

Health-e Bytes™

An eNewsletter published by Hepatitis Foundation International

Vol. 2, No 1 • Feb.-March 2014

Dear Friends,

In 1994 Founder and Board Chair, Thelma King Thiel opened the Hepatitis Foundation International's (HFI) doors and hit the ground running. She continued her crusade to educate everyone about their liver, appeared on local television, and wrote a letter to her friend and colleague Ann Landers, which was published in newspapers nationwide. HFI received over 40,000 letters and the telephone rang off the hook with people seeking information and assistance. All of this took place during HFI's first month in operation.

As we celebrate our 20 Year Anniversary, HFI remains as relevant as when our doors first opened. Today we serve nearly 5 million patients, families and healthcare providers nationwide. While we take 2014 to reflect on our successes, we do not rest on our laurels. HFI's message has remained consistent, however, the need for our services increases daily. We need your assistance more than ever and ask that you not only help us celebrate, but continue to stand with us.

**Ivonne Perlaza Fuller, CEO
Hepatitis Foundation International**



New York Viral Hepatitis Summit

March 20, 2014

Harlem Hospital Center, NY

[Read More...](#)

Inside Health-e Bytes...

T.I.P.S... HFI in the Know...
Lifestyle... Grand Rounds...

[Read More...](#)

COMPARISON OF SOVALDI™ AND OLYSIO™

[Read More...](#)



Have you heard
of the poor man's
heroin, Krokodil?

[Read More...](#)



THE LIVER LADY ADDS MOTIVATIONAL MESSAGES TO WAR ON DRUGS/HEPATITIS



"You put the fear of God in me in an entertaining and memorable way", commented an attendee at SAMHSA's Prevention Conference. He reported that Thelma King Thiel, Board Chair, Hepatitis Foundation International, provided exciting new techniques to motivate every one – young and old– to avoid behaviors that could damage their liver– their personal

internal power plant. "Thelma, you really got to me!"

Say "No" to drugs did not work. The drug problem continues at an alarming level nationwide. We all know that individuals make their own decisions about food and lifestyle behaviors. However, until they understand the devastating impact their choices can have on their liver and their life most will unknowingly continue to participate in risky behaviors that can threaten their future health and quality of life.

Studies show that even highly educated health professionals are unaware of the key role the liver plays in converting the food they eat into hundreds of life sustaining body functions. Why? Because liver health has been missing in the majority of school curricula across the nation for decades, partly due to the fact that the liver is a non-complaining organ unable to give warning of trouble until is it badly damaged.

Poor food choices and risky lifestyle behaviors are predecessors to *obesity, *fatty liver, *diabetes, *cardio-vascular disease (heart attacks), *high cholesterol, *cirrhosis (dead liver cells) due to *substance misuse and abuse, and *exposure to hepatitis and AIDS through unprotected sex or sharing needles. Even tattoos can present an increased risk.

All these liver related diseases are PREVENTABLE.

"Just think how many lives could be saved and devastating disabilities prevented due to these "liver related" chronic disease pre-K and beyond about their precious internal partner –their liver –and how to take good care of it, we would have a healthier nation".

HFI has developed 15 award winning DVDs for young children, adolescents, college students, those participating in high risk behaviors and training for professionals. Several are available in Spanish, Vietnamese, Mandarin and Korean. HFI has also partnered with SAMHSA providing over 3500 grantees with a training program called Foundation for Decision Making™. Easy to replicate commonsensical communication techniques and updated information on viral hepatitis empower grantees and their constituents to act on what they have learned making healthier food and lifestyle choices.

For additional information please contact: info@hepatitisfoundation.org.

Health-e Bytes

February-March 2014

Contents...

