

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

Eliminating the "Voodoo" from Hepatitis B 3rd Annual HBF Patient Conference

More than 60 attendees from across the country and as far away as India gathered July 20 – 22 for the *B-Informed 2003* patient conference, sponsored by the Hepatitis B Foundation (HBF) and the Hepatitis B Information and Support Listserv (HB-L). This year there was a diverse group in terms of age, gender, race, and experiences.

Molli Conti, HBF vice-president for Outreach, started the conference off with a warm welcome and introduced members of the HBF. She gave a brief history and update of HBF's growth over the past year, which has been substantial. **Steve Bingham** and **Sheree Martin**, co-owners of the HB-L, shared about how they started the HB-L and how rewarding it has been to become the "dad and mom" of so many people. They are celebrating five years with this hepatitis B support group, which remains the only one of its kind on the internet.

This year's keynote speaker was **Sam So, M.D., FACS**, founder and director of the Asian Liver Center at Stanford University, who spoke about "Eliminating the Voodoo from Hepatitis B". He described how "faulty science is often behind these voodoo beliefs" and how they cause unnecessary confusion about hepatitis B. His professional development from a "conventional" medical approach to one of activism was because these myths have resulted in unfair disparities in treatment access and options.

Christine Kukka and **Maureen Kamische** gave a fascinating description of two trips to China, which was sponsored by PKIDs (Parents of Kids with Infectious Diseases), to educate orphanages, doctors and laypeople about hepatitis B. They described the challenges in teaching universal precautions, prevention measures and safe injection techniques to the

Chinese medical community, when basic supplies are very limited.

In addition to research and clinical updates, there were new sessions that reviewed hepatitis B and kids; examined the impact of hepatitis B on families; and explained the realities of liver transplantation. In addition, the HBF conducted a special focus group to evaluate the redesigned HBF website.

Attendees were all given the opportunity to introduce themselves and many briefly

shared about living with chronic hepatitis B. During the conference, it was heartening to see the "old-timers" reach out to the newly diagnosed or "newbies".

As one young man said, "getting to know others with the same disease is an amazing experience. Everyone is allowed to be honest and to not worry about being honest."

Clearly, the patient conference continues to provide a highly visible focus for the growing hepatitis B community of friends.



A Gathering of Friends at B-Informed Conference in Doylestown, PA, July 2003.

"This conference is important and necessary! It provides me with the most current information and emotional support that I can't get anywhere else."



Message from the President

Timothy M. Block, Ph.D.

Getting Along . . .

Three significant examples of coordination, reported in this issue of B-Informed, should give us all a bit more hope about the future of those affected with hepatitis B.

First, the establishment of a Liver Disease Research Branch at the National Institutes of Health (NIH) is an important step toward consolidating research programs at the nation's largest research facility (see page 7). With hepatitis virus research performed by dozens of scientists in different locations at the NIH, central management of these programs will be a great contribution.

Under the leadership of Dr. Jay Hoofnagle, a world renowned hepatitis clinician and scientist, this branch will have an effective and credible voice. It will need to be heard, since there is stiff competition for resources in Washington, DC, these days. The question is whether or not a Liver Disease Branch will be sufficient to fully handle the needs of the hepatitis community. It is my hope that eventually there will be a separate NIH institute dedicated to liver diseases - a National Institute for Liver Research- now that would be a voice no one could ignore!

Coordination and cooperation isn't just necessary for the NIH, though. The National Viral Hepatitis Roundtable (NVHR) is, to my mind, the first major effort to coordinate leading federal and private organizations with an interest in viral hepatitis, in the proposal and establishment of national health policy (see page 7). The HBF is proud to be a charter member with other distinguished national organizations of the NVHR. We will make certain that hepatitis B remains a priority.

On the home front, we have been doing some coordination, too. The 3rd Patient Conference was another triumph of bringing people together (see highlights on page 8). With the emotional, spontaneous, personal stories and the useful expert presentations, this conference is as moving as it is informative.

Thus, there are several good initiatives that have taken hold this year, and we at the Hepatitis B Foundation are pleased to have played a role in each successful one.



Make a Donation Today
The HBF's Annual Appeal is in the Mail

PS: We can now accept both U.S. and international donations on our secure website at www.hepb.org

In The News



Short Term Therapy with Lamivudine in Pregnant Women with High HBV-DNA May Prevent Perinatal Transmission

Vertical transmission of hepatitis can occur occasionally despite vaccination of the child. This vaccination breakthrough has been associated with high maternal viraemia. In a recent study in the *J. of Viral Hepatitis*, eight highly viraemic mothers were treated with 150 mg of lamivudine daily during the last month of pregnancy. Twenty-four children, born to untreated HBsAg-positive mothers with equally high levels of HBV-DNA, served as historical controls. All children received passive-active immunization at birth. In the lamivudine group, only one of the eight children (12.5%) was still HBsAg and HBV-DNA positive at the age of 12 months. In the untreated control group, perinatal transmission occurred in seven children (28%). The authors conclude, "In highly viraemic HBsAg-positive mothers, reduction of viraemia by lamivudine therapy in the last month of pregnancy may be an effective and safe measure to reduce the risk of child vaccination breakthrough." [*HBV Research List 8/4/03*, <http://archive.mail-list.com>]

HBV Reactivation Common During Breast Cancer Treatment

Hepatitis B reactivation may complicate chemotherapy used in the treatment of breast cancer, according to a report in the *August J. of Medical Virology*. Researchers from Chinese University of Hong Kong followed 41 breast cancer patients found to be HBsAg positive prior to treatment. Ten patients (24%) developed clinical HBV reactivation during chemotherapy and seven more were diagnosed by the detection of HBV-DNA. All 17 of those with reactivation had normalization of liver function after treatment with lamivudine. HBV reactivation, however, prompted premature termination of treatment in 6 women. No risk factors could be identified to distinguish those who developed reactivation from those who did not. The authors conclude that regular testing of HBV-DNA and ALT be done "to facilitate prompt antiviral therapy, prior to hepatic inflammation and destruction, and if HBV-DNA testing is unavailable, prophylactic use of an antiviral drug should be considered in all patients before and throughout chemotherapy." [www.medscape.com, 8/4/03]

Costly Lawsuits Dampen Outlook for Clinical Trials

Human clinical trials face a rising tide of liability lawsuits that could alter U.S. medical research, suggested a Harvard study published in the *June Annals of Internal Medicine*. Within the past 3 years, researchers say, legal claims including class-action suits have begun targeting universities and research institutions that recruit millions of people for clinical trials of new drugs and other medical treatments. As a result, research costs are likely to rise while trial methods could fall victim to tough regulation to minimize legal exposure. The NIH estimates there are 6,300 clinical trials underway in the U.S., which involved more than 2 million people. Where lawsuits once focused on consent issues, legal claims now include fraud or even allege violation of international laws. Lawsuits have come to name larger number of defendants, from drug company sponsors and top university officials to review board members and consulting bioethicists. [www.medscape.com, 7/9/03]

Clevudine: All Dressed Up and Nowhere to Go

Reports of the death of Clevudine, arguably the best potential agent for chronic hepatitis B disease to come along in years, may be a bit premature.

Clevudine (L-FMAU) is a nucleoside analogue inhibitor that interferes with the viral DNA polymerase enzyme used for HBV replication. It was discovered by scientists at the University of Georgia and Yale University, and after extensive preclinical testing in woodchuck models of HBV, was subsequently licensed to Bukwang Pharm. Ind. Co. in South Korea.

