Open access Original research

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

To cite: Sud A, Strang M, Buchman DZ. et al. How the Suboxone Education Programme presented as a solution to risks in the Canadian opioid crisis: a critical discourse analysis. BMJ Open 2022;12:e059561. doi:10.1136/ bmjopen-2021-059561

Prepublication history and additional supplemental material for this paper are available online. To view these files. please visit the journal online (http://dx.doi.org/10.1136/ bmjopen-2021-059561).

Received 26 November 2021 Accepted 20 June 2022



Check for updates

@ Author(s) (or their employer(s)) 2022. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by

For numbered affiliations see end of article.

#### **Correspondence to**

Dr Abhimanyu Sud; abhimanyu.sud@utoronto.ca

#### **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 crisisrelated 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

#### STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study was conducted by a multidisciplinary group with expertise in opioid crisis policy, opioid prescribing education, opioid use disorder and opioid agonist therapy, discourse analysis, bioethics, policy analysis, critical theory and pharmaceutical industry influence in healthcare.
- ⇒ The data sources did not include content directly from the educational programme.
- ⇒ Through three iterations of analysis, we examined 69 documents published over 13 years from multiple professions and from every health system in Canada.
- ⇒ To our knowledge, this is first study using critical discourse analysis to examine aspects of a continuing health professions education programme.
- ⇒ As we only analysed publicly available documents, some additional relevant data, such as around regulatory decision making, were not available for analysis.

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. 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 buprenorphinenaloxone 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.<sup>2 3</sup> This was unusual and



# Box 1 Commitments in the joint statement of action to address the opioid crisis with direct references to Suboxone

#### **Health Canada:**

⇒ Improve access to Suboxone treatment in rural and remote First Nations communities by taking steps to ensure that the supports are in place to safely store, handle and undertake the daily witnessing of Suboxone.

#### Ministry of Health and Long-Term Care, Province of Ontario:

- ⇒ Expand Access to Suboxone: Effective on 11 October 2016, Suboxone is available as a General Benefit on the Ontario Drug Benefit Formulary. Ontario will ensure that access to Suboxone treatment is better integrated into a holistic, primary care approach to opioid addiction treatment(...)
- ⇒ Healthcare Delivery and Primary Care Integration: Enhance integration of comprehensive primary care, mental health and Suboxone/methadone treatment to better support patients with opioid addiction.

### Ministry of Health and Community Services, Province of Newfoundland and Labrador:

- ⇒ By December 2016: Determining updated physician licensure requirements to prescribe Suboxone.
- ⇒ By December 2016: Identifying training/operational requirements for physicians/pharmacists/others working with clients on Suboxone.
- By January 2017: Communicating and consulting on the plan with Newfoundland and Labrador Medical Association, Association of Registered Nurses of Newfoundland and Labrador, Prescribers, Pharmacy Association of Newfoundland and Labrador and others as required.
- ⇒ By February 2017: Finalising and implementing training and any operational requirements, for example, revised billing codes.
- ⇒ By March 2017: Communicating publicly.
- ⇒ By March 2017: Initiating coverage of Suboxone under special authorisation, until an Atlantic Common Drug Review can be completed.

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.<sup>45</sup>

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 pharmaceuticals, such as 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,<sup>7</sup> and despite concerns of the close involvement of industry in the development and deployment of this programme, 8 Canada too has

### Box 2 Suboxone Risk Mitigation Programme (from Suboxone Canadian product monograph)<sup>6</sup>

SUBOXONE sublingual tablets should only be prescribed by physicians who meet the following requirements

- ⇒ Experience in substitution treatment in opioid drug dependence.
- ⇒ Completion of a recognised Suboxone Education Programme.

The Suboxone Education Programme is a risk management programme that is founded on the following four core components that provide for the safe and effective use of the drug within a framework of medical, social and psychological support:

- ⇒ Training of the prescribing physicians in the use of Suboxone sublingual tablets.
- ⇒ Maintenance of a list of Suboxone Education Programme trained physicians.
- ⇒ Daily dosing supervised by a healthcare professional, progressing to unsupervised.
- ⇒ Administration as the patient's clinical stability permits.
- ⇒ Take-home doses once the patient has sufficient clinical stability and is able to safely store Suboxone. Take-home doses should be assessed and reviewed on a regular basis.

