

Conquer Hepatitis B Now!

The Hep B Cure Campaign: Science+ Advocacy = Cure

PROGRESS 2018

1. Science

- **Roadmap for a Cure** – Publications reflecting the consensus of HBF’s virtual workshop for curing HBV and HCC:
 - (1) **“Research Priorities for Discovery of a Cure for Chronic Hepatitis B; Report of a Workshop,”** T. Block, H. Alter, N. Brown et al, *Antiviral Research*, March 2018. (comprehensive report listing specific research tasks)
 - (2) **Professional Judgment Budget** developed for NIH support of above-referenced “Research Priorities” totaling \$232 million new funding over six years.
 - (2) **“A Research Agenda for Curing Chronic Hepatitis B Virus Infection,”** H. Alter, T. Block, N. Brown et al, *Hepatology*, March 2018 (reflects some of the priorities of the more comprehensive report – above)
 - (3) **“Funding needed for Cure Research to Eliminate Hepatitis B,”** (letter), A. Brownstein and C. Cohen, *The Lancet*, March 2018
 - (4) **“The Critical Role of a Cure in the Global Elimination of Hepatitis B,”** (letter), T. Block, C. Cohen, A. Brownstein and R. Gish, publication pending.
- **Distribution of HBF Scientific Publications.** The above scientific publications were distributed at 20 congressional meetings on January 27 and February 2, and meetings with NIAID, NIDDK, and NCI leadership on March 12 and meeting in NIH Director’s office on April 23.
- **Universal HBV Screening** - Universal Adult HBV screening test policy statement finalized.

2. Advocacy

- **FY 2019 Appropriations Report Language.** Great victory as Congress **approved (9/13/18)** FY 19 Appropriations Bill including **all** of HBF recommendations (see attached) which includes highly aggressive appropriations report language for NIH (including directors’ office), CDC. Language urges NIH (NIAID, NIDDK and NCI) to issue targeted calls for HBV/liver cancer research in keeping with “Roadmap...”(A-1, above); and CDC, to develop plan to implement NASEM

recommendations (2017) to eliminate hepatitis B by 2030 and to establish formal hepatitis B surveillance in U.S. to target high risk areas and measure progress.

- **Congressional Visits.** HBF proposed FY 2019 appropriations report language was well received on The Hill on January 27 (10 Senate leadership meetings) and on February 2, (10 House leadership meetings) - HBF participation in these meetings included Tim and Joan Block, Kate Moraras, Rhea Racho, Mike Hall and Alyson Lewis. These visits and follow-up congressional office relations provided the groundwork for FY 19 appropriations success.
- **Hep B United/HBF Hill Day and Summit Events (July 24-27)**
 - Advance advocacy training webinars organized
 - 67 Attendees; 61 Hill visits with follow-up communications.
 - Government Panel on implementing NASEM recommendations for HBV elimination by 2030
 - HBU legislative champion award (at the summit) to Sen. Mazie Hirono (D-HI)
- **FY 2018 Appropriations.** HBF's FY 2018 appropriations language was largely included in the House and Senate appropriations reports. But it was stuck for 7 months into the fiscal year in Congressional spending bill log-jam that was finally approved in March.
 - **NIH.** Congressional spending package has \$3 billion (8.8%) increase for NIH, but much is earmarked for NIH priorities. The good news is that an estimated \$1.242 billion remains available for new NIH research support across NIH. In competing for these funds HBF will have the advantage of strong report language and broad-based scientific consensus and specific projects identified for HBV cure. HBF provided support to congressional offices to facilitate their requests to the appropriations committee by completing over 115 congressional office forms.
 - **DOD.** FY 18 \$20 million increase in HCC research to a total of \$80 million (BSBI awarded \$1.3 million in 2017); \$30 million increase in medical research program (including HBV) to a total \$330 million.
 - **CDC.** FY 2018 spending bill provides for additional \$5 million to CDC Division of Viral Hepatitis (DVH).
- **CDC Opportunities** – historically, hepatitis B has been a low priority at CDC/DVH given hepatitis C priority. Given a number of factors (including a cure for HCV) the potential for improved CDC attention to HBV exists at this time:
 - **\$5 Million Increase in DVH Funding** - offers the potential for hepatitis B needs to receive increased support in keeping with passed spending bill. The need for this has been communicated to DVH and the newly appointed director of CDC.
 - **NASEM Report (2017)** – calls for the elimination of HBV in U.S. by 2030. HBF is participating in DVH planning in addressing this report scheduled for late fall. HBF is being proactive in convening HBF and other experts to develop a proposed plan for addressing NASEM recommendations for CDC.
 - **FY 19 appropriations language** – proposed by HBF is more powerful and specific in relation to NASEM recommendations and surveillance requirements for HBV.
 - **New DVH director** – John Ward stepped down as director of DVH. HBV was not a priority for Dr. Ward and recruitment of new director offers the potential for a more balanced approach, given all the above. HBF will have well-documented hepatitis B recommendations prepared for new DVH director when he or she arrives. Chari Cohen is on the search committee to recruit new director providing HBF excellent input to the selection process.
- **NIH Meetings/Follow-up**
 - **Meetings with NIAID, NIDDK and NCI** (March 12) – Tim Block, Carol Brosgart, Bill Mason, Alan Brownstein, Mike Hall and Alyson Lewis met with leadership of institutes central to HBV/HCC cure research priorities.

