

B HEPATITIS B

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CAUSE FOR A CURE

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

INFORMED

HBF AND UNIVERSITY OF OXFORD Hope to STEER Graduates to Science



The Hepatitis B Foundation (HBF) took a big step forward in June, literally, when it extended its educational reach across the pond and joined with the University of Oxford in the United Kingdom to create a research training program.

Called the STEER program (STEERING post-secondary students into Science and Technology Entrepreneurship and Research career paths), it's aimed at preparing college graduates for careers in the fast-growing areas of biomedical research, public health and biotechnology. The HBF will select up to three individuals who will begin training at the HBF and then enroll in scientific studies, leading to a doctoral degree from the University of Oxford.

"It's very important to try to train people in basic research, and this program provides the wherewithal to do it," said world-renowned scientist **Prof. Raymond Dwek, FRS**, Head of Oxford University's Department of Biochemistry. "Oxford has one of the largest biochemistry departments in the western world, and there is only one other place in the United States we have this program set up. Achieving this agreement has been a triumph and it's a real token of esteem for both the university and the foundation."

Prof. Dwek, who has served on the HBF's scientific board for the past 12 years, provided strong leadership for this exciting new program. "The foundation is doing some very important work, and I have been impressed with their effectiveness, worthiness of cause and, frankly, the outstanding quality of the

people," he noted. "This arrangement will go a long way to building up awareness by way of two well-known institutions."

According to **Timothy Block, PhD**, HBF president, the new training program with the University of Oxford is designed to provide college graduates the opportunity to gain experience in a research laboratory or in a public health field in a sponsored laboratory – either in the HBF's labs or in the newly formed Drexel Institute for Biotechnology and Virology Research, formerly the Jefferson Center for Biomedical Research (see page 3).

"It's a chance for graduates to get experience in research or public health. Since hepatitis B will be their model, our hope is that there will be increased awareness of the HBF's mission," said Block. "Everything combined – the internship and its emphasis on translational, mission-oriented research, and the opportunity to be accepted into the University of Oxford – makes it a unique program," he added.

The HBF and University of Oxford training program is sponsored, in part, by a U.S. Department of Education training grant, awarded through the efforts of **U.S. Senator Arlen Specter**. "It's geared for people who are interested in graduate work but aren't sure about making the commitment yet," said **Pamela Norton, PhD**, the program's academic director. "Participants work fulltime as research technicians, but with a mentoring component, with the expectations of working closely with professional scientists to achieve career goals."

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Message from the President

Timothy M. Block, Ph.D.

New Initiatives

At this time of the year, the Hepatitis B Foundation (HBF) makes its annual appeal for financial contributions. In this issue of *B Informed*, there are two new relationships of historic importance to the HBF that should provide additional incentive to make a donation. These new programs can do a great deal to advance our mission and we hope you agree!

First, the HBF is proud to announce its new training program in joint sponsorship with the University of Oxford (front page). What, you may ask, does one of the world's most venerable institutions of learning, with nearly 1,000 years of history, have in common with a 14-year old U.S.- based public health organization? A lot, it turns out. That the Oxford initiative was championed by one of the HBF's most accomplished allies - Prof. Raymond Dwek, FRS, an internationally acclaimed scientist and Head of Biochemistry at Oxford - didn't hurt.

The University of Oxford is interested in identifying outstanding students who will work on matters of great importance. The HBF is interested in finding cures for one of the world's most confounding, serious diseases. To do our work, we must recruit the best people who will find the cures. Fortunately, these are the same types of individuals that the University of Oxford hopes to attract, too.

Second, the HBF has formed a partnership with Drexel University of Philadelphia, PA (page 3). Drexel is one of the nation's most innovative universities, and at present, Philadelphia's most exciting academic institution. With a tradition of practical research, Drexel took a keen interest in our mission. The HBF's research goals are highly focused and practical: we want to make discoveries that will help those affected by hepatitis B. Drexel nurtures this kind of mission-oriented discovery. With the complementary talents of Drexel and HBF, our cause should really get a lift.

So, we hope you add us to your holiday list. These new HBF initiatives really deserve your support.

Make a Donation Today!

Look for our annual appeal in your mailbox.
Please give generously this holiday season.
Thank you!

In The News



Drug for Crohn's Disease May Activate Chronic Hepatitis B

Infliximab therapy for Crohn's disease may be associated with reactivation of chronic hepatitis B infection, Spanish researchers report in the September 2004 issue of *Gut*. In fact, lead investigator Dr. Maria Esteve from Hospital Universitari Mtua de Terrassa, Barcelona, told Reuters Health, "When possible, all patients with Crohn's disease should be vaccinated to avoid reactivation related to immunosuppression," particularly when being treated with infliximab. She added, "Careful monitoring of viral hepatitis infection is advised in Crohn's disease patients requiring immunosuppressives." Moreover, "antiviral therapy—with lamivudine or adefovir dipivoxil—should be administered to those patients requiring infliximab therapy who exhibit positive surface antigen (HBsAg), with or without active viral replication." *Medscape: Reuters Health, Sept 6, 2004*

Kids with Arthritis Respond to Hepatitis B Vaccine

Hepatitis B vaccination can generate an adequate immune response in children with juvenile idiopathic arthritis (JIA); this response is unaffected by immune-suppressing drug usage, new research suggests. As many as 300,000 children in America have JIA, a group of joint diseases for which the cause is poorly understood. Antibody levels [after vaccination] were lower in the JIA group than in the healthy group, but were still considered adequate for protection. Treatment with methotrexate or prednisolone, two commonly used immune-suppressing drugs, did not influence antibody levels in the JIA group. The findings have important implications for developing countries where hepatitis B virus (HBV) infection is a common problem, noted lead author Dr. Ozgur Kasapcopur from Istanbul University in Turkey. *Annals of the Rheumatic Diseases, September 2004*

