

HCV ADVOCATE WEEKLY NEWS REVIEW

Review of HCV, HBV and HIV/HCV Coinfection Related News and Highlights

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Editor-in-Chief*

Week Ending: November 29, 2008

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Dr. Block's license put on indefinite probation, can continue practice

<http://www.laurinburgexchange.com>

by Matthew Hensley

The state Medical Board ruled on Friday that Dr. Matthew Block can continue to practice medicine, but must adhere to several sanctions.

As part of the signed consent order, Block was placed on indefinite probation and will be required to take an ethics course.

In the order, Block admitted to prescribing drugs to a family member as well as to current and former employees without keeping proper records — all violations.

The consent order does not say that Block was involved in diverting drugs to the family member through his staff, but does say that he should have been aware of the activity as a "reasonable supervisor of his practice."

The consent order suspends Block's license to practice, but immediately stays the suspension, putting Block on indefinite probation.

Block called the decision "harsh," but added that he was glad that he could continue his cardiology practice in Laurinburg.

"My main concern was that I would have to stop practicing," he said Friday afternoon.

"While this is a black mark on my record and what I did was wrong, I am relieved to have this behind me."

The consent order also dismisses the prospect of pursuing additional punishment for the spread of Hepatitis C at Scotland Cardiology, Block's clinic.

State officials linked seven cases of Hepatitis C to Scotland Cardiology, Block's practice.

The board ruled that it was the fault of the technician and that Block's ability to practice medicine should not be impeded.

Dr. Zack Moore, the head of the North Carolina Public Health Department said that it is unlikely that there are patients who have contracted Hepatitis C at Block's clinic outside of the cases reported earlier this year. Moore said that there have been no other clusters found among patients. He indicated that there are still some questions left and the investigation is not over, but he said that, at this point, they are more or less tying up loose ends.

Conditions of Block's probation include:

- Block shall not issue any prescriptions to family members or employees of his office.

- Block shall maintain a proper level of supervision over his employees and shall only permit medical and nursing tasks to be taken by registered nurses and licensed practical nurses licensed and in good standing.
- Block will maintain complete, timely and thorough medical records on all patients.
- Block must also take the Vanderbilt Prescribing Course and a course on ethics within one year.

Failure to comply with any aspect of this consent order will land Block back in front of the board with the possibility of his medical license being revoked.

Block was initially accused of writing over 100 prescriptions for a range of psychoactive drugs to a family member suffering from alcohol abuse, bipolar disorder, chronic kidney disease and other ailments. He was also accused of prescribing drugs to five current and former employees, including two that were diverting drugs to the family member.

Inside-out cells offer target for antiviral drugs

www.reuters.com

CHICAGO, Nov 23 (Reuters) - An experimental drug cured guinea pigs infected with a fatal hemorrhagic fever virus, raising hope for its use in a broad range of viral diseases including influenza, hepatitis C, HIV, Ebola and others, U.S. researchers said on Sunday.

"This is a whole new strategy for making antiviral drugs," said Dr. Philip Thorpe, professor of pharmacology at the University of Texas Southwestern Medical Center at Dallas, whose research appears in the journal *Nature Medicine*.

Instead of attacking the virus directly, bavituximab, made by Peregrine Pharmaceuticals Inc (PPHM.O: Quote, Profile, Research, Stock Buzz), takes advantage of a defense mechanism used by the virus to hide from the immune system, Thorpe said.

When cells are under attack by a virus, this stress causes a fat molecule called phosphatidylserine, which normally lines the inside of the cell, to flip to the outside. "It's like wearing your clothes inside out," Thorpe, a scientific adviser to Peregrine, said in a telephone interview.

Bavituximab, a genetically engineered antibody, seeks out and attaches itself to these turncoat cells, flagging them for the immune system, which can then mount an attack,

"When injected into the bloodstream, bavituximab circulates in the body until it finds these inside-out lipids and then binds to them," Thorpe said in a statement.

"In the case of virus infection, the binding raises a red flag to the body's immune system, forcing the deployment of defensive white blood cells to attack the infected cells."

Thorpe said conventional antiviral drugs try to exploit some property of the virus, but these drugs are often quickly defeated as the virus mutates.

By targeting an aspect of infected cells in the host, he thinks bavituximab is less likely to lose effectiveness, which commonly happens when a virus mutates.

In the study, Thorpe and his colleagues tested the compound on guinea pigs in an advanced stage of infection with a form of the Lassa fever virus, a disease that affects parts of West Africa.

Half of the animals treated with the drug alone were cured. When the researchers tested it in combination with the antiviral drug ribavirin, a drug that keeps a virus from replicating, 63 percent of the guinea pigs lived.

Thorpe said the findings suggest the drug might be effective on other types of hemorrhagic viruses, such as Ebola and Marburg. But this lipid flipping also occurs in cells infected with many other viral infections, including influenza, smallpox and rabies.

Peregrine is conducting early phase clinical trials of the drug in people with hepatitis C and human immunodeficiency virus, or HIV, which causes AIDS. And it has more advanced trials under way in cancer.