HFI In The Know	3
<i>Summits, Events, Health Observances</i>	
Lifestyle	4-5
<i>Diverse Health Issues</i>	
Grand Rounds	6-7
<i>Science, Research and Medical Updates</i>	
In The Pipeline	8
<i>Clinical Trials and New Drugs</i>	
T.I.P.S.	9
<i>Free Resources</i>	
Helping Hands	9
<i>HFI's Fundraising Appeal Activities</i>	
Advocacy Alert	9
<i>Highlighting Important New and Pending Legislation</i>	



HEPATITIS FOUNDATION
INTERNATIONAL

Health-e Bytes™

Vol 2. NO.1 • ©2014

Published by
Hepatitis Foundation International

Editor: Thelma King Thiel, Chair
Assistant Editor: Ivonne Fuller, CEO
Writers: Susan Thiel, Jennifer Armah

504 Blick Drive, Silver Spring, MD 20904

800-891-0707

info@hepatitisfoundation.org

www.hepatitisfoundation.org

~ **Advertise With Us** ~



HFI in the Know...

Upcoming HFI Events

- March 20, 2014 New York Viral Hepatitis Summit, Harlem Hospital, Harlem, NY, (in collaboration with the National Black Leadership Commission on AIDS)

■ **Other Important Events – [HFI Calendar](#)**



February 2014

- AMD/Low Vision Awareness Month
- American Heart Month
- International Prenatal Infection Prevention Month
- National Children’s Dental Health Month
- Teen Dating Violence Awareness Month
- 1–7 Congenital Heart Defect Week
- 7 Give Kids a Smile
- 7 National Black HIV/AIDS Awareness Day
- 14 National Donor Day

National Health Observances

March 2014

- National Colorectal Cancer Awareness Month
- National Kidney Month
- National Nutrition Month
- Save Your Vision Month
- 2–9 National Sleep Awareness Week
- 2–9 Patient Safety Awareness Week
- 3–7 National School Breakfast Week
- 7–11 National Youth Violence Prevention Week
- 10–16 Brain Awareness Week
- 10 National Women and Girls HIV/AIDS Awareness Day
- 14 World Kidney Day
- 20 National Native American HIV/AIDS Awareness Day
- 24 World Tuberculosis Day
- 25 American Diabetes Alert Day

HCV DRUG PIPELINE – Phase 2 and Phase 3

Bristol-Myers Squibb Co. announced that the U.S. Food and Drug Administration (FDA) has granted its investigational DCV Dual Regimen (daclatasvir and asunaprevir) as Breakthrough Therapy Designation for use as a combination therapy in the treatment of genotype 1b chronic hepatitis C infection or HCV.

This regimen is BMS’ all-oral combination regimen of DCV, an investigational NS5A replication complex inhibitor, and ASV, an investigational NS3 protease inhibitor, without ribavirin.

According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation requires preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over currently available currently therapy.

Below is a quick look at HCV Genotype 1 treatments in clinical trials of Phase 2 or 3 that do not use Interferon.

Genotype 1 - FDA Interferon Free regimens in development				
AbbVie	ABT-450+ABT-267+ABT-333+ Rbv	Phase 3	92-99%	12 Weeks
AbbVie-GT 1B	ABT-450/r+ABT-267	Phase 2 results	95% SVR treatment naives 90%SVR prior null responders	12 Weeks 12 Weeks
BMS	Daclatasvir=Sofosbuvir (treatment-naives & protease experienced)	Phase 2 results Now Phase 3	100%	12-24 Weeks
BMS	Daclatasvir+Asunaprevire+BMS325 (with/without RBv in phase 3)	Phase 2 results Now Phase 3	94%	12 Weeks
BMS- GT 1B	Daclatasvir+Asunaprevir	FDA Breakthrough Designation Phase 3 results	84-87% SVR	24 Weeks
Gilead	Sofosbuvir+Ledipasvir	Phase 3	93%-99%	12-24 Weeks
Gilead	Sofosbuvir+Ledipasvir	Phase 3	95%	8 Weeks
Janssen	Sofosbuvir+Simeprevir	Phase 2	96%-100%	12 Weeks
Merck	MK-5172+MK8742	Phase 2	100%	12 Weeks



Lifestyle...