Coffee, Caffeine Consumption Associated with Reduced Liver Disease

A study of 5,944 adults conducted by the National Institute of Diabetes and Digestive and Kidney Diseases has found a strong association between coffee drinking and caffeine consumption, and a lower risk of liver injury in persons at high risk for liver disease. The researchers defined the high-risk population as those who reported being heavy drinkers of alcohol, or who had hepatitis B or C, iron overload, were obese, or had impaired glucose metabolism. The researchers reported that overall, the greater the coffee consumption, the greater the association with liver protection. Because caffeine consumption is associated with coffee drinking in the U.S., it is difficult to untangle the two statistically. Nonetheless, the researchers reviewed consumption of tea and soft drinks containing caffeine, and found a positive association, with less than 49 mg per day being the lowest threshold. *Digestive Disease Week Abstract, May 16, 2004*

HBF and Drexel University

Good Neighbors and Now Good Partners

This year, a special courtship led to a new relationship that will have great importance for those affected by viral hepatitis. The Hepatitis B Foundation (HBF) and Drexel University, in Philadelphia, PA, have been good neighbors for years, but discovered this past spring that they share a common interest in mission-oriented research and began to explore ways of working together more closely.

The result? The HBF and Drexel University are proud to announce a new partnership where they will share resources to further their mutual research goals. "This is an exciting beginning and with Drexel's scientific resources, this partnership will be the catalyst for a major hepatitis B research effort," said **Timothy Block, PhD**, HBF president.

In July, Drexel University created the *Drexel Institute for Biotechnology and Virology Research*, a new research division located at the site of the former Jefferson Center, in Bucks County, PA. This was accomplished under the energetic leadership of **Bill Stephenson, PhD**, vice provost for Research and dean of Graduate Policy at Drexel University, and CEO of the Drexel Research Foundation. "We have exciting plans for direct involvement with the HBF in its research efforts, arguably one of the best hepatitis B research programs in the world," said Dr. Stephenson.

Drexel University is ranked by *U.S. News and World Report* as one of America's top doctoral universities. The Drexel University College of Medicine, formerly MCP Hahnemann University, has been educating students in biomedical sciences for over 150 years. It is the largest private medical

school in the nation and a leader in health science education and research.

The relationship with Drexel University continues the HBF's successful tradition of partnering with academic institutions to leverage its resources. In 1994, the first HBF laboratory was established at the Jefferson Medical College of Thomas Jefferson University (TJU) in Philadelphia, PA, which was made possible through the support of **Joseph Gonnella, MD**, dean of the medical college.

In 1998, the HBF lab and offices moved into the Jefferson Center for Biomedical Research of TJU, which was created through a unique partnership between the HBF and TJU. The Center brought scientists together to focus on viral hepatitis in the pastoral setting of Doylestown, PA.

Today, the HBF is located in the new Drexel Institute, which is committed to continuing viral hepatitis and complementary cutting-edge biomedical research. The highly focused HBF scientific staff will work closely with Drexel scientists. In this way, ideas and numbers will be multiplied beyond what either organization would achieve alone.

"We are delighted to be working with Drexel University College of Medicine. They have embraced our mission and share our vision," said Dr. Block, professor and director of the Drexel Institute. "We will be extending and complementing each other's resources in a way that will advance hepatitis B research and result in world-class science."

HBF and University of Oxford - from page 1

"The STEER program started in June, and so far, two college graduates have been hired as trainees," said **Fonta Reilly**, HBF education and grants coordinator. "They will be eligible to complete the program at Oxford, where the university would admit them as doctoral students." This new HBF program should help steer students into science.



Prof. Dwek, Head of Biochemistry and director of the Glycobiology Institute at the University of Oxford.

Introducing the STEER Trainees

Natalie Pirog - "I look forward to becoming an active member of a scientific community that encourages

progressive research." Ms. Pirog graduated with her Bachelors of Science degree in Biology from Muhlenberg College, Allentown, PA. Most recently, she worked on an NIH-funded molecular biology project to create transgenic mosquitoes that express a human antiviral gene.

Anthony Damelio - "I want to work on something that will allow me to make the lives of people better, especially those who suffer from disease, such as hepatitis B." Mr. Damelio graduated from Duke University, Durham, NC, with a Bachelors of Science degree in biomedical engineering, where he developed a study that involved using pharmacokinetic methods to track a drug throughout the human body.

The new HBF research trainees. L to R: Anthony Damelio, Dr. Pamela Norton, program academic director, and Natalie Pirog (August 2004).