"We think it has tremendous potential," Steven King, president and chief executive of Peregrine, said in a telephone interview. Peregrine funded the research along with the National Institutes of Health. (Editing by Will Dunham and Todd Eastham)

Nov 24, 2008

The End of Peer Review and Traditional Publishing as We Know It

www.medscape.com

Peter Frishauf, MS

Two predictions:

Within 5 years, most medical journals will be open-access. That means every journal will do what *Medscape* has done since day 1 in May 1995: provide access to trusted articles and data at no cost.

Peer review as we know it will disappear. Rather than the secretive prepublication review process followed by most publishers today, including *Medscape*, most peer review will occur transparently, and after publication.

How will this look?

Three years ago I predicted medical articles in the future will look a lot like Wikipedia,[1] an encyclopedia with millions of user-created articles in 253 languages.[2] Today Wikipedia is the most referenced repository of information on the Web. Any user can start an article, link it to related sources, and publish revisions with a click of the mouse. Anyone who reads an article can edit it.

Wikipedia articles must be written with a neutral point of view -- NPOV: Anything not NPOV is quickly deleted. On Wikipedia, readers don't have to wade through thousands of articles written by a handful of authors. You read a single living article constantly updated, corrected, and improved by thousands.

Each Wikipedia community adopts its own quality controls. In German-language Wikipedia, anyone can edit an article, but it is only visible to the world at large after a trusted group of Wikipedians say the contributions are good.[3] Trust is gained by the number of contributions made that are not corrected. Changes are measured by a mathematical formula created by computer scientists and semantic intelligence experts.[4] It's more objective than traditional peer review, which is often clubby, biased, and incomplete.

Andrew Grove, the computer scientist who brought microprocessors to the masses at Intel Corporation, likens traditional peer-review systems to Middle Ages guilds. He calls for a "cultural revolution" in publishing to reinvent peer review.[5]

That revolution will emerge as a variant of Wikipedia. Medical publishing, peer review, research, patient care, and commerce will be transformed. And for the better.

That's my opinion. I'm Peter Frishauf, founder of Medscape.

Fibromyalgia patients show brain abnormalities

www.reuters.com

NEW YORK (Reuters Health) - French researchers have shown that patients with fibromyalgia have abnormal blood flow in the brain, which may be related to the underlying cause of the condition.

"We found brain functional differences between patients with fibromyalgia and those who do not have the disorder," lead investigator Dr. Eric Guedj told Reuters Health. "These brain functional abnormalities were correlated with the severity of the disease, but not with anxiety or depression, in regions of the brain known to be involved in pain processing."

To visualize these abnormalities, the researchers used single photon emission computed tomography (SPECT), a special type of CT scanning test in which a small amount of a radioactive compound is injected into a vein. This allows SPECT to make a detailed image of areas in which the radioactive material is taken up by the cells, providing information about blood flow to tissues and metabolism in the body.

Guedj of Center Hospitalo-Universitaire de la Timone, Marseilles, and colleagues studied 20 patients with fibromyalgia and 10 healthy individuals. The findings are reported in the *Journal of Nuclear Medicine*.

Overall, the findings "suggest that fibromyalgia may be defined as a brain functional disorder involving these regions," Guedj concluded.

The underlying cause of fibromyalgia is not known. Previously the classification of fibromyalgia has been questioned by some and thought by others to be associated with depression. Other possible causes are sleep disorders, infection, abnormalities of the nervous system and changes in muscle metabolism.

SOURCE: Journal of Nuclear Medicine, November 2008.

Peginterferon-induced depression is reversible

www.reuters.com

NEW YORK (Reuters Health) - Depression related to peginterferon therapy for chronic hepatitis C increases with duration of use, but reverses following treatment cessation, according to members of the Hepatitis C Antiviral Long-term Treatment against Cirrhosis trial.

After 48 weeks of therapy, 42 percent of the patients developed depression. Pre-existing depression and potential biomarkers of depression, such as blood levels of cortisol and the neurotransmitter serotonin, were associated with neurological or psychiatric side effects, the group reports in the *American Journal of Gastroenterology*.

"Depression is a common and dose-limiting side effect of antiviral treatment in hepatitis C patients," Dr. Robert J. Fontana, at the University of Michigan in Ann Arbor, and co-authors note. Their goal in the current analysis was to elucidate the incidence, risk factors, and biological basis for this condition.

Included were 201 patients with chronic hepatitis C and advanced fibrosis who previously didn't respond to treatment. The patients were treated with peginterferon alfa-2a and ribavirin for 24 weeks. The 74 patients who had undetectable hepatitis C virus (HCV) RNA at week 20 continued at the same doses to complete 48 weeks of antiviral treatment.

The cumulative incidence of peginterferon-induced depression was 23 percent at week 24, with the absence of a virological response at week 20 the only identified independent predictor.

According to the authors, this finding may be due, at least in part, to "the expected negative impact that the knowledge of persistent viremia could have on a patient's mood."

Among the 74 responders, the incidence of treatment-related depression was 9 percent at week 24, increasing to 42 percent by week 48. By week 72, however, mean scores on the Beck Depression Inventory-II "returned to pretreatment baseline levels...demonstrating the reversibility of interferon-induced depression."

Pre-existing depression was not associated with an increased risk of therapy-induced depression, the authors note. Morning plasma cortisol levels remained stable over time, indicating that alterations in the hypothalamic-pituitary-adrenal axis were not responsible for the changes in mood.

