

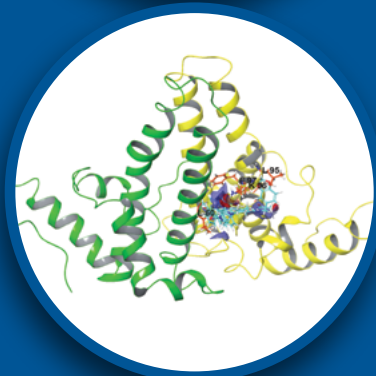
2019
ANNUAL
REPORT



Leading the Way to



2030



Dear Friends,

AS WE WRITE THIS, THE NATION AND THE WORLD ARE STRUGGLING WITH THE SARS COV-2 PANDEMIC. Similar to everyone else, we are gripped by this crisis. Hopefully, by the time you read this report, there will have been a resolution and return to normalcy. But at present, everyone, including the **Hepatitis B Foundation (HBF)** and its **Baruch S. Blumberg Institute** (the Blumberg), is pitching in. The HBF immediately posted information about the enhanced risks of those with chronic hepatitis B (CHB) and COVID-19 and emphasized the need for anyone with COVID-19 to know their hepatitis B status. Also, Blumberg scientists are collaborating with colleagues at the University of Pennsylvania and Utah State to test drugs for SARS-CoV-2 activity. So, we are responding to the call.

However, the hepatitis B and liver community should know that we never—not at any time during crisis—stopped working for hepatitis B and liver cancer (HCC) patients. HBF didn't miss a beat, addressing patient needs, answering caregiver questions and even advocating for research funding. Our labs, which cannot be entirely virtual, continued research on new drugs and cancer detection.

THE HBF REMAINS THE WORLD'S DEFINITIVE AUTHORITY AND MOST-TRUSTED VOICE AND EAR FOR PEOPLE LIVING WITH HEPATITIS B. With more than **4 MILLION** annual visits to our website and social media, the need for information is clear and growing. And we remain steadfast in meeting that need.

Our programs continued to grow and make an impact in 2019. Just a few months ago, we launched an online survey to assess patient perspectives on current and future hepatitis B treatment. In June 2020, we will be hosting an Externally-Led Patient Focused Development Meeting, coordinated with the FDA, which will help document patient perspectives on the kinds of drugs they want to see. These are all firsts! We should add that, although this conference will now need to go online because of the current COVID-19 crisis, we do plan face-to-face meetings in 2021.

Through its research arm, Blumberg, the Hepatitis B Foundation is a major contributor to finding a cure for hepatitis B. The Blumberg has a history of providing high-value, breakthrough research tools, new ideas, and even investigational therapeutics, that help open doors for new drug strategies to be explored. In 2019, our scientists produced more than 35 scholarly publications and two clinical trials resulted from their work. We saw the launch of an all-new technique to detect cancer non-invasively and at least two new compounds with cancer and HBV therapeutic activity were developed. We believe the next three to five years are critical, as commercial companies assess their opportunities and look, again, at research institutions for new innovations. We will be there, with new discoveries.

Taken together, at a time when the world, understandably, is distracted with another, very important crisis, the focused work of the Hepatitis B Foundation and Blumberg is all the more critical. Once again, it is on us. We will be there.

Sincerely,

■ **Timothy M. Block, PhD**
President and Co-Founder

■ **Joel Rosen, Esq.**
Chairman of the Board



Leading the Way to *a Cure*



The Baruch S. Blumberg Institute (The “Blumberg”) 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 valuable 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 2019, the Blumberg had more than **35 scholarly publications**, **2 clinical trials** resulting from our work, an **all-new technique** was developed to detect cancer non-invasively, and at least **2 new compounds** were identified with cancer and HBV therapeutic activity.

EXPERIMENTAL THERAPEUTICS FOR CHRONIC HEPATITIS B

The Blumberg has taken a two-prong approach to hepatitis B therapy. First, we are unraveling vulnerabilities in the viral life cycle. Second, we are screening and developing potential drugs to target these vulnerabilities, looking for direct acting antivirals and immune activators. Where these innovations are also beneficial in treating other diseases, it is our philosophy to collaborate and develop our discoveries opportunistically.

