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Where Next for Opioids and the Law? Despair, Harm Reduction, Lawsuits, and Regulatory Reform

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It is difficult to overstate the severity of the opioid crisis in the United States. The Centers for Disease Control and Prevention (CDC) estimates that at least 64 000 people died of drug overdose in 2016,[1] more than the historical mortality peaks of human immunodeficiency virus, car crashes, or guns.[2] The annual number of deaths from drug overdose is so high that, in 2015, life expectancy in the United States declined,[3] the first decline since the peak of human immunodeficiency virus mortality a quarter-century ago.[4] Even as communities, policy makers, and health workers struggle with the trauma of the opioid crisis, increased demand, globalization, and chemistry have changed the illegal opioids market for the worse, creating what will probably be a long-term niche for the counterfeit pills and fentanyl analogues that are now powering overdose deaths.[5,6]

CDC began to take notice of the increasingly dramatic rise of overdose mortality at least 15 years ago.[7,8] At this point, epidemiologists were themselves only catching up with harm reductionists, who had faced heroin overdoses for years at syringe-exchange programs and had, among other things, developed the take-home naloxone intervention.[9] Legislators were, like most Americans, slower to catch on to the problem. New Mexico, facing an epidemic of rural heroin overdose, created a take-home naloxone law as part of a comprehensive package of harm-reduction legislation that went into force in 2001. However, the legislation was in response to heroin, not to prescription opioids, and by 2009, only California, Connecticut, and New York had followed New Mexico's lead.[10] The opioid issue hit the policy agenda substantially only during the current decade, but by 2017, every state allowed some form of lay administration of naloxone. By 2016, 37 states also had enacted Good Samaritan immunity for people seeking emergency help for an overdose.[11] Modernization and strengthening of prescription drug monitoring programs (PDMPs) also became a priority, as these programs spread from 13 states in 1998 to 49 states and the District of Columbia by 2014.[12]

Lawmakers have been busy, but has their legal work been effective? That is harder to say. Research in the past few years shows positive effects for some laws: PDMP laws,[13,14] pill mill laws,[14,15] and hard-to-evaluate Good Samaritan and naloxone laws.[16-18] Some studies suggest that expanded access to medical marijuana could be helping through substitution of marijuana for opioids.[19,20] However, the evidence is emerging slowly and piecemeal, mostly examining interventions one at a time in settings where many things are going on at once. Even if these high-profile policies do have an impact, there is no indication that they have the same impact as better access to care for opioid dependency.[21] Congress has helped in providing better access to care through the Patient Protection and Affordable Care Act's insurance expansion and mental health parity provisions[22] and, in 2017, through the 21st Century Cures Act.[23] Funding, along with the Obama administration's moral support, helped more people than before gain access to medication-assisted treatment with methadone and buprenorphine, the often stigmatized but still best-evidenced treatment for opioid dependency.[24]

So far, then, it looks as if law has reduced the damage but not turned back the tide. Given that most states now have adopted some version of Good Samaritan, naloxone access, and PDMP laws, where do lawmakers go next?

Focus on Despair?

In theory, lawmakers could turn their attention to deeper socioeconomic drivers. The much-discussed work by Case and Deaton reaffirms the direct and proximal causal impact of opioid abuse on American health, with an important twist.[25,26] In their analysis, Case and Deaton analyzed the decline in US life expectancy powered in part by opioids, but

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also by suicide and alcohol abuse, all reflecting a profound social alienation in the working and middle classes. They argued that these deaths are "deaths of despair" among people who have lost out in the economic changes of the past 50 years—lost out to the globalization of industrial production and technological change but also in their experience of growing inequality. Life for the top 20% is better than ever, but public schools, colleges, parks, transportation systems, roads and bridges, and overall collective investment in planning and support have been neglected. Less affluent people in great swaths of the country have increasingly been left to their own devices as dramatic economic changes have overtaken them and, slowly but surely, the effects of lost hope and reduced social cohesion and opportunity have manifested in the mortality tables. Ethnography[27] and work by Chetty et al,[28] which shows a pattern of declining opportunity and shorter lives for less affluent Americans, reinforce this interpretation.

