

September 17, 2010

Jay Angoff, Director
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIO-9992-IFC
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Joint Comments of Gilead Sciences, Hepatitis B Foundation, Association of Asian Pacific Community Health Organizations, and National Viral Hepatitis Roundtable on the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services (OCIO-9992-IFC)

Dear Mr. Angoff:

Gilead Sciences, Inc. (“Gilead”),¹ the Hepatitis B Foundation (“HBF”),² the Association of Asian Pacific Community Health Organizations (“AAPCHO”),³ and the National Viral Hepatitis Roundtable (“NVHR”)⁴ appreciate this opportunity to comment jointly on the Interim Final Rules for Coverage of Preventive Services under the Patient Protection and Affordable Care Act (the “Interim Final Rules”).⁵ We are providing these joint comments to encourage the Department of Health and Human Services (“HHS”) to include routine testing for the hepatitis B virus infection (“HBV”) — as recommended by the Centers for Disease Control and Prevention (“CDC”) — in the Health Resources and Services Administration (“HRSA”) guidelines on

¹ Gilead is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet need. Gilead’s primary areas of focus include HIV/AIDS, liver disease, and serious cardiovascular and respiratory conditions.

² The Hepatitis B Foundation is a national non-profit organization dedicated to finding a cure for hepatitis B and improving the lives of those affected worldwide through research, education and patient advocacy. Our commitment includes funding focused research, promoting disease awareness, supporting immunization and treatment initiatives, and serving as the primary source of information for patients and their families, the medical and scientific community, and the general public.

³ The Association of Asian Pacific Community Health Organizations is a national association representing community health organizations dedicated to promoting advocacy, collaboration and leadership that improves the health status and access of Asian Americans & Native Hawaiians and other Pacific Islanders within the United States, its territories, and freely associated states, primarily through our member community health centers.

⁴ The National Viral Hepatitis Roundtable is dedicated to developing, implementing and maintaining a national strategy to eliminate viral hepatitis in the United States. Our programmatic work concentrates on national networking, partnership development and capacity-building to improve viral hepatitis programs, while our policy work focuses on increasing awareness, education, and resources at the federal level for an adequate federal response to viral hepatitis.

⁵ Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act. 75 Fed. Reg. 41,726 (July 19, 2010).

preventive care and screening for women, as described in the Public Health Services Act (“PHSA”) § 2713(a)(4).⁶

As HHS is aware, the CDC updated its recommendations for HBV testing in 2008.⁷ The CDC now recommends that those in the following groups be offered testing for HBV infection as a part of routine care: persons born in geographic regions with HBV prevalence above two percent;⁸ persons with behavioral exposures to HBV;⁹ persons receiving cytotoxic or immunosuppressive therapy;¹⁰ persons with liver disease of unknown etiology; hemodialysis patients; all pregnant women; infants born to HBV positive mothers; persons with household, needle-sharing, or sexual contacts of HBV-positive persons; persons who are the sources of blood or body fluids resulting in an exposure to others that might require post-exposure prophylaxis; and HIV-positive persons.¹¹ For many of these groups, the CDC recommends that patients either be vaccinated at the time of testing, or assessed for future risk of contracting HBV and then vaccinated if indicated.¹²

Furthermore, because some persons may have been infected with HBV prior to being vaccinated, the CDC now recommends routine HBV testing regardless of verifiable vaccination history for all persons born in geographic regions with HBV prevalence above two percent; all U.S.-born persons not vaccinated as infants whose parents were born in regions with HBV prevalence above eight percent;¹³ and all persons who received the HBV vaccination after the initiation of risk behaviors.¹⁴ The CDC recommendations are supported by not only the American Association for the Study of Liver Disease (AASLD), but by numerous patient advocacy organizations as well.

⁶ As added by the Patient Protection and Affordable Care Act, Pub. L. 111-148 (Mar. 23, 2010).

⁷ Centers for Disease Control and Prevention. *Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection*. 57 MORBIDITY & MORTALITY WKLY REP. 1-20 (2008) (hereinafter “CDC Recommendations”).

⁸ This recommendation includes practically all African, Asian, Middle Eastern, and Pacific Island nations, as well as much of Eastern Europe and South America.

⁹ This recommendation includes injection drug users and men who have sex with men.

¹⁰ Including chemotherapy, immunosuppression related to organ transplantation, and immunosuppression for rheumatology or gastroenterologic disorders.

¹¹ *CDC Recommendations*, *supra* note 7, table 4. The CDC also maintains a table of its recommendations at <http://cdc.gov/hepatitis/HBV/PDFs/ChronicHepBTestingFlwUp-BW.pdf>.

