Health-e Bytes™

An eNewsletter published by Hepatitis Foundation International

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Dear Friends,

As we come to the come to the close of 2013, on behalf of the Board of Directors and the National Office Staff of the Hepatitis Foundation International, we take this time to thank you for your support and goodwill which has made our progress possible.

We pause to remember each of you and the contributions you make to our international efforts. During this time of joy and celebration, we also look forward to 2014 with hopeful anticipation that as we begin our 20th year of operation, HFI will be able to offer more services and reach more than the 5 million patients, families, health care providers and communities we did during this past year. We hope the joy of the holidays will fill your hearts and homes with peace, love and health!

Ivonne Perlaza Fuller, CEO
Hepatitis Foundation International

Clinical Trial Process Explained

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Hepatitis Foundation International Selected for Patient Centered Research

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Through collaboration with a team from the Genetic Alliance, Hepatitis Foundation International has been approved for a funding award by the Patient-Centered Outcomes Research Institute (PCORI) to develop and expand a health data network that will be part of PCORnet: the National Patient-Centered National Clinical Research Network, Community-Engaged Network for All (CENA).

This collaboration will test the prospect of recruiting patients from academic medical centers into participant-led models. In addition to the HFI, the other patient support organizations participating in CENA are Alström Syndrome International, Dyskeratosis Congenita Outreach, Inflammatory Breast Cancer Research Foundation, Joubert Syndrome Foundation, KS&A, MLD Foundation, National Gaucher Foundation, National Psoriasis Foundation, and PXE International.

HFI and the other groups were competitively selected earlier this year from nearly 100 Genetic Alliance partners that had applied to take part in the pilot.

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HFI in the Know...

Thiel Invited to Speak at National Prevention Conference

Thelma King Thiel
Chair, Hepatitis Foundation International

At the invitation of SAMHSA's Director of The Center for Substance Abuse Prevention, Frances Harding, Thelma King Thiel, Board Chair of HFI, will conduct a workshop on liver health and hepatitis called "Quick and Easy Memorable Messages Affecting Changes in Behavior."

"I am delighted to have an opportunity to share my commonsensical communication techniques with substance abuse counselors working on the front lines," said Thiel, who received best in show evaluations at prior Prevention Conferences. "Surveys have shown that once individuals are aware of the important role the liver plays in their health, they are motivated to avoid liver damaging behaviors and adopt healthier lifestyle behaviors. This is my goal," commented Thiel.

The Conference is being held at the National Harbor Gaylord Conference Center on February 3rd in conjunction with CADCA 's Annual Leadership Forum. Attendees for the Prevention Day conference must register on the CADCA website; http://www.cadca.org/events/detail/forum2014.

Upcoming HFI Events

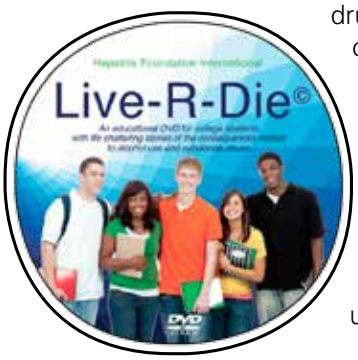
- **Jan 16 - 18** 2014 Gastrointestinal Cancers Symposium, San Francisco, CA
- **Feb 3** SAMHSA's 10th Prevention Day Washington, DC
- **Feb 28** NORD Rare Disease Day Nationwide
- **Mar 12 - 14** Building a Healthier Future 2014 Partnership for a Healthier America, Washington, DC
- **Mar 12-15** Asian Pacific Association for The Study of The Liver Brisbane, Australia
- **Mar 28-30** New Treatments in Chronic Liver Disease, La Jolla, CA
- **Other Important Events** – HFI Calendar

National Health Observances

January 2014

Alzheimer's Disease Awareness Month
Birth Defects Prevention Awareness Month
Blood Donor Month
Cervical Cancer Screening Month
Cervical Health Awareness Month
Glaucoma Awareness Month
Thyroid Awareness Month

19-25	National Non-Smoking Week
19-25	Healthy Weight Week
4	World Braille Day
23	Women's Healthy Weight Day



Live-R Die© educational DVD addresses liver health and the impact binge drinking, drug abuse and other liver damaging behaviors have on young adults specifically college-age students. Powerful images, personal testimonials and comments by Dr. Linda Hancock, Wellness Director, Virginia Commonwealth University and JD Bickel, PharmD from Ohio State University School of Pharmacy encourage the audience to change risky behaviors to prevent the negative consequences of liver damage that is preventable.

A valuable resource for health educators, resident assistants and other teachers of life skills, the DVD fills an identified gap in information available about the important role the liver plays 24/7 and how it can be seriously damaged unintentionally. To order your copy contact Media@HepatitisFoundation.org.

To order the DVD: contact: Media@hepatitisfoundation.org

Live-R-Die © is $15 with $5.00 S & H charge.

