

2015 ANNUAL REPORT





Dear Friends, 😹

The Hepatitis B Foundation (HBF) and the Baruch S. Blumberg Institute, which we established to fulfill our research mission, are both in very strong positions as we look to the future.

Next year HBF will celebrate its 25th Anniversary, so it is only fitting that our new strategic plan includes the ambitious goal that **no one will die from hepatitis B by 2030**. Although audacious, it is in alignment with the World Health Organization's global hepatitis plan that calls for the elimination of hepatitis B and C by 2030.

This will require national and international action, which the HBF is already helping to lead.

The HBF's international programs have become models of hepatitis B outreach. In Ho Chi Minh City, Vietnam we are partners in a project to reach **10,000** at-risk individuals with screening and linkage to care efforts. This effort builds on our ongoing Haimen City, China program, which has now reached **more than 1 million** individuals and brought almost **2,000** patients into care.

In the U.S., we continue to lead national advocacy efforts with Capitol Hill visits; ensure that hepatitis B and liver cancer are included in appropriation language; and host Congressional briefings on hepatitis B issues. At the Blumberg Institute, our drug discovery program is working at full speed, powered by the successful **\$3 million** Nobel Challenge campaign that enabled us to recruit 5 renowned scientists in the field! But it is our research collaboration with Arbutus Biopharma that will truly make a difference in rapidly advancing our discoveries from the lab to the clinic.

Within the next year, it is entirely conceivable that the drugs we discovered, or helped to discover, will start being tested in people. That speed of progress is almost unprecedented in drug discovery.

The HBF and the Blumberg Institute are very strong. But we can't be complacent. Our new strategic plan will lead us to transformational discoveries and provide a strong basis for our continued ability to provide vision and leadership in making hepatitis B history.

Joel Rosen, Esq. Chairman of the Board



Timothy M. Black, PhD President and Co-Founder





Cause for a Cure

The Hepatitis B Foundation is a national nonprofit organization dedicated to finding a cure and improving the quality of life for those affected by hepatitis B worldwide through research, education and patient advocacy.

Driving **Research**

The Baruch S. Blumberg Institute, established by the Hepatitis B Foundation to fulfill its research mission, is closing in on its search to find a cure for hepatitis B. With nearly 50 scientists, the Blumberg Institute may now be the largest group of nonprofit researchers working on hepatitis B in the world.

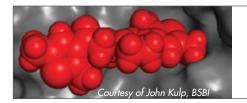


This year the HBF met A Nobel Challenge and raised **\$3 million** to help the Blumberg Institute recruit top scientific talent to accelerate the pace of research. Our goal, however, is not merely to support the development of new hepatitis B treatments or to raise awareness about this serious liver disease. Our mission is to eliminate hepatitis B, to relegate it to the history books. The extraordinarily successful Nobel Challenge campaign is powering our efforts to do precisely that.

The Blumberg Institute recruited 5 renowned scientists to work full time on hepatitis B research as a result of the HBF's successful \$3 million fundraising campaign. Standing L to R: **Drs. Tianlun Zhou, Jinhong Chang, Ying-Hsiu Su, Timothy Block, and Ju-Tao Guo.** (March 2015)

OUR BREAKTHROUGHS

The Blumberg Institute and its world-class researchers are significantly driving the scientific momentum towards innovative ways to combat the hepatitis B virus (HBV). Today, **we are committing everything we have**, every resource at our disposal, in pursuit of a cure to benefit the more than 240 million people living with hepatitis B worldwide.



Novel HBV Therapeutic Targets

cccDNA Inhibitors Fast Tracked

We are among the first, if not the only, to identify a small molecule inhibitor of HBV cccDNA formation, which is very significant since inhibition of cccDNA is considered essential in achieving a complete cure. The drug has now been made highly active and is licensed for further development to Arbutus Biopharma, the first company solely dedicated to HBV drug discovery (read more on page 4).

Designer Drugs

Drs. John Kulp and Yanming Du are using computer modeling to design and produce targeted HBV and liver cancer drugs that include **new HBV capsid inhibitors** and "YES kinase" inhibitors.

Harnessing the Immune System

Drs. Ju-Tao Guo and Jinhong Chang have developed a new HBV drug that works by activating an infected liver cell's own immune defenses, which has shown to be effective in animal studies.

