



U.S. House Committee on Oversight and Government Reform
Hearing on “Viral Hepatitis: The Secret Epidemic”
Testimony of Jeffrey Levi, Ph.D.
Executive Director, Trust for America’s Health
June 17, 2010

Thank you, Mr. Chairman. My name is Dr. Jeffrey Levi and I am the Executive Director of Trust for America’s Health a nonprofit, nonpartisan public health advocacy organization. I am grateful for the opportunity to be here today to discuss a major, yet largely silent public health crisis, viral hepatitis.

My testimony today builds on the foundation laid by the recently released Institute of Medicine (IOM) report and the work of other leaders in the field, especially the American Association for the Study of Liver Diseases (AASLD) and the National Viral Hepatitis Roundtable (NVHR). Today’s testimony also reflects the tremendous expertise shared with TFAH by an expert panel we convened last month. TFAH’s principal funding for its public health work comes from the Robert Wood Johnson Foundation and the Kellogg Foundation. We are particularly grateful to AASLD for their support of our hepatitis prevention initiatives.

Overview

Hepatitis is a ticking time bomb. Millions of people in our country are infected with the virus, yet, unfortunately, are not aware of their status, putting them at risk for developing chronic hepatitis, liver cancer, cirrhosis, or end-stage liver disease. The lack of appropriate and timely attention of the health care and public health systems to adequately prevent, identify, and treat hepatitis threatens the lives of individuals and looms as a great threat to the future fiscal stability of our health care system.

To be more precise: The Centers for Disease Control and Prevention (CDC) estimate that as many as 1.4 million individuals in the U.S. have hepatitis B (HBV), yet 65 percent are unaware of their status.¹ An additional 3.9 million are estimated to be infected with hepatitis C (HCV), yet 75 percent are believed to be unaware of their status.² This translates into almost 4 million people infected with a contagious disease who are unaware of their status, could inadvertently transmit the virus, and – even more tragically – are not being monitored and offered the opportunity to take advantage of existing treatment the could prevent or delay the onset of the tragic sequelae of hepatitis infection. With promising new treatments on the horizon that could dramatically improve our

¹ *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*, Heather M. Colvin and Abigail E. Mitchell, Editors; Committee on the Prevention and Control of Viral Hepatitis Infections; Institute of Medicine. 2010. p. 1. Available from: <http://www.nap.edu/catalog/12793.html>. 2

² Ibid, p. 1.

chances for effectively treating these individuals, we have a moral obligation to make sure that all who can benefit know their status and have access to them.

However, this is more than a moral argument. It is also a practical financial issue for our reforming health care system. Although difficult to determine, the direct annual medical costs associated with HBV and HCV infections have been estimated at \$7.6 billion.³ If we continue down the present course of late identification of people with viral hepatitis – at the point where they are symptomatic and often suffer from late-stage liver disease – the costs to the health care system will continue to grow. Indeed, one study has estimated that the medical costs of HCV alone could increase to \$85 billion in 20 years, if all who are infected are in care, with Medicare's taking on 39 percent of those costs.⁴ If we undertake aggressive actions, such as those I outline below, we could dramatically change that equation for the better. One modeling effort showed that if we expanded Medicaid coverage to all low-income people with hepatitis B and assured early and appropriate treatment, we could save money in the long run due to the number of liver transplants and end-stage liver disease treatment that would be prevented.⁵

Recommendations

The following recommendations represent an attempt to offer a comprehensive policy response to the problem and continuous threat of hepatitis. Many come at no additional cost to the federal government by simply working within existing authorities. Others require a modest investment in public spending but would greatly enhance our knowledge and response. And some would require a significant yet much-needed investment of federal dollars. But we have a choice: we can invest in prevention and early treatment now – and avoid new infections and the very costly specter of viral hepatitis left untreated – or we can delay our investment, incur far greater cost, and cause avoidable disease, disability, and suffering for millions of people in our country and their families.

Together, these recommendations address three important public health goals: (1) assuring that our public health and health care delivery systems are ready for the new, more effective treatments for hepatitis that are on the horizon. This will ensure that all individuals in the U.S. with hepatitis can benefit from improved health outcomes; (2) assuring that the current disparities associated with hepatitis are appropriately addressed; and (3) reducing the financial impact of hepatitis on our health care delivery system.

Let me now outline some key areas where federal policy change is critical:

1. We need much better situational awareness and surveillance. We do not have sufficient data regarding the scope of the problem and who is affected. This

³ IOM, 2010, p. 25.

⁴ Pyenson, B. et al. "Consequences of Hepatitis C Virus- Costs of a Baby Boomer Epidemic of Liver Disease," May 2009. Milliman, Inc. (Report commissioned by Vertex Pharma. Inc.)

⁵ Smith, Vernon. "Medicaid Hepatitis Expansion Project – Overview of Findings," Health Management Associates. Presented at *The Dawn of a New Era: Transforming Our Domestic Response to Hepatitis B&C*, September 10-11, 2009. Washington, DC.

affects not only our ability to prevent and treat disease, but it also creates a vicious cycle of inadequate evidence to support greater public resources to address the problem. For example, although HBV and HCV kill as many or more Americans as HIV every year, the disease receives less than two percent of the budget for the National Center for HIV, Viral Hepatitis, STD, and TB Prevention.⁶

We do not need to create a new surveillance system to track hepatitis. Viral hepatitis can be built into the existing, robust HIV/STD surveillance system. While the diseases are different, many of the risk behaviors and affected populations overlap enough to make this expansion feasible. We also need a functioning sentinel surveillance system, where selected facilities report infection rates, so we can identify new pockets of infection and know where to target new primary prevention efforts.