Even though normalized serotonin levels did decline significantly during therapy, these changes did not track with the development of peginterferon-induced depression. Nevertheless, Fontana's team concludes, additional studies of the pathways of serotonin are "warranted to identify the mediators of interferon-induced depression."

SOURCE: American Journal of Gastroenterology, November 2008.

Nov 25, 2008

U.S. women less likely for liver transplants: study

www.reuters.com

CHICAGO (Reuters) - Women are less likely than men in the United States to get a life-saving liver transplant, perhaps because of physical differences between the two sexes, according to a study published on Tuesday.

The report from Dr. Cynthia Moylan and colleagues at Duke University Medical Center in Durham, North Carolina, also found that blacks have gained a more equal footing with whites for liver transplants since 2002, when a new system was put in place emphasizing severity of disease rather than length of time on a waiting list.

That same screening system has not helped women, said the study, which was published in this week's Journal of the American Medical Association. It looked at more than 45,000 patients who were waiting for liver transplants before and after the system was changed in 2002.

The research team found that women were less likely than men to receive a transplant within three years of being put on a wait list under both the old and new systems.

"Sex differences persist despite the (new system)," the authors said. "Whether these differences result from true anatomic differences or represent a problem not addressed by the use of the (system) mandates further investigation."

In an editorial in the same issue commenting on the study, Drs. David Axelrod of Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire, and Elizabeth Pomfret of the Lahey Clinic Medical Center in Burlington, Massachusetts, said women may get fewer transplants because of size differences.

"Women are smaller, limiting the pool of available organs," they said. When a smaller liver becomes available it often goes instead to a child waiting for a transplant.

"In addition a small organ can be used in a larger individual but the converse is not always possible," they said.

Another factor may be that one of the liver function measurements used to determine extent of the disease may show up at less severe levels in women because of their lesser body mass, the editorialists said.

The study found the odds of death or becoming too sick for a transplant were higher for blacks than whites before the screening change was made but that difference disappeared under the new system.

The authors said that is likely because blacks -- who have a higher incidence of liver problems to begin with -- tend to have more advanced stages of the disease by the time they are put on a waiting list.

Because the new system is based on risk of death rather than time on the list, that has helped equalize things. But the authors said blacks still face health care barriers, such as insurance and access to specialists, which result in delays in getting care.

In 2005 there were 6,500 liver transplants performed in the United States.

(Editing by Andrew Stern and Bill Trott)

Schering-Plough Provides Update on Boceprevir Clinical Development and Introduces Potent Next-Generation Oral HCV Protease Inhibitor for Treating Patients With Chronic Hepatitis C

<http://biz.yahoo.com>

Company reaffirms its innovation leadership and long-term commitment to hepatitis research

KENILWORTH, N.J., Nov. 24 /PRNewswire-FirstCall/ -- Schering-Plough Corporation (NYSE: SGP - News) today provided a clinical update on boceprevir, its lead investigational oral hepatitis C protease inhibitor currently in Phase III development. The company believes boceprevir has the potential to be a first-in-class and best-in-class protease inhibitor for treating chronic hepatitis C. The company also announced that it is developing a highly potent next-generation oral hepatitis C protease inhibitor that has future best-in-class potential. The compound, known as SCH 900518 is currently in Phase IIa clinical development. The update was presented today as part of the company's 2008 R&D Update meeting at its headquarters in Kenilworth, N.J.

"As pioneers in the hepatitis field, our vision is to apply our experience and innovation, as we have in the past, to continue to redefine and improve treatments for chronic hepatitis C, in the near term and in the future," said Thomas P. Koestler, Ph.D., executive vice president and president, Schering-Plough Research Institute.

The company reported for the first time that in a Phase II study, a 48-week boceprevir regimen achieved an unprecedented 75 percent sustained virologic response (SVR) rate at 24 weeks after the end of treatment (SVR 24) in patients who received 4 weeks of PEGINTRON(TM) (peginterferon alfa-2b) and REBETOL® (ribavirin, USP) prior to the addition of boceprevir (800 mg TID) (P/R lead-in). This represents a near doubling of the 38 percent SVR 24 rate for patients in the control group receiving 48-weeks of PEGINTRON and REBETOL alone (ITT).(1,2) In a 28-week boceprevir P/R lead-in regimen, the SVR 24 rate was 56 percent. Importantly, for patients who received the boceprevir P/R lead-in regimen and had rapid virologic response (RVR), defined as undetectable virus (HCV-RNA) in plasma after 4 weeks of boceprevir treatment, SVR was 94 percent in the 48 week regimen and 82 percent in the 28-week regimen. RVR has been shown to be a reliable predictor for achieving SVR. These final results are from the HCV SPRINT-1 study in 595 treatment-naive patients with chronic hepatitis C virus (HCV) genotype 1.

"We are very encouraged by the strong boceprevir results to date. We look forward to our ongoing Phase III studies, which are designed to demonstrate that boceprevir has the potential to

benefit a broad range of patients by significantly increasing sustained response rates with a potentially shorter course of treatment," Koestler said.

He noted that the company has now completed patient enrollment in the HCV RESPOND-2 study, a pivotal Phase III study in patients who failed prior treatment, and has screened more than 1,200 patients in the HCV SPRINT-2 study, a pivotal Phase III study in treatment-naive patients.

