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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.

Informed

Hepatitis B Discrimination Alive and Well in the U.S.

Should people with chronic hepatitis B infection be prevented from working in health care? Should they be barred from training in health care professions? The answer to both is no, according to official recommendations from the Centers for Disease Control and Prevention (CDC) and the Society for Healthcare Epidemiology of America (SHEA).

Despite these national recommendations, the Hepatitis B Foundation (HBF) has fielded calls over the years from health care workers infected with hepatitis B. In 2011 the HBF was galvanized into action after receiving four calls within six months from distraught students who were either denied admission to medical and dental schools, or threatened with dismissal from their training program because of a hepatitis B infection.

"It was a painful wake-up call to realize that hepatitis B-related discrimination occurs not only in China, but also right here in the United States," says **Joan Block**, executive director of the HBF. "In an era of universal vaccination and effective antiviral therapies, there is absolutely no reason that hepatitis B should prevent anyone from pursuing their dreams."

The HBF quickly mobilized support from national thought leaders and the CDC then convened a meeting on June 4, 2011, in Atlanta. The goal was to update the CDC's 1991 hepatitis B recommendations for health care workers and students. Since most medical and dental schools look to the CDC for guidance, it is essential that their recommendations accurately reflect advances in the field and clearly state that



hepatitis B is not a reason to deny or dismiss a person from studying or practicing a health care profession.

With the full support of **John Ward, MD**, director of the CDC's Division of Viral Hepatitis (DVH), the June meeting was productive and reaffirmed agreement on key updates of the recommendations. Under the leadership of **Scott Holmberg, MD, MPH**, chief, epidemiology and surveillance branch of the DVH, the recommendations were written within a few months and reviewed extensively by outside experts and organizations, including HBF, as well as within the CDC and the CDC director's office. The updated recommendations will be published in the CDC's *Morbidity and Mortality Weekly Review* in early summer 2012.

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Dr. Howard Koh Receives Inaugural Blumberg Prize.
Read more on page 5



From the Editor's Desk

Joan M. Block, Co-Founder and Executive Director

Turning Up the Heat

The Hepatitis B Foundation is definitely turning up the heat, from confronting hepatitis B discrimination head-on, to publishing clinical recommendations that will change practice, adding liver cancer to our growing portfolio, and spearheading a new national hepatitis B campaign to advance the HHS Action Plan.

Alarmed by the increasing number of health care students facing discrimination because of their hepatitis B status (front page), we urged the CDC to update its 1991 hepatitis B recommendations for health care workers. Once approved, they will provide the public with a new reality—hepatitis B is not a condition that should be used to deny or dismiss anyone from pursuing their dreams.

Universal infant vaccination programs have done an outstanding job of preventing perinatal HBV transmission. But infected moms have been left by the wayside and treated as mere vessels of disease. This will change. Our

recent publication with consensus OB recommendations for the care of infected pregnant women (see below) is a milestone worth celebrating.

Hepatitis B is the primary cause of liver cancer—a medical diagnosis that no one wants to hear. Thus, we created www.LiverCancerConnect.org as a dedicated program of the Foundation. Through the website, we provide comprehensive information about the prevention, diagnosis and treatment of liver cancer to empower and give hope to patients and their families.

As a national nonprofit research and disease advocacy organization, we take seriously our responsibility to address unmet needs and advocate for issues to improve the lives of those affected.

The Hepatitis B Foundation thanks everyone who contributed to our Annual Fund Appeal in 2011. We sincerely appreciate your support and donations to help us continue our valuable work in research, outreach, public health and patient advocacy. **Thank you!**

In the News

HBF Recommendations for Chronic Hepatitis B in Pregnancy

Consensus recommendations for the evaluation and management of pregnant women who test positive for hepatitis B virus (HBV) were published as a two-part series in *The Female Patient* (April and May 2012). The new recommendations are the result of a workshop of prominent practitioners convened by the Hepatitis B Foundation in 2010 to help improve the HBV-related outcomes of infected women during and after pregnancy. Existing evidence-based guidelines were reviewed and a clinical algorithm was developed to aid providers who may be the main point of contact for a pregnant patient. Although most pregnant women are screened, a significant number may not be referred for further evaluation or management either during pregnancy or after. The new recommendations and simple algorithm should make it easier to provide optimal care for these patients.

Read both articles at www.hepb.org/pdf/Final_OB_publications_The_Female_Patient.pdf.



