Smart Regulation: Will the government's strategy work?

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The regulatory activities of Health Canada safeguard the health of Canadians by ensuring that new drug products and medical devices meet the highest standards of safety, efficacy and quality. Some industry advocates and policy-makers deem that our present regulatory system is inefficient, that it delays market access for useful food and drug products and that it thwarts research by making investment costs prohibitive. These claims notwithstanding, health practitioners would be well advised to examine proposed regulatory changes that have the potential to adopt lower standards harmonized for international competitive advantage and that introduce food and drug products into the market before independent scientific assessment has been completed.

In late March 2005 the federal government declared a major restructuring of Canada's regulatory policy, affecting everything from the automotive industry to the economic development of First Nations communities.[1] If legislated, this Smart Regulation strategy will streamline and speed up approval for new drugs, foods, biotechnology products, veterinary products and pesticides and will harmonize standards, especially between Canada and the United States. Although the government's declaration recognizes the key role of regulatory policy in the preservation of the environment and the maintenance of public health, its emphasis lies elsewhere — on economic growth, increased trade and faster market access.

The impetus for the Smart Regulation strategy dates back to 2002, when the federal government launched a 10-year plan to move Canada to the front ranks of the world through the use of innovative financial, marketing and knowledge-translation strategies. It created the External Advisory Committee on Smart Regulation "to recommend areas where government needs to redesign its regulatory approach to create and maintain a Canadian advantage." The composition of the committee, however, did not reflect the range of Canadian interests. Eight of the 10 committee members had either extensive corporate experience or work experience as management consultants. Remarkably, one member is the managing director of an international consulting firm that proudly advertises privatization, deregulation and liberalization as the pillars of its business.[2]

On Sept. 23, 2004, a news release accompanying the final report of the External Advisory Committee on Smart Regulation quoted the prime minister as saying "Our objective is to modernize regulation to enhance conditions for an innovative economy while finding improved ways to meet high standards of social and environmental protection." The news release continued with an emphasis on the importance of regulation: "Regulation is a key way by which governments work to protect the health, safety and socio-economic well-being of Canadians as well as Canada's natural environment."[3]

Characteristically, this news release was self-contradictory in what another critic of the project identified as "an invisible balancing act."[4] In the first sentence, an "innovative economy" is given priority and "high standards of social and environmental protection" are subordinated, but later "making the system less complex, more responsive and effective" is subordinated to "finding improved ways to protect the health and safety of Canadians."[3] This kind of equivocation is an essential component of the rhetoric of Smart Regulation.

In April 2005 the Standing Committee on Health examined Bill C-28 which, if passed, will amend the Food and Drugs Act to allow interim marketing authorization of some food products and exempt food products containing pesticides at levels below some "maximum residue limit." Yet scientific evidence supporting this amendment remains uncertain. As Michael McBane, the national coordinator of the Canadian Health Coalition, informed the standing committee, "If it's science-based regulation at Health Canada, show us the science."[5]

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The Smart Regulation strategy has not been adequately scrutinized by regulatory scientists or the Canadian public; instead, it has been marketed as an unquestionable advance in industrial and economic policy. If the strategy becomes law, the government risks no longer being a protector of public health but a cheerleader for economic growth.

In only a few years, a grammar of "smart" has exploded onto the national and international scene. We hear of smart communities, smart drugs, smart labels, smart risk, smart weapons, smart cars, smart hydro and smart marketing, but we are blocked from getting answers to necessary questions: What sort of smart analysis determines the balance between cost-effectiveness and health impact? Whose evidence do the regulators use to evaluate these data? How effective and safe are the vaccines or therapies that might be fast-tracked through a reformed regulatory process? Which populations, communities and people are protected? Who is left out? Who profits and who benefits from therapeutic intervention programs?

The government calls for public input to the direction of its regulatory policy; yet by framing the policy as "smart," it pre-empts any critique from an informed public. As Robert Heilbroner has observed about the use of words such as "efficiency," "cost" and "value," the word "smart" "smuggles into

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the evaluation process the prerogatives and requirements of the social order to which that economy caters."[6]

There is no quarrel with effectiveness, efficiency, timeliness, transparency and accountability, the 5 principles set out by the External Advisory Committee on Smart Regulation, but proper deliberation has been lacking in at least 4 instances.

