about their underlying causes. "Effects" mean changes that could have both negative or positive impacts on ways of life, health, etc.; however, even for positive impacts (benefits), individuals could not be sure that the distribution of benefits would remain as before. Therefore, our scheme encourages the citizen to go further through the Stations, whether or not she is convinced that there is something specific to worry about.

2. Causes, I: Weather, climate and greenhouse gases. (↺)

There is a strong relationship between weather, climate and concentrations of greenhouse gases in the atmosphere. (Y ⇓ N ⇒)

Comment: We presume that from a common-sense standpoint what matters most to humans about climate is weather, and what matters most about weather is precipitation, temperature and extreme events. Of course, weather and climate are fundamental aspects of the entire history of human societies. The

hypothesis that human activities since the beginning of the last century have been "forcing" climate change, and that increasing emissions of GHGs from human activities are the primary means by which this type of climate forcing has occurred, turns the scientific conjecture also into a public policy issue.

3. Causes, II: The role of human activities. (↻)

Human activities are now changing the greenhouse gas concentrations and will continue to do so in the future. (Y ⇓ N ⇒)

Comment: Anthropogenic emissions are still a relatively small part of global GHG cycles. However, what is a "significant" human addition to global GHG cycles could turn out to be a relatively small number, *if* the current natural climate cycle has elements of major instability in it, so that a relatively small anthropogenic addition to the natural sources of GHG emissions were to be found to have an impact out of all proportion to the percentage of the total attributable to us.

4. Lag effects. (↻)

There is a significant lag between emissions and concentrations and between concentrations and climate system changes; actions taken now could have full effect only after one or more centuries hence. (Y ⇓ N ⇒)

Comment: There are two types of lags. One is the relation between emissions and concentrations: Because of the long lifetime of GHGs in the atmosphere, they remain suspended and accumulate over long periods. The second lag is the delay in the impact of increasing GHG concentrations on the global climate system; for example, it takes a long time for the oceans to warm up, and when GHGs are stabilized it will still take the climate anywhere from decades to centuries to reach a new equilibrium. The longer action on reducing emissions is delayed, the greater the cumulative effect will be.

This is one of the "critical" decision points in the policy-relevant discussion. If "significant" action is deemed to be necessary at some point in time, and if international agreement is ineffective due to continuing disputes over "cause-and-effect proof" among major players, then action could be delayed beyond the point where changes in the pattern of human contributions to GHG emissions are relevant at all. There may be aspects of the natural climate system that are so complex as to defy our attempt to represent them in models, and so an "adequate" level of proof may be lacking for a very long time.

5. Offsetting factors. (↻)

Other natural forces may come into play to offset the impacts of rising GHG concentrations. (Y ⇓ N ⇓)

Comment: This is another key "critical" point in the scientific analysis from a policy perspective. Some forceful arguments by scientists have been made in support of this factor. If it comes into play to a sufficient degree, we may not have to do anything at all about anthropogenic contributions to GHGs.

6. Exacerbating factors. (↺)
Other natural forces may come into play to exacerbate the impacts of anthropogenic GHG emissions. (Y ⇓ N ⇓)

Comment: Obviously, this is the converse of Station 5. The degree of urgency of action rises dramatically if we believe that this is possible.

B. Transition to action scenarios — Other relevant judgments:

6. Intergenerational responsibility. (↺)
Since the lag time is so long, we can expect new technologies to solve the problem later in the 21st century, and therefore it's not likely that we will be imposing either severe disadvantages or unavoidable environmental catastrophes on future generations. (N ⇓ Y ⇒)

Comment: There is some probability that a) either natural offsetting factors may come into play (Station 5), b) or technological change will make it possible to change human actions quite quickly, c) or both, thus reducing the anthropogenic contribution dramatically.

7. Regional variation. (↺)
Canada is at elevated risk from climate change because generally impacts are more serious in the Northern Hemisphere and at higher latitudes. (Y ⇓ N ⇓)

Comment: It has been argued that the Northern Hemisphere will experience relatively more serious adverse impacts from global climate change. Answering either yes or no affects the type of preferred action scenario that is likely to be chosen (Stations 10-12).

8. Relation to other global issues. (↺)
Climate change is occurring within a larger set of global changes, affecting both humanity and the natural environment, and our response to it should be proportional to its relative importance in that larger setting.
(Y ⇓ N ⇓)

Comment: One of the great problems with policy formation is that it tends to deal with one issue, or set of issues, at a time. Debates about climate change illustrate this perfectly. Obviously, there are many other forces and

interactions occurring today, both human and natural, that are interacting with climate change; for example, there are other sources of environmental degradation besides the effects of climate variation. The "let's deal with one problem at a time" syndrome can waste resources and even have perverse effects, if allocation (or denial) of resources across an entire spectrum of issues does not take these interactions into account. The "decision choice" at this Station has both arrows pointing down to indicate that where one stands on this matter will have an effect on choices of action scenarios on climate change (Stations 10-12).

For the wealthier industrialized countries, significant co-benefits can be realized by taking significant action on air pollution which, in reducing emissions from fossil fuels, would also help them to meet their Kyoto targets.

→ **C. Three sets of policy responses / Action scenarios:**
Comment: The scenarios are arranged in order from the policy choice having no impact on "business as usual" to the one requiring substantial changes in economy and current lifestyles. "Adaptation" means that we believe climate change of some kind is going to happen; it cannot be influenced significantly by policy choices and we have to be prepared to adapt our economy and society to it. "Mitigation" means that through policy choices we seek to reduce our anthropogenic GHG emissions to some targeted level, that (we believe) our choices ultimately can reduce human-caused climate forcing, and that it is prudent to incur the economic costs, as well as to reap the spin-off benefits, in doing so.

9. No action response is necessary now. (↺) (Y ⇒ N ⇓)

10. Modest mitigation response only is necessary now. (↺)

Meet our Kyoto commitments for emissions reductions and begin adaptation planning (e.g., in the North). Keep fossil fuel energy prices as low as possible in order to maximize economic growth to pay for future adaptation costs.
(Y ⇒ N ⇓)

11. Greater combined mitigation plus adaptation response is necessary now. (↺)

Urge Kyoto-plus (bring rest of world into the protocol) now, announce Kyoto-plus commitments in Canada, begin adaptation programs, begin planning for bio-based industrial future. (Y ⇒ N ⇓)

END.

Peeling the onion of climate change as a policy-relevant decision problem, second round (assign various weights to specific decision factors).

On the first level of analysis all of the decision elements represented in Stations 1-9 would be assigned, purely arbitrarily, equal weights (significance). However, it is unlikely that all citizens would assign the same significance to all elements; some factors will appear to be more important, or more decisive, to some people than to others. Therefore, on the next "pass" through Stations 1-9, the suggestion would be made to think about the importance of each element and assign a crude measure of how important each one seems to be in the personal judgment of an individual (say, Low, Medium, High).

To be sure, some elements are likely to be of "high significance" almost by definition, especially Stations 5 and 6; unfortunately, one is the converse of the other, and in effect they cancel each other out if each is assigned the same level of significance. This is a crucial point where the relation between what we are persuaded to believe (based on what we hear various scientists saying), and what we want to hear (because our belief will have consequences on the policy choices we urge upon our government), stands in what was called earlier a "close and sinister" connection. In other cases, assigning low or high confidence to critical elements clearly will have a major impact on the ultimate outcome of the decision process each of us goes through. And here is where expert systems for decision support can help us, by providing an algorithm to combine the effect of our choices in these different dimensions (likelihood or probability of occurrence, confidence level and degree of significance of each element).

Conclusions.

In the foregoing, we have presented a policy-relevant framing of the climate policy issue and an overview of the decision-analytic tools available to tackle them. We have also noted why it is that the sinister link between "fear of costly action" and "uncertainty" generally leads to inaction, rather than action. There are three areas in which new information will be critical to making informed decisions about climate policy.

- We need a better handle on our changing climate and the role of human activity in how it unfolds. This must be followed up with a clear

understanding of the impacts of such climate change (on humans and nature) both globally and locally.

- We need time to think up ways of controlling climate change or adapting to such change. This is a new problem and our imagination has not had much time to grapple with it. Most of the options we think of and evaluate in decision-tools may not be relevant or appropriate (e.g., OPEC oil crisis as a model for GHG controls).
- We need to better understand (and perhaps give definition to) the public's view on responsibility with respect to climate change and its impacts. For example, if science shows that humans are primarily responsible and the public adopts a rights-based perspective, the economic arguments against strict control measures can be dispensed with altogether. If on the other hand the public sees this as another area where aggregate costs and benefits for the majority must be balanced, a different set of policy options and outcomes are likely.

Better science both natural and social and quantitative decision tools are needed to address the first area above. The second and third areas, however, are implicitly part of the process of public perception and participation. The climate change problem is sufficiently complicated that it is reasonable to expect that such public participation and decision making will require facilitation. Decision-support tools (both qualitative and quantitative) are good candidates to facilitate the decision-making process of individuals and subsequently of society as a whole. While the list of ideal attributes of a qualitative decision-support tool for climate change is somewhat daunting, recent developments in tools for interactive exchange with citizens on the Internet greatly increase the feasibility and suitability of this approach to qualitative (and subsequently quantitative) climate change decision making.

In summary, we believe that the complexity of the climate change problem can be boiled down to its essential elements using decision-analysis. The characterization of these elements elucidates what is known and what needs to be learned before informed decisions can be made. These

kinds of problems do not have a single "right" answer. For example, if we are responsible for climate change, mitigation action of sufficient magnitude to save low-lying islands will undoubtedly annihilate communities and activities that have prospered in the shadow of inexpensive fossil energy. If we do not take action, on the other hand, almost certainly the homes of millions of people now living within one meter of current sea levels will be inundated. Our decisions will have consequences such as these within the lifetime of children born today. Participatory approaches can help the public come to grips with unfamiliar situations and better recognize the consequences of decisions they are contemplating. The perplexed need not worry. They are not alone. Even the experts in this area know that the short time we have spent on this issue has left many critical factors yet to be understood before we tackle the decisions ahead.

APPENDIX

High probability = ρ 68% – 100%; Medium = ρ 34% – 67%; Low = ρ 0% – 33%. We assume that a Low ρ ranking will generate the No Option in Stations 2–4, and that either a Medium or High ρ will result in choosing a Yes Option.

Note that the outcomes of the decision options switch at certain stations. When we get to "responses" (Stations 10–12), it is obvious that there is an almost infinite variation in the "mixes" of both policy responses and policy instruments that could be chosen. We have represented here only the most general notion of choices.

"Confidence level" is how confident the assessor is that the guess about probability is a good one (thus it only applies where probabilities have been assigned). We have not used it in this preliminary sketch, and it is listed here for illustration only.

This option may be selected for a number of quite different reasons, for example: 1) "I just don't believe that there is a problem here at all"; 2) "There may be a problem here, but if so it's so unclear as to not be worth worrying about"; 3) "I am a bit concerned, but we need to have a lot more science before I'm willing to pay for any mitigation costs"; 4) "Climate warming is a good thing, so why are we trying to stop it?" 5) "There are a lot of other problems in the world that need attention first." And so forth.