HBV Drugs, Naturally

Drs. Tianlun Zhou and John Kulp have screened thousands of plant and fungal extracts from our extensive Natural Products Collection, donated to us by Merck & Co. in 2011, to mine for drugs derived from "natural products" that inhibit HBV cccDNA and viral proteins. The exciting news is that their work has resulted in **two new leads** that show activity against HBV.

RESEARCH BREAKTHROUGHS at the Blumberg Institute, continued

Detecting Liver Cancer Early

A blinded study using DNA markers developed by **Dr. Ying-Hsiu Su** in collaboration with researchers at Thomas Jefferson University were found to detect liver cancer more effectively than currently approved methods. The study results showed that Dr. Su's markers were superior to alpha-feto protein (AFP) in detecting liver cancer in people. Indeed, her urine-based assay **detected at least 90% of primary liver cancer** at early stages.

A Better Formula for Predicting Cancer

The **Doylestown Algorithm**, developed by Blumberg Institute and Drexel University scientists, is ready to take center stage! No new tests are required for this formula to be used, just the tests a doctor already orders. In a study with more than 2,000 people, the *Doylestown Algorithm* was found to be **a better predictor of liver cancer** than current blood test markers alone.

<u>In 2015...</u>

Nearly **DU** HBV researchers work at the Blumberg Institute. internationally renowned scientists and their research staff recruited to the Blumberg Institute to work full time on HBV. **444** articles published in prestigious scholarly journals.

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(Dr. Anand Mehta et al)

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\$6 million in research revenue from federal and state grants,

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A "Doylestown Algorithm" risk calculator for cirrhosis and liver cancer

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New Blumberg Institute Partnership with Arbutus Biopharma



In 2015, the Blumberg Institute entered into a three-year research agreement with Arbutus Biopharma, a company focused solely on HBV drug development. This unique partnership will allow us to **move our discoveries more rapidly** from proof-of-principle stage — through translational research — into human clinical trials. Our scientists will work collaboratively with Arbutus on novel approaches to HBV and liver cancer, based on an overarching research plan with the **shared goal of developing a cure** for hepatitis B, which causes up to 1 million deaths each year worldwide. (*April 2015*)

Our Liver Cancer Recommendations Published by Journal of the National Cancer Institute



A group of 20 of the **nation's leading liver cancer experts were convened** for the HBF's bi-annual *Princeton Workshop* in March 2015 to focus on improving screening and care for those with HBV-related liver cancer. Over two days, the group discussed the gaps and limitations in current approaches for the detection and treatment of primary liver cancer, and **defined research priorities and opportunities for advocacy**. A summary of the liver cancer recommendations has been published in the *Journal of the National Cancer Institute*, which is available online and will appear in the April 2016 print issue.

International HBV Meeting Goes Viral

The International HBV Meeting, coordinated by the Hepatitis B Foundation and the annual definitive meeting on the molecular biology of hepatitis B and D, is truly **going viral as interest in HBV as a curable disease gains momentum**. The 2015 HBV Meeting was held in October with more than 400 scientists from around the world traveling to Bad Nauheim, Germany. Co-chairs **Drs. Haitao Guo** (Indiana U, USA) and **Dieter Glebe** (Giessen U, Germany) kicked off the meeting with a clinical symposium that brought HBV molecular biologists together with physicians and drug development professionals to stimulate collaborations and accelerate the pace of drug discovery research for hepatitis B.

2015 Bruce Witte Lecturer: Dr. Hashem El-Serag

Each year HBF invites an outstanding leader in the field to give the *Bruce Witte Distinguished Lecture* and **Hashem El-Serag**, **MD**, **MPH** (right) was invited to present his important research on hepatitis B and liver cancer. This named lectureship is generously sponsored by **HBF co-founders Paul and Janine Witte**. (*March 19, 2015*)

3 Student Winners at the 2015 Siemens Competition

The **HBF Summer Research Internship Program** is advancing the national STEM priorities by providing college and high school students with valuable "hands-on" experience in the Blumberg Institute labs under the supervision of professional scientists. Since the year 2000, we have graduated **126 alumni** who have gone on to college, graduate or medical school, and employment in biotech or pharmaceutical companies. This summer 3 of our high school interns in Dr. Ying-Hsiu Su's lab won team honors for their research project at the Siemens Competition. (L to R: HBF Summer High School Student Interns Gerald Liu, Emily Cheng, and Kelly Jiang at the Siemens Competition in Math, Science and Technology held at George Washington University. Photo provided by Emily Cheng).