First is the government's claim that Canadian policy must be in sync with American policy. This is especially true with the regulation of pharmaceuticals and biologics, where the practices of the US Food and Drug Administration do not set an acceptable standard for either licensing or review.[7–9] Getting drugs to the market faster is neither effective nor efficient when those same drugs later have to be withdrawn because of their harmful side effects.[10]

Second is the claim that risk assessment should be governed by instrumental cost–benefit analysis. Although an important aspect of any regulatory practice, cost–benefit analysis must never be allowed to determine policy. Equal attention must be given to the precautionary principle, which states "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof."[11] Application of the precautionary principle acts as a brake on the adoption of novel drugs and treatments, yet smart regulation turns it on its head — no evidence of harm appears to be taking precedence over the requirement of scientific evidence for a drug or pesticide's safety.

Third is the degree of optimism about the ability of the private sector to cooperate effectively in the regulatory process. For example, although the pharmaceutical industry has made laudable contributions to national well-being, it invariably lobbies for deregulation policies that would allow it to quickly get its new patented products to market.

Fourth is the claim that smart regulation does not mean deregulation. If that is true, why, then, does Jayson Myers, senior vice-president and chief economist of the Canadian Manufacturers & Exporters, pin his hopes on smart regulation as "the key plank of this Government's economic agenda" and as "the right idea at the right time for Canada"?[12] Perhaps Ottawa will be less insistent about its claim after looking at the Government of British Columbia's Web site (www.sbr.gov.bc.ca/deregulation/default.htm), where an initiative for deregulation is spelled out explicitly and where the concepts of "deregulation" and "smart regulation" amount to the same thing.

"Smart" rhetoric has pre-empted the policy discussion the government claims it desires. Regardless of the fate of our present minority government, we must provide the public with a better understanding of the relation of sound regulation to public health; otherwise physicians will run the risk of prescribing drugs high in hype, yet low in efficacy.[13] May Health Canada's regulatory authorities be strengthened and left able to do their job. That would be a wise and good outcome for all of us.

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REFERENCES

1. *Smart regulation: report on actions and plans*. Ottawa: Government of Canada; Mar 2005. Available: www.regulation.gc.ca/docs/report1/rap_e.pdf (accessed 2005 May 27).
2. Government of Canada. External Advisory Committee on Smart Regulation. Committee members. Available: www.pco-bcp.gc.ca/smartreg-regint/en/01/mb-01.html (accessed 2005 Nov 7).
3. Office of the Prime Minister. Prime Minister receives report on smart regulation from the External Advisory Committee on Smart Regulation. 2004. Available: www.pm.gc.ca/eng/news.asp?id=269 (accessed 2005 May 27).
4. Canadian Environmental Law Association. Letter to External Advisory Committee on Smart Regulation. 2004 May 17. Available: http://cela.ca/uploads/f8e04c51a8e04041f6f7faa046b03a7c/EACSR_mayltr.pdf (accessed 2005 Nov 7).
5. Standing Committee on Health. Evidence contents of meeting 31: Bill C-28, an Act to Amend the Food and Drug Act (interim marketing authorizations). Ottawa: House of Commons (2005 Apr 11) at 16:40 [McBane M]. (Chair: B Brown). Available: www.parl.gc.ca/committee/CommitteePublication.aspx?SourceId=111843 (accessed 2005 Nov 8).
6. Heilbroner R. *21st century capitalism*. New York: WW Norton; 1993. p. 91.
7. Okie S. What ails the FDA? *N Engl J Med* 2005;352:1063-6.
8. Wood AJ. The safety of new medicines: the importance of asking the right questions. *JAMA* 1999;281:1753-4.
9. Lasser KE, Allen PD, Woolhandler SJ, et al. Timing of new black box warnings and withdrawals for prescription medications. *JAMA* 2002;287:2015-20.
10. Lexchin J. Drug withdrawals from the Canadian market for safety reasons, 1963–2004. *CMAJ* 2005;172(6):765-7.
11. Wingspread statement. Ames (Iowa): Science and Environmental Health Network; 1998. Available: www.sehn.org/precaution.html (accessed 2005 Nov 7).
12. "Smart Regulation" is a smart idea for Canada [press release]. Ottawa: Business Coalition on Cost Recovery; 2004 Sept 23. Available: www.ccpa.ca/files/Public_Affairs/BCCR_-_Smart_Regulation_News_Release_Sept_2004.doc (accessed 2005 Nov 7).
13. Mintzes B, Barer ML, Kravitz RL, et al. How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA. *CMAJ* 2003;169(5):405-12.

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