Krokodil – Poor Man's Heroin



Desomorphine (Dihydrodesoxymorphine) is a synthetic morphine analogue synthesized since the 1930's in the United States. Desomorphine or "Krokodil" a heroin substitute popular in Russia produces an opiate-like action, is a morphine derivative, and is ten times more potent than morphine.

The skin, in long-term abusers of Krokodil, may present as greenish and scaly due to damaged blood vessels, thrombosis and damaged soft tissues surrounding the injection sites. The skin's appearance is similar to a crocodile's scaled and rugged skin. Skin injuries can eventually develop into severe tissue damage leading to skin abscesses and gangrene. These conditions usually result in limb amputation or sometimes death. Further consequences also include severe withdrawal, spread of HIV and HCV through the use of contaminated needles.

Homemade Krokodil is derived from codeine, iodine, gasoline, paint thinner, red phosphorus and other various toxic and corrosive substances. Although media coverage has touted krokodil as the next U.S. drug epidemic, the Drug Enforcement Administration has indicated heroin and pain killers are much more cause for concern and are used at a greater rate currently than Krokodil in the U.S.

Transplant Survival Rates Lower In Minority Children

The Division of Transplantation at Emory University study is the first to investigate the impact of race and socioeconomic status on graft and patient survival among white and minority children. Researchers included 208 liver transplant recipients, aged 22 or younger, who were transplanted at Children's Hospital of Atlanta between January 1998 and December 2008 and followed through November 2011.

Results show that 51% of transplant recipients were white, 35% were black and 14% were other races or ethnicities. At 1, 3, 5, and 10 years following liver transplant the graft and patient survival was higher among white children compared to the minority children. The 10-year graft survival was 84% for white, 60% among black and 49% for other minority patients. Patient survival at 10 years post-transplant was 92%, 65%, and 76% among whites, blacks, and other races, respectively.

While the study determined differences in post-transplant outcomes between minority and white pediatric liver transplant recipients, researchers were unable to fully explain the reason for these disparities.

"Diabetesity" — A Growing Concern For Children And Teens

Type 2 diabetes, which is commonly known as 'adult-onset' diabetes, is being diagnosed among children and adolescents with increasing frequency, especially if they are overweight. Termed "diabetesity", it is becoming a national healthcare crisis. To void the risk of developing diabetesity, lifestyle adjustments should be made as young as possible, maintaining weight in a healthy range. To reduce diabetesity risks, eat portion controlled healthy meals, limit fast foods, choose low fat milk and water instead of soft drinks, exercise on a regular basis and have regular physical exams that include testing blood glucose levels especially if children and/or adults are overweight.

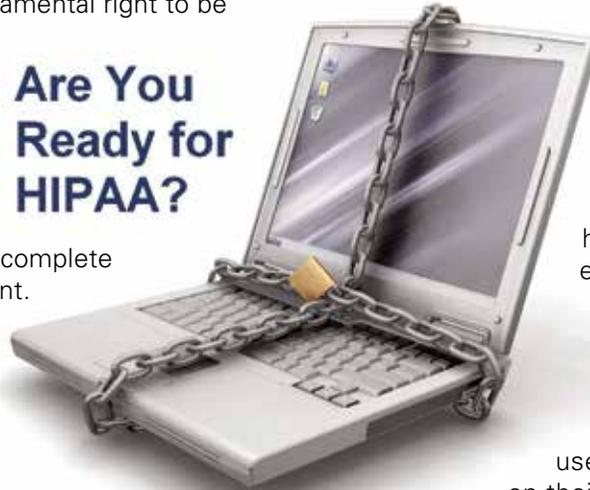


Lifestyle...