HBV Drug Watch

HBV Compounds in Development Fall 2004

FAMILY/DRUG NAME	MECHANISM	COMPANY	WEBSITE	STATUS, USA
INTERFERONS Mimic naturally occurring infection-fighting immune substances produced in the body				
Intron A (Interferon alpha-2b)	Immunomodulator	Schering-Plough, Madison, NJ	www.schering.com	FDA Approved 1991
Pegasys (PegInterferon alfa-2a)	Immunomodulator	Roche, Switzerland	www.roche.com	Phase III, outside USA
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
Emtricitabine (FTC)	Inhibits viral DNA polymerase	Gilead Sciences, Foster City, CA	www.gilead.com	Phase III / NDA Filed
Entecavir	Inhibits viral DNA polymerase	Bristol-Myers Squibb, Princeton, NJ	www.bms.com	Phase III / NDA Filed
Clevudine (L-FMAU)	Inhibits viral DNA polymerase	Bukwang, Seoul, Korea	www.bukwang.co.kr	Phase III, South Korea Phase II, U.S.
Telbivudine (LdT)	Inhibits viral DNA polymerase	Idenix, Cambridge, MA	www.idenix.com	Phase III
Valtorcitabine (monoval LdC)	Inhibits viral DNA polymerase	Idenix, Cambridge, MA	www.idenix.com	Phase II
Amdoxovir (DAPD)	Inhibits viral DNA polymerase	Gilead Sciences, Foster City, CA	www.gilead.com	Phase II
Remofovir B (Hepavir B)	Inhibits viral DNA polymerase	Valeant, Costa Mesa, CA	www.valeant.com	Phase II, Europe, USA
Elvucitabine (ACH-126,443)	Inhibits viral DNA polymerase	Achillion New Haven, CT	www.achillion.com	Phase II (Central & Eastern Europe)
RCV (Racivir)	Inhibits viral DNA polymerase	Pharmasset, Tucker, GA	www.pharmasset.com	Phase II, Europe
MIV-210	Inhibits viral DNA polymerase	Medivir, Sweden	www.medivir.com	Phase I, U.K.
Pentacept (L-3'-FD4C)	Inhibits viral DNA polymerase	Pharmasset, Tucker, GA	www.pharmasset.com	Preclinical
Robustaflavone (ALS-920)	Inhibits viral DNA polymerase	Advanced Life Sciences, Woodbridge, IL	www.advancedlifesciences.com	Preclinical
LB80380	Inhibits viral DNA polymerase	LG Life Sciences, Seoul, Korea	www.lgls.co.kr/eng	Preclinical
NON-NUCLEOSIDE ANTI-VIRALS				
BAM 205	"Small Molecule"	Novelos, Newton, MA	http://novelos.com	Phase II/III China
HepeX-B (XTL-001)	Human monoclonal antibodies	XTL Biopharm, Rehovot, Israel and Cambridge, MA	www.xtlbio.com/	Phase II, Israel & U.S.A. Orphan drug approval in US for liver transplants
UT 231 *Discovered by HBF scientists	Small Molecule	United Therapeutics Silver Spring, MD	www.unither.com	Preclinical HBV (Phase II HCV)
HepBzyme	Nuclease resistant ribozyme	Ribozyme, Boulder, Co	www.rpi.com	Preclinical
Bay 41-4109	Inhibits viral nucleocapsid	Bayer AG, Germany	www.bayer.com	Preclinical
NON-INTERFERON IMMUNE ENHANCERS Boost T-cell infection-fighting immune cells and the body's natural interferon production				
HE2000	Immune Stimulator	Hollis-Eden, San Diego, CA	www.holliseden.com	Phase II, Singapore
Theradigm	Immune Stimulator	Epimmune, San Diego, CA	www.epimmune.com	Phase II
EHT899	Oral Viral Protein	Enzo Biochem, NY, NY	www.enzobio.com	Phase II, Israel
Zadaxin (Thymosin alpha-1)	Immune Stimulator	SciClone, San Mateo, CA	www.sciclone.com	Phase II w/lamivudine Orphan drug approval in US for liver cancer
HBV DNA Vaccine	Immune Stimulator	PowderJect, Oxford, U.K.	www.powderject.com	Phase I
SpecifEx-HepB	Immunological Cell Transfer	CellExSys, Seattle, WA	www.cellexsys.com	Preclinical/Phase I
NEW eiRNA Technology	Expressed Interfering RNA	Nucleonics, Horsham, PA	www.nucleonicsinc.com	Preclinical
POST-EXPOSURE AND/OR POST-LIVER TRANSPLANT TREATMENT				
BayHep B	HBV immunoglobulin	Bayer U.S., Pittsburgh, PA	www.bayer.com	FDA Approved 1977
Nabi-HB	HBV immunoglobulin	Nabi, Boca Raton, FL	www.nabi.com	FDA Approved 1999
Anti-hepatitis B	HBV immunoglobulin	Cangene, Ontario, Canada	www.cangene.com	FDA Filing 2001

Sincere thanks to Brent Korba, Ph.D. (Georgetown University Medical Center, Rockville, MD) and Raymond Schinazi, Ph.D. (Emory University Medical School, Atlanta, GA) for their regular review of the HBF Drug Watch Update.

HBF Gathering of Friends 4th Annual B-Informed Patient Conference June 26-27, 2004

Chris Kukka and Maureen Kamische

What happens when you combine the spontaneity and informality of a "virtual" online support group with the "real" face-to-face humanity of a conference? Synergy! This combination creates a unique gathering of friends; in late June, more than 80 people gathered on the campus of Stanford University to share their medical and emotional journey with hepatitis B.

What they found at the fourth annual "Gathering of Friends," sponsored by the Hepatitis B Foundation (HBF), was compassion, friendship, and a team of experts who were willing to share all they could about hepatitis B. This one-of-a-kind patient conference has become an important event because it provides the only opportunity for patients, families, and health care providers to gather in a relaxed, supportive environment.

This year, the Asian Liver Center at Stanford University generously offered to host the patient conference on the west coast. Although the venue changed, the HBF's tradition of mixing formal presentations with informal question-answer periods was successfully continued. **Molli Conti**, HBF vice-president for Community Outreach, kicked off the conference with a warm welcome and a brief introduction of the foundation.