HEPATITIS B FOUNDATION

3805 Old Easton Road • Doylestown, PA 18902

We are a national nonprofit organization dedicated to finding a cure and improving the quality of life for those affected by hepatitis B worldwide.

Tele (215) 489-4900 • Fax (215) 489-4920
info@hepb.org • www.hepb.org

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Editor: Joan M. Block
Managing Editor: Anu Hosangadi
Contact: editor@hepb.org

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HBV Research Is Hot

2011 International HBV Meeting

October 9-12, 2011 • Lake Buena Vista, FL

The field is heating up again, and not just because we were in Florida

More than 140 oral and poster presentations were sandwiched between the keynote presentations, which is a lot of science in only three days. But the attendees met day and night with hardly any time to go on Disney rides. Fortunately, the meeting was a rollercoaster with more ups than downs. Once again, the work of scientists from the HBF research institute and their Drexel University partners was well represented in seven presentations.

Of the numerous terrific presentations, those with special implications for HBV therapy are briefly outlined here. Using a woodchuck model, **Menne et al** found that Gilead's oral drug GS-9620 reduced sAg and serum DNA levels, with



The 2011 International HBV Meeting was a success due to a great team: L to R: Dr. Maura Dandri, meeting co-chair; Dr. Timothy Block, HBF president; Ms. Peggy Farley, HBF associate director; and Dr. Michael Robek, meeting co-chair. (Oct. 2011)

some animals forming antibodies to sAg. **Lutgehetmann et al** reported that the entry inhibitor *Myrcludex B*, which was effective in a mouse model of human HBV infection, is moving into human trials. **Levrero and Liu** described how cytokines and interferons can shut down transcription of HBV cccDNA in tissue culture. **Riviere L, Zhang and Pollicino** reported on environmental and chemical changes to cccDNA that can regulate how it is expressed. These findings raise the hope that drugs may eventually be able to

repress cccDNA. **Liu et al** discussed how blocking the PD1 pathway in chronically infected woodchucks could restore T cell function, which is important in antiviral immunity. **Compagna et al** described a new class of drugs that inhibit pregenomic RNA, the intermediate genetic material of HBV.

Registration is now open for the 2012 International HBV Meeting scheduled Sept. 22-25 at the University of Oxford, UK. Visit www.HBVMeting.org for more information.

HBF Natural Products Discovery Institute: Open for Business!

World-class natural products collection now available to all scientists

The **Natural Products Discovery Institute (NPDI)** is up and running and now open for business. The NPDI, a division of the Hepatitis B Foundation's research institute, houses the priceless natural products collection that was donated by Merck and Co. in June 2011.

As one of the world's largest, most diverse and carefully curated natural products collections, it is being made public to all scientists for the first time through the NPDI.

According to **Michael Goetz, PhD**, NPDI director, "The library is a huge scientific treasure for the global research community and offers a completely virgin reservoir of possible hepatitis drugs."

Of course, "we don't know beforehand which chemicals will be useful," Dr. Goetz explains. The drug discovery process is somewhat random. But drug discovery also uses the knowledge and expertise of many scientists and cultures. Scientists may



Dr. Roy Vagelos, former CEO of Merck (center), gives Keynote at launch of NPDI. L to R: Robert Zivin, HBF board member; Chris Ball, entrepreneur; Roy Vagelos; Tim Block, HBF president and co-founder; and Mike Goetz, NPDI director. (Oct. 2011)

study a natural product because they know some cultures already use it for medicinal purposes.

And the library's potential is vast. As Dr. Goetz points out, less than 10 percent of the current collection has been studied in detail. "There is much, much more to be discovered in the collection ..." *Read the full interview with Dr. Goetz at www.hepb.org.*

For more information about accessing the collection, contact Dr. Bill Kinney at bill.kinney@ihvr.org or visit www.npdi-us.org.