Digital Privacy Notice Challenge – Calling All Designers, Developers And Patient Privacy Advocates

Patients have the fundamental right to be informed of their rights of their protected health information. The receipt and signing of a HIPAA Privacy form is now familiar for patients to complete when seeking treatment. The paper forms are supposed to be easy to read and understand. Recently a collaboration with the Office of the National Coordinator of HealthIT.gov (ONC) and the Office for Civil Rights (OCR) developed model notices of privacy practice that communicates required information to patients in an accessible format on paper. However, this is not always the case and when converting from paper to online, or digital which may become even more confusing for patients and caregivers. The next step is to create a user-friendly digital notice of privacy

Are You Ready for HIPAA?



practices.

ONC, in collaboration with OCR launched the Digital Privacy Notice Challenge. This is an opportunity to create an online model notice of privacy practices for health care providers and health plans that is compelling, easy to read, and understand by patients and easily integrated into existing Web sites. The online model notice should creatively inform and educate the

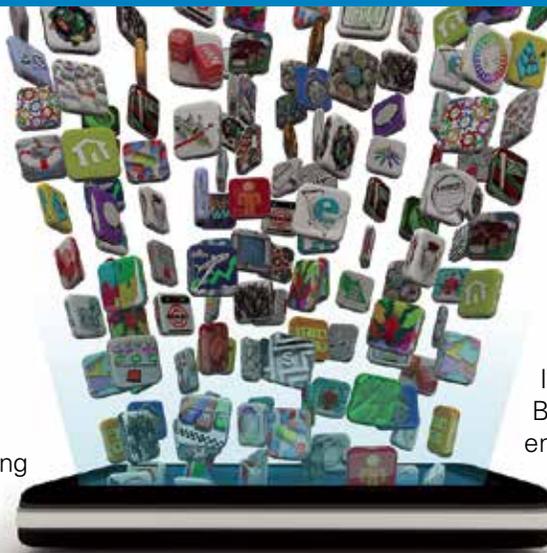
user on their rights and responsibilities regarding their medical information.

Visit the Digital Privacy Notice site at <http://oncchallenges.ideascale.com/> for complete details of the challenge and sign up to receive updates.



There's An App For That

Can Social Media track an infectious disease? Can diabetics manage their disease with more accuracy and compliance by using a smartphone? Survey, studies and trends all indicate the answer is a resounding yes! Mobile apps for smartphones and tablets are changing the way patients and healthcare providers approach health. Growing numbers within the medical profession are embracing social media for sharing helpful medical information and providing patient care.



A recent Pricewaterhouse Cooper survey asked patients and healthcare executives what they thought of the way many healthcare companies are utilizing social media and the Web. Survey results indicated most trusted resources online posted by doctors (60%), followed by nurses (56%), and hospitals (55%).

In the next edition of Health-e Bytes™, HFI will launch a section entitled, *There's an App for That*, to profile apps and social media health information that is vetted and #trending.



Grand Rounds...



Comparison Of Sovaldi™ And Olysio™

SOVALDI™

The U.S. Food and Drug Administration has approved Gilead Sciences' hotly anticipated SOVALDI™ (sofosbuvir), a once-daily oral nucleotide analog polymerase inhibitor plus Ribavirin to treat people with hepatitis C virus (HCV), including those coinfecting with HIV and those who have liver cancer and are awaiting a transplant. For those with genotypes 2 and 3 of the virus, SOVALDI™ offers the first-ever opportunity for a treatment that is interferon free.

SOVALDI™ in combination with ribavirin for 24 weeks can be considered as a therapeutic option for CHC patients with genotype 1 infection who are ineligible to receive an interferon-based regimen. Treatment decision should be guided by an assessment of the potential benefits and risks for the individual patient. For those waiting for a liver transplant SOVALDI™ in combination with ribavirin is recommended for up to 48 weeks or until the time of liver transplantation, whichever occurs first, to prevent post-transplant HCV reinfection.