Physicians may obtain more information about the Suboxone Education Programme by calling the following toll-free phone number 1-877-782-6966.

begun to implement a similar risk programme for opioid analgesics which includes components of health professions education.<sup>9</sup>

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 internationally. 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. 10 Similar federal regulatory processes are in place in other jurisdictions such as the UK, USA and Australia. 11-13 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.<sup>14</sup>

#### **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. 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<sup>14</sup>; 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 favour—especially since health professions education, including in the area of opioid prescribing, so far has limited evidence for impacting patient or population health outcomes. 19 20

#### **METHODS**

### Study design and objectives

We conducted a critical discourse analysis<sup>21</sup> <sup>22</sup> 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 suboxonecme. ca and suboxonetrainingprogram.ca. We followed a process similar to those described for other critical analyses of health policy, <sup>23–25</sup> medical education <sup>26</sup> and media coverage of the opioid crisis. <sup>27</sup>

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.<sup>24</sup> 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.<sup>22</sup> 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.<sup>22</sup> 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.<sup>28</sup> 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.

#### **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. <sup>21</sup>

Our next step was to develop an appropriate systematic archive of documents for analysis.<sup>29</sup> 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.<sup>30</sup> 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', 'suboxonecme' 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.

#### **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.

#### **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. <sup>21</sup> 22 31 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, OG) 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 by different kinds of groups suggesting the importance of analysing the document archive by the kind of group. Two researchers (AS, QG) used these refined themes to guide coding of the secondary archive. On completion of this second round of coding, narrative summaries were created (by AS) for each code and discussed with the larger research team to identify the primary discourses of interest. As one example, at this stage of analysis the team identified discursive associations between the Programme and other educational programmes. One researcher (AS) conducted a final search in May 2021 to identify any additional new documents (tertiary archive) against which our findings were further reflected through discussion with the full research team. At this stage of analysis, as an example, 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 analgesics, 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.<sup>32</sup> 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



Table 1 Document archive by source, type, industry and brand reference, and authorship

Document source (total no)	Geographic distribution by province (no)	Document types	No identified programme as industry developed	No referenced suboxone independent of programme	Named authorship
Regulatory bodies (19)	MB, SK (3 ea); AB, NL, PE (2 ea); BC, NB, NS, NT, NU, ON, QC, YT (1 ea)	Information notices (10); Practice guidelines (6); Newsletters (3)	Main text: 2 (10%) References: 1 (5%)	15 (79%)	0 (0%)
Clinical and scientific opinion leaders (18)	ON (6); National (5); BC (4); AB, MB, QC (1 ea)	Professional presentations (10); Clinical Primers (3); Peer-reviewed scientific articles (2); Information sheets (2); Book chapter (1); Policy recommendations (1)	Main text: 2 (11%) References: 1 (6%)	13 (72%)	14 (78%)
Health authorities, professional associations, and educational institutions (28)	ON (8); National (5); BC, NL (4 ea); AB (3); SK (2); QC, YT (1 ea)	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)	Main text: 3 (11%) References: 0 (0%)	16 (57%)	14 (50%)
Industry (4)	National (2); AB, ON (1 ea)	Posters (2); Publicly available portions of suboxonecme.ca (1); Publicly available programme handbook (1)	Main text: 4 (100%)	N/A	0 (0%)

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.

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 pharmacological 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 buprenorphine/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 participation. 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



Table 2	Main thamps	with illustra	itive examples

Theme	Main finding	Illustrative examples
Justifying the programme: a multiplicity of risk-problems	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.	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 issueWe 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.'  Environmental risk—toxic drug supply: A 6-page publication in a medical journal outlines a quick-reference guide for prescribing buprenorphine/naloxone and states that 'opioid-related deaths continue to climb because opioid use is increasing and illicit drugs are being contaminated with devastatingly potent opioids such as fentanyl and carfentanil.' Throughout the publication the term Suboxone is used and the reference guide tool itself is titled 'Prescribing Suboxone in the Outpatient Setting'. The Programme is listed as a reference in the publication.  Pharmacological risk—methadone as risker than Suboxone: Using text and an unreferenced graph, a 12-page handbook entitled 'Training Programme-Suboxone Use in Primary Care'' compares the poorly defined 'Opioid-agonist Effect' of Suboxone to 'full agonists such as heroin and methadone'. It characterises Suboxone as a 'partial' agonist with a 'ceiling' effect that does not cross a threshold for respiratory depression.
Programme function: the moral imperatives to surveil and to prescribe	The Programme is captured as a solution to address moral imperatives to surveil healthcare professionals and for healthcare professionals to prescribe Suboxone	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'.  Prescribing: A 24-page medical association periodical has a focused issue on opioids. A two-page article from a member physician titled 'The Opioid Crisis and What You Can Do About it' includes 18 mentions of the brand name Suboxone, and states: 'But how does this impact YOU? There are many patients who could benefit from Suboxone but who need prescribers. Likely, a few of these patients are in your practice. In my opinion, the demand cannot be met solely by referral to specialised clinics. The good news is that prescribing Suboxone is not as challenging as you may think! By using thoughtfulness, expert advice when necessary, your own practice experience, and by erring on the side of caution, the process of prescribing Suboxone is similar to many other medications you already prescribe, for example, insulin.' The article references the Program as strongly encouraged by the provincial medical regulator, and notes that the Programme is free compared to an alternative, non-industry program which costs US\$350.
Bolstering the programme: associating with institutional medical authority	The documents projected various kinds of medical authority which lent credibility to the programme	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="https://www.suboxonecme.ca.">www.suboxonecme.ca.</a> .  Professional education authority: A 1-page 'upcoming events' communique from a provincial medical association promotes several half-day sessions for family physicians on 'subaxone (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="https://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.

