



# Maintaining Momentum thru

- · Letter from Tim Block and Joel Rosen
- Blumberg Institute research
- Expanding our home and research facilities
- Outreach and patient education
- Public health programs
- · Pandemic responses, statement from our advisors
- · Hep B United impact
- · Going global with storytelling
- · Patient-Focused Drug Development
- · New award for advocacy given to Joan and Tim Block
- · Thank you to our donors
- · Financial report
- Our leadership

#### This has, in many ways, been the longest year.

The COVID-19 pandemic has dealt a painful blow to world health and prosperity, but it has also shown us at least two very important things:

First, development of the COVID-19 vaccine makes it clear just how much can be accomplished when there is will and sufficient investment.

Second, despite remarkable success in scientific discovery in vaccine development, it is also clear how useless that all is in the absence of a robust public health infrastructure.

These two facts are immediately relevant to the **Hepatitis B Foundation's** mission; with enough investment, there is no doubt that there will be breakthrough medical advances in curing hepatitis B, D, and liver cancer. **The Baruch S. Blumberg Institute's** (the Foundation's research organization) contributions to cure research are here for that reason. Just as important is what the HBF is doing to build public health programs for linkages to care. These infrastructures will enable outreach and could even surge in times of more general public health need.

Yes, the COVID-19 pandemic changed life for everyone this year. But one thing it didn't change was our commitment to our mission, which is to improve the quality of life of those affected by hepatitis B and the diseases with which it is associated.

We are in our 30<sup>th</sup> year and have never ceased going full throttle on this mission. Even during the pandemic year, the Foundation has had a breathtaking number of accomplishments and activities. These are described more fully in this report but include some big firsts:

- The first-ever Externally Led Patient-Focused Drug Development Meeting on hepatitis B, in partnership with the U.S. Food and Drug Administration. This brought both attention and useful data to the question of what drugs and clinical trials those with hepatitis B need, expect and, frankly, will tolerate. We went virtual (because of the pandemic) but this allowed for participation of more than 650 people. The findings are being reported in virtual town halls, webinars, and journals, and are hotly sought after by people living with hepatitis B, nongovernmental agencies, and of course, the biopharmaceutical industry.
- Another first: The pandemic is forcing more and more of us to use telemedicine, and it's making hepatitis B experts more and more available worldwide. Along these lines, the Foundation introduced our first-ever training with the "ECHO" model (a telemedicine format for continuing education about hepatitis B for physicians and other health care professionals).

Despite the strange times (or perhaps because of them), we are also finding an uptick in interest in HBV from patients, pharma scientists and donors/investors.

Take a look at the HepIndex which has doubled since its creation in October 2020 (at \$759, very recently). This is a "Dow Jones"-like aggregate of stocks of companies focused on HBV we put together. Increased interest is also reflected by the number of consults the Foundation does online as well as "investor" calls we receive, asking about the HBV and HCC investigational landscape.

We at the Blumberg are ready for the new surge of demand. We're really excited about the wave of new discoveries that are developing—here. As described in this report, we have had important fundamental discoveries involving how HBV cccDNA is transcriptionally repressed, new targets for antiviral action on HBV surface protein, and even new and improved HBV capsid inhibitors.

This has also been a year of tremendous success and progress for the **Pennsylvania Biotech Center (PABC)**. The Foundation created the PABC to be its home and to provide an environment in which its research programs could thrive. The Center also serves as an incubator for startup companies, both those launched to commercialize our research and others begun by outside scientists, especially from area universities. The Foundation and Blumberg Institute are (as planned) the keystone residents of the PABC, which is more than 110,000 ft² of labs, offices and instructional space, on our own 14-acre campus.

As with the rest of the nation, the pandemic shook up the region's economy, and, just as with the 2008 recession, unfortunately many jobs were lost. However, the PABC was able to operate safely, with restrictions, and even with our new building scheduled for a Fall 2021 opening, the PABC is expected to be oversubscribed for space, with several new HBV, liver disease, and cancer-oriented companies.

This has certainly been a long year, but we think you will find the Foundation and its research organizations have made more than the best of it and are now in one of the best positions we have ever been in to make break through contributions.

Sincerely,

#### Timothy M. Block, PhD

President of the Hepatitis B Foundation and its research organizations, Baruch S. Blumberg Institute and Pennsylvania Biotechnology Center, and

#### Joel Rosen, JD >

Chair of the Board, Hepatitis B Foundation

On behalf of:

#### Wayne Yetter

Chair of the Board, Baruch S. Blumberg Institute, and

#### Loren Danzis, JD

Chair of the Board, Pennsylvania Biotechnology Center

The Baruch S. Blumberg Institute is the research arm of the Hepatitis B Foundation, responsible for fulfilling the promise of finding new therapies and improved methods of detection for chronic hepatitis B and liver cancer.

