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Commentary

A public health based vision for the management and regulation of opioids

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ABSTRACT

Prohibition of the possession of opioids for non-medical purposes and medical/pharmaceutical commercialization of opioids are important contributors to the current opioid overdose epidemic. A new model of regulation is urgently required. Within the context of a public health framework, we explore supply control, demand reduction, health promotion, and harm reduction and describe an alternative regulatory model that includes access for medical and non-medical purposes. Oversight of this proposed new system would include a control structure with an explicit public health mandate to minimize harms and maximize benefits of opioids. Medical access would be achieved through multi-disciplinary teams who would prescribe a range of opioids for 1) pain, 2) treatment for patients who develop opioid use disorder, and 3) other medical indications. Non-medical access could be achieved through models that would allow adults to purchase and use opioids for either supervised or take-home use. We describe three possible models to support jurisdiction specific discussions around the world. The first includes education and training that could result in certification with a basic or advanced license or a purchase authorization card. The second includes mandatory training that allows general access to opioids, but excludes people with problematic opioid use. The third model has optional training and excludes people with problematic opioid use. Allowing for inclusion of people dependent on the current illegal market during transition is highlighted. With any of these models, this approach, while attending to illegal market drivers, would result in a greatly reduced illegal opioid market and its attendant toxic products, reduced violence and corruption, and at the same time, provide a sharper focus for medical use with more appropriate prescribing and indications.

Introduction

The current system of prohibition of psychoactive substances, which stems from the United Nations Single Convention on Narcotic Drugs (United Nations, 1972), and criminalization of people who possess them has had limited impact upon drug supply control. Moreover, this approach is associated with significant negative health, social, financial and political consequences, leading to growing interest in alternative approaches to drug harm prevention and control (Global Commission on Drug Policy, 2018 and earlier papers; Canadian Public Health Association, 2014; Carter & MacPherson, 2013; Health Officers Council of British Columbia, 2011; Wood et al., 2012; Rolles, 2009; King County Bar Association, 2005).

The widespread epidemic of opioid related deaths in North America, substantially related to illegally produced opioids but also driven by inappropriate prescribing, resulted in the Global Commission on Drug Policy making a number of key recommendations. Of note, the Commission advocated for bringing an end to the criminalization and incarceration of people who use drugs in Canada and the United States and allowing and promoting pilot projects for the responsible legal regulation of currently illicit drugs – including opioids – to replace and bypass criminal organizations that drive and benefit from the current illegal market (Global Commission on Drug Policy, 2017).

The Health Officers Council of British Columbia, which represents the public health physicians of British Columbia, Canada, has proposed a public health based regulatory framework (Health Officers Council of British Columbia, 2011), which has been used to articulate substance-specific, post-prohibition regulatory models for stimulants (Haden, 2008), cannabis (Haden & Emerson, 2014), and psychedelics (Haden, Emerson, & Tupper, 2016). Other organizations, including the Transform Drug Policy Foundation and the Beckley Foundation (both based in the United Kingdom) have also made substantial contributions to the literature in the articulation of post-prohibition models of drug control.

The purpose of this paper is to acknowledge that the current system of opioid and other drug prohibition has failed and a new system is urgently needed. Therefore, we offer a vision for post-prohibition, pub-

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lic health-based management and regulation of opioids that could be considered in any jurisdiction, with the goal of minimizing harms and maximizing benefits.

Demand for opioids and risk factors for problematic opioid use and harms

Effective management of opioids needs to consider the drivers of demand as well as risk factors for opioid related harms and problematic use. In terms of demand, it appears to be driven by a wide range of factors, including for the relief of physical, psychological or emotional pain, to get high, to experiment, to relax or relieve tension, and to improve sleep (van Amsterdam & van den Brink, 2015). Other factors include aggressive promotion of opioids by the pharmaceutical industry, with claims of exaggerated benefits and minimization of risks (Kolodny et al., 2015; Van Zee, 2009). This has contributed to medical/pharmaceutical commercialization of opioids and a lack of consideration for complementary non-pharmacologic pain therapies, especially for chronic pain (National Advisory Committee on Prescription Drug Misuse, 2013). A further demand driver is the presence of an opioid use disorder, which results in the need to take opioids to mitigate withdrawal symptoms when the dosage is reduced or terminated.