Bukwang later sold worldwide distribution rights to Triangle Pharmaceuticals in 1998, which in turn was taken over by Gilead Sciences, Inc., in December 2002. But optimism for the drug's development took a hit in June 2003, when Gilead announced that it had decided to drop plans to develop the drug and was returning the distribution rights to Bukwang.

That meant that while extremely promising Phase II clinical trials against chronic hepatitis infection wrapped up in the United States this spring, Clevudine currently is only being studied in Phase III clinical trials in South Korea, with little hope, some worry, of seeing the clinical light of day in the U.S.

According to **Brent Korba, Ph.D.**, professor of microbiology and immunology at Georgetown University Medical Center who led the early woodchuck studies of the drug, Gilead made a business decision. Gilead had certain milestones to meet, he says, and given Triangle's lagging development of the drug and the fact that the company had three other FDA-licensed antiviral drugs – including the highly touted Hepsara, another nucleoside inhibitor – in its pockets, the company decided to move on.

Bukwang, in the meantime, said Korba, was not waiting around for Triangle to complete Phase II trials of the drug. It had already begun plans for Phase III trials, and Clevudine currently is in Phase III trials in South Korea in about 30 centers.

But some are concerned about the halt in U.S. testing and what it will mean for the drug's future. **Hie-Won Hann, M.D.**, professor of medicine at Jefferson Medical College of Thomas Jefferson University, said she was "heartbroken" to hear the development had stopped in this country. Hann enrolled six patients in the Triangle-sponsored Phase II trial. None of the patients had prior treatment or disease, though all had tested positive for the virus, in a 12-week trial. According to Hann, after three weeks of treatment, the viral levels in the patients' blood dropped to barely detectable levels. Some 20 weeks after treatment had stopped, the virus returned to pre-treatment levels. She saw no significant side effects.

Hann is convinced of the drug's efficacy. "I've never seen such a striking antiviral effect," she said, noting the drug's ability to rapidly drop viral levels in the bloodstream. She

hopes the drug will eventually be tested in a Phase III trial in the U.S. "If Clevudine was tested in both the U.S. and Asia in a multicenter Phase III trial, it would have been approved in two to three years and licensed right away and now would be one of the best medicines available," she said.

For now, Korba is extremely bullish on Clevudine's future. "Clevudine will definitely stay on the drug radar screen," said Korba. "The data reported so far from the Phase II clinical trial is just as good as what we saw in woodchucks."

He thinks development will be slow, however, because current trials are limited to S. Korea and perhaps Taiwan for now. If the South Korean trials turn out just as well, he sees the drug eventually making it to the marketplace, first in Asia, and possibly elsewhere, depending on Bukwang's ability to find another partner and resources.

For clinicians like Dr. Hann who treat hepatitis B patients, the hope is that successful results in the Asian trials may eventually get the attention of the U.S. Food and Drug Administration.

Steve Benowitz is a science writer from Philadelphia, PA.

Editor's Note:

In December 2002, Gilead Sciences bought Triangle Pharmaceuticals for \$464 million and acquired three new hepatitis B drugs in development.

Gilead	Hepsara (Adefovir Dipivoxil)	FDA Approved 2002
From Triangle	Coviracil (FTC)	Phase III (FDA Approved for HIV)
	Clevudine (L-FMAU)	Phase II
	Amdoxivir (DAPD)	Phase II

New Book! Hepatitis B Virus Guide 2003 by Stephen Locarnini and Ching-Lung Lai

This is the first book in a series of Human Virus Guides, published by International Medical Press, and is an ideal introduction for students and an indispensable reference for both scientists and physicians. It includes research about the virus structure and function; the natural history and clinical manifestations; and the prevention and management of this disease. To order a copy, visit www.intmedpress.com

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, RTP, NC	www.gsk.com	FDA Approved 1998
Hepsera (Adefovir Dipivoxil)	Inhibits viral DNA polymerase	Gilead Sciences, Foster City, CA	www.gilead.com	FDA Approved 2002
Coviracil (FTC)	Inhibits viral DNA polymerase	Gilead	www.gilead.com	Phase III / NDA Filed
Entecavir	Inhibits viral DNA polymerase	Bristol-Myers Squibb, Princeton, NJ	www.bms.com	Phase III
Clevudine (L-FMAU)	Inhibits viral DNA polymerase	Gilead	www.gilead.com	Phase III, South Korea
Telbivudine (LdT)	Inhibits viral DNA polymerase	Idenix, Cambridge, MA	www.idenix.com	Phase III
Valtorcitabine (monoval LdC)	Inhibits viral DNA polymerase	Idenix	www.idenix.com	Phase II
Amdoxovir (DAPD)	Inhibits viral DNA polymerase	Gilead	www.tripharm.com	Phase II
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
MCC478	Nucleoside analog "prodrug"	Eli Lilly, Indianapolis, IN	www.lilly.com	Phase I, Germany
MIV-210	Inhibits viral DNA polymerase	Medivir, Sweden	www.medivir.com	Phase I, U.K.
Hepavir B	Inhibits viral DNA polymerase	Ribapharm, Costa Mesa, CA	www.ribapharm.com	Phase I, Europe, USA
Pentacept (L-3'-FD4C)	Inhibits viral DNA polymerase	Pharmasset	www.pharmasset.com	Preclinical
Robustaflavone (ALS-920)	Inhibits viral DNA polymerase	Advanced Life Sciences, Woodbridge, IL	www.advancedlifesciences.com	Preclinical
ICN 2001-3	Inhibits viral DNA polymerase	ICN, Costa Mesa, CA	www.icnpharm.com	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	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	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
HBV Antigen	Oral Tolerance	OraGen, Philadelphia, PA	Tel: 215-923-5124	Preclinical
HBV DNA Vaccine	Immune Stimulator	Jefferson Center, Doylestown, PA	Tel: 215-489-4949	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.

Drug Notes

L-3'-FD4C Shows Promise Against Lamivudine-Resistant HBV

Pharmasset presented data highlighting the discovery of two non-toxic L-nucleoside analogs, including L-3'-FD4C (Pentacept), with activity against wild type and lamivudine-resistant HBV with potent activity against hepatitis B viruses at the 43rd Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in September. Over 1,500 nucleoside analogs were evaluated in cell culture against wild-type and mutant HBV strains. Among those nucleosides tested were known antiviral agents such as Lamivudine (3TC) and Emtricitabine, which were active against wild type virus, but none showed any marked reduction in viral DNA synthesis in the mutant cell line. L-3'-FD4C and a 5-fluorocytidine analog were found to be potent inhibitors of wild-type and mutant viruses and were essentially non-toxic to cells. "New therapies that are effective against 3TC-resistant viruses are needed for combination therapies or as alternative treatment options," said Michael J. Otto, Ph.D., Chief Scientific Officer. "Nucleoside analogs, such as L-3'-FD4C, could be useful as first line therapy." [Pharmasset Press Release 9/16/03, www.pharmasset.com]

EHT899 Completes Phase II Trials in Israel

U.S. Treasury Secretary John W. Snow visited Hadasit in Israel, a subsidiary of Hadassah Medical Organization, where he received an overview of a project being conducted by the company in conjunction with U.S. Enzo Biochem, Inc. The project is based on the regulation of an immune response by introduction of specific antigens via the gastrointestinal tract. A Phase II clinical trial for treatment of chronic liver disease associated with hepatitis B infection has been completed. "The team is currently preparing for the next phase, leading to submission to the U.S. FDA for approval for the drug," claimed Dr. Rafi Hofstein, CEO of Hadasit. "The widespread incidence of chronic liver disease worldwide raises its treatment priority to a global emergency," he emphasized. [Enzo Press Release, 9/16/03, www.enzo.com]

