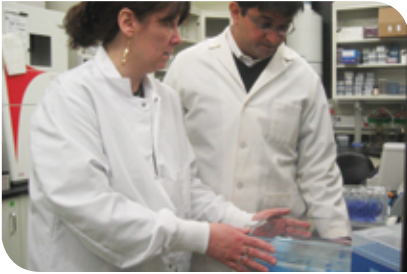




# Hepatitis B Foundation

Institute for Hepatitis and Virus Research

## 2012 Annual Report



*Excellent Science Rooted In Human Compassion*



## Hepatitis B Foundation

Institute for Hepatitis and Virus Research

### *Dear Friends,*

The Hepatitis B Foundation (HBF) continues to be *the* beacon of hope for those concerned about and affected by hepatitis B and liver cancer. After 20 years, we have become the nation's leading nonprofit research and disease advocacy organization for hepatitis B.

Our twin goals of significantly increasing awareness about hepatitis B and of delivering new discoveries that help people with hepatitis B and liver cancer—within the next 3 years—is highly ambitious. But we are well on our way.

To achieve this, the HBF Board adopted a comprehensive strategic plan in 2012 that leverages its many partnerships. We are building on our research institute, the Institute for Hepatitis and Virus Research (IHVR); our academic partner, Drexel University College of Medicine; our biotech partner, the Pennsylvania Biotechnology Center that we created to incubate companies; our federal partners that include the Centers for Disease Control and Prevention, U.S. Office of Minority Health, National Institutes of Health; and our national nonprofit partners.

So, we are not going it alone. Partnerships are key to our success and future growth.

This annual report shows that 2012 has been one of our most productive years. For example, we have been at the forefront of creating the first *Hep B United* national campaign that has more than 15 community-based coalitions participating from across the country; and helping to protect HBV-infected healthcare workers and students from discrimination by urging the CDC to update its 1991 HBV recommendations.

We are not only making noise in outreach, however, but in discovery research as well. With our academic partner, we have discovered new "lead" compounds with promising activity against hepatitis B and liver cancer, as well as new ways for the early detection of liver cancer.

We have made great progress since our creation in 1991. Simply put, the Hepatitis B Foundation has found a way to get even closer to our goal of... *making hepatitis B history!*

With appreciation,

Timothy M. Block, Ph.D.  
*President and Co-Founder*



Joel D. Rosen, Esq.  
*Chairman*




### *Our Mission*

The Hepatitis B Foundation is the nation's leading 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.

[ THE HEPATITIS B FOUNDATION IS ONE OF THE BEST NONPROFITS THAT PUTS THE HEALTH OF THE COMMUNITY FIRST. THE STAFF IS WITHOUT A DOUBT VERY DEDICATED TO THIS IMPORTANT CAUSE. HEPATITIS B IS A SILENT KILLER AND A THREAT TO MANY. I AM GLAD THAT THE FOUNDATION ENCOURAGES TESTING AND VACCINATION FOR THE COMMUNITY'S OWN PROTECTION. ] — SARAH





*Our nonprofit research institute has one of the largest number of hepatitis B scientists in the U.S. working to find a cure and for early detection biomarkers of liver cancer.*



## Innovation + Research

### RESEARCH HIGHLIGHTS

HBV/IHVR scientists work in teams with our academic partner, Drexel University College of Medicine, on biomarker and drug discovery and understanding the disease process.

#### I. Detect Liver Cancer Early

Hepatocellular carcinoma (HCC or primary liver cancer) and cirrhosis are the most serious consequences of chronic hepatitis infections. Detecting these diseases early, to allow for interventions to be used when the disease is most responsive, is considered to be one of the best ways to improve patient outcomes.

- **HCC and liver cirrhosis have a characteristic fucosylation profile**

Our work has shown that people with HCC have elevated levels of fucosylated glycan (a sugar attached to proteins) in their circulation. This is important to know, since it will help in the design and use of new cancer detection markers, as well as in understanding more about the disease. (Mehta et al, 2012; Norton 2012; Liang et al, 2012)



**Our research training program** is building the ranks of the next generation that includes high school and college summer internships; post-baccalaureate apprenticeships; and post-doctoral fellowships.

