



Testimony for Submission

Hepatitis Appropriations Partnership

To the House Committee on Oversight and Government Reform
For a Hearing on "Viral Hepatitis: The Secret Epidemic."

June 17, 2010

On behalf of the Hepatitis Appropriations Partnership (HAP), a national coalition that includes community-based organizations, public health and provider associations, national hepatitis and HIV organizations, and diagnostic, pharmaceutical and biotechnology companies, we respectfully submit testimony for the record regarding the federal response to the hepatitis epidemics. We thank the Committee for holding this hearing to call for action on hepatitis since its last hearing, "Stalking a Furtive Killer: A Review of the Federal Government's Efforts to Combat Hepatitis C," which was held in 2004.

We are hopeful that the hearing will bring about positive change and increased attention to the national response under the Department of Health and Human Services (HHS), particularly as it relates to the current resource allocation and coordination of activity at the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA) the Health Resources and Services Administration (HRSA), the National Institutes of Health, the Centers for Medicare and Medicaid Services, and the Agency for Healthcare Research and Quality. These Agencies are critical stakeholders in addressing existing challenges and barriers to current efforts on the prevention, management and control of these diseases, and to determine ways in which the government can better address these epidemics. In addition, we hope HHS will work with other key Departments such as the Department of Veterans Affairs, Department of Justice, and the Department of Homeland Security to address vulnerable populations.

With the recent release of the Institute of Medicine (IOM) report, [*Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*](#), the federal government has a unique opportunity to make the report a reality and call for the implementation of its recommendations, most of which are directed at HHS. The report

attributes the profound ignorance among the American public and providers, the large health disparities and the current hepatitis morbidity and mortality, to the lack of adequate financial resources.

The Assistant Secretary for Health, Dr. Howard Koh, plays a key role in leading the HHS response to the hepatitis epidemics by convening an interagency workgroup representing key stakeholders across the HHS agencies in order to prioritize and coordinate hepatitis activity. We hope that the workgroup will be able to develop an inventory of current activities by Agency, improve coordination and prioritization of hepatitis activities at HHS, implement the IOM recommendations, raise the level of awareness and leadership within HHS and the Administration, and develop a national strategy on hepatitis.

Policymakers must be made aware of the consequences of continued inaction. The costs to the healthcare system generated by advanced liver disease associated with chronic hepatitis C infection will increase from \$30 billion to \$85 billion per year. Medicare will be especially hard hit because two-thirds of Americans with chronic hepatitis C infection are baby boomers and the vast majority (75 percent) is unaware; these patients will soon age into Medicare and are likely to progress to advanced liver disease unless they are identified, evaluated and treated soon. In addition to causing 15,000 deaths each year, hepatitis will continue to be the most common cause of non-AIDS-related death in co-infected Americans with HIV with as many as 25 percent co-infected with hepatitis C and 10 percent with hepatitis B. Acute hepatitis B will continue to disproportionately impact African Americans, particularly in the southern states, and chronic hepatitis B among Asian Americans where it is the leading cause of death and 10 percent remain infected. Even with a safe and effective vaccine against hepatitis B, 3,000 Americans will continue to die and roughly 1,000 babies will still be infected at birth.

In addition to investing in more funding, Congress needs to pass the Viral Hepatitis and Liver Cancer Control and Prevention Act (HR 3974). This legislation, which is co-authored by Chairman Ed Towns, authorizes a comprehensive prevention, education, research and medical management referral program to reduce the disease burden associated with hepatitis infections, and includes the development of a national plan and expansion of SAMHSA's authority to include hepatitis. In addition, Congress can raise the level of awareness of hepatitis by passing the World Hepatitis Day and Month of May as National Hepatitis Awareness Month Resolutions (H RES 1302, S RES 531).

It is critical that Americans at-risk receive preventative services and those infected are identified in order to mitigate the disease burden and to prevent transmission in addition to increasing knowledge and capacity among health providers. There are new effective diagnostic and treatment options soon available for people at-risk or living with chronic hepatitis C. A recent study from the Journal of Hepatology notes that despite significant

gains in treatment for hepatitis C, to increase the cure rate among chronic carriers and non-responders to the current standard of care, the lack of investment in our public health infrastructure such as routine screening and testing present as barriers to access to care. Hence it is not enough to have a cure for hepatitis C to eradicate the hepatitis C epidemic. The cure must rely on infrastructure such as funding for screening and testing, staff capacity in medical settings and educated health providers in order to identify those who need treatment in the first place.

Prevention

CDC's Division of Viral Hepatitis received only \$19.3 million in FY2010 for hepatitis prevention and control, which represents less than 2 percent of the budget of CDC's National Center of HIV/AIDS, Hepatitis, STD, and TB Prevention. This is the only dedicated funding for prevention that the federal government gives to hepatitis. CDC needs a robust infusion of resources in order to effectively carry out its mission. President Obama's budget proposal includes a \$1.8 million increase for a total of \$21.1 million for DVH, which is woefully insufficient to address infectious diseases of this magnitude. States and cities receive \$5 million in total that averages to \$90,000 per jurisdiction. This is only enough for a single staff position and is not sufficient for the provision of core public health services such as counseling and testing, surveillance, vaccination, nor direct care services. These services are essential to preventing new infections, increasing the number of people who know they are infected, and following up to help those identified to remain healthy and productive. An increase in this funding is an important first step to making hepatitis prevention services more widely available. The expanded services should include hepatitis B and C education, counseling, testing, and referral in addition to delivering hepatitis A and B vaccine, and establishing a surveillance system of chronic hepatitis B and C.