The Blumberg has a history of providing critical breakthrough research tools and new, investigational drugs. Several of the hepatitis B antiviral assays and drugs in clinical development today have origins at the Blumberg.

In 2020, the Blumberg and colleagues at the Foundation had more than 27 scholarly publications, two clinical trials resulting from our work, an all-new technique was developed to detect cancer non-invasively, and at least two new compounds were identified with cancer and HBV therapeutic activity.



## Five-year retrospective on W. Thomas London Distinguished Professorship

The W. Thomas London Distinguished Professorship was created in 2015 to recognize the extraordinary contributions of internationally renowned physician-scientist, W. Thomas London, MD, who died in 2017.

A key member of the research team that discovered the hepatitis B virus in the early 1960s, Dr. London was a longtime member of the Board of the Hepatitis B Foundation and the Baruch S. Blumberg Institute, where he was a distinguished scientific and medical advisor.

Dr. London's seminal contributions were "world changing in magnitude, but done quietly, and modestly," said Nobel Prize winner Harvey Alter, MD, an eminent scientist at the NIH and co-discoverer of the hepatitis B and C viruses.

A professorship is among the highest academic awards granted to any faculty member and it was quite fitting that the highly accomplished **Ju-Tao Guo**, **MD**, was named Chair at the inception of the W. Thomas London Distinguished Professorship.

After receiving his doctorate from Lanzhou University School of Medicine in China, Dr. Guo did postdoctoral training with Blumberg Prize winner Dr. Christoph Seeger at Fox Chase Cancer Center in Philadelphia.

Dr. Guo has focused his work on the *molecular pathogenesis and antiviral research* of hepatitis viruses, flaviviruses and human coronaviruses. He has published more than 90 peer-reviewed research papers, review articles, commentaries, and book chapters in the related fields.





W. Thomas London, MD Courtesy of Fox Chase Cancer Center Ju-Tao Guo, MD
Courtesy of Baruch S.
Blumberg Institute

"The IN. Thomas London
Distinguished Professorship is
imbued from the outset with a
legacy of scientific integrity and
achievement that will inspire the
occupants of this professorial chair
for generations to come."

TIMOTHY BLOCK, PhD

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## Major achievements in the last five years at Dr. Ju-Tao Guo's laboratory

#### This research has been supported by the National Institutes of Health, Department of Defense, Arbutus Biopharma and the W. Thomas London Distinguished Professorship

- 1 The team has identified host cellular proteins required for key steps of HBV replication, such as pre-genomic RNA packaging and synthesis of covalently closed circular (ccc) DNA.
- 2 They discovered interferon alpha-induced cellular proteins that epigenetically suppress the transcription of cccDNA minichromosome.
- 3 HBV capsid assembly modulators (including the compounds discovered from our laboratory) are currently in preclinical and clinical development for treatment of chronic hepatitis B. The team found that this class of compounds not only disrupt capsid assembly, but also induce the premature disassembly of HBV nucelocapsids, which results in the inhibition of cccDNA synthesis. Therefore, the CAMs inhibit HBV replication via dual mechanisms. Fig 1
- 4 A structural motif of HBV small envelope protein essential for the morphogenesis of subviral particles (SVP) has been identified, which paves the way for the discovery of antiviral agents that can specifically inhibit SVP production and facilitate the functional cure of chronic hepatitis B.
- 5 Dr. Guo and his team have demonstrated that activation of STING in both macrophages and hepatocytes efficiently suppresses HBV replication and they have discovered two chemotypes of small molecular human STING agonists for further preclinical development.

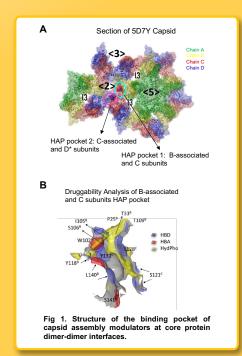


Fig 1

## Additional projects being conducted by Blumberg researchers

#### Novel STING Agonists: A Potential Cure for HBV and Liver Cancer

From the lab of J. Chang, with Y. Du and J.T. Guo: We discovered new STING agonists that are highly effective in turning on an immune response against HBV and cancers. Activation of STING with small molecular agonists not only induces the production of antiviral cytokines that restrict viral replication, but also activates a powerful adaptive immune response that can clear the virus-infected cells and cure chronic viral infections, such as HBV. We have also found that intratumor delivery of STING agonists can induce the programmed cancer cell death and activate anti-cancer immunity for sustained control of tumor growth. We plan to further optimize our lead STING agonists and refine our liver-targeted delivery vehicle to develop the STING agonists as a potential drug to cure HBV and liver cancers. Fig 2

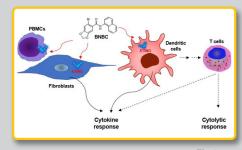


Fig 2

#### New Drug Targets HBsAg: To Improve Recognition of HBV by the Immune System

From the lab of T. Zhou: We have discovered a concept-proving drug (252-C4-MPI) that suppresses HBV production and appears to change its antigenic 'face' (HBsAg) with the expectation that it will cause virus recognition by the immune system. An important new strategy is to find a drug that can selectively modify the HBV proteins (or antigens) such that the virus becomes recognized and can then be eliminated by the immune system. We hope to pursue preclinical models for determining if our drug has the ability to alter the HBV's protein (antigen) structure so that it is safely recognized and attacked by the immune system. If so, we can further develop this drug or identify other drugs that work similarly through our screening process, which could then become 'first in class' HBV drugs.