Next-Generation HCV Protease Inhibitor SCH 900518

As part of its long-term commitment to hepatitis C therapy, Schering-Plough also is developing SCH 900518 ("518"), a next-generation HCV protease inhibitor. A Phase IIa study with 518, known as the NEXT-1 study, is currently ongoing. The company said that 518 has been shown to be 10 times more potent in-vitro than other protease inhibitors currently in Phase III development and has the potential for once daily dosing. 518 also has shown decreased emergence of resistance in vitro. Given its pharmacokinetic (PK) profile, the company anticipates that 518 may be active against some HCV strains that are resistant to other protease inhibitors. Phase I proof of concept studies with 518 in treatment-naive patients and those who failed prior treatment, both as monotherapy and in combination with peginterferon (without ribavirin), demonstrated enhanced antiviral activity, with up to 4 log₁₀ and 5 log₁₀ decreases in circulating HCV, respectively.

Full results of the boceprevir HCV SPRINT-1 study and early phase clinical results with SCH 900518 are being submitted for presentation at a future medical meeting.

About the Boceprevir HCV SPRINT-1 Study

In this Phase II study, known as HCV SPRINT-1 (HCV Serine Protease Inhibitor Therapy-1), boceprevir (800 mg TID) was evaluated in three treatment regimens: 4 weeks of PEGINTRON (1.5 mcg/kg once weekly) and REBETOL (800-1400 mg daily based on patient weight) therapy followed by the addition of boceprevir to the combination for 24 or 44 weeks (totaling 28 or 48 weeks of treatment), boceprevir in combination with PEGINTRON and REBETOL at the doses described above for 28 or 48 weeks, and, in Part II of the study, boceprevir in combination with PEGINTRON and low-dose REBETOL (400-1000 mg daily based on patient weight) for 48 weeks, compared to a control of PEGINTRON (1.5 mcg/kg once weekly) and REBETOL (800-1400 mg daily based on patient weight) alone for 48 weeks (an approved treatment regimen). The primary endpoint of the study is SVR after 24 weeks of follow up (SVR 24). SVR rates are not yet available for Part II of this study evaluating boceprevir with low-dose REBETOL (n=59) compared to contemporaneous control (n=16) as described above.

About Boceprevir Phase III Studies

Schering-Plough is conducting two large ongoing pivotal Phase III studies of boceprevir in patients chronically infected with HCV genotype 1. One study is in treatment-naive patients and the other in patients who failed prior treatment (relapsers and nonresponders). The two randomized, double-blind, placebo-controlled studies evaluate the efficacy of boceprevir in combination with PEGINTRON and REBETOL compared to standard of care with PEGINTRON and REBETOL alone.

The study in treatment-naive patients is known as HCV SPRINT-2 and the study in patients who failed prior treatment is known as HCV RESPOND-2. The two studies are expected to enroll a total of more than 1,400 patients at U.S. and international sites.

For more information about these ongoing Phase III studies, please visit www.clinicaltrials.gov , search term boceprevir.

Endnotes

1. SVR, the protocol specified primary efficacy endpoint, is defined as achievement of undetectable HCV-RNA at 24 weeks after the end of treatment. Per protocol, if a patient does not have a 24-week post-treatment assessment, the patient's 12-week post-treatment assessment will be utilized.
2. Intention-To-Treat (ITT) analysis includes any patient who has taken at least one dose of any study drug.

Source: Schering-Plough Corporation

Valeant Reports Encouraging End of Treatment Results with Taribavirin at Treatment Week 48 in Phase IIb Study

www.marketwatch.com

-- Continues to Demonstrate Similar Efficacy to Ribavirin with Lower Anemia --

ALISO VIEJO, Calif.--(BUSINESS WIRE)--Valeant Pharmaceuticals (NYSE:VRX - News) today reported results at end of treatment, week 48 analysis point in the Phase IIb clinical trial for its antiviral compound, taribavirin, a prodrug of ribavirin in development for the treatment of chronic hepatitis C in conjunction with a pegylated interferon. Similar to the treatment week 12 results reported earlier this year, the 48-week viral response (EOT) data continue to show comparable reductions in viral load for weight-based doses of taribavirin and ribavirin. The anemia rate was statistically significantly lower for patients receiving taribavirin in the 20mg/kg and 25mg/kg arms versus the ribavirin control arm.

In the Phase IIb study, 278 treatment naïve, genotype 1 patients were randomized with the following patient demographics: mean age 48.8 yr, 61.1% male, 30% African-American or Latino, 80.7% viral load $\geq 400,000$ IU/mL and 82.1 kg mean weight. Treatment week (TW) 48 efficacy and safety results for the intention-to-treat (ITT) population are shown in the table below.

“The results of this phase II study are encouraging, and suggest that comparable efficacy on therapy can be achieved when compared to ribavirin,” stated Fred Poordad, M.D., Chief of Hepatology at the Center for Liver Disease and Transplantation, Cedars-Sinai Medical Center, Los Angeles, CA. “If the sustained response rates are also similar with less anemia, this will be a significant step forward in the development of taribavirin.”

“We are pleased that the 48-week data continues to demonstrate sustained comparable efficacy between taribavirin and ribavirin given that the genotype 1 group is a difficult to treat population and a third of the patients in this study were either African-American or Latino,” said J. Michael Pearson, chairman and chief executive officer. “We believe that taribavirin will be a promising alternative to ribavirin in the treatment of chronic hepatitis C and, with Valeant’s strategic shift

away from the infectious disease market, we plan to out-license this compound in order to maximize its potential for these patients.”

