The Baruch S. Blumberg Institute, established by the Hepatitis B Foundation, is proud to announce it has recruited a new research team of nationally renowned scientists to focus exclusively on developing a cure for hepatitis B. The move nearly triples the Institute’s research capacity and has created the largest concentration of nonprofit scientists in the United States focusing solely on hepatitis B and liver cancer.

On March 1, 2015, four principal scientists—Drs. Timothy Block, Jinhong Chang, Ju Tao Guo and Ying-Hsiu Su—and 16 of their staff members and laboratory researchers—joined the Blumberg Institute full-time. Establishing this world-class scientific team of leading hepatitis B researchers lays the groundwork to support an aggressive plan to develop breakthrough therapies to combat the hepatitis B virus (HBV) within the next three years.

“In the 12 years that I have been involved with the Hepatitis B Foundation, I have never been more optimistic that a cure is within reach,” said Joel Rosen, Chairman of the Foundation’s board. “It’s an exciting time for everyone involved.”

The scientists will build on their recent discoveries that are accelerating the research momentum around HBV and liver cancer. Those breakthroughs include the development of new screening methods to search for effective drugs, new ways to treat HBV using different approaches to shut down the virus, a new biomarker that aids in the early detection of liver cancer, and a promising drug in animal studies that selectively kills liver cancer cells.

“This is an incredibly exciting time in HBV research, with the field poised to develop a cure. The Blumberg Institute is fortunate to have attracted Tim Block and his colleagues, positioning it to maintain its world-class stature in hepatitis B research.”

— Dr. Thomas Shenk, one of the nation’s leading virologists, a professor at Princeton University, and a member of the Foundation’s Board of Directors.

Continued on page 3
From the Editor’s Desk

An Ambitious Time Line

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 time line for results because we believe the opportunity is now, and the need is urgent.

The Foundation and the Blumberg Institute have pledged to identify breakthrough therapies for hepatitis B in the next three years. This is entirely possible because our outstanding and dedicated researchers are working alongside some of the most accomplished drug discovery professionals in the world as well at our research center. We want, and plan for, our discoveries to go from the lab to human use as quickly as possible.

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. Dr. Baruch Blumberg believed eliminating hepatitis B in our lifetime was entirely possible. So do we.

The Hepatitis B Foundation and the Baruch S. Blumberg Institute are committed and ready to make a bold new push to truly make hepatitis B history!

50th Anniversary of Hepatitis B Virus Discovery!

Drs. Baruch S. Blumberg, Harvey Alter and Sam Visnich published the first article about the “Australia antigen” (later named the hepatitis B virus) in the February 1965 issue of the Journal of the American Medical Association. Dr. Blumberg and his colleagues, including Dr. W. Thomas London, Emeritus, Fox Chase Cancer Center and Vice President of the HBF Board, discovered the hepatitis B virus, the blood test to detect the virus, and the first vaccine to prevent infection. As a result of these discoveries, hundreds of millions of lives have been saved worldwide. Dr. Blumberg was awarded the Nobel Prize in 1976 for his discovery that a viral infection (in this case, the hepatitis B virus) could cause a chronic infection. In 1991, he helped create the Hepatitis B Foundation where he served as its Distinguished Scientist until his passing in 2011.

Read the original article on our website at www.hepb.org/news/Blumberg%201st%20HIV%20Article_JAMA_Feb.1965.pdf

HBV Drug Also Stops Hepatitis Delta Virus (HDV)

Hepatera announced the results of phase 2a clinical trials investigating Myrcludex B in patients with chronic hepatitis B virus and hepatitis delta virus (HDV) at the annual AASLD meeting in November 2014. The results suggest that Myrcludex B may become an option for treating hepatitis delta. The trials also indicate positive results for the treatment of HBV infection. Hepatitis delta is the most severe form of viral hepatitis affecting 15-20 million individuals worldwide and there are currently no effective treatment options. Myrcludex B blocks the receptor essential for both HBV and HDV replication, thus inhibiting new infection of liver cells. This is good news for the 5-10% of HBV patients who are coinfected with the delta virus. Read more at www.hepatera.ru/news?ln=en (Nov, 19, 2014).

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.