HepeX-B Receives Orphan Drug Designation from the U.S. FDA

XTL Biopharmaceuticals reported that the U.S. FDA has granted its investigational therapeutic product, HepeX-B, "Orphan Drug Designation" for prevention of hepatitis B infection in liver transplant patients. About 5% of chronic hepatitis B patients will develop end-stage liver disease, a condition which necessitates liver transplantation. Without proper treatment, the newly transplanted liver can become re-infected, leading to rapid disease progression and graft failure in many cases. HepeX-B is a combination of two fully human monoclonal antibodies acting on the hepatitis B virus surface antigen. Dr. Martin Becker, XTLbio's CEO, commented, "XTLbio is pursuing a vigorous commercialization program for HepeX-B, with Phase 2b studies scheduled to commence later this year for liver transplant patients." [XTLbio Press Release 8/4/03, www.xtlbio.com/news]

Phase I Trials of SpecifEx-HepB Anticipated

CellExSys presented data in support of the anticipated initiation of a Phase I clinical trial with SpecifEx-HepB for HBV patients at the 38th Annual EASL Meeting in Geneva, Switzerland, in July. Results from this study support a novel approach to treatment of this disease, whereby HBV-specific Cytotoxic T Lymphocytes (CTL) are isolated and expanded for the purpose of fighting disease. Previous studies have shown that chronic HBV patients mount only a weak CTL response, resulting in progressive liver disease. By infusing HBV-specific CTL into these patients, it may be possible to boost their immune system so they can eliminate HBV-infected liver cells. "There is significant evidence for the role of HBV-specific CTL in the control of hepatitis B infection," said Susanne C. Schneider, Ph.D., Director of Research at CellExSys. "These results prepare us for the initiation of Phase I clinical trials to treat chronic HBV patient who have no other treatment options," she added. [PRNewswire 7/7/03, <http://biospace.com/news>]

International Conference on Antiviral Research (ICAR)

The 16th ICAR was held April 27-May 1 in historic Savannah, Georgia, with almost 400 scientists, representing 29 countries, in attendance. Although there were many topics, **Anand Mehta, D.Phil.**, assistant professor of Jefferson Medical College and *HBV's Bruce Witte Scholar*, summarizes only the highlights from the hepatitis B sessions.

The hepadnavirus session, co-chaired by **Drs. Timothy Block and Joe Colacino**, started with a plenary talk by Dr. G. Gosselin describing the development of a set of anti-HBV compounds by Idenix Pharmaceuticals called the L-nucleosides/nucleotides. Their lead compound, Telbivudine (LdT) is currently in Phase III clinical trials and is showing great promise as an antiviral agent. This compound is well tolerated in people and reduces viremia by > 6 logs at a dose of 400-600 mg/day.

This was followed by an excellent talk by Dr. A. Bartholomeusz who showed that patients co-infected with HIV and HBV generally have lower ALT levels than those infected with HBV alone, but have increased serum HBV-DNA levels, and unfortunately, an increased risk of developing cirrhosis. In addition, Dr. Bartholomeusz's data showed that in these patients, the development of lamivudine-resistant virus may be associated with increased levels of viral pathogenesis. However, more data will be required to make this connection clear.

Finally, this meeting also provided some of the first clinical data on the emergence of virus resistance of Hepsera (adefovir dipivoxil). The rate of resistance was approximately 1.6% after two years of treatment. Specifically, the resistant virus isolated from patients showed a 5 - 23 fold decrease in sensitivity as compared to un-mutated virus.

Although the clinical benefit of compounds like Epivir-HBV (lamivudine) and Hepsera are great, new methods of treatment and therapy are still needed to combat this deadly disease.

NAME	TYPE VACCINE	COMPANY	WEBSITE	STATUS
Hepatitis B Vaccines - Recommended for those at risk and patients with chronic HCV				
Engerix B	Recombinant HBV	GlaxoSmithKline Phila, PA	www.gskvaccines.com	Market, USA
Recombivax HB	Recombinant HBV	Merck West Point, PA	www.merck.com	Market, USA
Gen Hevac B	Recombinant HBV	Aventis Pasteur Lyons, France	www.aventispasteur.com	Market, Europe
Hepacare (formerly, Hepagene)	HBV preS1, preS2	PowderJect Oxford, U.K	www.powderject.com	Market, Europe
Bio-Hep B	HBV S, preS1, PreS2	Biotech. Gen. Corp	www.btgc.com	Market, Israel
Hepavax Gene	Recombinant HBV	Berna Biotech, Switzerland	www.bernabiotech.com	Market, Europe
Hepatitis A Vaccines - Recommended for those at risk and patients with chronic HBV and HCV				
Havrix	Inactivated HAV	GlaxoSmithKline	www.gskvaccines.com	Market, USA
VAQTA	Inactivated HAV	Merck	www.merck.com	Market, USA
Avaxim	Inactivated HAV	Aventis Pasteur	www.aventispasteur.com	Market, Europe
Combination Hepatitis Vaccines				
TwinRix (Adult)	HBV and HAV	GlaxoSmithKline	www.gskvaccines.com	Market, USA
Comvax (Pediatric)	HBV and HiB	Merck	www.merck.com	Market, USA
Pediarix (Pediatric)	HBV, Polio, DTP	GlaxoSmithKline	www.gskvaccines.com	Market, USA
Hexavac (Pediatric)	HBV, DTP, HiB, Polio	Aventis Pasteur	www.aventispasteur.com	Market, Europe
Hepatitis Vaccines In Development				
Extra Strength Hep B (for poor or nonresponders)	Recombinant	GlaxoSmithKline (with Corixia)	www.gskvaccines.com www.corixia.com	Phase III
Hep B Vaccine	ISS-linked to HBsAg	Dynavax Technology Berkeley, CA	www.dynavax.com	Phase I/II
Hep B DNA Vaccine Px	HBV DNA Vaccine	PowderJect	www.powderject.com	Phase I

Vaccine News

HBV Prevention Mandates for U.S. Colleges and Universities There is a nationwide movement to protect a gap generation of college students who are at high risk for hepatitis B infection. These young adults have not been vaccinated because they were born before universal infant HBV vaccination requirements (1991) and they missed the catch-up programs targeted at middle-school students in the late '90s. Today many colleges are addressing this gap by adding the HBV vaccine to its required immunizations.

Currently, 9 states have legislative mandates that require HBV vaccination for college students: **CA, DC, FL, MA, NJ, OK, RI, SD, TX.**

4 states require HBV education but do not require the vaccine, however, it's recommended: **MN, MS, SC, TN.**

HBV Threatens to Wipe Out Two Amazon Tribes The United Nations (UN) announced it has launched a vaccination campaign to save two tribes in the remote Peru-

vian Amazon that are threatened with extinction by a mysterious hepatitis B outbreak. "Local leaders warned that they could face extinction within 10 to 12 years, if preventive action is not taken", said UNICEF, the children's fund of the UN. Peru's Minister of Health asked for help after 40 deaths were reported in 2002 in one tribe with only 2,500 members. Although there are no figures for the neighboring tribe, it is also considered at high risk. [Reuters Health, 9/23/03, www.story.news.yahoo.com]

Free Hepatitis A and B Vaccination for MSM GayHealth.com recently compiled a list of clinics nationwide providing free or low-cost hepatitis A and hepatitis B vaccines to men who have sex with men (MSM). Visit their new website at www.HepClinics.com.

