

March 11, 2024

The Honorable Mandy Cohen, MD, MPH
Director
U.S. Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Dear Dr. Cohen:

I write with regard to the Centers for Disease Control's (CDC) proposed guidance that recommends the use of doxycycline post-exposure prophylaxis (Doxy PEP) to prevent bacterial sexually transmitted infections (STIs). There is considerable unease that widespread use of this medication will contribute to the problem of antimicrobial resistance (AMR) in the United States. AMR is a serious public health threat that kills thousands of Americans every year. I am concerned that this proposal is motivated more by politics than scientific rigor or long-term effects to patient health.

On October 2, 2023, the CDC issued proposed clinical guidance that recommends prescribing doxycycline post-exposure (an approach known as Doxy PEP) to certain populations because of the drug's ability to reduce chlamydia, gonorrhea, and syphilis infections. Prescribing a PEP medication is a common approach to prevent infections like HIV and is accomplished by taking a medication after a possible exposure. The proposal provides "updated clinical guidelines" for providers to better understand how they can prescribe Doxy PEP to prevent bacterial STI infections. The guidance recommends that "men who have sex with men" and "transgender women" with a history of at least one STI in the past year or who participate in activities that increase the likelihood of exposure to STIs would benefit most from taking 200mg of doxycycline within 72 hours of sex.¹

Though the CDC did reference the risk of antibiotic resistance to patients who are prescribed Doxy PEP for this purpose, it is concerning that the agency has not adequately considered the severity of the threat that this guidance could pose to patient and public health. The document specifically notes that the evidence used to evaluate the long-term impacts on doxycycline on the development of AMR pathogens was not "graded,"² calling into question the quality of evidence that was reviewed. Furthermore, the guidance points out that there is limited data on the impact of doxycycline on AMR and that there are "no studies to date on long-term, intermittent use of doxycycline and the microbiome."³ It is particularly concerning that the CDC

¹ <https://www.regulations.gov/document/CDC-2023-0080-0002>

² Ibid.

³ Ibid.

has not clarified whether it seeks to commission any additional studies to evaluate the impact of this guidance on the AMR of patients.

In 2019, AMR caused nearly 5 million global deaths, including more than 35,000 deaths in the U.S.⁴ The CDC champions “antibiotic stewardship” precisely to ensure that antibiotics remain effective treatments for serious disease. Despite public health officials’ longstanding concern about the danger of AMR and overprescribing of antibiotics, the CDC appears now to be throwing caution to the wind. The CDC’s draft guidance is already influencing government policy and provider decision making. Major city health departments, including Chicago⁵ and New York City,⁶ have implemented this guidance. Patients are at risk of antibiotic resistant infections as a result. Because antibiotic resistant bacteria can spread between humans through proximity and poor hygiene, the risk is not confined to one subset of the population and could ultimately affect the broader public. This is the definition of a public health problem.

It is important for public health officials to combat STIs with innovative methods, but it is similarly critical that the CDC makes decisions based on science, not demands from activists that downplay the risks of novel treatments. The agency must consider the full consequences of its proposals and not mistake short-term successes for long-term solution without rigorous, high-quality study of available data. I remain concerned that the lack of long-term data on the impacts that frequent doxycycline use may have on an individual’s AMR could cause significant issues for these individuals’ health, as well as the health of the broader public. Therefore, I request a response to the following questions:

1. Please list the names and/or affiliations of the AMR experts that were consulted when constructing its guidance.
 - a. What role did these experts play?
 - b. What are their conclusions about the guidance as currently proposed?
 - c. Did the CDC incorporate all of the suggestions from the AMR experts?
2. In the proposed guidance notice, the CDC notes that it “plans to use multiple surveillance systems to monitor impacts of the proposed guidelines including potential impacts on antibiotic use and antibiotic resistance.” Please outline what the agency’s plan is to monitor antibiotic resistance among Doxy PEP users.
 - a. How often does the CDC intend to review data on the guidance’s impact on individuals AMR?
3. Does the CDC intend to commission any long-term studies on the impact of long-term, intermittent use of doxycycline on a patients’ microbiomes?
 - a. If yes, when can I expect these studies to begin? Will the agency hold the guidance until they receive conclusive data on these long-term impacts?
 - b. If no, why not?
4. When does the CDC plan to issue its final guidance?

⁴ <https://www.cdc.gov/drugresistance/national-estimates.html>

⁵ https://www.chicago.gov/city/en/depts/cdph/provdrs/infectious_disease/supp_info/doxy-pep-for-bacterial-stis.html

⁶ <https://www.nyc.gov/assets/doh/downloads/pdf/std/dear-colleague-doxy-PEP-to-prevent-bacterial-STI-11092023.pdf>

Thank you for your consideration. I look forward to your prompt response.

Sincerely,

A handwritten signature in blue ink, appearing to read 'M. Rubio', with a stylized flourish at the end.

Marco Rubio
U.S. Senator