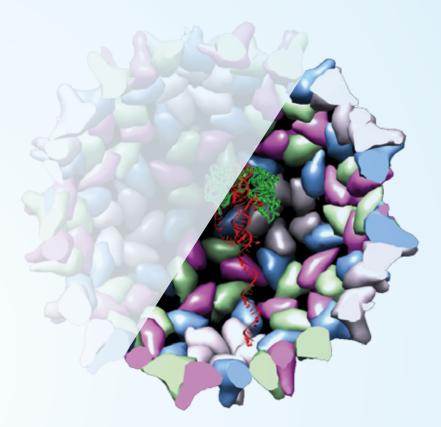
Making Hepatitis B History

2014 Annual Report







Making Hepatitis B History

December 2014

Dear Friends,

The next three years will be the **"make-it"** period for the *Hepatitis B Foundation* and its research arm, the *Baruch S. Blumberg Institute*. We have imposed an ambitious timeline for results because we believe the opportunity is now, and the need is urgent.

Our world-class research institute—renamed in 2013 as the *Baruch S. Blumberg Institute* in honor of our co-founder and Nobel Laureate Dr. Blumberg—is poised to significantly accelerate the pace of research. We have recruited a group of first class scientists to join us fulltime at the Blumberg Institute in 2015.

Our new scientists, however, aren't starting from zero. Indeed, they will have a head start since we have been preparing and building toward this goal for more than two decades. And all of our scientists have pledged to identify breakthrough therapies for hepatitis B in the next three years.

We want, and plan for, our discoveries to go from the lab into human use as quickly as possible. We know that this will require drug development experts with pharmaceutical company experience and we have already made arrangements to create technology development partnerships. This means that our scientists can focus on pioneering discoveries and our partners can carry them all the way to the clinic.

Our hope for the next 5 to 10 years is simple—**that a complete cure is found**, which will benefit everyone living with chronic hepatitis B worldwide.

We are ready to make a bold new push to truly make hepatitis B history!



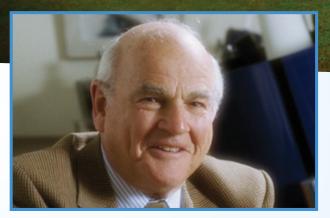
Timothy M. Block, Ph.D. President and Co-Founder



Joel Rosen, Esq. Chairman of the Board

Building for a Cure

Our Baruch S. Blumberg Institute is home to the largest concentration of nonprofit scientists working on hepatitis B and liver cancer Baruch S.



Hepatitis B Foundation's Research Institute Renamed in Honor of Nobel Laureate Dr. Baruch S. Blumberg

he Hepatitis B Foundation (HBF) hosted a grand re-opening celebration on October 7, 2013 for the renaming of its research institute in honor of Dr. Baruch S. Blumberg, who won the Nobel Prize for his discovery of the hepatitis B virus. The new name of **Baruch S. Blumberg Institute** honors the scientific legacy of Dr. Blumberg who co-founded the HBF and

served as an active member of the scientific advisory board and as "Distinguished Scholar" until his passing in 2011.

> For his discovery of the hepatitis B virus, Dr. Blumberg was awarded the Nobel Prize in Medicine in 1976.



Our Scientific Achievements

Blumberg Institute

Our researchers have greatly improved understanding of the biology of hepatitis B and the most innovative ways to target the virus in partnership with scientists onsite from Drexel University. They have pioneered systems that are useful in the discovery of new liver disease biomarkers, as well as potential therapeutics that are revolutionizing how scientists design treatments for hepatitis B.

New Ways to Treat Hepatitis B

We have developed screening methods to search for drugs that achieve the 3 elements critical to finding a curereduce virus levels, silence the viral DNA, and stimulate the immune system. We are now targeting critical steps of the virus life cycle with promising drugs in the research pipeline.

Early Detection of Liver Cancer

We have discovered and developed a new blood biomarker (GP73 or Golph2) for the early detection of liver cancer that has been tested in human clinical trials. Earlier detection means better outcomes for patients. We are working to ready our liver cancer biomarker, which is already approved in China, for approval in the U.S. in 2015.

