How the Suboxone Education Programme presented as a solution to risks in the Canadian opioid crisis: a critical discourse analysis

Abhimanyu Sud 1,2,3 Matthew Strang,4 Daniel Z Buchman,5,6 Sheryl Spithoff1,7 Ross E G Upshur,1,3,5 Fiona Webster,8 Quinn Grundy 9

ABSTRACT

Objectives Pharmaceutical industry involvement in medical education, research and clinical practice can lead to conflicts of interest. Within this context, this study examined how the ‘Suboxone Education Programme’, developed and delivered by a pharmaceutical company as part of a federally regulated risk management program, was presented as a solution to various kinds of risks relating to opioid use in public documents from medical institutions across Canada.

Setting These documents were issued during the Canadian opioid crisis, a time when the involvement of industry in health policy was being widely questioned given industry’s role in driving the overprescribing of opioid analgesics and contributing to population-level harms.

Design A critical discourse analysis of 69 documents collected between July 2020 and May 2021 referencing the Suboxone Education Program spanning 13 years (2007–2021) from medical, nursing and pharmacy institutions sourced from every Canadian province and territory. Discursive themes were identified through iterative and duplicate analyses using a semistructured data extraction instrument.

Results Documents characterised the Programme as addressing iatrogenic risks from overprescribing opioid analgesics, environmental risks from a toxic street drug supply and pharmacological risks relating to the dominant therapeutic alternative of methadone. The programme was identified as being able to address these risks by providing mechanisms to surveil healthcare professionals and to facilitate the prescribing of Suboxone. Medical institutions legitimised the Suboxone Education Programme by lending their regulatory, epidemiological and professional authority.

Conclusions Addressing risk is considered as a central, moral responsibility of contemporary healthcare services. In this case, moral imperatives to address opioid crisis-related risks overrode other ethical concerns regarding conflicts of interest between industry and public welfare. Failing to address these conflicts potentially imperils efforts of mitigating population health harms by propagating an important driving force of the opioid crisis.

INTRODUCTION

In November 2016, 42 Canadian health agencies released the Joint Statement of Action to Address the Opioid Crisis, meant as a landmark national document identifying specific organisational policies to address the alarming growth in opioid-related harms.1 In their written commitments (box 1), Health Canada, the federal health agency tasked with pharmaceutical regulation, as well as the Health Ministers of Ontario and of Newfoundland, made direct references to Suboxone, the brand name of the buprenorphine-naloxone sublingual tablet used to treat opioid use disorder (OUD), the medical diagnostic label for opioid addiction. This repeated use of the brand name in a major policy forum was coupled with wide referencing and linking to a ‘Suboxone Education Programme’ (the ‘Programme’) developed by Indivior, the corporate rights-holder for Suboxone, in Canadian regulatory, scientific and policy documents relating to the Canadian opioid crisis.2,3 This was unusual and
programme have been delineated, and despite concerns constitutive element. Though no clear benefits from this crisis of which health professions education was a central major regulatory policy response to that country’s opioid deployment to attend to multiple perceived risks of phar-

regulation, mitigation schemes have been increasingly for market access of Suboxone. In pharmaceutical document, reflecting Health Canada’

curious given existing regulations in Canada for health professional education that prohibit the use of brand names in accredited continuing education as a means to counter promotional bias and given the growing concern about the persistent and insidious role of industry in promoting opioid analgesics.

The Suboxone Education Programme is referenced in the product monograph as part of a ‘risk mitigation programme’ (Box 2). This monograph is a regulated document, reflecting Health Canada’s 2007 approval for market access of Suboxone. In pharmaceutical regulation, mitigation schemes have been increasingly deployed to attend to multiple perceived risks of pharma-

cal, toxicity or death. For example, the opioid Risk Evaluation and Mitigation Strategy (REMS) of the US Food and Drug Administration (FDA) was a major regulatory policy response to that country’s opioid crisis of which health professions education was a central constitutive element. Though no clear benefits from this programme have been delineated, and despite concerns of the close involvement of industry in the development and deployment of this programme, Canada too has begun to implement a similar risk programme for opioid analgesics which includes components of health professions education.

