Français à la page suivante

We need Romanow's National Drug Agency

> [D]rugs should be approved for use and coverage … solely on the basis of their effectiveness or efficiency, not … because pharmaceutical companies have invested a lot in their development.[1]

Roy Romanow's proposal to create a new National Drug Agency[1] is, we hope, the last of such recommendations: the last, because we hope this one will finally stick. This idea existed embryonically in Justice Emmett Hall's report of 1964, which proposed an expanded role for the then Drug Advisory Committee.[2] A detailed "blueprint for a national pharmacovigilance system" was set out in the Gagnon report of 1992,[3] and ways and means of improving drug approvals and monitoring in this country have been discussed by health ministers and federal–provincial task forces ever since.

Annual expenditures on prescription drugs have increased 10-fold since 1980, reaching $12.3 billion in 2001 (12% of total health expenditures).[1] Canadians fill 300 million presciptions a year — about 10 for every adult and child. Almost 22 000 drug products are available in Canada (5200 of them by prescription), and a new one is added every 4.5 days.[1] More than ever before, we need unbiased evaluation of new products, unconstrained postmarketing surveillance of adverse events and effective mechanisms to keep health care providers and patients informed.

Romanow proposes a national agency to fulfill these tasks. It would be responsible for "ensuring the safety, quality and cost-effectiveness of all new drugs before they are approved for use in Canada," and would have the equally important tasks of "reviewing drugs on an ongoing basis, monitoring their use and outcomes across the country, and sharing high quality, timely information" with physicians, researchers, policy-makers and the public.[1] And he proposes other functions, such as evaluating cost-effectiveness, speeding up the approvals process for new drugs, establishing a national formulary to reduce disparities across the country and even negotiating drug prices on behalf of the provinces.

Some of the core regulatory functions that Mr. Romanow envisages already lie within the remit of Health Canada's Therapeutic Products Directorate (TPD). Indeed, he proposes the transfer of TPD budgets and staff to the new body. Taxpayers may wonder why it is necessary to decant this old wine into new bottles. Is this just another expensive, fruitless exercise in restructuring? Isn't it the role of government health ministries to act as guardians of safety and the public interest?

Yes, but government is also the guardian of industry. Moveover, the state's closest collaborator in the regulation of industry is industry itself. Citing recent controversies in the United States between the FDA and pharmaceutical companies,[4] Romanow points to the need for a system with "strong safeguards" to overcome conflicts of interest that can arise in the relationship between regulators and industry.

Certainly, the relationship between the state and the pharmaceutical industry has undergone a "reorientation" in the last decade or so[5] in response to cost-cutting and downsized bureaucracy, an ideology of public–private partnerships, and cost-recovery schemes that, in the case of drug approvals, transform manufacturers into clients for whom the regulatory agencies provide a service.[5] In a broader context, international trade agreements and the fierce defence by multinational corporations of their intellectual property rights have given rise to patent laws and other protections that appear to be more favourable to stockholders than to patients.

Establishing a National Drug Agency will not change the economics of big business and big research. But it can shine a stronger light on certain accountabilities. First, it will increase the emphasis on postmarketing surveillance of usage, outcomes, adverse reactions and cost-effectiveness. And, it will ensure that accurate, unbiased information about the drugs — their benefits, correct use and adverse effects — will be available to patients and their physicians. More symbolically, but also crucially, the new agency would report directly to Parliament and have federal regulating powers, currently absent, thus drawing a sharper line between industry regulation and political motivations.

We've argued for the creation of a National Drug Agency ever since the preventable death of 15-year-old Vanessa Young from an adverse drug reaction[6–9] provided a tragic demonstration of the inadequacy of drug surveillance in Canada. Although we might quibble with some of the specifics — that the new agency should be responsible for negotiating drug prices, for example — we urge Health Minister McLellan and her government to act on Mr. Romanow's recommendation for a National Drug Agency before the end of their current mandate. It's time to act. — *CMAJ*

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