¹² *CDC Recommendations*, *supra* note 7.

¹³ The 8 percent figure includes much of Africa, South-East and Central Asia, and the Pacific Islands, as well as areas of South America, Eastern Europe, and the Middle East.

¹⁴ *CDC Recommendations*, *supra* note 7.

We agree with the position taken by HHS in the Interim Final Rules that in certain circumstances, market failures (such as the lack of incentives for insurers to cover preventive services and the failure of markets to capture the full societal benefits of preventive services) lead to underutilization of preventive services.¹⁵ We believe that testing for HBV is precisely one of these circumstances. While routine HBV testing among at-risk groups leads to greatly improved patient outcomes in a cost-effective manner, it has nevertheless been underutilized as a public health tool. A striking example of the failure of past HBV testing coverage is the continued perinatal transmission of HBV in the United States. The CDC estimates that each year, an estimated 1,000 infants are chronically infected with HBV during birth from their HBV-positive mothers.¹⁶ Expanding HBV testing access to all women in at-risk groups will lead to reduced rates of perinatal transmission and increase the proportion of individuals aware of their chronic HBV status. We thus believe that expanded insurance coverage of preventive services (such as those subject to PHSA § 2713(a)), can lead to expanded utilization as well as to substantial health benefits to both patients and society.¹⁷

For these reasons, Gilead, HBF, AAPCHO, and NVHR strongly urge that HHS include routine HBV testing in the HRSA guidelines on preventive care and screening, for female members of the at-risk groups identified in the CDC’s recommendations. Furthermore, while we acknowledge that the United States Preventive Services Task Force (“USPSTF”) currently does not recommend routine HBV screening for the general asymptomatic population, we also observe that the USPSTF rating, issued in 2004, neither binds HHS in promulgating the HRSA guidelines, nor reflects the current state of the research on the value and efficacy of routine HBV screening. Most importantly, by assessing only two categories of persons – pregnant women and the general asymptomatic population – the USPSTF fails to focus on the population subgroups at greatest risk of HBV infection (for whom the CDC now expressly recommends testing). Given the CDC’s more recent and thoroughly researched recommendations, we urge HHS to encourage the USPSTF to reassess and refine its outdated and overbroad “do not recommend” rating for HBV screening.

I. Ensuring Routine HBV Testing for Women in At-Risk Populations will Increase Diagnoses, Enable Earlier Treatment, and Reduce Adverse Health Consequences.

HBV is known as a “silent killer”: Its infections often have no visible symptoms, and thus frequently go undiagnosed. Unfortunately, it is precisely this asymptomatic nature that prevents millions of individuals from knowing that they have HBV until it is far too late. Even more discouraging is the fact that almost all HBV infections are eminently preventable: While an

¹⁵ See 75 Fed. Reg. 41,731.

¹⁶ Ward JW. *Time for Renewed Commitment to Viral Hepatitis Prevention*. AMERICAN JOURNAL OF PUBLIC HEALTH (2008). 98(5):779-781. (“In 2006, a total of 86 perinatal HBV cases were reported to the CDC, but testing and reporting are incomplete; thus, the true number of perinatal HBV cases per year is likely 10 to 20 times higher”).

¹⁷ See 75 Fed. Reg. 41,733 (citing Jonathan Gruber, *the Role of Consumer Copayments for Health Care: Lessons from the RAND Health Insurance Experiment and Beyond*, Kaiser Family Foundation (Oct. 2006)).

estimated 1.4 million people in the United States are currently living with chronic hepatitis B, an effective HBV vaccine has been available for more than 20 years.¹⁸

Chronic HBV infections cause devastating damage to the liver, and many people living with HBV often learn of their HBV-positive status only after presenting with serious additional conditions such as liver cancer — caused by a disease they never knew they had. Expanded testing for HBV in high-risk groups is crucial to both improving patient outcomes and preventing unnecessary serious health complications and deaths, because it is the “silent” nature of chronic HBV infections that allows liver damage to go unchecked.

Fortunately, the urgency of this situation has begun to be recognized. Earlier this year, the Institute of Medicine (“IOM”) issued a report commissioned by the CDC, HHS, and other federal agencies, proposing a National Strategy for control and prevention of hepatitis B and C. The IOM report concluded unequivocally that current efforts for identifying viral hepatitis are simply inadequate. The IOM therefore issued a call for better outreach, expanded screening, and improvements in other related services that will help reduce the adverse impacts of HBV.¹⁹ Notably, the IOM expressly recommended that all federally funded health-insurance programs — including Medicare, Medicaid, and the Federal Employees Health Benefits Program— incorporate guidelines for risk-factor screening for HBV as a required core component of preventive care.