That the origin of the Programme is regulatory in nature is not surprising given that OUD is perhaps the most highly regulated area of medical practice interna-

tionally. For example, in Canada, opioid agonist therapy (OAT)—the primary medical treatment for OUD—is in part regulated at the federal level through legislation such as the Controlled Drugs and Substances Act (CDSA) which sets the parameters for the use of substances such as methadone and buprenorphine. Until recently, Canadian prescribers had to individually gain an exemption from the CDSA to prescribe methadone and sometimes buprenorphine. Similar federal regulatory processes are in place in other jurisdictions such as the UK, USA and Australia. While other medical therapeutics may require certain levels of training, expertise or monitoring to be used (perhaps thalidomide and isotretinoin as the most well-known examples in the USA), it is highly unusual to require exemption from federal law or approval from federal authorities. Likewise, although clinical practice guidelines are typically developed by independent scientific and clinical authorities, OAT practice guidelines are often instead determined by regional regulatory authorities—such as state or provincial health professions regulators—implying both an increased level of regulatory surveillance around this practice and more direct disciplinary consequences for not following this guidance.

Research question

Even outside of opioid analgesics, many scholars have drawn attention to how pharmaceutical companies have appropriated medical research and education as part
of complex and detailed strategies of product promotion.\textsuperscript{15–18} However, the fact that a federally regulated risk management programme has adopted an educational programme developed and delivered by a pharmaceutical company has to date escaped scholarly attention. As such, we sought to answer the question ‘How has the Suboxone Education Programme been presented as a solution to various kinds of risk relating to OUD and the Canadian opioid crisis?’ We anticipated that the risks potentially being mitigated ranged from the ‘inherent dangerousness’ of people who use drugs\textsuperscript{14}; to the pharmacological and medical risks of opioid agonists themselves; to the knowledge and behaviour of healthcare professionals given that this risk management scheme primarily took the form of an educational programme. Delineating the nature of the risks being mitigated is essential to determining the interests that the promotion of the Programme favours—especially since health professions education, including in the area of opioid prescribing, so far has limited evidence for impacting patient or population health outcomes.\textsuperscript{19,20}

\section*{METHODS}

\subsection*{Study design and objectives}

We conducted a critical discourse analysis\textsuperscript{21,22} of publicly available documents that specifically referenced or linked to the Suboxone Education Programme, including to live in-person versions of the Programme or to the online Programme accessed through the URLs suboxonene.ca and suboxonetrainingprogram.ca. We followed a process similar to those described for other critical analyses of health policy,\textsuperscript{23–25} medical education\textsuperscript{26} and media coverage of the opioid crisis.\textsuperscript{27}

There is a plurality of approaches to critical discourse analysis, and multiple levels (micro, macro and meso) of social life, and interactions between the levels, to which it can be applied. Within this plurality, Shaw and Bailey identify three commitments common across discourse analyses.\textsuperscript{24} These include commitments to analysing language and interaction within their social context, to understanding knowledge as socially constructed, and to examining the social functions of discourse. In this study, using critical discourse analysis allowed us to identify and analyse the assumptions underlying the Programme that present it as a logical and integral policy intervention for addressing the opioid crisis and thus Indivior as a legitimate and beneficent intervenor.\textsuperscript{22} As a policy intervention, the Programme explicitly and implicitly describes the problem of the opioid crisis, including assumptions about OUD, OAT, and people who use drugs, while also suggesting the particular changes required to solve this problem.\textsuperscript{22} Our express purpose was not to identify thoughts or biases of, or assign blame to, individual policy actors. Nor were we interested in questioning the effectiveness of buprenorphine as a harm reducing pharmacological intervention for OUD, which has been well established.\textsuperscript{28} Instead, we were interested in tracing how an industry-developed and delivered programme became embedded in government policy, professional communications and clinical practices despite a climate in which such conflicts of interest, especially in relation to pharmaceuticals, were widely being questioned.

\subsection*{Data sources and sampling}

One author (AS) collected documents with specific reference or direct links to the Programme through internet searches, social media references, searches of bibliographic databases of the scientific literature and discussions with key informants with extensive involvement in Canadian opioid crisis policy development. Archived web pages, using tools such as Wayback Machine, were also searched to identify any historical changes to texts and documents subsequently taken down from the web. These texts were first read in an open-ended manner to identify the most significant characteristics.\textsuperscript{21}

Our next step was to develop an appropriate systematic archive of documents for analysis.\textsuperscript{25} The content of the Programme was not specifically our primary object of interest as we were more concerned with the wide inclusion of the Programme in a variety of official documents. Furthermore, we determined such a use of the content in the online portal might be construed as a violation of Indivior’s Terms and Conditions of Use policy which restricts use of the Programme content only to the personal use of healthcare professionals.\textsuperscript{30} The full research team examined the already collected documents as our primary archive and then included all additional documents through a comprehensive web search in July 2020 using Google as a secondary archive (online supplemental file 1). One researcher (AS) used the search terms ‘Suboxone Education Programme’, ‘Suboxone Training Programme’, ‘suboxonene’ and ‘suboxonetrainingprogram’ in Google. For both the primary and secondary archives, we included any documents that specifically referenced the title or URL of the Programme. Based on our familiarisation phase (see below), we also included the publicly facing portions of the online Programme portal in the primary archive. Given that this was a programme targeting Canadian healthcare professionals, we only included documents from Canadian sources.