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).

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



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.<sup>33</sup> (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.<sup>34</sup> 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 6hours of continuing medical education credit by the CFPC. <sup>36</sup> 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. 17 37 38 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<sup>39</sup> and also the abuses of regulatory processes that Indivior has engaged in to maximise its profit-making including 'securing potentially undeserved orphandrug status for its buprenorphine products, manipulating the availability of such products, filing questionable citizen petitions and engaging in abuses of the FDA REMS plan to attenuate safety risks associated with buprenorphine products'. 40 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.<sup>17 41</sup> 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. 42 43 These risks can be multifarious, ranging from environmental to behavioural to psychological. 44 45 with the process of selecting and locating the relevant risks being subject to the input and assessments of interests with various levels of influence. 46 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<sup>47</sup> 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), <sup>48 49</sup> 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'. <sup>16</sup> 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. <sup>16</sup> 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.<sup>50</sup> Similar to how others identified a kind of 'ghost authorship' 15 51 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.<sup>52</sup> 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.<sup>16</sup> A new generation of scholarship may be forthcoming given the substantial and ongoing opioid-related litigation in the USA and Canada.<sup>53</sup> 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. 46 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. 18 As has been identified in other scholarship, 41 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 nonindustry 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.<sup>54</sup> 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. 55 56 Thus, we see a normalisation of industry promotion of harm reduction interventions such as increasing naloxone uptake<sup>57</sup> and reducing opioid-related stigma.<sup>5</sup> 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.<sup>59</sup> 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.<sup>60</sup>

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 as 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**

<sup>1</sup>Department of Family and Community Medicine, University of Toronto, Toronto, Ontario, Canada

<sup>2</sup>Institute of Health Policy Management and Evaluation, University of Toronto, Toronto, Ontario, Canada

<sup>3</sup>Bridgepoint Collaboratory for Research and Innovation, Sinai Health System, Toronto, Ontario, Canada

<sup>4</sup>Department of Sociology, York University, Toronto, Ontario, Canada

<sup>5</sup>Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada

<sup>6</sup>Bioethics Program, University Health Network, Toronto, Ontario, Canada

<sup>7</sup>Department of Family and Community Medicine, Women's College Hospital, Toronto, Ontario, Canada

<sup>8</sup>Arthur Labatt Family School of Nursing, Western University, London, Ontario, Canada

<sup>9</sup>Lawrence 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.



**Ethics approval** This study was exempted from ethics review by the University of Toronto Research Ethics Board as it did not involve human participants or data from human participants.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. N/A.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

#### ORCID iDs

Abhimanyu Sud http://orcid.org/0000-0001-8354-6153 Quinn Grundy http://orcid.org/0000-0002-7640-8614