Fast Fact

Of the 20 vaccines sold worldwide, 3 include the hepatitis B vaccine.

In The Spotlight

Official Launch: National Viral Hepatitis Roundtable December 7 – 9, 2003 Washington, D.C.

The Centers for Disease Control (CDC), in collaboration with Hepatitis Foundation International, initiated the formation of the *National Viral Hepatitis Roundtable* (NVHR) this past January in order to bring together individuals and organizations concerned about the public health impact of viral hepatitis. Their mandate is to help reduce the burden of viral hepatitis nationwide.

Twenty-four advocacy organizations, federal agencies, and health insurers have been invited to help create a blueprint for the NVHR. The HBF is proud to be a charter member of this distinguished coalition.

Molli Conti, HBF vice-president and member of the NVHR Executive Committee notes, "fortunately, there is good hepatitis B representation on the board, so we should have a strong voice in the national discussion." HBF board member **Steve Bingham** recently joined NVHR as chair of the Communications Committee and said enthusiastically, "Forming a national roundtable dedicated to eliminating viral hepatitis is a lofty goal, and when I heard that wording, it sent a shiver down my spine."

According to NVHR administrator **Mr. Richard Conlon**, the seed for this coalition was first planted in July 2002 when "Congress authorized the CDC to work with voluntary health organizations and professional societies to promote liver wellness and prevention of viral hepatitis." He added, "The CDC was urged to review options for a National Viral Hepatitis Roundtable, similar to the CDC's Colorectal Cancer Roundtable."



A small working session of the NVHR in Washington, DC. Sitting L to R: Dan Riedford (CDC/Hepatitis), Andi Thomas (Hep C Alert) Yvonne Fuller (NMA), and Deborah Wexler (IAC). Standing L to R: Kelli Scanlon (ASHA), Steve Bingham (HB- List), Maureen K. (PKIDs), Dick Conlon (NVHR administrator), Glenna Crooks (NVHR facilitator), Katherine Roeder, (CDC/Hepatitis), Molli Conti (HBF), Debbie Vega (LOLA), Hal Margolis (CDC/Hepatitis), Laurie Showalter (NASTAD), and Thelma Thiel (HFI).

The NVHR will eventually bring together more than 150 organizations, which are currently working independently of each other, to coordinate the "formulation and promotion of a national strategy for viral hepatitis prevention, vaccination, education, treatment, research, and advocacy," he adds.

The official launch of the NVHR is scheduled for December 7 – 9, 2003, at the Wyndham Hotel in Washington, DC.

For more information, visit www.nvhrregistration.com or call (404) 483-2826.

NIH Establishes the Liver Disease Research Branch

Dr. Jay Hoofnagle Appointed as Founding Director

As of June 1, 2003, the National Institutes of Health (NIH) created the Liver Disease Research Branch within the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). **Dr. Jay H. Hoofnagle**, recipient of the Hepatitis B Foundation's *Founders' Award 2003*, was appointed as its founding director. The Branch will also include **Dr. Leonard Seeff**, an expert on viral hepatitis, and **Dr. Jose Serrano**, director for the Liver and Biliary Disease Program.

This new branch will serve to focus and accelerate research on liver disease in the NIDDK and help coordinate and stimulate liver-related research across the NIH and within other Federal agencies such as the Centers for Disease Control, the Department of Defense, the Bureau of Prisons, and the Veterans Affairs Administration.

The mission of the Liver Disease Research Branch will include the following: to plan and direct the program of research grants, cooperative agreements, epidemiological studies, clinical trials; prepare analyses of national research efforts and help identify gaps in research; assess needs for clinical and translational research; develop recommendations to the NIDDK Advisory Council regarding priorities, initiatives, and funding; advise and participate with outside lay organizations in responding to needs of patients with liver disease; and set national research priorities.

An initial important task set for the Liver Diseases Research Branch is to prepare an *Action Plan for Liver Disease Research* that will be completed in 2004. This Action Plan will provide an overview of current research funding in liver disease, summarize challenges to advancing liver disease research, delineate the major needs for future research, and prepare a tactical plan for meeting these needs.

During this process, the advice, suggestions and participation of all members of the liver disease research community is actively sought.

Further information on the Liver Diseases Research Branch can be found at the NIDDK web site and progress in developing the Action Plan will be regularly updated. Visit www.niddk.nih.gov.

Patient Conference B-Informed 2003 in Review

Despite the fact that July in Pennsylvania is usually horrendously humid, the weather was kind to the attendees of the 3rd Annual B-Informed held July 20 -22. Every day the conference began with a meditation workshop, which was a great way to clear our brains for new information.

DAY ONE

Eliminating the Voodoo from HBV

Keynote speaker **Dr. Sam So** gave a highly impassioned and informative presentation demystifying hepatitis B. He rapidly demolished some of our beliefs as "voodoo". For example, many in the conventional medical community believe that Caucasians will do better on certain treatment than Asians, or that those with alcoholic cirrhosis will be better transplant candidates than those with chronic hepatitis B.

Dr. So challenged us to explore our own assumptions and biases – what tests we should have, how often we should be screened, the importance of including liver cancer screening in the regular monitoring, and how and what we should consider "normal".

He recommends treatment based on evidence of active liver damage and elevated ALT and viral load because the goal of treatment is to prevent further damage to the liver and hopefully prevent liver cancer. For treatment purposes, it is important to differentiate between HBV infections acquired as an infant or an adult, since it is easier to treat those infected as adults. He also believes that measuring viral load is a better treatment guide than ALT since liver damage can and does occur even when the ALT is "normal".

He also recommends twice a year screening with ultrasound and AFP blood tests for the early detection of liver cancer. Although ultrasound is not always the best test, it is painless and better than AFP alone.

AFTERNOON

A sign of a growing conference is when there are choices! This year there were several different breakout sessions.

Hep B Info Plus

This packed session bombarded **Dr. Minh Nguyen, Dr. Misra, and Dr. So** with challenging questions. It became obvious that experts don't always agree or follow the same

treatment protocol. This was both the good news and the bad news. Good, as it means HBV is a growing and changing field and it is through experts challenging each other and being challenged in return by hepB'ers, that effective treatments will be developed. Bad, as this is confusing and means the buyer must beware!

The two most important reminders were that not everything relates to hepatitis B and that blood tests can be confusing or misleading. For example, an elevated ALT can be related to common medications or other infections.

Treatment Topics and Liver Cancer

The entire group remained to hear more from **Drs. Nguyen, Misra and So**. Liver cancer is a significant complication of chronic HBV affecting 1:4 unscreened or unmonitored people living with the disease. The statistics drop to 1:2 for unscreened or unmonitored males. These are not statistics for the faint hearted! Chronic HBV is also the cause for 80% of the world's liver cancer.

There was no consensus on treatment protocols, although all the doctors agreed that combination therapy offers the best hope. Of special interest is that the American-based docs were less enthusiastic about interferon (IFN) because of the unpleasant chemo-like side effects. The international doc pointed out that IFN is very effective, and that given the risk of mutations from antivirals, it can be a smart move to prescribe IFN, if appropriate.

We heard about reversing fibrosis - by curing (treating effectively) the primary disease and inhibiting activation of the stellate cells directly or by reducing inflammation. We learned that active HBV and e-Ag positive increases the risk of developing both cirrhosis and HCC. Having cirrhosis increases the risk of HCC.

