

Background to Health Canada's ***“Technical Consultations on Regulatory Modernization”***

Canadian Health Coalition, January 2011

The Harper government introduced Bill C-51, *An Act to amend the Food and Drugs Act*, into the House of Commons on April 8th, 2008 together with Bill C-52, *An Act respecting the Safety of Consumer Products*. C-52 was recently passed as Bill C-36. Bill C-51 died on the order paper but Health Canada plans to re-introduce it this spring. C-51 is the legislative framework for the proposed regulatory changes outlined in Health Canada's materials prepared for the Technical consultations.

Bill C-51 will:

1. **Lower safety standards** by shifting the basis of drug approvals from the current Precautionary approach to a Risk Management approach where a Minister can decide, based on secret industry data, that 'benefits' outweigh 'risks'.
2. **Speed up drug approvals** by providing a legal framework for 'progressive licensing' of pharmaceuticals, with less evidence of safety or effectiveness. Speedy drug approvals have already led to harm (remember Vioxx) and now Health Canada wants to speed up approval further.
3. **Eliminate barriers to direct-to-consumer advertising** and could allow the introduction of any kind of prescription drug advertising with new regulations. Drug ads give misleading and harmful information and drive up spending on new drugs that are costlier but not usually better.
4. **Fail to protect the public from off-label promotion** and ghostwriting. Last year, nearly 700,000 prescriptions for such antipsychotics were dispensed for kids under 13 in Canada, an increase of 168% in 5 years. In the U.S. drug companies faced criminal charges for these practices and settled for \$ billions in fines. Health Canada has done nothing and has no plans to do anything.
5. **Enshrine secrecy and commercial confidentiality** for the first time in the *Food & Drugs Act*, instead of enshrining the citizen's right to know the scientific evidence on the safety and effectiveness of medicine.
6. **Lower the Minister of Health's legal 'duty of care'** so that Health Canada can evade liability for regulatory negligence when Canadians are harmed by inadequately tested new drugs. Currently, Health Canada faces billions of dollars in regulatory negligence law suits because of a high standard of care in the current legislation.

References:

- Bill C-51: <http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=3398126>
- In depth analysis: <http://www.healthcoalition.ca/safetylast.pdf>

QUOTES:

The relationship between a 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.

- Justice Krever, *Commission of Inquiry on the Blood System in Canada*, 1996

Industry can't be regulated by government – and for environmental and health reasons they must be – if that government is in bed with them.

- *Globe & Mail* editorial following the Westray Mine disaster, Dec. 2, 1997

Food & Drugs Act: 'too focused on safety'

“The Act is outdated and needs to be reviewed. For one thing, it not well enough adapted to deal with a number of issues raised by modern technology such as the use of human organs for medical purposes, genetically engineered products, xenotransplants, etc.

“NARROW FOCUS ON SAFETY”

“The Act does not allow for the taking into account of considerations other than safety and efficacy in managing health risk (ethical issues; social, economic and cultural considerations; need to improve the economy and to promote competitiveness; etc.)...”

Source: Health Canada, “Food And Drugs Act”, document obtained through Access to Information by Ken Rubin for the Canadian Health Coalition, April 24, 1998.
<http://healthcoalition.ca/archive/overhaul-FDA.html>

Food & Drugs Act: “ill-suited to trade”

“The extent to which Canada’s legislative framework is fostering a pro-competitive regulatory environment is somewhat unclear, and certain aspects may be hindering Canada’s pursuit of greater market openness. Although the WTO and other trade agreements have served as important drivers of regulatory reform on this issue, current design features of Canadian legislation may be inhibiting their implementation in practice. For example, many current legislative frameworks do not include authority for the development of performance-based regulation – an important tool for avoiding unnecessary trade restrictiveness. Regulators are thus faced with the obligation to use performance-based requirements as the basis of domestic regulation wherever possible, but lack the legal authority to do this in practice. As a result, **major pieces of legislation, such as the Food and Drugs Act, often constrain regulators to adhere to the command-and-control, prescriptive style of regulation and perpetuate an old-style approach ill-suited to the dynamics of good regulatory practice in general and trade and investment-friendliness in particular.** And even where there have been moves to build more flexibility into regulatory compliance (an approach once embraced but ultimately defeated in the proposal for a *Regulatory Efficiency Act*), the power of special interest groups to dissuade government from trusting business to “do the right thing” to achieve a regulatory objective risks paralyzing government’s intentions in this area.”

Source: OECD, “Enhancing Market Openness Through Regulatory Reform”, Review of Regulatory Reform in Canada, 2002, p. 59 (<http://www.oecd.org/dataoecd/48/26/1960546.pdf>) Emphasis added.