#### **REFERENCES**

- 1 Government of Canada. Joint statement of action to address the opioid crisis. Ottawa, ON: Government of Canada, 2016.
- 2 Moving towards improved access for evidence-based opioid addiction care in British Columbia. recommendations from the British Columbia node of the Canadian research initiative on substance misuse. BC Centre for Excellence in HIV/AIDS 2016.
- 3 Kahan M, Srivastava A, Ordean A, et al. Buprenorphine: new treatment of opioid addiction in primary care. Can Fam Physician 2011;57:281–9.
- 4 Canadian Medical Association. Guidelines for physicians in interactions with industry. Ottawa, ON: Canadian Medical Association, 2007.
- 5 Royal College of Physicians and Surgeons of Canada, The College of Family Physicians of Canada, College des Medecins du Quebec. National standard for support of accredited CPD activities, 2018.
- 6 Indivior UK Limited. Suboxone (buprenorphine and naloxone) product monograph. Indivior UK Limited, 2007.
- 7 Heyward J, Olson L, Sharfstein JM, et al. Evaluation of the Extended-Release/Long-Acting opioid prescribing risk evaluation and mitigation strategy program by the US food and drug administration: a review. JAMA Intern Med 2020;180:301–9.
- 8 Lurie J. Doctors Receive Opioid Training. Big Pharma Funds It. What Could Go Wrong? Mother Jones [Internet]. Available: http://www.motherjones.com/politics/2018/04/doctors-are-required-to-receive-opioid-training-big-pharma-funds-it-what-could-go-wrong/[Accessed 1 Sep 2021].
- 9 Health Canada. Submission of targeted risk management plans and follow-up commitments for prescription Opioid-Containing products: guidance for industry. Health Canada, 2018: 29.
- 10 Recommendation M. National consultation on the Sectionsection 56 exemption requirement for methadone prescribing. CRISM, 2017.
- 11 Strang J. Drug misuse and dependence: UK guidelines on clinical management, 2017. Available: https://researchportal.bath.ac.uk/ en/publications/drug-misuse-and-dependence-uk-guidelines-onclinical-management
- 12 Longman C, Lintzeris N, Temple-Smith M, et al. Methadone and buprenorphine prescribing patterns of Victorian general practitioners: their first 5 years after authorisation. *Drug Alcohol Rev* 2011;30:355–9.
- 13 Fiscella K, Wakeman SE, Beletsky L. Buprenorphine deregulation and Mainstreaming treatment for opioid use disorder: X the X Waiver. JAMA Psychiatry 2019;76:229–30.
- 14 Fraser S, Valentine K. Substance and substitution: methadone subjects in liberal societies. Springer, 2008: 203.
- 15 Sismondo S. Ghosts in the machine: publication planning in the medical sciences. Soc Stud Sci 2009;39:171–98.
- 16 Applbaum K. Getting to Yes: corporate power and the creation of a psychopharmaceutical blockbuster. Cult Med Psychiatry 2009;33:185–215.

- 17 Steinman MA, Bero LA, Chren M-M, et al. Narrative review: the promotion of gabapentin: an analysis of internal industry documents. Ann Intern Med 2006;145:284–93.
- 18 Fugh-Berman A. Industry-funded medical education is always promotion-an essay by Adriane Fugh-Berman. BMJ 2021;373:n1273.
- 19 Grundy Q, Mazzarello S, Brennenstuhl S, et al. A comparison of educational events for physicians and nurses in Australia sponsored by opioid manufacturers. PLoS One 2021;16:e0248238.
- 20 Sud A, Molska GR, Salamanca-Buentello F. Evaluations of continuing health provider education focused on opioid prescribing: a scoping review. *Acad Med*. In Press 2022;97:286–99.
- 21 Carvalho A. MEDIA(TED) DISCOURSE AND SOCIETY. *Journal Stud* 2008;9:161–77.
- 22 Bacchi C. Policy as discourse: what does it mean? where does it get us? Disco: Stud in the Cultu Polit Educa 2000;21:45–57.
- 23 Greenhalgh T, Procter R, Wherton J, et al. The organising vision for telehealth and telecare: discourse analysis. *BMJ Open* 2012;2. doi:10.1136/bmjopen-2012-001574. [Epub ahead of print: 19 Jul 2012].
- 24 Shaw SE, Bailey J. Discourse analysis: what is it and why is it relevant to family practice? *Fam Pract* 2009;26:413–9.
- 25 Grundy Q, Habibi R, Shnier A, et al. Decoding disclosure: comparing conflict of interest policy among the United States, France, and Australia. Health Policy 2018;122:509–18.
- 26 Whitehead C, Kuper A, Freeman R, et al. Compassionate care? A critical discourse analysis of accreditation standards. Med Educ 2014;48:632–43.
- 27 Webster F, Rice K, Sud A. A critical content analysis of media reporting on opioids: the social construction of an epidemic. Soc Sci Med 2020;244:112642.
- 28 Sordo L, Barrio G, Bravo MJ, et al. Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies. BMJ 2017;357:j1550.
- 29 Arribas-Ayllon M, Walkerdine V. Chapter 6 | Foucauldian Discourse Analysis. In: The SAGE Handbook of qualitative research in psychology. Sage. 2008: 91–108.
- psychology. Sage, 2008: 91–108.