\subsection*{Data collection and analysis}

The full research team gathered as a multidisciplinary group of researchers with expertise in opioid crisis policy, opioid prescribing education, OUD and OAT, discourse analysis, bioethics, policy analysis, critical theory and pharmaceutical industry influence in healthcare.

\subsection*{Public and patient involvement}

The full research team collectively participated in a familiarisation phase beginning with discussions with experts in the Canadian opioid crisis policy process. This process included people with lived experience with opioid-related harms who had subsequently been engaged with crisis policy. We also solicited feedback...
from the public, including people with lived experience, through presenting preliminary findings at a national OUD conference.

The full research team then read broadly about Suboxone as a pharmaceutical agent including the history of its development and clinical applications, its regulatory approval processes, its role in opioid crisis policy and the activities of the various companies that have held its marketing and manufacturing rights. This included reviewing information from a variety of information sources including academic journals, media reports and press releases, legal documents, lobby records, conference proceedings, meeting minutes, clinical practice guidelines and policy documents.

Three researchers (AS, MS and QG) then constructed a semistructured data extraction instrument (online supplemental file 2) based on congruent approaches to critical analysis of policies, media and industry-authored educational materials. This instrument was first piloted by three researchers (MS, AS and QG) with three documents from the primary archive. The instrument and pilot results were reviewed with the full research team. Working through each document in the primary archive, investigators answered a series of open-ended questions while documenting supporting evidence from the sampled documents such as quotations or providing detailed descriptions of images, formats and layouts. Each document was analysed in duplicate (AS, QG, SS, PS), with one investigator (MS) as a consistent coder for each document. Using NVivo to store and manage the collected data, three researchers (MS, AS, QG) then led the production of narrative summaries across each question and identified preliminary themes.

These preliminary themes and the relationships between them were identified through a process of discussion and further refined with the entire research team through multiple meetings. As an example, at this preliminary stage of analysis, the team identified key discursive distinctions between documents issued in the preliminary stage of analysis, the team identified specific instantiations of the surveillance of healthcare professionals. We used the Standards for Reporting Qualitative Research checklist for reporting this research.

RESULTS

We included 69 documents and identified four distinct kinds of sources (table 1):

1. Regulatory bodies such as provincial professional colleges outlining policies and guidelines for OAT prescribing (n=19; medicine n=10, nursing n=5, pharmacy n=3, joint medical and pharmacy n=1).
2. Clinical and scientific opinion leaders characterising the appropriate use of OAT in contemporary clinical and social contexts (n=18) through presentations, primers, peer-reviewed articles and information sheets.
3. Documents from regional health authorities, professional associations and educational institutions (n=28) usually in the form of newsletters, information sheets, proceedings and meeting minutes.
4. Documents from industry itself (n=4) including webpages, promotional posters and a Programme handbook.

Only nine (14%) of non-industry documents identified (either in the main text or references) the drug’s manufacturer, Indivior as the Programme developer. Likewise, across all types of documents, the majority (44 documents or 68%) referred to the brand name Suboxone independently of references to the title of the Programme, typically without use of the registered trademark and frequently without identifying the scientific name buprenorphine/naloxone (online supplemental file 1).

In analysing the documents, we identified a multitude of risks that the Programme was characterised as addressing, including the overprescribing of opioid analogues, the presence of toxic street drug supplies, and the greater relative risk of full opioid agonists such as methadone. To address these risk-problems, the Programme facilitated two important functions: the surveillance of healthcare providers and the prescribing of Suboxone. This status as a solution to these risk-problems was bolstered by the Programme’s association with regulatory, epidemiological and professional educational authorities which also obscured its industry origins.

Justifying the programme: a multiplicity of risk-problems

Defining health problems as ‘risks’ implies a need for intervention—a key role of contemporary health services is to mitigate the variety of primarily human-made risks that societies face. Thus examining the kinds of risks identified in documents that reference the Programme as an intervention can provide important insights into the roles that the Programme, especially a Programme that was developed as part of a Health Canada regulated risk management programme, is expected to fulfil. Throughout the archive, rather than a single, specific risk that the Programme was characterised as addressing, a multitude of risks including iatrogenic, environmental and pharmacological were described.