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*Baruch S. Blumberg, MD, DPhil (1992-2011)
HBF Co-Founder & Distinguished Scientist

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Layout & Design: CP Commercial Printing

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Making the Big Move

Dr. Tim Block and his wife Joan, with friends Paul and Janine Witte, co-founded the Hepatitis B Foundation in 1991 to find a cure. In 2003, the Foundation formed a research institute that was renamed the Baruch S. Blumberg Institute in 2013 to honor Nobel Laureate Dr. Blumberg, who worked with the Foundation from 1991 until his passing in 2011 (see News).

For the past 25 years, Block donated his time as president of both organizations while working full-time as a professor, first at Thomas Jefferson U. Medical College and then at Drexel U. College of Medicine (DUCOM) for the past 10 years. On March 1, he left his tenured position to commit 100% of his time and focus to the research mission of the Foundation and the Blumberg Institute. Drs. Chang, Guo and Su also left DUCOM where they were assistant professors of Microbiology and Immunology.

Focusing on Cause for a Cure

“The fact that Tim Block and other world-class scientists have chosen to join the Blumberg Institute in its drive to find a cure for hepatitis B speaks volumes about the Institute’s cutting-edge science and potential to impact global health,” said Wayne Yetter, former president and CEO of Novartis, USA, and member of the Foundation’s Board of Directors.

With promising drugs in the research pipeline, the Hepatitis B Foundation and the Blumberg Institute are solidifying partnerships with technology development companies to move the Foundation’s discoveries from the lab to the clinic, where they can benefit people worldwide.

“The years that we all have spent working towards a cure for hepatitis B have laid the groundwork for this final phase.”
— Dr. Timothy Block, HBF and Blumberg Institute president.

“We are committing everything we have, every resource at our disposal, to developing the therapies that will improve the lives of the millions of people worldwide who live with the hepatitis B virus every day, as well as the risk of dying prematurely from its most fatal consequence, liver cancer.

HOLLYWOOD ENDING for International HBV Meeting

The campus setting was beautiful, full of glamorous celebrities, and the weather warm. But what was really hot was the science … and the stars of this show were the scientists! This was the Hollywood ending for the 30th International HBV Meeting held September 3-6, 2014 at the University of California, Los Angeles.

With 350 attendees from around the world, it remains the definitive scientific meeting covering all aspects of hepatitis B and D biology and the latest drug discovery research. Having been the best attended hepatitis meeting in the U.S. for over a decade, it clearly reflects the growing interest in hepatitis B nationally and internationally.

Co-chairs, Prof. James Ou (UCLA) and Prof. Michael Kann (U. Bordeaux), emceed an excellent meeting with more than 160 presentations and posters, which was organized by the Hepatitis B Foundation.

The 2014 Best Picture award goes to Dr. Matteo Iannaccone for a stunning video clip of T-cells migrating through the liver, slowing down when they see HBV infected cells!

Other stars include:

- AML12HBV10 mouse hepatocyte-derived cells produce cccDNA. The cells were originally created in the lab of Blumberg Institute scientist JT Guo, but the findings were reported by J. Hu.

- cccDNA can be selectively cleaved inside the cell with the CRISPR CAS system, reported both C. Seeger and A. Shlomai. These systems could potentially be used to study the virus or as antivirals to selectively destroy cccDNA.

- cccDNA can apparently survive cell division, according to JT Guo whose chicken hepatoma culture system with labeled cccDNA showed its expression is repressed, and nucleocapsids are lost after interferon treatment.

- SMAC mimetics were shown by G. Ebert to promote in-vivo Hbv clearance in mouse systems.

- GS9620 can induce TLR7 and 8 responses, but the TLR8 responses require much higher doses of the drug, reports A. Palazzo for this first-in-class, potential breakthrough approach to treat Hbv by stimulating “Toll Receptors.”