In Stations 2–6 we try to distill the key stages in the scientific reasoning about global climate change *that are policy-relevant*, in other words, the reasoning which encourages us to move from what we think we *know* to what (if anything) we should *do* now. We have relied on the following scientific summaries: US NAS 2001 and McBean et al 2001.

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CHAPTER 15

THE CASE FOR MANDATORY LABELING OF GENETICALLY-MODIFIED FOODS

A paper prepared at the request of the
Consumers' Association of Canada (November 2003)

Introduction: GMOs and food safety.

1. Product vs. "process."

Among all the health and environmental risks known to be of elevated concern to the public, food safety always stands at or near the top of the list. This is true for all countries but for some, even more so – for Japan, for example, and Europe (for many reasons, including the terrible BSE tragedy, which goes on).

Like other industrialized countries Canada has decent food safety regulations as well as highly capable personnel to oversee them. (Mistakes are made and surveillance can be inadequate, such as in the regular outbreaks of illness caused by food-borne *E. coli*, listeriosis, and salmonella.) When a new form of food crops – based on gene technologies – came to market in the mid-1990s, food safety regulators were ready, having developed protocols to assess the novel health and environmental risks. [The best overview of such risks done to date in Canada is the one issued by the expert panel established by The Royal Society of Canada, *Elements of Precaution* (RSC 2001).]

But at the same time, industry and regulators in the United States (followed faithfully later on by their Canadian counterparts), had also prepared a novel strategy for pushing these new products into international

markets, which had the effect – whether explicitly intended or not doesn't matter – of severely circumscribing the public debate about these new crops. The regulatory structure for biotechnology was "politicized" from the outset, as detailed in a brilliant piece of investigative journalism by *New York Times* reporters Kurt Eichenwald, Gina Kolata, and Melody Petersen (Eichenwald 2001). They show how Monsanto went directly to then Vice-President George Bush in 1986 to lay out their requirements for an appropriate regulatory structure (including limiting the authority of the Food and Drug Administration): "What Monsanto wished for from Washington, Monsanto – and, by extension, the biotechnology industry – got." Then it all fell apart (Leiss 2001, chapter 2, "Frankenfoods, or the Trouble with Science").

Simply put, this strategy says: *Only risk factors that are properly characterized on the basis of accepted scientific principles* may be considered in the formal processes of international regulatory evaluation – including the WTO trade rules which determine what restrictions on international trade are acceptable. The labeling issue, along with every other issue, was subordinated to trade interests (Chaitoo and Hart 2000). One can see immediately what is ruled out of bounds by this strategy, namely, the entire category of ethical, social, and religious values. These are deemed to be "external" considerations in the process of science-based risk assessment, which means that they cannot even be put on the table when nations meet to negotiate the rules of trade.

This was an apparently clever strategy, to be sure, but it was doomed to fail from the start. For one thing, it has become a monumental exercise in global hypocrisy, especially for the country (the United States) which designed it: This is now a nation in which religiously-based values increasingly dominate public policy choices in huge areas of public and private life, including sexually transmitted diseases, abortion, drugs, education, and the war on terrorism. [The administration of George W. Bush imposed values derived from its bizarre religiosity on the promised aid package for HIV/AIDS victims in Africa as well as on international human rights issues: see Editorial 2003 and Bumiller 2003.] Thus, one

can imagine the reaction of other players, such as the EU, when they were told that something so sensitive as food was to be dealt with strictly on a scientific basis, with no "extraneous" values brought to the table. On the issue of growth hormones used in raising cattle, for example, the EU has said that its citizens don't want beef from these sources, no matter what the formal health risk assessment says, and they have maintained this position, against U. S. opposition and threats, for twenty years.

The strategy was also doomed to fail because these new crops are produced by molecular genetics, that is, by direct manipulation of DNA. And genetics is perhaps the most sensitive issue of all, for most people. Most people in the world, outside of North American at least, are not about to be told that they can't talk about religious and other values pertinent to genetic manipulation. The technological process itself (gene manipulation) – what it is now, and where it will be going in the future – is of significant concern to them, and will remain so. This is the fundamental basis in consumer perception for the demand for the mandatory labeling of foods containing GMOs or processed from GM-crops.

2. <u>The "Substantial Equivalence" doctrine.</u>

This doctrine is a regulatory device designed essentially to deal with the foods produced from crops with novel DNA or proteins in which, as a result of refining and processing, no trace of the novel material remains in the finished product. In a nutshell, the doctrine says that no novel food risks (to health, at least) should be present in principle under these conditions. But the "flip side" of this doctrine is important as well: for the same reason that there are no novel risks, there are no new consumer benefits in the first generation of GM-based foods.

For decades now, industry and governments in North America have been harping on the unreasonableness of public attitudes about risk, especially about the alleged desire on the public's part for "zero risk." The message from these sources has been, "there's no such thing as zero risk." And indeed, it is acknowledged by everyone that those same first-generation

novel foods, which may indeed present no human health risks not already described and well-controlled-for (such as allergenicity), do indeed present unavoidable, novel *environmental* risks. [See the some of the history of controversy in Great Britain about risks to wildlife from GM-crops in *Guardian* 2003.] Thus, the inescapable conclusion: Consumers are asked to acquiesce in the creation of additional risks for no additional benefit. This is a poor deal no matter how one looks at it. [Future generations of GM-based foods promise to have significant, direct benefits to consumers (such as improved nutrition and vitamin content). This will represent a different situation. One waits to see if the producers will in this case want to boast to consumers about their cleverness in gene manipulation.] The proponents of the novel technology add insult to injury when they also insist that they need not tell consumers what they are up to.

Gene Technology: A radical new technology for the creation of life-forms.

Most of those in favor of mandatory labeling believe it is a straightforward case of the "consumer right to know," and I agree. Again, as in the case of the regulatory strategy discussed above, the industry/government lobby in North America has tried to side-step this issue by, in effect, dictating to the consumer the terms under which one's right to know should be conceptualized. The bottom-line is this: If the issue is not food safety, there's no justification for labeling; also, as the Council for Biotechnology Information puts it, "biotech labeling can confuse people." Well, yes, life too can confuse people, and it often does. That's hardly a reason for denying them information they think they need. What concerns many of them is gene technology itself.

As the industry/government biotechnology lobby in North America is so fond of saying, "humans have been modifying crop plants for centuries by plant breeding":

> The late 20th century version of this is the production of transgenic plants. Traditional breeding techniques are limited to genetic mating between related species, and require several generations (often years) to achieve the desired results. With transgenic technology, a genetic trait can be introduced into a selected plant via the direct

> introduction of the gene responsible for that trait, a process not constrained by genetic similarity and one that broadens the number of potential sources from which desirable genetic traits can be obtained.

[Council for Biotechnology Information: "Today, the majority of biotech products in the marketplace are not labeled as such since they are nutritionally equivalent and are not derived from known allergens" (CBI 2009). CBI's members are "the leading agricultural biotechnology companies." (The statement quoted in the text was on this website in 2003, but as of May 2009 I can no longer find it there.) The report goes on from that point to give a pretty good exposition on how transgenic technologies operate, although the account is probably too advanced and brief for a non-expert audience. Still, if a greater effort were to be made to "translate" the scientific jargon into layperson's terminology (see below), the result would be beneficial for those interested citizens who have concerns about this technology and its future directions.]

For many people – especially in Europe, and especially there in Germany and Austria – the mention of "genetic technologies" leads inevitably to thoughts of "eugenics." In this context the calming message ("It's something we humans have been doing for hundreds – or thousands – of years already, so what's the big deal?") is erroneous, patronizing, and inappropriate. The key point is: Gene technology based on molecular biology has some of the same objectives as "traditional breeding" does, but the potential scope of its applications extends so far beyond its predecessors as to represent a qualitatively new dimension in human understanding and manipulative potential. By the time the molecular biologists are done, probably in the next decade or so, they will not only be able to move hundreds or thousands of genes around, but they will have the capacity to create entirely new life-forms "from scratch." [See "Elementary, my dear Watson" in Prelude: A Risk Sampler, this volume.]

Public concerns about GMOs are not primarily focused on the plants used as food crops. They are primarily about the science and technology of gene transfer itself – especially, about where it is ultimately headed. For

many people, their first major *personal* encounter with gene technology is in the context of seeing foods derived from GM-crops appear suddenly in grocery stores. Therefore, it is quite appropriate that consumers should be introduced to reliable and disinterested information about gene technology through labels that food producers are required to put on their products.

The labeling issue: Introduction.

In a paper published on the Internet five years ago, Peter Phillips and Grant Isaac of the University of Saskatchewan wrote: "Labeling goes to the heart of private sector, biotechnologically-based research and development in the agri-food business. Mandatory labeling is clearly a threat to the continued development of biotechnology products and processes." The reasoning behind this contention still drives the campaign, led jointly by business and governments in North America, against mandatory labeling of GMOs, and so it is worthwhile outlining it here (Phillips and Grant 1998):

> With mandatory labeling of … GMOs, producers would be forced to visibly label their goods (e.g., with a double helix to demonstrate presence of GMO) to signal that the good has been transformed using transgenic technologies, even though scientific tests may not be able to distinguish between the end-use attributes of the GMO and traditionally-produced good [*sic*]. In this case, producers would be forced to assume the costs of all the risks and uncertainties … [associated by the public with GMOs], with the result that they would likely suffer a discount for their good in the market, which would dampen the production and consumption of this product. This is not socially desirable as firms are required to bear through government actions uncertainties related to the food safety system and *misinformed judgment* [my italics: WL].

There is a most curious twist of logic here! As the application of a radically new scientific discipline, gene technology can frighten some people and lead to a variety of popular reactions, some reasonable and some (arguably) unreasonable – in the sense of being based on views that actually violate accepted scientific principles, for example. Undoubtedly reactions both *pro* and *con* can be either generated spontaneously by individuals, and also, for others, be influenced by views expressed by interest groups (industry, governments, ENGOs, NGOs).

But Phillips and Isaac appear to be making, at least by implication, the astonishing argument that, if "misinformed" judgments (however arising) about GMOs exist in the marketplace, presumably to any extent, this constitutes a justification for industry to refuse to identify the products it makes using gene technology. Thus if there were otherwise a consumer right to know about the applications of this technology, the fact that a few were misinformed would cancel the rights of the majority to be appropriately informed. Needless to say, one only has to try to generalize the argument to other areas of life to see that it is a self-contradictory proposition.

The example of food irradiation will help to clarify this point. Like gene technology, irradiation is a controversial food-processing technology, albeit one which has been in use in Canada, for some time already, for small classes of substances (e.g., imported spices). On the other hand, irradiation of meat (ground beef) – to protect against *E. coli* contamination – which is now permitted in the U. S., is still being considered for approval by Health Canada. But where it is permitted, in the U. S., it is accompanied by appropriate labeling, and almost certainly this practice will be followed in Canada when and if approval is given. Very few think it ought to be introduced without such labeling, even though there are in fact quite a number of popular judgments circulating that are, in the opinion of knowledgeable experts, misinformed to a high degree. To the best of my knowledge no one has suggested that mandatory labeling of irradiated meat is "unfair" to industry because this misinformation exists.

