

## **OxyContin Abuse Problem Appears NOT limited to the US: The Ethics of Post-Market Surveillance of Pharmaceuticals in Canada**

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Abstract

In January 1996, following the decision of the Food and Drug Administration (FDA), Health Canada (HC) approved OxyContin (an opioid) for the treatment of chronic pain. HC stated at the time of approval, in the drug's product monograph (used to inform medical professionals about the safety and appropriate use of the drug), that OxyContin was safe and effective for chronic pain with low abuse potential. However, during the late 1990s and early 2000s, growth in the use of OxyContin was accompanied by widespread reports of addiction, abuse and deaths (GAO, 2003). This prompted the FDA, in 2001, to change the label of OxyContin, strengthening the warning (adding a "black box warning" to the drug packaging) regarding the drug's abuse liability and risk of addiction. HC, based on available evidence at that time, believed the problem of OxyContin was limited to the United States and decided not to change the product monograph (Sullivan, 2001). Only in 2006, did HC change the OxyContin monograph, strengthening the warning of OxyContin abuse. Drawing on philosophical discussions of inductive risk (Douglas, 2000, 2009; Rudner, 1953), we investigate the ethical obligation of HC to revise and change the original product monograph of OxyContin. We examine how much evidence—and what kind of evidence—should be sufficient for the agency to act.

Evidence shows that Purdue Pharma (manufacturer of OxyContin)—knowing that physicians routinely view drugs monographs to learn about drugs' efficacy and proper use—used the erroneous information, as it appeared on the monograph, as a principle selling point to influence physicians to increase prescribing (Meier, 2018). By 2001, OxyContin had become the most frequently prescribed narcotic drug in the United States for treating moderate to severe pain (GAO, 2003). A steep increase in opioid prescriptions, with OxyContin at the center of the problem, was the gateway to the opioid epidemic. Many individuals who developed opioid dependency eventually turned to cheaper or more potent street drugs, including heroin or synthetic opioids such as fentanyl. High rates of addiction, overdose, and death make the opioid epidemic one of the most urgent public health issues in the Canada, with nearly 4,000 opioid-related deaths in 2017 (Health Canada, 2018).

We approach the ethics of this issue from the perspective of the argument from inductive risk. According to this argument, value judgments about how bad an error would be in a moral sense are relevant to deciding what should count as sufficient evidence for asserting a claim (Douglas, 2000, 2009; Rudner, 1953). In this case, we argue that a consideration of inductive risks would have supported taking lower quality evidence as sufficient for revising the product monograph. In fact, Health Canada did the opposite, and demanded stronger evidence than it normally requires. Thus, we recommend that inductive risks be explicitly considered in future cases.

### References

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Theme: Public health ethics

3 learning objectives

- 1.To explore the moral consequences of errors in decision about what is sufficient evidence for claims included in product monographs of pharmaceuticals
2. To examine how might considerations of inductive risk be incorporated in the regulatory process
- 3.To investigate the responsibility of Health Canada in the opioid epidemic

3 valuable questions:

- 1.Should regulatory agencies consider moral consequences of errors in decisions about what is sufficient evidence for claims included in product monographs of pharmaceuticals?
2. How might considerations of inductive risk be incorporated in the regulatory process?
3. What is the responsibility of Health Canada in the opioid epidemic?