If the opioid crisis was referenced in the regulatory documents, it was typically associated with the overuse of opioid analgesic medications (table 2). By identifying this as a problem of specifically prescribed opioids, risk in
these documents was implicitly focused on the prescription process and the behaviour of healthcare professionals. This justifies interventions that may change and surveil their knowledge and behaviour and thus mitigate iatrogenic risk.

References to the opioid epidemic were quite distinct in the clinical and scientific documents. There was much less emphasis on inappropriate prescribing and much more so on harms from a toxic street drug supply—namely the nature of the risk at hand was characterised more as an environmental one rather than an iatrogenic one (table 2). Discussions of opioid-related harms in these documents were much more centred on the specific issue of OUD rather than the much more vague problem of ‘opioid dependence’ of the regulator documents.

The clinical and scientific documents, similarly with the industry documents, identified a third pharmaco-logical risk-problem that the Programme could address. Suboxone was repeatedly characterised as safer (‘less risky’) and equally efficacious compared with methadone. Suboxone was described as a ‘partial’ agonist with a ‘ceiling’ effect, both words meant to contrast with the ‘full’ agonist effect (and thus dangerous overdose potential) of methadone (table 2). Striking visual comparisons were made between the two medications, such as one from an educational presentation to healthcare professionals that depicted methadone as a sleek sports car ‘going 180 km per hour’ but buprenorphine as a cartoonish family car ‘going 50 km per hour.’ This distinction in terms of safety and risk of buprenorphine vs methadone was extensively elaborated in other documents, which in turn argued that because of these characteristic differences, buprenorphine should be considered first line therapy for the treatment of OUD over methadone and is particularly suited for use in primary care settings.

**Programme function: the moral imperatives to surveil and to prescribe**

The programme fulfilled two functions which were emphasised as moral imperatives to address the risks identified above: the surveillance of healthcare professionals and the facilitation of Suboxone prescribing (table 2). In the regulatory documents, education was cast as a regulatory requirement for OAT prescribing—that prescribers would not be granted prescriptive authority for buprenor-phine/naloxone and could face punitive consequences if they did prescribe without first undertaking the recommended education, which typically included the Programme. Enforcement of such policies required mechanisms to report and track Programme participants. The Privacy Policy of the Programme, issued by Indivior, reflected this surveillance imperative, describing a variety of reasons for collecting personal information about health professional participants. This imperative recalled one component of the risk management programme from the product monograph which specified the maintenance of ‘a list of Suboxone Education Programme trained physicians’ (box 2). It also recalled

<p>| Table 1 Document archive by source, type, industry and brand reference, and authorship |
|--------------------------------------|---------------------------------|--------------------------------------|---------------------------------|</p>
<table>
<thead>
<tr>
<th><strong>Document source</strong></th>
<th><strong>Geographic distribution by province (no)</strong></th>
<th><strong>Document types</strong></th>
<th><strong>No identified programme as industry developed</strong></th>
<th><strong>No referenced suboxone independent of programme</strong></th>
<th><strong>Named authorship</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory bodies (19)</td>
<td>MB, SK (3 ea); AB, NL, PE (2 ea); BC, NB, NS, NT, NU, ON, QC, YT (1 ea)</td>
<td>Information notices (10); Practice guidelines (6); Newsletters (3)</td>
<td>Main text: 2 (10%) References: 1 (5%)</td>
<td>15 (79%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td><strong>Clinical and scientific opinion leaders (18)</strong></td>
<td>ON (6); National (5); BC (4); AB, MB, QC (1 ea)</td>
<td>Professional presentations (10); Clinical Primers (3); Peer-reviewed scientific articles (2); Information sheets (2); Book chapter (1); Policy recommendations (1)</td>
<td>Main text: 2 (11%) References: 1 (6%)</td>
<td>13 (72%)</td>
<td>14 (78%)</td>
</tr>
<tr>
<td><strong>Health authorities, professional associations, and educational institutions (28)</strong></td>
<td>ON (8); National (5); BC, NL (4 ea); AB (3); SK (2); QC, YT (1 ea)</td>
<td>Newsletter (6); Info sheet or handbook (6); Programme description (4); Report (3); News notice, news release or programme promotion (3); Proceedings (2); Presentation (1); Meeting minutes (1); Training link (1)</td>
<td>Main text: 3 (11%) References: 0 (0%)</td>
<td>16 (57%)</td>
<td>14 (50%)</td>
</tr>
<tr>
<td>Industry (4)</td>
<td>National (2); AB, ON (1 ea)</td>
<td>Posters (2); Publicly available portions of suboxonecentre.ca (1); Publicly available programme handbook (1)</td>
<td>Main text: 4 (100%)</td>
<td>N/A</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