The position taken by Phillips and Isaac is all the more remarkable because they identify so clearly the reasons why consumers might be mystified by the technology of genetic modification and, as a result, might wish to be further informed about it by those who wish to use it in growing and processing the foods they eat:

> Due to the level of sophistication associated with the production of GMOs, it is difficult for consumers to know or completely understand: the scientific techniques which have

> been utilized in the production of the good; the impact of consumption on human health and safety, both in the short-term and over the long-term; or the impact of production and consumption upon broader consumer concerns such as animal welfare, environmental protection or moral, ethical and religious concerns.

This is a most satisfactory summary of the bases of consumers' information deficit with respect to GMOs. In fact, it forms a solid basis for a strong case in favor of an appropriate form of mandatory labeling. This case will be outlined in the concluding section of this paper.

To summarize the case to be made later: The information deficits outlined above by Phillips and Isaac justify a specific form of mandatory labeling for products and processes where GMOs are present – namely, one which steers the interested and concerned consumer to readily-accessible (internet-based) and easily understandable sources of "disinterested" information about gene technology and its applications. Before proceeding to outline this case, I shall present and review some definitions and issues pertinent to it.

Various definitions of "genetically modified."

1. The European Union (as of 2009):

"GMOs are organisms whose genetic material (DNA) has been altered not by reproduction and/or natural recombination but by the introduction of a modified gene or a gene from another variety or species" (EU 2009).

2. Japan (as of 2009):

Definition of genetically modified food (Japan 2009):
"Genetic recombination techniques consist of introducing into a crop or other organisms a gene extracted from another organism that gives useful characteristics to the crop or organism.

"A genetically modified food is a food produced using these techniques. Herbicide tolerant or harmful insect resistant soybeans, rapeseeds, and corns are among those that have been developed and produced."

3. Canada, House of Commons, Bill C-410 (Canada 2009):

"An Act to amend the Food and Drugs Act (mandatory labeling for genetically modified foods)," introduced by Charles Caccia, defeated at first

reading (18 March 2003): "'Genetically modified', with respect to a food or one of its components, means that the genetic make-up of the food or component has been modified by a technique that combines DNA fragments of the food or component with DNA fragments from another source in a way that could not occur without the use of modern technology…" [This was later Bill C-51, which had not been passed before the dissolution of Parliament on September 7, 2008 (I do not believe that the latest version carries any provision about GMOs).]

4. Food Standards Australia – New Zealand (ANZA 2009):

Food Standard Code 1.5.2: "… a food produced using gene technology means a food which has been derived or developed from an organism which has been modified by gene technology … [which] means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms."

These few examples pose the crucial issue, legitimately raised by opponents of labeling: What exactly is it that the label should refer to? They illustrate – paradoxically – both the difficulties in answering that question *as well as* the need for mandatory labeling!

Recall the first-mentioned of the information deficits identified by Phillips and Isaac, the mystery about the scientific techniques lying behind gene technologies. Just what are the molecular biologists doing at present in their laboratories? And what are they planning to do in the future, when their knowledge about the genomes of all living things, plants and animals alike (including humans), is more complete, and their skills in manipulating genes very much more sophisticated?

The definitions selected above try to capture in a sentence or two the essence of both the new science and the technological applications based on it. More specifically, the definitions try to epitomize what is radically different about this science and technology, as a way of manipulating the characteristics of plants and animals in the pursuit of human interests, by comparison with the far more limited and cruder techniques of the past. This is a very hard thing to do, which explains both why the definitions differ from each other and why none of them seems entirely satisfactory.

Yet this insufficiency in the definitions used by regulators is another reason why there is a need for enlarged sources of trustworthy information to be provided to the public about this new technology. As indicated below, the chief purpose of a mandatory labeling scheme should be to point consumers to such sources.

Illustrations of labeling requirements.

As of 2003 labeling was mandatory for GM foods in the following countries and regions: Australia and New Zealand, the European Union, Japan, South Korea, and Indonesia (Carter and Gruere 2003; cf. Phillips and McNeill 2000). In 2002 China announced that it would require mandatory labeling as well (China 2002). Three examples are detailed below.

1. The European Union*:*

In September 2003 the EU extended its existing labeling requirements – covering all foods made with GM ingredients – into two new areas: (a) food ingredients and foods that are highly refined, which have been processed from genetically-modified crops (such as soya or maize-oil), even where no trace of the novel DNA is present in the final product; (b) all animal feed made from genetically-modified crops. The threshold for labeling is now 0.9%, and accidental contamination of up to 0.5% is permitted without labeling. The choices for label wording are: "This product contains genetically modified organisms" and "… produced from genetically modified [name of organism]."

At the same time, an elaborate system of traceability has been established which is, in the words of the Regulation, designed "to facilitate accurate labeling of such [GMO] products, … so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner as well as to enable control and verification of labeling claims" (EC 2003). [Regulation (EC) No 1829/2003 on genetically modified food and feed, and Regulation (EC) No 1830/2003, "concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from

genetically modified organisms" (both promulgated 22 September 2003).] As of 2007 the United States was still battling against the 2003 EU regulations at the WTO (Euractiv 2007).

2. Japan:

"In the safety assessment system of genetically modified foods provided under the Food Sanitation Law, all foods are classified into one of three groups: (1) genetically modified foods that have been assessed; (2) GM foods that have not been assessed; and (3) non-GM foods." The purpose of labeling is "to inform consumers of the constituents of foods they consume." There are two forms of labeling for foods in category (1): "Labeling is mandatory when a product contains genetically modified ingredients that have been handled according to identity preserved handling." Example: "soybeans (genetically modified)." Second: "Labeling is mandatory when a product contains both genetically modified ingredients and non-GM ingredients that have not been handled according to identity preserved handling." Example: "soybeans (not segregated from GM product)."

"Identity-preserved handling" is the Japanese term for the EU's "traceability." Japan provides a blanket exemption for (a) processed foods in which any novel proteins from DNA manipulation are absent in the finished product, and (b) products in which GM ingredients are not "among the three main ingredients" and do not "account for 5% or more of the total weight of the product" (Japan 2009).

3. Food Standards Australia – New Zealand:

Labeling is mandatory for any "food produced using gene technology" which "contains novel DNA and/or novel protein." Excluded are refined foods where "the effect of the refining process is to remove novel DNA and/or novel protein" and "a processing aid or food additive, except where novel DNA and/or novel protein from the processing aid or food additive remains present in the food to which it has been added." There are also exclusions for small amounts of flavoring agents and of ingredients unintentionally present. Where the requirement applies, the simple phrase, "genetically

modified," is specified for use on the label (NZ 2009). ["Standard 1.5.2 – Food produced using gene technology" (NZ 2009).]

Some other issues about GMO-labeling.

A. Who should pay for labeling?

The idea that consumers who want foods containing genetically modified organisms (GMOs) to be labeled as such should pay a premium, for the additional costs involved in labeling, symbolizes the rampant confusions in issues about GMOs more generally. Peter Phillips and Robert Wolfe kicked off this discussion by using a superficially deft analogy: a consumer asking for GMO-labeling is just like a consumer asking for kosher, halal, or "organic" foods (Phillips and Wolfe 2003). Such consumers are in effect demanding additional services or benefits from the food industry, and thus it is appropriate to ask them to pay a premium. But note the hidden presumption – these consumers *want* those benefits. The certifying of foods as kosher, halal, or organic represents an incremental value they desire, and actual consumer behavior tells us that they are willing to pay for these values. So far, so good.

But the analogy immediately collapses, because no consumer ever asked for genetically-modified ingredients to be incorporated into the foods supplied to the marketplace! Companies like Monsanto developed the technology, the United States government developed a specific regulatory strategy for approving them (Canada jumped on this bandwagon early on), the ingredients started to appear in foods sold to consumers, *and only then* were consumers told about this whole new enterprise. Some of them, especially in Europe but also on our own shores, don't like these kinds of surprises in their food system, so they made their opposition quite clear to both industry and regulators. The controversy goes on.

Now let's go back to the analogy suggested by Phillips and Wolfe and see how it plays out in this light:

(1) I may cheerfully choose to pay a premium for kosher, halal, or organic foods in order to obtain an incremental benefit (a value to me) *which I explicitly seek* – namely, authoritative and reliable certification that my food has been grown or prepared in accordance with certain values that are important to me.

(2) At the same time, I used to have GMO-free foods everywhere in the marketplace. I never asked anyone to change these conditions. More specifically, as a consumer I never expressed a preference for obtaining a new value or presumptive benefit: foods made with genetically-modified (in the sense indicated above) ingredients. Now, here comes the kicker: When my government, which regulates this stuff, finally comes clean and tells me that it has approved these new ingredients for the food system, I am also told explicitly, *that there is no incremental consumer benefit* in having them! Foods made with the new, GM version of familiar crops (such as canola) are, for all practical purposes, identical to the old, non-GM foods, in terms of nutrition, chemical composition, etc.

(3) Some consumers now say, "Well, I'd rather not, thanks. If you're determined to push ahead down this path, just label them for me, so that, if I want to do so, I can choose to purchase the old type with which I'm familiar."

(4) Then I'm told: "All right, if you want us to restore the *status quo ante* for you, and allow you to choose non-GM foods by having GM foods properly labeled, you'll have to pay for that benefit." Is it so surprising that I might say at this point: "You're completely nuts."

Now things should be clearer. If the food industry, and the government which regulates it, want to change the conditions under which the food delivered to my plate is produced, they have to take responsibility for that decision. In particular, they ought to (a) inform me adequately *before the fact* that they have done so; (b) they should continue to give me a choice in

the matter, since obviously I cannot do without food, and food represents all kinds of special values for me and my family. They can do this most responsibly by labeling the foods they have modified, so I can decide whether I want to purchase them or not. It is only commonsensical to suggest that, of course, any incremental costs for this service should be borne by those who chose to produce the novel foods and those who make an explicit choice to consume them.

What are these costs? The European Union is moving quickly to establish production systems which, first, *segregate* novel from older types of crops and seek to prevent cross-contamination between them; second, *trace* the products of modified plants through the harvesting and processing system; third, *certify* to both producers and consumers that the segregation and tracing technologies are performing adequately; and fourth, *identify (label)* meaningfully the resulting end products for consumers, who can then exercise their rights of choice.

To date both industry and government representatives in North America have resisted mightily the introduction of such a tracking system. But I suspect that they might yield on this point, and before long. What will force them finally to come to their senses on this matter is GM wheat, now awaiting a regulatory approval in Canada and the U. S. This approval will be forthcoming, but, I predict, not without our first putting into place an adequate tracking system. For Canada to approve GM wheat without such a system would be suicidal (Fulton et al. 2003; see the extensive material at Farmers 2009).

Once we do this, we can stop the idiotic EU-bashing that North American governments love to indulge in, and cooperate with Europe in making the tracking systems work well. And – by the way – the EU is most certainly not going to back down on its new regulations, no matter how many trade-related disputes are initiated by the United States, so we might as well just accept the fact and move on.