OLYSIO™

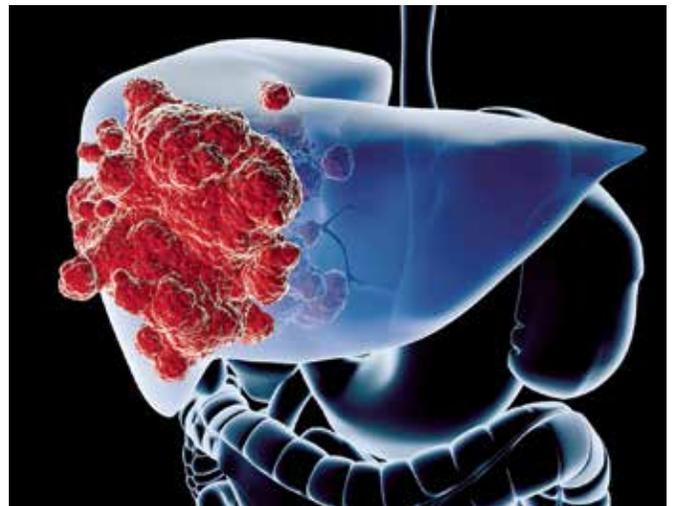
U.S. Food and Drug Administration (FDA) has approved OLYSIO™ (simeprevir), an NS3/4A protease inhibitor, for the treatment of chronic hepatitis C infection as part of an antiviral treatment regimen in combination with pegylated interferon and ribavirin in genotype 1 infected adults with compensated liver disease, including cirrhosis. OLYSIO™ may benefit patients with chronic hepatitis C, including those who are treatment naïve or who have failed prior interferon-based therapy.

OLYSIO™ works by blocking the viral protease enzyme that enables the hepatitis C virus (HCV) to replicate in host cells. The goal of treatment for chronic hepatitis C is cure, also known as sustained virologic response (SVR), which is defined as undetectable levels of HCV in the patients' blood 12 to 24 weeks after the end of treatment. For treatment-naïve and prior-relapsed patients, a fixed treatment regimen of 12 weeks of OLYSIO™ combined with 24 weeks of pegylated interferon and ribavirin is recommended. For prior partial and null-responder patients, a treatment regimen of 12 weeks of OLYSIO™ combined with 48 weeks of pegylated interferon and ribavirin is recommended.



Identified Protein Involved In Liver Cancer

Obesity, alcoholism, and chronic hepatitis all increase the risk of developing liver cancer. In the U.S. liver cancer has doubled over the past 20 years and is the third leading cause of cancer death worldwide. These factors also cause cellular stress and induce expression of CHOP, a transcription factor that is known to promote cell death. The study conducted by University of Iowa researchers show that in mice, despite its role in cell death, CHOP is actually elevated in cancerous liver cells. Furthermore, mice without CHOP are partially protected from liver cancer, developing fewer and smaller tumors than the normal mice in response to liver cancer-causing drugs. Tissue samples from human patients show that CHOP is also elevated in human liver tumors compared to surrounding non-tumor tissue from the same patients. More research is needed to identify other proteins that affect liver cancer development.



Grand Rounds...

