

Regulation in Whose Interest?

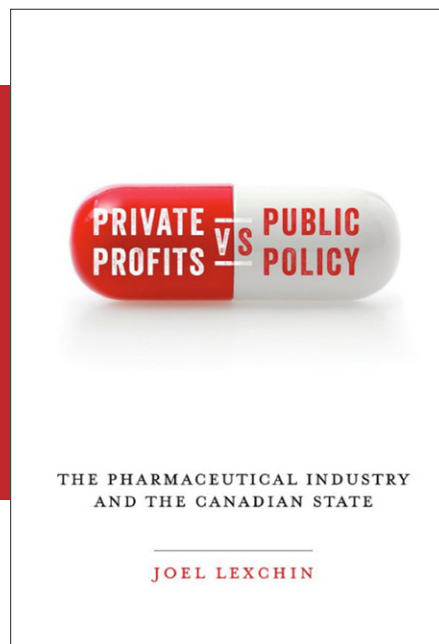
A Review of *Private Profits versus Public Policy: The Pharmaceutical Industry and the Canadian State*

Reviewed by Katherine Fierlbeck

There is no possibility of failing to grasp the argument in this book. Health Canada, having ceded effective regulatory control of the pharmaceutical industry to the industry itself, “stands on the sidelines, content to let industry or industry-influenced organizations continue to do a grossly inadequate job” (227). Lexchin has, for years, poked and prodded the regulatory apparatus to determine its fitness in performing its main function: to protect citizens’ well-being and, more precisely, to ensure that they have access to safe and effective drugs. This new volume is a rigorous and exacting *j’accuse* not of the pharmaceutical industry per se – there are many books taking on that topic – but rather of the Canadian state, for placing “safety at a lower priority than its mandate to get new drugs on the market” (117). It is a systematic, detailed and dispassionate compendium of the ways in which Canada’s regulatory framework fails Canadians.

The regulation of pharmaceuticals in Canada, as others (Herder 2015, Gagnon 2013) have documented, has historically been a phthisic enterprise punctuated by occasional moments of tentative bravery. As Lexchin explains, a reinvigorated pharmaceutical sector was able to ride the crest of an increasingly globalized economy in the 1980s by capitalizing on the belief that international competitiveness required substantial deregulation. This solidified the industry–regulator relationship into one that has, at times, resulted in “an abrogation of public safety on the part of Health Canada” (22) owing to the blurring of Health Canada’s mandate. To the extent that the pharmaceutical sector is viewed as a desirable engine of economic growth, the expectation that a drug regulator must both facilitate corporate success and protect citizens from it is inescapably riddled with conflicts of interest. Yet such a fundamental tension is steadfastly ignored, confirming Upton Sinclair’s observation that it is difficult to get a man to understand something when his salary depends on his not understanding it.

There is no outrage or frustration in this book. There is just evidence. Few Canadians understand just how tenuous the evidence about drug safety and effectiveness is. Health



Private Profits versus Public Policy: The Pharmaceutical Industry and the Canadian State

Joel Lexchin

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Canada accepts the structuring of clinical trials such that effectiveness is not ascertained as accurately as it could be (i.e., in the use of placebos rather than active substances as comparators; the use of surrogate markers; poor monitoring of adverse events; weak monitoring of trials; inadequate oversight of manufacturing). There is little transparency in the regulatory process, even in comparison with other drug regulators. There is unchallenged acceptance of the pharmaceutical industry’s blanket claim that all its data are proprietary business information. And there is a failure to properly regulate the promotion of drugs, be it through advertising, the shilling of drugs to healthcare professionals or the education of medical students. One particularly topical example Lexchin recounts is the requirement that medical students at one Canadian university in the mid-2000s attend a series of “pain pharmacotherapy” lectures supported by the very companies that supplied opioid analgesics to the Canadian market (100).

The behaviour of pharmaceutical companies in attempting to maximize profits and to minimize regulatory obstacles is certainly not unique to Canada. Neither is it atypical corporate behaviour when viewed across sectors. Corporations, as Valeant’s CEO maintained, are legally obliged to their shareholders to provide them with profits within the confines of whatever the law allows. That, as Lexchin reminds us, is the point of regulation. The problem is in allowing the regulated interests to define the nature of evidence, the rules under which they operate or the priorities of a nation. The institutional terrain within which the relationship between Health

Canada and the pharmaceutical industry is situated is largely based on the Faustian bargain made by the Government of Canada in the negotiation of the free trade agreement in 1987. From that point, the pharmaceutical industry made it clear that investment in Canada was contingent upon respecting intellectual property rights (136). According to the industry, this information is proprietary, and thus confidential. The catch is that this is the very information that permits a state to determine the safety and effectiveness of the products produced, as well as the reasonableness of their cost. This lack of information permits the perpetuation of at least two problematic assertions.