Treatment for Liver Cancer

We have identified a new molecule called DAT (disubstituted aminothiazole) that is active and remarkably selective against liver cancer in pre-clinical studies. We aim to validate customized therapies for liver cancer that are targeted to an individual's specific cancer biology.

Pioneering Research

Our scientists achieve excellent science rooted in human compassion in pursuit of a cure

The Baruch S. Blumberg Institute is home to one of the largest concentrations of nonprofit scientists working on the problem of hepatitis B and liver cancer in the U.S. Our researchers are at the forefront of drug discovery and early detection biomarkers for these two deadly diseases. We are passionate about continuing the work of Dr. Blumberg who was committed to finding a cure and eliminating hepatitis B in our lifetime.

New Ways to Treat Hepatitis B

Putting the STING in Hepatitis B: Using an innovative assay developed in the labs of Drs. Guo and Chang, a new method of treating HBV was discovered. Our small molecule "Stimulator of Interferon Genes" (STING) is one of the most exciting leads in the field and shows that in tissue culture all detectable viral gene products can be eliminated. This finding was confirmed in a small animal study, too. The STING approach has moved to the front of our research strategies and is one of the more innovative immunotherapeutic approaches. *Guo et al, Antimicrobial Agents & Chemotherapy, 2014.*

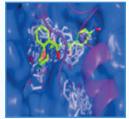
HBsAg Inhibitors: We have developed some of the only drugs that target the hepatitis B virus surface antigen (HBsAg). HBsAg is essential for viral replication and may also help the virus avoid detection by the patient's immune system. We have produced several drugs that reduce the amount of HBsAg secreted by infected cells, in tissue culture. Animal results are ongoing, with as yet inconclusive data. But this is a very promising treatment approach. *Cuconati et al, in preparation.*

Capsid Inhibitors: We have identified novel inhibitors of the virus capsid assembly process. The capsid is the protein shield that surrounds the viral DNA and is an

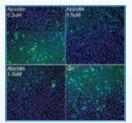
essential protein. It may also play a role in regulating viral gene expression from its covalently closed circular (ccc) DNA as well as immune evasion. Our new capsid inhibitors have been shown to be potent inhibitors of viral production in vitro (tissue culture) and may even have immune altering functions. One class of our compounds has been validated as active in animal studies, too. *Campagna et al, J Virology, 2013.*

Inhibitors of cccDNA: We have identified compounds that repress hepatitis B cccDNA (*Liu et al, 2013, PLOS Pathogens*) and there is great interest in their development. Some of these leads were found by testing our comprehensive natural products collection (*Cuconati et al, in preparation*), which was donated to the Blumberg Institute by Merck & Co. in 2011.

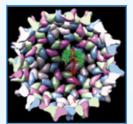
Seeing is Believing: Our computational chemists have created models of the intact hepatitis B virus that are 3-D depictions of the genome surrounded in its protein capsid home. We are using these images to help produce more potent capsid inhibitors. *Kulp et al, in preparation.*



Computer assisted drug design of HBV capsid inhibitor (*Dr. John Kulp, Dec. 2014*)



HBV infected liver cells treated with cccDNA inhibitor in vitro (Dr. Ju-Tao Guo et al)



Computer model of the hepatitis B virus (Dr. John Kulp, Dec. 2014)

Pioneering Research at the Baruch S. Blumberg Institute

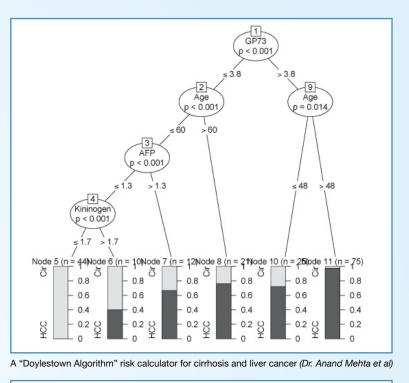
Early Detection of Liver Cancer

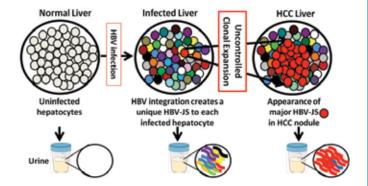
Risk Calculator to Get People Into Care: We have developed a better way to identify people with cirrhosis and liver cancer using current screening tools. The "Doylestown Algorithm" is a risk calculator that uses standard screening data such as age, gender and lab values (e.g ALT and AFP) to compute a "risk" value. This value provides a relatively easy way for providers to determine whether or not a patient should receive further testing for liver disease. It has now been used experimentally with thousands of human samples and appears able to identify many people who have liver cancer, who would have otherwise been missed. The next iteration will include our new biomarkers and is expected to be even better in identifying cancer early. Wang, Mehta et al, submitted.