These steps, if implemented, will indeed constitute significant advances in the fight to eliminate HBV. Yet additional efforts to reach all high-risk individuals remain critical. Ensuring routine HBV testing for women in high risk populations is an essential step toward increasing diagnoses, enabling earlier treatment, and reducing the adverse and unnecessary health consequences of HBV.

A. The Lack of Visible HBV Symptoms and Serious Late-Stage Conditions Make HBV a “Silent Killer,” but Also Suggest that Expanded Testing Could Significantly Improve Health Outcomes.

HBV is silent, virulent, and deadly. The hepatitis B virus is found in blood and other bodily fluids and can be spread through mother-to-child transmission, unprotected sex, illicit drug use, and the sharing of personal hygiene items.²⁰ Indeed, HBV is up to 100 times more easily transmitted than HIV.²¹ While most adults with fully functioning immune systems can

¹⁸ INSTITUTE OF MEDICINE. HEPATITIS AND LIVER CANCER: A NATIONAL STRATEGY FOR CONTROL AND PREVENTION OF HEPATITIS B AND C (2010), available at http://www.nap.edu/catalog.php?record_id=12793 (hereinafter “IOM REPORT”).

¹⁹ *Id.*

²⁰ Centers for Disease Control and Prevention. *Hepatitis B FAQs for Health Professionals*. Available at <http://www.cdc.gov/hepatitis/HBV/HBVfaq.htm#b1> (hereinafter “CDC FAQs”).

²¹ World Health Organization. *Hepatitis B Fact Sheet* (2008). Available at <http://www.who.int/mediacentre/factsheets/fs204/en/index.html>.

clear an HBV infection from their system within six months, up to 10 percent of adults, 50 percent of young children, and 90 percent of infants who are not appropriately vaccinated will develop chronic hepatitis B infections, a serious and potentially fatal liver disease.²² Unfortunately, 25 to 40 percent of patients with chronic hepatitis B develop chronic liver disease, cirrhosis, or primary liver cancer,²³ and the five-year survival rate for liver cancer is less than 10 percent.²⁴ Because HBV is believed to cause 80 percent of all liver cancer cases worldwide, HBV is second only to tobacco among known human carcinogens²⁵ and is one of the world's leading causes of death due to infectious disease.²⁶

Unfortunately, partly because chronic hepatitis B is characterized by an extended asymptomatic period followed by the onset of very serious conditions, an estimated two-thirds of people living with chronic hepatitis B are unaware they are infected.²⁷ As a result, up to one-quarter of individuals with chronic hepatitis B will die from what is a preventable and treatable disease.²⁸ Moreover, chronic hepatitis B need not be a death sentence if diagnosed early enough through a simple blood test. Once diagnosed, chronically infected patients can receive regular monitoring to detect disease progression, and receive treatment, if appropriate, to reduce potential injury to the liver. As a result, the serious health complications resulting from untreated chronic hepatitis B infection can be mitigated, postponed, or even avoided by early detection. Because effective treatments for HBV exist, early diagnosis is critical to avoiding the devastating and preventable consequences associated with the later stages of chronic hepatitis B.

B. Routine HBV Testing of Women in Groups Deemed “High Risk” by the CDC Would Provide the Most Significant and Cost Effective Benefit.

Because of high HBV vaccination rates in the United States, the general population is not at high risk for infection with HBV. However, there remain millions of individuals living in the

²² CDC FAQs, *supra* note 20.

²³ World Health Organization. *Hepatitis B Fact Sheet*, *supra* note 21. See also Man-Fung Y. *Revisiting the Natural History of Chronic Hepatitis B: Impact of New Concepts on Clinical Management*. JOURNAL OF GASTROENTEROLGY & HEPATOLOGY (2007). 22(7):973-976.

²⁴ Lin S et al. *Why We Should Routinely Screen Asian American Adults for Hepatitis B: A Cross-Sectional Study of Asians in California*. HEPATOLOGY (2007). 46:1034-1040.

²⁵ World Health Organization. *Hepatitis B* (2002). Available at http://www.who.int/csr/disease/hepatitis/HepatitisB_who.cdscsrlyo2002_2.pdf.

²⁶ World Health Organization. *Hepatitis B Fact Sheet*, *supra* note 21; World Health Organization. *The World Health Report* (2004), available at <http://www.who.int/whr/2004/en/index.html>.