Key Efficacy and Safety Data Table at Treatment Week 48 (ITT Population)

	Phase IIb			
	TBV 20 mg/kg n=67	TBV 25 mg/kg n=70	TBV 30 mg/kg n=68	RBV 800-1400mg n=70
TW4				
Undetectable ¹	11 (16.4%)	10 (14.3%)	11 (16.2%)	8 (11.4%)
TW12				
Undetectable ¹	28 (41.8%)	29 (41.4%)	17 (25.0%)	22 (31.4%)
TW24				
Undetectable ¹	35 (52.2%)	29 (41.4%)	27 (39.7%)	28 (40.0%)
TW48				
Undetectable ¹	29 (43.4%)	23 (32.9%) ³	20 (29.4%)	23 (32.9%)
Anemia rate TW 48 ²	9 (13.4%)*	11 (15.7%)**	19 (27.9%)	23 (32.9%)

¹ HCV RNA < 39 IU/mL

² Anemia rate defined as percentage of patients with Hgb level <10g/dL.

³ Includes data on two patients who were virus undetectable at TW36 and FW52, but missed TW48 assessment

*p=0.009

**p=0.03

The most common adverse events were fatigue, nausea, flu-like symptoms, headache and diarrhea. The incidence rates among treatment arms were generally comparable except with respect to diarrhea, where diarrhea was approximately twice as common in taribavirin patients as ribavirin patients. However, the diarrhea was generally mild and not treatment limiting for taribavirin or ribavirin patients.

The Phase IIb trial is a U.S. multi-center, randomized, parallel, open-label study in 278 treatment-naïve, genotype 1 patients evaluating taribavirin at 20 mg/kg, 25 mg/kg, and 30 mg/kg per day in combination with pegylated interferon alfa-2b. The control group is being administered weight-based dose ribavirin (800/1000/1200/1400mg daily) and pegylated interferon alfa-2b. Overall treatment duration is 48 weeks with a post-treatment follow-up period of 24 weeks.

About Taribavirin

Taribavirin is an investigational compound that has not been found by the Food and Drug Administration (FDA) or any other regulatory agency to be safe or effective in the diagnosis, mitigation, treatment or cure of any disease or illness. It may not be sold or promoted in the United States unless and until FDA has approved a New Drug Application. Similar restrictions apply in other countries.

About Valeant

Valeant Pharmaceuticals International (NYSE: VRX - News) is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of neurology and dermatology. More information about Valeant can be found at www.valeant.com.

Source: Valeant Pharmaceuticals

Indiana Addresses Viral Hepatitis

<http://www.emaxhealth.com>

State health officials say between 3.5 to 4 million Americans are living with viral hepatitis. In 2006, there were 4,723 reported cases of chronic and acute hepatitis C in Indiana, as well as 80 cases of hepatitis B, 33 cases of hepatitis A, and one case of hepatitis E. To address the problem in the state, the Indiana Viral Hepatitis Advisory Council has released "Indiana's Strategic Plan for the Prevention, Care, and Elimination of Viral Hepatitis."

"The purpose of the plan is to help our state move forward in raising awareness of viral hepatitis, to provide additional education and support for those living with the disease and their loved ones, and to ultimately reduce the burden of viral hepatitis in Indiana," said State Health Commissioner Judy Monroe, M.D.

"I applaud the members of the Indiana Viral Hepatitis Advisory Council for their hard work and dedication in developing this plan," said Dr. Monroe. "I am confident the initiatives outlined in the plan will help increase the public's understanding of viral hepatitis and help Hoosiers to avoid getting sick."

The "Strategic Plan for the Prevention, Care, and Elimination of Viral Hepatitis" is divided into four main principles: surveillance; prevention and education; comprehensive care; and grants, legislation, and policy. Each section includes objectives and action items guiding specific goals.

Hepatitis is an inflammation of the liver. The liver is the body's largest internal organ and filters everything that an individual eats, breathes, absorbs through the skin, or comes in contact with. Many things can cause the liver to become inflamed, but the most common sources are hepatitis A, B, and C. Hepatitis D and E are serious but less common forms of hepatitis. Hepatitis D is only found in individuals who are already infected with hepatitis B and hepatitis E is extremely rare in the United States:

- **Hepatitis A** is a liver disease that can cause tiredness, stomach pain, nausea, diarrhea and jaundice. It rarely causes long-term damage or death. It can be spread by eating or drinking contaminated food or water, or by eating something contaminated by an already infected person. The best protection is frequent and thorough hand washing. Be sure to also cook food thoroughly, especially meat. A vaccine is available for this disease.
- **Hepatitis B** is a serious disease of the liver that can lead to severe illness, liver damage or even death. It is spread by direct contact with blood or certain body fluids of an already infected person. It can also be spread through shared household items like razors or toothbrushes. A safe and effective vaccine is available and recommended for all children and other at risk individuals.
- **Hepatitis C** is a liver disease found in the blood of infected people. It is primarily spread through direct contact with the blood of an infected person. Symptoms include a yellowing of the skin and eyes, nausea, vomiting, fever and tiredness. Most people with hepatitis C have no symptoms, but can still infect others, while others become very ill and some may never fully recover.