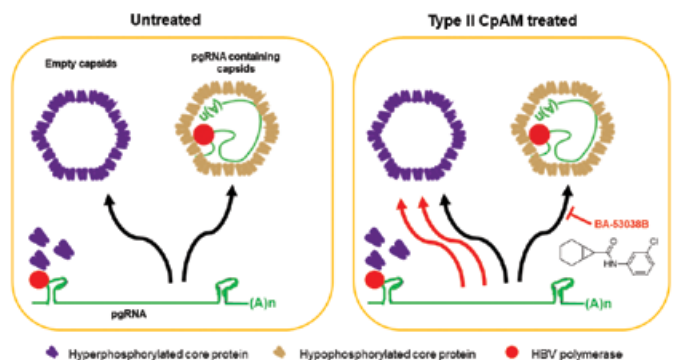
Targeting HBV cccDNA

cccDNA is the stable form of the viral genome that appears to persist inside liver cells, even after years of effective antiviral therapy. There is a general consensus that suppression or elimination of cccDNA is necessary for a “cure.” Researchers at the Blumberg have made important progress that can lead to strategies for eliminating cccDNA in the future:

- › Identification of several host cellular proteins that are required for HBV cccDNA synthesis or control of cccDNA transcription. (Lab of J.T. Guo)
- › Development of cell-based assays for discovery of antivirals that can eliminate or functionally inactivate HBV cccDNA. (Lab of J.T. Guo)

Targeting and understanding HBV capsid formation

Blumberg researchers discovered that the hepatitis B core protein which forms the outer shell of capsids must go through changes (“de-phosphorylation”) by a specific cell enzyme in order to assemble viral RNA and support DNA synthesis. Building on this discovery, Blumberg research teams identified a new family of capsid-targeting compounds. These compounds have unique chemical structures and activities not present in the drugs currently being investigated. (Lab of J.T. Guo, with J. Chang, Y. Du, J. Kulp)

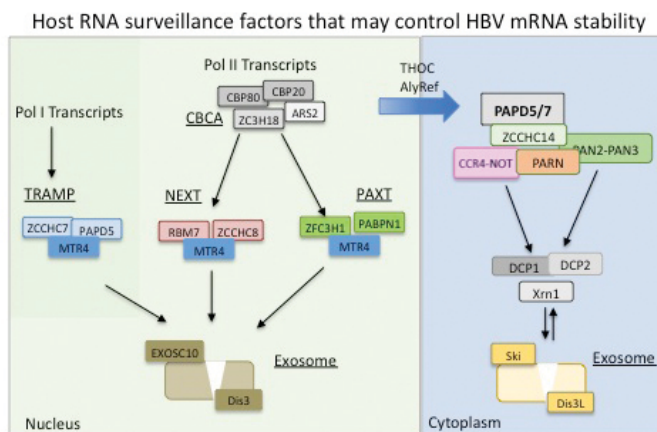


Discovery of novel hepatitis B virus nucleocapsid assembly inhibitors. Zhang et al, ACS Infectious Diseases, 2018;5(5):759-768.

Understanding new vulnerabilities in the hepatitis B virus life cycle

Hepatitis B RNA metabolism as an antiviral target

Understanding the pathway of hepatitis B RNA metabolism reveals enormous antiviral opportunities. Working with colleagues at Arbutus Biopharma, Blumberg researchers discovered differences in hepatitis B mRNA metabolism that present entirely new mechanisms for future antiviral targeting. Our scientists are now working with Arbutus Biopharma to study a new drug (dihydroquinolizone) that seems to target this step. This drug appears to have remarkable antiviral activity in the lab, and will be entering clinical trials in the next year. Blumberg scientists are trying to produce even better versions of this drug. (Lab of T. Zhou)



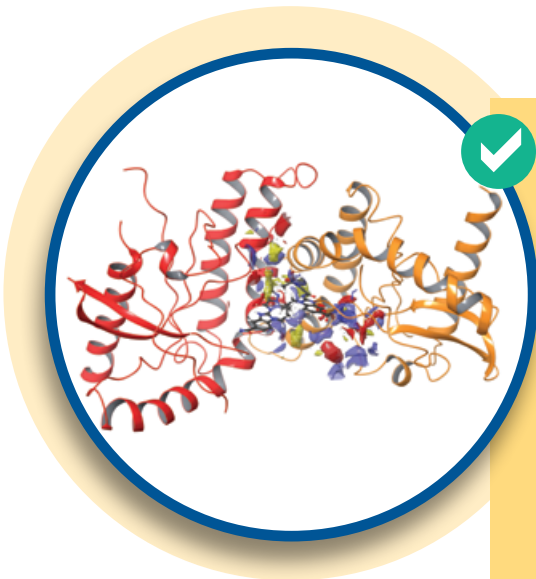
Targeting the hepatitis B surface protein

