Submission Id: 3603

Title

Permissive regulation: How North America's regulation of buprenorphine supported manufacturer profits over equitable access

Priority 1 (Research Category)

Pain management

Presenters

Meghan McGee, PhD, MSc, BASc

Abstract

Context: Suboxone (buprenorphine-naloxone) is an opioid product approved in the US and Canada for the treatment of opioid use disorder. The drug is considered an important response to the opioid overdose epidemic with consistent calls for wider prescribing and deregulation in primary care. But there are documented irregularities, or "abuses", in the US pharmaceutical regulation process that support manufacturer profit-making.

Objective: We aimed to critically examine the regulatory history of Suboxone in Canada – and compare it to that of the US – to determine how federal regulators balance profit-making and equitable access during an epidemic.

Study Design and Analysis: First, we investigated Suboxone's entry into the Canadian market to understand how it achieved market exclusivity. Second, we examined Health Canada's risk mitigation process to address extramedical use and diversion to understand the intersection of regulation and brand promotion. Third, we extended these insights to the recent approval of two related buprenorphine products and their pathways to market exclusivity.

Setting or Dataset: Public drug and patent registries.

Population Studied: Canadian and US government regulatory bodies.

Results: We identified inconsistencies in Suboxone's regulatory history that suggest Health Canada's functions of health protection and promotion were compromised in favour of a profit-making "innovations" agenda. Despite six years of market exclusivity in Canada, there was no evidence suggesting Suboxone achieved formal exclusivity (i.e., through patent or data protection). Health Canada's process to address Suboxone's safety concerns was compromised and ultimately allowed the manufacturer to develop and deliver a branded "education" program to providers. In the US, we found similar inconsistencies like orphan drug approvals and "product hopping" between therapeutically interchangeable formulations that served to extend market exclusivity.

Conclusions: Health Canada's regulatory duties were compromised in favour of manufacturer profit-making. This approach can adversely affect public health due to unnecessarily high costs for drugs deemed essential to stem a major health crisis. Alternative pharmaceutical policies are urgently needed to safely expand primary care treatment for opioid use disorder.