Dr. Sam So, founder and director of the Asian Liver Center at Stanford University, was the keynote speaker and gave a lively overview of his efforts to promote hepatitis B awareness in China, where 60 percent of the population has been infected with the hepatitis B virus and 10 percent remain chronically infected.



"Helping Patients Work within the Healthcare System" was moderated by Steve Bingham (far right). L to R: Dr. Emmet Keeffe and Dr. Sam So (June 2004).

While China is trying to vaccinate all newborns against hepatitis B, there is no campaign available to immunize adults and children, who remain at high risk for exposure to the virus because of re-used medical equipment, such as syringes and needles,

he reported. Individuals infected with hepatitis B in China continue to face severe discrimination in employment and education. Some are even prevented from marrying if they test positive for hepatitis B, he added.

Dr. So discussed the urgent need to test and treat Asians in the United States for hepatitis B. This population has the highest chronic hepatitis B infection rate, yet many doctors across the country do not know they should screen Asian patients for hepatitis B. As a result, Asians have the highest rate of liver cancer in the U.S. due to undiagnosed and/or untreated chronic hepatitis B infections, he said.

Dr. Emmet Keeffe, chief of Hepatology and co-director of the liver transplant program at Stanford University Medical Center, and president of the American Gastroenterological Association, discussed the latest treatments for hepatitis B. He fielded tough questions about which antiviral to use first: the more costly adefovir (Hepsera), or the more affordable lamivudine (Epivir-HBV).

For first-time treatment, Dr. Keeffe suggested adefovir for HBeAg-negative hepatitis B, and lamivudine for HBeAg-positive hepatitis B. He suggests lamivudine-treated patients switch to adefovir if they develop viral resistance to lamivudine.

Dr. Keeffe also expressed optimism about pegylated interferon, a new time-release interferon that has proven more successful against hepatitis B than conventional interferon. Shortly after the conference, Hoffmann-La Roche issued a press release stating it had asked the U.S. Food and Drug Administration for permission to market its pegylated interferon product, Pegasys, to treat chronic hepatitis B.

During a discussion about supporting adults and parents of children living with hepatitis B, led by **Chris Kukka** and **Maureen Kamische**, a newly diagnosed grandmother tearfully asked, "How do I tell my children about my hepatitis B? What if I have infected my children? Can I still hold my grandchildren and kiss them?" Other attendees wondered, "Will I ever find someone to love me? When do I tell a potential partner?"

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Fast Fact

One-third of the 400 million people worldwide with chronic hepatitis B live in China.

The Asian Liver Center at Stanford University



Participants enjoy a special one-on-one session with Dr. Emmet Keeffe.

A highlight of the conference was an eight-course Chinese banquet at a local restaurant where two families shared their personal stories.



"If I tell them too early, I risk losing them. If I wait too long, I risk losing their trust and risk infecting them." The fear of social discrimination was a familiar topic to everyone; however, the group offered the best gift possible: an embrace of accurate information, reassurance and support.

Parents also came with questions about the best treatment for their children with hepatitis B. Several struggled with the reality that no treatment was available that would effectively lower high levels of hepatitis B virus in their children who were still in the "immune tolerant stage" – a period when the immune system has not yet noticed the hepatitis B virus infecting the liver.

Patients and doctors alike lamented the inadequacy of health insurance to cover the high costs of hepatitis B treatment. "Our healthcare system often doesn't help the doctor or the patient," Dr. Keeffe observed. "We physicians have been silent. If we advocate (for better insurance

coverage of expensive drug treatments), it looks like we're trying to increase our own revenue flow. However, with 40 million uninsured people in the U.S., lack of insurance is a big challenge."

Dr. Sam So and colleague **Dr. Mahmood Razavi**, assistant professor of radiology at Stanford University, reassured many at the conference that liver cancer need no longer be an automatic death sentence. Approximately 30 percent of liver cancers can be safely, surgically removed. In addition, there are many innovative procedures under development to remove liver tumors without invasive surgery, such as burning, poisoning and even freezing them.

Dr. So strongly encouraged all patients to have a simple blood test, called alpha-fetoprotein (AFP), every six months. It is imperative, because about 60 percent of patients who develop liver cancer will have elevated AFP levels. If AFP levels are highly elevated, Dr. So does not recommend a liver biopsy; the needle could puncture the tumor and spread the cancer.

He further explained that early detection, through AFP and ultrasound tests, is critical in identifying liver tumors while they are small and can be safely removed, and before it spreads. A liver tumor can double in size in just six months.

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Chris Kukka (left) and Maureen Kamische share their expertise in the session "Supporting Adults and Parents of Children with HBV."

Tips for a Pro-Active Patient

- Every six months (or more often if you have liver damage or are receiving treatment), make sure the following special tests are included with your other hepatitis B blood tests:
 1. Alpha-fetoprotein (AFP) blood test to screen for liver cancer.
 2. HBV DNA blood test. Get tested for your viral load even if you have the "e" antibody to make sure you don't have HBeAg-negative viral mutations.
 3. Consider an ultrasound if there have been signs of liver damage, if you're 35 or older, or if you have liver cancer in your family.
- Get the Hepatitis A vaccine.
- Keep copies of all your lab tests and other medical records. Record your ALT, AFP and other lab test results on a spreadsheet so that you and your doctor can more easily track any significant changes.