While there are a variety of factors influencing demand for opioids, there are particular social and demographic factors where risk for harm is concentrated. One of the greatest contributors to risk is age. In Canada, data indicate that the majority of apparent opioid toxicity deaths and most accidental opioid-related poisoning hospitalizations were among individuals aged 20 to 49 years (Government of Canada, 2021). Gender also shapes risk with males predominating in deaths (77%), hospitalizations (64%) and attendance by emergency medical services (73%) (Government of Canada, 2021). In addition, certain marginalized and stigmatized groups are overrepresented in data on opioid related harms, including those who experience homelessness, which is highly correlated with negative health status and polysubstance use (Cicero et al., 2014; Wood et al., 2006), Indigenous peoples (First Nations Health Authority, 2020), and those who have a history of trauma(s), especially related to sexual abuse at an early age and mental health comorbidities (Mate, 2009). Other documented risk factors for opioid related harms include ineffective addiction treatment (Fischer et al., 2004); poor prescribing (e.g. overlapping prescriptions); the availability of higher potency opioids (Pardo & Reuter, 2018), especially when combined with other drugs (Hirsch et al., 2014); and overlapping prescriptions and high daily dosages (Paulozzi et al., 2012). Certain occupations are also associated with increased risk for opioid harms, with construction, extraction (e.g., mining, oil and gas extraction), and health care practitioner occupations having the highest risk of opioid overdose deaths (Harduar Morano, Steege, & Luckhaupt, 2018).

Harmful effects of opioids

Opioid use can result in a wide range of negative acute and chronic effects, including somnolence (hence the species name "*somniferum*"), reduced bowel motility that can result in constipation, cognitive impairment, and respiratory suppression, which can result in death, particularly when opioids are taken in combination with other sedating psychoactive substances such as antidepressant medications, benzodiazepines, and alcohol, and especially if taken without supervision (Kalant, 1997; Labianca et al., 2012). In addition, the use of opioids is associated with a decrease in circulating sex hormones, resulting in decreased libido and erectile dysfunction, depression, fatigue, hot flashes, and reduced quality of life (Coluzzi et al., 2015; Katz et al., 2007) as well as with myocardial infarction (Chou et al., 2015). While there are a number of physical harms that are associated with opioids, a particularly concerning outcome is the development of opioid use disorder, which includes physical dependence and increased risk for mortality from causes other than overdose (Gomes et al., 2011).

Vision of a public health approach applied to opioids

A new paradigm for the management of opioids is urgently needed to mitigate serious opioid related harms, including the overdose and death epidemic. Both prohibition and the current regulated supply (i.e., prescription) have failed to restrict access and have increased problematic opioid use patterns and harms. For example, the criminalization of people who use illegally obtained opioids is related to profound health and social harms (Global Commission on Drug Policy, 2018). Moreover, illegal markets produce increasingly concentrated and contaminated products, heavily contributing to the current epidemic of overdose and death (Pardo & Reuter, 2018). The medical/pharmaceutical commercialization of opioids through pharmaceutical industry promotion and co-opting of the medical profession has further increased consumption and harms (Van Zee, 2009). Indeed, poorly regulated medical access has resulted in individuals moving from medical system access into the illegal market, with resulting increases in harms (Cicero et al., 2014; Kolodny et al., 2015).

A successful approach to minimizing the harms of opioids will have to address the fact that throughout human history, people have always found a way to access and use opioids (Courtwright, 2001). As such, building for controlled, structured access reflects a "reality based" approach. The challenge is to balance the benefits of opioids alongside the harms, primarily opioid related overdose deaths, infectious diseases, and opioid use disorder. Our proposed model – which accounts for these realities – is informed by work conducted by the Canadian Public Health Association (Canadian Public Health Association, 2014) and the Health Officers Council of BC (Health Officers Council of British Columbia, 2011). It further draws on lessons learned from the regulation of alcohol and tobacco, which informed public health-based cannabis (Haden & Emerson, 2014) and psychedelics regulation (Haden et al., 2016). Such an approach is already being implemented in Canada with respect to cannabis, and to varying degrees, in many US states, and in Uruguay (Rolles & Murkin, 2016).

Principles

Our proposed model is grounded in principles of promoting public health and reducing harm, safeguarding "vulnerable" populations, supporting human rights, and facilitating participatory democracy (Moore, Wells, & Feilding, 2019). Specific to opioids, these principles guide acknowledgement that legitimate non-medical use of opioids will be a feature and must comprise access to a wide range of opioids of varying concentrations and with different modes of consumption. Moreover, incremental, increasing levels of control need to be implemented for products as the risk profile/concentration increases. Health system capacity and prescriber competence to support patient use of opioids, as well as their use of non-opioid medications and non-pharmacologic methods of pain management are needed. Additionally, identification of and treatment for opioid use disorder needs to be better supported. This could take the form of enhanced professional education on these topics, alongside health system changes to improve access and quality of mental health and substance use services.