Genotypes – to complicate things even more, genotypes are an alphabet soup just like viral hepatitis! So far, HBV has genotypes A through H. There are theories being studied that genotypes may predict clinical course. At this point, genotype testing is only available in the research setting.

Mutations – it appears that all mutations develop as a result of viral adaptation, either naturally and

through time or as a survival strategy to treatment interventions. HBV mutations appear to follow antiviral therapy. E-antigen negative status seems to have some bearing on the development of mutants as well as high viral load. This is a very important arena for the future, particularly as treatment options become more diverse.



Steve Bingham and Sheree Martin, the HB-List "Dad and Mom", welcome old and new friends alike.

"I was diagnosed with chronic HBV back in 1996 and had never met another person with HBV until now. It's been an enormous relief to share with others who are in the same 'canoe club' as me."

Continued on page 9

Pegylated Interferon

Monica L'Tainen, Roche, presented information about peg-interferon as an exciting alternative to interferon alpha. To everyone's disappointment, though, only HCV data was presented since HBV data is limited. Everyone is keeping an eye on this promising new drug, which is in phase III trials outside the U.S.

Partners, Friends and Families

Living with a chronic illness is a challenge not only for the person with HBV. This session provided a forum for those affected to look at their own lives and needs. They learned about the importance of "self care" while providing support to their loved ones.

DAY TWO

Breakfast was packed and the meditation session well attended, despite the lack of sleep. Rejuvenated, we jumped into the second day's sessions.

Hepsera Update

There were more questions than answers as usual during this session with **Wendy Cunning**, who reported that Gilead's latest research suggests that Hepsera (adefovir dipivoxil) improved fibrosis. In those who are lamivudine-resistant, Hepsera did not appear to reduce the viral load. Although Hepsera also produces mutations, evidence so far suggests that it takes longer. There was no information on cross-resistance. ALT flares have been reported following discontinuation of Hepsera, which means careful monitoring is necessary. The current recommendation is that once seroconversion occurs, Hepsera should be continued for at least 6 months.

Concerns were raised about the lack of long-term follow up from Gilead's Expanded Access Program. Given that Hepsera is a DNA chain terminator, the implications that this has for pregnancy and fetal development was another concern. Children's trials are just beginning, so little information was available.

As expected, we asked about the availability of Tenofovir (Viread) for HBV. Several attendees reported they were taking it "off-label" and getting good results. We were pretty much told, albeit politely, that it was an HIV drug and would stay that way.

Psychological and Social Issues

In the rush to obtain as much medical information as possible, we often forget the enormous emotional pressures. **Dr. Cynthia Weaver** reminded us on ways to support family strengths in order to cope with chronic illness.

Hep B and Kids

See "Impact of HBV on Families" on page 10.

AFTERNOON HBV Drug Watch Update

Another packed session greeted **Dr. Timothy Block**, HBF president. Although there are unlimited "potential" pharmaceutical treatments, few are being studied. New FDA rules ensure that studies will include other countries with high incidences of HBV. The hope is that as scientific knowledge advances and clearer virologic profiles emerge, it will be easier to target treatment that is more effective.

The future of HBV treatment is wide open with no answers yet. For example, do we take immune enhancers with the risk of a liver crisis, are single medications the answer, or is a multi-medication approach better? HBV is only just beginning to deal with the potential role of different genotypes and the consequences of viral mutation, but they are rapidly becoming significant issues.

I Need a New Liver!

Dr. Cosme Manzarbeitia (liver transplant surgeon) and **Dr. Ken Rothstein** (hepatologist) led a very lively session. More myths were challenged. For example, HBV does not always recur in the new liver, particularly in those who are e-antigen negative. We also learned that experts can disagree even about post-transplant treatment protocols!

Unfortunately, the scarcity of organs in America means that an "exclusion model" operates whereby potential candidates are screened out, not in. Therefore, candidates for a liver transplant should never take "No" for an answer

and should be prepared to contact every U.S. center. Each center has its own idiosyncratic guidelines.

A spirited discussion on donor procedures illustrated the many different points of view. For example, in Spain there is no shortage of organs as availability is assumed, unless the deceased or his family has objected. In this country, we assume that organs will not be available unless advance directives have been made.

A Gathering of Friends

The 3rd B-Informed Conference was another huge success. A more diverse and hep-aware audience made for fascinating discussions. The speakers were excellent, encouraging active participation. Although it would be nice to have easy answers and a simple "one-size fits all" treatment plan, this is not the reality. We learned that experts do disagree, and that treatment approaches can differ greatly.

As B-Informed 2003 came to a close, attendees said goodbye to each other, promising to be back next year. We are grateful to both the HBF and the HB-L for hosting this important event!

Pam Ladds, CQSW, RN, HV Cert, is a psychotherapist, writer and health activist who lives in New York

"The HBF and HB-L, along with the wonderful Doctors who availed themselves to us, are very special people to whom I will be always be grateful. I definitely look forward to the next meeting."



Chris Kukka (left) and Maureen Kamische (right) describe their trip to China, sponsored by PKIDs, to provide education about hepatitis B prevention and safe injection techniques.

Impact of Hepatitis B on Families

B-Informed 2003 provided a rich opportunity for parents to learn more about hepatitis B and its impact on families. Whether through biology or adoption, parents of infected children enter the complex world of hepatitis B as newcomers. Like newly diagnosed adults, parents struggle to learn about hepatitis B, how the virus works, and what treatments are available.

Good Information Hard to Find

Parents talked about the difficulty in finding doctors who were knowledgeable about hepatitis B. Since most pediatricians know little about hepatitis B, and there are few pediatric liver specialists who have experience treating children with hepatitis B, finding information can be difficult.

The conference was a wonderful opportunity for parents to learn about the basics of hepatitis B: what do the blood tests mean, why is the e-antigen so important, why should HBV-DNA be tested, and when should a child be treated?

Children and Hepatitis B

In children, hepatitis B can travel a different course than in adults. The infection can exist without triggering a response from the immune system. The virus can be replicating at a staggering rate in children, yet their immune systems appear to take little notice of the virus infecting their livers. In this case, a child's liver tests can appear "normal". It may take years or even decades before the immune system finally notices the virus and goes on the attack to vanquish the infection.

In other children though, perhaps because they were infected after birth when their immune systems were better developed, the immune system attacks the infected liver cells and their tests show signs of liver damage. For these children, treatment may be recommended.

Treatment Options for Children

Unfortunately, while the drug arsenal to treat adults with hepatitis B is small, it's even smaller for children. Parents learned that finding an effective treatment for children, and ultimately a cure, remains an uphill journey.

- Eпивir-HBV (lamivudine) is the only antiviral medication approved for children under the age of 18 years. While this drug successfully kills off a lot of hepatitis B virus, viral mutations can occur over time.
- Hepsera (adefovir dipivoxil) was recently approved for adults, but not yet for children. According to Gilead, there are plans to enroll 100 children in phase II/III studies in the U.S. and Europe later this year.
- Tenofovir is an antiviral drug approved for HIV, but has also shown some promise against HBV in adults. Although Gilead is currently testing tenofovir in children with HIV, they say there are no plans to test the drug in children with HBV.
- Interferon alpha, an immune booster, was the first drug ever approved for adults and children with HBV. It is an injection given three times a week and has more side effects than antivirals. Although peg- interferon, a new formulation injected only once a week, seems to be highly effective, Roche said they don't plan to test the drug in children with HBV; however, it is being tested in children with HCV and other types of cancer.

Families Are Not Alone

In addition to discussing medical information, parents wanted help dealing with the emotional aspects of the infection. Parents shared their experiences, their heartaches and their hopes. Fortunately, each family learned that they are not alone.

