PREPARED BY
PAMELA FORWARD, M.A.
WITH PALOMA RAGGO. PH.D.

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

How Reprisals Occur ?

POLICY BRIEF S 1.3

Whistleblowing Canada Research Society

LAW CULTURE AND REPRISALS: Whistleblowing and Health Canada's drug approval process

HOW REPRISALS OCCUR?

How an organization functions can impact whether it facilitates or precludes unethical behaviour. Strict, vertical hierarchies can foster dysfunctional cultures. There is little or no recourse to circumvent reporting relationships when employees are faced with top-down unethicality. Leaders have a large impact on the ethical climate.

Background

This is the third in a series of Policy Briefs originating from the in-depth case study *Law, Culture and Reprisals: A Qualitative Case Study of Whistleblowing & Health Canada's Drug Approval Process.* This study explores 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 is a topic of discussion in this Policy Brief series. The topics are:

1. The Case – An Overview Read More
2. Why Blow the Whistle? Read More
3. How Reprisals Occur?
4. Why Reprisals Occur?
5. The Role of Law
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.

Key Points

* Dysfunctional ethical behaviour regarding the migraine drug Imitrex by the Director with no knowledge of prescription drugs triggers whistleblower to join a legal challenge of Director's appointment. Officials prioritize self–interest over public safety.

* The Public Service Commission finds the Director does not have qualifications for the job and the Federal Court orders a new competition. Result? The same Director is reappointed - on a permanent basis this time.

* The same day of reappointment, the position of Acting Assistant Director – Medical is abolished and Dr. Brill- Edwards is demoted. Further, her appointment to the World Health Organization is blocked

* Four years later another unsafe drug, nifedipine capsule, becomes controversial. Health Canada declines to remove it from the market as recommended by an Expert Advisory Committee. Senior bureaucrats misinform the Minister. This moved the whistleblower to resign to speak publicly. Results? A CBC documentary, a defamation law suit and a legal decision that denigrated the Doctor and clouded the drug safety issue. A 2020 study has confirmed the drug should not be used for cardiovascular disease for which it was approved. This unsafe drug is still on the market.

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.

EM: info@whistleblowingcanada.com
PH: (236) 317-3949
WS: www.whistleblowingcanada.com

HOW REPRISALS OCCUR?

There were two critical incidents regarding prescription drugs that Dr. Brill-Edwards regarded as potentially harmful, and which prompted her to raise her concerns.

Imitrex/sumatriptan – Unsafe Labelling

In 1991, a new drug for migraine headaches - Imitrex/sumatriptan – was going through the marketing approval process at Health Canada. Dr. Brill-Edwards warned the wording in the labelling i.e. product monograph, did not describe adequately for doctors the conditions of use of this drug and asked for the appropriate changes. The information in the Product Monograph/labelling is important as this is the information that helps doctors safeguard patients they are treating. Dr. Brill-Edwards who was the Acting/Assistant Director-Medical, was concerned that this new drug could have serious adverse cardiac effects that could be lethal. The Director, who was not a physician, overturned Dr. Brill-Edwards's decision regarding correct wording and the drug was approved with inadequate labelling putting patients at risk. The labelling was corrected over the months and years ahead, however, not before harm and deaths had occurred.

Dr. Brill-Edwards raised her concerns internally to no avail. Ignoring her authority for final medical decision-making posed a risk to public safety in this case and prompted her to actively support a legal challenge to the appointment of the Director without competition. This resulted in an acknowledgement by the *Public Service Commission* that the Director at the time did not have the necessary qualifications for the job and ultimately, a Federal Court ordered a new competition to be held. The result? The same Director, who still did not have the required qualifications, was reappointed, this time permanently.

The same day, Dr. Brill-Edwards's position was abolished and she was demoted from her management position to her old position of Reviewer of new drug submissions.

Shortly after this event, Dr. Brill-Edwards stated that she was blocked from accepting a position with the World Health Organization in 1992 because she refused to sign a non-disclosure agreement and what she saw as a "gag order" swearing her to secrecy and requiring she would not be involved in any legal actions against the Department.

Nifedipine capsule – Unsafe Drug still on the market

The second incident was the heart drug, nifedipine capsule, approved in 1981 for angina. Studies had been accumulating over almost 15 years demonstrating the potential for harm. The original approved use was for angina but it was often used "off-label" i.e. unapproved use, for hypertension. The controversy was sparked by a 1995 New York Times article, *Heart Attacks May Have Tie To Drug Type.* It discussed the results of a study led by Dr. Psaty indicating that people using calcium channel blockers (CCB's) such as short acting nifedipine capsule to treat their hypertension were more likely to have heart attacks and/or die than those taking other drugs (Kolata 1995). Health Canada declined to remove the drug from the market as suggested by an Ad Hoc Expert Advisory Committee (EAC).