- **Total serum glycan analysis is superior to lectin-ELISAs for the early detection of HCC**

We have identified more than 30 glycoproteins that contain increased fucosylation with HCC and/or cirrhosis and have tracked their N-glycans in plate-based assays to detect HCC. (Communale et al, 2013)

- **New biomarker to detect AFP-negative liver cancers**

We have found that increased levels of alpha (2,6) linked sialic acid on serum alpha-1-anti-chymotrypsin could be used for the early detection of HCC in patients who test negative for alpha fetoprotein. (Mehta et al, 2012)

- **Possible marker for Cholangiocarcinoma (CCC)**

There is no effective blood test for CCC, or bile duct cancer. Not even AFP has any use. We have found that fucosylated Fetuin-A was promising as a marker of CCC. (Mehta et al, 2013)

- **Liver cancer DNA detected in the blood and urine can be both a disease and treatment marker**

We have discovered that liver cancer cells methylate “proto-oncogenes” in a way that is distinct from healthy cells, and developed new assays to detect “cancer cell” derived DNA in the urine and blood of patients. (Lin et al, 2011, 2012; Jain et al, 2012; Song et al, 2012)

*continued...*



**HBF coordinates the International HBV Meeting**, which continues to be the only scientific meeting focused on hepatitis B. In 2012, the HBV Meeting was held in Oxford, UK.

# STORY OF A YOUNG SCIENTIST

By Minh Vong

I was already in the middle of my senior year when I decided to drop my med-school application. Medicine seemed monotonous; but research was always changing and growing. A question would lead to an answer, which would lead to a new question, which led to a different answer and question. It was constantly progressing. It was exciting.

In my gap year, I thought it would be wise to immerse myself in research so I joined a DNA lab [at the Hepatitis B Foundation]. After three months, I decided to resign. Nothing was working. I felt like a failure.

When I went to see Dr. Block [HBF President and Professor, Drexel U. College of Medicine], rather than shaking my hand and showing me out the door, he offered to find me another lab as an apprentice. This was just the opportunity I needed. I even had the chance to enjoy the company of Dr. Baruch Blumberg, the Nobel Laureate who discovered the hepatitis B virus!

I would definitely say that my time in the Hepatitis B Foundation's research labs really helped me. My time in the lab provided the confidence I needed. It wasn't just having a rich environment to grow and learn; it was realizing that we had a unique scientific community to support, and rocket, us towards our dreams.

*Minh had been selected into the HBF/IHVR "Apprentice" program, which offers recent college graduates the opportunity to work in our research labs for 1 or 2 years with a scientific mentor to help guide them in their career decisions. In September 2012, Minh was accepted into the PhD molecular biology program at Harvard University.*



*continued from page 3...*

## II. New Therapies for Chronic Hepatitis B and Liver Cancer

Treatment of chronic HBV infection is very different today than 20 years ago since there are now clear medical options. However, half of those eligible for treatment do not benefit from these drugs, so we are focused on helping these patients and looking for new ways to cure hepatitis B.

Of particular interest is inhibiting the HBV covalently closed circular DNA (cccDNA), thought to be the permanent fingerprint of the virus in the liver. Liver cancer treatments is a high priority for us as well.

- **New cell-based assay** for studying transcription regulation of cccDNA and discovery of several "hit" compounds. (*Cuconati, in progress; Liu et al, 2013*)
- **Discovery** that interferon-alpha inhibits hepadnavirus transcription by epigenetic modification of cccDNA mini-chromosomes and methods to suppress cccDNA. (*Chang 2012; Guo et al, 2012*)
- **Discovery** that host cellular non-homologous end joining DNA repair pathway is essential for cccDNA formation from double-strained linear DNA. (*Guo H et al, 2012*)
- **Discovery** of new inhibitors of HBV pregenomic RNA-nucleocapsid formation. (*Campagna et al, 2013*)

- **Screening** of our Natural Products Library for cccDNA inhibitors is ongoing.
- **Discovery** of novel broad-spectrum antivirals through selective modification on innate immune response. (*Chang 2012; Guo et al, 2012*)
- **Discovery** of a compound that is highly selective and toxic to HCC in cell culture and animals. (*Cuconati et al, 2012*)

## III. Understanding the Disease Process

We have focused on understanding the molecular pathway of HBV covalently closed circular (ccc) DNA formation and viral egress (i.e. movement of virus within host cell). Our most current study showed that deproteinization of viral double-stranded linear DNA also took place in the cytoplasm. (*Guo et al, 2012*)

## Our Natural Products Institute

In 2011, Merck & Co. gave us their entire U.S. collection of natural products. As much as 50% of all medicines in use today came from natural products. So, we have been busy with this precious gift. **In addition to making it available to the entire research community, we have already identified several promising "hit" compounds that show activity against hepatitis B.**





## HBF's Baruch S. Blumberg Prize presented to Dr. Howard Koh

HBF presents the inaugural *Baruch S. Blumberg Prize* to Howard Koh, MD, MPH, Assistant Secretary for Health, U.S. Department of Health and Human Services, at the Crystal Ball.