#### New Platform Technology: For the Early Detection of Liver Cancer

From the lab of A. Sayeed: We have detected a specific "mRNA" in the blood that could be used as a new early detection marker of liver cancer. The mRNA we detected is associated with cancer proteins that are not normally in the blood and could, therefore, become part of a simple blood test. *People living with chronic HBV are at significant risk for dying prematurely from liver cancer.* Early detection is critical to survival, but current screening methods for liver cancer are expensive, inaccurate or unreliable. Fig 3

#### Precision Medicine Approaches and Treatments for Breast Cancer

From the lab of R. Pestell: We have discovered, in an animal study, that a drug used to treat HIV shows potential in treating triple-negative breast cancer, a particularly virulent type of the disease.

Our researchers identified a potential genetic target in triple-negative breast cancer called CCR5 after analyzing more than 2,200 breast cancers.

A humanized monoclonal antibody targeting CCR5 called leronlimab, which has a strong safety profile in clinical trials for HIV, has proven effective in blocking the metastatic spread of human triple-negative breast cancer in mice. Leronlimab also reduced the progression of many of the established metastases. Fig 4

"Triple-negative breast cancer often has a poor prognosis with limited treatment options—typically surgery, chemotherapy and radiation—with associated significant side-effects reducing the patients' quality of life," Pestell said. "The effectiveness of leronlimab in preventing metastasis and reducing the size of the metastases provides further support for carefully controlled clinical trials."

In related precision medicine studies of breast cancer, Pestell's laboratory revealed that cyclin D1 (thought to be a nuclear oncogene) has an additional function in the cell membrane. Cyclin D1 is overexpressed in a large proportion of human breast cancers, but targeted therapies help only a subset of patients. The studies show that cyclin D1 (which resides outside the nucleus in a membrane pool) activates another pathway to induce tumor growth called Akt.

"A detailed understanding of the molecular events by which cyclin D1 promotes tumorigenesis is essential to provide more effective and longer lasting remissions for breast cancer survivors." Pestell said.

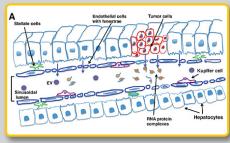


Fig 3

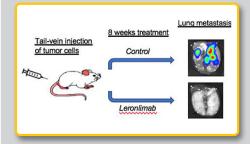


Fig 4



#### **Expanding our home and research facilities**

Construction has begun on a \$20 million expansion of the nonprofit Pennsylvania Biotechnology Center (PABC).

Managed by the Baruch S. Blumberg Institute, which is the Hepatitis B Foundation's research arm, the PABC is home to both the Blumberg Institute and the Foundation. Blumberg Institute researchers are focused primarily on hepatitis B and liver cancer treatment, prevention and diagnostics.

The PABC, which is one of America's most successful life sciences incubators, will be expanded by 40%, providing new labs, office space and more. The center has nearly 80 member companies, more than half of which have operations on site.

About 400 people worked at the PABC prior to COVID-19; the expansion will mean another 100 or more jobs.

Work should be finished by October 2021. You can follow the project on the PABC website and social media. <a href="https://www.pabiotechbc.org">www.pabiotechbc.org</a>



## Building Programs During Challenging Times

## Hepatitis B Foundation receives grant from Bristol Myers Squibb

#### Reducing disparities in liver cancer for high-risk minority groups in the United States is the goal

Bristol Myers Squibb has awarded a one-year grant to the Hepatitis B Foundation to close the disparity gaps related to hepatitis B-associated liver cancer in the U.S. among Asian Americans, Pacific Islanders, African immigrant communities and other high-risk groups.

Hepatitis B is the primary cause of liver cancer worldwide and more than 2 million people in the U.S. are living with chronic hepatitis B infection. Liver cancer is one of the deadliest cancers, with a five-year survival rate of less than 20%. Over the past decade, liver cancer incidence and mortality has steadily risen each year, even while rates of most other cancers have been in decline. Diagnosing hep B in its earliest stages is the key to preventing progression to liver cancer. This can be accomplished through ensuring that people with hepatitis B are diagnosed, appropriately managed, and receive ongoing liver cancer screenings.