This isn't about food safety. It's about the rights of citizens in a well-ordered democracy to have their freedom of choice respected by their own governments.

B. <u>How should mandatory GMO-labeling be done so that it is useful?</u>

With reasonably reliable tracing regulations in place, foods can be segregated into one or more categories (as the Japanese do) and be labeled accordingly. Without traceability, the situation becomes more difficult – including, of course, for those producers who wish to seek to attract customers with the stipulation, "GM-free." In other words, in order to be useful to consumers, mandatory labeling must be accompanied with a regulatory structure that deals with all of the following dimensions:

(a) Tracing of inputs,
(b) Maximum threshold for unwanted ingredients (e.g., EU, 0.9%),
(c) Maximum threshold for accidental contamination (e.g., EU, 0.5%),
(d) Exceptions (see Japanese, Australia – New Zealand illustrations above).

The general purpose is, as EU regulation 1830 puts it, "to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner." The best choice for the specific wording on the label itself can be a matter of debate; it is more important to recognize that only the larger context, indicated above, makes mandatory labeling useful and meaningful.

A recent case study.

Throughout the entire debate over GMOs in North America, the industry/government lobby has argued that mandatory labeling will make some consumers wary of GM products, and therefore labeling poses an unacceptable risk to the biotechnology industry. I leave aside here the important question about how this argument possibly could be seen as somehow trumping the more fundamental consumer right to know. Rather, I wish to refer to a recent published study which bears directly on the plausibility of the contention itself. The study is based on survey research about consumers' perception of risk, in the context of the labeling of milk

produced with rBST in the United States. The study's conclusions are as follows (Zepeda et al. 2003):

> The results indicate that greater availability of labeled milk would not only significantly increase the proportion of consumers who purchased labeled milk, its availability would also reduce the perception of risk associated with rBST, whether consumers purchase it or not. In other words, availability of rBST-free milk translates into lower risk perceptions toward milk produced with rBST.

In an age where public trust in industry and governments has been sinking ever lower, this study has important lessons for those institutions. Many consumers think about their food purchases, and they appreciate having choices. When they have such choices, based on the provision of information that they think is important to them, they tend to respond in quite rational ways. What annoys them is the idea that major institutions are hiding things from them through inadequate disclosure. What really annoys them, I suspect, is having someone impute "misinformed judgments" to them.

A mandatory labeling proposal for Canada.

Canada now (2009) has an "official" national standard, produced by the Canadian General Standards Board, for "Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering" (CAN/CGSB-32.315-2004)" (CGSB 2009). This development, which I suspect remains unknown to most citizens, almost certainly is and will remain of little moment. In fact, voluntary labeling is a simple absurdity; it is a self-defeating exercise because it undermines the very principle (the right to know) to which it ostensibly pays lip-service. To understand the reason why this is so, let us return to the wise words of Phillips and Isaac quoted earlier:

> Due to the level of sophistication associated with the production of GMOs, it is difficult for consumers to know or completely understand: the scientific techniques which have been utilized in the production of the good; the impact of consumption on human health and safety, both in the short-term and over the long-term; or the impact of production and consumption upon broader consumer concerns such as animal welfare, environmental protection or moral, ethical and religious concerns.

No better statement of consumer information needs about GMOs has ever been penned. Satisfying those needs requires mandatory labeling. [The 2000 KMPG Consulting study on the costs of mandatory labeling in Canada does not have to be taken seriously (KPMG 2001).] This is how it ought to be achieved in Canada:

- Establish a regulatory scheme for tracing and labeling GM products that allows consumers to "exercise their freedom of choice in an effective manner" (the EU formulation);
- Use a small number of simple label texts, such as "genetically modified" or "produced from genetically modified [name of organism]";
- Add only a website URL and a toll-free telephone number;
- Establish one or more Internet-based public information resources, *with content provided by disinterested third-party sources only*, on all aspects of gene technology and its applications to food crops, continuously updated, and including a question-reply facility. [A template for such resources will be found at Emcom 2009, which deals with the issue of endocrine disruptors; the information provider is a university-based research team. The site features a "science translation" modality where scientific description is expressed in layperson's terms; animated graphics to illustrate biological processes; "layered" information to respond to different levels of need; a question – reply function ("Ask a Scientist"); and other features.]

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Part Three:

Case Studies in Risk Management

CHAPTER 16

RISK MANAGEMENT OF CARBON CAPTURE AND STORAGE: OVERVIEW AND FUTURE STEPS

A paper prepared for the
Institute for Sustainable Energy, Environment, and Economy
University of Calgary (2009)

See Update 2017 at the end

Abstract

Carbon capture and storage (CCS) is the attempt to prevent large quantities of carbon dioxide from escaping into the atmosphere and contributing to the greenhouse effect. The paper opens with an introduction to what is involved in capturing carbon dioxide both from natural and industrial sources, processing it, and then injecting it deep beneath land or oceans where it will remain sequestered for a very long time. Public policy, regulatory, and public acceptance issues related to CCS are reviewed briefly. The next sections of this paper first offer a sketch of how risk management is undertaken, using what is known as an "integrated risk management framework" to explain its unique, step-by-step approach. Then two prominent, long-running and quite different Canadian cases in which a risk-based approach has been worked out in some detail – long-term storage of nuclear waste (used nuclear fuel) and prion diseases (especially so-called "mad-cow disease") – are presented. The purpose of this case-comparison exercise is to provide some real-world dimensions to the otherwise abstract discussion of risk management, and to anticipate some of the ways in which the risk management approach to carbon capture and storage is likely to unfold. The paper concludes with some comments on the nature of the risk assessments, and the risk management framework, that will be required in order to build public confidence in the demonstration stage of carbon capture and storage.

1. Introduction and Overview

According to the International Energy Agency, carbon capture and storage [CCS] "in power generation, industry and fuel transformation could account for 20% of CO_2 savings (6.5 Gt of CO_2 captured and stored annually in

2050)," making it one of the most important strategies in any greenhouse-gas emissions stabilization scenario. [*Near-term Opportunities for Carbon Dioxide Capture and Storage* (Paris: OECD/IEA, 2007), p. 3.] CCS includes three separate processes and their associated technologies:

(1) CO_2 capture: Isolating the carbon dioxide gas that is naturally present in fossil fuels (coal, oil, natural gas), as well as the gas produced in industrial waste streams, such as at ethylene plants, and compressing it into a liquid state;

(2) CO_2 transport: Moving the liquified CO_2 from its point of origin to a suitable site for long-term storage, either on land or beneath the ocean;

(3) CO_2 sequestration: Injecting the liquified CO_2 into a suitable geological medium that is likely to hold it in place, deep underground, for thousands of years.

The longest-running project utilizing these processes is the one in Norway, at the Sleipner West gas field operated by Statoil in the North Sea. Since 1996, one million tonnes (1 Mt) of CO_2 annually have been injected into a sandstone formation aquifer at a depth of 1000 meters beneath the ocean floor.

Other current operations include the Salah field in Algeria, run by British Petroleum and its partners, which has been sequestering 1 Mt/year of CO_2 annually beneath the Sahara Desert, and the world's first CCS coal plant near Spremburg, Germany (a relatively small facility). There are also complete demonstration projects such as Australia's Otway Basin facility, where methane and CO_2 are separated, then the CO_2 is liquified and transported through a pipeline to a well drilled into a depleted natural gas field, where 100,000 tonnes per year are being injected some 2 km underground.

Finally, in addition to simply storing compressed CO_2 underground, a process known as EOR (enhanced oil recovery) first uses the gas to increase the amount of oil that may be pumped out of a field when it is close to being depleted. Canada's Weyburn-Midale Project in Saskatchewan, the largest CO_2 sequestration facility so far, takes 1.5 Mt of compressed CO_2 annually, which is shipped through a 300-km pipeline from a coal gasification plant in

North Dakota, for use in EOR (resulting in a 50% increase in oil recovered), and which is then to be sequestered permanently underground. There is also a natural gas facility in Fort Nelson, British Columbia that presently captures both CO_2 and hydrogen sulphide (H_2S). In 2008 a feasibility project for a storage phase was announced, involving the drilling of test wells into a saline aquifer; if successful, the facility will sequester 1 Mt/year of carbon dioxide.

There are many challenges still to be overcome before CCS can fulfill its potential for being a major contributor to GHG emissions reductions ("Trouble in store," *The Economist,* 5 March 2009). At the moment, there is general agreement that cost represents a formidable obstacle to commercial-scale development: When CO_2 does not have an economic value, as it does when it is used in enhanced oil recovery, all activities associated with CCS will represent an additional cost of production. For the earlier phases of development, incremental costs in Canada are estimated to be in the range of $40-$140 per tonne of CO_2 abated, although costs will fall later. (A recent McKinsey & Company report looked at the period beginning in 2020, when the early full commercial-scale CCS projects are expected in Europe, and estimated the costs per tonne of CO_2 abated at €35-50, totaling €30 for capture, €5 for transport, and €10 for storage [*Carbon Capture & Storage: Assessing the Economics,* 2008, p. 16]).

Another way of representing these costs, for an energy-production facility such as a coal-fired electricity plant, is to calculate the expected increase in the costs and price of energy when CCS is added. Again, estimates vary widely at this early stage of analysis; one 2007 projection for coal-fire electricity-generating plants, from the U. S. DOE, forecast a cost increase of between 150 and 300 per cent and something close to a doubling of electricity prices (U. S., General Accounting Office [2008], p. 23). Everyone agrees that it will be necessary for governments to create a market for carbon (in other words, treating carbon as a commodity), in which the

market price is sufficiently high to justify the costs of CCS, before any commercial-scale CCS-only facilities can be built and operated.

Another significant challenge is the need for a comprehensive policy, regulatory, and legal framework for CCS in every relevant jurisdiction; for Canada, this will involve some type of joint federal–provincial framework. [For the U.S. see Marston & Moore (2008), Wilson et al. (2003), and Wilson et al. (2007); for a brief overview across the developed world, see International Risk Governance Council (2008) and Resources for the Future (2007).] In addition, international agreements will be needed, through which national or regional GHG-management initiatives can be integrated – for example, emissions trading regimes and the Clean Development Mechanism under the Kyoto Protocol.) The policy dimension would cover, for example, the sharing of responsibilities as between different levels of government as well as between governments and the private sector, including possible public – private partnerships. The regulatory dimension would include GHG emissions-reduction targets over time as well as health, safety, and environmental protection standards and environmental monitoring protocols. The legal dimension must include specification of ownership of the commodity and the liabilities associated with all the phases of CCS (capture, transport, storage), especially the risks of re-release or other adverse events, especially over longer time-frames, at the storage facility.

