October 18, 2022

Dr. Francis Collins
Acting Science Advisor to the President
Eisenhower Executive Office Building
725 17th Street NW,
Washington, D.C. 20500

RE: **Considerations for the Proposed National Hepatitis C Elimination Program**

To Dr. Collins:

On behalf of the 39 undersigned organizations, we greatly appreciate the opportunity to provide feedback on the recently proposed federal program to eliminate hepatitis C (HCV) in the United States.

We agree with your sentiments that the proposed plan is both "truly groundbreaking" and "truly historic" and we strongly support the initiative. The country's public health infrastructure – especially as it relates to viral hepatitis testing, treatment, vaccination, and surveillance – is woefully under-funded. The $8-10 billion investment the White House proposed for HCV would bring the United States closer to the World Health Organization's goal of eliminating viral hepatitis as a public health threat by 2030 and greatly improve how care is delivered in these healthcare settings for years to come.

While we would prefer to see this plan address hepatitis B elimination as well, we believe this Elimination Plan has great potential to support hepatitis B elimination in ways that intersect with hepatitis C care delivery. We offer the following comments to bolster the proposed Elimination Plan's success:

Follow FDA HCV Treatment Standard of Care

We are concerned the proposed plan does not currently include screening patients for hepatitis B as part of their HCV screening. In 2016, the Food and Drug Administration (FDA) issued a warning about hepatitis B virus reactivation in patients receiving direct-acting antivirals (DAA) therapy for their HCV infection. Hepatitis B reactivation can occur quickly after the start of DAA therapy and all DAAs currently on the market have demonstrated risk for hepatitis B reactivation.[1] The clinical outcomes of hepatitis B reactivation in this patient population may resemble the outcomes seen in immunosuppressed patients receiving chemotherapy and

[1] Holmes JA, Yu ML, Chung RT. Hepatitis B reactivation during or after direct acting antiviral therapy - implication for susceptible individuals. Expert Opin Drug Saf. 2017 Jun;16(6):651-672. doi: 10.1080/14740338.2017.1325869. Epub 2017 May 19. PMID: 28471314; PMCID: PMC5589072.

should be avoided.[2] As a result, all DAAs now contain a black box warning stating that all HCV-infected patients should be tested for current or prior infection of hepatitis B before beginning treatment with DAAs. The American Association for the Study of Liver Diseases (AASLD) – the group that determines guidelines for treating viral hepatitis in the US – recommends patients going on DAA therapy be screened for hepatitis B prior to starting therapy.[3]

Currently, 60%-75% of people with hepatitis B don't know they are living with the disease, making reactivation a significant risk for many.[4] This is especially important as data shows that 25% of people living with HCV showed markers for a current or past infection of hepatitis B, putting them at risk for reactivation.[5] Because of poor surveillance, the actual number of people at risk could be much higher. Without including hepatitis B testing, the HCV Elimination Plan as currently described could exacerbate hepatitis B in the US, leading to a public health crisis of increased viral hepatitis-related liver failure, and liver-related deaths – much to the detriment of the goals the plan aims to achieve.

Often the biggest barriers to care in viral hepatitis is finding patients, engaging them in screening, and then starting and keeping them in care. By including hepatitis B screening in the HCV Elimination Plan, providers could see a patient and on the first visit, take a blood draw for HCV and hepatitis B, and administer the first dose of hepatitis B vaccination or link them to vaccination. After the initial visit, the provider could schedule a follow-up appointment to discuss the patient's results for both hepatitis B and C, continue the hepatitis B vaccine series or link them to further care depending upon their test results, or begin the patient on DAA treatment for hepatitis C and/or antiviral treatment for hepatitis B. Using these office visits to tackle both hepatitis B and C lessens the likelihood of losing patients during follow-up, and reflects best practices suggested in many hepatitis elimination plans.

We strongly recommend hepatitis B screening be included in the plan and that sufficient funding is given to ensure programs can provide this necessary test and resulting follow-up steps prior to starting their patients on curative HCV DAA treatment, as recommended in the current HCV treatment guidelines.