  Indivior PLC. Terms and Conditions of Use of Web Site [Internet]. Suboxone Training Program. Available: https://www.suboxonetrainingprogram.ca/ [Accessed 10 Mar 200].
- 31 Grundy Q, Millington A, Cussen C, et al. Promotion or education: a content analysis of industry-authored oral health educational materials targeted at acute care nurses. BMJ Open 2020;10:e040541.
- 32 Beck U, Lash S, Wynne B. Risk society: towards a new modernity. SAGE Publications, 1992: 260
- SAGE Publications, 1992: 260.
   Alberta College of Pharmacy. Medication-Assisted treatment for opioid dependence: guidelines for pharmacists and pharmacy technicians. Alberta College of Pharmacy, 2014.
- 34 Freidson E. Profession of medicine: a study of the sociology of applied knowledge. University of Chicago Press, 1988: 419.
- 35 Indivior PLC. Privacy Policy of Web Site [Internet]. Privacy Policy Suboxone Training Program. Available: www.suboxonetraining program.ca [Accessed 10 Mar 2020].
- 36 Brissette S. La buprénorphine dans Le traitement de la dépendance aux opioïdes: lignes directrices. Collège des médecins du Québec, 2009: 45.
- 37 Persaud N. Questionable content of an industry-supported medical school lecture series: a case study. J Med Ethics 2014;40:414–8.
- 38 Van Zee A. The promotion and marketing of OxyContin: commercial triumph, public health tragedy. *Am J Public Health* 2009;99:221–7.
- 39 Saloner B, McGinty EE, Beletsky L, et al. A public health strategy for the opioid crisis. Public Health Rep 2018;133:24S–34.
- 40 Haffajee RL, Frank RG. Abuses of FDA Regulatory Procedures The Case of Suboxone. N Engl J Med 2020;382:496–8.
- 41 Shnier A, Lexchin J. Continuing medical education and pharmaceutical industry involvement: an evaluation of policies adopted by Canadian professional medical associations. *Int J Risk* Saf Med 2017;29:1–16.
- 42 Nigel P. Risk advanced liberalism and child welfare: the need to rediscover uncertainty and ambiguity. Br J Soc Work 1998;28:5–27.
- 43 SAGE Books The New Public Health: Health and Self in the Age of Risk. Available: http://sk.sagepub.com/books/the-new-public-health/ n1.xml [Accessed 1 Sep 2021].
- 44 Helén I. Technics over life: risk, ethics and the existential condition in high-tech antenatal care. *Econ Soc* 2004;33:28–51.
- 45 Beck U, Wynne B. Risk society: towards a new modernity. SAGE, 1992: 260.
- 46 Timmermans S, Berg M. *The gold standard: the challenge of evidence-based medicine*. Temple University Press, 2010.
- 47 Ogden J. Psychosocial theory and the creation of the risky self. Soc Sci Med 1995;40:409–15.



- 48 JJ L. Blockbuster drugs. Oxford University Press, 2014.
- 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.
- 50 Light DW, Lexchin J, Darrow JJ. Institutional corruption of pharmaceuticals and the myth of safe and effective drugs. J Law Med Ethics 2013;41:590–600.
- 51 Fugh-Berman AJ. The haunting of medical journals: how ghostwriting sold "HRT". PLoS Med 2010;7:e1000335.
- 52 Lobbyists Registration. Office of the integrity commissioner. Available: http://www.oico.on.ca/home/lobbyists-registration/ overview [Accessed 19 Nov 2019].
- 53 Haffajee RL. The public health value of opioid litigation. *J Law Med Ethics* 2020;48:279–92.
- 54 Salamanca-Buentello F, Cheng DK, Sabioni P, et al. Mal/adaptations: a qualitative evidence synthesis of opioid agonist therapy during major disruptions. Int J Drug Policy 2022;101:103556.
- 55 Friedman J, Kim D, Schneberk T, et al. Assessment of racial/ ethnic and income disparities in the prescription of opioids and

- other controlled medications in California. *JAMA Intern Med* 2019:179:469–76.
- 56 Friedman JR, Hansen H. Evaluation of increases in drug overdose mortality rates in the US by race and ethnicity before and during the COVID-19 pandemic. *JAMA Psychiatry* 2022;79:379–81.
- 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
- 58 Indivior Calls for Widespread Commitment to Tackling Stigma in Patients with Opioid Use Disorder [Internet]. Indivior Press Releases, 2020. Available: https://www.indivior.com/en/media/press-releases/indivior-calls-for-widespread-commitment-to-tackling-stigma-in-patients-with-opiod-use-disorder [Accessed 10 May 2022].
- 59 Knopf A. Indivior-sponsored event focuses on opioids during COVID-19. Alcohol Drug Abuse Wkly 2021;33:5–6.
- 60 Shaw DM, Etter J-F, Elger BS. Should academic journals publish e-cigarette research linked to tobacco companies? *Addiction* 2016;111:1328–32.