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Impacting Public Health

Elimination of hepatitis B is the ultimate goal of the Hepatitis B Foundation and the focus of our public health programs. To achieve this goal, we have developed successful **community-based programs** to increase vaccination, screening and linkage to care to **stop the spread** of this deadly virus.

To harness the community energy and maintain the momentum, we are *building coalitions* at the local, national and international levels to improve capacity to **ensure that every person knows their hepatitis B status** and has access to the care they need to prevent a new infection or treat a chronic infection.

OUR **LOCAL** IMPACT

In 2008 the HBF created a program to address hepatitis B in its own backyard – Philadelphia! Over the past 7 years this program has grown into a **thriving hepatitis B coalition** of 75 members that work together in high-risk communities to educate, screen and link individuals to care. It has also become a **model to test promising best practices** to improve efficiency and health outcomes around hepatitis B nationwide. In 2012, the coalition was renamed *Hep B United Philadelphia*.

> Led by HBF leaders and the Hep B United Philadelphia coalition, more than 60 advocates stormed City Hall to demand an end to the silence around viral hepatitis. (May 2015)



OUR NATIONAL IMPACT

HBF, in partnership with AAPCHO (Association of Asian Pacific Community Health Organizations), created and leads Hep B United, a national coalition of 24 member coalitions across the country that are working to address hepatitis B in their local communities. Hep B United members are finding success in **bringing together key stakeholders** such as community-based organizations, healthcare providers, hospitals and clinics, state and local health departments, student groups, and elected officials and community leaders to increase HBV awareness, screening, vaccination and linkage to care in high-risk communities.

Hep B United is also proud to be an official partner of the Centers for Disease Control and Prevention and is co-branded with its **Know Hepatitis B** campaign, their first national multi-lingual awareness campaign on hepatitis B.



The Hep B United 3rd National Summit in Washington, DC also included visits to members of Congress on World Hepatitis Day. Advocates stand with **Congressman Mike Honda** from California (center) who is our key HBV champion! (July 28, 2015)

Hep B United Across America



OUR INTERNATIONAL IMPACT

Since 2011 the HBF has conducted an ambitious public health HBV program in Haimen City, **China** to reach all **1 million residents**. The citywide campaign included educating physicians, government officials, community leaders, the general public, and testing all pregnant women over a 12-month period.

Today we are focused on strategies to **empower patients** to take control of their own care and to partner with their providers to improve their long-term health.

As we look to the future, we plan to **build on our success** and use Haimen City as a model for other high-prevalence countries, which currently includes supporting a program in **Vietnam** and sharing our experiences with leaders in **Mongolia**.



"I am so **grateful** for the advice given. You have given me so much hope and **reason to live** again."

Hepatitis B Foundation in Haimen City, China

1 million (100%) residents educated

"You have restored a lot of strength and hope in me."

 1,441 (90%)

 healthcare providers trained

 6,407 (100%)

 regnant women screened over one-year period

 12,000

 people screened for hepatitis B

enrolled in patient empowerment program

living Outreach

The Hepatitis B Foundation is a **beacon of hope** for the more than 240 million people worldwide who live with hepatitis B. We provide valuable **information and support** through our Help Lines via phone, email and social media. Our counselors answer questions about test results, transmission, vaccination, and treatment. We **link people to care** by referring them to healthcare providers, clinical trials and other resources in the U.S. and abroad.



from 200 countries visited www.hepb.org

4,000 people directly contacted us via phone, email, and social media

<u>10 languages</u>

included on our website with translated information about hepatitis B for our non-English speaking visitors **Nearly 5,000** Facebook followers Scoring

this impressive Klout Score reflects our strong social media influence

Connections for the Liver Cancer Journey



Our web-based *LiverCancerConnect.org* program provides people diagnosed with primary liver cancer accurate information and timely referrals to expert medical care.