International HBV Meeting co-chairs Drs. James Ou (center) and Michael Kann (right) receive hepatitis B ties from HBF and Blumberg Institute president Dr. Timothy Block. (Sept. 2014)
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<tr>
<th>FAMILY/DRUG NAME</th>
<th>MECHANISM</th>
<th>COMPANY</th>
<th>WEBSITE</th>
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<td><strong>NUCLEOSIDE ANALOGUES</strong></td>
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<tr>
<td>Epivir-HBV (Lamivudine)</td>
<td>Inhibits viral DNA polymerase</td>
<td>GlaxoSmithKline, Phila., PA</td>
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<td>Hepsera (Adefovir Dipivoxil)</td>
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<td>Baraclude (Entecavir)</td>
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<td>Tyzeka (Tebivudine)</td>
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<td>Clevudine (L-FMAU)</td>
<td>Inhibits viral DNA polymerase</td>
<td>Bukwang, Seoul, Korea, Eisai, Japan</td>
<td>bukwang.co.kr</td>
<td>Approved in S. Korea 2006 (Levovir)</td>
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<td><strong>NON-NUCLEOSIDE ANTIVIRALS</strong></td>
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<td>Myrcludex B</td>
<td>Blocks viral entry</td>
<td>Hepatera, Russia with Myr-GmbH, Germany</td>
<td>hepatera.ru</td>
<td>Phase II for HBV &amp; HDV</td>
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<td>ARC520</td>
<td>RNAi gene silencer</td>
<td>Arrowhead Research, Pasadena, CA</td>
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<td>SB 9200</td>
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<td>Rep 2139-ca (Rep 9AC)</td>
<td>HBsAg release inhibitor</td>
<td>REPLiCor Inc., Montreal, Canada</td>
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<td>Bininapant (TL32711)</td>
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<td>TetraLogic, Malvern, PA</td>
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<td>Bay 41-4109</td>
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<td>Alinia (Nitazoxanide)</td>
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<td>BSBI-25</td>
<td>cccDNA inhibitor</td>
<td>Baruch S. Blumberg Institute, Doylestown, PA</td>
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<td>CpAMS</td>
<td>HBV Core Protein</td>
<td>Assembly Biosciences, New York, NY</td>
<td>assemblybio.com</td>
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<td>CPI-431-32</td>
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<td>Ciclofilin Pharma, San Diego, CA</td>
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<td>dd-RNAi compound</td>
<td>Gene silencing</td>
<td>Benitec, Australia and Biomics, China</td>
<td>benitec.com</td>
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<td>NVP018</td>
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<td><strong>NON-INTERFERON IMMUNE ENHANCERS</strong></td>
<td>Boost T-cell infection-fighting immune cells and natural interferon production</td>
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<td>ABX 203</td>
<td>Therapeutic vaccine</td>
<td>ABIVAX, France</td>
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<td>HyperHEP B S/D</td>
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<td>Nabi-HB</td>
<td>HBV immunoglobulin</td>
<td>Biotest, Boca Raton, FL</td>
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<td>Hepa Gam B</td>
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<td>Cangene, Ontario, Canada</td>
<td>cangene.com</td>
<td>FDA Approved 2006</td>
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<td><strong>Hepatitis Delta Virus (HDV) Drug Watch</strong></td>
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<td>Myrcludex B</td>
<td>Prenylation Inhibitor</td>
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<td>hepatera.ru</td>
<td>Phase II for HBV &amp; HDV</td>
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<td>Lonafarnib</td>
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<td>Rep 2139-ca (Rep 9AC)</td>
<td>HBsAg Release Inhibitor</td>
<td>REPLiCor, Canada</td>
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<td>Phase II for HDV</td>
</tr>
</tbody>
</table>

Thank you to Timothy Block, PhD (HBF President), Brent Korba, PhD (Georgetown U) and Raymond Schinazi, PhD (Emory U and RFS Pharma) for their regular review of the HBF Drug Watch.
HBF Welcomes New Board Members

The Hepatitis B Foundation is pleased to welcome two new members to its board of directors. Both bring with them broad and deep experience in the healthcare arena and are a great fit for the Board at a time when even more promising research is on the near horizon.

Wayne Yetter has a 30-year career as a pharmaceutical executive at Pfizer, Merck, Astra Merck (now Astra Zeneca) and as President/CEO of Novartis USA and served on the Boards of Directors of the Pharmaceutical Research and Manufacturers Association, and the National Pharmaceutical Council.

Craig Esterly co-founded and is the managing member of SD Asset Group, a holding company for captive co-founded engineering and construction companies, and private investments. He serves on the Board of Directors of U. of Pittsburgh Medical Center’s Presbyterian Shadyside Hospitals and Shadyside Hospital Foundation.