Recent contributions have advanced our understanding of three of the significant public policy issues, in a Canadian context, associated with CCS, namely: (1) economics and financing, (2) ownership and liability of the carbon captured for long-term storage, and (3) the legal framework for regulation. [See Pembina Institute and ISEEE, "Carbon Capture and Storage: Forum Proceedings" (November 10, 2008), especially the papers by Nigel Bankes, Mary Griffiths, and Marlo Reynolds & David Keith: http://pubs.pembina.org/reports/ccs-forum-proceedings.pdf.] However, the nature of the risk assessment and risk management frameworks needed

for CCS in Canada have not been adequately described to date. The situation in the U. S. is quite different; see, e.g., the discussion of the FutureGen project in section 5, below. Also relevant is this: "The United States has considerable experience injecting fluids underground – both on land and under the sea floor – for purposes of storage, recovery, and disposal" (Wilson et al. [2003], p. 3481; see also Keith et al. [2005]). It is important that a sustained discussion of these frameworks, involving all interested parties, should be begun as soon as possible, in the context of the imminent launching of large-scale demonstration projects for CCS in Alberta.

Finally, there are challenges arising out of public awareness and acceptance of CCS, in terms of the understanding of the technologies, the policy objectives in relation to climate change issues, and the risk assessment and risk management methodologies for CCS. Citizens are likely to evaluate the prospects for CCS in the context of broad energy policy criteria, that is, the way it may affect the whole mixture and balance of future energy supply alternatives – in particular, the relation between fossil-fuel sources, nuclear, hydro, and "alternatives" (solar, wind). [Palmgren et al. (2004) and Chapter 6 (pp. 117-39), "The public perception of carbon dioxide capture and storage in the UK," by S. Shackley, C. McLachlan, and C. Gough, in Gough and Shackley (2005).]

As stated in a recent document from the Pembina Institute: "It is critical that CCS be considered as part of a portfolio of solutions, and that adequate attention also be paid to more sustainable, low-impact energy solutions, especially renewable energy and energy efficiency ("The Pembina Institute's Perspective on Carbon Capture and Storage," 19 February 2009")."

According to the International Energy Association's *World Energy Outlook 2008*, the world's level of dependence on fossil-fuel energy in 2030 will be about the same at it is today – roughly 80% of the primary energy mix. When energy mix scenarios are discussed, a key factor for many people

is the distribution of various types of public subsidies across energy types. A number of governments, notably in Canada, have announced large subsidies, in the billions of dollars, for R & D on carbon capture and storage, dwarfing by several orders of magnitude the support for alternative-energy projects. Thus in this context CCS could be interpreted as a strategy to "lock in" our dependence on fossil fuels, over the long term, and thereby to inhibit the "rebalancing" of energy options. This perceived bias in favor of fossil fuel sources of energy is very likely to be a major public policy issue throughout the period of the demonstration phase of the feasibility of large-scale carbon capture and storage, and it will have to be addressed by proponents of CCS.

This paper is devoted largely to only one of these challenges, namely, the need to develop robust risk assessment methods and risk management practices for carbon capture and storage. Such methods and practices become part of the response to every one of the challenges outlined above: for example, with respect to the policy dimension, they are essential for the determination of acceptable levels of risk and thus the validation of CCS as a strategy for GHG emissions reduction; with respect to the regulatory dimension, they specify not only the risks but the cost of risk control options, thus allowing us to do risk-risk, risk-benefit, and risk-cost-benefit analyses; and finally, with respect to public awareness and acceptance, when risk assessment and risk management are carried out in credible ways, they make up an essential component of the public's responses to new technologies.

The remainder of this paper first offers a sketch of how risk management is undertaken, using what is known as an "integrated risk management framework" to explain its unique, step-by-step approach. Then two prominent, long-running and quite different Canadian cases in which a risk-based approach has been worked out in some detail – long-term storage of nuclear waste (used nuclear fuel) and prion diseases (especially so-called "mad-cow disease") – are presented. The purpose of this case-comparison exercise is to provide some real-world dimensions to the otherwise abstract

discussion of risk management, and to anticipate some of the ways in which the risk management approach to carbon capture and storage is likely to unfold. The paper concludes with some comments on the nature of the full risk assessment that will be required for carbon capture and storage.

2. The Risk Management Approach

Risk management has been called "a comprehensive, systematic process that assists decision makers in identifying, analyzing, evaluating, and treating all types of risks, both internal and external to the organization." Further, "the objective of risk management is to ensure that significant risks are identified and appropriate action is taken to manage these risks to the extent that is reasonably achievable (Jardine et al., 2003, p. 129)." In more concise terms, we may refer to risk management as *an attempt to anticipate and prevent or mitigate harms that may be avoidable*.

The effort to manage risks takes place on a daily basis at every level of activity in present-day society: at the level of individuals and families, neighborhoods and communities, urban and rural regions, large private enterprises, provincial and federal governments, and in many dimensions of international affairs for global issues. Individuals and families, for example, have a very broad range of primary responsibilities for their well-being, particularly in the areas of health and personal security; this is indicated by the fact that some three-quarters of lifetime health outcomes are related to risk factors over which individuals have some large measure of personal control. Large corporate enterprises, especially in the industrial sector, have both legal and fiduciary responsibilities to both their shareholders and governments in the areas of employee health and safety, environmental protection, and prudent financial management.

Senior levels of governments within nations have the broadest range of formal duties in this regard; through regulatory systems, for example, they set levels of acceptable risk, in occupational settings and for the general public, for literally thousands of different types of exposures to potentially

hazardous substances, activities, and technologies. Even within some specific areas, such as the safety of donated blood, the risks are diverse, complex and ever-changing, requiring ceaseless vigilance on the part of the regulators (Canadian Blood Services and Héma-Québec). Finally, there is a wide variety of global risks – armed conflict, infectious diseases, environmental pollution, climate change, and many others – which can only be dealt with through concerted action at the international level.

Risk itself is defined here as "the chance of harm." The conception of risk management as *an attempt to anticipate and prevent or mitigate harms that may be avoidable* indicates its key objectives. Seeking to anticipate events that may prove to be harmful and investigating risk control options that will at least reduce the scope of possible future harms, if they cannot be prevented entirely, is a program of action that can have very large payoffs in terms of avoiding costs that otherwise might be payable. The purchase of insurance is, of course, the best-known activity of this type. The whole of preventive medicine, such as smoking cessation and many other types of behavioral modification programs, is an exercise in risk management as defined. Environmental protection regulations are designed to prevent release of pollutants, and other types of adverse human impacts, as opposed to cleaning up after the fact.

One of the great strengths of the risk-based approach is that it can find various ways of accommodating progressively larger sets of decision inputs while maintaining an acceptable level of technical rigor. This is shown in the following schematic:

Science ⟷ **Risk Management** ⟷ **Public Policy**

(1) **(2)**

Interface (1):	**Interface (2):**
Risk Assessment	**Public Perception of Risk**
Risk Control	**Risk Acceptability**
Risk Mitigation	**Public Trust**

Commentary:
At the interface of science and risk management, we find the technical disciplines of risk assessment, control, and mitigation, which ideally tell us

what are options are, how well certain precautionary measures are likely to perform, what consequences are likely to follow from failures in risk control, and what it will cost us to achieve certain levels of risk mitigation. And yet this is now known to be only one-half of the full equation. Decisions on how to manage a whole host of major risks, such as pandemic influenza and climate change, occur in an open international arena in which a large number of interested parties, members of the general public, and governments consider their options and maneuver for relative advantage. On a purely domestic level, the same types of interveners debate narrower issues, such as vaccines, diets and obesity, and drug use; their conflicts and engagements are played out for all to see in the daily mass media. Increasingly, in all of these engagements contributions from scientists and professional risk assessors are explicitly referenced in the public debates.

Both risk assessment and management involve a high degree of technical complexity, in terms of the scientific characterization of the possible harms and how very diverse risk factors expose us to those harms. But perhaps the greatest technical challenge lies in the field of risk estimation, where the probabilities of harm for any given situation and population are calculated in quantitative terms, and where the nature of the uncertainties in that estimation are stated. For example, in Canada today, there is approximately a 1-in-8 million-chance that a unit of blood will be infected with HIV. The 95% confidence interval gives us a range of uncertainty from about 1 in 20 million at the lower end of the range to about 1 in 3.6 million at the upper. This means, in effect, that we can be very much more confident that the true residual risk number is somewhere between 1 in 3.6 million and 1 in 20 million, than we can be that the number is precisely 1 in 8 million.

In response to this high degree of technical complexity, governments and others decided to set out the risk management process as a formal decision-making scheme, which breaks it down into a discrete series of specific steps in sequential fashion. These are known as risk management frameworks. The basic idea is to encourage consistency in the application of risk management [RM] techniques across the entire range of risks which much be managed. When they are applied rigorously, these schemes can provide a level of transparency, accountability, and credibility to RM decision-making that is hard to achieve by using less formal strategies and

also can contribute to an enhanced level of public confidence in the management of public health risks. Public confidence can be severely tested when risk assessors are required to make predictions about the reliability of risk control measures far into the future. For carbon capture and storage processes involving sequestration of CO_2 in underground geological formations, for example, a retention period of 7000 years needs to be assured. [IEA, *Prospects for CO_2 Capture and Storage* (2004), cited in Natural Resources Canada, *Canada's CO_2 Capture and Storage Technology Roadmap* (Ottawa, 2006), p. 28.]

The practice of displaying the sequential steps that should be undertaken in the process of risk management [RM] decision-making, in the form of schemata using flow-chart diagrams, began in the early 1980s. This was itself the outcome of the increasing interest in "formal" risk assessment practices, including the use of either quantitative or qualitative risk estimations. The landmark document in this regard is the famous "Red Book," *Risk Assessment in the Federal Government: Managing the Process* (US, National Research Council, 1983). On the very first page of this pathbreaking document, two themes are mentioned which continue to characterize the field down to the present day: (1) the domain of risk assessment involves "the intricate relations between science and policy"; (2) regulatory decisions about health hazards can be "bitterly controversial." Another interesting aspect of this document is its statement about the need "to ensure that risk assessments are protected from inappropriate policy influences."

The major "structural" aspect of the flow-chart design was the distinction between the poles of risk assessment and risk management (see Figure 1). The former stands closest to science and is, in fact, represented as the intermediate stage that stands between science and policy (which includes risk management decision making). Two other aspects of this early diagram became standard features in all later versions: (a) a "logical" breakdown of the components of each dimension—e.g., hazard and exposure in assessment; (b) a sequential flow from a beginning (hazard

identification) to a final end-point (the risk management decision). This early model was refined during the following years, as is shown in the Health Canada version, dated 1990 (see Figure 2). One of the main improvements in the later version is its more comprehensive listing of the components or inputs for all of the stages, and especially for the "options analysis" box. What is especially noteworthy in the listing of factors to be taken into account at the options analysis stage is the inclusion of "public perception of risk" and "risk acceptability," which marked a transition to later stages in the conception of the risk management process.

Analysis of past cases indicates that risk management decision-making most often fails because some critical decision inputs are either missing entirely or in part, have been analyzed inadequately, or have not been delivered when needed (Hrudey and Leiss, 2003; Hrudey & Hrudey, 2004; Leiss, 2005). Therefore, the framework requires regular re-examination, with a view to determining whether all of the necessary decision inputs are specified; in addition, the separate inputs must be specified, as clearly as possible, in a form that can be readily *integrated* with all others. For example, the analysis of psychosocial effects and their impacts must be capable of being "rolled up" and "converted" into an *operational form*, that is, into a form that can be assimilated, along with other factors, within a decision exercise.