HBsAg is a protein found on the surface of the virus and is essential for viral infectivity. It is also believed to be involved in suppressing immunity to the virus in those with chronic hepatitis B, and its suppression is considered to be vital for a “cure.”

We have two projects aimed at studying and targeting HBsAg that had important advances, this year:

› Blumberg scientists found that a new drug, called “C4”, appears to change the structure of HBsAg. It is possible that this can be used to alter the antigenic properties of the protein and induce an immune response to the virus. (Lab of T. Zhou)

› Our scientists have identified structures on HBsAg that are needed for proper formation of subviral particles. An assay for discovery of compounds that induce HBsAg degradation is currently under development. (Lab of J.T. Guo)



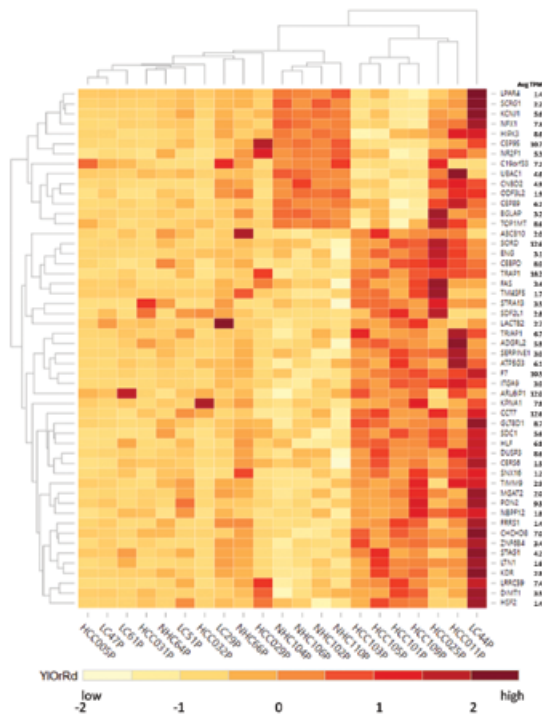
Targeting the Immune System

A major problem in chronic hepatitis B is the failure of the immune system to beneficially recognize the virus in order to fight it. At Blumberg, we have made progress in developing a new method to stimulate immune responses to attack virus-infected cells by activating a pathway called “Stimulator of the Interferon Genes” or “STING.” Our research team was among the first labs to discover small molecule activators of STING and use them to treat hepatitis B virus infection. This year, a new compound, called BNBC, was identified that activates STING, and induces an antiviral and anticancer state. We also modeled an innovative method to introduce STING proteins and the drug into cancer cells. (Lab of J. Chang, with J.T. Guo)

EARLY DETECTION AND EXPERIMENTAL THERAPEUTICS FOR CANCER

Early detection of liver cancer

Early detection of liver cancer remains the best way to improve cancer-related outcomes and save lives. Blumberg researchers are making great strides towards developing new, non-invasive methods to improve early detection of liver cancer.



Detecting mRNA — Human blood has a diverse set of mRNA that might be useful in detecting liver cancer. Our researchers found that not only is there mRNA in the blood, but more than 20,000 different genes are represented, and almost everyone has the same amount of each gene’s mRNA. (Lab of A. Sayeed)

Detecting “micro” DNA — In a blinded study of more than 300 patients, Blumberg researchers have shown that urine DNA can be used with as much success in detecting HCC as DNA taken from tissue or blood. The hope is that in the future it will be possible to determine if someone has cancer by examining DNA from their urine, rather than needing to perform a biopsy, or even take blood. (Lab of Y. Su)

Experimental therapeutics for liver cancer

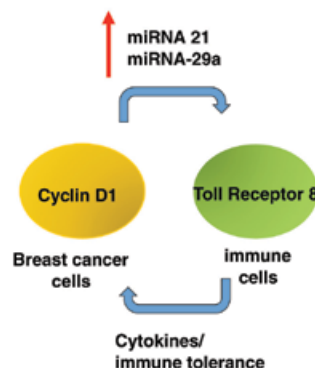
At the Blumberg, we are making progress in finding new therapies to improve survival for people diagnosed with hepatocellular carcinoma (primary liver cancer).