"This is vitally important work because the communities we will be working with experience a significantly higher rate of liver cancer caused by hepatitis B, in some instances up to thirteen times higher than the general U.S. population," **Chari Cohen, DrPH, MPH**, senior vice president of the Foundation, said. "We greatly appreciate this generous grant from Bristol Myers Squibb."

The grant will fund an initiative to develop and implement a culturally appropriate, community-focused awareness and education campaign to improve knowledge about the link between hep B and liver cancer, dispel common myths and misconceptions, reduce disease-related stigma, and normalize conversation around hepatitis B and liver cancer among highly impacted communities.

Changing the perceptions of hepatitis B and liver cancer can lead to health behavior change, especially when integrated into programs that improve access to care and treatment. These efforts can lead to more high-risk people in target communities seeking out and receiving liver cancer screening, thus diagnosing liver cancer at earlier stages, when it is still treatable.

## Training the hepatitis B leaders of tomorrow

#### Educational programs continued through the Blumberg Institute, despite the pandemic, in 2020

Seven Post-doctoral Fellows from universities worldwide, six Junior Research Fellows (recent college graduates) and eight college undergraduate students worked research in Blumberg labs. Also, seven students from Xavier Medical School conducted research rotations in Blumberg's operation at the Lankenau Institute for Medical Research.

Advanced placement chemistry students from the Central Bucks School District returned to our campus late in the year for regular classes and lab work. Those outstanding scholars, 28 last year, continue to win awards and scholarships. **Rishi Vaidyanath**, a CB East senior, last summer won a Gold Medal at the Delaware Valley Science Fair, qualifying him for international competition.

The summer science enrichment program continued in a hybrid approach, with experiment kits being shipped to students to facilitate work at home, along with online learning. The Blumberg team, led by **John Kulp, PhD**, director of academic affairs, delivered two sessions of the innovative program to **15 high school students**.



Baruch S. Blumberg Institute students

## National Recognition Making an Impact

#### Hepatitis B Foundation co-founders chosen for major new award from the American Association for the Study of Liver Diseases (AASLD)

Hepatitis B Foundation co-founders Joan Block, RN, BSN and Timothy M. Block, PhD, received a very significant honor on Nov. 14 during the annual meeting of the AASLD

AASLD is the leading organization of scientists and health care professionals committed to preventing and curing liver disease.

The Blocks received the AASLD's inaugural Distinguished Advocacy Service Award, which "recognizes service provided to the hepatology community over an extended period that raises awareness or garners public and federal legislative support and promotes liver health and quality patient care."

The award was presented by **T. Jake Liang, MD**, Director, Chief, Liver Diseases Branch, National Institute of Diabetes, Digestive and Kidney Diseases and former President, AASLD.

"The Hepatitis B Foundation has grown from a one-person crusade to a well-funded multi-tier organization with a large staff and deep influence in the advocacy community," Dr. Liang wrote in his nominating letter. "The Foundation has effectively represented and advocated for patients with chronic hepatitis B and raised prominent awareness of the disease by implementing innovative educational, patient-oriented, community-based and public health programs."

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T. JAKE HANG, MD



Timothy M. Block, PhD and Joan Block, RN, BSN were honored to receive the AASLD Distinguished Advocacy Service Award Outreach and Patient Education Leading the Way to Better Health

Hepatitis B can be an overwhelming and confusing diagnosis. Our trained staff answer questions about test results, transmission, vaccinations, and care, and help patients to understand what their diagnosis means for their health and their future. We guide people with hepatitis B as they face their diagnosis and provide guidance for telling loved ones, finding care, starting a family, and hope for a bright future ahead.



\*Phone consult callers were mostly patients (61%). Of those we had information on, 47% were age 19-34.

Callers were from 27 states (plus D.C.) and 11 countries. Most common call topics were test results, vaccine, transmission, newly diagnosed, medication access help, finding a doctor, possible exposure, and treatment options.

We saw a significant drop in consult requests in April, May and June, with rebound beginning in July and continuing to rise or hold steady each month. We are seeing an increase in consult requests specifically about COVID-19 – focusing on outcomes in people who have HBV, and safety/efficacy of vaccine.

## #justB national storytelling campaign shines a spotlight on hepatitis B

Our #justB national storytelling campaign features real people sharing their stories about hepatitis B to increase public awareness, decrease stigma and discrimination, and to promote testing and treatment, which will ultimately save lives.

Forty storytellers share their experiences with hepatitis B and liver cancer both online and at in-person educational events throughout the U.S. Over 2.2 million people have viewed our stories, improving awareness around the world. **You can watch all our 19 multi-lingual #justB stories at www.hepb.org/justb.** 

#### #justB is a national, multi-lingual, digital storytelling campaign that aims to:

- ✓ Increase awareness and advocacy around hepatitis B
- O Decrease **stigma** and **discrimination** associated with the disease
- ✓ Promote testing, vaccination, linkage to care, and treatment
- ✓ Empower people living with hepatitis B to share their stories to help educate the public and inspire action

## #justB Everyone has a story







## Public Health Leading the Way to Eliminating Hepatitis

To bring hepatitis B to the forefront, we must be aggressive in our efforts to test, vaccinate, treat, and prevent spread. But we can't stop there. We will continue to build new coalitions and support existing efforts to ensure that every infected person knows their status and has access to care that can save his or her life.