Thus, a new framework, revised in response to earlier challenges, has been designed according to a set of key requirements derived from the study of the development of risk management models in the period after 1983, in the context of the extensive case-study literature that has grown up in the same period (developed in Leiss et al. 2010: see Chapter 17 in this volume). These are:

1. The model must clearly identify one or more agencies which have "core" responsibility for a major risk issue, as well as the one agency which bears the leadership role among them, thus satisfying the need for clear accountability; it must also show the relation between both lead and core agencies and all other associated agencies, both domestic and international;

2. The model must use a sequential decision-making structure, and also show clearly what key inputs are required, thus satisfying the need for clarity and transparency in the decision process;

3. The model must respond to the need for *timeliness* in decision-making, by incorporating a requirement for an initial phase of informal risk estimation that precedes the later, more elaborate exercises;

4. The model must stipulate the operationalization of all decision inputs, in terms of either qualitative or quantitative measures, or both, thus permitting the integration and "rolling up" of all inputs;

5. The model must be able to show interactions with external stakeholders that are specific in nature, and are related to the generation of equally specific decision inputs;

6. The model must show clearly the points where the lead agency is responsible for communicating risk assessment results to the public and stakeholders;

7. The model must be sensitive to the dynamics of the interface of science and policy, and in particular, how the risk assessment may be "protected against inappropriate policy influences" (using the mechanism of independent and external peer review for the key analytical documents).

The integrated risk management framework (Chapter 17 in this volume) responds to the seven requirements listed above by its inclusion of the following provisions which are not found in previous versions:

A. The first-named agency should have lead responsibility to ensure accountability throughout the entire subsequent decision process.

B. In Step 1, "risk forecasting" ("foresight") exercises are recommended as a way of implementing the "anticipate and prevent or mitigate" approach which is incorporated in the IRMF structure as a whole.

C. In Step 3, a provisional risk estimation (which may be qualitative in nature) is called for at a very early stage in the process, in those cases where early notification to potentially affected parties, and early action of a precautionary kind, may be appropriate here.

D. The "impacts estimation" phase (Step 5) specifically requires formal consideration of consequences (ideally in the form of a quantitative algorithm), including socio-economic and psychosocial dimensions, which must use standard measures (social indicators, social impact assessment, risk perception) to ensure an adequate level of methodological rigor.

E. For the first time, this framework model uses an expanded format so as to indicate clearly the responsibilities that the core agency should discharge with respect to both inter-agency collaboration (left side) and non-governmental partners (right side), including responsibilities for timely public communication.

F. The model indicates that seeking an independent, external peer review of the risk estimation is a fundamental requirement of "best practices."

Risk-based decision-making is very much a work in progress, and even after many years in the development of robust decision-making frameworks, many substantial challenges remain. [For a good review see Chapter 9, "Toward improved risk-based decision-making" (pp. 258-272), in National Research Council, *Science and Decisions* (2008).]

3. Risk Management of Prion Diseases in Canada

The key characteristics of the Integrated Risk Management Framework, as shown in Figures 3 through 6, were developed in the context of reflections on Canada's experience with "mad cow disease" in the period beginning in 2003. After a brief introduction, the prion diseases case will be used to illustrate the structure and the twelve steps in the risk management framework.

Prion diseases, which affect a large number of animal species, including humans, are rapidly progressive, fatal and untreatable neurodegenerative syndromes, characterized by spongiform change in the brain. These types of diseases include bovine spongiform encephalopathy (BSE, or "mad cow disease"), Creutzfeldt-Jakob disease (CJD, the human form), and Chronic Wasting Disease (CWD, affecting deer, elk, and moose). The experience with BSE in particular presented a severe challenge, over more than two decades, to all aspects of the established risk management frameworks and practices for zoonotic diseases in over twenty countries in Europe, North America, and Asia. The United Kingdom, where the outbreak of BSE began, suffered huge impacts from it, which have been carefully

documented in the report from a major public inquiry. [Phillips et al., *The BSE Inquiry;* Van Zwanenberg and Millstone, 2003, 2005.

Canada has been a major beef-exporting country for some time. The BSE episode, during which some seventeen cases of the bovine disease have been discovered since 2003, resulting in the closure of major export markets for Canadian beef, caused severe impacts on families involved in beef production; the economic losses probably exceed $10 billion. This experience has led to a major re-thinking of important aspects of established risk management frameworks, especially in three important dimensions: the scope of risk estimation, public perception of risk, and the evaluation of psychosocial factors in risk assessment.

Structure.

The central core in the framework describes the functions that must be performed in order to carry out credible risk management decision-making processes. These functions are assigned to the national government agencies that have the senior level of responsibility for them; however, they may also be carried out jointly with provincial agencies (as in the case of the joint federal-provincial environmental assessment panels). The exact nature of the balance between federal and provincial authority will depend on the specific set of issues to be addresses. In the prion diseases case, the overriding issues are animal and human health protection, and the federal agencies have had lead responsibility for them.

The panels to the left of the core specify the full range of other international and national government agencies which share both authority and responsibility for managing certain risks, which for prion diseases includes the World Organisation for Animal Health (OIE), WHO, the EU, and other national governments. The panels to the right seek to capture the involvement of all other interested parties, such as producers and consumers, environmental organizations, and the general public.

The twelve steps itemize the specific types of information and analysis that are required in order to produce a credible output. They can form the basis of a checklist to ensure the proper allocation of responsibilities, a basis for reporting to all other involved parties on how and when specific responsibilities have been carried out, and as a basis for both accountability and the ongoing refinement of best practices.

Steps One through Eight: The Risk Assessment Phase.

Steps One and Two involve important, ongoing surveillance activities, the attempt to anticipate potential future threats through forecasting, and ongoing review of relevant policies, laws, and regulations. http://www.foresight.gov.uk/index.asp: "The UK Government's Foresight Programme and its Horizon Scanning Centre use the best evidence from science and other areas to provide visions of the future. While no one can predict what will happen, 'futures research' can help us to identify potential risks and opportunities. In this way, Foresight can assist policymakers in developing strategies to manage our future better."

Risk estimation specifies the nature of the expected harms; who may be exposed to them, including subpopulations at elevated risk; the primary risk factors (the routes through which harms affect individuals, e.g., the ingestion of infected beef); and probabilistic estimates of the likelihood of various types of harms and the potential consequences resulting from them. Step Three encourages risk managers to undertake a preliminary risk estimation, with respect to new and emerging threats, even if full information is not yet available, in those cases where cost-effective precautionary measures can be deployed.

A fuller and more formal risk estimation exercise begins in Step Four, which is intended to provide a check that all relevant risks have been identified, and at which the first major efforts in risk communication should be undertaken. Step Five expands the scope of impacts assessment beyond what has traditionally been the case, and it does so in recognition that the failure to do this in the past has resulted in serious underestimation of

impacts. Step Six is a formal process that will be familiar to experienced risk managers; it is intended to lay the foundation for a full-blown QRA (quantitative risk assessment), in which the magnitudes of the likelihood and severity of potential harms, as well as uncertainties, have been estimated using a variety of well-established formal methods. In Step Seven one proceeds immediately to the review of available risk control options, where the QRA outputs are considered in the light of established standards of acceptable risk; and, where risk reduction measures appear to be called for, cost-effectiveness criteria can be employed in order to rank them. The formal consultation process in Step Eight seeks to test the recommended options for both the risk management decision and the chosen risk mitigation strategies in consultations with affected parties and the public.

Steps Nine through Twelve: The Risk Management Phase.

Step Nine is the decision phase, where the risk manager uses regulatory and legal authority to implement risk control measures, and sets in motion an implementation phase (Step Ten) designed to achieve the specified targets. Increasingly, major risk issues have international dimensions, and so it may be desirable to coordinate, so far as possible, domestic measures in Canada with the actions of other nations and/or international bodies. For environmental risks, where impacts may be widely distributed, monitoring and compliance activities (Step Eleven) are especially important, and may involve verification protocols and audits of performance that are coordinated under international agreements. In Step Twelve, periodic evaluation, review and adjustment is carried out on an ongoing basis; and there will be occasions when new information or analysis requires one to go back to an earlier step, somewhere in the risk assessment phase, redo the calculations leading to the QRA outputs, and reconsider the risk management decision made earlier.

4. The Case of Nuclear Waste.

About thirty countries have been accumulating nuclear waste material in temporary storage facilities for many decades (in the case of the United

States, since the Second World War). Most of this waste is now produced in civilian electricity-generating plants using nuclear fuel of various types. Currently, there are strong pressures to increase the share of nuclear power in the energy mix of many countries, which will also increase the number of countries that will be stockpiling the waste. Permanent storage or disposal of nuclear waste in secure underground facilities within suitable geological media is a safety requirement, due to the long life of the radioactive materials. For this reason, nuclear waste disposal is the closest analogue to the issue of the long-term sequestration of carbon dioxide. Two countries (Sweden and Finland) are the most advanced in terms of planning for such a facility. Canada, through its Nuclear Waste Management Organization (NWMO), which was mandated by federal legislation in 2002, will soon begin the process of seeking a willing host community for its own site.

Canada currently has twenty-two nuclear power plants, located in three of its provinces: Ontario (20), Québec (1), and New Brunswick (1). Together they supply 14% of Canada's total electricity output (whereas hydro provides 60% and coal 25%) – but in Ontario, Canada's largest province, nuclear's share is 40%. The CANDU reactor used in all Canadian installations is a pressurized heavy-water type that uses natural (unenriched) uranium as an energy source. The fresh fuel is composed of 99.28% U-238 and 0.72% U-235. When it is removed from the reactor at the end of its useful life (a period of 12 to 18 months), the used fuel bundle is both highly radioactive and hot; it is placed in a pool under water and after one year both heat and radioactivity have decreased to 1% or less of their initial values.

After 100 years the radioactivity will have decreased to 0.01% of its initial level, and after about 1 million years it will approach that of natural uranium. After ten years the fuel bundles are removed from the pool and transferred to reinforced concrete casks on the plant site. As of the end of 2004 Canada had accumulated in temporary storage about 1.9 million used fuel bundles, representing about 36,000 tonnes of uranium. When projected to the end of the useful life of the current generation of CANDU reactors, the

volume of waste will approximately double from its 2004 level. Of course, should new nuclear reactors be built and operated in Canada, the volume of waste will increase, requiring either an expanded single facility or perhaps multiple operations.

The chief risk factor for used nuclear fuel is leakage of radioactive material from a storage regime into the environment, with human exposures to unacceptable levels of radioactivity occurring either directly or through environmental media, especially water. The so-called "safety case" entails a combination of technological and natural barriers to leakage, under which exposures to radioactivity from waste remains within acceptable limits for very long time frames – a minimum of 10,000 years, sometimes as long as 100,000 years, and even (as mandated in the United States) up to 1 million years. All of the regimes proposed so far by various countries which hold nuclear waste in interim storage, including Canada, involve some kind of "multi-barrier" approach: First, the waste is sealed inside large stainless-steel containers; second, those containers are encased in copper, which resists corrosion; third, the steel-copper containers are placed inside cavities that are filled with bentonite clay, which resists water entry; fourth, these cavities are excavated out of a suitable geological medium such as unfractured granite, found widely in the Canadian Shield, at a depth of 500 meters or so.