Christine Kukka is a health writer and hepatitis B advocate who lives in Maine. She is editor of PKIDs' comprehensive "Pediatric Hepatitis Report", which is available on-line at www.pkids.org.

Protecting Public Health and Individual Privacy - One Family's Journey

Last week, my daughter and I each reached our own personal and political milestones. The catalyst was her annual physical exam, which included a "blood draw" to monitor her chronic hepatitis B infection.

She has experienced nearly a decade of blood draws since she arrived from China. Once she became old enough to recognize the intrusion of that needle, the trauma escalated with each visit. This year she tamed her panic and there were no tears or kicking - she emerged from the doctor's office victorious and smiling.

Before leaving, I handed a school health form to the nurse. For me, this simple form was a potential legal landmine. Six years ago, I walked into this same office with a kindergarten health form on which the pediatrician wrote "chronic hepatitis B". This triggered a nightmare initiation into the stigma associated with bloodborne infections in public schools. First, the school nurse asked me about hepatitis B in the most delicate way possible. Then she told my daughter's teacher, who proposed that my daughter be transferred to a different classroom.

Since then, my family and the U.S. have come a long way in recognizing the rights of infected children. Medical organizations and the U.S. Department of Justice have clarified what schools and daycare providers can - or cannot - ask about bloodborne infections such as hepatitis B.

Bottom line, a school can ask about tuberculosis (spreads easily through the air) or epilepsy (requires an immediate medical response), but they cannot ask about hepatitis B, C or HIV.

This year, when the pediatrician's office assured me that my daughter's privacy would be protected on the school form, I felt my throat tighten and tears of relief well in my eyes. As my daughter has grown over the past decade, so has our society's commitment to protect her right to privacy and protection against discrimination. Learning how to simultaneously protect public health and individual privacy is an ongoing journey for my family and this country.

Anonymous Mother

Foundation at the Forefront

Dr. Block Receives Bulgarian Academy of Medicine and Science Award



Dr. Block (center) receives Academy Diploma from the Bulgarian National Academy of Medicine and Science. L to R: Prof. Michail Protichy, Vice-President of the Academy, and Prof. Angel Galabov, director of the National Institute of Microbiology.

To the sounds of the Bulgarian national anthem, a formal procession marked the induction ceremony of **Dr. Timothy Block**, HBF president, into the Bulgarian National Academy of Medicine and Sciences, held Sept. 12 in Sofia, Bulgaria. Dr. Block is only the 18th person to be inducted as a "Foreign Member" into this 180-member society. He was elected into this historically prestigious institution for his contributions toward advancing hepatitis B research.

Prof. Michail Protichy, vice-president of the Academy, and **Dr. Angel Galabov**, director of the National Institute of Microbiology, jointly presented the Academy Diploma to Dr. Block. They commended him for his "creative thinking and beautiful ability to move easily from virology, glycobiology and immunology to address hepatitis B."

In his acceptance speech, Dr. Block spoke of his desire to strengthen the relationship between U.S. and Bulgarian science. He also stressed that his best thanks for this honor is to continue to search for a cure for hepatitis B, which chronically infects almost 10% of the Bulgarian population

HBF Provides Leadership for API Task Force

Chari Cohen, MPH, HBF's program coordinator, successfully obtained a seed grant to continue the CDC's API Task Force, which was created in 1998 to increase the rates of HBV screening and immunization in the Asian American and Pacific Islander (API) population nationwide. The HBF is on the steering committee and serves as Treasurer/Grant Director for the Task Force. In its newly expanded role, the HBF will assist in securing and managing grants for educational programs.

Originally funded by the CDC, the API Task Force is now an independent organization and has been renamed "The National Task Force on Hepatitis B for Asians and Pacific Islanders". It is made up of over 15 volunteer organizations across the U.S., including non-profits and state health departments. This year the Task Force plans to develop comprehensive screening guidelines for hepatitis B in the API communities.

Nagy Golf Tournament Benefits HBF

On July 11, the 4th Annual Joseph Nagy Golf Tournament teed off in Princeton, NJ. The charitable outing has become a huge success, with this year topping out at 70 plus participants. HBF board members **Gurney Sloan** and **Bob Goldberg** brought friends and joined in the day's fun. A huge thanks goes to **Kevin Drake** and the **Nagy Family** for coordinating this annual event. Without their unstinting and generous volunteer efforts, this golf outing would not be as successful as it has become. As Kevin says, "we have a lot of fun doing this for the Foundation and it's a way we can honor my father-in-law Joseph Nagy, who passed away due to complications of hepatitis B. He enjoyed all sports, but especially golf." To date, the Nagy Golf Tournament has raised almost \$12,000 for the HBF.



HBF Board Members Gurney Sloan (left) and Bob Goldberg (right) teed off with "eagle on a par three" at the 4th annual Nagy Golf Tournament.

Meet Our New Vice-President

Welcome to **Bonnie B. Schalm** who joined the HBF in July to serve as Vice-President for Foundation Development. In this new position, Bonnie will bring her vast experience and talent to prepare a plan to ensure the continued success and growth of the Foundation. "I feel privileged and committed to being an important part of helping the HBF to fulfill its mission," she says. Bonnie has a solid record of accomplishment in fundraising, especially with major gifts and capital campaigns, in both the corporate and private arena. She has worked for Chase Manhattan Bank, the Putnam Trust Company, UNICEF, the CARE Foundation, Boston Symphony, and most recently for Bankcroft NeuroHealth.

Giving Before December 31st Act Now for Greatest Benefit!

As the year draws to a close, most people begin to think about charitable giving to their favorite organizations. We hope that the Hepatitis B Foundation is one of yours! Remember, a gift now can result in maximum tax savings and other financial benefits to you and your family.

Please feel free to contact Bonnie Schalm at 215-489-4900 or email bonnieb@hepb.org with any questions or to request additional information.

Your support is important to the fulfillment of our mission and is greatly appreciated.

Make A Donation today on our secure website at www.hepb.org. Now we can accept both U.S. and International donations.

Future Hepatitis B Scientists



College summer interns gain valuable research experience. L to R: Mark Schmidt (DVC), Kristy Walter (DVC), Emily Clementi (DVC), Sarah Nungesser (DVC), Kate Donigan (Lehigh U), Sarah Muse (Lehigh U), and Ron Long (DVC), August 2003.

Every summer junior and senior college students study in HBF supported labs for 10-weeks, supervised by professional scientists. "The students have an opportunity to not only learn cutting-edge research techniques, but they also learn about the global health problem of hepatitis B", says **Pamela A. Norton, Ph.D.**, associate professor of the Jefferson Center and director of the HBF Summer Internship Program. All eight of the summer interns presented their findings to the faculty scientists at the end of the program. The importance of this educational initiative was affirmed by a student who said, "The time I spent in the HBF lab, and the knowledge and experience I gained as an intern are invaluable." The HBF is grateful to the Merck Community Foundation for a \$5,000 grant that helped support this year's internship program.

What A Summer for Hep B Kids!

For the past two years, the national non-profit PKIDs has sponsored the "Camp for Life" program that is an all-expense paid experience for kids with HBV, HCV and HIV to meet other kids "just like them". The HBF provided funds to send a 14-year old boy with HBV to camp and were richly rewarded by his letter - "I realize how fortunate I am to be going here...I made friends with many people and could talk to people about themselves. I can't find anyone at school to talk about hepatitis B." To learn more about the "Camp for Life" program or to make a donation to PKIDs, please contact **Trish Parnell** at pkids@pkids.org or visit www.pkids.org.