Master Li Shu Dong led Tai Chi in the hotel courtyard, which was a refreshing way to start every day of the conference.

Fast Facts

ABOUT LIVER CANCER

- **80% of liver cancers worldwide are caused by hepatitis B.**
- **60% of patients who develop liver cancer will have elevated AFP levels.**
- **A liver tumor can double in size in just six months.**
- **If caught early, 30% of liver cancers can be surgically removed.**

The Asian Liver Center at Stanford University

Dr. John F. Flaherty, from Gilead Sciences, reviewed the performance of adefovir (Hepsera), the second oral drug approved for hepatitis B, in comparison to the other approved drugs (Intron A and Epivir-HBV). According to Dr. Flaherty, hepatitis B results in 17,000 hospitalizations each year in the U.S. and is the sixth leading reason for liver transplant in the U.S.

The interest in learning about alternative and complementary therapies among hepatitis B patients is high; therefore, it was a special treat to have **Dr. David D. Liu**, an alternative medicine expert who specializes in acupuncture and traditional Chinese medicine, discuss his approach to treating liver disease. He reviewed several herbs used in traditional Chinese medicine to strengthen liver function and stressed the importance of exercise and meditation or tai chi to improve one's overall health.

Once again, the *B Informed* patient conference was enlightening and fulfilling; people reached across age, social, and economic strata to share a common experience. "Several people I met this weekend have become my closest friends," said one woman who attended. "I have shared things with them that I cannot share with friends and family at home. They have been there for me during the worst of times, and during the best of times. No matter where we come from, here, we all meet as friends."



Special awards were given to each of the speakers. L to R: Dr. David Liu, Ms. Mollie Conti, and Dr. Sam So.

B-Informed 2004: Gathering of Friends Speaker Program

Welcome & Introductions

Molli Conti, Dr. Samuel So, and Steve Bingham

Keynote Address: Hepatitis B in China

Samuel So, MD, FACS

Evolving Treatment Strategies for Chronic Hepatitis B

Emmet B. Keeffe, MD

Supporting Adults and Parents of Children with HBV

Chris Kukka and Maureen Kamische

Helping Patients Work Within the Healthcare System

Emmet B. Keeffe, MD and Samuel So, MD, FACS

Moderator: Steve Bingham

Liver Cancer: Screening, Diagnosis and Treatment

Mahmood Razavi, MD and Samuel So, MD, FACS

HBV Drug Update: Gilead Sciences

John F. Flaherty, Jr. Pharm.D., FCCP

Traditional Chinese Medicine and Liver Disease

David D. Liu, Ph.D., LAC

Concluding Remarks and Forum

Samuel So, MD, FACS

Wrap Up and Evaluation of Program

Molli Conti, Dr. Samuel So and Steve Bingham

The Hepatitis B Foundation gratefully acknowledges the Asian Liver Center at Stanford University for hosting this year's patient conference. A special thanks to Dr. Sam So for inviting such stimulating expert speakers, Jordan Su for coordinating all the conference details, Steve Bingham and Sheree Martin for serving as our expert patient advisors, and to Molli Conti and the HBF staff - Fonta Reilly, Peggy Farley, and Chari Cohen - for their hard work. This year's success was due to everyone's efforts!

Find Out What Attendees Thought About the Conference!

The results are in - the conference was very well received and continues to fill an important need for information and support. When asked why they attended, 90% of the respondents said they wanted to learn more about treatment options; 70% to meet other people living with hepatitis B; 70% to learn how to manage their disease; and 38% to learn how to help a loved one with hepatitis B.

The general consensus was that most participants felt they learned something new during the conference. They were impressed with the speakers and pleased with the topics, but hope next time to see more of the following information: healthy foods and diet for liver patients; monitoring and treating late-stage cirrhosis; how to effectively push for "off-label" drugs; more vaccine and prevention information; long-term planning, such as wills,

preparing for liver transplant if necessary; and health insurance issues.

Specific recommendations for the next conference include: increase publicity to get a larger group; provide more opportunities for parents to discuss their unique issues; include a "patient roundtable" where individuals can share their experiences; consider webcasting to reach a larger audience; and extend the length of the conference to allow more time for discussions.

While a majority of respondents said that they would be happy to travel somewhere else for the next conference, many said that they would definitely like to return to the home of the Hepatitis B Foundation in Doylestown, PA!

Foundation at the Forefront

The following events that were hosted to benefit the HBF are very special. We greatly appreciate the generosity and are truly motivated by these families who lost loved ones due to chronic hepatitis B and then created memorial tributes that will help us help others. Thank you!

Tee-ing Up for a Good Cause

Family and friends gathered on July 16 at the Wedgewood Golf Course in Coopersburg, PA, to celebrate the 5th Annual Joseph Nagy Golf Tournament that benefits the HBF. Joe Nagy was an avid golfer who contracted hepatitis B through a blood transfusion and succumbed in 2000 to complications from the disease. The tournament began as a tribute in memory of the well-loved man called "Gramps". Visit www.informationfairway.com (site access keyword: Nagy) and be sure to join us next year!

Answer to Cancer Race for Liver Cancer

More than 150 runners and walkers gathered in McMinnville, OR, on August 8 to participate in the second annual Answer to Cancer Race, which raised almost \$24,000 for the HBF and three other nonprofit organizations. **Adrian Elkins** passed away from liver cancer eight days after the first race he organized in 2003; he was only 20 years old (read his story in *B Informed*, Summer 2004). "We are honored to carry on with Adrian's mission to raise awareness about liver cancer and hepatitis B," said his brother **Chris Elkins**. Visit www.answertocancer.org to learn more.