In addition to representatives from the Indiana State Department of Health, the Council comprises representatives of the American Liver Foundation, the Centers for Disease Control and Prevention (CDC), the Citizens Health Center, Dialysis Centers, Inc., the Family and Social Services Administration, the Fort Wayne-Allen County Department of Health, the Henry County Health Department, the Indiana Department of Correction, the Indiana Immunization Coalition, the Indiana University Medical Center, the Marion County Health Department, Matthew 25 Health and Dental, and the Richard L. Roudebush Veterans Administration Medical Center.

Source: Indiana Department Of Health

Schering-Plough to develop new oral hepatitis drug

<http://www.tradingmarkets.com>

Schering-Plough, a science-based healthcare company, has announced that it is developing a highly potent next-generation oral hepatitis C protease inhibitor that has future best-in-class potential.

As part of its long-term commitment to hepatitis C therapy, Schering-Plough is developing SCH 900518 (518), a next-generation hepatitis C virus (HCV) protease inhibitor. A Phase IIa study with 518, known as the Next-1 study, is currently ongoing.

The company said that 518 has been shown to be 10 times more potent in-vitro than other protease inhibitors currently in Phase III development and has the potential for once daily dosing. The protease inhibitor also has shown decreased emergence of resistance in vitro. Given its pharmacokinetic profile, the company anticipates that 518 may be active against some HCV strains that are resistant to other protease inhibitors.

Phase I proof of concept studies with 518 in treatment-naive patients and those who failed prior treatment, both as monotherapy and in combination with peginterferon, demonstrated enhanced antiviral activity, with up to 4log₁₀ and 5log₁₀ decreases in circulating HCV, respectively, the company said.

Nov 26, 2008

Hepatocellular Carcinoma Patients Have High Prevalence of Diabetes

www.medscape.com

NEW YORK (Reuters Health) Nov 14 - Patients with hepatocellular carcinoma (HCC) have a significantly higher prevalence of type 2 diabetes mellitus (DM) compared to the general population, according to findings from a case-control study conducted in Italy.

"The association of type 2 diabetes mellitus (DM2) ... with hepatocellular carcinoma (HCC) has been long suspected," Dr. Valter Donadon, at Pordenone Hospital, and co-authors note in the October 7 issue of the *World Journal of Gastroenterology*. "However, the temporal relationship between onset of diabetes and development of HCC, and the clinical and metabolic characteristics of patients with DM2 and HCC have not been well examined."

Their study included 465 consecutive Caucasian HCC patients and 490 age- and sex-matched controls.

Overall, 145 hepatocellular carcinoma patients (31%) and 62 control cases (13%) had type 2 diabetes (odds ratio 3.1). Moreover, the authors note, diabetes had been diagnosed at least 6 months prior to the diagnosis of hepatocellular carcinoma in 84% of cases, suggesting that diabetes may be a cause rather than a consequence of liver cancer.

Men with DM and HCC were more likely to be treated with insulin than male diabetics in the control group (38% vs 18%, $p = 0.009$), leading the researchers to recommend "close surveillance for HCC in patients with chronic liver disease and DM2, particularly (among) males and (those) treated with insulin."

They also advise that metabolic control be attempted with insulin-sensitizers, such as metformin and glitazones, in preference to insulin or oral secretagogues.

World J Gastroenterol 2008;14:5695-5700.

Milestone in cancer war: For the first time, rate of new cases in both men and women is declining

<http://www.chron.com>

By JUDITH GRAHAM McClatchy-Tribune

By the Numbers

A new report has found that cancer incidence – the rate at which new illnesses are diagnosed – is declining:

- New cases: Cancer incidence dropped 0.8 percent annually between 1999 and 2006, a small but statistically significant reduction.
- Deaths: A 15-year decline in cancer death rates accelerated between 2002 and 2005, approaching nearly 2 percent a year. Patients are living longer.

CHICAGO — The United States has passed an important milestone in the fight against cancer, researchers reported Tuesday: For the first time, the recorded rate of new cancer cases has fallen for both men and women.

At the same time, a 15-year decline in cancer death rates has accelerated, meaning people in whom the disease has been diagnosed are living longer.

The report, published online Tuesday in the *Journal of the National Cancer Institute*, found the leading cancer scourges – including lung cancer, colon cancer and breast cancer – are on the wane, prompting experts to conclude that aggressive cancer-prevention and treatment efforts are paying off against the nation's No. 2 killer.

If the trend holds, people may hear the words "it's cancer" from their doctors less frequently in the years ahead.

"The drop in incidence seen in this year's annual report is something we've been waiting to see for a long time," Dr. Otis Brawley, chief medical officer of the American Cancer Society, said in a statement.

While heralding the development, Brawley and other cancer experts sounded notes of caution. Fewer men and women are being screened for prostate and breast cancer, they noted, which can mean fewer tumors get identified. And as the population ages and the economy worsens, access to screening and medical treatments may decrease, eroding the gains.

The downward trend in new cancer diagnoses spans several years and was teased out through careful statistical analysis by researchers from the American Cancer Society, the National Cancer Institute, the U.S. Centers for Disease Control and Prevention and the North American Association of Central Cancer Registries.