The idea that underlying social conditions express themselves in population health is not new. From Durkheim's book in 1897 on suicide[29] to the landmark 2008 report of the World Health Organization's Commission on Social Determinants of Health,[30] mounting evidence indicates that the conditions of daily life are the deep drivers of the level and distribution of health. Case and Deaton's thesis stands on this tradition, but the authors doubt that any simple causal relationship exists between rising inequality and rising mortality among those who have lost out in the changing economy. Economic factors, they state,

> work through their effects on family, on spiritual fulfillment, and on how people perceive meaning and satisfaction in their lives in a way that goes beyond material success. At the same time, increasing distress and the failure of life to turn out as expected is consistent with people compensating through other risky behaviors such as abuse of alcohol and drug use that predispose towards the outcomes we have been discussing.[25(p45)]

The "deaths of despair" idea may or may not prove to be true from an epidemiologic and demographic point of view,[31] but it has legs as a policy meme. The *American Journal of Public Health* recently published several articles on the topic,[32] and it now comes up regularly in opinion editorials and blogs. The hard part here is thinking of a viable legislative agenda driven by a social determinants of health assessment. Legislation has a bias toward addressing immediate causes. For example, substantial evidence and plausible policy remedies for the nation's poor showing on infant mortality have not led to substantial investment in better lives for children.[33-35] Proponents of addressing social determinants of health face this problem any time they propose legislative action, and they face it with opioids. It seems to be both politically and culturally easier for Americans to see substance use as a poor choice than as a symptom of social injustice or mismanagement. Talking about despair as a policy problem asks legislators to agree that substantial economic inequality is, in itself, a bad thing and then to take their concern about inequality into questions such as how much the tax code should reduce post-tax income inequality; how much of the new revenue to devote to better schools, access to college, and other social investments; and whether and how legislative power can be used to support stronger families and communities. It is a great debate to start having; however, while it develops, several important legal questions appear on the opioid policy horizon. Although these policies do not take on the roots of despair, they do start to get at some legally neglected structural factors in the opioid crisis.

Going After Pharmaceutical Makers

New lawsuits from cities and states may take aim at structural factors that Congress refuses to touch. At least 25 cities and states have filed lawsuits against opioid manufacturers since the start of 2016, and more are actively investigating new cases.[36] These lawsuits, which echo the strategy that produced the tobacco Master Settlement Agreement, are built around claims of civil liability for fraudulent, negligent, or reckless marketing behavior, but their ultimate legal merits may not matter. The litigants will press for a settlement and, as in the earlier tobacco litigation, the plaintiffs could get the defendant companies to agree to remedies that legislators have been unwilling or unable to enact. In a settlement, pharmaceutical manufacturers could voluntarily agree to forgo consumer-directed marketing for opioids and better educate citizens and physicians on risks. A settlement could even take on the cost of naloxone. Opioid manufacturers could agree to produce more of the drug, at affordable prices, or could contribute substantial sums to a fund to offset the costs that governments and private organizations are facing. The defendants could even agree to pursue, and pay for, the development of an over-the-counter formulation. None of this would require an admission of any wrongdoing or action by Congress or the US Food and Drug Administration.

Doubling Down on Harm Reduction and a Public Health Drug Policy

Naloxone and Good Samaritan laws emerged from the harm-reduction experience, which has not always been beloved by legislators across the 50 states. Likewise, the somewhat warmer political embrace of methadone and buprenorphine is a departure from the old line that these evidence-based treatments merely replace one addiction with another. Overall, the opioid epidemic seems to have contributed to a more open and broader discussion of treating problematic drug use as primarily a health problem rather than a law enforcement problem.[24]