Foundation Hires New Chief Operating Officer

The HBF welcomes Louis P. Kassa, III, MPA as its new Chief Operating Officer. Formerly the COO of a national behavioral health organization, Kassa will provide professional management of the daily finances and operations at the Foundation and its affiliated nonprofit entities, the Blumberg Institute and the PA Biotech Center, which was established by the HBF in 2006.

Crystal Ball Raises $110,000 to Fund the Cure for Hepatitis B

The Hepatitis B Foundation hosted its annual Crystal Ball, themed as a “Paper Lantern Festival,” on Friday, April 17 at the Warrington Country Club in Warrington, PA, which raised a record-breaking amount of $110,000 to help fund its research, outreach, public health and patient advocacy programs.

Dr. Eugene Schiff was honored this year with the 2015 Baruch S. Blumberg Prize for his pioneering clinical work in advancing the care and treatment of chronic hepatitis B. Dr. Schiff is an internationally renowned liver specialist and serves as Director of the Schiff Center for Liver Disease at the University of Miami Miller School of Medicine.

Baruch S. Blumberg Institute professors Drs. Bruce and Cyndie Maryanoff were also honored with the Community Commitment Award for their generous philanthropic support of the Hepatitis B Foundation and the community at large.

In addition, a young girl shared her story of living with hepatitis B and the battle she fought to survive the disease, which brought the audience to a standing ovation for her.

The Crystal Ball is the Foundation’s signature fundraising event and attracts hundreds of leaders from academia, industry, government, and the community. Major sponsors included Presenting Sponsor Univest National Bank, Platinum Sponsors Gilead Sciences and OnCore Biopharma/Tekmira, and Diamond Sponsors Arrowhead Research Corporation and Contravir. Emerald Sponsors included Allure West Studios, deArt Folio, Fulton Bank, Furia Rubel Communications and High Swartz LLP.
HBF Princeton Workshop Focuses on Reducing Liver Cancer
March 17-19, 2015 in Princeton, NJ

Braving gale force winds and delayed flights, the nation’s leading liver cancer experts arrived at Princeton’s historic Nassau Inn – weary but ready - for the bi-annual Princeton Workshop, a small, highly interactive roundtable meeting sponsored by the Hepatitis B Foundation with thought leaders on topics of importance to advancing the HBF mission.

This year’s workshop, led by Drs. Brian McMahon, member of HBF’s Medical & Scientific Advisory Board, and Tim Block, HBF president, focused on hepatocellular carcinoma (HCC), or primary liver cancer, the world’s 2nd leading cause of cancer deaths. As the fastest growing cancer in incidence in the U.S. with a 5-year survival rate of only 10%, liver cancer is on track to become the 3rd leading cancer killer in the country by 2030, according to Dr. Hashem El-Serag, who also gave the HBF Distinguished Bruce Witte Lecture after the workshop.

Dr. Morris Sherman, who co-authored the HCC screening and management guidelines for the American Association for the Study of Liver Diseases, noted that compliance with current guidelines is poor as most patients were unaware of their risk and were not in screening programs. More certainly needs to be done to improve compliance by both patients and providers.

Key highlights from the workshop included the powerful role of genotypes in development of HCC, presentation of HCC in low incidence populations, and promising new approaches for the early detection of liver cancer, including biomarkers and an algorithm that provides a “risk score” to identify individuals with cirrhosis and liver cancer.

Acknowledging that several drugs in development have failed in patients with advanced HCC, scientists from NIH’s National Cancer Institute reviewed the potential of immunotherapy for HCC treatment. The heterogeneous nature of HCC, however, makes a single agent unlikely to be universally effective, so combination therapies may need to be pursued.

Capitol News: Hepatitis on the Hill

HBV and HCV advocates numbering almost 100 joined the Hepatitis on the Hill rally on March 9-10 in Washington, DC to call for increased federal funding to address the viral hepatitis epidemic. The event was co-sponsored by the Hepatitis Appropriations Partnership, National Viral Hepatitis Roundtable, and Hep B United, which is led by the Hepatitis B Foundation and AAPCHO.

Patients and family members affected by HBV and HCV were front and center at this rally to humanize the devastating impact of viral hepatitis and the urgent need for a significantly more robust response from the U.S. government.

