

Congress of the United States
Washington, DC 20515

DOJ.Correspondence@usdoj.gov

April 26, 2022

The Honorable Merrick Garland
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Dear Attorney General Garland:

In August 2020, Members of Congress wrote a letter to the Food and Drug Administration (FDA) regarding the \$48 billion global opioid settlement which allowed one drug manufacturer to supply their medication assisted treatment (MAT) drug to states for “free” in lieu of monetary compensation. At that time, concerns centered on the impact of global opioid settlement and FDA responded that this would be better posed to the Department of Justice (DOJ). These same concerns have escalated in light of recent announcements that multiple states – Florida, Rhode Island and Texas – are allowing the drug manufacturer to not only provide MAT treatment drugs but also opioid reversal agents, like naloxone.¹

As you are well aware, the Centers for Disease Control and Prevention (CDC) provisional data indicates over 100,000 Americans lost their lives to opioid overdose in 2021.² This nearly 16 percent increase in drug overdose deaths between October 2020 and October 2021 further underscores the need for patient access to both MAT treatments and naloxone.³

The unintended consequences that could result from these misguided settlements are even more concerning. Allowing one company to provide free drugs to entire patient populations is taking a vitally important choice away from physicians and patients. These settlements span 10 or 15 years, depending on the agreement, fundamentally altering the market and stifling innovation in that space.

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 these settlements on patient access to both MAT medications and naloxone products and respectively submit the following questions for your review, please respond as soon as possible:

1. FDA stated in its response that the Department of Justice (DOJ) is “coordinating any federal involvement” in relation to the global opioid settlement. What role and actions has the DOJ taken to date in relation to the global opioid settlement?
2. What factors does the Department of Justice (DOJ) consider when determining whether competition has been stifled and patients are limited in their choices?
3. 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?

¹ (Teva, AbbVie ink opioid settlements worth nearly \$330M with Florida, 2022)

² (Vital Statistics Rapid Release - Provisional Drug Overdose Death Counts, 2022)²

³ (Vital Statistics Rapid Release - Provisional Drug Overdose Death Counts, 2022)³

4. DOJ's Antitrust Division has signaled that it is taking more aggressive actions to ensure robust competition in marketplaces. Does DOJ have the authority it needs to assess the impact the global opioid settlement will have on the MAT and naloxone markets?
5. How would DOJ, in conjunction with cross-agency partners, ensure that any decisions do not limit the access of these life-saving treatments and naloxone are available to patients and their families?

Communities are working continuously to ensure that patients with substance use disorders have the tools needed. Any actions by states with companies that alters the entire market should be considered with care.

Please review the proposed global settlement to ensure any settlement framework structured by states does not have unintended consequences of causing a drug shortage in either the MAT medication or naloxone market.

Thank you for your consideration to this matter. Should you have any further questions, please contact Margaret McInnis of Representative Marcy Kaptur's office at Margaret.McInnis@mail.house.gov or Hannah King of Representative Andy Harris's office at Hannah.King@mail.house.gov.

Sincerely,



Marcy Kaptur
Member of Congress



Andy Harris, M.D.
Member of Congress

Cc:

The Honorable Xavier Becerra, J.D., Secretary of the U.S. Department of Health and Human Services