HBF's **B Informed Patient Conference 2012** focused on the needs of parents of children living with hepatitis B. More than 60 parents traveled from across the country to participate and learn from medical experts in the field.

## NEW DEDICATED LIVER CANCER PROGRAM

HBF launched [www.LiverCancerConnect.org](http://www.LiverCancerConnect.org), the first patient-focused website that provides information and support to those facing the challenge of primary liver cancer.



"**Einstein's Table: The Search To Find A Cure for Chronic Hepatitis B**" written by Kimberly Jungkind is the first publication that chronicles the Hepatitis B Foundation story and its mission.

## Preventable Loss of My Brother

By John

A frantic call from my sister-in-law shattered our Labor Day weekend in 2010. My brother was in the ER for severe abdominal pain. We learned he had stage 4 inoperable liver cancer due to hepatitis B. We had no idea that he had chronic hepatitis B. He was a healthy 47-year old architect, avid skier, and father.

This was the beginning of the most heart-wrenching six months for our family. For me it was the most intense period of my life as I saw the older brother whom I loved and admired deteriorate so quickly. My brother passed away on March 6, 2011.

Naturally my thoughts went to how his death could have been prevented. The more I learned, the more anguished I became knowing that his death could have been prevented. As a result, I am committed to improving public awareness of this devastating disease. I share our family's story with the hope that those at risk may be diagnosed earlier and benefit from treatment.



## HBF Receives \$125,000 Grant Award from CDC

The HBF's Philadelphia Coalition was selected as 1 of 2 CDC demonstration sites in the U.S. We have educated 2,000 people, screened almost 1,000 high-risk adults, and linked 100% of those tested to appropriate care.

## "B A Hero" Theme is Saving Lives!



Philadelphia Mayor Michael Nutter joined our "B A Hero" media event during May Hepatitis Awareness Month to increase visibility of our **Hep B United Philly** coalition efforts to increase testing and vaccination rates in the city. We have 70 partner organizations and more than 100 student volunteers.

### By the Numbers

Our **website** receives **1 million** unique visits each year from **180 countries**

Our **telephone** and **email** help lines serve **more than 2,000 people**

Our **print** and **online newsletters** reach **more than 10,000 readers**

### Changing Practice and Policy

We are publishing articles in peer-reviewed journals that are helping to change clinical practice and national policy around hepatitis B.

- **Our screening algorithm and recommendations** for primary care providers have been published in prestigious medical journals for family doctors, internists, obstetricians, and nurse practitioners (an article for physician assistants is in the works).
- **Our public health research** has been highlighting the under-estimation and under-treatment of hepatitis B. The most recent publication questions whether treatment is needed for patients who fall outside of the current treatment guidelines since they are still at considerable risk for developing liver cancer.

### CDC Updates Recommendations for HBV-Infected Healthcare Workers and Students

We have succeeded in working with the CDC to update its recommendations for HBV-infected healthcare workers and students based on our experience in assisting many young people facing discrimination because of their chronic hepatitis B infections. **The CDC's new recommendations clearly state that hepatitis B is not a condition that should preclude any infected person from pursuing a career or practice in healthcare.**



## Impact + National Advocacy



### Launch of Hep B United National Campaign

The HBF is proud to have been at the forefront of starting “Hep B United” in partnership with the Association for Asian Pacific Community Health Organizations. It is a national campaign comprised of more than 14 local coalitions from across the country, federal partners that include the CDC, U.S. Office of Minority Health, White House Initiative for Asian and Pacific Islanders, and the U.S. Department of Health and Human Services, and corporate partners including Gilead and GlaxoSmithKline. We hosted the first Hep B United National Summit at the HBF headquarters in Bucks County, PA.