When the NWMO reviewed its risk management options in 2004, it was obliged by its government terms of reference to include three "technical" methods of permanent waste storage in its assessment: (1) leaving the waste at the reactor sites; (2) moving the waste to a centralized facility, with storage either above-ground or shallow underground; (3) moving the waste to a centralized facility and storing it deep underground in a suitable geological medium. The group which was given the responsibility of finding an acceptable method for ranking these options, in order of priority, selected multi-attribute utility analysis (MAU) for this purpose.

The real key to the whole exercise lies in the choice of objectives that must be satisfied by any technical solution. (A more precise way of expressing this is to ask: How well will a specific solution perform, within one of the chosen time-frames, with respect to a specific objective? [See the special issue of the journal *Risk Analysis* (Vol. 19, no. 5, October 1999) on "Performance Assessment for Radioactive Waste Disposal."]

When asked in this form, the answer can be given by means of a score along a scale, say 1–100.) Here is where the integration of the social and the technical dimensions takes place, as can be seen in the final list of eight objectives chosen by consensus of the assessment team members:

1. Fairness (including inter-generational fairness);
2. Public health and safety;
3. Worker health and safety;
4. Community well-being;
5. Security (e.g., against terrorist attack);
6. Environmental integrity;
7. Economic viability;
8. Adaptability.

A key decision in the MAU method is to initially assign all objectives equal priority; at a later point, weighting exercises are performed as a test of robustness. The length of time specified in the safety case (minimum 10,000 years) means that timelines must be dealt with explicitly. In this case, the group decided to score the expected performance of each option twice, that is, as near- and far-term solutions (more precisely, about 0-200 years and 200+). The final result is a set of "situations" or matrices: 3 [technical solutions] x 2 [time-frames] x 8 [objectives] = 48 scores (except that the objective of fairness was not divided into two time-frames.) Each of the resulting 45 situations was individually scored, on the relative performance scale of 1-100, by each of the team members (collectively, therefore, with nine team members there were 405 separate scores). A dedicated software program keeps track of the scoring and "rolls up" the results at the end: The final tally showed a strong preference for the deep underground storage option. It is possible that this type of method could be used for ranking decision options for carbon capture and storage (see NWMO 2004)

1. Risk Assessment for Carbon Capture and Storage.

A 2006 document from Natural Resources Canada, *Canada's CO_2 Capture and Storage Technology Roadmap*, states (p. 58): "The top priority for storage research is the confirmation that CCS is a safe, reliable and environmentally beneficial practice for long-term CO_2 storage ([on] the order of thousands of years)." Such a confirmation can only be derived from arraying evidence and judgment within careful, comprehensive, and credible risk assessment and risk management frameworks. This effort has not yet been started in Canada.

The International Energy Agency conducted a very preliminary risk assessment workshop in July 2004 (IEA2004b). There are several good presentations, in the form of PowerPoint slides, available on the Web that illustrate the risks associated with CCS (see Selmer-Olsen [2006], Brockett [200]), Dawes [2007] and Rohner [2007]). According to the important article by Damen et al. (2006, p. 290): "Risk assessment is a first step in a strategy to set up management and control measures to minimize risks of underground CO_2 storage. Also, it helps to facilitate the formulation of standards and regulatory frameworks required for large-scale application of CCS."

They further recommend (p. 311) that "a common risk assessment methodology able to assess long-term effects of underground CO_2 storage should be further developed." Finally, they comment (p. 305): "The lessons to be learned from underground disposal of nuclear waste should be found in the area of risk assessment methodology, monitoring, and public outreach (specifically what went wrong in this process)." [For "what went wrong" in nuclear waste siting see Flynn and Slovic (1995).] More recently a team at Lawrence Berkeley National Laboratory produced a short document entitled "Carbon Sequestration Risks and Risk Management" (Price, 2007).

A report of the Intergovernmental Panel on Climate Change (IPCC, 2005) offered an early discussion of the major risks and risk factors associated with CCS, dealing separately with capture, transport, and sequestration in land-based geological formations and deep ocean ecosystems. The major risks identified in this report, and others, are as follows:

1. CO_2 Capture:
    a. Occupational risk (chronic, and acute cardiovascular and respiratory risk at concentrations exceeding 3%);
    b. Asphyxia at concentrations above 15%.

2. Transport:
    a. Acute risks as above, due to leakage from pipeline failure (hazards to humans and wildlife), especially in low-lying areas;
    b. If H_2S is included in the pipeline mixture, acute risk at 100ppm;
    c. Ships (tankers) and terminals: accidental release through collision.

3. Storage – Land:
    a. Local effects (e.g., elevated concentrations in near-surface environment);
    b. Leakage by vertical transport into the atmosphere;
    c. Leakage by vertical or lateral transport into aquatic ecosystems or underground drinking-water reservoirs.

[Leakage may occur as a result of failures in injection boreholes or through undocumented or abandoned wells; slow or quick release through failure of cap-rock seals; from existing faults due to increased pressure, or from induced seismicity resulting in new fracturing and fault activation. There is a nice graphic in Figure 2-1 (PDF file, p. 25) of the "FutureGen" risk assessment (see next section).]

4. Storage – Oceans: not included (unlikely to be approved due to general prohibitions against ocean disposal).

Another formulation of the set of risks, using different terminology, and referring only to the storage phase, is as follows:

A. Global:
    - Release of CO_2 to the atmosphere

B. Local:
    1) CO_2, in atmosphere or shallow subsurface:
        a. Suffocation of humans or animals above ground
        b. Effects on plants above ground
        c. Biological impacts below grounds (roots, etc.)

2) CO_2 dissolved in subsurface fluids:
    a. Mobilization of metals or other contaminants
    b. Contamination of potable water
    c. Interference with deep-subsurface ecosystems

3) Displacement:
    a. Ground heave;
    b. Induced seismicity;
    c. Contamination of drinking water by displaced brines;
    d. Damage to hydrocarbon or mineral resources

[Wilson et al. (2003), p. 3477. Wilson et al. (2007), pp. 5945-6, write: "Effective regulatory and legal frameworks for GS [geological sequestration] must ensure that the activity is both safe and effective. Deployment will require development of a comprehensive risk characterization and management strategy for GS that both responds to existing requirements and addresses risks not covered by the current regulatory and legal frameworks." See also the long list of research requirements in Table 1, p. 5947, as well as the discussion of policy implications on pp. 5949-50; altogether, this article provides a first-rate guide on regulatory considerations for CCS. The demand to push ahead in this area is especially urgent for Canada, since the risk assessment framework for CCS is at present quite undeveloped here; Wilson et al. (2008) comment on the urgency.]

6. U. S. "FutureGen" Risk Assessment/Environmental Impact Statement (2007)

The FutureGen Power Plant is conceived as a nominal 275MW, near-zero-emissions facility producing hydrogen from coal to generate electricity; it would be designed to remove 90% of the coal's carbon and 99% of its sulphur (the latter to be processed for sale), capturing between 1-2.5MMT/year of CO_2 for sequestration. Four separate candidate sites, two in Illinois and two in Texas, were considered in the environmental assessment. Some idea of the scope of the project analysis undertaken by the U. S. Department of Energy is given by the sheer size of the final published reports – close to three thousand pages. The risk assessment report itself runs to 400 pages, and this document provides what is, to the best of my knowledge, the only published presentation to date of a comprehensive risk assessment methodology for CCS.

To begin, the twin charts dealing separately with pre-injection and post-injection scenarios outline the environmental pathways for three broad types of risk: acute and chronic human health risk and ecological risk. The

site characterization summary for the four sites includes approximately thirty different parameters, dealing with the nature of surface ecosystems (aquatic and terrestrial ecology), subsurface features, seismicity, and the geologic features of the seal and reservoir in the deep underground zone (target area). An overview of the risk assessment approach is provided for both the pre- and post-injection scenarios, which consists of the following steps:

1. Specifying health and ecological toxicity criteria for both scenarios;

2. Failure modes, release scenarios, exposure analysis, and consequences analysis for the pre-injection scenario;

3. Leakage pathways and exposure and consequences analyses for the post-injection scenario. The four post-injection leakage pathways evaluated are: upward leakage through caprock and seals; release through faults; migration into non-target aquifers; and upward migration through wells. The exposure analysis considers both human and ecological receptors.

A comprehensive Risk Summary is summarized in nine tables, broken down (for human health impacts) into adverse effects, irreversible adverse effects, and life-threatening adverse effects; predicted probabilities of release for all scenarios, uncertainties, and data gaps are specified.

Impact Assessment of CCS in the European Union.

At the beginning of 2008 the European Union issued a guidance document for assessing the impacts of CCS across all three of its principal dimensions, in which there is some discussion and quantitative estimation of hazards and risk factors (e.g., accidental releases of CO_2), but not yet a full QRA (including uncertainties). However, this does seem to be the most complete review to date of the entire range of considerations related to the hazards associated with CCS, for example [European Union (2008b), section 7.6.3, "Societal risks and impacts of CCS deployment," and following, pp. 67-76; and annexes II – VIII, pp. 90-120]:

1. Hazards are specified for each of the major components (capture, transport, storage) in a systematic way;

2. There is an explicit recognition that risks associated with the increased energy generation required for CCS must be included;

3. A storage site selection process, including use of a scientific panel to certify the safety case for any site, is outlined;

4. Financial security mechanisms, related to the long duration of the project (similar to those applicable to nuclear waste storage) are reviewed.

There are one or two good independent discussions of regulatory needs in the EU context, as well as an excellent, brief overview document on risk assessment and management in the EU context. [ECN, "Choices for regulating CO_2 capture and storage in the EU," 2007; World Resources Institute, "Impacts of EU and international law on the implementation of carbon capture and geological storage in the European Union," 2005; cf. Mace et al. (2007).]

Risk Management.

As noted briefly in Section 2 of this paper, risk management moves the outputs from the risk assessment into a decision-making process. Those outputs represent a detailed estimation, in quantitative terms, of the probabilities that certain types of harms will occur, under specific circumstances, and the full range of consequences (ecosystem and human health, monetary, social impacts) that might result, if they should occur. With this information in hand, and with the objective to *anticipate (and prevent or mitigate) serious potential harms before they occur*, risk management undertakes:

1. To review and evaluate the level of risk and risk acceptability, according to criteria that are presumed to have wide public confidence;

2. To consider the availability of risk control options for risk reduction, as set out in risk-risk, risk-benefit, cost-benefit, and risk-cost-benefit analyses;

3. To communicate effectively and transparently, with all affected stakeholders, about the decisions and decision process;

4. To establish robust protocols for monitoring of expected results, the utilization of new knowledge, and the implementation of corrective measures where necessary.

An "integrated risk management framework" (IRMF) – explained and illustrated in Chapter 16 – is designed specifically to move away from the usual "black box" character of the risk-based decision-making process by requiring risk managers to provide a higher degree of transparency in all stages of that process. One of the greatest advantages of increased transparency is the encouragement it supplies for continuous improvement and the adoption of the latest best practices. It can also serve as the basis of a "checklist" to document the timely completion of necessary decision inputs, thus reducing the risk that important inputs may be overlooked and establishing a more rigorous form of retrospective performance evaluation.

