GLI GLOBAL LIVER INSTITUTE

Health Policy Update

Liver Matters for Advocates

21st Century Cures Act

On December 13, 2016, after almost 3 years of bipartisan and multi-stakeholder activity and advocacy, President Obama signed the 21st Century Cures Act into law. [link: www.govtrack.us/congress/bills/114/hr34]

What could its major provisions mean for liver patients and those at risk?

- $4.8 Billion for NIH can provide opportunities for additional research. We must be diligent, through *Friends of NIDDK*, the *Digestive Disease Coalition* and other collaborations, to ensure that hepatology topics are prioritized, hepatology reviewers are available, and that researchers, particularly young post-docs are aware of funding to attract and retain them in hepatology careers.
- $1.8 Billion of the NIH funds are dedicated to the *Beau Biden Cancer Moonshot* and *NIH Innovation Projects*. Although the NCI's latest annual report highlighted the rise in liver cancer, the National Cancer Institute should be encouraged to apply new emphasis on liver cancer with this infusion of funds.
- *The Precision Medicine Initiative*, now referred to as *Accelerating Research for Us All*, also received a call out in funding and can increase the understanding of the genetic basis and improve diagnosis for liver diseases, including pediatric, autoimmune conditions and the different rates of disease progression from various types of liver disease to end stage liver disease and liver cancer.
- $500 million to FDA though 2026 is intended to increase the capacity of FDA to approve drugs more quickly with additional hiring flexibility. Specific aspects of applicability to the liver space are provisions supporting regenerative medicine that may advance the development of replacement organs for transplant through human cell and tissue products. Antimicrobial testing and approval based on small populations may benefit transplant recipients and other immunocompromised individuals.
- $1 Billion for opioid epidemic amelioration including new treatment centers along with additional support for mental health may help slow the spread of viral hepatitis among those with substance and behavioral health issues.

POLICY PERSPECTIVE

The Times They Are A-Changing

2017 was going to be a reset after the November 8th election with new members of Congress, the anticipated retirement of long tenured federal agency staffers, Supreme Court Justice nominations and change in White House personnel, however, the Electoral College victory of Republican Presidential candidate Donald Trump is likely to result in a wholesale upset of most every tenet of healthcare policy we have come to understand not just in the past 8 years, but in some cases, for decades.

This Transition Edition of the *LiverMatters Healthcare Policy Update* will discuss the implications of:

1. The Signing of 21st Century Cures by President Obama
2. Repeal and Replace of the Patient Protection and Affordable Care Act
3. The Trump Transition Prospective Nominees for HHS, CMS, and FDA
4. Value, Quality, and Drug Development Opportunities for Patients and Patient Advocates to Look for in 2017

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

ON THE HILL

The fate of the Affordable Care Act is concerning for several important reasons: 1) The Congressional Budget Office (CBO) estimated that repeal of the ACA would increase the federal deficit by $137 – $353 billion over 10 years (2016-2025): 2) since enactment, the uninsured rate has fallen to 8.6% and an estimated 20 million Americans have gained coverage, while 27 million remain uninsured; 3) with control of all three branches of government and with one of the lead opposition voices, House Budget Chairman, Thomas Price, MD (R-GA) being proposed for Secretary of Health and Human Services, and with Repeal and Replace being one of the few healthcare-related proposals in President-Elect Trump's 100 Day Plan, Congressional Republicans and the President have the opportunity to make dramatic changes to the program which affects many patients, providers and the entire healthcare enterprise. A key outstanding issue is the timing and fullness of repeal.

Using Congressman Price's *Empowering Patients First Act* as a likely roadmap [link http://tomprice.house.gov/sites/tomprice.house.gov/files/Section%20by%20Section%20of%20HR%202300%20Empowering%20Patients%20First%20Act%202015.pdf] several issues for patients, particularly liver patients or others with chronic or severe conditions:

- Reversion from nondiscrimination based on pre-existing conditions back to high-risk pools
- Advanceable tax credits at age-based levels that do not come close to covering

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CONTENT CONTRIBUTIONS WELCOME!

Contact policy@globallliver.org to send relevant content for our next issue.

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the average annual cost of about $7,000 or even the average premium of $4,000 for individual plans currently on the market

- Emphasis on Health Savings Accounts (HSAs)
- Legal reforms based on promulgating clinical guidelines with specialty societies as affirmative defenses in malpractice lawsuits and the establishments of administrative health tribunals. Patients whose care needs fall outside of the average of a clinical guideline and experience negligent harm would have the burden of proving their case by a clear and convincing evidence standard
- Provisions for concierge and private pay physicians are throughout the legislative proposal that may open coordinated care options for chronic disease patients but may also subject patients to additional costs now disallowed by Medicare.
- Information on health plans cost and other information through web portals, but those portals may not assist in direct enrollment

Call to Action for Advocates

The 21st Century Cares Act paid for much of the law by raiding $3.5 billion from the Prevention and Public Health Fund. Inasmuch as preventing liver diseases is an essential aspect of their ultimate control and eradication this seems short-sighted. Public health and acute health should not be pitted against each other. Public health is the greatest infrastructure project of the nation! If you agree please read and consider signing onto this letter that groups from the Global Liver Institute to Research!America have already endorsed. Here is the letter, led by Trust for America's Health, urging Congress not to repeal—indeed to expand—the Prevention and Public Health Fund. We hope your organizations will consider signing on.