The first is that the high price of drugs is essential to maintain ongoing research and development into “innovative” products; the second is that Canada will benefit from a strong pharmaceutical industry. The veracity of these claims is rather important to Canadians, as we collectively spend more per capita on drugs than any other country except for the United States (161). Yet, as Lexchin argues, “no relationship exists between what it costs to research and produce a drug and what companies think that the market will pay” (159). More specifically, high prices are owing to the fragmentation of drug purchasing; the way in which the Patented Medicine Prices Review Board calculates “acceptable” costs for new drugs; and the success of the industry in getting their drugs listed on provincial formularies as quickly as possible, often by expanding the range of conditions to which drugs apply (e.g., psychotropics), or by expanding the nature of specific illnesses (e.g., prediabetes).

Some European countries (such as Ireland) tend to tolerate higher drug prices because the pharmaceutical industry is a major component of the countries’ industrial base. This is not true for Canada. When the 1987 free trade agreement was ratified, the hope was that Canada would be a net beneficiary of the rapid expansion of the pharmaceutical sector that resulted from the development of numerous blockbuster drugs. More recently, Industry Canada (2013) has expressed an optimism that the burgeoning orphan drug market could be an area in which to develop greater capacity. And yet, as Lexchin shows, the ratio of research and development to sales for the Canadian pharmaceutical industry has declined significantly since the mid-2000s (Lexchin uses 2011 data; a recently published PMPRB report shows even more decline to 2015: see Patented Medicines Prices Review Board, 2016). If the purpose of a generous regulatory framework is to support the expansion of research and development in Canada as an industrial strategy, concludes Lexchin, this strategy is not working particularly well.

Private Profits vs Public Policy is empirically dense, but it is well structured and highly accessible. Lexchin gets good mileage from simple words and straightforward sentences.

Much of the material he compiles here has been presented elsewhere, but bringing together the various critical themes and responses is highly effective. A distinct, if minor, theme running through this work that will doubtless resonate with health services researchers is the dismal state of health departments’ websites. Information on these portals is often poorly organized, vague or simply missing. These sites are liberally sprinkled with statements that strategies, plans and solutions “are in the works,” “are being addressed” and “will soon be released.” E-mail links on such webpages that promise responses to all queries often feel like “close door” buttons in elevators, and do not seem to have an actual operative function. If the future of accountability in healthcare rests upon IT, then we will be waiting some time longer.

If there is one aspect of the book that could have been developed in more depth, it would be the analysis of the role of federalism in shaping, and preserving, the particular regulatory relationship that defines the pharmaceutical sector in Canada. Certainly, Ottawa has jurisdiction over pharmaceutical regulation and the negotiation of international treaties. But it is probable that federal officials were willing to countenance the intellectual property rights regimes that resulted in huge increases in drug prices simply because the provinces, and not the federal government, bear the brunt of such costs. Likewise, if Canada ever does enact a national pharmacare program, a secondary effect will be that an Ottawa that is fiscally responsible for paying drug costs will likely be much more willing to confront the regulatory practices that generate higher prices. These are the kinds of dynamics that unitary states (and also some federal ones) do not have to address. Moreover, the particular federal structure of healthcare in Canada makes it far more complicated to negotiate drug costs (resulting in the practice of whipsawing), to monitor adverse events and even to determine the effectiveness and cost-effectiveness of new drugs (despite the achievements of CADTH and the Common Drug Review, much health technology assessment is still done by discrete evaluative bodies within provinces).

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The question that remains is how much of Canada’s regulatory regime for pharmaceuticals is ideological (and largely dependent upon the party in power), and how much is structural (and difficult for any party in power to change). We have gone from an administration that promoted the commercialization of health research to an administration that has appointed a socially progressive physician as Minister of Health. If there is little or no

change in the next four years, we will have our answer. But even structural obstacles can be resolved, and the more a government's election or re-election depends upon it, the more likely it is to get done. That is why everyone must read this book. And those spitting with outrage over the arguments Lexchin presents should read it first, and respond to his charges. The intricacies of Canada's regulatory regime for pharmaceuticals have for years provided a reasonable excuse not to learn about the problems of regulating pharmaceuticals in this country. This book eliminates such an excuse. Those who license drugs, or pay for them, or prescribe them, or use them, have an obligation to read Lexchin's indictment of the current regulatory process. And, if our refusal to engage in this discussion results in the needless death of yet another Vanessa Young, then we are all complicit in it. **HQ**

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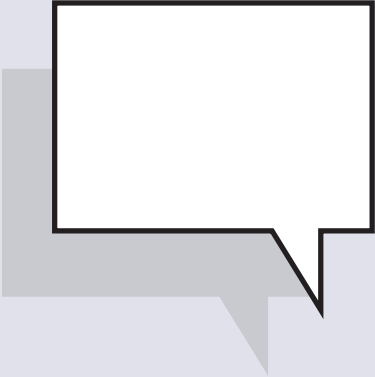
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