Swim-A-Thon Honors Andrew Wise

Team members at the Nassau Swim Club in Princeton, NJ, have organized an annual Andrew Wise Swim-A-Thon, to benefit the HBF, in tribute to his brief but shining life. Andrew died at age 24 years in 2002 from liver cancer due to chronic hepatitis B (read his story in *B Informed*, Winter 2004).



PA Secretary of Health Makes A House Call!

Pennsylvania Secretary of Health **Calvin B. Johnson, MD**, visited the HBF in June to see first-hand our important research and outreach efforts that are being funded, in part, by a PA state grant. "The kind of work that you do here is what changes lives," said Dr. Johnson, a former pediatrician who is committed to the prevention of chronic diseases such as hepatitis B. He expressed confidence that

great things will result from our research and he wants to return to share in the excitement. "Pennsylvania has a number of points to be proud of, and the HBF is one."

The HBF summer internship program steers college students into scientific research: Back row, L to R: Michael Thompson, Ronald Long, Yi Wei. Front row, L to R: Sumana Narayanan, Sarah Muse, Marilyn Laurelli (August 2004).



An Evening to Remember

Friends of the HBF enjoyed the "Mozart in Paris" music extravaganza held in June by The Philadelphia Orchestra in Philadelphia, PA. Guests were invited to a private reception after the concert at the Union League with **Concertmaster David Kim**, the internationally acclaimed violinist. He addressed the audience in both Korean and English, expressing his commitment to the HBF mission and encouraging everyone to help support our efforts. Future musical benefits with Mr. David Kim will be orchestrated!



L to R: Mr. David Kim and Dr. Block (June 22, 2004).



Visit www.hepb.org for new information!

- Subscribe to **B News... You Can Use**, our free monthly e-Newsletter.
- Listen to our **Expert Speakers Forum** to hear leaders in the field talk about hepatitis B. Dr. Harold Margolis, Director of the Division of Viral Hepatitis, Centers for Disease Control and Prevention, currently presents "Viral Hepatitis - A National Perspective: Closing the Gaps."
- Use our **NIH National Library of Medicine Learning Guide** to learn how to navigate their websites.
- Read our **Foreign Language Chapters** of comprehensive hepatitis B information translated into Chinese, Korean, Spanish and Vietnamese.



Speaking Personally

Steve Bingham
Co-Owner of the Internet Hepatitis B Information and Support List (HB-L)

Tricky Treatment Issues

On behalf of all the “hepBers” and their families and friends, I want to thank the Hepatitis B Foundation for their continuing dedication to sponsoring the annual patient conference, which was another resounding success. We also thank our California friends, both the Asian Liver Center at Stanford University and patient participants, for their hospitality and helpfulness.

I especially enjoyed meeting face-to-face, for the first time, “old friends” from our online support group. The bonding that occurred at a fun, impromptu mini-gathering we had in San Francisco before the conference was a lot of fun, too.

Not surprisingly, the primary topic of interest was hepatitis B treatment. Major issues that were raised included: (1) who should seek treatment and who should just wait and monitor their HBV? (2) which treatment will have the best chance of success for which patients? (3) what is the goal of treatment? These are the same kinds of questions that come up most frequently on the HB-List.

Attendees were also very interested in learning more about alternative and traditional treatments for hepatitis B. This interest, in my opinion, is partially due to the confusing state of conventional hepatitis B treatment protocols. Searching for alternatives is a result of patients being frustrated with the lack of consistent information and the relatively low success rates of available hepatitis B treatments.

We were very fortunate to have Dr. Emmet Keeffe, an expert on hepatitis B treatment, as a key speaker at the conference. He explained some complicated concepts in simple terms, but still, many questions remain:

- 1 Is the ALT blood test reliable in defining which patients are candidates for therapy?** This is not clear.
- 2 How do the various hepatitis B mutations affect treatment decisions?** Hepatitis B has a mutation rate 10 times greater than that of most other viruses, which leaves patients with one of four main forms of the hepatitis B virus – the so called “wild-type”, precore, core promoter, or YMDD virus.
- 3 How do the various hepatitis B genotypes impact treatment decisions?** Hepatitis B has been classified into 8 genotypes (A through H). Recent research is confirming that hepatitis B genotype is associated with disease severity and treatment outcome. Hepatitis C patients routinely are tested for genotype, but genotype

testing has not caught on with hepatitis B. Few of us know what our genotype is.

- 4 Which treatment is recommended as first-line for hepatitis B?** From the panel of experts at the conference, and the discussion on the HB-List, it seems that doctors have their favorite hepatitis B treatments. In other words, the doctor you choose may determine what treatment you’re going to be offered. Another concern is that much of the research that we depend on to answer treatment questions has either been done by pharmaceutical companies or underwritten by them. I thank these companies for the hepatitis B drugs they have discovered and are continuing to develop, but I still worry that there’s the possibility of untoward bias creeping into the evaluation of their products.

Patients and health care providers need much clearer guidelines for treatment. Many of us feel this would be best served if the National Institutes of Health (NIH) sponsored a *Hepatitis B Consensus Conference* with the goal of developing standard treatment guidelines. Interestingly, there have been two such NIH consensus conferences focused on hepatitis C, but none for hepatitis B – this despite the fact that there are now three approved drugs for hepatitis B and several in phase III clinical trials!

The Hepatitis B Foundation has done its part to clarify hepatitis B issues by sponsoring the annual patient conference and their annual Princeton Workshop for scientists, but it’s time we heard from our hepatitis experts at the federal level.