Induction of death in hepatocellular carcinoma cells by prolonged activation of STING — Our researchers have used their novel STING agonists to activate programmed cell death pathways in a variety of tumor cells, including hepatocellular carcinoma (HCC) cells. The anti-tumor activity of STING agonists against HCC has now been confirmed in a mouse model. (Lab of R. Thapa, with J.T. Guo and J. Chang)

Selective killing of hepatocellular carcinoma cells in people with hepatitis B — Our scientists are exploiting HBsAg, using the virus itself to target cancer cells to be “killed.” Our scientists have been able to activate HCC death during HBV infection. We are currently trying to outline the exact mechanism of this selective death and evaluate if we can exploit other hepatitis B virus proteins to activate this kind of selective killing of HCC cells. (Lab of R. Thapa)

Cyclin D1 promotes secretion of pro-oncogenic immuno-miRNAs and piRNAs

The molecular mechanisms governing the secretion of the non-coding genome are poorly understood. Many of these gene products are critical to cancer development. The Pestell lab showed that cyclin D1, the regulatory subunit of the cyclin-dependent kinase that drives cell-cycle progression, governs the secretion of miRNA governing the tumor immune response. More than 85% of the cyclin D1-induced secreted miRNA transcripts (miR-21 and miR-93) bind Toll-Like Receptor 8 to trigger a pro-metastatic inflammatory response. The cyclin D1-mediated secretion of pro-tumorigenic immuno-miRs may contribute to tumor initiation and progression. (Lab of R. Pestell)



Other research work:

The Lab of R. Pestell has identified drugs that can be re-purposed to protect against Cardiotoxicity associated with cancer breast and prostate cancer chemotherapy. This has immediate clinical implications.

The Lab of J. Chang has identified new Yellow Fever antiviral drugs.

The Lab of J. Clement is developing new micro-organisms optimized for producing antibiotics.

Bringing Leaders Together

2019 PRINCETON WORKSHOP

In August 2019, HBF convened the Princeton Workshop, a prestigious annual meeting bringing together some of the world's thought leaders for highly focused discussions on strategies to treat hepatitis B and liver cancer.



In 2019, we brought together leaders in immunology, virology and clinical research. At this workshop, participants identified critical research questions that need to be answered, and the resources that are needed, to further research to find a cure for hepatitis B. Results of this workshop will hopefully lead to new innovations and resources for future research.

2019 HBV MEETING IN MELBOURNE, AUSTRALIA

The International HBV Meeting on the Molecular Biology of Hepatitis B Viruses has been coordinated by the HBF since 2005.

Led by an international counsel of thought leading scientists, it is an essential forum for researchers to share their discoveries, questions and insights in a highly interactive environment. The meeting is the definitive international conference focused exclusively on the hepatitis B (HBV) and hepatitis D (HDV) viruses. With more than 600 delegates, the 2019 meeting held in Melbourne, Australia was the largest international HBV meeting ever held.



Signing of the Melbourne Declaration

TRAINING THE HEPATITIS B LEADERS OF TOMORROW

9 Postdoctoral Fellows

from universities worldwide



76 High School Students

trained through our new educational programs this year as part of our commitment to tomorrow's scientists. This number includes 31 advanced placement chemistry students from the Central Bucks School District, 18 students that participated in our 2-week science enrichment program, 4 students that pay to do after school research, 5 international students (2 of whom returned as paying students), and 20 students that completed the Science Enrichment Day.