With liver cancer rates exploding – it is now the 2nd most common cause of death from cancer worldwide, with HBV being the primary cause of liver cancer – there is a tremendous need for patient-focused information.

In the United States, liver cancer is one of the only cancers that is increasing in incidence while most cancer rates are decreasing.

Behind all of these staggering facts, however, are **patients and families struggling**

with liver cancer, which is why we created *LiverCancerConnect.org*. Our goal is to connect people with the information, support and resources they need to bring hope to their liver cancer journey.



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You /hepbfoundation



Leading Advocacy

Hepatitis B is the most common, serious liver disease in the world and it thrives on silence. To bring hepatitis B out of the shadows, the Hepatitis B Foundation is leading the effort to **turn up the volume** to prioritize hepatitis B as an urgent health priority. As the foremost research and disease advocacy organization for hepatitis B, we are speaking out on the national and international stage to demand **increased attention and funding** to eliminate hepatitis B once and for all.

1st World Hepatitis Summit Held in Scotland





The World Health Organization (WHO), in joint partnership with the Scottish Government and the World Hepatitis Alliance, co-organized the 1st World Hepatitis Summit in Glasgow, Scotland on September 2-4, 2015.

More than **80 countries** were represented with **600 leaders** from government, public health agencies, and non-governmental organizations participating.

The HBF presented about its successes and challenges in the U.S. during a pre-summit conference.

The message was serious. Hepatitis B and C kill more people each year than HIV/AIDS and tuberculosis combined, and represent the **7th leading cause of death worldwide**,

yet viral hepatitis as a global health concern remains mostly invisible and under-funded.

Without significant intervention, WHO estimates there will be **20 million needless deaths** over the next 15 years around the world. WHO leaders unveiled their draft global viral hepatitis plan, the first of its kind. Its twin goals of reducing chronic viral hepatitis cases by 90 percent and deaths by 65 percent by 2030 are ambitious, but possible.



CAPITOL HIGHLIGHTS

- HBF helped organize the first joint Hepatitis on the Hill visits to members of Congress in March that brought more than **100 hepatitis advocates** to Washington, DC. Patients and family members shared their stories to put a human face on the devastating impact of viral hepatitis and to call for increased federal funding to address the viral hepatitis epidemic.
- On July 28, designated World Hepatitis Day by the World Health Organization in honor of Dr. Baruch Blumberg's birthday, a commemorative White House Briefing honored national leaders, including Joan Block, HBF executive director and cofounder, for advancing the goals of the U.S. National Viral Hepatitis Action Plan.
- The National Academy of Medicine
 (formerly the Institute of Medicine or
 IOM) invited Dr. Robert Gish, HBF
 medical director, and Dr. Chari
 Cohen, HBF director of Public
 Health, to share expert testimony as
 the Academy prepares its report on the
 elimination of viral hepatitis in the
 United States, slated for release in 2016.

Funding Our Vision

The Hepatitis B Foundation's valuable research and patient programs are made possible by the commitment of our donors. We are grateful to everyone who has generously supported our mission through individual gifts, grants, matching gift programs, in-kind donations, and sponsorships and attendance at our special events. **Thank you!**

OUR 18-MONTH DONOR HONOR ROLL

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"In the twelve years that I have been a member of the foundation's board of directors, I have never been **MOTE OptimiStic** that a cure is within reach. It's an exciting time for everyone involved."

— Joel Rosen, HBF Board Chairman

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Drs. Cyndie and Bruce Maryanoff (center and right) received the 2015 Community Commitment Award from HBF Board Chairman Joel Rosen at the HBF Crystal Ball. (April 2015)

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"I can't thank you enough for your help and the **peace of mind** it gave me while waiting for my results. The work you do is very important to people."

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Priscilla Smith

"I can't begin to express how much I appreciate your efforts to assist me in this tough situation. Thank you so much for all the information you have provided me so far. Although the news is overwhelming, it is much less so with

your help."

Dr. Eugene Schiff (center) receives the 2015 Baruch S. Blumberg Prize at the HBF Crystal Ball and was joined in the celebration by the HBF Board of Directors, Mrs. Jean Blumberg (3rd from right) and her daughter Ms. Anne Blumberg Dorfman (2nd from right).