DNA Markers to Identify HBV-Associated Liver

Cancer: HBV DNA integrates into the genomes of infected liver cells. Methods to detect these integrations using blood and urine are exploiting the integration phenomenon to detect liver cancer. This has been done in Dr. Su's lab and complements the ongoing studies in which "cancer DNA" can be detected in the urine and blood, as evidence of malignancy. *Su, Jain, Lin et al, in preparation.*

GP73 Gets Ready for U.S. Debut: Our liver cancer detection assay (GP73), which is already approved in China, is being readied for human use in the U.S. in partnership with a commercial company.



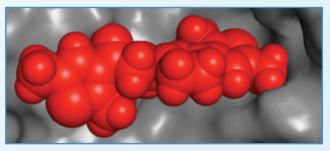


Treatment for Liver Cancer

HBV DNA integration assay for clonal expansion of HCC cells (Dr. YH Su, et al)

Improving the DAT Cancer Compound: We reported on the discovery of DAT (disubstituted aminothiazole), which has a remarkable selective activity against all liver cancer lines. It has little activity against "non-cancerous" lines in tissue culture, and was effective in an animal study. New versions of this compound that are 10 to 20 times more potent have been made, which will be tested again in animal models. Then it will, hopefully, advance to human explants cells in preparation for safety studies needed for human use studies. *Cuconati et al, in preparation.*

When YES means NO: The YES kinase is believed to be important in the growth of liver cancer. Drs. Cuconati and Kulp modeled the YES kinase by virtual screening and identified compounds from our natural products collection that they predicted would be inhibitory. They were right! A new series of YES kinase inhibitors has now been found and is the subject of active investigation. *Cuconati, Kulp, in preparation.*



Blumberg Institute HCC drug docking into the YES kinase (Dr. John Kulp, Dec. 2014)

Dr. Robert Gish Joins Hepatitis B Foundation as Medical Director



The HBF is proud to announce the appointment of **Robert Gish**, **MD**, as its new medical director. An internationally renowned researcher in the field of viral hepatitis, Dr. Gish has made invaluable contributions to the understanding and treatment of hepatitis B. As a member of the HBF Scientific and Medical Advisory Board for almost a decade, Dr. Gish's new role will

further strengthen its research and advocacy efforts worldwide.

International HBV Meeting 2014 Abuzz with Cure Talk

The annual International HBV meeting, which is coordinated by the Hepatitis B Foundation, remains the only dedicated meeting for hepatitis B scientists since 1985. This year it was held September 3-6, 2014 at the University of California Los Angeles and more than 300 scientists from around the world participated. With hepatitis C now curable, attendees were abuzz about the real possibility of now finding a cure for hepatitis B.



The International HBV Meeting co-chairs **Dr. James Ou** (*center*) and **Dr. Michael Kann** (*right*) receive hepatitis B ties from **Dr. Timothy Block**, HBF president (*left*), for their leadership.

Head Start for Top Students

HBF's highly competitive summer research program attracts the best students from local high schools and top-tier colleges to give them a head start for careers in science, medicine, public health, biotech and more. This year's program was funded in part by the PA Dept. of Health, Genesis Biotechnology Group, The John J. McDonell Margaret T. O'Brien Foundation, U.S. Naval Academy, and Marvin and Dee Ann Woodall.





Dr. Baruch Blumbera's granddaughter, **Emilie Thompson** from Harvard (right) was one of the first college interns to participate in the newly renamed Baruch S. Blumbera Institute this year. She received the Marvin and Dee Ann Woodall Scholar certificate from academic coordinator Dr. Pam Norton (Aug. 2014).