The Transition

Healthcare was not a major part of the Mr. Trump's campaign but several points came through: https://assets.donaldjtrump.com/_landings/contract/O-TRU-102316-Contractv02.pdf

- Repeal & Replace Obamacare
- Ability to Purchase Health Insurance Across State Lines
- State Management Through Block Grants or other mechanisms
- Cutting Red Tape at FDA to Speed Approval of Life-Saving Medications
- Reducing Drug Pricing through Negotiation by Federal Programs

NAMES TO KNOW

Announced Nominees:

- **HHS Secretary – Thomas Price, MD (R-GA)** Currently Chair, House Budget Committee is an orthopaedic surgeon who has served 6 terms in Congress and has been an active and vocal opponent of the ACA.
- **CMS Administrator – Seema Verma** was instrumental first in leading Indiana's Medicaid expansion under now Vice-President elect Mike Pence and subsequently developed Healthy Indiana Plan 2.0 and consulted on similar plans for Michigan, Tennessee, and Iowa. A key element across plans were patient contributions even for very-low income individuals.
- **FDA Commissioner – Jim O'Neill**, a former Principal Associate Deputy Secretary under George W. Bush, and friend of Silicon Valley investor/ Mithril Capital Management colleague Peter Theil, a close Trump advisor has been proposed for FDA Commissioner but not formally nominated as of this date. Many are alarmed by prior statements by O'Neill that FDA should accelerate approvals by considering safety only, and gaining efficacy evaluation afterwards from real world use and reliance on biomarkers and surrogate endpoints rather than outcome trials; yet the dual outcome requirement has set a global standard for efficacy and quality. O'Neill has also advocated for payment for organ donation as opposed to the current altruistic system.
- Other names circulated have included former FDA official

HHS NEWS

CMS

MACRA/Quality Payment Program https://qpp.cms.gov/

Although geared towards clinicians whose reimbursement under federal public health programs like Medicare will be increasingly aligned with quality process and outcomes measures, participation in quality improvement activities, and advancing care information (formerly meaningful use including patient engagement through health information technology and exchange of patient data with other providers) there are opportunities for public comment.

Examples of liver-related quality measures under consideration are:

- Childhood immunizations including Hepatitis A and B dose schedules
- Hepatitis C and Hepatocellular Carcinoma screenings and shared decision making
- Assessment of Hepatitis B status before Initiating Anti-TNF Therapy in IBD

2017 Physician Fee Schedule final rule

On November 2, CMS finalized the 2017 Physician Fee Schedule final rule that recognizes the importance of primary care by improving payment for chronic care management and behavioral health. The rule also finalizes many of the policies to expand the Diabetes Prevention Program model test to eligible Medicare beneficiaries, the Medicare Diabetes Prevention Program (MDPP) expanded model, starting January 1, 2018. To review the final rule, click on: https://www.federalregister.gov/documents/2016/11/15/2016-26668/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions

FDA

- Expand the number of disease areas addressed in the Patient-Focused Drug Development (PFDD) initiative (20 meetings are slated to be held in 2017, conditions TBD)
  - The FDA welcomes patient advocacy organizations to organize externally-led PFDD meetings. The FDA recommends submitting a Letter of Intent (LOI). If your organization is interested in participating, please submit your LOI to patientfocused@fda.hhs.gov. To read more about the externally-led PFDD meetings, please visit the FDA's website, click on: http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm453856.htm.
  - To review LOI submission guidelines, click here: http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM453857.pdf?_cldee=Y3RvbWFuQGJpby5vcmc%3d&urlid=1
- Last month, the U.S. Food and Drug Administration (FDA) hosted a public hearing to obtain input regarding communications by biopharmaceutical and device companies about their products. The webcasts from this two-day meeting are available on the FDA's website. Electronic and written comments will be accepted until January 9, 2017. Please view the Federal Register Notice for instructions on how to submit comments.
- The U.S. Food and Drug Administration is requesting nominations for voting members to serve on the Center for Devices and Radiological Health (CDRH) Patient Engagement Advisory Committee. The Committee will provide advice to the FDA Commissioner on issues relating to the regulation and use of

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medical devices. Submission instructions for nominations are available on the Federal Register Notice.

