

Health Canada and the Pharmaceutical Industry: A Preliminary Analysis of the Historical Relationship

Santé Canada et l'industrie pharmaceutique : analyse préliminaire d'une relation historique



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Abstract

In the past two decades, Health Canada has been accused of favouring the pharmaceutical industry over the public in areas of pharmaceutical policy. This orientation has been tied to the introduction of user fees by the industry in 1994 that help finance key aspects of drug regulation. This paper provides a preliminary examination of the history of the relationship starting in 1939 until the mid-1980s in an attempt to discern whether 1994 really represented a key turning point. Clientele pluralism, a theory that explains the relationship between the state and interest groups, is used to explain the nature of the events described.

Résumé

Au cours des vingt dernières années, Santé Canada a été accusé de favoriser l'industrie pharmaceutique au détriment de la population canadienne dans le secteur des politiques sur les produits pharmaceutiques. Cette situation est liée à la mise en place par l'industrie, en 1994, de tickets modérateurs qui aident au financement d'importants aspects de la réglementation pharmaceutique. Cet article étudie l'histoire de cette relation, de 1939 jusqu'au milieu des années 1980, afin d'établir si l'année 1994 constitue réellement un point tournant. La théorie du pluralisme de clientèles, qui décrit la relation entre l'État et les groupes d'intérêt, est employée pour expliquer la nature des événements décrits dans l'article.

HERE IS ONGOING CRITICISM ABOUT THE NATURE OF THE RELATIONSHIP BETWEEN Health Canada and the pharmaceutical industry, fuelled by a number of observations. Among other things, there is the imbalance in the amount of money and number of personnel dedicated to reviewing new drug applications versus monitoring the safety of products already on the market. The Therapeutic Products Directorate and the Biologic and Genetic Therapies Directorate, which review new drug applications, receive three to four times the funding and number of personnel compared to the Marketed Health Products Directorate, which monitors the safety of medications (and other health products) already on the market (Wiktorowicz et al. 2010). In addition, Health Canada withholds safety and efficacy data from industry-run clinical trials on the grounds of business confidentiality, with the result that no one outside of industry and Health Canada has access to these data (Herder 2012). A third point of contention is the department's business transformation plan, which prioritizes the "speed[ing] up [of] the regulatory process for drug approvals" (Therapeutic Products Directorate n.d.), because drugs with shorter approval times have more serious safety problems (Lexchin 2012).

User Fees and Principal-Agent and Capture Theories

Critics often point to 1994 as a turning point in the relationship (Lexchin 2006). That was the year when Health Canada began collecting user fees from pharmaceutical companies for performing various regulatory activities, including reviewing new drug applications. Prior to that time, all the operating costs concerned with drug regulation had come from parliamentary appropriations. The introduction of user fees coincided with a marked decrease in the time it took to get new active substances (molecules never before marketed in Canada) approved and a significant increase in the number of positive decisions on new drug applications. Both these changes were favourable to the pharmaceutical industry and are consistent with principal-agent and capture theories.

Principal-agent theory proposes that there is a relationship between a principal who has a task that needs to be performed and an agent who is contracted to do the task in exchange for compensation. Prior to the introduction of user fees, the principal was the Canadian public with its desire for safe and effective drugs, and the agent charged with ensuring safety and effectiveness was Health Canada. However, since 1994, a new principal has been added: the pharmaceutical industry, which now provides a substantial fraction of the money needed to run the drug regulatory system. Although the industry does not deliberately seek to market unsafe or ineffective drugs, as a for-profit industry its objective is to increase the revenue it obtains from the sale of pharmaceuticals. At times, the for-profit motive and public safety are not compatible.

Regulatory capture theory asserts that over time, regulators tend to become advocates for the industry they are supposed to regulate as a result of conflict avoidance and influence

from the industry. The theory predicts that Health Canada will become less receptive to the needs of the public and more closely align its mission with that of the pharmaceutical industry. Perhaps the most visible symbol of the new relationship was the statement from Dann Michols, Director General of the Therapeutic Products Programme within Health Canada, that was contained in an internal bulletin in which he discussed the question of who is the client. With regard to the meaning of cost recovery for his program, he advised staff that “the client is the direct recipient of your services. In many cases this is the person or company who pays for the service” (Michols 1997).

In the United States, a number of books document the relationship between the Food and Drug Administration (FDA) and the pharmaceutical industry over time. Thus, it is relatively easy to see how historical events have affected the interactions between the two (Carpenter 2010; Hiltz 2003; Tobbell 2012). The same type of systematic historical investigation into the way that Health Canada and its predecessor (the Department of National Health and Welfare) interacted with the pharmaceutical industry has not been undertaken, and so the perception of a changing relationship may not in fact be accurate. However, there is anecdotal evidence that long before 1994 the two enjoyed a close symbiotic working relationship. This paper is a preliminary examination of the little that has so far been researched about the historical context of the relationship between the two. The aim is to stimulate a more detailed assessment of what happened in the past and to set the context for assessing the current relationship and the policy options that could be considered if that relationship is to change.

