Congress of the United States
Washington, DC 20515

August 17, 2020

The Honorable Stephen M. Hahn M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave WO1
Silver Spring, MD 20993

Dear Commissioner Hahn:

The COVID-19 pandemic is having a devastating impact on individuals, all facets of the economy, and has put significant strains on our healthcare system and on vulnerable populations, especially patients suffering from an opioid use disorder (OUD). According to a new report as many as 75,000 more people are projected to die from drug or alcohol misuse and suicide during the COVID pandemic[1]. As the nation grapples with the dual threats of the COVID-19 epidemic and the opioid epidemic, we are committed to ensuring patients can enter into and maintain their recovery.

However, in October of 2019, four State Attorney Generals (AGs) reached a $48 billion global settlement framework in which they allow one drug manufacturer to supply their medication assisted treatment (MAT) drug to the states for "free" in lieu of monetary compensation. The untested nature of this proposal and the possible unintended consequences that could result it if is adopted are very concerning. This approach could disrupt both the currently healthy and competitive MAT market and patients' treatment programs given this company supplies less than 1% of the MAT medication market today. Allowing one company to provide free drug to the entire patient population is taking a vitally important choice away from physicians and patients, tying their hands in choosing what is best for their treatment path based on patient-specific factors that can facilitate or deter medication adherence and recovery. Additionally, there are unanswered questions about how such a program could even be implemented and who would be responsible for ensuring its viability.

We are trying to better understand the implications of this proposal on patient access to MAT medications and respectively submit the following questions for your review, please respond as soon as possible:

1. What factors does the Food and Drug Administration (FDA) consider when determining which prescription drugs might be susceptible to a shortage?

2. What are the implications of a sole-sourced market, especially one that previously had multiple competitors in it? How does that effect the access to medication?

3. Does FDA need additional authority to ensure that this untested settlement provision does not disrupt patient care or result in shortages?

4. According to reports, OUD is rising again during the COVID-19 pandemic. Is this an appropriate time to disrupt the MAT medication market?

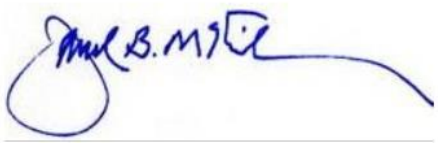
[1] Patternson, S., Westfall, J., Miller, B., (2020), Projected Deaths of Despair from COVID-19, retrieved on June 30, 2020 from https://wellbeingtrust.org/wp-content/uploads/2020/05/WBT_Deaths-of-Despair_COVID-19-FINAL-FINAL.pdf

Communities are working continuously to ensure that OUD patients have the tools needed to start and stay on a path to recovery despite the increased complexities and challenges associated with the COVID-19 pandemic. This includes difficulty accessing MAT and other SUD treatments.

We commend FDA's efforts, in combination with Congress's ongoing efforts to address and mitigate issues associated with drug shortages. Please review the proposed global settlement to ensure any settlement framework structured by states does not have unintended consequences of causing a shortage in the MAT medication market.

Thank you for your consideration to this matter should you have any further questions please contact Kirsten Wing of Representative David B. McKinley's office at Kirsten.Wing@mail.house.gov or Margaret McInnis of Representative Marcy Kaptur's office at Margaret.McInnis@mail.house.gov.

Sincerely,



David B. McKinley P.E.
Member of Congress

Marcy Kaptur
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