Letter to the Editor

To the Editor:

While the epidemic of opioid-related harm continues to devastate families and communities, nearly 4 in 5 Americans with opioid use disorder (OUD) do not receive evidence-based treatment for their condition.[1] Draconian restrictions on access to opioid agonist treatment (OAT) with methadone and buprenorphine contribute significantly to this distressing reality.

In this context, we read Mund and Stith's recent article with great interest. **[B. Mund and K. Stith, "Buprenorphine MAT as an Imperfect Fix,"** ***Journal of Law, Medicine & Ethics*** **46, no. 2 (2018): 279-291.]** Based on its title, we assumed the authors would provide a roadmap for reducing this treatment gap, as nearly every major medical and public health organization has recommended. Although reasonable minds can differ on the best legal and regulatory levers for increasing access to these life-saving medications, we were dismayed to discover that the piece travels the opposite road, lending credence to a litany of straw-man arguments and overblown fears.

The authors note that some people may misuse methadone and buprenorphine, that such misuse is sometimes associated with negative outcomes, and that the medications do not work for everyone. All of this is true. This framing, however, misses the fundamental question: whether increased access to OAT would be an improvement on the status quo.

The answer is a resounding yes. Numerous studies, reviews, and expert panels have concluded that OAT works. It reduces all-cause and opioid-related mortality in opioid-dependent individuals, often by 50% or more.[2] It also reduces the risk of relapse, needle sharing, injecting drugs, and similar behaviors. As HHS Secretary Alex Azar recently noted, treating OUD without medication is "like trying to treat an infection without antibiotics."[3]

Other concerns raised by the authors are either greatly exaggerated or entirely unsubstantiated. They repeatedly reference Finland, a small, Nordic country where heroin is both expensive and rare. However, France, in our view, offers a better corollary. In 1995, France lifted many of the regulatory restrictions previously applicable to buprenorphine. While diversion did increase, treatment retention increased, heroin use decreased, and opioid overdose deaths declined by 79%.[4] We consider that an eminently reasonable tradeoff.

They also claim that effective OAT requires "additional interventions" such as "behavioral or psychosocial therapies," and vilify providing buprenorphine without them as "unfair, even cruel." This is dogma, not science. Although behavioral interventions should be available to all who need or want them, little evidence suggests they improve health outcomes and incontrovertible evidence demonstrates that OAT is effective without them.[5] Refusing OAT to individuals because they cannot access other services is unethical, immoral, and antithetical to evidence-based policymaking.

Methadone and buprenorphine are proven to reduce harms associated with OUD, but are subject to many more restrictions than the prescription opioids partially responsible for causing the condition. Indeed, even the *exact same* medications (methadone and buprenorphine) are subject to far fewer restrictions when prescribed to treat pain. Increased access to OAT has the potential to save tens of thousands of lives every year. We agree that buprenorphine is not a "miracle," but speculative concerns about potential harms should not impede quick and dramatic reforms to a legal regime founded on stigma rather than science.

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The Journal of Law, Medicine & Ethics, 46 (2018): 811-812. © 2018 The Author(s)
DOI: 10.1177/1073110518804248

Response by Brian Mund and Kate Stith

We hope your readers consult our actual article and not the misrepresentation presented in the letter by Davis and Carr. If they do, they will learn that we agree that "increased access to OAT would be an improvement on the status quo." But as we detail in our article, although buprenorphine can help save lives, it also carries real limitations and risks. So while Davis and Carr clamor for "quick and dramatic reforms," we feel compelled to urge "well thought-out, measured steps to increase access as well as ongoing evidence-based evaluation of the consequences of each stage of increased access."[1]

It would be a mistake to ignore the untoward consequences of Finland's rapid increase in the availability of this medication on the ground that this "Nordic" country has a far smaller supply of heroin than does the United States. Finland's experience demonstrates that if unchecked, buprenorphine can serve as a heroin substitute and expand the opioid-dependent population.[2] Likewise, we urge that policymakers here examine the experiences of Malaysia, the Czech Republic, India, Germany, New Zealand and the United Kingdom — all of which we also reference in our article.

We also considered France, where "studies have linked relaxed prescribing regulations for buprenorphine to a thriving black market."[3] We went on to herald that France was able to reduce this diversion by "increased prescription monitoring"[4] — a regulatory precaution about which Davis and Carr are curiously silent.

In our article, we did not suggest denial of OAT for those unable to access adjunct interventions. Rather, we urged that buprenorphine provision be accompanied by "behavioral or psycho-social therapies"[5] for "those patients"[6] who are high-tolerance opioid users. As we explained, administering buprenorphine alone puts these patients at risk of supplementing with heroin or benzodiazepines because of buprenorphine's ceiling effect[7] — a significant limitation on the effectiveness of buprenorphine (as opposed to methadone) for this sub-population.

We regret that Davis and Carr, while saying they agree with us that buprenorphine is not a "miracle" drug, nonetheless refer to its potential downsides and risks, which we document, as "overblown" and "speculative." All of the non-miracle aspects of buprenorphine that we examined are recognized in the scientific and public health literature that we cited, including the critical ceiling-effect and its implications (which Davis and Carr do not acknowledge).

Our bottom line: We need eyes wide open, with real-time risk assessments as access is expanded. We must address this devastating crisis in a manner that is non-dogmatic and — we agree with Davis and Carr — "eminently reasonable."

References

1. B. Mund and K. Stith, "Buprenorphine MAT as an Imperfect Fix," *Journal of Law, Medicine & Ethics* 46, no. 2 (2018): 279-291, at 286.
2. *Id.* at 282.
3. *Id.*
4. *Id.*
5. *Id.* at 286.
6. *Id.*
7. *Id.* and *id.* at 283.

The Journal of Law, Medicine & Ethics, 46 (2018): 811-812. © 2018 The Author(s)

https://doi.org/10.1177/1073110518804248 Published online by Cambridge University Press