Control structure

Governance of this proposed new system would be undertaken by government directly or by a government empowered control structure, such as a Psychoactive Substances Commission (i.e., the Commission), guided by a public health-based vision and related principles, goals and objectives. This oversight would extend to all aspects of opioid production through to distribution and patient management (i.e. poppy cultivation, importation, distribution, retail and sanctions for those operating outside the defined parameters). Careful attention to the construction and representation of the challenges to be addressed will be essential to designing effective and impactful solutions

(Ritter, Lancaster, & Diprose, 2018). Further, while the system of controls could build on the mechanisms utilized for the regulation of other substances, such as MDMA (Moore, Wells, & Feilding, 2019) or new psychoactive substances (Feilding & Singleton, 2016), the Commission would explicitly draw on the latest scientific evidence and would be required to adjust policies based on specific population health status indicators (e.g. overdose hospitalization and death rates, opioid use disorder, communicable disease related to consumption practices).

Access models

Our proposed models recognize the importance of accounting for both medical and non-medical use of opioids. As such, medical oversight will be retained for opioids prescribed for treatment of conditions such as acute pain, chronic pain, as appropriate), and opioid use disorder (Chou et al., 2015; Nielsen & Bruno, 2011). Use without medical oversight will also be permitted.

Medical access model

In this model physicians will continue to prescribe a range of opioids for pain management based on evidence of effectiveness and safety, as well as long-term opioid maintenance for patients who have developed an opioid use disorder. Medication assisted treatment of opioid use disorder will include a wide range of opioid products such as methadone, buprenorphine, slow release oral morphine, diacetylmorphine and hydromorphone. These prescribed medications will be accompanied by psychosocial support, tapering and withdrawal management, outpatient and/or residential treatment. Prescription monitoring programs will also be a key component (Dormuth et al., 2012). To address the full continuum of care needs for people with opioid use disorder, recovery services must also be enhanced (Amato et al., 2005; Oviedo-Joekes et al., 2009; Strang, Groshkova, & Metrebian, 2012). Interdisciplinary teams of physicians, nurses and nurse practitioners as well as allied health professionals will contribute to expert risk assessment and assistance with the management of problematic use. Because of the high correlation between trauma and substance use disorders, including opioid use disorder, the model must be guided by a trauma informed approach to treatment and recovery services (Mate, 2009). Adequate pain management programs and services would be integral to a functional system.

Non-medical access models

Incorporating non-medical access into the model is critical and means that adults could legally purchase opioids or grow poppies to produce opium and extracts for personal use without needing to access opioids through a prescription process.

To minimize harms, there is a continuum of restrictions that could be placed on non-medical purchasing of opioids, the choice of which would depend on jurisdictional specific factors. Thus, we provide three possible approaches for consideration. The first approach requires people to obtain either a basic or advanced purchase licence to obtain opioids; the second approach allows people to purchase opioids if they have obtained a purchase authorization card; and the third approach allows any adult to purchase opioids, but has a system to restrict purchase by people who develop problematic patterns of opioid use. These three models are detailed in the following sections.

Model #1: License to Purchase

This model prioritizes the serious health consequences – for oneself and others – of opioid use. It is comprised of opioid use education and competency building and would operate to ensure that use is well controlled.

To achieve this, adults who want to consume opioids for non-medical use would need to obtain either a basic or an advanced government issued purchase licence. To obtain a basic licence, an individual would participate in training in assessing risks as well as harm reduction (i.e., safer use practices). The basic education program would include information about pharmacology, precautions, risks, lower risk use, overdose prevention and response, safe storage, legal obligations, warning signs of problematic use, and where to obtain assistance if concerned about use patterns. The participant would have to pass a knowledge test prior to obtaining approval to make a purchase or produce products for personal use.

