

## Presentation to the Roundtable on The Precautionary Principle and Canada's Approach to Risk

Sponsored by the Canadian Health Coalition, the Canadian Federation of  
Nurses Unions and the Council of Canadians

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### Burden of Proof: The Place of Precaution and Risk in Canada's Regulatory System

What an extraordinary day we have had together - invigorating, thought-provoking and challenging. I want to thank the sponsoring organizations - Canadian Health Coalition for providing us with the opportunity to discuss one of those writ-large, public policy issues which is extremely complex and multi-faceted in substance while underpinned by a system of citizen values. It is an issue which affects the lives of every Canadian. In the end though, I think it comes down to a pretty simple equation.

In matters of health protection, are we going to have a regulatory system which is governed first and foremost by the principle of precaution or a system which is governed by measuring and ultimately taking risks, with precaution applied in the narrowest circumstances?

The precautionary framework is concerned with preventing serious and irreversible harm from happening. The risk management framework attempts to determine what degree of risk is acceptable and what are the costs and net benefits of taking those risks. Both approaches are underpinned by completely different value systems, and as I will argue, have competing and incompatible priorities and objectives.

Some of our presenters reaffirmed a fundamental principle - when it comes to

protecting the health and the environment - governments - as regulatory authorities - have a duty of care. In a civilized, democratic society, how could it be anything but when the health of **even one** human being or the ability of the environment to sustain all forms of life hangs in the balance? The burden of proof must be to demonstrate safety first, and when uncertainty exists, demonstrate precaution.

Presenters from the federal government gave us a clear outline of the government's framework for future regulation in a wide range of areas across government departments, including the regulation of health protection and the environment.

The federal government's regulatory framework for the 21<sup>st</sup> Century is based on the concept of 'smart regulation', the newest regulatory buzzword making its way across the globe. The framework is grounded in regulation through risk management. Key elements of the framework as stated by the government in various documents, including the report on smart regulation, can be summarized as follows:

- providing a high level of protection to Canadians
- extending democratic values of transparency, accountability, and public involvement through consultation
- applying precaution within a risk management framework grounded in science-based decision-making
- developing new regulatory instruments as an alternative to legislation such as voluntary codes of compliance, performance-based assessments on compliance and economic instruments to foster compliance

- harmonizing Canada's regulatory standards with other countries
- implementing a life-cycle approach
- re-visiting regulatory approval as science, technology and public tolerance to risk evolves
- considering society's chosen level for tolerance
- meeting the non-discrimination requirements of trade agreements
- using the least trade-restrictive regulatory options
- fostering an economic climate that promotes innovation and investment  
(smart regulation.ca)
- playing a role in establishing and maintaining market access and creating a climate conducive to trade and investment (smartregulation.ca)
- creating conditions ripe for an innovative and competitive economy  
(Treasury Board Press Release, March 24, 2005)
- enhancing market performance and supporting innovation, competitiveness, entrepreneurship and investment in the Canadian economy (smartregulation.ca)
- and in the words of Minister Alcock, "...regulation can and must become a competitive advantage and a key instrument for achieving our social, environmental and economic objectives...." (press release above)

No one can argue with the first two elements of the framework - protecting the public and enhancing democratic values. Indeed, the overarching objective of

our regulatory system must be the protection of human health, safety and the environment. And as we heard earlier, there are ways to regulate which truly incorporate democratic ideals and practices.

These two elements do reflect values deeply held by Canadians when it comes to protecting public health. Values such as 'innovation', 'competitive advantage', 'entrepreneurship' and 'investment opportunities' are market values. They represent completely different objectives, primarily monetary in nature, and ultimately compete with, not complement, the values inherent in protecting public health and serving the common good. Public opinion research tells us that these are not values Canadians ascribe to health protection.

The so-called 'smart' regulation framework is not in the public interest. It mixes trade and industry objectives with the objective of protecting the health of the public. It is a framework which legitimizes the profitability of industry in the regulation of products which are potentially hazardous to human health or the environment. This poses a serious conflict of interest and provides no basis for faith or trust in the process. When a regulatory system is structured to allow the possibility that trade and industry priorities will trump health priorities, large and small scale disaster waits in the wings.

We have already had our share of disasters, not the least of which was the failure of the regulatory system to protect the blood supply. The smart regulation framework totally and completely ignores the wisdom given to us by the Krever Commission - that the relationship between the regulator and the regulated must **never** become one in which the regulator loses sight of the principle that it regulates **only** in the public interest and not in the interest of the regulated.

Combining industry and trade objectives with health protection is the same path that led to the BSE health disaster in the U.K., a path that has been thoroughly repudiated, and is still a matter for discussion in the U.K. Parliament. As

recently as two months ago, the UK House of Commons Health Committee accused the Department of Health of assuming that the interests of health and industry are the same. As a result, the expansion of industry influence has led to practices which act against the public interest. Smart regulation takes Canada in this direction.