Seizing this advocacy opportunity, members of the HBF’s Public Health team — Chari Cohen, MPH, DrPH, director of Public Health, Kate Moraras, MPH, senior program director, Pavitri Dwivedi, MPH, program manager — and HBF’s Outreach team — Maureen Kamischke, program manager for Social Media and Outreach, and Daniel Esterly, MS, Program Associate — visited key members of Congress to give voice to the more than 2 million Americans suffering from HBV.

Dr. Hashem El-Serag
Gives Witte Lecture 2015

Hashem El-Serag, MD, MPH (on right), receives a plaque from HBF co-founders and board members Jan and Paul Witte, after delivering the HBF Distinguished Bruce Witte Lecture on hepatitis B and liver cancer. (March 19, 2015)
I am a 76-year-old Chinese American, born and raised in China. I am a liver cancer survivor as of today. I think I have been extremely fortunate and blissfully ignorant for all the years I have lived.

But not everyone is so lucky, which is why I want to share my story. Too often, ignorance is deadly.

I have had chronic hepatitis B all my life but was not aware of it until I was in my 30’s, when I was married with two children. It was detected when I tried to donate blood.

Even after I was made aware of my hepatitis B infection, I still did not take it seriously. Instead, I just waited for the other shoe to drop. I did not do research and was unaware that it could do serious damage to one’s liver. I was quite ignorant then.

About a year and a half ago, I was diagnosed with liver cancer, which was discovered incidentally. The cancer had developed as a result of my chronic hepatitis B infection.

I was told that the tumor was 5+ cm and was located on the left lobe of the liver, which was considered to be favorable. Furthermore, the tumor was essentially isolated, with “clean margins,” which was another advantage.

I had the liver tumor surgically removed. And I am not taking any medication as of yet. I go for my check-ups every 6 months with an oncologist at the hospital where I had my surgery.

I want to point out that my wife had been concerned about my hepatitis B infection throughout our married life and urged me to seek treatment. But due to my ignorance of the disease, I did not seek treatment until the liver cancer was detected.

My wife has always been a firm believer in, and practitioner of, proper nutrition (more organic food and less meat), proper supplements and exercise. I do think that has helped me tremendously, along with my biological constitution, in combating the hepatitis B virus in my system.

However, I wish I had been more knowledgeable when I was first diagnosed and had done something about it instead of taking chances like I essentially did. The letter I received from the blood bank back then informed me that I should not donate blood; but it didn’t give me any other information.

I am still not sure how I became chronically infected with hepatitis B. I was not aware of anyone in my small family who suffered a liver ailment. But my sister told me that my uncle died of liver disease.

I was fortunate in many ways and hope to remain so. But I am no longer ignorant.

I urge others with hepatitis B – or who have loved ones with hepatitis B – to take action! Get tested. Get treated.

Because ignorance is not bliss; it can be deadly.
WHO Issues Its First Management Guidelines for Hepatitis B

The World Health Organization (WHO) issued its first-ever guidance for the treatment of chronic hepatitis B, which affects over 240 million people worldwide and puts them at increased risk of dying prematurely from cirrhosis and liver cancer.

While effective medicines exist that can prevent progression to deadly outcomes, most infected persons in the world cannot access these lifesaving treatments.

Moreover, current HBV guidelines are for high-income countries (USA and Europe) where access to good care and treatments is possible. For low- and middle-income countries (Africa and Southeast Asia), lack of resources is an enormous barrier to care and longevity.

Thus, the WHO recommendations are for resource-constrained countries, and promote the use of simple non-invasive tests to assess liver disease and determine who need treatments, what medicines to use, when to stop treatment, and how to monitor people longterm.

The WHO guidelines development committee, which was co-chaired by Brian McMahon, MD, a member of the HBF’s Medical & Scientific Advisory Board, and included the HBF executive director, Joan Block, worked to develop guidelines that balanced evidence-based standards of care with what is actually feasible in resource-limited countries.

The new guidelines indicate the global momentum around HBV and the WHO’s renewed commitment to reducing the burden of HBV worldwide.

To read the new WHO Guidelines for HBV, visit www.hepb.org/pdf/Guidelines_Persons_Chronic_Hep_B.pdf