[ I HAVE BEEN VOLUNTEERING WITH THE HEPATITIS B FOUNDATION AND PARTNER ORGANIZATIONS FOR OVER A YEAR. THE MEMBERS OF THE ORGANIZATION ARE PASSIONATE AND INSPIRING, AND I HAVE SEEN FIRSTHAND THE POSITIVE IMPACT THEY HAVE ON THE COMMUNITIES THAT THEY SERVE. ] – DORA

## Opportunity + International Programs

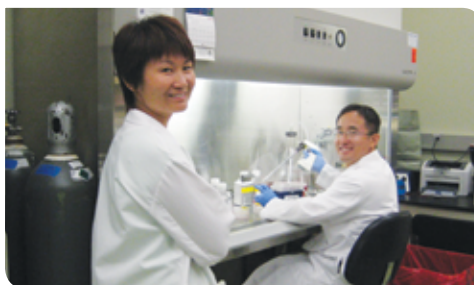
### Gateway to Care Project in Haimen City, China



Our public health campaign in Haimen City has screened 12,000 adults, educated 1,200 primary care physicians, and tested all 5,700 women in the city who became pregnant during 2011-2012. We are referring infected adults to care and ensuring that babies born to infected moms receive the birth-dose hepatitis B vaccine and HBIG to protect them from a chronic infection.

### Scientists Without Borders

Our “Scientists Without Borders” is an international research exchange program that currently includes agreements with three medical universities in mainland China. To date HBF has sponsored 6 international scientists for 2 to 3 year fellowships as part of this innovative program.



## Our Donor Honor Roll

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The Hepatitis B Foundation's valuable research and programs is supported by generous individual donations, grants, workplace and matching gifts, in-kind donations, donations of auction items and sponsorships for our Crystal Ball, and attendance at our special events. We are grateful to every individual and organization that has stepped forward to advance our *Cause for a Cure*. **Thank you!**

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[ TO THE WONDERFUL PEOPLE AT THE HEPATITIS B FOUNDATION, I'VE ATTENDED THE "B" INFORMED PATIENT CONFERENCES AND BEEN SO IMPRESSED WITH YOUR WHOLE ORGANIZATION. I'VE LEARNED SO MUCH AND BEEN ENCOURAGED AS WELL. ... THANK YOU FOR THE WONDERFUL WORK YOU ALL DO! ] – FAMILY FROM THE U.S. NORTH WEST



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## Federal and State Grants

Centers for Disease Control and Prevention  
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## HBF/IHVR Research Faculty Published More Than 50 Articles!

### Publication Highlights (2011-2012)

Cai D, Mills C, Yu W, Yan R, Aldrich C, Saputelli J, Mason W, Xu X, Guo JT, Block TM, Cuconati A and Guo H (2012). *Identification of the disubstituted sulfonamide compounds as specific inhibitors of hepatitis B virus covalently closed circular DNA formation.* Antimicrobial Agents and Chemotherapy, 56(8): 4277-88.

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Guo H, Xu C, Zhou T, Block TM and Guo JT (2012). *Characterization of the host factors required for hepadnavirus covalently closed circular DNA formation.* PLOS One.

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## Remembering R. Palmer Beasley, MD A Giant in Hepatitis B Research

April 29, 1936 – August 25, 2012

The Hepatitis B Foundation mourns the passing of **R. Palmer Beasley, MD**, a true loss to the global hepatitis B community. Dr. Beasley's groundbreaking research in hepatitis B and his numerous scientific contributions included the identification of mother-to-infant transmission and the fatal link between HBV and liver cancer. He worked tirelessly to persuade the World Health Organization to include the HBV vaccine in its global recommendations for immunizations, which have saved millions of lives worldwide. Dr. Beasley was the Ashbel Smith Professor and Dean Emeritus at the University of Texas School of Public Health. He also served as chair of the Institute of Medicine (IOM) committee that published the landmark 2010 IOM report on Hepatitis and Liver Cancer.

Dr. Palmer Beasley (right) received the HBF's *Distinguished Scientist Award 2012* and **Nobel Laureate Dr. Baruch Blumberg** (left) said during the presentation, "There are at least a million people alive today who would otherwise not be here if not for Dr. Beasley's pioneering research in hepatitis B."