**Best Wishes,
Steve**

Internet Support Groups



Hepatitis B Information and Support List
www.hblist.org

To subscribe, send a blank email to:
hepatitis-b-on@mail-list.com

Well-supervised list with useful information and lively exchanges between supportive members. For those with HBV, their caregivers, and anyone interested in or affected by HBV are invited to participate.

HBV Adoption Support List
www.onelist.com/community/hbv-adoption

For adoptive or biological parents of children with HBV. This is a restricted list to protect the privacy of parents and children, and requires pre-approval by the list owner to join.

Hepatitis B Foundation HBV Clinical Trials
www.hepb.org/clinicaltrials

National Institutes of Health Clinical Trials
www.clinicaltrials.gov

Centerwatch Clinical Trials
www.centerwatch.com/studies/cat79.html

Lamivudine and Adefovir to Treat Chronic Hepatitis B

This NIH study will evaluate the safety and effectiveness of lamivudine plus adefovir versus adefovir alone to treat chronic hepatitis B infection. Candidates may not have received lamivudine treatment in the past 6 months or prior treatment with adefovir and must not be taking other anti-viral treatments for their hepatitis. *Contact: NIH Patient Recruitment at 1-800-411-1222 or email prpl@mail.cc.nih.gov*

Telbivudine versus Lamivudine in Adults with Decompensated Chronic Hepatitis B and Evidence of Cirrhosis

Idenix Pharmaceuticals is conducting this research study to see if the investigational medication, LdT (Telbivudine), is safe and effective in the treatment of decompensated hepatitis B infection over two years. The results for patients taking LdT will be compared to results for patients taking lamivudine (Epivir-HBV). *Contact: Gloria Dubuc at 617-995-9814 or email dubuc.gloria@idenix.com*

Evaluate Efficacy, Safety and PK of Adefovir Dipivoxil Liquid Suspension in Patients with Chronic Hepatitis B

Gilead Sciences is sponsoring a multi-center phase 3, open-label, parallel-group study designed to evaluate the efficacy, safety and pharmacokinetics of adefovir dipivoxil liquid suspension in patients with chronic hepatitis B and varying degrees of renal impairment. *Contact: Anant Jain at 650-522-5523 or email ajain@gilead.com*

Comparison of Telbivudine versus Lamivudine in Hepatic Compensation

This is a trial for adults with compensated chronic hepatitis B who have never been treated. *Contact: Debora Goldman, RN, clinical trials coordinator for Dr. Douglas Dieterich at 212-241-7270 (Mt. Sinai School of Medicine, NY, NY).*

Comparison of Entecavir to Adefovir in Chronic HBV Patients with Hepatic Decompensation

A Phase IIIb comparative study of entecavir vs. adefovir in patients who have chronic hepatitis B and hepatic decompensation for up to 96 weeks. *Contact: Bristol-Myers Squibb toll-free at 1-866-892-1BMS.*

A Phase II Study of the Safety and Efficacy of Adding Entecavir to Current Lamivudine Therapy in HBV and HIV Co-Infected Patients

The purpose of this clinical research study is to assess the safety and effectiveness of adding entecavir in the treatment of adults with chronic hepatitis B infection who are co-

infected with HIV and are already taking lamivudine. *Contact: Bristol-Myers Squibb toll-free at 1-866-892-1BMS.*

Prevention of Recurrent HBV After Liver Transplantation

Eligible patients for this study MUST be on a liver transplant waiting list or have already received a liver transplant for hepatitis B. HBIG, Epivir-HBV and Hepsera will be evaluated. *Contact: Doug Armstrong at darms@umich.edu or call 734-936-1712 at the Univ. of Michigan Medical Center.*

Pegylated Interferon to Treat Chronic Hepatitis D

This NIH study will evaluate the effects of pegylated interferon, given once weekly, on hepatitis D (HDV) and hepatitis B. HDV is often severe and progressive and only infects people who already have hepatitis B infection. Patients with chronic hepatitis D over 6 years old may be eligible for this study. Patients who improve with treatment may continue therapy long-term. *Contact: NIH Patient Recruitment Office at 1-800-411-1222 or email prpl@mail.cc.nih.gov*

Low-Cost HBV Testing and Vaccination in San Francisco

The **Asian Liver Center at Stanford University** announced the launch of their "3 for Life" project. This initiative will offer low cost hepatitis A and B vaccination and hepatitis B testing to more than 4,000 Asians who reside in San Francisco, CA, beginning in September 2004. Testing and vaccinations will be available for one year.

Where: Richmond YMCA (18th and Geary), San Francisco, CA

When: 1st and 3rd Saturday of every month, beginning September 18th

Cost: \$45 hepatitis A vaccine series (2 shots); \$60 hepatitis B vaccine series (three shots) with hepatitis B testing; \$90 hepatitis A and B vaccine series and hepatitis B testing.

Contact: The Asian Liver Center at 650-736-1883
Visit <http://livercancer.stanford.edu>

Fast Fact

An estimated \$700 million is spent each year on treating hepatitis B and its related complications.

Resource Roundup



Hepatitis B Foundation

215-489-4900

www.hepb.org

info@hepb.org

Comprehensive website dedicated to hepatitis B. Facts, Drug Watch, clinical trials, liver specialist directory, and responsive email. Includes *Chinese, Vietnamese, Korean, and Spanish Language Chapters*. Subscribe to our free e-newsletter *B News You Can Use*.