FAMILY/DRUG NAME	MECHANISM	COMPANY	WEBSITE	STATUS, USA
INTERFERONS Mimic naturally occurring infection-fighting immune substances produced in the body				
Intron A (Interferon alfa-2b)	Immunomodulator	Merck, Whitehouse Station, NJ	www.merck.com	FDA Approved 1991
Pegasys (PegInterferon alfa-2a)	Immunomodulator	Genentech, South San Francisco, CA	www.gene.com	FDA Approved 2005
NUCLEOSIDE ANALOGUES Interfere with the viral DNA polymerase enzyme used for hepatitis B virus reproduction				
Epivir-HBV (Lamivudine)	Inhibits viral DNA polymerase	GlaxoSmithKline, Phila., PA	www.gsk.com	FDA Approved 1998
Hepsera (Adefovir Dipivoxil)	Inhibits viral DNA polymerase	Gilead Sciences, Foster City, CA	www.gilead.com	FDA Approved 2002
Baraclude (Entecavir)	Inhibits viral DNA polymerase	Bristol-Myers Squibb, Princeton, NJ	www.bms.com	FDA Approved 2005
Tyzeka (Telbivudine)	Inhibits viral DNA polymerase	Novartis, Switzerland	www.novartis.com	FDA Approved 2006
Viread (Tenofovir)	Inhibits viral DNA polymerase	Gilead, Foster City, CA	www.gilead.com	FDA Approved 2008
Clevudine (Levorvir)	Inhibits viral DNA polymerase	Bukwang, Seoul, Korea	www.bukwang.co.kr	Approved in S. Korea
MIV-210	Inhibits viral DNA polymerase	Medivir/Daewoong, S. Korea	www.daewoong.com	Phase II
Amdoxovir (DAPD)	Inhibits viral DNA polymerase	RFS Pharma LLC, Tucker, GA	www.RFSpharma.com	Phase II
NEW! AG X-1009	Pro-drug of tenofovir	Agenix, Australia	www.agenix.com	Phase I, China
NON-NUCLEOSIDE ANTI-VIRALS				
NOV-205 (Bam 205)	Small molecule	Novelos, Newton, MA	http://novelos.com	Approved in Russia
LB80380 (ANA380)	Inhibits viral RNA polymerase	LG Life Sciences, Seoul, Korea	www.lgs.com	Phase II
Myrcludex B	Entry inhibition	Myr-GmbH, Germany	Pending	Phase 1A, Germany
HAP Compound (Bay 41-4109)	Inhibits viral nucleocapsid	AiCuris, Germany	www.aicuris.com	Phase I
REP 9AC	HBsAg release inhibitor	REPLICor Inc., Montreal, Quebec	www.replicor.com	Phase I
Alinia (Nitazoxanide)	Small molecule	Romark Labs, Tampa, FL	www.romark.com	Pre-clinical HBV
NEW! dd-RNAi compound	Gene silencing	Benitec, Australia, Biomics, China	Benitec.com	Preclinical
NON-INTERFERON IMMUNE ENHancers Boost T-cell infection-fighting immune cells and the body's natural interferon production				
Zadaxin (Thymosin alpha-1)	Immune stimulator	SciClone, San Mateo, CA	www.scicClone.com	Orphan drug approval in U.S. for liver cancer
CYT107 (Interleukin-7)	Immunomodulator	Cytheris, Paris, France	www.cytheris.com	Phase I/IIA
DV-601	Therapeutic vaccine	Dynavax, Berkeley, CA	http://dynavax.com	Phase I
HBV Core Antigen Vaccine	Therapeutic HBV vaccine	Emergent Europe, UK	www.ebse.com	Phase I
POST-EXPOSURE AND/OR POST-LIVER TRANSPLANT TREATMENT				
HyperHEP S/D	HBV immunoglobulin	Talecris, RTP, NC	www.talecris.com	FDA Approved 1977
Nabi-HB	HBV immunoglobulin	Biotest, Boca Raton, FL	www.biostestpharma.com	FDA Approved 1999
Hepa Gam B	HBV immunoglobulin	Cangene, Ontario, Canada	www.cangene.com	FDA Approved 2006

Sincere thanks to **Timothy Block, Ph.D.** (Drexel U. College of Medicine, Philadelphia, PA), **Nat Brown, M.D.** (Presidio, San Francisco, CA), **Brent Korba, Ph.D.** (Georgetown U. Medical Center, Rockville, MD), and **Raymond Schinazi, Ph.D.** (Emory U. Medical School, Atlanta, GA), for their regular review of the HBF Drug Watch Update.

For More Information...