A Nobel Challenge Campaign

The Hepatitis B Foundation and its Baruch S. Blumberg Institute are ready to leverage powerful new technologies and bring to human use a new class of drugs that may, for the first time, offer a cure for hepatitis B. An infusion of philanthropic funding, however, is required to fast track our discoveries into new therapies. For more information, please email Joan.Block@hepb.org or visit *www.BlumbergInstitute.org*. "Hepatitis B is an important medical problem STILL and worldwide 1 in 3 people have the virus."

Dr. Baruch S. Blumberg (March 2011)

National Impact

We are raising the visibility of hepatitis B as a national health priority in the United States

Hepatitis B Foundation Receives Multi-Year Grant from CDC to Build National Coalition

The Hepatitis B Foundation (HBF) was awarded a highly competitive, three-year cooperative agreement from



the U.S. Centers for Disease Control and Prevention's Division of Viral Hepatitis to expand its network of hepatitis B partners across the country through *Hep B United*, a national coalition established by the HBF and Association of Asian Pacific Community Health Organizations (AAPCHO). The award will be used to support the organizational development and capacity building of coalition partners to improve hepatitis B screening

and linkage to care for affected individuals. Collectively, *Hep B United* serves 3.6 million Asian Americans at greatest risk who are located in 13 states and 22 cities. The grant will also help to increase dissemination of the CDC's "Know Hepatitis B" campaign materials that are co-branded with *Hep B United*.

Hep B United Rolls Out National Community Action Plan

Hep B United, under HBF's leadership, successfully rolled out the first phase of its national community action plan this year to address hepatitis B across the U.S. The key components of the action plan include providing technical assistance and training for coalition members, and distributing mini-grants to members to help increase their capacity for screening and linkage to care activities. Through monthly conference calls and e-newsletters, training webinars, Google "hangouts," and an Annual Summit, we are working together to build a strong hepatitis B community to eliminate this serious liver disease. The overall mission of our national hepatitis B coalition is to increase testing and improve linkage to care for those affected with the goal to, ultimately, save lives!







hepbunited.org

The 2nd Annual Hep B United National Summit, co-chaired by HBF and AAPCHO, was held May 21-23, 2014 in Washington, DC. From community coalitions and health centers to national nonprofit and federal partners, more than 40 participants focused on how to improve hepatitis B screening and linkage to care rates in the U.S.

Hep B United National Summit Held During May Hepatitis Awareness Month

More than 40 people representing community coalitions and health centers to national nonprofit and federal partners convened May 21-23 in Washington, DC for the second *Hep B United* National Summit. The focus was on updating the national community action plan, sharing best practices, and learning how to leverage federal resources like the CDC's "Know Hepatitis B" campaign materials. On the last day of the Summit, coalition members visited dozens of Congressional offices to advocate for increased federal funding for hepatitis B and liver cancer.

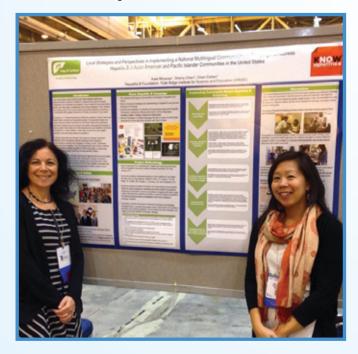


I recently came across your website and first of all, I'd like to thank you for providing so much valuable information for people living with hepatitis B. I am currently doing a lot of research about this disease, as my husband is infected with it and we want to find out the best treatment options for him.

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Hep B in the Spotlight at APHA 2014

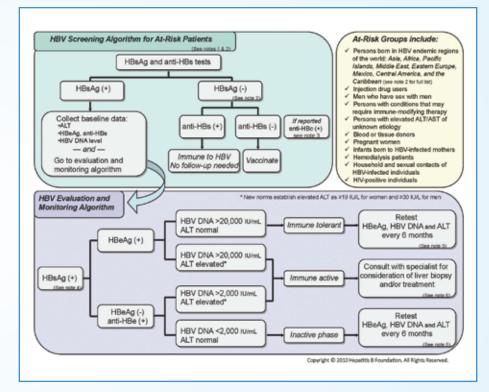
HBF's public health team—**Chari Cohen, MPH, DrPh(c)**, director of Public Health (*left*) and **Kate Moraras, MPH**, senior program director (*right*), with **Daniel Chen, MPH, CHES**, program manager (*not in photo*)—made sure that hepatitis B was well represented with 5 poster presentations at the American Public Health Association's (APHA) Annual Meeting in New Orleans, LA (Nov. 2014).