Despite greatly constrained funding for disease surveillance activities, some states have been able to gather limited information on the epidemics of HBV and HCV in their jurisdictions. One alarming trend seen in several states, including New York, Pennsylvania and Massachusetts, is the emergence of hepatitis C infections among those under the age of 25. For example, in Massachusetts, since 2006, there have been over 1,000 cases of newly diagnosed infection reported in that age category every year (approximately 13% of all cases reported). This is a striking increase over previous years where the majority of cases were largely in populations over the age of 40 years. While data are incomplete, there is evidence that this increase is largely due to heroin use among youth. Unfortunately, many states do not have the adequate infrastructure to detect whether this trend is occurring in their state, and the states that identified this as a serious problem often have no funding to address the prevention and screening needs of this population.

CDC identified funds through program cost savings in the Section 317 Vaccine Program, allocating \$20 million in FY2008 and \$16 million in FY2009 for purchase of

hepatitis B vaccine for high-risk adults. We commend CDC for prioritizing high-risk adults with this initiative, but relying on the availability of these cost savings is not enough. Additionally, this initiative does not support any supplies, infrastructure or personnel to support the delivery of this vaccine. We strongly urge a continuation of monies in FY2011 for an adult hepatitis B vaccination initiative through the CDC's Section 317 Vaccine Program.

Treatment and Care

While there are no dedicated funding streams for medical management and treatment of hepatitis, low-income patients can and do seek services at Community Health Centers (CHCs). We applaud Congress' continued commitment to increasing resources for CHCs. While we are supportive of the President's efforts to modernize and expand access to health care, we also support increased funding for existing safety net programs. Low-income patients who are uninsured or underinsured can and do seek services at CHCs. Even for those with health insurance, treatment of viral hepatitis is complex and requires care coordination among many different providers and services. With the growing importance of CHCs as a safety net in providing frontline support for these individuals, we support resources for CHCs to increase their capacity to serve people with chronic viral hepatitis.

Low-income individuals co-infected with hepatitis and HIV can seek services through the Ryan White Program. Increased resources to the Ryan White Program are needed to improve provider education on hepatitis medical management and treatment, to cover additional case management for patients undergoing treatment, and to allow more states to add hepatitis therapies and viral load tests to their ADAP formularies. Access to available treatments and treatment support services are critical to combat co-infection morbidity and mortality.

The Centers for Medicare and Medicaid Services play a critical role as payers of care for persons with chronic viral hepatitis. Too little is known about how much Medicare and Medicaid is paying for in terms of screening, vaccination, medical management and treatment for viral hepatitis. We strongly encourage CMS to collect data on these services, particularly given the cost burden on Medicare in the coming decade.

Research

Finally, research is needed to increase understanding of the pathogenesis of hepatitis B and C. Further research to improve hepatitis B and C treatments that are currently difficult to tolerate and have low "cure" rates are also needed. The development of clinical strategies to slow the progression of liver disease among persons living with chronic infection, especially to those who may not respond to current treatment must be addressed. With effective vaccines against hepatitis A and B, it is important to continue to work towards the development of a vaccine against hepatitis C infection. The Liver Disease Branch, located within the National Institute of Diabetes and Digestive and

Kidney Diseases (NIDDK) at the National Institutes of Health (NIH), has developed an *Action Plan for Liver Disease Research*. We request full funding for NIH to support the recommendations and action steps outlined in this plan. Until a vaccine for hepatitis C is available, enhanced prevention services for people at-risk are needed. These need to be evaluated and expanded to ensure that effective prevention programs are available nationally.

Health Reform

The new health reform law is an opportunity to expand coverage to people living with hepatitis. The new law removes pre-existing condition exclusions that have been a barrier for people living with chronic hepatitis B and C. The Medicaid expansion in 2014 will allow people with hepatitis with incomes below 133 percent of the federal poverty level access to care and treatment. The law also expands access to vaccines for adults, which will help close the hepatitis A and B vaccine gap. There remains a hurdle in terms of expanding access to screening for hepatitis B and C with the limitations in first dollar coverage for prevention services based on the U.S. Preventive Services Task Force (USPSTF) recommendations. The Agency for Healthcare Research and Quality plays an integral role in administering the USPSTF recommendations.

Another opportunity in the law to fund hepatitis prevention services is the Prevention and Public Health Fund. We have appealed to HHS to include hepatitis as eligible for these funds. We believe it will be an enormous missed opportunity to overlook one of the most underfunded chronic, infectious diseases that continues to take a heavy toll on the individuals infected and contribute to greater health system costs.

A strong public health response is needed to meet the challenges of these infectious diseases impacting over five million Americans. We welcome the opportunity to work with you on this important issue. It is essential that the United States continue to demonstrate its commitment and leadership in fighting the hepatitis epidemics and resources are available to meet its growing needs. The Hepatitis Appropriations Partnership thanks the Chairman, Ranking Member and Members of the Committee for their thoughtful consideration of our recommendations.