29 Graduate Students

from Geisinger, Drexel, Penn, and Xavier trained at Blumberg Institute

6 Junior Research Fellows

recent college graduates worked in labs to prepare themselves for careers in science and business

4 Medical Students

from Xavier Medical School conducted research rotations at Blumberg

1 Naval Intern

4 Undergraduate College Students

conducted research in our labs

**OUTREACH
& 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.



2019 CONSULT CALLER STATS

- 44.8%** Person living with hepatitis B
- 13.8%** Friend/Family member of someone who has hepatitis B
- 24.8%** Someone who wants General Information about Hepatitis B
- 9.5%** Individual with blood test results (unclear diagnosis/not infected)
- 6.9%** Healthcare worker or physician

OUR IN IMPACT IN 2019:

- OUR WEBSITE**  4 million visitors
From 100+ countries
- OUR SOCIAL MEDIA**  70,000 followers
- OUR PATIENT CONSULTS**  12,000 people helped
through phone, email, social media
- OUR YOUTUBE CHANNEL**  2.2 million have viewed
our #justB patient story videos!

#JUSTB NATIONAL STORYTELLING CAMPAIGN SHINES A SPOTLIGHT ON HEPATITIS B

There is no better way to raise public understanding about the true impact of hepatitis B than through personal stories. 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.

40 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
- 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 storytellers:

- A total of **40 storytellers** have been trained at **5 workshops** to educate people around the country
- **Serve as advocates** to help **prioritize hepatitis B** with state and federal policy makers.

Leading the Way to *Eliminating* Hepatitis B

To bring hepatitis B to the forefront, we must be aggressive in our efforts to test, vaccinate, treat, and prevent the spread of hepatitis B. 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 their life.**

HEP B UNITED

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 40 national organizations and local hepatitis B coalitions in 28 cities and 20 states and the District of Columbia. Through their national network of coalition partners, Hep B United has a reach of over 6 million people and more than 500 public health professionals.



The Hep B United model is being adapted by the CDC Division of Tuberculosis Elimination to help their efforts to end the disease and reduce health disparities through community partnerships and culturally appropriate communication strategies.

HEP B UNITED IMPACT

<p>HBV Education >72,000 hepatitis B education sessions</p>	<p>Mini-Grants \$361,000 awarded to 24 coalitions in 18 states</p>	<p>Training Webinars reached nearly 4,000 live and >25,000 online views</p>	<p>Know Hepatitis B Campaign >5,000 resources disseminated to HBU partners PSAs and materials: >461 million impressions</p>
<p>HBV Screening >20,000 screened each year</p>	<p>Peer Mentoring 15 organizations matched; 6 new hepatitis B coalitions formed</p>	<p>Annual Summit 2012 summit: 15 founding partners 2019 summit: >100 attendees</p>	<p>#justB Storytelling Campaign Partnership 15 HBU community awareness events > 500 educated</p>

HEP B UNITED PHILADELPHIA

Hep B United Philadelphia (HBUP) is a local community-owned coalition, led by the HBF, that was created to increase hepatitis B testing and vaccination in Philadelphia.



In 2019, with our local coalition partners, we participated in 34 health education and screening events for communities in need and provided trainings for over 100 health professionals and clinical students. We reached 1,727 individuals and screened 290 individuals. More than 80% of those found to be infected were successfully linked to care, and 60% of those who were not immune were linked with vaccination resources. Also, in 2019, HBF became co-lead of a statewide coalition and effort (Hep Free PA) to eliminate viral hepatitis in PA.

Our Voices Made a Difference

The Hepatitis B Foundation and Hep B United, along with our network of patients, providers and partners, has successfully advocated for improved access to the hepatitis B medication Vemlidy in the US.!

In July 2019 CVS Caremark—a subsidiary of CVS Health and one of the nation's leading pharmacy benefit managers—stopped providing coverage for Vemlidy. This decision impacted thousands of Americans who rely on this life-saving drug to manage their hepatitis B.

Our members took swift action. Together, we sent over 20 letters from partner organizations and gathered over 250 individual signatures for a petition encouraging CVS Caremark to provide coverage for this essential medication. In response, CVS Caremark added Vemlidy back onto their formulary, so that it would be covered as treatment for people living with hepatitis B!

COALITION AGAINST HEPATITIS IN PEOPLE OF AFRICAN ORIGIN

HBF leads the national Coalition Against Hepatitis in People of African Origin (CHIPO), a community coalition of organizations to address the high rates of hepatitis B infection among African communities in the U.S.

Working with CHIPO partners, we are developing and testing new culturally-competent strategies for improving awareness, screening and care among people of African origin in the U.S. In 2019, we completed a three-year project and are now actively disseminating an educational toolkit that includes a Train-the-Trainer for health educators, and simple flip-charts that educators can use to improve knowledge about hepatitis B in their communities.