#### Going global with the B the Voice Story Bank

Building on the great success of the #justB storytelling campaign, we've launched our new, international "B the Voice" Story Bank.

This initiative will document and share the impact that hepatitis B has on individuals, families and communities around the world by curating their unique stories.

"Centering the voices of people living with hepatitis B is critical to raising awareness, combatting stigma and discrimination, as well as encouraging more people to speak out or take action in other ways," **Rhea Racho, MPAff**, the Hepatitis B Foundation's public policy and program manager, said. "That's true whether it means getting tested for hepatitis B, talking to a doctor, educating family or community members about prevention or advocating for resources and policies to support countrywide hepatitis B elimination."

The international *B the Voice* Story Bank got off to a fast start. By year's end, more than 16 people from at least 10 countries have submitted stories for the new program. Ultimately, we would like to have people sharing their hepatitis B stories in even more countries around the world. People living with hep B are invited to share their stories by filling out the story collection form on our website *www.surveymonkey.com/r/bthevoice*.



Hep B United is the largest collaborative voice representing hepatitis B professionals, advocates and patients in the U.S. Together, we serve as a driving force to ensure that we make national, regional and local progress towards hepatitis B elimination.

Since its establishment in 2011, the Hep B United national coalition has more than doubled its community network. HBU is currently comprised of over 49 organizations and local hepatitis B coalitions in 29 cities, 23 states, and the District of Columbia. Through our national network of coalition partners, Hep B United has a reach of over 6 million people and more than 500 public health professionals.





### Hep B United impact

In 2020, the COVID-19 pandemic presented unique challenges that impacted community-based hepatitis B prevention and treatment programs.

Hep B United provided a space for partners to share local experiences, discuss barriers, and develop innovative strategies to continue critical hepatitis B outreach, education, and screening efforts among communities at high risk for infection.

Hep B United's 2019-2020 mini-grant program participants, whose projects were impacted by the pandemic, readjusted strategies and creatively achieved their goals and objectives. You can find the report at www.hepbunited.org.

## Hep B United hosted its **Eighth Annual** (and first virtual) **Summit** on Dec. 2-4, with participation from over 220 individuals from around the U.S.

The Summit's theme was "Standing Up for Hepatitis B: Creative Collaboration to Amplify Awareness, Access, and Equity." Sessions included innovative local, national, and global programs to prevent, diagnose, and treat hepatitis B, implementing screening and vaccination programs during the COVID-19 global pandemic, patient engagement, and voices from the **#justB** program. During the summit's reception on Dec. 4, Hep B United presented the first Hepatitis B Federal Champion Award to Corinna Dan, RN, MPH, former senior policy advisor, U.S. Department of Health and Human Services Office on Infectious Disease and HIV/AIDS Policy. Hep B United also presented 2020 Hep B Champion Awards to nine community leaders and organizations in recognition of their collaborative and successful initiatives to address hepatitis B. The report is on our website.

**Hep B United partners** continue to have a far-reaching impact in increasing hep B education, screening, and linkage to care. A recent survey of 13 coalition partners on activities conducted between 2017 and 2019 showed that Hep B United partners hosted over 400 screening events and tested over 13,800 people for hepatitis B infection. Additionally, partners conducted outreach and provided hepatitis B education to nearly 20,000 people. Hep B United reached over 70 communities including populations from Asian America, Pacific Islander, African and Latinx communities.



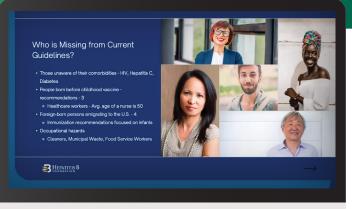
#### THIS YEAR MORE THAN 220 PEOPLE ATTENDED, DESPITE THE VIRTUAL NATURE OF THE EVENT.

The most attended sessions were "Integrating HBV into state elimination planning," "What happened to the cure for HBV?" "Expanding Hepatitis B Outreach in Non-Traditional Settings," and "Universal Adult Hepatitis B Vaccination."

#### 117 VISITED THE POSTER SESSION. 35 PEOPLE VISITED THE EXHIBIT HALL.

Overall, 90-95% of evaluation respondents stated that each session met or exceeded their expectations and would be useful in their daily work.

100% of respondents agreed that the Summit overall met their expectations and would be useful in their daily work, and 100% stated that they would recommend the Summit to colleagues.



