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What lessons from Europe's experience could be applied in the United States in response to the opioid addiction and overdose crisis?

Major differences exist between the United States and Europe regarding opioid-related morbidity and mortality. Regulatory restrictions, drug policy measures and large-scale implementation of proven-effective opioid dependence treatments and harm reduction strategies are advocated to effectively tackle the opioid crisis in the United States, using successful examples practised in Europe.

The United States faces an opioid epidemic, with 91.8 million (37.8%) adults using prescription opioids (POs), 11.5 million (4.7%) adults misusing POs, 1.9 million (0.8%) people suffering from a PO use disorder in 2015 and 49 860 opioid-related deaths (ORDs) in 2019 [1,2]. Initially, the increase in ORD was mainly due to POs, but since 2010 ORDs are mainly due to illicit heroin, and since 2014 to illicitly manufactured fentanyls (IMFs). Regulatory measures in the last decade decreased the availability of POs and patients who were meanwhile dependent upon POs shifted to heroin and later IMFs. Currently, IMFs are involved in about 75% of all ORDs in the United States.

Although in western Europe PO consumption increased by almost 40% between 2005 and 2015 [8967 daily defined doses (DDDs)/million per year in 2015], it remained only approximately half of the US volume in 2015 (16 491 DDDs/million per day). However, this increase in PO consumption was paralleled by a stable, relatively low number of 8000 ORDs (mainly heroin and methadone ORDs) in Europe (16/million), which is almost 10 times lower than in the United States (156 ORD/million) [3]. Overall, Europe is not experiencing an opioid overdose crisis, with Scotland (and, to a lesser extent, England, Wales and Northern Ireland) as the exception. In Scotland, the rate of 206 ORDs/million is even higher than in the United States [4–6]. This high rate of ORDs in Scotland was driven by a high number of problematic opioid users, a high frequency of polydrug use, particularly opioids with illicit benzodiazepines and the relatively low coverage and limited efficacy of the addiction treatment system [7].

A comparison of Europe and the United States shows that the following differences may explain at least some of the differences in PO consumption and ORDs: (a) regulation of prescription drugs with more short treatments without automatic refills in Europe, (b) availability of illicit drugs with no IMFs available in most European countries, (c) pharmaceutical advertising with no direct-to-consumer advertising in Europe, (d) attitudes about medical use of POs with more psychological pain management strategies instead of opioids as

a remedy for pain problems in Europe, (e) law enforcement with depenalization of possession of opioids for personal consumption in most European countries, (f) national drug policy with more emphasis on public health and harm reduction in Europe, (g) regulatory frameworks for pharmaceutical drugs with prescription drug monitoring programmes (PDMPs) to prevent doctor-shopping in most European countries and (h) opioid dependence treatment with higher availability, better accessibility and full financial reimbursement of addiction treatments, including different forms of opioid agonist treatment, in almost all European countries [8.9].

To reduce the number PO-prescriptions and iatrogenic opioid addictions in the United States, regulations should be developed that restrict such prescriptions for acute pain and chronic pain for chronic non-cancer pain only, provided that all patients receive adequate pain relief. Moreover, POs, preferably in abuse-deterrent formulations, should generally be prescribed for short periods with no automatic refills. PDMPs effectively limit doctor-shopping and diversion of POs, but only if prescriber access is mandatory. However, these measures may have the unintended consequence that those with an opioid use disorder move to illicit opioids (e.g. IMFs), potentially increasing the number of ORDs.

To reduce the number of ORDs, illicit opioid consumers must gain access to drug-testing services and free naloxone take-home kits and supervised consumption rooms, further facilitated by de-penalization of possession and consumption of illicit opioids. As evidence-based treatments are highly underutilized in the United States, high-quality addiction treatment services should become available, with full financial reimbursement, offering both abstinence-orientated treatments and opioid agonist treatments with methadone, buprenorphine and—for non-responders—injectable heroin or hydromorphone [10].

A prerequisite for any successful strategy to end the opioid crisis is sufficient funding. In 2021 an important \$945 million NIH initiative was launched: 'Helping to End Addiction Long-term' (HEAL) to speed scientific solutions to stem the national opioid public health crisis. Although important, this initiative will not offer direct solutions for the current crisis, whereas immediate implementation of prescription regulations and financial support for evidence-based addiction treatment and harm reduction services would almost certainly slow down or even (partly) resolve the opioid crisis in the United States and Scotland. Furthermore, most opioid dependence cases and ORDs occur in those who are either uninsured, unemployed or have a low income [1,7]. This calls for better health insurance plans and reduction of social, ethnic and financial inequalities: important tools to reduce

opioid dependence and ORDs and, more generally, to improve public health and social wellbeing. Finally, we would like to note that, like the United States and Scotland, Canada also experiences a serious opioid crisis, even though it has universal health care, better access to (imperfect) treatment and harm reduction services and less social and financial inequalities than the United States, suggesting that only a simultaneous implementation of a combination of measures, with emphasis on harm reduction strategies to counter the devastating effects of IMFs, can eventually resolve the opioid crisis in these constituencies.

KEYWORDS

Harm reduction, non-medical use, opioid crisis, opioid-related mortality, opioids, oxycodone

DECLARATION OF INTERESTS

Wim van den Brink was a consultant for Indivior and still is a consultant for D&A Pharma, Camurus, Opiant Pharmaceuticals and Clearmind Medicine. M.P. and J.v.A. have no disclosures to make.

AUTHOR CONTRIBUTIONS

WvdB conceptualized the paper and provided further comments. MP added some issues and provided further comments. JvA wrote the first draft and provided further comments.

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What policies the US Food and Drug Administration should pursue in response to the addiction and overdose crisis

The FDA should focus more intensive efforts to conduct evaluations and post market studies to inform regulatory policies like REMS, label changes, and abuse deterrent formulations.

We begin 2022 with an opioid epidemic that is still out of control, as evidenced by more than 100 000 overdose deaths in the 12 months ending in May 2021. Litigation that assigns blame for the carnage is ongoing throughout the nation [1]. What is clear is that the