- FDA is seeking applicants for its FDA Patient Representative Program
  - Applicants can be patients or caregivers who have direct experience with the disease. If selected, individuals will participate on FDA Advisory Committees and provide direct input to inform the Agency's approval process for drugs, biologics, and medical devices. To read more about the program and to learn how to apply, please visit the FDA's website, click on: http://www.fda.gov/forpatients/patientengagement/ucm505721.htm

NIH

- All of Us Research Program
  The Precision Medicine Initiative® (PMI) Cohort Program will now be called the All of Us Research Program and will be the largest health and medical research program on precision medicine. Informed by a Working Group of the Advisory Committee to the NIH Director, the program has begun building infrastructure and capacity and is expected to begin recruiting participants in 2017. You can learn more about the program and its requirements on their website, click on: https://www.nih.gov/research-training/allofus-research-program

NGOS

In anticipation of Rare Disease Day on February 28, 2017, the National Organization for Rare Disorders (NORD) announced the launch of new resources for advocates to begin preparations for planning events and raising awareness for the Day. The new resources include toolkits to plan an advocacy event, downloadable activities, sample press releases, and documents to obtain a Rare Disease Day Proclamation. If you have any questions about these resources, please contact rdd-us@rarediseases.org.

BIO's editorial website, BIOtechNOW, provides the opportunity for patient advocacy organizations to submit guest blog posts to highlight initiatives and bring awareness to their missions. If your organization would like to submit a guest blog post, please contact Cara Toman.

MARK YOUR CALENDARS

Jan 30-31, 2017, Washington, DC
AcademyHealth National Health Policy Conference 2017
http://www.academyhealth.org/events/site/2017-academyhealth-national-health-policy-conference

Feb 15, 2017
World Cholangiocarcinoma Day
www.worldcholangiocarcinomaday.org

RESOURCES

On a Path to a Science of Patient Input
In an April 2016 article published in Science Translational Medicine, it was reported that momentum is building to incorporate patient preferences into the biomedical R&D system so that products and services better align with patient needs, improve individual and public health and reduce time and spending on unproductive care. The article tracks more than 70 collaborative initiatives clustered in six categories that are defining and shaping a developing field: the science of patient input. To read the full article, click on: http://stm.science mag.org/content/8/336/336ps11.full

Health Care Stakeholders Identify Path Forward on Value Assessment
The NPC recently published their conference summary book *Assessing Value: Promise and Pitfalls*, providing a path forward to move value assessment frameworks from fledgling to functional. The book summarizes the perspectives of health care stakeholders with focus on the most critical issues in health care: how to measure the value of a medical treatment and its impact on patient care. In addition to the summary, NPC shared a white paper that evaluated how existing frameworks align with the organizations Guiding Practices for Patient-Centered Value Assessment. To review the complete summary book, white pages, and guide, click on:

- http://www.npcnow.org/publication/assessing-value-promise-and-pitfalls-conference-summary-report?utm_source=NPC+Contact+List&utm_campaign=1fe662c85fEMAIL_CAMPAIGN_2016_11_17&utm_medium=email&utm_term=0_3ddd3927eb-1fe662c85f245005125
- http://www.npcnow.org/publication/comparison-value-assessment-frameworks-using-national-pharmaceutical-councils-guiding?utm_source=NPC+Contact+List&utm_campaign=1fe662c85fEMAIL_CAMPAIGN_2016_11_17&utm_medium=email&utm_term=0_3ddd3927eb-1fe662c85f-245005125
- http://www.npcnow.org/guidingpractices

Read HIT Consultant' report focusing on how digital health may be impacted by the incoming Trump Administration. To read full report, click here: http://hitconsultant.net/2016/11/14/trump-digital-health-market-impact/?__s=phhy5fjfycs3ptk5idzk

GLOBAL

World Hepatitis Summit and World Hepatitis Alliance (WHA) Pre-Summit Member Conference, taking place from 30 October – 3 November 2017 at the World Trade Centre in São Paulo, Brazil.

The World Hepatitis Summit is a joint initiative between World Health Organization (WHO) and WHA and will be hosted in 2017 by the Brazilian government. The Summit brings together stakeholders including patients, civil society and policy makers to provide a focus for global efforts to tackle viral hepatitis.

The theme of this year's Summit is "Implementing the Global Health Sector Strategy on viral hepatitis (GHSS): towards elimination of hepatitis as a public health threat", which coincides with the recent adoption of the first WHO Global Health Sector GHSS Strategy on viral hepatitis whose goal is the elimination of viral hepatitis as a public health threat by 2030.

GRANTS AVAILABLE

Recruiting Satcher Health Policy Leadership Fellows for 2017 - 2018
The Satcher Health Leadership Institute at Morehouse School of Medicine is currently recruiting health policy fellows for 2017-2018. The Health Policy Leadership Fellowship is a multi-disciplinary training program that prepares physicians and postdoctoral professionals for leadership roles promoting policies and practices to reduce disparities and advance health equity. Started in 2009, the program's thirty graduates are taking leadership roles in academia, government agencies, health care, and community-based organizations across the country. The fellowship is uniquely focused at the intersections of leadership development, health policy, and health equity and is particularly interested in developing leaders from underserved, under-represented, and racial and ethnic minority populations with a strong commitment to health equity.

The application deadline for the 2017-2018 fellowship program is January 13, 2017. Additional information and application materials are available at: http://fellowship.satcherinstitute.org or applicants can contact Ebony S. Townsend, MSPH, Health Policy Program Manager, at healthpolicyfellowship@msm.edu.