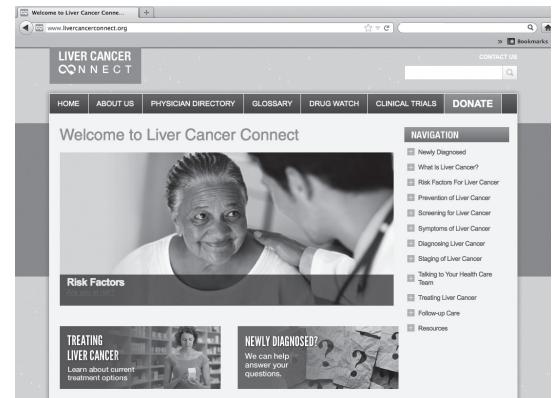
- **HBV Clinical Trials @ www.hepb.org/clinicaltrials**
- **Resource Round-Up @ www.hepb.org/resources**
- **Hepatitis B Info and Support List @ www.hblist.org**
- **HBV Adoption Support List @ <http://health.groups.yahoo.com/group/hbv-adoption/>**

HBF at the Forefront

HBF Launches LiverCancerConnect.org *A Patient-Focused Website*

Hepatitis B is the leading cause of liver cancer, which is one of the few cancers that are increasing in incidence each year in the U.S. Liver cancer is also one of the deadliest cancers, so people who receive this diagnosis need urgent support and accurate information about their options.

To address this challenge, the Hepatitis B Foundation created a patient-focused website, LiverCancerConnect.org, which is currently the only one of its kind. The website aims to provide information and support to help people better understand how liver cancer is diagnosed and staged, how it can be treated or prevented, and what additional resources are available to those facing this difficult challenge. A Drug Watch of liver cancer therapies and a clinical trials listing are included on LiverCancerConnect.org.

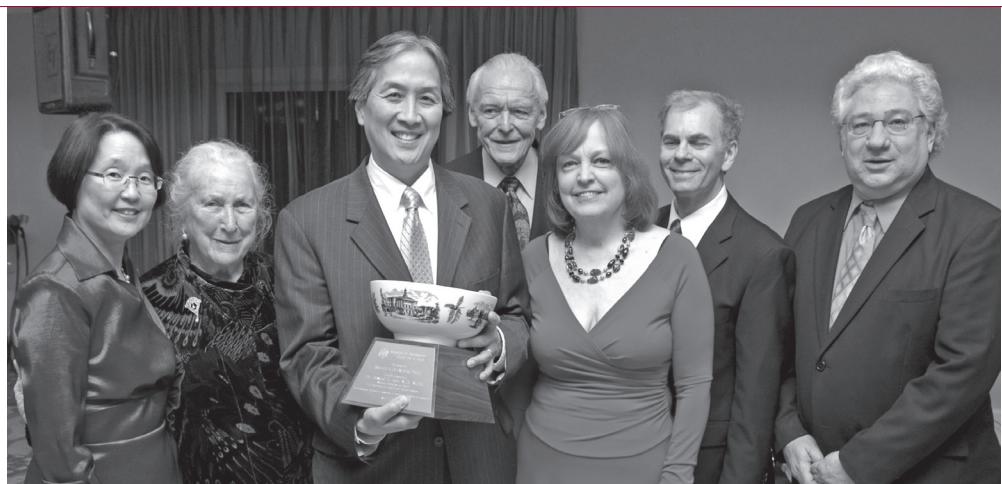


HBF 2012 Crystal Ball

HBF Honors Dr. Howard Koh, U.S. Assistant Secretary for Health, at 2012 Crystal Ball

The Hepatitis B Foundation proudly presented its inaugural *Baruch S. Blumberg Prize* to **Dr. Howard Koh**, assistant secretary for Health, U.S. Department of Health and Human Services (HHS), at HBF's Crystal Ball on April 27 in Bucks County, Pa. This prize was established in memory of HBF's co-founder, Nobel laureate **Dr. Baruch S. Blumberg**. Dr. Koh was selected as the first recipient of this prestigious award for his outstanding leadership in spearheading the first HHS Action Plan on Viral Hepatitis and making hepatitis B a national public health priority.

Graciously acknowledging the honor and saluting the legacy of Dr. Blumberg, Dr. Koh remarked that "Initiating the HHS Action Plan was an opportunity to seriously address the silent epidemic of hepatitis B and C. I am excited to work with the HBF, which has become a national resource and is well known for its many



Dr. Howard Koh receives HBF's inaugural Baruch S. Blumberg Prize. L to R: Joan Block, Mrs. Jean Blumberg, Dr. Koh, Paul and Janine Witte, Timothy Block, and Brad Segall (April 27, 2012).

accomplishments. Tonight I have met the most compassionate, committed group of people who are dedicated to hepatitis B; you all are the incredible heroes."