Making Hepatitis B Screening Easy for Primary Care Providers

HBF's Primary Care Algorithm for Hepatitis B Published in Major Medical Journals

The HBF convened a special workshop of medical experts a few years ago with leaders from family medicine, internal medicine, maternal and fetal medicine, pediatrics, and nurse practitioner and physician assistant groups. The goal was to develop a simple flowchart with recommendations for hepatitis B screening and monitoring in the primary care setting. HBF board member **Dr. W. Thomas London** and HBF medical and scientific advisory board member **Dr. Brian McMahon** facilitated this highly productive meeting. To date, our algorithm and recommendations for hepatitis B have now been published in the five major peer-reviewed primary care medical jounals.



A simple HBV clinical screening and monitoring algorithm published by the Hepatitis B Foundation in the five major medical journals focused on primary care providers.

Hi, I am a daily reader of your publications. Most people in Uganda are also dying of Hep b. My family relatives in particular have been victims. I am too scared of going for tests. please advice. I may not have a donation to give, but your information is a great donation to some of us. God bless you.

55

Published HBV Screening and Monitoring Algorithm and Recommendations for Primary Care Providers

Download HBF publications at www.hepb.org

Physician Assistants

The Role of Primary Care Physician Assistants in Managing Chronic Hepatitis B (2014). Beckett GA, Block JM, Cohen C, McMahon BJ. <u>J Am Acad Physician</u> <u>Assistants</u>;27(3):51-54.

Nurse Practitioners

Screening and Management Algorithm for Hepatitis B in Primary Care (2013). *Tarrant D, Block JM, McMahon BJ.* <u>J Nurse Practitioners</u>;9(4): 233-237.

OB/GYN Physicians

Chronic Hepatitis B in Pregnancy: A Workshop Consensus Statement on Screening, Evaluation & Management, Part 1 (April 2012). *Apuzzio J, Block JM, Cohen C, Cullison S, Leong SL, London WT, McHugh JA, McNellis RJ, Perrillo R, Squires R, Tarrant D, McMahon BJ.* <u>The Female Patient</u>;37(4):22-27.

Chronic Hepatitis B Infection: A Workshop Consensus Statement on Screening, Evaluation & Management, Part 2 (May 2012). *Apuzzio J et al. <u>The</u> <u>Female Patient</u>;37(5):30-4.*

Internal Medicine

Internist Diagnosis and Management of Chronic Hepatitis B Virus Infection (2012). *McMahon BJ, Block JM, Haber B, London WT, McHugh JA, Perrillo R, Neubauer R. <u>Am J of Medicine</u>;*125, 1063-1067.

Family Medicine

Chronic Hepatitis B Infection: A Workshop Consensus Statement and Algorithm (2011). *McHugh JA, Cullison A, Apuzzio J, Block JM, Cohen C, Leong SL, London WT, McNellis RJ, Neubauer RL, Perrillo R, Squires R, Tarrant D, McMahon BJ. J Fam Practice*;60(9):E1-8.

(Uganda)

R and a

The World Health Organization invited the Hepatitis B Foundation to join their Guidelines Development Group for Hepatitis B, which met in Geneva, Switzerland to finalize the hepatitis B management recommendations for low-resource countries. *HBF executive director Joan Block is 4th from left in front row and HBF medical and scientific advisory board member Dr. Brian McMahon is 4th from left in back row (June 2014).*

Global Impact

We are a trusted global authority and resource on hepatitis B

World Health Organization Invites HBF to Join Guidelines Committee for Hepatitis B



The World Health Organization (WHO) established a Guidelines Development Committee for Hepatitis B that has been working together for the past year to develop recommendations for the management of hepatitis B in resource-constrained nations. HBF medical and scientific advisory board member **Dr. Brian McMahon** is co-chair of this WHO guidelines committee

and HBF executive director **Joan Block** is a committee member. There is a tremendous need for guidance in countries where the disease burden is high, but available resources are low. The new WHO guidelines, slated for release in early 2015, will focus on low-resource countries since most available guidelines are for high-income countries.