INTERNATIONAL REACH

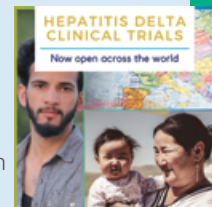
Since 2011, the Hepatitis B Foundation has sponsored an ambitious public health campaign in Haimen City, China to reach all 1 million residents with information about hepatitis B.

Building on our success in China, we have partnered with organizations to help them bring hepatitis B awareness, testing and care in Ho-Chi Minh, Vietnam and Accra, Ghana. In 2019, we participated in an international public forum on hepatitis B at the International HBV Meeting and participated in working groups for eliminating hepatitis B worldwide. We worked with our international collaborators (such as World Hepatitis Alliance, ICE HBV, HBV Forum, and WHO) to develop key educational and public health materials to improve hepatitis B awareness globally.



Hope for Hepatitis B and Delta Co-Infected Patients

This year, many new clinical trials opened globally, inspiring hope for millions of patients with hepatitis delta, a serious HBV co-infection. Through Hep Delta Connect, HBF is educating people worldwide and informing them about new research and opportunities.



Leading the Way by Taking Action

For the past 29 years, the Hepatitis B Foundation (HBF) has been diligently advocating to raise awareness and prioritization of hepatitis B, and to ensure that the 2 million people living with hepatitis B in the U.S. have unhindered access to screening, appropriate medical care and treatment.



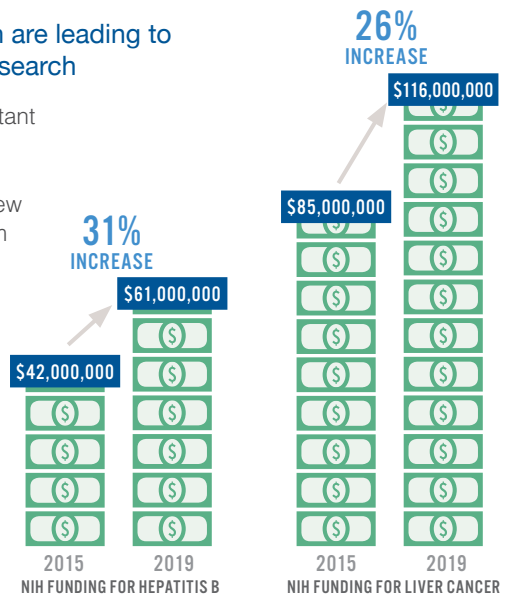
HBF's long-standing commitment has resulted in many groundbreaking successes that have prohibited discrimination, increased focus and dollars for research to find a cure, and improved access to medication across the U.S. In 2019, we completed an analysis of hepatitis B drug prices in 14 states to assess discriminatory drug pricing practices. In 2020, we will build on what we found, working to eliminate discriminatory drug pricing and make hepatitis B medication more affordable across the U.S.

HEP B CURE CAMPAIGN

HBF advocacy efforts through the Hepatitis B Cure Campaign are leading to increased federal funding opportunities for hepatitis B cure research

Over the past decade, HBF's legislative advocacy has played an important role in significant funding increases at the federal level. Not only has funding for hepatitis B and liver cancer increased at the NIH, but new opportunities for funding through the Department of Defense Peer Review Medical Research Program and Peer Review Cancer Research Program have led to \$25 million of new funding awarded to hepatitis B and liver cancer research across the U.S.

HBF advocacy efforts through the Hepatitis B Cure Campaign are leading to increased federal funding opportunities for hepatitis B cure research



Hep B United Advocacy Day Bring the Message to Washington

HBF was instrumental in the creation of the Congressional Viral Hepatitis Caucus, a bipartisan group of legislators committed to addressing viral hepatitis A, B and C. Since 2014, HBF has organized an annual Hepatitis B Hill Day, bringing up to 80 patient and provider advocates to Washington, D.C. each year to meet with legislators and discuss the importance of prioritizing hepatitis B and liver cancer. Our most recent Hepatitis B Hill Day in July 2019 brought 73 participants, including 20 patient storytellers. These participants represented 19 states and conducted 57 legislative meetings.