The HBF's second annual Community Commitment Award was presented to **Bridget and Joseph Wingert** of the *Bucks County Herald* for their tremendous commitment to promoting the work of the HBF in their widely read newspaper.

Brad Segall, Suburban Bureau Chief for KYW Newsradio 1060 and long-time HBF supporter, served as the evening's emcee. Univest Bank and Trust was the presenting sponsor and major sponsors included Gilead Sciences, Kevin Kruse, Citrin Cooperman, de Art Folio Design, Drexel



Publisher and Editor Joe and Bridget Wingert of the Bucks County Herald receive HBF's 2012 Community Commitment Award. (April 27, 2012).

University, Furia Rubel Communications, and High Swartz, with media sponsor *Bucks County Herald*.

This year's gala, which brought together 230 community, academic, corporate, government and biotech leaders, raised an historic \$102,000 to support the HBF's mission.

Hepatitis B Discrimination in the United States

(continued from page 1)

Although the CDC and SHEA guidelines, which are based on scientific evidence, have consistently stated that most HBV-infected health care workers pose little risk to patients, some medical and dental schools and hospitals have not fully adopted these recommendations.

And public opinion is not always aligned with the science either. In a 2005 survey of the general public, only 38 percent of respondents thought that infected providers should be allowed to provide patient care of any kind. And 82 percent believed health care providers with hepatitis B or C infections must inform their patients.

Clearly, misperceptions about how HBV is spread, and lack of knowledge about the current antiviral drugs that reduce transmission risk to almost zero, have unnecessarily shut out many students from health care training programs (read *Speaking Personally* on page 7).

Transmission Risk Now Negligible

During the June 2011 meeting convened by CDC, the group noted that dismissal of HBV-infected individuals not only goes against the 1991 CDC

monitoring of HBV DNA (or viral load) have also helped reduce transmission risk.

"Most importantly," emphasizes **Anna Lok, MD**, a renowned hepatologist at the University of Michigan, "we now have seven approved treatments for hepatitis B, [whereas there were] none in 1991," when the CDC last issued recommendations. "The new antiviral drugs are highly effective in suppressing the hepatitis B virus," helping to reduce the already low risk of transmission to patients. Moreover, denying HBV-positive students admission to medical school "is unfounded because students can complete necessary training without being involved in exposure-prone procedures," Dr. Lok added.

Rationale for New CDC Recommendations

The CDC has found no documented instance of medical or dental student transmission of HBV to patients, none from dentists to patients since 1987, and only one instance of surgeon-to-patient transmission since 1994. Thus, the CDC and the group it convened reaffirmed that HBV should not be cause for stopping providers from training or

"The denial [of admission to medical school] is unfounded because students can complete necessary training without being involved in exposure-prone procedures."

*Anna Lok, MD, FRCP
Director, Clinical Hepatology, University of Michigan*

recommendations but also is unwarranted. Over the past 20 years, the risk of transmission has become negligible, thanks to greater use of the HBV vaccine to prevent infection and widespread adoption of universal precautions in the workplace. Improved detection and

practicing in health care professions. To prevent unwarranted actions, institutional expert panels should evaluate HBV-positive health care students and providers on a case-by-case basis to ensure patient safety and the individuals' confidentiality.

"These [updated CDC] recommendations ... will have a beneficial impact on the public and providers."

*Scott Holmberg, MD, MPH
Chief, Epidemiology and Surveillance Branch, CDC
Division of Viral Hepatitis*

According to Dr. Lok, students can be counseled early on to avoid careers in health care fields that involve significant exposure-prone procedures, such as surgery. And medical, dental and allied health schools and hospitals should follow reasonable monitoring and treatment recommendations for HBV-infected health care workers and students. These recommendations should be based on the SHEA guidelines and others published by medical societies such as the American Association for the Study of Liver Diseases.

Greater awareness of current advances in HBV prevention and control is clearly needed. With the CDC aiming to screen and vaccinate 90 percent of U.S. health care providers, more HBV-infected students and providers will be identified. Therefore, schools and hospitals need to know how to appropriately handle such cases to prevent unwarranted denial or dismissal of affected individuals from their institutions.

"These [updated CDC] recommendations ... will have a beneficial impact on the public and providers," says the CDC's **Dr. Holmberg**. Both the Hepatitis B Foundation and CDC believe that the updated CDC recommendations will help put the risk of transmission into proper perspective and be consistent with the advances made in the prevention and control of HBV infection.