AB, Alberta; BC, British Columbia; MB, Manitoba; NB, New Brunswick; NL, Newfoundland and Labrador; NS, Nova Scotia; NT, Northwest Territories; NU, Nunavut; ON, Ontario; PE, Prince Edward Island; QC, Quebec; SK, Saskatchewan; YT, Yukon.
Table 2  Main themes with illustrative examples

<table>
<thead>
<tr>
<th>Theme</th>
<th>Main finding</th>
<th>Illustrative examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Justifying the programme: a multiplicity of risk-problems</td>
<td>The programme was characterised as addressing a multitude of risks relating to healthcare professional knowledge and attitudes, a toxic street drug supply, and even risks related to methadone as treatment for OUD.</td>
<td>Latrogenic risk—opioid overprescribing: In a 27-page provincial regulatory College newsletter which includes a full-page poster titled ‘Interested in prescribing Suboxone?’ that promoted the Programme and for which the contact person was a company representative, the message from the College Registrar focuses on prescription drug abuse and reads: ‘Prescription drug abuse/misuse is a significant problem in Canada. It is a public health and safety issue…We know that Canada is the second largest consumer of opioids in the world. Only the US consumes more opioids on a per capita basis. The United States has declared prescription drug abuse a national Public Health crisis.’</td>
</tr>
<tr>
<td>Programme function: the moral imperatives to surveil and to prescribe</td>
<td>The Programme is captured as a solution to address moral imperatives to surveil healthcare professionals and for healthcare professionals to prescribe Suboxone</td>
<td>Surveillance: The Privacy Policy for the Program describes the Program as ‘the pre-requisite education required to treat opioid dependent patients with SUBOXONE’ and outlines reasons for collecting personal information which include validating participants identities as Canadian healthcare professionals, providing feedback to professional associations for accreditation purposes, confirming programme completion for continuing education requirements and ‘to comply with, any legal, regulatory or compliance requirements or provisions’.</td>
</tr>
<tr>
<td>Bolstering the programme: associating with institutional medical authority</td>
<td>The documents projected various kinds of medical authority which lent credibility to the programme</td>
<td>Regulatory authority: A 10-page provincial medical regulatory newsletter headed by a coat of arms outlines routine regulatory matters, such as licence renewal, together with substantial discussion of new legislation which notes the potential for investigation and discipline by the College for non-compliance with opioid prescribing policies. Subsequent text emphasises College initiatives around methadone and buprenorphine prescribing within which it is stated, ‘Prior to prescribing Buprenorphine for addiction, it is expected that the physician will have completed the online Suboxone Education Program available at <a href="http://www.suboxonecme.ca.%E2%80%99">www.suboxonecme.ca.’</a> Professional education authority: A 1-page ‘upcoming events’ communiqué from a provincial medical association promotes several half-day sessions for family physicians on ‘suboxone (sic)’ treatment being offered by three physicians. The ‘Suboxone Training Programme’ (with hyperlink included) is described as ‘useful for advance preparation’ and listed along with two non-industry education programmes. Epidemiological authority: A 20-page joint report from two provincial research organisations advocates for buprenorphine/naloxone as a first-line OUD treatment and recommends policies for reducing barriers to its access to address the opioid crisis. It makes extensive use of epidemiological evidence with text, graphs and 91 references regarding drug use, as well as buprenorphine and methadone safety and efficacy, to make this case. It outlines provincial prescribing requirements for buprenorphine prescribing with multiple references to <a href="http://www.suboxonecme.ca">www.suboxonecme.ca</a>. There is no mention of the Programme being industry-developed and some references identified it as ‘accredited’. Individual authors are listed at the conclusion of the document while the organisational logos and titles are forefronted on the title page.</td>
</tr>
</tbody>
</table>

OUD, opioid use disorder.

A mandate to track and surveil Programme participation was most evident in the pharmacy regulatory documents where the expectations of surveillance were turned from one of regulators surveilling health professionals to a ‘DoctorLocator’ initiative outlined in a regulatory newsletter that intended to collect information about all ‘trained’ prescribers and make this available to the public (table 2).