"What we're seeing is clear evidence that cancer prevention is working," said Dr. Therese Bevers, medical director of clinical cancer prevention at M.D. Anderson Cancer Center.

Death rates fall

Cancer death rates have been falling since 1993, but the report found that the rate of decline accelerated between 2002 and 2005, approaching nearly 2 percent a year. Experts credit more effective therapies and improved detection.

The positive trends don't apply to all types of cancer. New cases are up for myeloma, non-Hodgkin lymphoma, melanoma, and cancers of the liver, kidney and esophagus. Death rates have risen for esophageal cancer in men, pancreatic cancer in women, and liver cancer for men and women.

Esophageal and liver cancers appear to be related to obesity, which is on the rise in the U.S., and liver cancers also may be associated with hepatitis C, which thousands of drug users contracted in the 1960s and 1970s.

Nonetheless, the latest numbers underscore important victories in the war against cancer.

New cases of lung cancer, the second-most common cancer diagnosis for men and women, have skidded to their lowest level in more than 30 years for both sexes as increasing numbers of men and women have given up smoking. This month, the CDC reported the number of adults who smoke has dropped below 20 percent.

Meanwhile, new cases of colon cancer fell by more than 2 percent annually for men and women between 1998 and 2005, which experts attribute to more adults getting screened. By 2005, half of all adults 50 and older were being checked for colon cancer, up from 27 percent in 1987.

Why would more colon screenings mean fewer cases of cancer? Screening for this disease often allows pre-cancerous polyps to be detected and removed before colon cancer gets established. Colon cancer is the third-most common cancer diagnosis for men and women.

PSA tests down

Less clear is the story surrounding prostate cancer, the No. 1 cancer for men, whose incidence rates plunged 4.4 percent annually between 2001 and 2005 after rising 2.1 percent in each of the previous six years.

Because it's highly unlikely that risk factors for prostate cancer changed dramatically during that period, the drop-off is "probably due to changes in detection practices," said Ahmedin Jemal, director of cancer surveillance for the American Cancer Society.

Dr. William Catalona, a professor of urology at Northwestern University's Feinberg School of Medicine, cites data indicating that 52 percent of men 50 or older reported having a test for PSA (prostate-specific antigen) in 2004, down from 58 percent in 2001.

The picture for breast cancer, the No. 1 cancer for women, is similarly mixed.

Two years ago, researchers from M.D. Anderson announced a surprising 7 percent drop in breast cancer cases, which coincided with sharp reductions in women's use of hormone replacement therapy.

But the new report shows that new breast cancer cases fell 2.2 percent a year between 1999 and 2005, indicating the drop started several years before hormone replacement therapy became an issue. That suggests other factors are also involved.

Nov 27, 2008

Hepatitis C Educators workshop at Wilcox Hospital

<http://www.kauaiworld.com>

By The Garden Island

Malama Pono in partnership with the state Department of Health, Kaua'i Medical Clinic, Wilcox Memorial Hospital and the Hepatitis C Support Project of San Francisco presents the Hepatitis C Educators workshop from 8 a.m. to 4:30 p.m., Dec. 12, at Wilcox Hospital conference rooms B & C, a news release states.

Instructor Alan Franciscus has designed this all-day workshop for any person concerned about or working with Kaua'i's estimated 1,500 residents living with Hepatitis C. A complete overview of the disease, its health implications and medical treatments, whether traditional or complementary, will be presented.

Successful participants will be awarded certification as a Hepatitis C Educator and would be prepared to guide and educate persons infected with the Hepatitis C virus. Six hours of continuing education credit will also be awarded to substance abuse counselors. The workshop is free and includes lunch plus morning and afternoon refreshments.

Malama Pono's mission is to stop the spread of this disease and even eliminate it, if possible. It's a blood borne virus that is responsible for much of the liver failure and liver cancer on Kaua'i.

According to Peter Whiticar, branch chief of the Department of Health STD/AIDS division, "chronic infectious hepatitis is the leading cause of liver cancer of which Hawai'i has the highest

rate in the nation. The rate of hepatitis C-related deaths in Hawai‘i is expected to triple in the next 10 years. A cure for the disease was announced in late 2007, but not all patients are good candidates for therapy. In addition, it appears that nearly 900 of those infected with Hepatitis C on Kaua‘i don’t even know they carry the virus.”

The Hepatitis C Educator workshop is one in the series of Dr. Jimmy Yoon’s Infectious Disease Seminars being presented to Kaua‘i’s medical and lay community throughout 2008 and 2009.

For more information or registration forms prior to the Dec. 10 deadline, contact Malama Pono Executive Director D.Q. Jackson at 246-9577 or e-mail dq@malama-pono.org

Chief angry after officer injured by needle during traffic stop

<http://www.phillyburbs.com>

By GEORGE MATTAR

Bucks County Courier Times

Tullytown police Chief Patrick Priore is livid and warns that anyone caught with illegal drugs in his town is going to jail if he has anything to say about it.

“I am very angry. A routine traffic stop turns into a nightmare and one of my officers gets stabbed with a needle and the person has Hepatitis C,” Priore said Wednesday. “I am not happy right now.”

The incident Priore is talking about took place about 1 p.m. Tuesday when Officer John Finby stopped a Buick Rendezvous with four people inside for allegedly speeding on Levittown Parkway. The vehicle was traveling 60 mph, nearly twice the 35 mph speed limit, Finby said.

