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NOVEMBER 2021

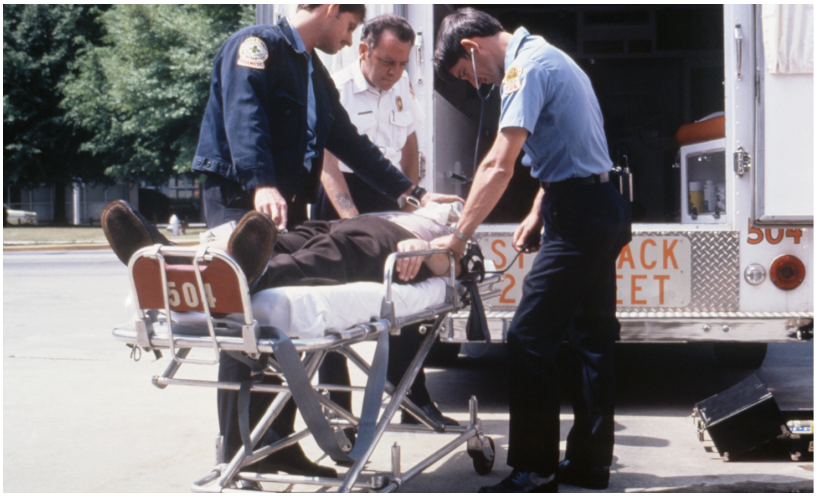
LAW,CULTURE AND REPRISALS: WHISTLEBLOWING & HEALTH CANADA'S DRUG APPROVAL PROCESS

WHY BLOW THE WHISTLE?

POLICY BRIEF S1.2

Whistleblowing Canada Research Society

LAW CULTURE AND REPRISALS: A qualitative case study of whistleblowing and Health Canada's drug approval process



WHY BLOW THE WHISTLE?

Changes in the role of the state as regulator of new drugs entering the market raise concerns for public safety.

BACKGROUND

This is the second in a series of Policy Briefs originating from the findings of an in-depth case study, a rarity in the limited whistleblowing literature in Canada. For an overview of the case, please click here to see Policy Brief No. S1.1. The study – *Law, Culture and Reprisals: A Qualitative Case Study of Whistleblowing & Health Canada's Drug Approval Process* – from which these briefs are derived, sought to better understand the whistleblowing phenomenon - how and why people who tell the truth about apparent wrong-doing are punished and wrong-doers often are not. Each finding – answering a research question – is the topic of discussion in a Policy Brief in this series. The topics are

1. The Case - An Overview
2. Why Blow the Whistle?
3. How Reprisals Occur?
4. Why Reprisals Occur?
5. The Role of Law and
6. The Role of Culture.

These findings were informed by the whistleblower's experience and supported by official documents obtained from Court files. While the findings are case-specific, there are many important lessons transferrable to other organizations and whistleblowers in difficult situations

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KEY POINTS

- Professional ethics, a sense of duty to uphold the law and administrative authority for final medical decision-making on drug approvals prompted the whistleblower to raise concerns when she witnessed behaviours that she viewed as a threat to public safety.

- At this time in the 1990's, the organization, Health Canada, was rocked by change apparently sparked by deregulation. This caused divided loyalties and organizational and cultural dysfunction.

- The role of the state was shifting from one where government alone was responsible for the regulation of public safety, to one where responsibilities were shared among government, industry, academia, and consumers themselves.

- This change highlighted concern for the public interest as the intent of the law - the Food and Drugs Act - "to protect the public against health hazards and fraud in the sale and use of foods, drugs, cosmetics and medical devices" was being altered by a policy - deregulation - without democratic deliberations by Parliament.

Whistleblowing Canada Research Society is a non-profit charity dedicated to advancing education on the whistleblowing phenomenon in Canada through research. This research is shared publicly to inform public dialogue and public policy.

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WHY BLOW THE WHISTLE?

Professional Ethics and a sense of duty to faithfully perform her role as senior medical regulator and uphold the law motivates the whistleblower to act in the face of a threat to public safety despite great professional risks.

Early research on whistleblowing challenged the myth that whistleblowers were "disgruntled" employees. Whistleblowers were generally motivated by professional ethics, deeply held religious beliefs and community ties. Some have argued that whistleblower's motivations or ethics are irrelevant because what is relevant is "the whistleblowers perception or reason to believe that there has been wrongdoing" (Latimer and Brown 2014) and the facts and evidence.