HBF Creates National Coalition to Serve African Immigrant Communities



The Hepatitis B Foundation has established a national network—*Coalition Against Hepatitis in People of African Origin (CHIPO)*—that numbers more than 50 representatives from the CDC, medical centers, community groups and more. "CHIPO" is an African word meaning "gift" and under the leadership of HBF director of Public Health, **Chari Cohen**, CHIPO is making

good progress in living up to its name as the group tackles the high rates of hepatitis B and liver cancer in African immigrant communities.

Our Haimen City China Project Reaches 1 Million People

The Hepatitis B Foundation's ambitious public health campaign reached all 1 million residents of Haimen City, China. The city is located outside of Shanghai and has one of the highest incidences of liver cancer and mortality in China — and the world — due to chronic hepatitis B infection. The citywide campaign, which is the first of its kind in China, was funded by a competitive multi-year grant from the Bristol-Myers Squibb Foundation.



From 2011-2013, every household in Haimen City (280,000) received educational literature about hepatitis B. During one 12-month period, 100% of pregnant women (5,407) in the city were registered and screened for hepatitis B, with 5% testing positive. Educational seminars were held with 90% of healthcare providers (1,441) and 80% of community leaders and local officials (1,883) in attendance.

The first paper summarizing the campaign was published this year and a second paper focusing on perinatal hepatitis B transmission is under review. Three additional papers are in the works to share the wealth of the campaign's measurable outcomes and impact.

Gateway to Care campaign: a public health initiative to reduce the burden of hepatitis B in Haimen City, China (Aug 2014). Chen G, Block JM, Evans A, Huang P, Cohen C. BMC Public Health 2014;14:754. Download @ www.biomedcentral.com/1471-2458/14/754.



HBF's Gateway to Care: Haimen City Project in China, funded by BMS Foundation, was a huge success. Dr. Gang Chen, HBF director of China Programs (center) with Dr. Wen-yao Lin, Haimen City CDC (left), gives a tour of the HBF project in China to BMS Foundation president Mr. John Damonti (right) and program director Ms. Phangi Mtshali (2nd to left).

"I am so sorry to inform you that my husband & me are having hepatitis B. We live in Libya and have two children. They are not having it. We went to meet doctor and he advised to visit him yearly. We find it difficult to visit him due to lack of money. Only we pray & trust in the Lord Almighty. I am happy that you are a group who is a helping hand to help the affected people.

(Libya) ____

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Thanks for the advice and the level of education. Presently, I have stop drinking any forms of alcohol and taking in plenty of good as was recommended by [a doctor] at the John F. Kennedy Health Center in Monrovia, Liberia.

(Liberia) ____



11

Funding the Cure

We are grateful to every individual and organization that has made a donation to support our Cause for a Cure!

The Hepatitis B Foundation is very grateful for the generous support from individual donations, major gifts, foundation and corporate grants, matching gifts programs, and sponsorships and attendance at our special events. We depend on your philanthropic donations —and valuable in-kind donations—to fund our important research, outreach, public health and patient advocacy programs to fulfill our mission. Thank you!

Our Donor Honor Roll July 1, 2013 - June 30, 2014

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Presentation of the Baruch S. Blumberg Prize

Dr. Thomas Starzl (*center*) received the HBF's highest scientific award, the *Baruch S. Blumberg Prize*, for his pioneering work in liver transplantation, which has saved tens of thousands of lives worldwide. HBF president **Dr. Timothy Block** (*right*) and **Mrs. Jean Blumberg** (*left*), wife of the late Dr. Blumberg, presented the award at the annual Crystal Ball (April 2014).



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Community Commitment Award 2014

Jim and Teri Holton (on left) received the Community Commitment Award at the Crystal Ball from HBF board chairman Joel Rosen (2nd on right) and HBF associate director **Peggy Farley** (far right). Teri has served as chair of the HBF gala auction committee for the past four years and volunteers regularly in the community. Jim supports local food pantries with donations from Kellogg where he is a senior vice-president (April 2014).