Lifestyle...

Obesity's Impact on Kidneys

Researchers at the University of California, San Francisco (UCSF) have shown that declines in kidney function are detectable long before the emergence of other obesity-related diseases and high blood pressure. The team analyzed 10 years of health data from CARDIA (Coronary Artery Risk Development in Yong Adults), a national multi-center research project that has traced the health of thousands of black and white young adults since its beginnings in 1985.

Over 2,891 CARDIA participants included in the study were categorized according to four ranges of body mass index (BMI): normal weight, overweight, obese and extremely obese. The patients averaged 35 years of age and all had normal kidney function in the normal range. However, it was noted, patients with higher BMI were at the lower end of that normal range. According to Vanessa Grubbs, MD of UCSF, when they accounted for diabetes, high blood pressure and inflammatory processes, the body mass index was still a predictor of kidney function decline.

Tighter Regulations Make for Safer Drugs

November 18, 2013, the Senate passed the Drug Quality and Security Act, sending President Obama a bill that will create a drug tracing system and clarify FDA's authority over drug compounding. Sen. Ed Markey (D-MA), one of the first lawmakers to introduce drug compounding legislation following the outbreak that originated in his Congressional district in Massachusetts, said: "For the first time, hospitals and healthcare facilities will have access to safer compounded drugs that are subject to rigorous FDA standards and oversight. Since day one of the tragic outbreak, I have led the investigation into manufacturers that were masquerading as pharmacies and putting the public at risk. This bill will go a long way to ensure that public health is protected and compounded drugs are safe."

The bill creates a category of outsourcing facilities that fall outside the bounds of traditional compounding pharmacies, and are subject to federal registration, fees and reporting requirements.

Plain Soap and Water Still the Best

According to the FDA, data suggest that long-term exposure to certain active ingredients used in anti-bacterial products could pose health risks such as bacterial resistance or hormonal effects. Manufacturers of nonprescription anti-bacterial hand soap and body wash will soon be required to show their products are safe for long-term daily use and are more effective than plain soap in stopping the spread of infections.

Until the FDA takes further action, consumers should make an "educated choice" about what products they use, said Sandra Kweder, MD, Deputy Director of the FDA's Office of New Drugs at the Center for Drug Evaluation and Research. "Washing with plain soap and running water is one of the most important steps consumers can take to avoid getting sick and to prevent spreading germs to others."

Grand Rounds...

Understanding The Clinical Trial Process

During a clinical trial, additional information is learned about an intervention, its risks, and its effectiveness and/or efficacy. See below the process to approve drugs to help develop solutions that will benefit individuals worldwide:

Phase I

Phase I clinical trials primarily test the safety of the investigational drug and how it may interact in the human body of hundred of healthy volunteers for a period of about 2 years. At this point, the drug's dosage range will start to be determined. If these trials show the potential drug is safe, phase II clinical trials can begin.

Phase II

Phase II clinical trials begin testing for safety and efficacy in people who have the condition the drug is designed to treat to determine potential side effects and associated risks. This data is compared to a standard treatment or a placebo to prevent bias. These trials can last several years and often included hundreds of patients. If the drug is shown to be safe and effective, phase 3 clinical trials may begin.

Phase III

Phase III clinical trials attempt to provide definitive proof of safety and efficacy in patients who have the condition the drug aims to treat. These trials may last several years treating thousands of patients to determine the potential risks and benefits associated with the investigational drug and may determine the safety and efficacy in combination with other approved medicines, devices or therapies. If the drug has demonstrated safety and effectiveness, the potential drug may be submitted to the Food and Drug Administration (FDA) for review and approval.

FDA Approval

Upon completion of phase III clinical trials, a pharmaceutical company must submit a New Drug Application (NDA) to the FDA for their determination whether the drug is safe, effective and the benefits of the drug outweigh the risks.

1. Submission of an NDA is the formal step asking the FDA to consider a drug for marketing approval.
2. After an NDA is received, the FDA has 60 days to decide on whether to file it so it can be reviewed.
3. If the FDA files the NDA, an FDA review team is assigned to evaluate the sponsor's research on the drug's safety and effectiveness.
4. The FDA reviews information that goes on a drug's professional labeling (information on how to use the drug).
5. The FDA inspects the facilities where the drug will be manufactured as part of the approval process.
6. FDA reviewers will approve the application or issue a complete response letter.

Reducing Viral Load – Saves Lives

Patients who achieved an undetectable HCV viral load through treatment had decreased hepatic morbidity and mortality long-term, according to Dr. Jeffrey McCombs, PhD, University of Southern California in Los Angeles, (UCLA) and colleagues. Viral suppression was associated with a 45% lower risk of death and a 27% reduced composite risk of newly diagnosed cirrhosis, hepatocellular cancer, and liver-related hospitalization. Suppressed HCV patients in the veterans' population had an unadjusted death rate of 6.8 per 1,000 person-years (95% CI 6-7.7) versus 21.8 per 1,000 person years who did not achieve viral load suppression.