With a basic licence, individuals would be allowed to purchase either weak opioid products (e.g. poppy seeds, dried poppy pods and stems, poppy tea, opium, and low concentration pill formulations to use at home). An individual who wants to use higher concentration opioids for non-medical purposes at home or in other non-supervised settings would need to take an advanced education course that would include information about inhalation and injection risks and harm reduction methods. Such individuals would then graduate to an advanced licence by meeting criteria such as possession of a basic licence for two years without criminal involvement, have no convictions for driving while impaired, have stability (e.g. have stable housing, be employed or be a regular volunteer or student), and be able to identify at least one person who will be present when they are using the product in a higher risk fashion. Purchasers would have to show their licence and identification as part of their purchase, and retailers would check the database as part of each purchase transaction. An individual would lose their basic or advanced licence if they became criminally involved (e.g. assault, selling to others, etc.), were found to be driving or operating machinery while impaired, or developed an unstable opioid use disorder which required supervision of use (i.e. lack of consistent dosing and significant negative life consequences).

Individuals who lose their licence could be offered opioids under medical supervision where the dosage is more closely monitored. They would be able to reapply for a basic or advance licence upon obtaining an opinion from an expert in opioid use disorder that the person would be able to safely self-manage use. Medical buy-in for this role will have to be a component of this model. An additional feature of this model would be to allow people who develop problems with opioid use to self-register in the database that would be part of a self-exclusion program, like those that operate for people with problematic gambling conditions. This could be extended to mandatory registration in such a database for people with severe opioid disorder, but caution would have to be exercised to avoid them returning to the illegal market to avoid state surveillance of their activities. Recognizing that many current users of opioids who are dependent on the illegal market would not meet the criteria of this licensing program, and that shifting these users to the regulated market will be an important strategy to undermine the illegal market, special transition arrangements will need to be made to accommodate them into the new system.

Model #2: Purchase Authorization Card

This model prioritizes the recognition that as most people can moderate their own use of substances, including opioids. This is based on the observation that perception of drugs as a “cause” of problematic substance use, is a widely held misperception. This belief was challenged over 4 decades ago by Alexander and colleagues (Alexander et al., 1981; Alexander, Coambs, & Hadaway, 1978). Specifically, these researchers demonstrated that rats kept in cages characterized by an ideal social and physical environment developed behaviours indicative of a substance use disorder at rates much lower than rats who were isolated in small and unstimulating cages. This work was later replicated by others (e.g., Bezard et al., 2003; Xu, 2007; Whitaker et al., 2013). The understanding that drugs themselves do not cause substance use disorder has also been demonstrated in humans. In studies exploring outcomes of soldiers

returning from Vietnam, researchers found very low risk of persistent addiction to heroin upon return to United States, with treatment playing a negligible role (Robins et al., 2010; Robins, 1993; Robins, Davis, & Goodwin, 1973).

In this model limited government oversight and intervention is warranted. This is in recognition of the fact that most people who use drugs do not develop problematic use, that problematic use is determined by many factors that may or may not warrant government intervention and the criminalization of some substances is an important determinant of harms.

As in model 1, model 2 adults who want to consume opioids for non-medical use would need to take a basic or advanced education program about opioid use. The individual would have to pass a knowledge test, which would result in a third party (non-government) agency providing them with a purchase authorization card. To protect privacy, personal information collected by the educational agency would be prohibited by law from disclosing personal information to anyone, including disclosure to the government. As a further privacy safe-guard, government would be prohibited from collecting personal information from the educational agency about people who take the course.

With a basic purchase card, individuals would be allowed to purchase weak opioid products (e.g. poppy seeds, dried poppy pods and stems, poppy tea, opium morphine, and low concentration opioid pill formulations). Purchasers would have to show their purchase card and identification as part of their purchase, and retailers would verify that the card is authorized with the card database as part of each purchase transaction. To protect privacy, no product purchase information would be linked to the personal information on the card. An individual who wants to purchase higher concentration opioids for non-medical purposes would need to complete an advanced course and meet the criteria mentioned in model 1.

Like the principal of "innocent until proven guilty", individuals would be allowed to freely pursue their use of opioids unless they developed patterns of use that become a threat to their health or the health or safety of others. In such a circumstances, the Commission would be notified, and the purchasing card could be de-activated after following an appropriate process that would include allowing the person to appeal such an action.

A purchasing card could be deactivated if an individual became criminally involved related to substances (e.g. selling to minors or others who do not have a purchase card), was found to be driving or operating machinery while impaired, or developed an unstable opioid use disorder which required supervision of use. Individuals whose card is deactivated would be referred to the medical access system and offered opioids under medical supervision. They would be able to reapply for a purchase card upon obtaining an opinion from an expert in opioid use disorder that they would be able to safely self-manage use.