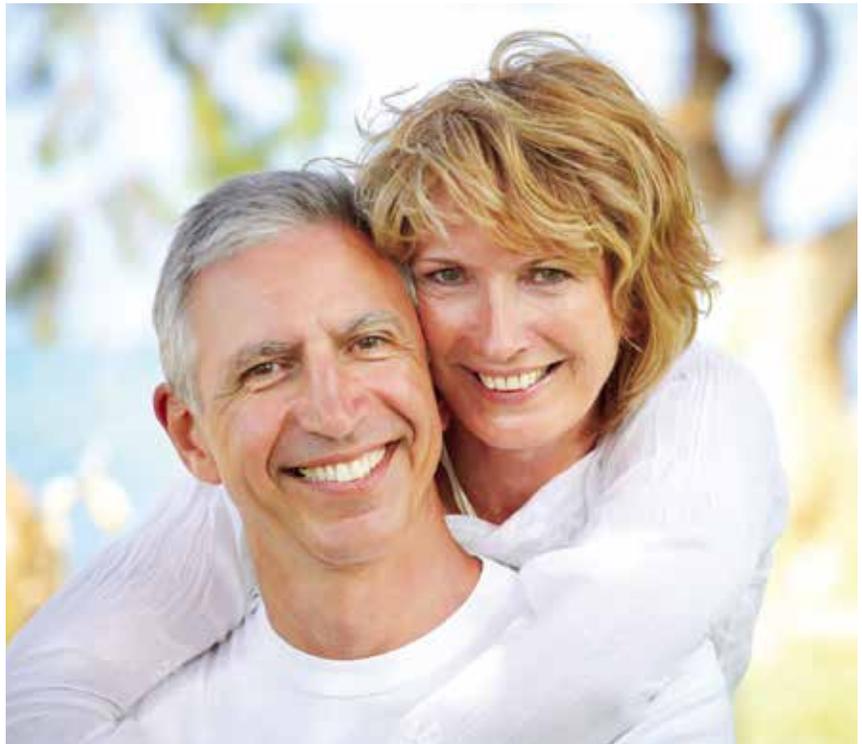
Improving Life Expectancy With New Antiretroviral Therapy

Due to improvements in antiretroviral therapy, a 20-year-old man or woman with HIV in treatment in the United States or Canada can expect to live into their early 70s, according to new study data in PLoS One.

“HIV-positive individuals can benefit now more than ever from combination antiretroviral therapy (cART),” study researcher Hasina Samji, PhD, an epidemiologist at the British Columbia Centre for Excellence in HIV/AIDS.

“Significant gains in life expectancy have been achieved so that an HIV-positive individual on treatment can now live almost as long as those in the general population.”

However certain patient subgroups experienced lower life expectancies, which included non-white patients, patients with a history of injection drug use, and patients with baseline CD4 counts of less than 350 cells/mcL. Researchers concluded additional investigation should focus on HIV patients’ quality of life since this population continues to age.



Prevalence Of HCV Varies In Hispanic Groups

Recent studies at Yeshiva University show that there is a dramatic variation in prevalence of hepatitis C infection rates ranging from less than 1% in Hispanic men of South American or Cuban background to 11.6% in men of Puerto Rican background – a more than 10-fold difference. This suggests that it’s not appropriate to lump all U.S. Hispanics into a single, broad at-risk group. The prevalence of hepatitis C infection found for men in other Hispanic groups are: Mexican (1.9%), Dominican (1.5%), Central American (1%), South American (.4 %), and Cuban (0.8%). Hispanic women generally had a lower prevalence of hepatitis C infection than men, with Puerto Rican background women having the highest prevalence (3.9%) among Hispanic women. The overall prevalence of hepatitis C among men and women in the U.S. is 1.3%, according to the National Health and Nutrition Examination Survey (NHANES). The researchers stated it was not clear why the prevalence of hepatitis C was highest among Hispanic men and women of Puerto Rican background compared with Hispanics of other backgrounds. These findings strongly support the need for community-based campaigns to increase testing and treatment in the Hispanic population.