2. We need to routinize screening for hepatitis B and C. As many as 65-75 percent of people with hepatitis are unaware of their status. We must and can do better to address this problem. We have already done so in the HIV arena, where CDC estimates that only 20 percent of people with HIV infection don't know their status.⁷ For HBV, providers and patients need to have better awareness of who is at risk and assure they get screened, including all pregnant women. For HCV, it is time to move from screening only those deemed at risk to include nation of birth and age, as many adults are unaware that the behaviors of their youth may have put them in danger of infection. Health IT would be an excellent mechanism for enabling providers to screen for hepatitis and to remind providers about vaccine history.
3. We must assure that the reformed health care system provides quality prevention and care for hepatitis. HBV and HCV screening should be the standard of care in the reformed health care system, and we must significantly improve HBV vaccination until we reach 100 percent coverage. This should include defining hepatitis screening as an essential benefit under the new health exchanges. Providers must be assured they will be properly reimbursed for preventive services, screening, and referral to appropriate treatment, and there needs to be an expansion of training of the health care workforce to screen, identify, and treat viral hepatitis. HHS should begin now to establish the standards of prevention and treatment that will be required of all public and private plans.
4. We must also assure that people stay in care, with appropriate and culturally and linguistically sensitive support services that will assure adherence. Treatment requires a continuum from the point of screening throughout care, as there is a high risk for falling through the cracks. This is especially relevant when working

⁶Centers for Disease Control and Prevention Congressional Budget Justification, FY 2011. http://www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY2011_CDC_CJ_Final.pdf

⁷ CDC. HIV prevalence estimates – United States, 2006. MMWR 2008; 57(39):1073-76.

with marginalized populations, such as immigrants, incarcerated individuals, or injection drug users. Although many of the adherence issues are similar, our health care system has been much more effective at assuring adherence for HIV than for HCV. This is in part due to the additional services supported by the Ryan White Care program. Just as with HIV, there is a strong public health rationale for assuring adherence to and successful completion of hepatitis treatment. Expanding the mission of the Ryan White Care program, which currently services people with hepatitis who are co-infected with HIV but not those only infected with hepatitis, may be one approach to assuring access to these critical services. This proposal is not as burdensome as it may seem, because, unlike HIV, the course of treatment and services for HCV is time limited. And it is worth noting that the Ryan White Care program has been successful in reducing disparities in outcomes because of the support it provides.

5. As we focus on assuring treatment, we must also remember that there are major opportunities for primary prevention of hepatitis. We continue to see pockets of outbreaks of hepatitis B and hepatitis C. We must close the gaps in hepatitis B vaccination coverage, and we must use all educational and structural tools at our disposal to prevent transmission of hepatitis C. This includes federal funding of syringe exchange programs (SEPs). While we are delighted that Congress has lifted the ban on states and localities opting to use SEPs as part of their fight against hepatitis and HIV, we are very concerned that the Department of Health and Human Services has not yet issued guidance to their grantees about how they may use their federal funding for SEPs. These should be issued without delay so that jurisdictions can use FY 2010 money for this lifesaving intervention.
6. Within the area of primary prevention, we have within our reach the capacity to virtually eliminate perinatal – or mother to child – transmission of hepatitis B. CDC estimates that 1,000 children born in the U.S. to HBV-positive mothers will develop chronic HBV infection each year.⁸ Yet transmission of HBV from mothers to newborns is entirely preventable. HRSA, CMS, and CDC must all work to incentivize routine HBV screening of all pregnant women, pregnancy testing of HBV-positive women, and first HBV vaccination to all newborns within 12 hours of birth and treatment protocols of newborns born to HBV-infected women.
7. Finally, there needs to be an increased emphasis on research. In addition to research for better countermeasures, such as a single-dose HBV vaccine or more effective treatments for HCV, we desperately need to understand the reason for the disparate response to HCV treatments. African-Americans have the highest rates of HCV in the United States, more than twice that of whites,⁹ yet treatment is nearly half as effective in African-Americans as compared to the general

⁸ Ward, J. W. 2008b. "Time for Renewed Commitment to Viral Hepatitis Prevention." *American Journal of Public Health* 98(5):779-781.

⁹ IOM, 2010, p. 2.

population (28 percent success rate versus 50 percent).¹⁰ We need to require that clinical trial cohorts are diverse enough to assure that we know the safety and efficacy of new treatments for all who are affected by hepatitis.

Conclusion

We are delighted that the federal government, under the leadership of Assistant Secretary for Health Koh, is developing a national strategy for hepatitis, and we hope it will reflect the comprehensive effort that the problem demands. We are at a critical junction in our nation's fight against hepatitis. New treatments offer great promise; a reforming health care system will improve coverage and access; and, in the case of hepatitis B, we have a vaccine that could effectively eliminate it. The question remains whether as a nation we will seize this moment to prevent and reduce needless suffering for millions of people in our country and their families.

I thank you for the opportunity to discuss this issue with you today, and I look forward to your questions.

¹⁰ *Hepatitis C: The Importance of Screening for this Silent Disease*, Isaac Itman, HHS Office of Minority Health. Available from: <http://minorityhealth.hhs.gov/templates/content.aspx?ID=5116>