Instead, they sent out an ambiguous warning letter which had little effect because ten years later many seniors were still being treated with the problematic drug. (1)

In addition at least nine instances of deception were found in official documents signed by senior officials, including by the Deputy Minister, in written answers to questions about the affair from the Minister. A letter from a Health Canada official indicated some of the motivations for their actions were " . . . to better reflect our regulatory environment", ". . .not to leave the Health Department open to legal challenges" and ". . . to make sure that manufacturers of these drugs are neither favoured nor disadvantaged unfairly" (Krupa to Leenen Jan. 24, 1996).

Dr. Brill-Edwards felt she could not continue working in an organization where the law and regulations to protect the Canadian public from health hazard and unsafe drugs was being ignored in deference to "self-protection". The only way she could bring this situation to the public's attention was to resign. She decided to cooperate with the CBC's Fifth Estate and a documentary they were doing on the controversial drug called "The Heart of the Matter".

What allowed such a situation to exist? During these years there were major policy changes in the Department such as de-professionalization and deregulation which facilitated the shift from health protection and regulation of companies in the public interest toward more emphasis on increasing "freedom" for companies to self-regulate. This context made it easier for an employee standing in opposition to these political imperatives to be censured.

The Judge, the Whistleblower and the CBC

The policy of deregulation continued, Dr. Brill-Edwards was without a job, and Canada's national television broadcaster, the CBC was sued for defamation by Drs. Leenen and Myers, members of the Expert Advisory Committee to Health Canada.

The legal decisions found for the plaintiffs and both received awards from the courts to compensate them. The award made by Justice J. Douglas Cunningham to Dr. Leenen was the largest ever awarded against the media in Canadian legal history.

The Judge's decision cast a shadow on Dr. Brill-Edwards reputation, even though she and the plaintiff agreed the drug should not remain on the market. It is unclear why the decision contained no mention anywhere that Dr. Leenen had advised the senior Health Canada Regulators that the drug was not safe to use for angina, the condition for which it had been originally approved and used for fifteen years. It is also unclear why the doctors on the EAC remained silent knowing a harmful drug was going to stay on the market. Dr. Brill-Edwards remained without adequate employment for four years and she and her family suffered as a result. (pers. comm. April 6, 2014)

(1) Furmaga, Elaine M., Peter A. Glassman, Francesca E. Cunningham, Chester B. Good. "Reducing the Use of Short-acting Nifedipine by Hypertensives Using a Pharmaceutical Database." Advances in Patient Safety: Vol. 3 (2005) – 277- 89.

The evidence contained in official documents suggests support for Dr. Brill-Edwards's perceptions and experience in both cases. She suffered a demotion and an appointment to the World Health Organization was blocked following the Imitrex incident. In the case of the nifedipine capsule, her resignation and cooperation with the CBC's Fifth estate did not change things at Health Canada. The legal decision in the defamation case *Leenen vs the CBC* clouded the safety issue and served to help perpetuate the status quo. In fact, a 2020 study has confirmed what was conveyed by the *Expert Advisory Committee* to Health Canada Regulators twenty-five years ago that the use of short-acting nifedipine "should be avoided in patients with cardiovascular disease" – the very use it was approved for in 1981. This harmful drug is still on the market. [2]

How can we end the illegal behaviour of reprisals against honest people who disclose wrongdoing?

Recommendations

In Policy Brief S1.2 *Why Blow the Whistle?* we made recommendations such as training on ethics, reprisal prevention through self-awareness, the role of public-servant, accountability to the law, democratic governance, conflict resolution, and evaluation of deregulation.

Here are some proposals to address the issue of how reprisals occur more specifically i.e. unwarranted demotion, prevention of career advancement, harassment, inability to do one's job ethically and in accordance with the law:

- Create effective, less symbolic whistleblower protection laws, and include the Five Gold Standards for such legislation - (a) Full free speech rights. (b)The right to disclose all illegality and misconduct. (c) No harassment of any kind. (d) Forum for adjudication, with the realistic burden of proof and appropriate remedies; and (e) Mandatory corrective action

- Ensure regular reviews of legislation and amend according to experience and international best practice

- Prosecute individuals responsible for regulatory wrongdoing in organizations (including reprisals) – both private and public - rather than merely fine their organizations under civil law in private organizations and conferring immunity from prosecution on regulatory wrongdoers in public organizations as in Canada currently.

[2] Parker, J.D., D' Iorio, M., Floras, J.S. et al. "Comparison of short-acting versus extended-release nifedipine: Effects on hemodynamics and sympathetic activity in patients with stable coronary artery disease." Sci Rep 10, 565 (2020). https://doi.org/10.1038/s41598-019-56890-1

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Note: For a list of Key Documentation and Sources see Appendix A – "Law, Culture and Reprisals. A Qualitative Case Study of Whistleblowing & Health Canada's Drug Approval Process".

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2656 Gulfstream Road
Roberts Creek, BC VON 2W4
Email: info@whistleblowingcanada.com
Phone: (236) 317-3949
Website: www.whistleblowingcanada.com

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