## Public Health Leading the Way to Eliminating Hepatitis

## Pandemic prompts Hep B United Philadelphia to pilot contactless screenings

Hep B United Philadelphia reached more than 1,500 people at risk for hepatitis B in Greater Philadelphia in 2020. In March, when in-person gatherings, including health fairs and community outreach events, were canceled due to the COVID-19 pandemic, Hep B United Philadelphia pivoted to provide "contactless screening" for hepatitis B. The concept entails referring people at risk directly to the laboratory for free hepatitis B testing. So far, 48 high-risk adults have signed up to participate in screening, 22 individuals have completed screening for hep B and, of those screened, we identified six positive hepatitis B infections and three individuals in need of additional vaccination. All of those people were linked to care.

One aspect of this program includes promotion of hepatitis B awareness and screening through WeChat groups. The Foundation is working with Medical Mandarin students at Penn and Penn Medicine APAMSA students to share information on hep B through WeChat, a popular social media platform. We will continue promoting the contactless screening program in Philadelphia as an additional resource for the community beyond the pandemic.

We also have transitioned our activities online and created a hepatitis B community presentation that describes the importance of screening for hep B in Mandarin, Vietnamese and English. Additional hep B specific resources were created through a grant received from the National Network for the Library of Medicine in Vietnamese, Khmer, Indonesian, and Chinese. Additionally, we have continued expanding outreach through partners who provide direct services to people who inject drugs or have a history of injection drug use. We hosted a virtual health fair in August for community partners in Philadelphia to share resources particularly during the challenging COVID-19 pandemic.

Much of our work on addressing hep B in Philadelphia and beyond was published in 2020, marking another impactful year for public health research for Hep B United Philadelphia.

## Coalition Against Hepatitis in People of African Origin

The Foundation leads the national Coalition Against Hepatitis for People of African Origin (CHIPO), which is working to address the high rates of hepatitis B infection among African immigrant communities in the U.S.



CHIPO serves as a forum for sharing information and best practices, and improving national capacity to improve hep B awareness, testing, vaccination and treatment among highly affected African communities.

Working with CHIPO partners, we are developing and testing new culturally and linguistically appropriate strategies for improving awareness, screening, and care for both hep B and liver cancer among U.S. immigrants from Africa. We completed a three-year project to provide a train-the-trainer toolkit for health educators and simple flip charts that educators can use to improve knowledge about hep B in their communities. CHIPO also is working on a similar project focused on liver cancer.

For several years, CHIPO has been involved working on federal recognition of National African Immigrant and Refugee HIV/AIDS and Hepatitis Awareness (NAIRHHA) Day, observed annually on Sept 9. Making NAIRHHA Day official would go a long way toward bringing greater awareness and resources to HIV/AIDS and viral hepatitis in African immigrant communities in the U.S., which are disproportionately impacted by these two diseases.



#### International reach 2020

The Hepatitis B Foundation has a global reach, working with partners towards worldwide elimination of hepatitis B. Our public health campaign in Haimen City, China continues to serve as a model for increasing awareness, testing and sustainable care in endemic populations. We are now focusing our global efforts on documenting stigma and discrimination around the world. and growing a grassroots movement to raise the voices of people living with hepatitis B that can lead to lasting policy change. Talking with people facing discrimination around the world is helping us understand the true social and professional impact. In 2020, we also collaborated with ICE-HBV and the World Hepatitis Alliance to create an educational resource for governmental leaders, to help them understand the urgent need to address hepatitis B. That tool will be available widely in multiple languages. We also disseminated results of our Patient Focused Drug Development Meeting to global groups, to encourage similar patientfocused meetings in other countries.



#### NEW CLINICAL TRIAL DIRECTORY

The Foundation created a new
Clinical Trial Directory with partner Antidote.
People around the world can now find information on hepatitis B, hepatitis D and liver cancer clinical trials near them in 60 seconds or less!

## Advocacy Leading the Way by Taking Action

#### **HHS discrimination letter**

Awareness and advocacy efforts guided by our team have led to renewed interest and federal action from the U.S. Department of Health and Humans Services (HHS). Despite nondiscrimination policies, we regularly hear about students being denied admission to health professions schools due to their hepatitis B status. HHS issued an updated letter in November 2020 to all U.S. health profession schools to ensure their compliance with federal civil rights laws that protect individuals living with hep B from discrimination. The Hepatitis B Foundation played an integral role in a landmark settlement by the U.S. Department of Justice in 2013, which ruled that a medical school had violated the Americans with Disabilities Act (ADA) when they denied applicants because they had hepatitis B. Since 2013, we have continually brought federal attention to the issue and encouraged students to file formal complaints against discriminatory policies.