- Presented research priorities from consensus “Roadmap...” prepared by Bill and Tim targeted to each institute;
- Acknowledged \$8 million new NCI funding for HCC;
- Discussed NIAID priority commitment of focus on HBV mono-infection research.
- All institutes encouraged HBF to stimulate more HBV/HCC research applicants – RO1s and R21s [*HBF issued “Message to scientific community...” (600 U.S. researchers) encouraging applicants to apply*]; and,
- Tim Block appointed to NIAID AIDS Clinical Trial Group (ACTG) providing HBF excellent input into development of HBV clinical trials.
 - **Meeting with NIH Director’s Office** (April 23) – Tim Block, Alan Brownstein, Mike Hall and Alyson Lewis met with NIH Principal Deputy Director Lawrence Tabak (and Anna Mazzucco). The Director’s Office will explore potential for:
 - trans-NIH coordination of NIAID, NIDDK and NCI;
 - private-public partnerships to stimulate industry; and,
 - dedicated research that might be funded by NCI, NIAID, and NIDDK
- **Liver Illness Visibility, Education, and Research (LIVER) Act.** New bill drafted by Rep. Nydia Velazquez (D-NY) to be introduced in October during Liver Cancer Awareness month. The bill would direct NCI to create new funding opportunities for liver cancer and make hospitals and healthcare facilities eligible to receive funding for experimental treatment and prevention programs. The bill also creates two new HHS grant programs: one for liver cancer prevention activities and another for awareness activities targeted towards Americans in communities at a higher risk. Bill will not pass this session and requires substantial redrafting. HBF is providing support Ms. Velazquez’s office in strengthening this bill which will support HBCC.
- **Community-Based Initiative for Hep B Awareness, Advocacy and Congressional Support**
 - May 2 – HBF Joins Forces with NYC Hep B Coalition and Congresswoman Meng in Asian-American Community – “Eliminating Hepatitis B in NYC” (coordinated by Kate Moraras);
 - Major Ethnic Media Coverage;
 - Potential Model HBF/HBU Hep B Awareness/Advocacy Forums replicated in targeted congressional districts nationwide with HBF staff support.
- **Expanded Congressional Support.** HBF to secure broader-based congressional support which is important as we seek to garner expanded support for HBCC as well as other public policy initiatives. (See attached)
- **Increased Research Funding per HBCC**
 - \$8 million NCI
 - \$7 million DOD
 - AND \$5 million CDC/DVH for viral hepatitis programs and research