

FDA Vaccines and Related Biological Products Advisory Committee Meeting
July 28, 2017

Public Comment by Ryan Clary, Executive Director, National Viral Hepatitis Roundtable

My name is Ryan Clary and I am the executive director of the National Viral Hepatitis Roundtable. NVHR is a coalition of over 500 organizations around the country working together to fight and ultimately end the hepatitis B and C epidemics in the United States. I want to thank the Committee for the opportunity to speak today. I can't think of a better way to spend World Hepatitis Day than addressing the need for new tools to end the hepatitis B epidemic in the United States.

NVHR thanks the Advisory Committee and the Food and Drug Administration for your commitment to review the Biological License Application for HEPLISAV-B, a two-dose vaccine regimen developed for hepatitis B prevention. There is a tremendous need to address prevention and elimination of hepatitis B. We respectfully encourage the FDA to consider the public health benefit that the 2-dose, over 1 month, regimen this vaccine offers, considering the current state of unmet medical need in hepatitis B prevention.

As you review this application, I ask that you consider the following points:

1. First and foremost, hepatitis B disproportionately affects Asian Americans and Pacific Islanders (AAPIs). Hepatitis B affects 1 in 12 AAPIs and while Asian Americans and Pacific Islanders make up 5% of the U.S. population, they account for more than 50% of hepatitis B cases in the country. These are unacceptable statistics that require a sense of urgency in providing new effective prevention tools to address a serious health inequity.
2. In March 2017, the National Academies of Sciences, Engineering and Medicine released the *National Strategy for the Elimination of Hepatitis B and C*, stating emphatically that the public health impact of hepatitis B and C could be eliminated by the year 2030 and outlining specific recommendations to lead the nation towards this goal. One of the recommendations calls for expanded access to adult hepatitis B vaccinations, noting that as of 2014, only a quarter of adults over the age of 19 were fully immunized. The public health benefit of a 2 dose, over one month, hepatitis B vaccine would move the United States forward in achieving elimination goals outlined by the National Academies, while saving lives.
3. In May 2017, the Centers for Disease Control and Prevention released disturbing statistics showing a 20% increase in acute hepatitis B infections in 2015. This increase is largely the result of injection drug use tied to the nation's opioid crisis. While administrative and elected officials have rightfully worked in a bipartisan manner to address overdose prevention and substance use treatment, they have not acted sufficiently on the public health impact of the opioid crisis, including the rise in hepatitis B infections. An effective vaccine with fewer doses taken over a shorter time could be provided to at risk adults at syringe access programs, substance use treatment services,

and other appropriate settings to protect them from a serious and sometimes fatal disease and to slow or stop new infections.

4. Finally, I would to share give a personal story that led me to this work. In March 2001, my partner was rushed to the emergency room with internal bleeding. Five days later, he learned he had chronic hepatitis B and inoperable liver cancer. He was given 6 months to live and lived 5 months, dying at the age of 33. It's impossible to know what might have saved his life but every day I hope for advancements in hepatitis B and liver cancer prevention, care and treatment so that no one else endures a similar tragic loss. A new hepatitis B vaccine that improves the chance an individual will complete the series will make it more likely that my hope is fulfilled.

In summary, NVHR respectfully urges the FDA to consider this public health and personal perspective. As advocates who work directly with hepatitis B patients and expert clinicians who treat them, we see the value in a 2-dose vaccine providing a new tool in the marketplace to help us come closer to eliminating hepatitis B.

Thank you very much for your consideration.

Ryan Clary
Executive Director
National Viral Hepatitis Roundtable