HBV Enthusiasm Infects High School Students



Students from the National Youth Leadership Forum on Medicine learn about cutting-edge hepatitis B research, July 9, 2003.

For the third year, students from the National Youth Leadership Forum on Medicine visited the Jefferson Center and HBF Labs in July. This program introduces high school students to professional scientists and the field of biomedical research. One participant summed up the day's experience with, "The people who spoke about hepatitis B were very enthusiastic about what they were doing and were very interested in sharing their knowledge with us. This trip helped me figure out what area of medicine I want to work in."

An Award Winning Website: www.hepb.org

The HBF's redesigned website by Refinery won the prestigious *World Wide Web Health Award 2003 in the category of Patient Education Information*.

The HBF website was selected because "it provides comprehensive information that is credible, relevant, interactive and is easily navigated by the consumer living with a chronic medical condition," according to the Health Information Resource Center (HIRC), a national clearinghouse for consumer health information programs, which sponsors this award.

The award, the largest of its kind, was created to provide a "seal of quality" for electronic health information geared towards consumers and professionals. For more information about this award program, visit www.healthawards.com.



Bookmark the HBF Website! New Features Coming to www.hepb.org

Read Our Regularly Updated:

- **HBF Drug Watch**
Approved drugs and compounds in development for HBV
- **HBF Clinical Trials**
Lists only HBV clinical trials

New Features to be Added Soon:

- **Interactive NLM Tutorial**
Simple instructions for navigating MEDLINE, MEDLINEplus, and clinicaltrials.gov
- **Spanish and Hindi Language Chapters**
"More than a brochure, less than a book"
- **Expert Speakers Forum**
Inaugurated by Dr. Sam So of the Asian Liver Center
- **E-newsletter**
News for the hepatitis B community



Speaking Personally

Steve Bingham

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

Pilgrimage

Another successful B-Informed 2003 patient conference has come and gone. It's not easy planning something like this, especially when the organizers are in three far-flung locations - Pennsylvania, Ohio, and Idaho. But the end product is certainly worth the effort.

Congratulations to our first-time attendees who had to overcome their fear of the unknown (and fear of sharing their story for the first time) to make the pilgrimage to Doylestown. I try to put myself in their shoes. It's a leap of faith to leave one's home, travel hundreds of miles to a strange place, and then sleep with people you've never actually met! For one young Californian, it was the first time he had been out of his state.

So, what is it that calls us to Doylestown each year? Of course, there are as many different reasons why we make this annual migration as there are people who attend. One person from Connecticut swears that he came to entirely by accident after having had an attack of "brain fog" on the way back from his grocery store!

For the rest of us, the journey was a little more purposeful. One reason we come to the conference is to meet others who struggle with hepatitis B. Some of these people are already cyber friends through the HB-List, but B-Informed is where we meet at last. The delight of seeing the face of a good on-line friend is indescribable. I can't help but think that it's ironic that such a wicked disease can bring about such deep bonding.

We also come to Doylestown to meet the experts and to get the latest information on hepatitis B. This year we weren't disappointed. Our keynote speaker, Dr. Sam So, reassured us that the treatments we have for hep B are effective - maybe not in curing the disease, but certainly, in controlling it so we can live normal lives.

Dr. Ken Rothstein agreed, and said that he's not seeing as many hepBers needing liver transplants, probably because of the effectiveness of drugs such as Epivir-HBV and Hepsera. Dr. Rothstein also assured us that fibrosis of the liver is indeed reversible, something that I personally was happy to have reaffirmed.

We all smiled when Dr. Rothstein joked that hepBers are his favorite patients because we "don't whine much". I can't wait to tease my hep C friends with that quote.

A perverse highlight of the conference was when the experts actually disagreed with one another. I was pleased that our speakers felt comfortable enough to let us in on these friendly debates. It was an eye-opener that confirmed what we already knew - hepatitis B is a very complicated disease.

Other hepatitis groups have frequent conferences, but they haven't been as successful in mixing the social and informational components that we look forward to each year. The one thing I noticed about our B-Informed participants is that they all seemed determined to make the conference a success. I've been to conferences where there are always a few people who come with the attitude, "OK, I'm here. Now entertain me". But not our group. Everyone participated, got involved, and those with special skills readily accepted assignments to moderate some of our conference sessions.

Finally, we come to Doylestown to renew our friendship with the Hepatitis B Foundation. Getting to tour the HBF and Jefferson Center facilities is always a highlight, but it's the gracious and enthusiastic HBF folks who really make our conference special.

Thank you Sarah, Molli, Tim, Joan, Paul, Jan, Fonta, and Chari.... See you next year!

Best wishes,
Steve

Internet Support Groups



Hep B Information and Support List New Address! 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

<http://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.

PKIDS Support List

<http://www.pkids.org/>

For adoptive and biological parents of children with chronic viral infectious diseases, including HBV, HCV, and HIV.

Hepatitis B Clinical Trials

Hepatitis B Foundation HBV Clinical Trials
www.hepb.org

National Institutes of Health Clinical Trials
www.clinicaltrials.gov

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

Open Enrollment for Phase III Trial of LdT (telbivudine)

Idenix Pharmaceuticals Inc. is sponsoring a phase III clinical trial of LdT for treatment of chronic hepatitis B, conducted at over 100 sites in North America, Asia, Europe, Australia, and New Zealand. Adults with chronic hepatitis B who have never been treated with lamivudine or other nucleoside or nucleotide analogues are eligible and will be randomized to receive either LdT or lamivudine for 2 years. *Contact: Barbara Fielman, RN at 617-250-3100, ext. 145 or email fielman.barbara@idenix.com.*

Open Enrollment for Phase II Trial of Clevudine

Clinical trials stopped August 2003.

Open Enrollment for Phase III Trials of Entecavir

Bristol-Myers Squibb (BMS) is conducting studies of this once daily oral drug in approximately 130 sites in more than 30 countries worldwide. Three different studies are being conducted based on the results of patients' serological status (hepatitis B e-antigen positive or negative), and whether the patient is currently on lamivudine therapy and has evidence of resistance to lamivudine. *Contact: BMS toll-free at 1-866-892-1BMS.*

Columbia-Presbyterian Medical Center Entecavir Study

The safety of Entecavir (BMS 200,475) will be evaluated in adults with chronic HBV. Those co-infected with HIV are not eligible to participate. *Contact: Ms. Cabilia Gomez at 212-305-3839 (New York, NY).*

A Randomized, Double Blind Trial of LdT (Telbivudine) versus Lamivudine

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).*

Phase II Comparison of Adefovir and Tenofovir for the Treatment of Lamivudine-Resistant HBV

This NIAID study will compare the combination of adefovir and lamivudine with the combination of tenofovir and lamivudine to determine which drug combination is most effective in people who are infected with both HBV and HIV. *Contact: NIH Patient Recruitment at 1-800-411-1222 or email prpl@mail.cc.nih.gov. Visit the HBF website at www.hepb.org for the locations and contact information in 12 states.*

Pilot Study of Telbivudine Treatment for HBV Prior to Starting Anti-HIV Drugs in Co-infected Patients

This NIAID study will evaluate telbivudine (LdT) for the treatment of hepatitis B in HIV infected patients. Patients will take telbivudine alone for 24 weeks, add anti-HIV drugs

for 24 weeks, then stop taking telbivudine while continuing their anti-HIV drugs. The primary aim of this study is to assess the safety of telbivudine alone and in combination with a lamivudine-based highly active antiretroviral therapy (HAART) regimen in patients coinfected with HBV and HIV. *Contact: Karen Savage, RN, CCRC, at 205-975-7925 (kgsavage@uab.edu) at the Univ. of Alabama.*

