Issue No. 5 2017 April



Health Policy Update

A National Strategy for the Elimination of Hepatitis B and C: Phase Two Report

The National Academies have been convening on Hepatitis B (HBV) and C (HCV) with Phase Two of the National Strategy for the Elimination of Hepatitis B and C. The committee dedicated to the cause consists of experts from the Centers for Disease Control and Prevention (CDC), the U.S. Department of Health and Human Services (HHS), the National Viral Hepatitis Roundtable (NVHR), the American Association for the Study of Liver Diseases (AASLD), and the Infectious Diseases Society of America (IDSA). In its first report, the committee revealed that HBV and HCV could be ended as public health problems in the United States and that 90,000 lives could be saved by 2030.

The Phase Two of the report provides several interventions, delivery of service recommendations, cost reduction plans, and research objectives that will help the committee reach its goals. To read the highlights, recommendations, press release, and the Phase One report, visit: www.nationalacademies.org.



FDA Commissioner Hearings

The Trump administration has been working to fill the more than 2,000 appointed positions still currently vacant. The confirmations of Tom Price as the secretary of the U.S. Department of Health and Human Services (HHS) and Seema Verma as the administrator of the Centers for Medicare and Medicaid Services (CMS) were followed by the nomination of Scott Gottlieb for commissioner of the United States Food and Drug Administration (FDA).

POLICY PERSPECTIVE

Trumpcare = Predicate for Tax Reform

With Republicans in the White House and holding majorities in both houses of Congress it seemed that nothing could stand in the way of repealing and replacing the Affordable Care Act (ACA), also known as ObamaCare, however, after years of campaigning on this issue, no consensus bill, in fact, has been developed by either Congress or the new Administration. The first attempt to repeal and replace the (ACA) came on March 6, 2017 with the introduction of the American Health Care Act (AHCA). On March 24, 2017, the ACHA bill was withdrawn. It failed for many reasons, tops among them the Congressional Budget Office assessment that 24 million people would be rendered uninsured by 2026 relative to current law, concentrated ironically in low-income demographics who had voted for the president, pushback from Republican governors who had had expanded Medicaid, and coverage for people with pre-existing conditions.

Focus has turned to ensuring the government does not close on April 28th and on tax reform. However, the Administration keeps signaling that they would like Congress to take up healthcare again, to fulfill campaign promises, but also to secure the \$337 billion in deficit reduction gained from pulling subsidies and reduced revenues from repealing the ACA. This money has been discussed as wanted to pay for infrastructure projects, a wall on the southern border, or further tax cuts.

The immediate danger is the threat by the Administration to withhold cost-sharing payments to insurers. This would result in the destabilization of healthcare exchange markets, furthering the withdrawal of insurers from markets, leaving less choice and likely higher premiums on the lower base of insured.

A lesson for those constructing healthcare policies: Healthy people are the nation's true infrastructure. Hard lesson to learn when the Surgeon General, the top Administration envoy on public health, is now one of the many health and science positions that stands empty.

Donna R. Cryer, JD President & CEO, Global Liver Institute



Dr. Gottlieb's nomination hearing, supervised by the U.S. Senate Committee on Health, Education, Labor, and Pensions, examined Dr. Gottlieb's professional, educational, and moral qualifications for the position. Many of the questions asked of Dr. Gottlieb centered on his extensive financial involvement in

pharmaceutical and medical technology companies. If confirmed, this will be Dr. Gottlieb's third position within the FDA, making him a knowledgeable and experienced candidate.

To watch the April 5th full hearing, go to: www.help.senate.gov.

Continue >

Issue No. 5 2017 April



APRIL:

National Minority Health Month: Bridging Health Equity Across Communities: minorityhealth.hhs.gov

National Donate Life Month: www.donatelife.net

STD Awareness Month: www.cdc.gov

APRIL 24 - 25: National Minority Quality Forum Leadership Summit and Spring Health Braintrust, Washington, D.C.: www.nmqf.org

APRIL 29 - MAY 3: ASTS 2017 American Transplant Congress, Chicago: www.atcmeeting.org

MAY:

National Hepatitis Awareness Month: www.cdc.gov/hepatitis

MAY 6 - MAY 9: Digestive Disease Week Annual Meeting 2017, Chicago: ddw2017.org

MAY 18: HIV Vaccine Awareness Day: www.aids.gov

JUNE:

JUNE 2 - JUNE 3: 2017 Clinical Hepatology Update, San Diego: www.aasld.org

JUNE 4: National Cancer Survivors Day: www.ncsd.org

JUNE 12: Comments due on FDA's "Enhancing Patient Engagement Efforts Across the Food and Drug Administration: Establishment of a Public Docket; Request for Comments." The announcement can be found on pages 13632-13634 at: www.qpo.gov

JUNE 19 - JUNE 22: BIO International Convention, San Diego: convention.bio.org



European Liver Patients' Association (ELPA)

ELPA recently released the 2016 ELPA Hep-CORE Report: Monitoring the Implementation of Hepatitis B and C Policy Recommendations in Europe. The report outlines facts, policy developments, and information on the Hep-CORE program, and provides conclusions and recommendations for viral hepatitis in the EU. To read the report, go to: www.easl.eu.