American Liver Foundation

1-800-GO-LIVER

www.liverfoundation.org

Information about all liver diseases, including viral hepatitis.

Asian Liver Center at Stanford University

650-725-4837

<http://livercancer.stanford.edu>

Educates people about hepatitis B and liver cancer among Asians and Asian-Americans.

Centers for Disease Control, Hepatitis Division

1-888-443-7232

www.cdc.gov/ncidod/diseases/hepatitis

The national authority for viral hepatitis information.

CDC Hepatitis Immunization Hotline

1-800-232-2522 (English)

www.cdc.gov/nip

1-800-232-0233 (Spanish)

Hepatitis B Research List

To subscribe, send a blank email to:

HBV_Research-on@mail-list.com

A free electronic research list maintained by Sheree Martin.

Hepatitis B Research Archive Website

http://archive.mail-list.com/hbv_research.

Archived research bulletins from the Hepatitis B Research List.

HCV Advocate

www.hcvadvocate.org

HCV website that also includes hepatitis B information.

Hep C Connection

1-800-522-4372

www.hepc-connection.org

Comprehensive information about hepatitis C.

Hepatitis Foundation International

1-800-891-0707

www.hepfi.org

Information about viral hepatitis, support groups and research.

HepLink

www.heplink.org

A search engine that gathers viral hepatitis information.

Hepatitis Magazine

1-800-310-7047

www.hepatitismag.com

The only print magazine about hepatitis published bi-monthly.

HepTrec

1-866-HEPTREC

www.heptrec.org

The Delaware Valley Hepatitis Treatment, Research and Education Center (HepTREC) in the greater Philadelphia area.

HIV and Hepatitis Treatment Advocates

www.hivandhepatitis.com

Professional online publication with free e-mail updates.

Immunization Action Coalition

651-647-9009

www.immunize.org

www.vaccineinformation.org

www.hepprograms.org

Comprehensive source of immunization information. The first website is for health professionals, the second is for the general public and the third highlights preventive programs. "IAC Express" and "HEP Express" are free e-mail announcement services.

Memorial Sloan Kettering "About Herbs"

www.mskcc.org/aboutherbs

Scientific information about herbs, their side effects and drug interactions. Maintained by experts at Memorial Sloan Kettering.

Nat'l Center for Complementary and Alternative Medicine

1-888-644-6226

www.nccam.nih.gov

Sponsored by the National Institutes of Health (NIH).

Parents of Kids with Infectious Diseases

1-877-55-PKIDS (toll-free)

www.pkids.org

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The National Library Of Medicine

The National Library of Medicine (NLM), which is a division of the National Institutes of Health, provides online resources of comprehensive biomedical information for the general public and health care professionals.

Visit the NLM at www.nlm.nih.gov and learn more about their premiere health websites:

MEDLINEPlus - Search for health topics and drugs alphabetically. Find links to other health resources or health care providers. Visit www.medlineplus.gov

MEDLINE/PubMed - Access 11 million published biomedical journal articles written for health professionals. Search by author or keyword. Visit www.ncbi.nlm.nih.gov/entrez

ClinicalTrials.gov - Learn about clinical trials for hundreds of diseases, including hepatitis B. Visit www.clinicaltrials.gov

Calendar of Events



- Oct 24-27** **International Meeting of the Molecular Biology of HBV**
Marine Biological Laboratory, Woods Hole, MA
www.mbl.edu/housing/conferences/hbv_meeting.html
- Oct 29- Nov 2** **AASLD Annual Meeting**
American Association for the Study of Liver Disease
John B. Hynes Convention Center, Boston, MA
www.aasld.org
- Oct 30- Nov 2** **Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)**
American Society for Microbiologists Convention Center, Washington, DC
www.icaac.org
- Oct 29- Nov 3** **ACG Annual Meeting**
American College of Gastroenterology
Gaylord Palms Resort, Orlando, FL
www.acg.gi.org
- Nov 2-3** **Therapies for Viral Hepatitis 2004**
International Medical Press
Sheraton Boston Hotel, Boston, MA
www.intmedpress.com/hepatitis

- Nov 4-5** **Princeton HBV Workshop**
Hepatitis B Foundation
Nassau Inn, Princeton, NJ
www.hepb.org
- Nov 12-14** **HBV Prevention and Management in Asian Americans**
American Liver Foundation
The Parker-Meridien Hotel, New York, NY
www.liverfoundation.org

2005

- April 10-14** **International Conference on Antiviral Research**
International Society on Antiviral Research (ISAR)
Intercontinental Princesa Sofia Hotel, Barcelona, Spain
www.isar-icar.com
- April 13-17** **40th Annual EASL Conference**
European Association for the Study of the Liver
Palais des Congrès, Paris, France
www.easl.ch/easl2005
- April 30** **Crystal Ball Awards Gala**
Hepatitis B Foundation
Occasions, New Hope, PA
www.hepb.org
- May 15-18** **Digestive Disease Week**
AASLD, AGA, ASGE, SSAT
McCormick Place, Chicago, IL
www.ddw.org/



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Yes! I wish to join the *Cause for A Cure*. Enclosed is my tax deductible gift.

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City _____ \$250 Fellow
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 \$1,000 Leader
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Signature _____

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A copy of the official registration and financial information may be obtained by calling the Pennsylvania Department of State toll-free within PA at 800-732-0999 or out-of-state at 717-783-1720. Registration does not imply endorsement.



HEPATITIS B FOUNDATION
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Doylestown, PA 18901-2697

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

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