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, Eпивir-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.*

Treatment of Hepatitis in Patients Who are Triple-Infected With HIV, HBV and HCV

This NIAID phase II study will investigate the safety and effectiveness of using adefovir, pegylated interferon, and ribavirin in patients with HBV, HIV, and HCV. All patients in this study must be taking lamivudine. *Contact: Karen Savage, RN, CCRC, at 205-975-7925 (kgsavage@uab.edu) at the Univ. of Alabama or M. Ray at 303-372-5535 (graham.ray@uchsc.edu) at the Univ. of Colorado Health Sciences Center.*

Pegylated Interferon to Treat Chronic Hepatitis D

This NIDDK study will evaluate the safety and effectiveness of pegylated-interferon in treating hepatitis D virus (HDV). Patients with HDV over 6 years old may be eligible for this study. *Contact: NIH Patient Recruitment at 1-800-411-1222 or email prpl@mail.cc.nih.gov.*

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. The study began July 2003 and trial sites are located throughout the US. *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.*

Fast Fact

The NIH estimates there are 6,300 clinical trials underway in the U.S. with more than 2 million people involved.

Resource Roundup



Hepatitis B Foundation

215-489-4900

www.hepb.org

info@hepb.org

Comprehensive website dedicated to hepatitis B. Facts, useful advice, Drug Watch, liver specialist directory, and a responsive email service. Includes *Chinese, Vietnamese and Korean Language Chapters*.

American Liver Foundation

1-800-GO-LIVER

www.liverfoundation.org

webmail@liverfoundation.org

Information about all liver diseases, including viral hepatitis. Fact sheets, legislative advocacy, research funding.

Asian Liver Center at Stanford University

650-725-4837

<http://livercancer.stanford.edu>

This website informs, updates, and educates people about hepatitis B and liver cancer among Asians and Asian-Americans. Information is available in English, Chinese and Korean.

Centers for Disease Control, Hepatitis Division

1-888-443-7232

www.cdc.gov/ncidod/diseases/hepatitis

The national authority for viral hepatitis information: epidemiology, disease facts, prevention, scientific studies, national recommendations, and more.

CDC Hepatitis Immunization Hotline

1-800-232-2522 (English)

www.cdc.gov/nip

1-800-232-0233 (Spanish)

nipinfo@nip1.em.cdc.gov

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 that provides abstracts, reports and notices.

Hepatitis B Research Archive Website

http://dispatch.mail-list.com/archives/hbv_research

Archived research bulletins posted on the Hepatitis B Research List, from 1998 until current year.

Hepatitis B Virus Page

<http://www.globalserve.net/~harlequin/HBV/index.html>

Maintained by Robert Garces, Ph.D. Candidate in Virology, at the University of Toronto.

Hep C Connection

1-800-522-4372

www.hepc-connection.org

info@hepc-connection.org

Comprehensive information to assist Hep C-challenged individuals and their families.

Hepatitis Foundation International

1-800-891-0707

www.hepfi.org

mail@hepfi.org

Information about viral hepatitis, support groups, research articles, and education programs.

Hepatitis Magazine

1-800-310-7047

www.hepatitismag.com

editor@hepatitismag.com

The only print magazine published bi-monthly for those affected by viral hepatitis.

Hepatitis Neighborhood

www.hepatitisneighborhood.com

info@HepatitisNeighborhood.com

Features a Town Hall with a Live Speakers Forum. Sponsored by Priority Healthcare Corporation.

HepTrec

1-866-HEPTREC

www.heptrec.org

The Delaware Valley Hepatitis Treatment, Research and Education Center (HepTREC) provides support group information, training and prevention programs in the greater Philadelphia area.

HCV Advocate

sfhecat@pacbell.net

<http://www.hcvadvocate.org>

Excellent research, education and support information for the HCV community. One of the few HCV websites that also includes information about hepatitis B.

HIV and Hepatitis Treatment Advocates

www.hivandhepatitis.com

Professional online publication with updates, conference reviews, free teleconferences, and an e-mail service.

Immunization Action Coalition

651-647-9009

www.immunize.org

www.vaccineinformation.org

Comprehensive resource of immunization information. "IAC Express" is a free email announcement service. "Vaccine Information" is a new complementary website launched by IAC and is specifically written for the general public.

MEDLINEplus Health Information

www.medlineplus.gov

A goldmine of reliable health information from the world's biggest medical library of medicine, the National Library of Medicine. This database is maintained in collaboration with the NIH.

Memorial Sloan Kettering "About Herbs"

aboutherbs@mskcc.org

www.mskcc.org/aboutherbs

Objective information about herbs, their side effects, drug interactions, and links to scientific research. This site is maintained by experts at Memorial Sloan Kettering.

National Center for Complementary and Alternative Medicine

1-888-644-6226

www.nccam.nih.gov

Sponsored by the National Institutes of Health (NIH), this site contains databases galore and research articles.

Parents of Kids with Infectious Diseases

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

www.pkids.org

pkids@pkids.org

An excellent resource for parents and professionals. Pediatric clinical trials, research list and support listserv.

Calendar of Events



Oct. 24 - 28 Annual AASLD Meeting
 American Association for the Study of Liver Diseases
 Hynes Convention Center, Boston, MA
 Contact: jdeal@aasld.org
www.aasld.org

Nov. 9 - 12 IX International Antiviral Symposium
 Organizasyon DIAS
 Renaissance Antalya Resort
 Beldibi, Antalya, Turkey
 Co-Chairs: Drs. Yung-Chi Cheng, Raymond Schinazi, and A. Bozdaya
www.antiviral.dias.com.tr

Nov. 10 - 11 Hepatitis Summit 2003
 Hepatitis Foundation International
 Hilton Hotel, Mystic, Connecticut
 Contact: (800) 891-0707
www.hepatitisfoundation.org

Nov. 11 - 12 HIV and Hepatitis Co-Infections Conference
 The Haemophilia Society of London
 Oxford Hotel, Oxford, U.K.
 Contact: info@haemophilia.org.uk
www.haemophilia.org.uk

Dec. 7 - 9 National Viral Hepatitis Roundtable
 NVHR Consortium
 Wyndham Hotel, Washington, DC
 Contact: rconlon@plantationcable.net
www.nvhrregistration.com

Dec. 14 - 18 HepDART: Frontiers in Drug Development for Viral Hepatitis
 Kauai Marriott Resort, Kauai, Hawaii
 Contact: info@informedhorizons.com
www.informedhorizons.com/hepdart2003/

Dec. 16 Princeton HBV Workshop
 Hepatitis B Foundation
 Kauai Resort, Kauai, Hawaii
 Contact: info@hepb.org
www.hepb.org

2004 Feb. 14 - 17 Hong Kong - Shanghai International Liver Congress
 Hepatitis Research Foundation
 Hong Kong Convention and Exhibition Centre, Hong Kong SAR, China
 Contact: info@hepa2004.org
www.hepa2004.org

SAVE THIS DATE

The Hepatitis B Foundation is proud to honor
 Pennsylvania Governor Mark Schweiker

Crystal Ball Awards Gala
 April 3, 2004
 Doylestown Country Club
 Doylestown, PA



HB FOUNDATION
 700 East Butler Avenue
 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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Contributions will be acknowledged in our Winter newsletter unless otherwise requested.

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