---

health professionals surveilling each other. For example, in one guideline for pharmacists and pharmacy technicians, the document began with extensive descriptions of the regulatory requirements for prescribers (eg, physicians and nurse practitioners) and began its guidance for drug dispensing with a short description of training requirements and then stated:

On receiving a new patient, pharmacists are required to confirm that the prescription is written by a valid prescriber who meets the legislative requirements for the medication assisted treatment prescribed to the patient (see previous section). The pharmacist must screen and assess the appropriateness of the treatment at the dose prescribed.35 (emphasis added)

Second, in identifying Suboxone as a potential corrective to previous opioid analgesic overprescribing—and identifying education as the means through which to begin doing this appropriately by improving knowledge, skills and behaviour—the regulatory documents also cast education as a moral imperative to address previous iatrogenic harms. The clinical and scientific documents also consistently reiterated this message of the Programme as a facilitator of prescribing by identifying that participation in the Programme was either required or useful for Suboxone prescribing. The moral imperative in these clinical and scientific documents, however, was to facilitate the prescribing of Suboxone as a corrective against growing harms from OUD (table 2). Suboxone was thus cast as a safe and effective therapeutic that was being underused by health systems given the scale of the opioid crisis. The Programme, then, could help remedy this by changing health professional behaviour and better meeting population health needs for the drug.

Bolstering the programme: associating with institutional medical authority

The credibility of the programme as a solution for these risk-problems was bolstered by the programme’s association with institutional medical authority—either regulatory, epidemiological or professional (table 2). Throughout the archive, the Programme was identified alongside other non-industry, accredited educational programmes as among the available and, in the case of the regulatory documents, authorised, programmes of record. Medicine holds much social power because of the collective value we place on health, science and expertise.34 By identifying the programme as a useful resource alongside other accredited non-industry programmes, these documents lent their authority to the programme by association. The repetition of text and images between the industry and non-industry documents emphasised this association. Likewise, the obfuscation of document authorship in regulatory and industry documents (table 1) further emphasised institutional authority without individual accountability for the content of the documents and its implications, including the legitimisation of industry as a risk mitigator.

The references to the programme throughout the archive documents can best be summarised by characterising the Programme as a ‘useful resource’. For example, most of the professional association documents were newsletters—some were focused on general business matters while others focused specifically on substance use. The majority of these documents listed helpful resources for addiction treatment and include a reference to the programme or hyperlink to the programme website as one such resource (table 2). Through these kinds of references, the health authorities, professional associations and educational institutions projected a professional authority and credibility through everyday communication. In the few cases where specific authors were identified in the regulatory documents, they were typically high-ranking and/or credentialed organisational executives (eg, college CEOs) or officials (eg, college registrars).

There were no individual named authors of the industry documents. In these documents, we noted the use of terms and phrases that draw on the authority of accreditation in continuing education, though there was no evidence that the Programme was in fact accredited. In the two programme posters the term ‘Planning Committee’ recalled the planning processes of accredited continuing medical education—though nowhere on the posters was there an official statement of accreditation. Likewise, the posters included six specific ‘learning objectives’ that are phrased exactly as learning objectives might be for accredited continuing medical education. An archived page of the suboxonecme.ca Privacy Policy specifically mentions that personal information of programme participants may be ‘collected, used and disclosed … to Health Canada, the College of Family Physicians of Canada (CFPC) and/or other professional associations for accreditation purposes’.35 This recalls an earlier Quebec regulatory document from 2009 which identified that the programme was accredited for up to 6 hours of continuing medical education credit by the CFPC.36 This accreditation statement is no longer present on more current versions of the Programme Privacy Policy.

The industry handbook did appeal to professional authority by listing highly credentialed health professionals (physicians and a pharmacist) at the outset of the document as having contributed to ‘the initial draft of this programme’. The posters promoting live versions of the programme follow this appeal to professional authority exactly—they list the same group of health professionals (and their credentials) as the ‘Planning Committee’ for the programme. Both imply a kind of authoritative production of the programme without relying explicitly on authorship and the accountability that that entails.

**DISCUSSION**

The use of education programmes by the pharmaceutical industry to drive profit-making through the
overprescribing of opioid analgesics and other pharmacotherapies has been widely discussed and well established. To our knowledge, this is the first empirical study examining industry involvement in health professions education for opioid agonist therapies like buprenorphine. This is highly relevant given both the importance that agonists have been given as opioid crisis interventions, and also the abuses of regulatory processes that Indivior has engaged in to maximise its profit-making including ‘securing potentially undeserved orphan drug status for its buprenorphine products, manipulating the availability of such products, filling questionable citizen petitions and engaging in abuses of the FDA REMS plan to attenuate safety risks associated with buprenorphine products’. This analysis comprehensively covered 69 distinct documents over 13 years from every Canadian province and territory and included representation from medicine, nursing, pharmacy as well as a wide range of health institutions.