Alerting all Americans to assess their own risk of infection and seek testing is the most important life saving message possible. Individuals can be infected for years before any signs or symptoms appear indicating severe liver damage. However, if identified early in the infection through routine screening programs, treatments can reduce the viral load to improve survivability.

Hepatitis C PHASE III Drugs Treatment Pipeline

These new treatment regimens are approved or are pending approval by the U.S. Food and Drug Administration (FDA). Another round of approvals will likely occur in late 2014 or early 2015.

COMPANY	DRUG	PATIENTS	DOSAGE	TREATMENT	APPROVAL
Boehringer Ingelheim	**Faldaprevir** 2nd generation (protease inhibitor)	HCV/HIV co-infected in advanced liver disease [Genotype 1]	Once daily Oral With or without interferon	**76%** Sustained Viral Response 12 weeks post completion of treatment	PENDING
GILEAD	**Sovaldi [Sofosbuvir]** (Nucleotide analogue)	HCV/HIV co-infected Treatment naïve [Genotype 1]	Once daily Oral Interferon free + ribavirin	Treatment 12- 24 weeks **76%** Sustained Viral Response 12 weeks post treatment	Sovaldi FDA APPROVED 12/7/13
janssen	**Olysio Simeprevir** (protease inhibitor)	Treatment naïve & relapse Those with fibrosis [Genotype 1]	Once daily + Pegalyated interferon + ribavirin	Treatment 24 – 48 weeks **83%** Sustained Viral Response post completion treatment	Olysio FDA APPROVED 11/22/13
abbvie	**3D direct-acting-antiviral regimen:** 1)Ribivarin-ABT-450 (protease inhibitor) 2) ABT-276 (NS5A inhibitor) 3) ABT-333 (non nucleoside polymerase inhibitor)	Treatment naïve Null responders [Genotype 1b]	Once daily Interferon free	**90%** Sustained Viral Respons at 24 weeks **95%** Sustained Viral Response 24 weeks post completion treatment	PENDING
Bristol-Myers Squibb	**Daclatasvir** (NS5A inhibitor) with **Asunaprevir** (Protease inhibitor)	Non Responders, Interferon Intolerant [Genotype 1b]	All Oral Interferon & Ribavirin Free	**84%** Sustained Viral Response at 24 weeks	Approved in Japan PENDING approval in U.S.

Helping Hands

—Holiday Giving—

Remember HFI during your holiday shopping. Amazon will donate 0.5% of the price of your eligible AmazonSmile purchases to Hepatitis Foundation International, Inc. whenever you shop on *AmazonSmile*.

Advocacy Alert:

Representative Bill Cassidy (R-LA) introduced H.R. 3723, the Viral Hepatitis Testing Act of 2013 on December 13, 2013. Representatives Charles Dent (R-PA) and Brett Guthrie (R-KY) signed on as original co-sponsors. This bill would provide $80 million over three years to expand hepatitis B and C education, testing and linkage to care services, with a priority of reaching those most at risk. It also would establish a public-private partnership that would generate additional revenue for viral hepatitis services. Representative Mike Honda (D-CA), released a statement that he will work with Representative Cassidy to find a bipartisan agreement that will ensure passage of the legislation. The HFI will forward additional information on how we can best support these efforts to assure this key piece of legislation is passed.

As part of HFI's efforts to support legislation relevant to the liver wellness community, HFI has developed advocacy initiatives that are consistent with the mission and serves to bolster HFI's efforts to work with key legislative offices, keep the pulse of and promote liver related concerns. HFI has signed on the following letters of support:

- Tri-Caucus Efforts to Reintroduce Health Equity Bill
- Call to Action End Hepatitis C Health Disparities for African Americans
- NORD's Letter to Congressional Leaders
- Casey Burr Letter to Budget Conference
- Orphan Tax Credit to Budget Conference Committee
- NDD's United Letter to Urge Congress to End Sequester
- Senate Special Committee on Aging hearing on Medication labeling
- Campaign Letter to End Obesity Action Fund

For additional information on collaboration and to learn more about HFI's advocacy initiatives contact Advocacy@HepatitisFoundation.org.

T.I.P.S.

- **Qualifying for SSI Disability with HCV**
- **Free Consumer Action Handbook: The New Year is just a few weeks away, and it's never too early to start thinking about your resolutions. Make 2014 your healthiest year yet with a free packet of publications from USA.gov! Get the facts on some of the most common health concerns that could impact you or your loved ones -- like high blood pressure and sleep problems -- and resolve to find healthy ways to manage them. Learn how to recognize and avoid quick fixes including money-saving tips from the Consumer Action Handbook.**