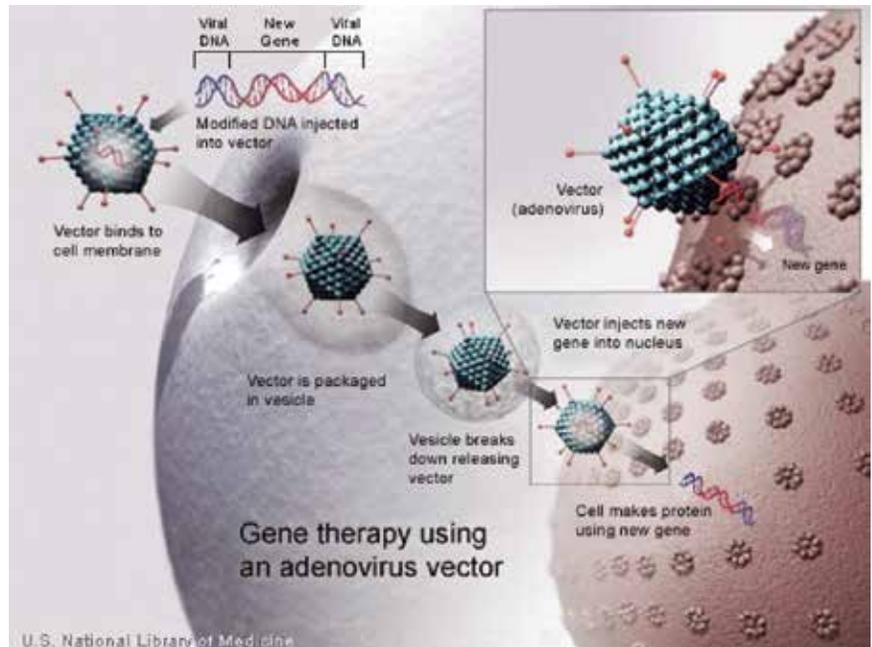
In the Pipeline...

Gene Therapy Targets Tumors

By designing an injectable viral vector that targets blood vessels of tumors, researchers from Washington University School of Medicine in St. Louis, MO, have opened new avenues for gene therapy against cancer and other diseases that have abnormal blood vessels.

Researchers have shown it is possible, in mice, to use a deactivated virus to carry chosen genes directly to target cells in the lining of tumor blood vessels, but they also managed to do it without the virus getting stuck in the liver.

In the study, the team designed the viral vector to carry a gene payload to target the abnormal blood vessels that drive and nurture tumor growth, but not to destroy them. This strategy could be used to either stop tumor growth, or assist in making chemotherapy and radiation more effective.



Encouraging News For Treatment Of NASH



Nonalcoholic steatohepatitis or NASH, a complex and poorly recognized liver disorder occurs most often in people who are overweight or have diabetes. NASH demonstrates a slow but dangerous buildup of fat and inflammation that can damage the liver often without any symptoms making it difficult to diagnose.

A new drug, a form of obeticholic acid, developed by Intercept Pharmaceuticals Inc. showed a dramatic response in an early trial, indicated a marked improvement in lab tests prompting an expansion of the numbers of patients in the trials. However, early findings indicate that it may also boost LDL and HDL cholesterol casting a pall on a therapy for

a condition that's not widely understood. It is unclear what caused the increase or what significance it may have. The National Institute of Diabetes and Digestive and Kidney Diseases sponsored the trial.

Helping Hands

The holidays are over but the HFI's work still continues to reach over 5 million patients, families, health care providers annually. Help us make our 20 Year Anniversary a banner year for the Hepatitis Foundation International and contribute to increasing our programs and services.



Advocacy Alert:

The US Preventive Services Task Force (USPSTF) released their draft recommendations for hepatitis B during February 2014. The USPSTF gave a "B" grade to those individuals at increased risk of infection including:

- Individuals coming from countries with at or greater than 2% endemicity;
- Men who have sex with men;
- Those who are co-infected with HIV;
- Injection drug users;
- Individuals with multiple sexually transmitted diseases;
- Household contacts of those who are hepatitis B-positive; and
- Immunosuppressed individuals, or those undergoing hemodialysis.

Hepatitis Foundation International will provide comments by March 10, 2014 to assist in reinforcing USPSTF's decision to www.uspreventiveservicestaskforce.org/tfcomment.htm.

T.I.P.S.

Updated 2014 Vaccination Schedule

■ The [linked graph](#) shows the recommended ages for routine administration of currently licensed vaccines updated as of January 31, 2014, for ages 0 – 18 years. See the Footnotes along with the vaccination schedule for complete and accurate information. There is also a link for the recommended catch-up schedule for those children 4 mos – 18 years who start late or are more than one month behind.

Go to: <http://www2.aap.org/immunization/izschedule.html>