Operational details for decision criteria vary according to the nature of each major type or set of risks to be assessed and managed. So far as carbon capture and storage is concerned, the literature published to date indicates that there are strong similarities to technologies and practices, developed for other purposes, which provide a firm basis for the risk assessment of CCS. On the other hand, there are also certain important and unique aspects to the risk profile for CCS that demand the application of new criteria and practices designed specifically for this case. In addition, the promise represented by CCS – to be one of the most significant mitigation strategies for controlling GHG emissions – means that CCS is likely to have, in Canada and elsewhere, a high public profile. This expectation suggests that, as large demonstration projects get under way, no effort should be spared in order to put in place credible and transparent risk assessment and risk management frameworks for CCS as soon as possible.

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UPDATE 2017

A Special Issue of *International Journal of Risk Assessment and Management (IJRAM) will be published in early 2018:*

"Risk Assessment and Management of Carbon Capture and Storage: A Canadian Perspective"

http://www.inderscience.com/jhome.php?jcode=ijram

Guest Editors: Shalu Darshan; Donald C. Lawton; James Meadowcroft; and Michael Mehta

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CHAPTER 17

BSE IN CANADA

Original Publication:

W. Leiss, M. G. Tyshenko, N. Cashman, D. Krewski, L. Lemyre, C. Amaratunga, M. Al-Zoughool. "Managing Prion Disease Risks: A Canadian Perspective." *International Journal of Risk Assessment and Management,* Vol. 14, no. 5 (2010), pages 381-436.

1 Introduction

Risk management (RM) has been called "a comprehensive, systematic process that assists decision makers in identifying, analyzing, evaluating, and treating all types of risks, both internal and external to the organization." Further, "the objective of risk management is to ensure that significant risks are identified and appropriate action is taken to manage these risks to the extent that is reasonably achievable" [Jardine et al., (2003), p.129]. Here we propose a more concise definition, referring to RM as *an attempt to anticipate and prevent or mitigate harms that may be avoidable*.

For the past quarter-century governments have been constructing and fine-tuning formal schemes which are intended to represent the necessary stages in RM decision-making. Throughout this time they have been regularly

revised in order to incorporate an up-to-date version of 'best practices' in this domain. When they are applied rigorously, these schemes can provide a level of transparency, accountability, and credibility to RM decision-making that is hard to achieve by using less formal strategies – and that can contribute to an enhanced level of public confidence in the management of public health risks.

However, during this same period the formalized practice of RM has been severely challenged by ongoing public controversies about some well-known risk issues, such as industrial chemicals (Leiss and Chociolko, 1994; Leiss, 2004) and civilian nuclear power (Mehta, 2005); by egregious cases of mismanagement, such as drinking water (Hrudey and Hrudey, 2004) and the blood supply (Picard, 1995; Krever, 1997); and by novel risks, such as BSE (Leiss, 2004) and SARS (Tyshenko and Paterson, 2010). The case studies published elsewhere in this Special Issue show just how difficult it was to bring the international epidemic of bovine spongiform encephalopathy (BSE) under control, and how extensive the impacts were in terms of animal morbidity, impacts on farmers, and monetary costs.

Section 4 of this paper takes a detailed look at BSE RM in Canada. A very significant lesson for future RM challenges emerges from this analysis, namely, the vital importance of having risk managers provide a credible risk estimation (and risk communication based on it) to potentially affected stakeholders as soon as possible, *even when that risk estimation has not been fully elaborated*. The documentary record shows that Canada had done a preliminary risk estimation of BSE in its domestic herd in May 1994, nine years prior to the actual discovery of its index case. The essential accuracy of the 1994 analysis was confirmed much later – but the analysis had never been communicated to beef producers, who had thus not been given the opportunity to adapt their own risk control strategies in a precautionary way, and who were then entirely unprepared for the events that began to unfold in May of 2003.

These and other challenges indicate that the process of RM decision-making is still in need of further development and renewal. This paper draws on the experience of over 20 countries with managing the risk of BSE as a guide to the types of improvements in RM frameworks that might be made. The paper first looks in detail at the experience of different countries that have reported BSE, then reviews the development of RM frameworks, lists the major policy issues raised by the long BSE saga, and finally proposes an updated, integrated BSE RM framework. By the term 'integrated', we mean the need to unify the results of separate, and qualitatively different, decision inputs into an overall judgment of the severity of the risk, taking into account both expected frequency and expected consequences.

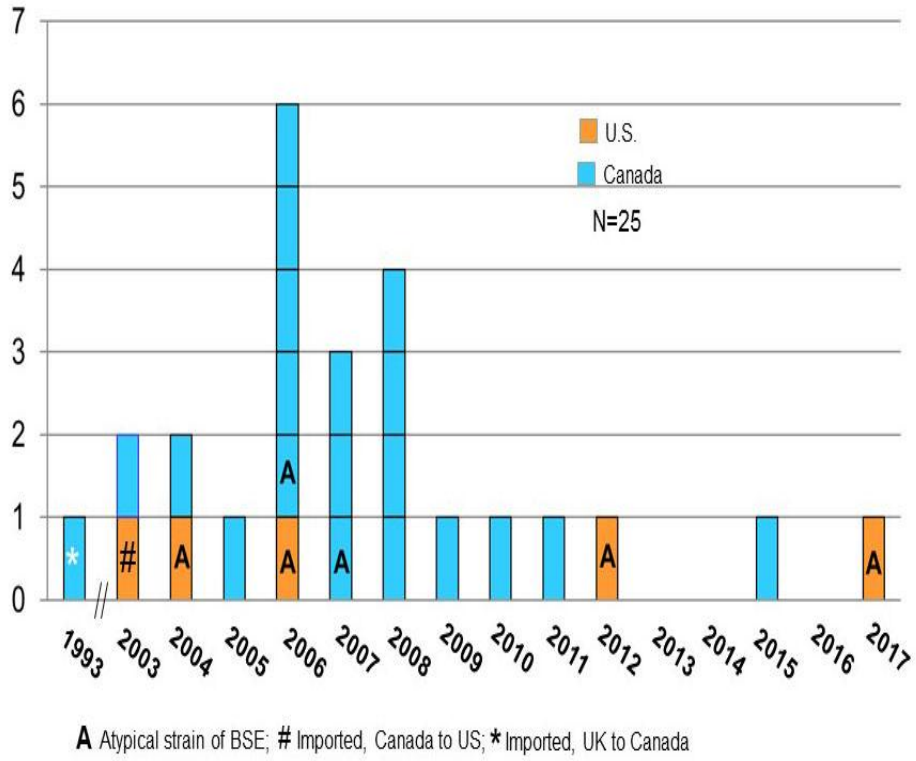
UPDATE 2017

The worldwide epidemic of "classic" BSE has been dramatically slowing since 2010 and may be on its way to disappearing entirely. "Classic" BSE is caused by infected feed, has a unique neurological signature, and can cause variant Creutzfeldt-Jakob disease (vCJD) in humans. The "atypical" kind is very rare and is thought to arise spontaneously.

THE U.S. CDC WEBSITE AS OF 2017:

https://www.cdc.gov/prions/bse/bse-north-america.html

Through July 2017, BSE surveillance has identified 25 cases in North America: 5 BSE cases in the United States and 20 in Canada. Of the 5 cases identified in the United States, one was born in Canada; of the 20 cases identified in Canada, one was imported from the United Kingdom (see graph below).



This figure illustrates the 25 BSE cases identified in North America, of which 6 were the atypical BSE cases and 19 were classic BSE cases. The only classic BSE case identified in the United States was imported from Canada.

Strong evidence indicates that classic BSE has been transmitted to people primarily in the United Kingdom, causing a variant form of Creutzfeldt-Jakob disease (vCJD). In the United Kingdom, where over 1 million cattle may have been infected with classic BSE, a substantial species barrier appears to protect people from widespread illness. Since vCJD was first reported in 1996, a total of only 227 patients with this disease have been reported worldwide.

THE WEBSITE OF THE OIE

http://www.oie.int/animal-health-in-the-world/bse-specific-data/

OIE data showed just six cases of BSE worldwide in 2015, of which four were in the EU. That was down from 1,957 in 2000, 561 in 2005 and 125 in 2008. There was 1 case only (France) in the rest of the world in 2016

In the UK, where the annual number of cases had peaked in 1992 at 37,280, there has been a total of only 8 “classic” cases since 2012, and none in 2016, the last year of reporting.

CHAPTER 18:

CHRONIC WASTING DISEASE

Original Publication:
William Leiss, Margit Westphal, Michael G. Tyshenko, Maxine C. Croteau, Tamer Oraby, Wiktor Adamowicz, Ellen Goddard, Neil R. Cashman, Shalu Darshan, and Daniel Krewski. "Challenges in Managing the Risks of Chronic Wasting Disease." *International Journal of Global Environmental Issues* (2017), Vol. 16, No. 4, pages 277-302.

Abstract

This article summarizes efforts at disease surveillance and risk management of Chronic Wasting Disease (CWD). CWD is a fatal neurodegenerative disease of cervids and is considered to be one of the most contagious of the transmissible spongiform encephalopathies (TSEs). Evidence has demonstrated a strong species barrier to CWD for both human and farm animals, other than cervids. CWD is now endemic in many U.S. States and two Canadian provinces. Past management strategies of selective culling, herd reduction, and hunter surveillance have shown limited effectiveness. The initial

strategy of disease eradication has been abandoned in favor of disease control. CWD continues to spread geographically in North American and risk management is complicated by the presence of the disease in both wild (free-ranging) and captive (farmed) cervid populations. The article concludes that further evaluation by risk managers is required for optimal, cost-effective strategies for aggressive disease control.

UPDATE SINCE TIME OF PUBLICATION

The first case of CWD in a free-ranging Norwegian reindeer was discovered in the central region of Norway in March of 2016 (Benestad et al 2016); subsequently, two additional cases in wild deer were discovered in the same area. Norway has decided to use hunters and sharpshooter to eradicate the entire herd of 2,000 animals in this area; then, also in 2016, two cases of CWD in moose were discovered near Trondheim in northern Norway (Stokstad 2017). The European Commission has asked the European Food Safety Authority (EFSA) to introduce surveillance and sampling activities in the entire northern sector of the European Union (Estonia, Finland, Iceland, Latvia, Lithuania, Norway, Poland and Sweden) with respect to the threat of CWD to seven wild, semi-domesticated and farmed cervid species: Eurasian tundra reindeer, Finnish (Eurasian) forest reindeer, moose, roe deer, white-tailed deer, red deer and fallow deer (Ricci et al 2016). In addition, recent research on CWD in North America (Edmunds et al 2016, Meyerett-Reid et al 2017) includes a major review (Zabel and Ortega 2017) of environmental factors in the spread and persistence of the cervid prion protein. *Finally, a new risk control strategy has been proposed for CWD in North America, namely, using controlled*

burns of fires in forest areas where vegetation and soil is found to be heavily contaminated with prions.

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