Provide Hepatitis B Linkage to Vaccination and Care

Incorporating hepatitis B screening into the National HCV Elimination Plan is only one step to ensure patients have the best chance to learn their status and cure their HCV. Settings also need the resources and knowledge to link patients to hepatitis B care or vaccination to close the loop once patients receive their hepatitis B results. Imagine you're a patient who learned they

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[2] Pockros PJ. Black Box Warning for Possible HBV Reactivation During DAA Therapy for Chronic HCV Infection. Gastroenterol Hepatol (N Y). 2017 Sep;13(9):536-540. PMID: 29038644; PMCID: PMC5635429.

[3] Ghany MG, Morgan TR. Hepatitis C Guidance 2019 Update: American Association for the Study of Liver Diseases–Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Hepatology. 2020 February.

[4] Kim HS, Rotundo L, Yang JD, Kim D, Kothari N, Feurdean M, et al. Racial/ethnic disparities in the prevalence and awareness of Hepatitis B virus infection and immunity in the United States. J Viral Hepat. 2017;24:1052-1066.

[5] Hepatitis B and C Coinfection. Hep Mag. 2019.

are living with or are at risk of hepatitis B. Your provider fails to link you to care. You don't know how to process the news, start treatment (if needed), or vaccinate yourself or your family. You become disengaged with your care, including any HCV treatment. Any person living with hepatitis that isn't actively engaged in care risks liver failure or liver cancer, so keeping individuals engaged in care is a top priority.

Linkage could be as simple as community organizations building partnerships with local pharmacies and other vaccinators to ensure their patients can receive vaccination when needed. These organizations can also build relationships to link clients to a provider who specializes in hepatitis B treatment, and coordinate care between the provider overseeing HCV treatment and the one overseeing hepatitis B treatment. Providers on the ground know the best way to approach and engage their community but need the resources and policy flexibility to do so. Much of this infrastructure has already been build through the Hep B United coalition in 29 cities and 25 states across the U.S., and through the recent creation of hepatitis B ECHO hubs in every region of the U.S., which offer training for primary care providers to manage and treat hepatitis B.

Incorporating hepatitis B testing and linkage to care and vaccination would also support the cancer elimination goals laid out in President Biden's Cancer Moonshot, as hepatitis B is also a leading cause of liver cancer in the United States.

We strongly urge the HCV Elimination Plan include resources that ensure programs receive proper education and support to provide hepatitis B linkage to care and/or linkage to vaccination as part of the HCV screening and/or treatment process.

Incorporate Existing Recommendations for Hepatitis Elimination

Many reports from federal agencies and global health organizations show how to eliminate hepatitis B and C federally and globally. Doing so requires a syndemic approach where we break down disease-specific silos and focus on care delivery among priority populations in a streamlined way. Many of these reports recommend increasing hepatitis B and C service delivery among priority populations and providing services in settings frequented by those priority populations as key ways to break down those silos. Because the National HCV Elimination Plan is targeting populations with high prevalence of viral hepatitis, it is a great opportunity to also include hepatitis B services when interacting with these priority populations.

The National Academies of Science, Engineering, and Medicine released *A National Strategy for the Elimination of Hepatitis B and C* which recommends that the "[Centers for Disease Control and Prevention] (CDC) work with states to identify settings appropriate for enhanced viral hepatitis testing based on expected prevalence." It also recommends "screening, vaccinating, and treating hepatitis B and C in correctional facilities according to national clinical practice guidelines." Additionally, they recommend that "states expand access to adult hepatitis B vaccination, removing barriers to immunization in pharmacies and other easily accessible

settings."[6] Given the HCV Elimination Plan's focus on providing barrier-free testing and treatment in priority communities including justice-involved individuals and people who use drugs (PWUDs), it would be an ideal opportunity to follow recommendations also to screen for hepatitis B and link to care and vaccination in these communities, especially since hepatitis B screening should occur before HCV therapy begins anyway.