The whistleblower's account in this case indicates the motivation for raising concerns was rooted in medical ethics, and a sense of duty to uphold the law (the Food and Drugs Act) when faced with what she perceived as wrongdoing and a threat to public safety. The job description when Dr. Brill-Edwards was appointed as Acting Assistant Director - Medical in 1988, gave her authority for the final word on medical decision-making in the process for approving drugs for marketing. However, in 1992, in the case of a migraine drug – Imitrex - this authority was not respected as her direction regarding the correct description of the conditions of use of the drug to safeguard patients was over-turned by a Director with no knowledge of prescription drugs and no medical credentials. Dr. Brill-Edwards' perception and experience of the organizational culture was one of chaos and dysfunction likely exacerbated in the context of deregulation and pressure to get the drug to market.

Dr. Brill-Edwards described two opposing factions – people who knew their duty regarding health protection/public safety and wanted to uphold the law faithfully and those who were more interested in "self-protection" or doing what the boss wants- right or wrong. The effect of deregulation "- - - was to pit allegiance to the law that protected Canadians, against allegiance to the hierarchy" (pers. comm. April 8, 2014).

The appointment of a Director in the Bureau of Human Prescription Drugs without the requisite qualifications for the job increased dysfunction within the department. This appointment was officially challenged by Dr. S. Chopra. Dr. Brill-Edwards and another colleague eventually actively supported this action. The challenge was upheld by the Public Service Commission Appeal Board and eventually the Federal Court. These controversies added to the unrest in the Department.

The official documents pointed to problems in the organization's culture which could interfere with its ability to carry out its mandate as regulator of public safety effectively. The evidence presented in the Chopra vs. Dept. of National Health and Welfare 1992 case and other documents suggest support for Dr. Brill-Edwards account of the culture in the organization.

Challenges to the ability of Health Canada to carry out its mandate were noted by others. Regarding deregulation and the shifting priorities at Health Canada in the 1990s, Wiktorowicz wrote:

> [. . .] realignment of the Health Protection Branch's (HPB) roles and responsibilities may be characterized as leading to a shift from a comprehensive approach to public health protection to one based on strategic risk management, with responsibilities dispersed among government, industry, academia, and consumers. The rebalancing of goals in the redesign of the regulatory process suggests a change in the role of the state in the context of public-health protection and highlights issues of concern to the public interest that may not be fully recognized as deregulation occurs in other sectors of the economy" (1-22).

These shifts persist to this day. The changes wrought by deregulation have not been evaluated nor have they received due authorization from Parliament.

What can we do to change a dysfunctional organizational culture and avoid conflicted loyalties?

Recommendations

(a) Training

Staff - including managers - would benefit from regular training and refreshers on

i. ethics, barriers to ethical behaviour and how to overcome often invisible, psychological forces that enable unethical behaviour as understanding and knowledge of such forces can foster prevention of wrongdoing

ii. the role of public servants - and regular training to revitalize and reinforce the role of public servants as guardians of the rule of law and the public trust

iii. the intersection of politics and law, political accountability to law and democratic governance or put another way, what comes first, politics/policy or law?

(b) Consultant assistance. Provide this support to managers to help them surface their theories-in-use vs espoused theories of how they manage, leading to more effective, productive reasoning rather than defensive reasoning when dealing with error or criticism.

(c) Audits. Regularly conduct ethical climate audits done by internal auditors and/or external auditors.

(d) Independent Ethicist Consultants. Provide access to independent ethicists with whom employees can consult.

(e) Professional and Management Council. Establish a council of professionals and senior managers and an ongoing consultative process to resolve conflicts between the demands of professional accountability versus public service regulations/policy to avoid any adverse consequences of politically based scientific or health decisions or policy.

(f) Evaluate the impact of deregulation on all sectors of the economy and specifically, on the ability of Health Canada to fulfil its statutory responsibilities.

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Cite as: Forward, Pamela, with Paloma Raggo. 2021. Law, Culture, and Reprisals: A Qualitative Case Study of Whistleblowing and Health Canada's Drug Approval Process. Why Blow The Whistle? No. S1.2. Whistleblowing Canada, Roberts Creek, B.C.