Historical Vignettes in the Relationship between Industry and Health Canada

1939 – labels on prescription medications

Prior to 1939, provincial pharmacy acts placed restrictions on which drugs were available without a prescription, but there was no consistency in the list of such drugs from province to province. The Dominion Council of Health, formed in 1919 as an advisory body on public health matters to the federal Minister of Health, recommended that some action be taken under the *Food and Drugs Act* to deal with the problem. As a result in 1939, under an amendment to the Act, the government was given the authority to make regulations defining the conditions of sale of any drug likely to be injurious to health. One measure that was proposed was the placement of a cautionary statement on the label of drugs that required a prescription. This approach was discussed with representatives of the Canadian Pharmaceutical Manufacturers Association (later the Pharmaceutical Manufacturers Association of Canada [PMAC] and now Rx&D). The Association wanted to modify the proposed cautionary statement. “However, as it was considered [that] the one recommended by the Association would nullify the intention of the original suggestion, the matter was dropped at that time” (Pugsley 1967).

1953 – inspection of manufacturing plants

Since the proclamation of the revised *Food and Drugs Act* in 1953, an inspection program has existed for all drug manufacturing plants to ensure cleanliness and requirements such as dosage accuracy. Representatives of PMAC worked with government in drawing up the standards for manufacturing, and a number of PMAC member companies helped to train the inspectors who applied them (PMAC 1966). As a further refinement in regulating manufacturing practices, a joint industry and government committee was struck that led to the development of good manufacturing practices (GMPs), and these came into effect in 1981. After that, the companies continued to be provided with a regular opportunity for input into refinements of GMP regulations in the form of an annual meeting between Health Canada officials and PMAC. Other interested parties, such as workers in pharmaceutical plants and consumers, were notably excluded from participation in such meetings.

1962 – thalidomide

Thalidomide, the medication that caused children to be born missing limbs, was removed from the Canadian market in March 1962, four months after it had been withdrawn in Germany. After the manufacturer was ordered to stop selling thalidomide, a number of doctors wrote to the government protesting the move. In reply to one such letter, Dr. C.A. Morrell, head of the Food and Drug Directorate of Health Canada, responded on April 27, 1962: “I think if the medical profession would take a stand, such as you have taken, that there is every possibility that thalidomide could indeed be reinstated on the Canadian market and to this end I would encourage you to urge strongly your colleagues to express themselves to us on this question” (Sjöstrom and Nilsson 1972). (After Dr. Morrell left Health Canada he joined the board of Ciba, now part of Novartis, a major Swiss drug company.)

1964 – Department of National Health and Welfare and the Pharmaceutical Manufacturers Association of Canada

Judy LaMarsh, who was the Minister of National Health and Welfare at the time, delivered the welcoming address at the Fifth Annual General Meeting of the PMAC. During her speech she noted that the “task [of the Director of the Food and Drugs Directorate] would be immeasurably more difficult if he did not have access to the combined knowledge of the industry and receive its support.” She went on to say further, “the role of a responsible trade association, in my view, is the advice and assistance it can offer to the government in carrying out its responsibility to the Canadian people. ... In the past [we have received from you] valuable help and assistance in the development and administration of our drug regulations. ... In the formulation of our present Act, committees of your Association met with officers of the Department and worked out matters which are now reflected in the provisions of the law itself” (Anderson 1977). As Anderson notes, the speech clearly indicates that the PMAC and bureaucrats in the Department were well known to each other and the bureaucrats knew the degree of influence that the industry had on policy making.

1973 – regulation of promotion

From 1966 until the early 1970s, the Principles and Code of Marketing Practice of the Pharmaceutical Manufacturers Association of Canada guided promotion activities in Canada (PMAC n.d.). Compliance with the code was voluntary, even for PMAC members, and there was increasing criticism of pharmaceutical advertising from consumers and health professionals. A 1973 meeting of federal and provincial health ministers recommended that the federal government “review controls on the advertising of drugs with the aim of strengthening them where necessary.” The federal Minister of Health and Welfare, Marc Lalonde, issued an ultimatum to the industry to reform its practices or else face the prospect of government action. In response to this challenge, the PMAC initiated a sequence of events that resulted in the creation of the Pharmaceutical Advertising Advisory Board (PAAB) in 1975 (Raison 1989). It had representatives from the generic companies (the Canadian Drug Manufacturers Association) and the Canadian subsidiaries of the multinational companies (PMAC), the medical and pharmacy professions, consumers and the advertising industry. The members of PAAB were, and continue to be, answerable only to their associations. The PAAB developed a Code of Advertising Acceptance (PAAB 1978); however, among its deficiencies, the code is not legally binding, its decisions are not legally enforceable, and as a voluntary, independent body, the PAAB is not accountable for its actions to the government or any other organization.