Many legal opportunities, large and small, will arise for a wider adoption of models such as Law Enforcement Assisted Diversion[37] that mobilize police officers to directly divert drug users from jail into health care as well as for

maintaining the pressure on drug court judges to allow and even encourage methadone and buprenorphine.[38] One of the most interesting issues, though, is the deployment of medically supervised drug consumption programs, most commonly referred to as safe injection sites. Safe injection sites, which have almost 2 decades of evidence and overseas experience behind them, reduce communicable disease and wound infections (through provision of sterile consumption equipment and facilities) and drug overdose deaths (through rapid diagnosis and treatment).[39] Several cities, including Boston, New York, Philadelphia, San Francisco, and Seattle, have taken at least some steps to consider the idea. In Seattle, a task force recommended the launch of safe injection sites, and at least 1 underground safe injection site is operating.[40]

One might think of a safe injection site as a syringe-exchange program with chairs and, legally, the 2 interventions pose similar challenges. As with syringe-exchange programs in their early days, often no state law explicitly forbids safe injection sites, but numerous drug control laws could be construed to do so.[41] Also, as with syringe-exchange programs, early adopters, despite having good science on their side, are worried that they could be prosecuted if they launch the intervention. The development of safe injection sites seems slowly to be following the syringe-exchange program playbook: first, underground sites, then city-level action, coupled with advocacy for enabling legislation at the state level (already considered in California and Maryland). A medical marijuana parallel also exists; probably the law most obviously interpreted as a barrier to safe injection sites is a provision of the federal Controlled Substances Act that was passed to deal with rave parties and crack houses.[42] Will the federal government intervene if states or cities authorize safe injection sites? It is as much a political question as it is a legal question.[43]

More investment in a public health, harm-reduction approach makes sense given the evidence of what works, but there is every reason to expect that actual policy will be more mixed. The first report from the President's Commission on Combating Drug Addiction and the Opioid Crisis was focused on public health approaches.[44] In contrast, Attorney General Sessions has taken steps to reverse the less penally oriented approach of the Department of Justice under the Obama Administration, ordering federal prosecutors to pursue longer sentences for drug cases. With the additional pressure of illicit fentanyl, some commentators fear a return to counterproductive but resonant tough-on-drugs policies.[45]

Better Regulation of Treatment

With help from researchers and the press, more attention will be paid to how cities, states, and the federal government regulate drug treatment. On the one hand is the question of how difficult it should be to get evidence-based methadone and buprenorphine. The rather amazing fact remains that there are more regulations on methadone and buprenorphine than there are on prescribing opioid drugs. Congress recently increased the number of patients whom certified buprenorphine prescribers can treat, but both buprenorphine and methadone are still regulated more than most prescription drugs.[46] States also regulate methadone clinics, and even cities can get involved through land-use restrictions that potentially allow not-in-my-backyard limits on clinics. The impact of these regulations on access to treatment and success has not been evaluated, so it is possible that they do not actually cause harm. However, overall, a world in which methadone and buprenorphine is more accessible would surely also be one in which opioid morbidity and mortality were lower.

On the other hand is the problem of bad treatment. More funding for drug treatment has attracted unqualified or unscrupulous providers into the largely unregulated world of residential treatment programs, sober houses, and other modes and facilities that do not deploy methadone and buprenorphine. Given the life-or-death stakes and the amount of public and private insurance money at stake, several states are beginning to look at better regulations or better enforcement of regulations to prevent fraud and abuse.[47] Preventing fraud or abuse will require policy makers to potentially define what counts as quality treatment and to take on an industry that does very well by the status quo.

Conclusion

The United States has seen a vigorous legislative response to the opioid epidemic, but legislators are running out of easy targets as the most popular ideas are adopted in all the states. Meanwhile, the epidemic is taking a bigger toll. No realist would foresee social or political consensus any time soon on the roles of inequality, despair, and their structural determinants in the crisis; however, there is a huge reservoir of compassionate concern that cuts across parties and ideologies. Safe injection sites and other harm-reduction measures, better access to more effective drug treatment, and safer marketing of opioid medicines are all viable ways to act on that compassionate concern. Although these measures will not get at root causes, they will certainly soothe a lot of despair.

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