²⁷ IOM REPORT, *supra* note 18; Lin, *supra* note 24; Taylor VM et al. *Hepatitis B Knowledge and Practices Among Cambodian American Women in Seattle, Washington*. JOURNAL OF COMMUNITY HEALTH (2002). 27(3):151-163.

²⁸ World Health Organization. *Hepatitis B* (2002), *supra* note 25; see also Centers for Disease Control and Prevention (CDC). *Hepatitis B: FAQs for Health Professionals* (2008) available at <http://cdc.gov/hepatitis/HBV/HBVfaq.htm#overview>.

United States who are not vaccinated. The CDC therefore correctly recommends targeted routine HBV testing of those persons who are at high risk of infection, which includes not only those with behavioral risk factors, but many individuals who were born abroad. Indeed, while the CDC recommends testing of individuals born in countries with an HBV prevalence above two percent, the CDC also reports that as of 2005, nearly 100 countries had an HBV prevalence exceeding eight percent, including all but six African countries, every Southeast Asian country except Malaysia, every Antipodean country except Australia, Guam, and New Zealand, six East Asian countries (including China), and twelve Eastern European countries (including Armenia, Bulgaria, and Georgia). Moreover, many highly populous nations have an HBV prevalence above the CDC's recommended routine testing threshold of two percent, including India, Pakistan, Japan, Brazil, Turkey, Egypt, and Russia.²⁹

Although many immigrant groups are clearly deemed at high risk for HBV by the CDC, Asian and Pacific Islanders (APIs) in the United States have been the most thoroughly studied, because of the size of the group and the high prevalence of HBV therein. Although APIs account for only five percent of the American population, they comprise more than 50 percent of Americans living with chronic hepatitis B.³⁰ An estimated one in ten foreign-born APIs are living with HBV,³¹ and up to two-thirds of Asian immigrants to the United States have been exposed to HBV.³² Unfortunately, the lack of routine HBV screening in API communities in the United States leads to elevated rates of liver cancer – members of these communities are 2.7 times more likely to develop liver cancer and 2.4 times more likely to die from the malignancy than are Caucasians.³³ As with many immigrant populations, there are often numerous cultural, informational, and economic barriers that prevent people in these groups from receiving hepatitis B testing and treatment.³⁴

APIs are only one of many groups that face high risks from HBV, and many of these risks could be ameliorated or eliminated with earlier diagnosis and either vaccination or treatment. The CDC recommendations rightly cast a broad net, advising testing for persons born in any region with HBV prevalence greater than two percent (as well as for all persons exhibiting

²⁹ *CDC Recommendations*, *supra* note 7, at 9 (Figure 4) & 32 (Box).

³⁰ IOM REPORT, *supra* note 18. Some estimates are that 1 million Asian Americans are now living with chronic HBV. See Department of Health & Human Services, Office of Minority Health. *National Hepatitis B Initiative for Asian Americans and Pacific Islanders: Background* (2008). Available at <http://www.omhrc.gov/templates/content.aspx?ID=7240&lvl=2&lvlid=190>.

³¹ Office of Minority Health, *Chronic Hepatitis B in Asian Americans, Native Hawaiians and Other Pacific Islanders: Background* (2008).

³² Nguyen TT et al. *Hepatitis B Awareness, Knowledge, and Screening Among Asian Americans*. JOURNAL OF CANCER EDUCATION (2007). 22:266-272.

³³ Lin S et al., *supra* note 24.

³⁴ See, e.g., *id.*

behavioral characteristics indicating high risk).³⁵ The research on the API communities offers a powerful illustration of how providing routine HBV testing for women in high risk groups could have a significant positive impact on improving the health of women from populations that are both at high risk for infection and generally underserved.

C. Including HBV Testing in the HRSA Guidelines Would Increase Access to HBV Screening.

Pursuant to PHSa Section 2713(a)(4), HRSA is tasked with developing guidelines that establish the preventive care and screening procedures for women that health care insurers must cover without cost-sharing. As described in this joint comment letter, routine HBV screening is currently underutilized, resulting in an unacceptably high number of preventable catastrophic health outcomes for those who are diagnosed late, as well as concomitant increased costs to the health care system as a whole.