Akim Kasimin Nina & Paul Katz Dorothy Kent & Harry Hellerman Chengchun Lee Mabel Lee Villa Rachel G. Lefkowitz King & Ying Liang M/M Michael D. Line Anonymous Marlene Madincea Tony Manzo James Massie M/M Jim McGowan Jacqueline & Juan Medina M/M Shanti Mehta Karen E. Mera John & Wendy Miller Nancy B. Miller Robert & Veronica Mitchell Arthur & Edith Mock Tulin Morcol Jack Morton Richard W. Moyer Louis Muzekari Meredyth Nash Carmen Nestares Thuan P. Nguyen Mark G. Obermann M/M John P. Oldani Michael & Maryellen Ovitt Fatma Fusun Ozer Joseph Paguiligan Aldersen Picar Ted Popper **Dmitry** Prokopets Alexander Propopets

Carol W. Rico Charles & Lorie Roth Amy & Perry Sanderson Anonymous Rita S. Shiue Vicki J. Shteir-Dunn Michael & Patricia Sinn Ayotunde Sodipe Herbert & Diane Stevens Linhui Sui David Sul M/M James Talamonti John Tavis Robert S. Thran M/M Harry C. G. Tse Hin Wing Tse Wallis Urmenvhazi Isha Weerasinghe Carrie Welch & Sherman Labarge Endale Weldevohannes Douglas Wenny Vanessa Wenzell Karen & Hilary Wilson Donna Wu Kechang Wu Mai Chong Yang Li- Chiu Yao Yuan Zhang Ling Zhu Lucille Zing Marcia Zinger

M/M Thomas Zipp

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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 contact editor@hepb.org or call (215) 489-4900 so that we can print corrections in our next newsletter. Thank you for your understanding.

I feel thankful and grateful for very detail and useful information in my mail. It was almost like god sent. I really appreciate your kind gesture. I feel confident and relieved after reading your wonderful explanation.

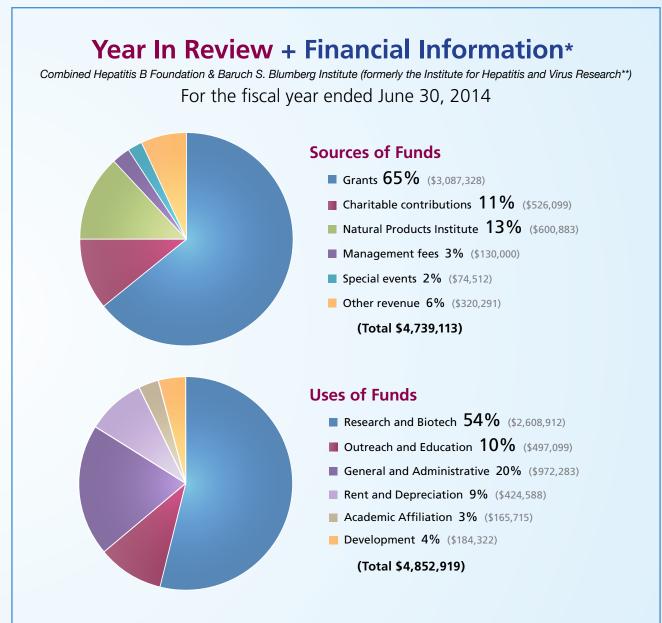
(India)



It is comforting to know that your Foundation and its staff are all concerned and united in a single cause—to find a cure for hepatitis B. I pray that your researchers will soon come out with a medication to save all those afflicted with this chronic liver disease.

(USA) _____

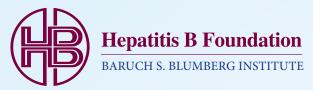




*The financial information presented above does not include the activity from Hepatitis B Foundation's 50% interest in the net assets of the Pennsylvania Biotechnology Center. At June 30, 2014, this interest was valued at, based on the equity method of accounting, approximately \$3.247 million per the audited Statement of Financial Position of the Hepatitis B Foundation. The Pennsylvania Biotechnology Center was founded in 2006 in partnership with a local college.

**Baruch S. Blumberg Institute is the reseach 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 Institute for Hepatitis and Virus Research audited by EisnerAmper, LLP for the year ended June 30, 2014. A copy of each financial statement is available upon request.



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.

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