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Many thanks to our in-kind donors who are too numerous to mention.

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 your understanding.

A Nobel Challenge Met

The HBF is proud to announce the successful completion of *A Nobel Challenge*, a special campaign that raised **\$3 million** for the Blumberg Institute to recruit top scientific talent and accelerate the pace of research. We appreciate the **Board of Directors**, **Vivek Ramaswamy**, and the **Blumberg Family** for making lead gifts to the campaign.



HBF and BSBI Board of Directors celebrate meeting A Nobel Challenge and raising \$3 million to recruit the finest minds in science from around the world to work on finding a cure for hepatitis B. (November 2015)

THANK YOU TO ALL OF THE GENEROUS DONORS WHO SUPPORTED OUR RESEARCH VISION TO MAKE HEPATITIS B HISTORY!

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W. Thomas London Distinguished Professorship

Part of A Nobel Challenge campaign, the W. Thomas London Distinguished Professorship is the first named "Chair"at the Blumberg Institute and was established in 2015 to honor **W. Thomas London, MD**, for his transformational contributions to the discovery of the hepatitis B virus and his unwavering professional commitment to HBV for the past 50 years.



Dr. London (left) presented an honorary chair to **Ju-Tao Guo, MD** (right), professor and director of Experimental Therapeutics at the Blumberg Institute, as the inaugural recipient of the new W. Thomas London Distinguished Professorship. (October 2015)

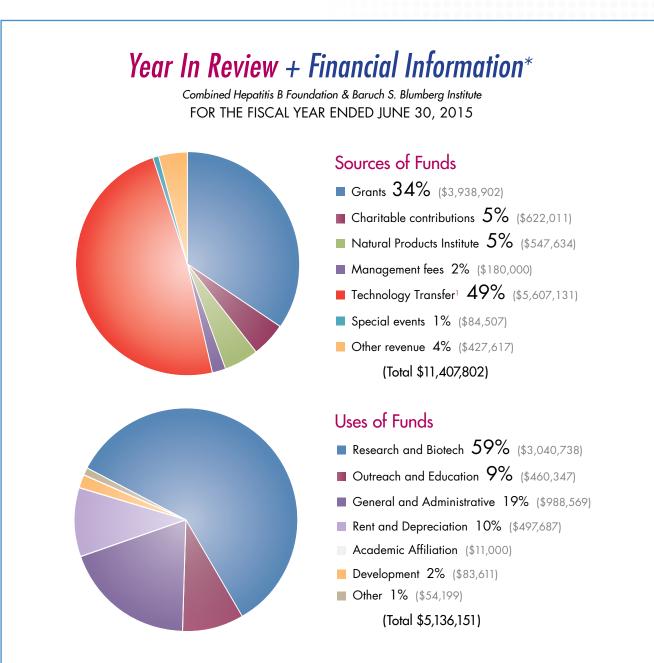
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"Your team has been extremely helpful, and I can't thank you enough for your kindness and prompt attention to our situation." "I have been treating hepatitis B for many years and I am thankful to you. Knowledge has been the legacy of your world, which you generously share with everyone and being a physician I always read your articles and discoveries. Well done, Hepatitis B Foundation."



¹ Proceeds from the sale of technology and shares of stock awarded for technology development were valued at the end of the fiscal year and documented as "Technology Transfer" revenue."

*The financial information presented above does not include the activity from Hepatitis B Foundation's 50% interest in the net assets of the Pennsylvania Biotechnology Center. At June 30, 2015, this interest was valued at, based on the equity method of accounting, approximately \$3.252 million per the audited Statement of Financial Position of the Hepatitis B Foundation. The Pennsylvania Biotechnology Center was founded in 2006 in partnership with a local college.

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, 2015. A copy of each financial statement is available upon request.

Hepatitis B Foundation 2015 Annual Report



The Hepatitis B Foundation and its Baruch S. Blumberg Institute are the nation's leading nonprofit research and disease advocacy organizations dedicated to finding a cure and improving the quality of life for those affected by hepatitis B worldwide. The Hepatitis B Foundation was founded in 1991, and established the Baruch S. Blumberg Institute in 2003 to fulfill its research mission.

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