Model #3: Exclusion if Problematic Use

This 3rd model is similar to model 2, except that while education courses would be readily available, they would not be required. Individuals could freely pursue their use of opioids unless they developed patterns of use that become a threat to their health or the health or safety of others. Such individuals would be referred to the medical access system and offered opioids under medical supervision.

In such circumstances, the Commission would be notified and the person would be registered in a problematic opioid use database following an appropriate process that would include allowing the person to appeal such an action. They would be able to reapply for removal from the database upon obtaining an opinion from an interdisciplinary expert team that they would likely be able to safely self-manage use.

Purchasers would have to show an official government identification card as part of their purchase, such as a driver's license or healthcare card. Retailers would use the card to verify that the person is not under supervised health care for problematic opioid use by cross referencing the identification against a database of people with problematic opioid use. To protect privacy, no product purchase information would be linked to the personal information on the card. As above, people could self-register in the database as part of a self-exclusion program. Again, special transition arrangements would be made for current users of opioids who are dependent on the illegal market.

For each of these models, measures would need to be in place to accommodate certain groups – including those who are marginalized and engaged in opioid use associated with significant harms. Without such measures the illegal market may continue to flourish. Factors to consider in analysing these models include the bureaucracy/cost, privacy risks, barriers to purchase, and purchaser acceptability. See Table 1 for Purchase Model Comparison.

Availability, accessibility and price

In terms of availability, accessibility and price, opioids would only be sold at outlets licenced or operated by the Commission, which could include existing pharmacies. Such outlets would be carefully regulated according to public health objectives. They would also sell paraphernalia such as vaporizers as well as harm reduction supplies (e.g., syringes, cookers, naloxone). Only people beyond a specified age (e.g. 19–21 years and older) would be allowed to purchase opioid products. Minimum price regulations and taxation policies would be used to influence cost, ensuring that they are appropriate so as to not act as an incentive. Prices would need to be flexible and responsive to prices observed in the illegal market, for competetive purposes. Retailers would have to achieve certification in providing basic pain management and opioid dispensing advice, as well as in emergency overdose treatment.

Purchase, consumption, and use controls

In terms of purchase, consumption and use controls, strict rules would be instituted on purchase quantities, putting limits on the amount that could be purchased/dispensed at one time. Rules against public smoking of opioids and opioid impaired driving would be enforced.

Supply control

Production

People would be allowed to grow their own poppies and home-make products for personal consumption, but would not be allowed to provide or serve homemade products to others. Commercial production (growing and processing) as currently happening would continue to be strictly regulated according to product and production standards for both medical and non-medical use. While current pharmaceutical industry producers would continue to be a source of opioids, due to the non-medical aspects of this approach, opportunities for producers of other products for non-medical use would arise. Production, distribution, promotion and retail sales would continue to be closely tracked and reported to government monitoring agencies. This is similar to what happens with medical and non-medical cannabis production in Canada, and is also the approach with other potentially hazardous products such as food, liquor, fuels and chemicals.

Many public health problems are determined by social and economic factors (Commission on Social Determinants of Health, 2008), of which a significant determinant of health is unequal wealth distribution (Pickett & Wilkinson, 2009). An equitable approach to the distribution of opioid-related wealth that supports small-scale growers and producers and prevents concentration of wealth by large corporations would be implemented. Such an approach is consistent with egalitarian public health objectives (World Health Organization, 1986). Those who formulate opioid policy would need to be alert to the potential for regulatory capture (Carpenter & Moss, 2014) and other pressures such as large corporations attempting to economically exploit the legitimization of the

Table 1
Purchase model comparison and relative proposed weighting.

Model	Bureaucracy/Cost	Privacy risks	Barriers to purchase	Purchaser acceptability
1. License to Purchase	High	High	High	Low
2. Purchase Authorization Card	Medium	Low	Medium	Medium to Low
3. Exclusion if Problem Use	Low	Medium	Low	High to Medium

opioid trade and subsequently exert profit-motive-driven pressure on weakening public health policy related to opioid control. Attention to the risk of exploiting "vulnerable" people will also need to be a feature, as has been seen in the medical/pharmaceutical commercialization of opioids.

Product

All commercially produced products would be subject to standard consumer protection quality assurance and manufacturing processes.