Continuing education for health professionals about opioid analgesics has often been explicitly promotional, delivered by company representatives or funded by ‘unrestricted’ grants that blur the distinction between education and marketing. In this case, we identified a different process that was premised on the notion of ‘risk’. The identification and mitigation of risk is a central, moral concern of contemporary, professionalised health systems and social services in general. These risks can be multifarious, ranging from environmental to behavioural to psychological, with the process of selecting and locating the relevant risks being subject to the input and assessments of interests with various levels of influence. In the case of strategies to facilitate the use of opioid agonist treatments, we see the primary risks framed as unruly opioid prescribers in need of surveillance, and unpredictable and dangerous drug supplies, in the form of methadone and street drugs. Here, various kinds of medical institutions (regulatory, epidemiological and professional) construct ‘risk’ in overlapping and complex ways, with the result that a branded, industry developed and delivered education programme presents as an effective and normalised ‘risk mitigation’ strategy. By extension, the manufacturer, Indivior, gains purchase as a legitimate and beneficent risk-mitigator in the Canadian opioid crisis and the brand name Suboxone becomes normalised in everyday discourse relating to the opioid crisis and treatment of OUD.

This process resonates squarely with the industry promotion strategy for other pharmaceuticals. In an analysis of Zyprexa and Prozac, other ‘blockbuster’ psychopharmaceuticals (defined as pharmaceuticals with more than US$1 billion in annual sales), Applbaum states, ‘getting to yes is the means whereby pharmaceutical corporations fuse divergent positions of market intermediaries under the banner of a more abstract, univocal and often ethical purpose, drawing even on the energy of those intermediaries to construct a single directed force projecting them towards company objectives’. Indeed, even the basic messaging around Suboxone identified here follows almost exactly that of Prozac, which included focusing on primary care professionals as market agents, identifying substantial population harms related to depression (such as suicide risk), and inspiring primary care professionals with confidence in the product based on its improved side effect profile and lower overdose risk compared with earlier, off-patent antidepressants. In this case, the toxic street drug supply and the documented lethality of methadone play the threatening roles that suicide and tricyclic antidepressants played for Prozac. Importantly, this analysis does not question important pharmacological differences between buprenorphine and methadone or other opioids, but identifies specific and contingent discursive productions of buprenorphine against these other substances. It is possible to imagine other ways to discuss buprenorphine to identify its utility that do not involve comparisons to the risks of methadone and street opioids, just as we might imagine ways to discuss the utility of selective serotonin reuptake inhibitors without specific mention of the risks related to tricyclic antidepressants.

This kind of co-opting of the medical infrastructure by industry through an education programme appears novel, though the process very much recalls tactics used in other areas of healthcare. Similar to how others identified a kind of ‘ghost authorship’ that facilitates the promotion of industry messaging through medical research, we saw a parallel kind of authorship vacuum among these policy and training documents, including specifically in the regulatory and industry documents. This absence both elides individual responsibility for industry promotion on the part of regulatory and sometimes professional leaders and also gives space for industry to gain credibility on the shoulders of medical institutional authority. It may also indicate a larger, concerted strategy by Indivior to promote its product by using not just medical education but also other means such as government lobbying. Future scholarship should focus on identifying, comparing, and analysing these additional processes of Suboxone promotion.

Much of the existing scholarship around the processes of industry influence on medical care has been based on analysis of publicly available litigation. A new generation of scholarship may be forthcoming given the substantial and ongoing opioid-related litigation in the USA and Canada. For this analysis, additional future research should focus on the original regulatory decisions for Suboxone’s 2007 approval which could provide more insight into the nature of the ‘risk’ that the Suboxone Education Programme was intended to address and the process of delegating risk mitigation from the public, federal drug regulator to the pharmaceutical industry. This could yield important knowledge similar to the analysis of the public hearings for the regulatory approval for Thalidomide by the FDA in 2008. Fortunately, Health Canada has committed to transparency as a drug regulator and documents relating to this
decision may be forthcoming (personal communication, Health Canada).

The moral imperative to intervene on the specific conglomeration of risks relating to the opioid crisis overrode other moral imperatives of avoiding industry involvement in medical education and risks attendant with this involvement. As has been identified in other scholarship, this indicates a relative absence and weakness of educational authorities in the Canadian medical landscape. At the same time, the only document in our collected archive which overtly identified the Programme as industry sponsored, and possibly the need for a non-industry alternative, was from a medical educational institution. This suggests that strengthening the independent authority of medical educational institutions within the larger medical landscape may help mitigate the influence of the pharmaceutical industry in determining priority health challenges and the appropriate means for intervention.