The framework subsumes the Precautionary Principle under a narrow risk-benefit approach. Even in this minimal nod to precaution, the principle is subverted. The presentation today defined the application of precaution in this way: applying precaution recognizes that the absence of full scientific certainty shall not be used as a reason for postponing decisions where there is a risk of serious or irreversible harm.

The real Precautionary Principle is stated differently. Where there are threats of serious or irreversible harm, the lack of full scientific certainty shall not be used for postponing cost effective measures to prevent adverse health outcomes or environmental degradation. The Precautionary Principle is itself a framework for regulating health protection. It is not a narrow subset.

The difference in meaning between the two definitions is immense. The government's formulation is a license to take a risk - put a potentially hazardous product on the market - wait and what? - pray that no harm will come or if it does, manage the damage - take comfort in the knowledge that, on paper, the net benefit outweighed the cost of stricter regulation, at least to the industry?

Other elements in the framework support this view. The life-cycle element of smart regulation is an example. This can only speak to the goal of getting the product on the market quickly and monitoring for adverse health impacts as its life-cycle progresses. It also fits in with the element of re-visiting regulatory approval as science, technology and public tolerance to risk evolves.

Going back to the BSE issue, the government as regulator did not adopt a total ban on animal ruminants being fed back to cows. As a result, there was no ban on animal blood being rendered into feed. Why? According to a CFIA spokesperson on CBC TV, there was no scientific evidence that the rogue protein was carried in the bloodstream. There was no evidence that it wasn't either. This is how the government applies precaution. Potential risk - no scientific evidence - therefore no precaution but take a life-cycle approach - no ban on animal blood in feed - net benefit to feed producers and the cattle industry at first - now net costs accrue to those industries and to any Canadian who may be a potential victim. Canadians do not want a health protection system in which they are cast in the role of guinea pigs.

Creating the conditions for economic growth is an important goal, but it has no place in regulating on matters of public health and the environment. It is only common sense that this cannot and must not be a rationale for lowering health protection standards. Moreover, it is indefensible and reckless. Health wins hands down over both economic and corporate interests every time.

It may very well be that smart regulation has a place in sectors of the economy where public health is not at issue. It's actually hard to find such sectors - perhaps the financial sector, mergers, or charitable operations.

We have a huge challenge before us. The government's paradigm is set. It has chosen to be a trader, not a public guardian. It reflects the interests of the large industrial lobby which has argued for the changes proposed in this framework. It places commercial interests above health interests. The goal of harmonizing regulatory standards is ultimately part and parcel of the larger thrust towards deeper integration with the United States, a public policy direction about which there has been no public debate.

The smart regulation agenda is being put in place as we speak, with Bill C-28

which makes smart regulation changes to the Food and Drug Act, Bill C-27 which seeks to achieve the same goal with respect to the Canadian Food Inspection Enforcement Act, and the proposed sweeping legislative changes to the Food and Drug Act next year. The steamroller is moving. Now it's a matter of getting liability protection in place.

In light of the evidence of the failings of a trade-oriented, risk management approach, health advocates and activists cannot enter into a consultation process where the framework is based on setting acceptable levels of risk rather than preventing harm, and where consultation will focus on how to implement a flawed framework.

Contrary to assertions by the government, the public's tolerance for risk is low and its expectations for precaution are high. We have to build on the inherent wisdom of the public. We need to work together to develop strategies and mobilize public opinion. We need to educate the press and encourage them to do some investigative journalism. We need to intervene at all levels of government.

The OECD's critique on our regulatory system actually said that the power of special interest groups to dissuade government from trusting business to 'do the right thing' to achieve regulatory objectives may paralyze the government's intentions in this area. This is the only time I'll ever say that we need to prove the OECD right. We need to stop the smart regulation juggernaut.

In closing, as I was preparing for today, I recalled the case of Djamshid Djan, the young Afghan boy who received medical treatment by Canadian doctors which resulted in the gift of life. What is at the heart of that? I believe it is about a belief system which places the highest value on a single life no matter what the cost. Was there a net benefit? Not an economic one to be sure, but there certainly was a net benefit to humanity - making a choice for life and preventing

harm enhanced our humanity immensely. This is the belief system I want to underpin the regulation of health protection. It's an ideal worth fighting for.

Thank you

Recommendation 46: Health Canada and the Department of Justice should explore and recommend, in the context of the renewal of the Food and Drugs Act and other health protection statutes, what immunity might be appropriate to the department and its staff. The recommended approach should be consistent with the protection provided to other leading therapeutic product regulators, including the U.S. Food and Drug Administration and Australia's Therapeutic Goods Administration.