#### Viral hep strategic plan

Over the past two years, the Foundation provided feedback at multiple stages to assist HHS in developing the Viral Hepatitis National Strategic Plan: A Roadmap to Elimination 2021-2025, which was released early in 2021. The plan provides objectives and goals specifically to eliminate viral hepatitis in the U.S. It features comprehensive strategies aimed at preventing viral hepatitis infections, improving viral hepatitis-related health outcomes of people with hepatitis, reducing hepatitis-related disparities and health inequities, improving viral hepatitis surveillance and data usage, and achieving integrated, coordinated efforts by all partners and stakeholders that address the hepatitis epidemics. HHS' integrated, ambitious approach to eliminating viral hepatitis is a major step towards achieving health equity amongst communities that are disproportionately impacted by hepatitis B.

#### **#HepBUnite Week of Action**

For World Hepatitis Day 2020, we coordinated a virtual advocacy week from July 21-28. More than 90 advocates joined our #HepBUnite Week of Action Kick-off Call, which included inspiring remarks from hep B champions U.S. Rep. Grace Meng (NY) and Judy Chu (CA), an overview of Hep B United's federal advocacy priorities, and a call to action to raise awareness and support around hep B prevention, surveillance and research to find a cure. Advocates from around the country sent a total of 118 messages to their Members of Congress, reminding them of the importance of continued funding and support for hepatitis B services and programs during the COVID-19 pandemic and beyond.



#### Advocacy Leading the Way to Taking Action

#### **Drug tiering update**

The Hepatitis B Foundation released a new report last October, "Health **Insurance Costs Impacting Shoppers** Living with Hepatitis B" (posted on our website), to help people living with hepatitis B and their caregivers make better-informed decisions when choosing health insurance plans. In recent years, we have received a growing number of messages through the patientconsult line expressing concerns about paying for their life-saving treatments due to a lack of affordable options. Our analysis of over 280 plans in 14 states sold on the health insurance marketolace in 2019 and 2020 found that health insurance companies implemented benefit plan designs that force people living with preexisting conditions such as chronic hepatitis B to bear the burden of their treatment costs. Such practices are prohibited under the Affordable Care Act, or the ACA. The report is a resource for consumers to examine which health insurance companies and plans may be engaged in discriminatory practices and to learn about trends and practices that may increase out-of-pocket costs for treatment. It also serves to bring awareness to policymakers and hepatitis B advocates to promote policy

#### First-ever externally led Patient-Focused Drug Development meeting for hepatitis B

In cooperation with the U.S. Food and Drug Administration (FDA), the Hepatitis B Foundation hosted an externally led Patient-Focused Drug Development (PFDD) meeting focused on hepatitis B on June 9, 2020. It was the first-ever PFDD meeting dedicated to hep B.

The Foundation produced a comprehensive report on the event and posted it on our website (along with a complete transcript of the meeting, the more than 300 email comments that were submitted, and a link to the official video recording). The FDA also reviewed and posted the report on its External Resources and Information Related to Patients' Experience page. The report's availability was promoted through our newsletters and social media, plus professional publications and meetings.

The Foundation was given approval by the FDA to organize and conduct this meeting, which was an online-only event due to COVID-19, making it the first PFDD to be conducted exclusively as a webcast since the agency began holding PFDD meetings in 2012.

The four-hour meeting allowed health care providers, FDA officials and drug developers to hear directly from patients and family members, specifically regarding their experiences living with chronic hepatitis B, to better inform these and other key stakeholders about the patient perspective. By incorporating personal anecdotes and firsthand experiences, the FDA can enhance its decision-making in terms of drug development and clinical trial design with relation to hepatitis B.

The PFDD meeting focused on two formal topics:

- living with chronic hepatitis B: symptoms and disease impacts
- 2 perspectives on current and future approaches to treatment

A panel of four individuals for each topic shared their opinions and experiences to begin the dialogue. An FDA facilitator led each discussion. Audience members who were viewing the webcast also were able to participate in the discussion by sending in comments on the Foundation website or by calling in. Additionally, participants online who are living with hepatitis B, or family members of someone living with HBV, were encouraged to participate in live polling with a series of questions and to submit comments and their own questions.

More than 650 people joined the online PFDD meeting from around the globe. Foundation Senior Vice President **Chari Cohen, DrPH, MPH**, organized the meeting.

"Overall, the discussion documented the significant physical and emotional impact for people living with hepatitis B, which leads to reduced quality of life and affects family and social relationships, as well as education and careers for many people," Dr. Cohen said. "We heard directly from the people who joined us about their experiences with fatigue, shame and isolation, stigma and discrimination, and their fear of dying prematurely from liver cancer."

Participants discussed major challenges with current treatment including finding a knowledgeable clinician to manage their hep, cost of medication and the burden of taking a daily pill for many years.

**Bright**a native of Ghana
now living in the U.S.:



"For me, the physical impact of living with hepatitis B has been debilitating and huge."

#### Patient-Focused Drug Development survey results



Almost 83% of survey respondents were from outside the U.S.

102 countries were represented.



About 78% of those individuals. when asked about the physical symptoms of their hepatitis B infection, said they feel tired a lot.

more than

people they

know.