This moral imperative to intervene is strengthened by the systemic marginalisation and manufactured vulnerabilities of people who use opioids. Namely, intervention—irrespective of the risks of industry involvement—may be deemed as required since the populations that may most benefit have historically been denied access to appropriate harm-reducing services and therapies. Thus, we see a normalisation of industry promotion of harm reduction interventions such as increasing naloxone uptake and reducing opioid-related stigma. Likewise, clinicians, researchers and policy-makers remain open to industry involvement in activities promoting the use of buprenorphine-naloxone in response to the steep and inequitable rises in opioid overdoses during the pandemic. A similar dynamic around industry involvement in harm reduction can be seen in other fields. As one example, the tobacco control community is currently polarised in relation to the promotion of e-cigarettes to reduce the harms of tobacco smoking and potential partnerships with tobacco or e-cigarette companies in achieving this goal.

There are important limitations to this analysis. The first is that our strategy for building the study archive selected only publicly available documents. Analysis of privately held documents such as minutes of lobbying meetings may identify new and different discursive constructions of the Programme that could influence the overall analysis. Likewise, this study does not account for the reach and impact of the various documents included for analysis. Discursive constructions in narrowly circulated meeting minutes from a small province or territory can hold as much weight in this analysis as widely disseminated policy documents from prominent medical institutions. These limitations could potentially be mitigated both by requesting additional documents through Access to Information Act requests and through formal interviews with key informants involved in the policy discussions around OUD care and opioid crisis responses in Canada. Both these activities present important avenues for future work that were beyond the scope of this study. Finally, this analysis was not able to examine the content of the Suboxone Education Programme itself. While other documents provided some insight into this programme content (eg, by referencing content from the programme), this was not sufficient to conduct a fulsome analysis of programme content.

CONCLUSIONS

In this analysis, we identified how the seemingly benign characterisation of a multitude of risks related to the Canadian opioid crisis opened the door for an industry developed and delivered education programme to become a legitimate and even morally appropriate solution for addressing these risks. Institutions from across the medical landscape lent their authority to this programme, overriding any concerns relating to conflicts of interest between industry and population health. This was despite explicit and persistent concerns around the role of industry in promoting the overprescribing of opioid analgesics, which was a crucial contributor to the opioid crisis and the related risks that this industry programme was meant to mitigate.

Author affiliations
1Department of Family and Community Medicine, University of Toronto, Toronto, Ontario, Canada
2Institute of Health Policy Management and Evaluation, University of Toronto, Toronto, Ontario, Canada
3Bridgepoint Collaboratory for Research and Innovation, Sinai Health System, Toronto, Ontario, Canada
4Department of Sociology, York University, Toronto, Ontario, Canada
5Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada
6Bioethics Program, University Health Network, Toronto, Ontario, Canada
7Department of Family and Community Medicine, Women's College Hospital, Toronto, Ontario, Canada
8Arthur Labatt Family School of Nursing, Western University, London, Ontario, Canada
9Lawrence S Bloomberg Faculty of Nursing, University of Toronto, Toronto, Ontario, Canada

Twitter Abhimanyu Sud @doc_sud and Quinn Grundy @QuinnGrundy

Acknowledgements Dr. Pamela Sabioni contributed to the familiarisation phase and document analysis.

Contributors AS: conceptualisation, methodology, formal analysis, writing—original draft, supervision, project administration, funding acquisition, guarantor. MS: methodology, formal analysis, writing—original draft. DZB: writing—review and editing. SS: formal analysis, writing—review and editing. REGU: conceptualisation, methodology, writing—review and editing, supervision, funding acquisition. FW: methodology, writing—review and editing, supervision. QG: conceptualisation, methodology, writing—review and editing, supervision, project administration.

Funding This work was supported in part by the Substance Use and Abuse Program, Health Canada (grant number 1920-HQ-000031).

Disclaimer The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.
REFERENCES
18 Fugh-Berman A. Industry-funded medical education is always promotion—an essay by Adrienne Fugh-Berman. BMJ 2021;373:n1273.

49 Marselis D, Hordijk L. From blockbuster to “nichebuster”: how a flawed legislation helped create a new profit model for the drug industry. *BMJ* 2020;370:m2983.


57 Reuter N. Saving lives with a single shot: strategies and challenges to expanded naloxone availability. in Indivior, PLC. Available: https://apha.confex.com/apha/144am/meetingapi.cgi/Session/48653?filename=144am_Session48653.html & template=Word