Demand reduction

Demand reduction was a key feature of the report of the Task Force that provided recommendations to the Canadian government on cannabis legalization (Task Force on Cannabis Legalization and Regulation, 2016), and which were subsequently implemented (Crépault, 2018; Government of Canada, 2020). Provision of information, such as labeling about the constituent ingredients, concentration, use instructions, prominent warnings, and health promotion material on harms and benefits would be required by producers and warnings would be prominently displayed by retailers. Health information about pain therapy options would be readily available, including alternative and complementary pain management information. Products would be non-branded in plain packaging. All product promotion such as branding, advertising, product placement, celebrity endorsement and sponsorship would be banned, as would product promotion to all health care professionals. Lower risk use guidelines would be part of the training and would be easily available and accessible in multiple languages.

Health promotion

Health promotion is an evidence-based approach to enhancing health outcomes that supports people and populations in increasing control over their health as elaborated in the *Ottawa Charter for Health Promotion* (World Health Organization, 1986). A health promotion orientation should be a fundamental underpinning to developing a public health approach to opioid regulation. The Charter outlines prerequisites for health as including peace, shelter, education, food, income, a stable eco-system, sustainable resources, social justice and equity. A key theme is "coordinated action by all concerned". To achieve such aims, evidence-informed public and school-based education about harms and benefits of opioids would need to be the norm (Tupper, 2014), as fear-based programs are ineffective (UNODC, 2015). Similarly, fear-based media campaigns aimed at the general public would not be supported, as such drug prevention approaches are also of dubious merit (Werb et al., 2011). Education would also include instructing about the links between problematic substance use and socioeconomic and legal drivers of harms.

Targeted health promotion programs such as ensuring adequate housing, income, and nutrition for marginalized members of society, adverse childhood event prevention, anti-stigmatization and anti-discrimination programs, and equity promotion programs would also be key. The revenue raised from a regulated market could be tagged for use to support these measures or deposited into general revenues for redistribution, depending on the government's revenue policy.

Harm-reduction

Harm-reduction includes pragmatic approaches that aim to reduce adverse consequences of substance use without requiring abstinence. Harm reduction includes measures such as low risk use guidelines; needle, pipe and other harm reduction supply distribution programs; supervised consumption services; and street drug testing programs (BC Ministry of Health, 2005). As the illegal market will continue to exist, at least at the initiation of the change, harm reduction services would need to be available and accessible.

Emergency preparedness and response

Within the current research there is overwhelming support of take-home naloxone programs being effective in preventing fatal opioid overdoses (Chimbar & Moleta, 2018). Naloxone would be widely available and inexpensive, for anyone to purchase, at regular pharmacies and all facilities where opioids are sold for take home use.

Population health monitoring, research and evaluation

Rigorous evaluation will be integral to monitoring for potential harms and unintended consequences. This should be done on a pre-agreed timetable and with reference to the model's aims, outcomes, and indicators. Baseline measures of opioid related harms and monitoring for changes will be critical for early detection of unanticipated effects and course correction. Close monitoring of the industry, supply chain, tracking purchasing patterns, and monitoring for potential adverse consequences will provide assurance that the regulated market is developing as predicted, that access by youth is being controlled, that harms are being minimized, and that anticipated benefits are accruing. Planning for necessary and potentially urgent course correction will be needed in the case that the market does not develop and shift as predicted.

Conclusion

Both prohibition and medical/pharmaceutical commercialization of opioids have failed to protect or improve health and social outcomes for people who use opioids and their communities. Additionally, these approaches are associated with substantial adverse consequences. Our vision is for a public health-based approach to the management and regulation of opioids. Such a vision is critical to enabling creative thinking about how to achieve practical solutions to a complex and deadly problem (Emerson & Haden, 2017). Part of getting the vision right will include accommodating and not further harming individuals, families, and communities who rely on the illegal market for their livelihood. Furthermore, strategies to address those who are dealing with the effects of being criminalized and considering reparations for those that have been adversely affected by the prohibition policies (e.g. those who have a criminal records or have been harmed by being incarcerated) will also be required.

Building from these three proposed models can assist jurisdictions around the globe in designing systems for their particular circumstances. Moreover, the implementation of these models will support health protection, health promotion and human rights; effectively undermine the illegal market in favor of a quality controlled, regulated system of opioid access and control; de-stigmatize people who choose to use opioids; and

work synergistically with effective pain management and problematic substance use treatment systems to ensure better outcomes for individuals, families, communities and the broader society. Only with significant systems change and approaches involving the legal regulation of opioids will the current and profound morbidity and mortality of the "opioid crisis" abate.

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Disclaimer

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Declarations of Interest

None.

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