World Health Organization (WHO)

The WHO released the program for the 2017 World Hepatitis Summit (WHS). This year's WHS will take place from November 1-3 in Sao Paulo, Brazil. To learn more, visit: www.worldhepatitissummit.org

March marked the first meeting of the WHO Strategic and Technical Advisory Committee on HIV and Viral Hepatitis (STAC HIV-HEP). The HIV and Hepatitis branches were once separate, but the similar nature of the two diseases and the committees' overlapping goals caused the WHO to combine the two into one united front. To learn more about the Committee and to stay up to date on their work, click here: www.who.int.

Canadian Liver Foundation (CLF)

In celebration of Liver Health Month in Canada, CLF published an article titled "Liver disease may be invisible but it's more prevalent than most people think" on their website. The article highlights the importance of recognizing the threat of liver disease, as 1 in 4 Canadians is affected by some type of liver disease. To read the article and take a closer look at CLF's resources, go to: www.liver.ca.



Food and Drug Administration (FDA)

The FDA recently released a press release revealing the approval of two hepatitis C drugs suitable for some pediatric patients. The drugs, Sovaldi (sofosbuvir) and Harvoni (ledipasvir and sofosbuvir), were previously approved to treat hepatitis C in adults, but are now approved for some children ages 12 to 17. This breakthrough is helping to reduce the disparities between adult and pediatric hepatitis treatment options. www.fda.gov.

National Institute of Health (NIH), National Cancer Institute (NCI)

NIH and NCI released the Annual Report to the Nation on the Status of Cancer in collaboration with the CDC, HHS, American Cancer Society (ACS), and the North American Association of Central Cancer Registries (NAACCR). The report found that cancer death rates have decreased for nearly every cancer type, with liver cancer being the only cancer to show increased death rates in both men and women. www.nih.gov.

Patient-Centered Outcomes Research Institute (PCORI)

The PCORI board recently approved the funding of \$34 million to further patient-centered comparative clinical effectiveness research (CER) studies. The money will support research on opioid abuse, moderate to severe traumatic brain injuries, and surgical and nonsurgical rotator cuff tears. The studies will also promote future clinical effectiveness research endeavors.

www.pcori.org.

PCORI announced in March that it was establishing the People-Centered Research Foundation (PCRF). PCRF was founded on the idea that there could be improvements in people-driven research, and that such research out improve the outcomes of health care systems, populations, and individuals

Issue No. 5 2017 April

by engaging people, patients, and health systems in all phases of research. PCRF hopes to both advance and support the sustainability of peopledriven research. Check out their website to learn more at: pcrfoundation.org

Centers for Medicare and Medicaid Services (CMS)

In recognition of National Minority Health Month, CMS released two studies on the racial, ethnic and gender differences in Medicare Advantage health care. The first report detailed gender based disparities in health care and quality of treatment. The second compared racial and ethnic group data stratified by gender as a follow up to a November 2016 report. To read the full reports, go to: www.cms.gov.

U.S. Department of Health and **Human Services (HHS)**

The National Viral Hepatitis Action Plan 2017-2020 outlines a plan to fight viral hepatitis in the United States. There are four main goals that HHS hopes to achieve by 2020: prevent new infection, decrease death rates while improving the health of those who suffer from viral hepatitis, reduce disparities in viral hepatitis health, and to focus on the implementation of viral hepatitis activities. To read the plan and its visions, goals, strategies, and indicators, visit: www.hhs.gov.



Pragmatic Clinical Studies to Evaluate Patient-Centered Outcomes - Cycle 1 2017. Funds available: \$90 million. Application deadline: May 17, 2017. http://www.pcori.org/funding-opportunities/announcement/pragmaticclinical-studies-evaluate-patient-centered-outcomes-1

Pipeline to Proposal Awards Tier A Pre-Engagement/Community Projects. Funds available: \$50,000. Application deadline: June 30, 2017. http://www. pcori.org/funding-opportunities/announcement/pipeline-proposal-awardstier-pre-engagementcommunity-projects



NAMES TO KNOW

SCOTT GOTTLIEB: Nominee for the United States Food and Drug Administration Commissioner. en.wikipedia.org/wiki/Scott Gottlieb

TOM PRICE: United States Secretary of Health and Human Services. en.wikipedia.org/wiki/Tom Price

SEEMA VERMA: Administrator of the Centers for Medicare and Medicaid. en.wikipedia.org/wiki/Seema Verma



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