Overall, 62% of the respondents said they feel their life is less enjoyable because of their chronic hepatitis B.



When asked about their concerns around the disease. 55% said they worry about developing liver cancer.



48% say they

fear living a

shorter life.

said they are concerned about discrimination. such as losing a job or being denied school admission, because of

their hepatitis

B infection.

Around 58%



About 49% of the respondents who currently are on a hepatitis B medication report that side effects are a real challenge.

PFDD participants stressed a strong desire for future treatments that will result in loss of hepatitis B surface antigen (HBsAg, the blood marker of infection) and reduced risk of liver cancer over a finite treatment period. There was strong interest in participating in future clinical trials that might lead to functional cure, as long as trials would not be too disruptive of daily lives and participants would receive adequate safety information on experimental treatments.

In addition to conducting the PFDD meeting, the Foundation collected patient experiences through an online survey and in-depth phone interviews. More than 2,100 people from 102 countries responded to the survey (results are above), and 24 people participated in the phone interviews.

Results coincide what the Foundation team learned from the PFDD meeting and also highlighted the different experiences and challenges faced by people living in other countries.

For example, outside the U.S., more people documented experiencing stigma and discrimination, and had difficulty finding and affording care and treatment for their hepatitis B.

All of the experiences collected from the PFDD meeting, the survey and the interviews will be used by the Foundation to help advocate for the needs of people living with hepatitis B, and ensure that drug and clinical trial development take the needs and concerns of patients into account.

Randv

whose son wanted to serve in the U.S. military but was denied due to hepatitis B:



'The disappointment is devastating, and we continually live with it."

David 31, a Michigan resident



"The possibility of transmission and fear of others' reactions to my hepatitis B is what has been the most impactful in my life."



now living in California:

"My family tends to feel shame for having a chronic illness."

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The Hepatitis B Foundation's valuable research and programs are made possible by the commitment of our donors. We are grateful to every individual and organization that has generously supported our mission to find a cure and improve the quality of life for those affected by hepatitis B.

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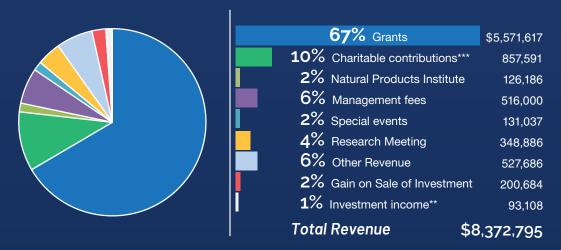
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We apologize in advance for any errors or omissions in our Donor List despite our best efforts to be as accurate as possible. Please email editor@hepb.org or call (215) 489-4900 so that we can print corrections in our next newsletter. Thank you for understanding.

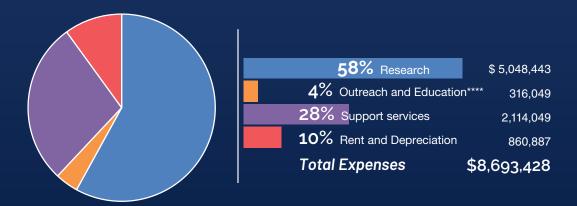
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COMBINED HEPATITIS B FOUNDATION & BARUCH S. BLUMBERG INSTITUTE<sup>1</sup> FOR THE FISCAL YEAR ENDED JUNE 30, 2020

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<sup>\*</sup> The financial information presented above does not include the activity from Hepatitis B Foundation's ownership of the net assets of the Pennsylvania Biotechnology Center. At June 30, 2019, this interest was valued at, based on the equity method of accounting, approximately \$5,148,000 per the audited Statement of Financial Position of the Hepatitis B Foundation.

The financial information in this report was prepared by management and presented in condensed form from the financial statements of the Hepatitis B Foundation and the Baruch S. Blumberg Institute audited by EisnerAmper, LLP for the year ended June 30, 2020. A copy of each financial statement is available upon request.

<sup>\*\*</sup> The financial information presented above excludes unrealized investment related activities.

<sup>\*\*\*</sup> Excludes in-kind donations

<sup>\*\*\*\* 4%</sup> reflects the combined HBF and BSBI budgets. Outreach and education comprises 12.6% of the HBF budget.

<sup>&</sup>lt;sup>1</sup> Baruch S. Blumberg Institute is the reseach institute established by the Hepatitis B Foundation in 2004



The Hepatitis B Foundation (HBF) was established in 1991 and remains the nation's only nonprofit organization solely dedicated to finding a cure for hepatitis B and improving the quality of life for those affected worldwide through research, education and patient advocacy. The HBF established the Baruch S. Blumberg Institute in 2003 as an independent, nonprofit research institute to fulfill its research mission. It was named to honor our Co-Founder Dr. Baruch S. Blumberg who won the Nobel Prize for his discovery of the hepatitis B virus.

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