Last year, the Department of Health and Human Services (HHS) released its Viral Hepatitis National Strategic Plan for 2021-2025 which also lists several recommendations to increase testing and linkage to treatment and vaccination among priority populations. The report recommends "expanding access to viral hepatitis prevention and treatment services by providing screening, vaccination, and linkage to care in a broad range of health care delivery and community-based settings." It also recommends "expanding innovative models for viral hepatitis testing in a range of settings such as community-based organizations, mobile units, substance use disorder treatment programs, correctional facilities, syringe services programs, [etc]".[7] The HHS sees an increase of hepatitis B and C services across a wide range of settings as the route to viral hepatitis elimination, and we agree.

Thankfully, testing and vaccination in a wider range of settings has become easier for many to access given new updates to hepatitis B testing and vaccination recommendations. Late last year, the CDC's Advisory Council on Immunization Practices (ACIP) recommended that adults aged 19–59 years and adults aged ≥60 years with risk factors for hepatitis B should be vaccinated against hepatitis B, and that adults aged ≥60 years without known risk factors for hepatitis B could be.[8] Additionally, the CDC has proposed a universal, one-time hepatitis B screening for adults aged 18 and older. These new recommendations also help reduce financial burdens by requiring insurers to cover more care than they previously may have. When combined with the HCV Elimination Plan proposal, these new recommendations place the US in a fantastic space to truly eliminate viral hepatitis. However, ensuring that they are part of all federal plans for eliminating viral hepatitis is critical to remaining on track to reach those goals.

Too many people are unaware of their hepatitis B status, too few people are protected against the virus, and the public health infrastructure is not currently capable of supporting hepatitis B elimination. Incorporating hepatitis B screening and linkage to care and vaccination into the National HCV Elimination Plan would be in-line with many of the recommendations laid out in recent national elimination reports.

We strongly urge the National HCV Elimination Plan to incorporate the expert recommendations laid out in the recent elimination reports, especially as it relates to incorporating hepatitis B screening and linkage to vaccination and care.

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[6] National Academies of Sciences, Engineering, and Medicine. 2017. A national strategy for the elimination of hepatitis B and C: Phase two report. Washington, DC: The National Academies Press.
[7] U.S. Department of Health and Human Services. 2020. Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination (2021–2025). Washington, DC.
[8] Weng MK, Doshani M, Khan MA, et al. Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022. MMWR Morb Mortal Wkly Rep 2022;71:477–483.

We again thank you again for the opportunity to offer comments. For additional information, please contact Frank Hood, Associate Director of Policy and Partnerships at the Hepatitis B Foundation and Director of Hep B United, at frank.hood@hepb.org.

Sincerely,
Hep B United
Hepatitis B Foundation
Association of Asian Pacific Community Health Organizations (AAPCHO)
AIDS Action Baltimore
AIDS Alabama
AIDS United
American Liver Foundation
Asian Center - Southeast Michigan
Asian Health Coalition
Asian Liver Center at Stanford University
Asian Pacific Health Foundation
Caring Ambassadors Program
Charles B. Wang Community Health Center
Clary Strategies
Community Welfare Services of Metro Detroit
Equality California
Hawai'i Health & Harm Reduction Center
Hep Free Hawai'i
Hepatitis B Initiative of Washington, D.C.
HIV Dental Alliance
Idaho Immunization Coalition
International Association of Providers of AIDS Care
La Maestra Community Health Centers
Latino Commission on AIDS
Louisiana Families for Vaccines
Maplewood Health Department
NASTAD
National Viral Hepatitis Roundtable (NVHR)
North East Medical Services
ONG ADILO
PCAF (formerly Pierce County AIDS Foundation)
Professional Association of Social Workers in HIV/AIDS
Robert G Gish Consultants LLC
The AIDS Institute
Treatment Action Group
Vaccinate Your Family
Vaccine Ambassadors
Vietnamese American Cancer Foundation (VACF)
Virginia Hepatitis Coalition