At present, however, misinformation, cultural and language challenges, and concerns about stigma often create barriers that prevent members of high-risk groups from seeking and receiving HBV testing.³⁶ At-risk women may feel uncomfortable requesting an HBV test from their health provider, and similarly, providers may be hesitant to affirmatively recommend such a test. At-risk women may also not even understand (or believe) that they are at risk, and thus may have no reason to consider — much less request — an HBV test.³⁷ And although many female immigrants are at higher risk for HBV due to a lower likelihood of vaccination, the attendant cultural and language barriers can often further compound the difficulty of ensuring that they receive HBV testing.³⁸ By establishing HBV testing as a routine medical service for women, HRSA can help significantly reduce many of these barriers, by sending women in at-risk groups the powerful message that routine HBV testing is a standard component of basic medical care. Finally, lack of adequate insurance coverage for testing — another common barrier — would be directly addressed by including HBV testing in the HRSA Guidelines.³⁹

For these reasons, incorporating HBV testing into the HRSA guidelines would expand access to testing and thereby save and extend lives — as well as the quality of those lives — of hundreds of thousands of women. Moreover, adopting routine HBV testing for at-risk women

³⁵ *CDC Recommendations*, *supra* note 7.

³⁶ IOM REPORT, *supra* note 18.

³⁷ *See, e.g.*, Bastani R et al. *Hepatitis B Testing for Liver Cancer Control Among Korean Americans*. ETHNICITY & DISEASE (2007). 365-373.

³⁸ Tran TT. *Understanding Cultural Barriers in Hepatitis B Virus Infection*. CLEVELAND CLINIC JOURNAL OF MEDICINE (2009). 76(3):S10-S13; Ma G et al. *Risk Perceptions and Barriers to Hepatitis B Screening and Vaccination among Vietnamese Immigrants*. JOURNAL OF IMMIGRANT & MINORITY HEALTH (2007). 9(3):213-220.

³⁹ Tran TT, *supra* note 38.

would have an added benefit: helping to avert perinatal transmission of HBV to an estimate of more than 1,000 newborns annually.⁴⁰

II. A USPSTF Rating of “A” or “B” for HBV Screening of the Groups Identified in the CDC Recommendations Would Facilitate Coverage of Such Testing under Medicare and Private Insurance.

Finally, Gilead, HBF, AAPCHO, and NVHR encourage HHS to engage in a dialogue with the USPSTF regarding the need for the USPSTF to review and refine its current rating for HBV screening of the general asymptomatic population. As present, the USPSTF rating is inconsistent with not only the more recent and more detailed recommendations of the CDC,⁴¹ but with the recent findings, conclusions, and recommendations of the Institute of Medicine.⁴²

The USPSTF currently assigns an “A” rating to HBV screening in pregnant women at their first prenatal visit, but assigns a “D” rating to HBV screening of the general asymptomatic population.⁴³ Yet this “D” rating — last updated in 2004 — is both outdated and overbroad. First, the existing rating fails to incorporate any of the significant peer-reviewed research that has been published in the past six years. As illustrated in this joint comment letter, there is significant evidentiary support for the health benefits of expanding testing for HBV in the at-risk asymptomatic populations identified by the CDC. Second, and perhaps more important, the existing USPSTF rating fails to recognize that while HBV may not be highly prevalent in the entire population, HBV is highly prevalent in certain identifiable at-risk population subgroups. It is precisely these at-risk asymptomatic populations for whom an upgraded USPSTF rating is not only warranted given the evidence, but absolutely crucial for both patient and public health.

Unfortunately, in the absence of a consistent message from the CDC and the USPSTF on this issue, it remains possible that the USPSTF’s outdated rating will be misinterpreted as implying that — despite contemporary evidence to the contrary — HBV testing is not an essential preventive service for women (or men) who are members of at-risk population subgroups. We therefore urge HHS to encourage the USPSTF to reconsider its current rating and recommend routine HBV screening for at-risk asymptomatic populations.

⁴⁰ Ward JW. *Time for Renewed Commitment to Viral Hepatitis Prevention*. AMERICAN JOURNAL OF PUBLIC HEALTH (2008). 98(5):779-781.

⁴¹ *CDC Recommendations*, *supra* note 7.

⁴² IOM REPORT, *supra* note 18.

⁴³ See USPSTF, *Screening for Hepatitis B Virus Infection*, at <http://www.uspreventiveservicestaskforce.org/3rduspstf/hepbscr/hepbrs.htm>.

III. Conclusion

Gilead, HBF, AAPCHO, and NVHR appreciate the opportunity to provide these joint comments on the Interim Final Rules, and to provide evidence regarding the importance of incorporating HBV testing into the HRSA guidelines on preventive care and screening for women. We appreciate your time and attention to these joint comments, and would be pleased to provide any additional information that may be of value in addressing these issues.

Sincerely,



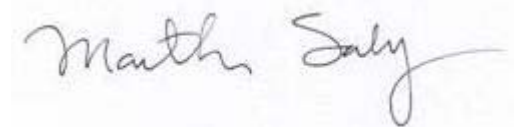
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