1980s – meetings between Health Canada and industry

The close interaction between Health Canada and the industry, illustrated by the quotation from Judy LaMarsh, continued into the early 1980s, when officials from the industry and Health Canada were meeting on a regular basis about every six weeks in joint committees to work on regulatory changes and their accompanying guidelines. For example, at a meeting of the Bureau of Human Prescription Drugs/PMAC Medical R&D Section Liaison Committee in the fall of 1983, the need for guidelines on filing an investigational new drug submission was discussed, primarily at the PMAC’s initiative (Goyer 1985). In addition, senior officials in the Health Protection Branch, including the assistant deputy minister, met with the PMAC board of directors, elected from senior executives of 15 companies, at the PMAC’s annual and semi-annual meetings (Atkinson and Coleman 1989). At these events the Health Protection Branch informed the industry of its plans for the following year. The informal nature of these discussions was highlighted by the lack of any minutes.

As part of a series of articles on prescription drug regulation in 1982, the *Montreal Gazette* interviewed Health Canada officials about their approach to drug companies. Officials repeatedly told the newspaper that they had opted for a cooperative “open door policy” with Canadian drug company officials instead of a tough adversarial stance. This collaborative approach was consistent with the attitude in the 1960s documented above. The Health Canada officials were also proud of their friendly relationships with representatives of Canadian drug subsidiaries of US companies. “We try to work things out together,” said one Canadian official (Regush 1982).

1991 – hiring practices at Health Canada

Crossovers between government and industry are not unexpected. Both groups talk the same language because people often come from the same background – doctors, pharmacists and people with degrees in biological and medical sciences. Not only will they talk the same, but they may well share the same world view when it comes to the role of drugs in the health-care system. We have already seen how Dr. Morrell left his position as head of the Food and Drug Directorate for a spot on the board of directors of Ciba. When Judy Erola left politics in 1984 after serving as the federal Minister of Consumer and Corporate Affairs, she went on to become the president of the PMAC. However, in 1991 this intermingling of officials was taken one step further. The hiring committee for a new person to head the Bureau of Non-Prescription Drugs consisted of a staffing officer in the Public Service Commission, the director general of the Drugs Directorate and Judy Erola. The official position from Health Canada was that the PMAC deals mostly with prescription drugs and as the person being hired oversaw the body dealing with non-prescription drugs, there was no conflict of interest. This explanation overlooks the fact that some companies manufacture both types of drugs (Regush 1993).

Discussion

Of course, these few vignettes cannot establish the overall pattern for the relationship between the industry and Health Canada over the period 1939 until the early 1990s. However, they are consistent with a model that describes the role of Health Canada when it comes to regulation in the area of pharmaceuticals. In discussing the evolution of regulatory systems in Germany and the United States, Daemmrich (2004) points out that regulatory frameworks reflect the therapeutic culture that has developed in an individual country. These “therapeutic cultures arise from networks of actors that produce regulatory policy, determine testing standards, and ultimately decide on market access for new drugs” (Daemmrich 2004).

Clientele pluralism

The relationship between Health Canada and the pharmaceutical industry, as represented by Rx&D, operates through a system termed clientele pluralism (Atkinson and Coleman 1985, 1989). As Atkinson and Coleman describe it, in such a system the state has a high degree of concentration of power in a single agency, in this case Health Canada, but it does not possess the ability on its own to meet the objective of providing safe and effective medications, and some authority must be relinquished to the drug manufacturers. This low degree of autonomy exists because of a lack of expertise and because of the political orientation of the state. An example of the former was the decision to allow the industry to co-develop the standards for the inspection of drug plants. An illustration of the latter was the delegation of responsibility for regulating promotion to the industry and its allies. On the other hand, the association representing virtually all of the multinational companies operating in Canada, Rx&D, is highly mobilized to assume a role in the making and implementing of drug policy through an

elaborate committee structure. It also has the ability to act on behalf of its members and the capacity to bind member firms to agreements.

In clientele pluralism, the state relinquishes some of its authority to private-sector actors, who in turn pursue objectives with which officials are in broad agreement. Not only does the state, in this case Health Canada, turn over some of its authority, but the objectives that are being pursued are ones that are often jointly developed between Rx&D and Health Canada. One of the manifestations of clientele pluralism was the system of meetings between Health Canada and the industry alluded to by Judy LaMarsh.

This assessment of the Canadian regulatory regime fits with Maor's (2011) characterization, which is based on the organizational reputation of a country through its actions on drug safety. In this scheme, Canada is positioned as a "shadow regulator" because it is not known for guaranteeing public safety through the release of timely, sufficient and effective warnings about drug safety, but rather "shadows" or mirrors the position of expert regulators, e.g., the United States, when it approves new drugs (Maor 2011).

Conclusion

The matter of how Health Canada has traditionally related to industry is of more than just historical or academic concern. The information currently available indicates that the introduction of user fees was not responsible for a quantum shift in the relationship between Health Canada and the industry, but rather just accelerated an already existing pattern. Therefore, while there is certainly merit in returning the funding of the drug section of Health Canada to full parliamentary appropriations, such an action will not lead to significant change. The relationship has longer and deeper roots, and this speaks to the need for a much more sweeping analysis of the culture within Health Canada and the political system within which it exists.

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