HEP B UNITED ADVOCACY DAY BRING THE MESSAGE TO WASHINGTON



THANK YOU TO OUR DONORS



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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Thank you

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 ARE TOO NUMEROUS TO MENTION.**

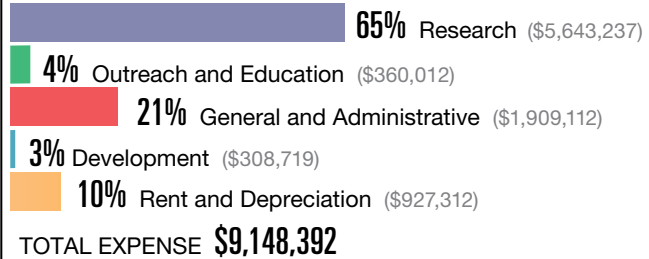
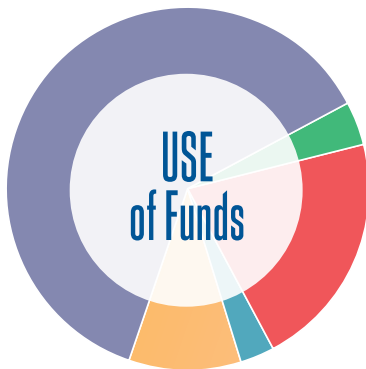
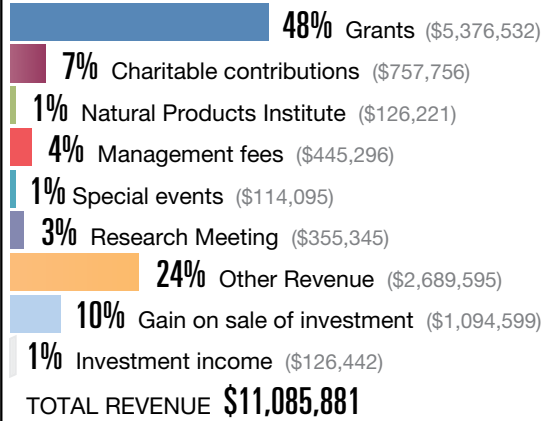
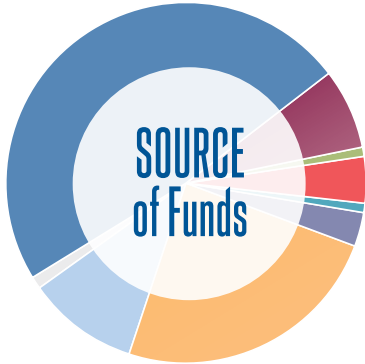
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We apologize in advance for any errors or omissions in our Donor List despite our best efforts to be as accurate as possible. Please email editor@hepb.org or call (215) 489-4900 so that we can print corrections in our next newsletter. Thank you for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

Year In Review + Financial Information*

COMBINED HEPATITIS B FOUNDATION
& BARUCH S. BLUMBERG INSTITUTE**

FOR THE FISCAL YEAR ENDED JUNE 30, 2019



* 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 \$5,021,000 per the audited Statement of Financial Position of the Hepatitis B Foundation.

** The financial information presented above excludes unrealized investment related activities.

*** Excludes in-kind donations

**** **Baruch S. Blumberg Institute** is the research institute established by the Hepatitis B Foundation in 2004

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, 2019. A copy of each financial statement is available upon request.

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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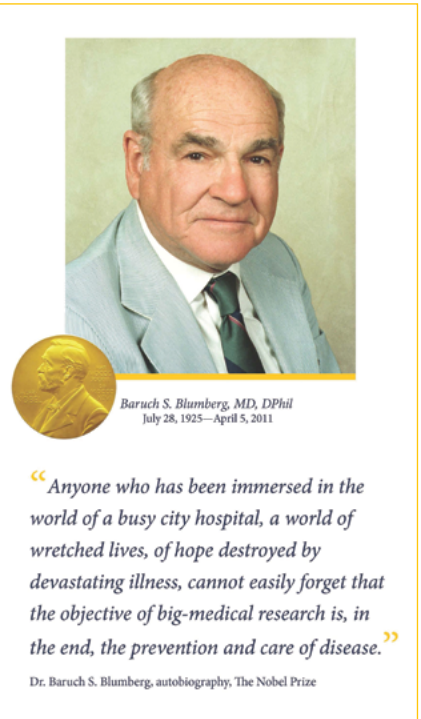
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