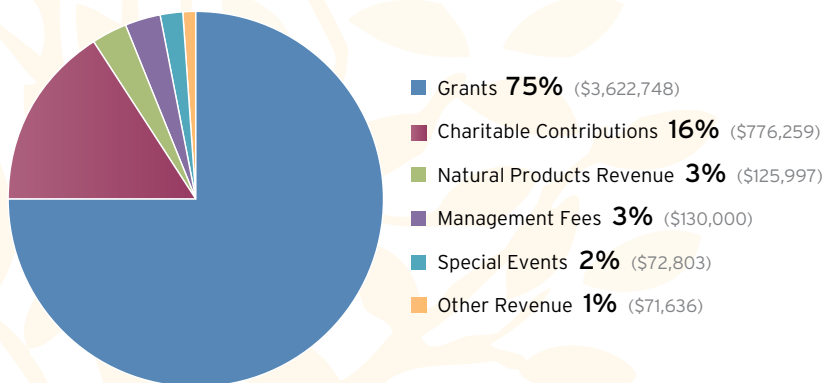
# Year In Review + Financial Information

For the fiscal year ended June 30, 2012

## Sources of Funds

HBF & IHVR Combined

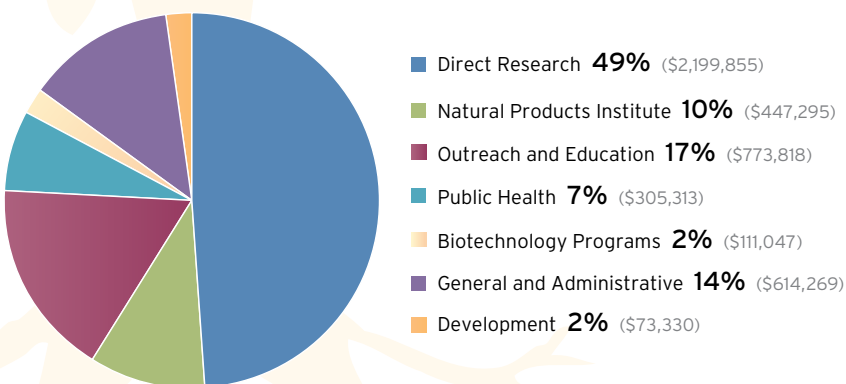
(Total \$4,799,443)



## Uses of Funds

HBF & IHVR Combined

(Total \$4,524,927)



[ OUR DAUGHTER WAS ADOPTED FROM CHINA AND MOST LIKELY INFECTED AT BIRTH. SHE IS NOW TEN (VERY HEALTHY!). YOUR WORK TO INCREASE AWARENESS OF HEPATITIS B WILL SURELY LEAD TO MORE EXTENSIVE RESEARCH, AND—I PRAY—AN EVENTUAL CURE. THANK YOU. ] – GRATEFUL MOM

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. On June 30, 2012, this interest was valued at approximately \$3.18 million per the audited Statement of Financial Position of the Hepatitis B Foundation. The Pennsylvania Biotechnology Center was founded by the HBF 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 Institute for Hepatitis Research audited by EisnerAmper, LLP for the year ended June 30, 2012. A copy of each financial statement is available upon request.



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*\*Baruch S. Blumberg, MD, DPhil (1992-2011)*

*Nobel Laureate and HBF Co-Founder*

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Songming Chen, PhD

Andy Cuconati, PhD

Yanming Du, PhD

David Horn, MD

Fred Klaessig, PhD

Xuanyong Lu, PhD

Tulin Morcol, PhD

Ramila Philip, PhD

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Michael Xu, PhD

## Natural Products Discovery Institute

Michael Goetz, PhD, Research Director

William Kinney, PhD, Technology Director

Anne Dombrowski, PhD

John Ondeyka, MS

## Adjunct Research Faculty

*These Drexel U. senior research faculty members are supported in part by HBF/IHVR funds*

Jinhong Chang, MD, PhD

Mary Ann Communale, MS

Alison Evans, ScD

Haitao Guo, PhD

Ju-Tao Guo, MD

Pooja Jain, PhD

Anand Mehta, DPhil

Brad Nefsky, PhD

Pamela Norton, PhD

Allen Reitz, PhD

Ying-Hsiu Su, PhD



## Hepatitis B Foundation

Institute for Hepatitis and Virus Research

Learn more about hepatitis B and the important work of the Hepatitis B Foundation by visiting [www.hepb.org](http://www.hepb.org).

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