Speaking Personally

Dreams on Hold

A personal story of an aspiring medical student

The summer before starting medical school, most of my friends traveled and had fun. But I could not.

The months of June and July marked 60 days of complete horror—the lowest point in my life. First, my sister suffered a near-death medical complication. Then, for the first time in my life, I experienced discrimination due to an unexpected medical diagnosis.

My discrimination story started on June 20, 2011. The director of admissions at (X) Medical School notified me that I had been accepted into their program and offered a generous scholarship to attend. Because of this scholarship and the potential to obtain in-state residence, I dropped the other medical school I had been considering, including a \$2,500 enrollment deposit.

I began the grueling paperwork to matriculate to (X) Medical School. It took nearly a week to schedule

doctor appointments, fill out health forms, get required blood work done, look for apartments, and apply for financial aid. The following week, I traveled across the country to finalize an apartment lease. I returned home less than 24 hours later, exhausted but having successfully signed a lease.

Then my doctor called and said, "You have hepatitis B." The nightmare began after that call.

The next day, (X) Medical School's Student Health Services demanded that I have further blood tests within three days; otherwise, their committee would not be able to review my file before the start of classes.

I completed all of the tests, and the results were sent to the committee within a week. I pleaded with the committee to keep me enrolled, and I even agreed to drop out of medical school if the antivirals did not work.

The response from (X) Medical School came one week before orientation started: I was deferred until next year. In addition, my scholarship was revoked. They demanded that I sign a contract accepting deferment with conditions, including no guarantee of readmission and I had to sign within a week of receiving this devastating news.

At that moment I had to juggle not only my new medical diagnosis, but also the

fact that I had a lease that could not be cancelled or sublet, a full year without any plans, and uncertainties about my future.

The nightmare still lingers. However, I am slowly getting back on my feet. The antivirals are lowering my viral load. I am working in public health and reapplying to medical schools. My future is still uncertain.

Editor's Note: This story is one of the four cases that galvanized the Hepatitis B Foundation into action. At a June 2011 meeting convened by the CDC, the HBF and other national thought leaders worked with the CDC to update their 1991 hepatitis B recommendations for health care workers and students.

With the help of Ms. Nadine Shiroma, a community legal advocate, the U.S. Department of Justice (DOJ) opened an investigation into two of the most recent cases of students being denied admission to medical schools due to their hepatitis B status. Once a final settlement with the schools is reached, the DOJ will notify all medical and dental schools in the country that they may not discriminate against hepatitis B-infected applicants or enrolled students.

Between the updated CDC recommendations to be published this summer and the DOJ ruling, the HBF's advocacy is making a dent in hepatitis B-based discrimination.

Hep B United Campaign Launched!

Hep B United is a new national campaign spearheaded by the Hepatitis B Foundation and the Association of Asian Pacific Community Health Organizations (AAPCHO) that aims to promote, support and leverage the success of local community coalitions to raise the profile of hepatitis B and liver cancer as urgent public health priorities. By working together to advance the HHS Action Plan on Viral Hepatitis, the Hep B United campaign will provide a strong voice and presence at the national level.

This broad-based national campaign includes local community-based coalitions across the country, national nonprofit organizations, federal health agencies (CDC, OMH, HHS), and private sector partners. For more information and to participate, visit www.HepBUnited.org.

Calendar of Events

2012

June 22-25	14th International Symposium on Viral Hepatitis and Liver Disease Tri-Annual Meeting of Clinical and Basic Researchers Shanghai International Convention Center Shanghai, PR China www.isvhld2012.org	Nov 9-13	The Liver Meeting 2012 American Association for the Study of Liver Diseases Hynes Convention Center, Boston, MA www.aasld.org
July 28	World Hepatitis Day WHO and World Health Alliance Events held around the world. www.worldhepatitisalliance.org/ WorldHepatitisDay		
Sept. 22-25	2012 International HBV Meeting Coordinated by the Hepatitis B Foundation University of Oxford, Oxford, UK www.HBVMeting.org		Einstein's Table: The Search to Find a Cure for Chronic Hepatitis B A new book by Kimberly D. Jungkind tells the inspirational story of the Hepatitis B Foundation. The book chronicles their start in New Hope, PA, to their remarkable efforts over the past 20 years to become a leading authority on hepatitis B research, education and advocacy. All proceeds from the sale of this book will benefit the Hepatitis B Foundation. To purchase your copy or for more information, visit www.hepb.org .

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Blumberg Prize
Receives inaugural
Dr. Howard Koch



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