The officer said he noticed blood droplets between the two rear seat passengers, and asked all to get out of the vehicle.

He said he was questioning rear seat passenger Michael Mungavin, 28, of Bristol and asked if he had any possessions on him. Mungavin said no, the officer said. Police said as Finby searched Mungavin's seat behind the driver, the cop's gloved hand hit an uncapped needle that was lodged in the seat. The bare needle pierced through the glove and jabbed into Finby's hand.

During Mungavin's arraignment Tuesday night, Finby said he believed the needle was positioned so that he'd be stabbed if he looked for it. Several other needles in the car were capped. It was initially reported that the suspect stabbed the officer, however Finby was injured during a search of the car, Priore said.

The patrolman said all four occupants of the car told him they are positive for Hepatitis C and share the same needle while doing drugs. Finby said he had no idea if the four are being treated for the disease.

A second suspect, who gave police a first name of Jennie, was later identified as Jessica Lynn Shaddinger, 23, of Morrisville, Finby said. She was arraigned by District Judge Joanne V. Kline

and sent to Bucks County prison in lieu of \$20,000 bail on a charge of possession of drug paraphernalia.

The driver, whose name was not released, was cited for speeding and not carrying a valid driver's license. He was let go pending further investigation. Police said the Buick was properly registered, insured and inspected. The fourth person also was let go and not charged with anything.

Mungavin, who failed to show up for a hearing in March on an unrelated matter and has other cases pending, was sent to prison by Kline in lieu of \$50,000 bail Tuesday. He's charged with giving false information to authorities and possession of drug paraphernalia. Finby added Mungavin had three empty baggies in his possession with residue inside. The residue is being tested to determine if it's an illegal drug.

FYI

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV). HCV infection sometimes results in an acute illness, but most often becomes a chronic condition that can lead to cirrhosis of the liver and liver cancer.

It is transmitted through contact with the blood of an infected person. There is no vaccine for this disease. The best way to prevent hepatitis C is by avoiding behaviors that can spread the disease, especially injection drug use.

Source: Centers for Disease Control and Prevention

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Nov 28, 2008

Health Professionals At Risk Of Bloodborne Viruses

<http://www.emaxhealth.com>

Healthcare workers are still being put at risk of bloodborne viruses through occupational exposure and a significant number of these incidents are preventable, according to a report released today by the Health Protection Agency.

'Eye of the Needle', the Agency's bi-annual report into the occupational exposure of healthcare workers to bloodborne viruses, reviews the trends and number of incidents involving exposures, via needlestick injury or sharp objects, to patients with hepatitis B, hepatitis C and HIV.

In total there were 914 incidents where healthcare workers were put at risk, over the last two years (2006/2007). Four healthcare workers were reported as having acquired hepatitis C infection as a result of their injury.

Between 2000 and 2007, most occupational exposures involved nursing professionals (48% 1447/3039). A recent report by the Royal College of Nursing showed the concerns of nursing staff about occupational exposure to bloodborne viruses and how one third of them feel at risk of contracting diseases such as HIV and hepatitis C following such injuries. Latest figures collected

by the Agency for 2007 show that, for the first time, medical and dental professionals reported a higher proportion of significant occupational exposures to bloodborne viruses (46% compared with 44% among nursing staff).

The Agency's research found that some healthcare workers injured at work with sharp objects or needles are still not going for appropriate tests and follow-up checks for hepatitis C. This puts them at unnecessary risk of developing chronic infections.

78% of those who had been put at risk of hepatitis C may not have been followed up adequately, potentially leaving some cases of hepatitis C undiagnosed without treatment or care. If untreated, hepatitis C can lead to chronic liver disease or eventually cancer of the liver.

Professor Mike Catchpole, Director of the Health Protection Agency's Centre for Infections, said: "Although the numbers of reported healthcare workers infected with hepatitis C following their injury were few, these cases should never have occurred. We all need to do everything we can to prevent occupational exposure injuries occurring. It is important for healthcare workers to report incidents of occupational exposure. Testing and follow up checks are vital as infections can remain undetected for many years. However, our main aim should be doing everything we can to prevent occupational exposure injuries occurring in the first place."

"Many incidents of occupational exposure can be prevented if there is proper adherence to standard precautions for the safe handling and disposal of clinical waste."

On the whole, the report shows encouraging results on the implementation of national policies in the management of these exposure incidents, with the exception of testing and follow-up for hepatitis C.

The report found that guidelines on the use of HIV post-exposure prophylaxis (PEP), administered to healthcare workers to help prevent them contracting HIV, were being adhered to. Other than the five HIV seroconversions reported up to 1999, no new cases of HIV have occurred in the UK among healthcare workers through occupational exposure. This is despite injuries involving HIV infected source patients representing 22% of all occupational exposures through needlesticks and other sharps, between 2000 and 2007.

Dr Fortune Ncube, Consultant Epidemiologist at the Health Protection Agency, said "It is so important that guidelines around the use of PEP are followed and that treatment is provided quickly. This can make the difference between good health or contracting a life-long infection."

"Healthcare workers must be vigilant in reporting possible exposures to infected patients. There is no place for complacency, contracting bloodborne viruses through occupational exposure is a real risk."

Source: Health Protection Agency