

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Nov 29, 2008

Michigan family on 'Extreme Makeover' Sunday

<http://www.freep.com>

ABC's "Extreme Makeover: Home Edition" helps a Michigan woman and her three young sons on Sunday's episode at 8 p.m. The show's cast and crew went to Holt (a small town outside Lansing) to transform an 1860s farmhouse for Arlene Nickless, whose husband, Tim, died in

January after a long battle with hepatitis C. Art Van Furniture donated furnishings for the rebuilt 3,500-square-foot home.

Dec 1, 2008

Antibiotics: Single largest class of drugs causing liver injury

<http://www.eurekalert.org>

Study finds CNS agents also commonly associated with drug-induced liver injury

Bethesda, MD (Dec. 1, 2008) – Antibiotics are the single largest class of agents that cause idiosyncratic drug-induced liver injury (DILI), reports a new study in *Gastroenterology*, an official journal of the American Gastroenterological Association (AGA) Institute. DILI is the most common cause of death from acute liver failure and accounts for approximately 13 percent of cases of acute liver failure in the U.S. It is caused by a wide variety of prescription and nonprescription medications, nutritional supplements and herbals.

"DILI is a serious health problem that impacts patients, physicians, government regulators and the pharmaceutical industry," said Naga P. Chalasani, MD, of the Indiana University School of Medicine and lead author of the study. "Further efforts are needed in defining its pathogenesis and developing means for the early detection, accurate diagnosis, prevention and treatment of DILI."

In this prospective, ongoing, multi-center observational study — the largest of its kind — patients with suspected DILI were enrolled based upon predefined criteria and followed for at least six months. Those with acetaminophen liver injury were excluded.

Researchers found that DILI was caused by a single prescription medication in 73 percent of the cases, by dietary supplements in 9 percent and by multiple agents in 18 percent. More than 100 different agents were associated with DILI; antimicrobials (45.5 percent) and central nervous system agents (15 percent) were the most common. Of the dietary supplements causing DILI, compounds that claim to promote weight loss and muscle building accounted for nearly 60 percent of the cases. The study found that at least 20 percent of patients with DILI ingest more than one potentially hepatotoxic agent.

DILI remains a diagnosis of exclusion and thus detailed testing should be performed to exclude competing causes of liver disease; importantly, acute hepatitis C virus (HCV) infection should be carefully excluded in patients with suspected DILI by HCV RNA testing. Researchers found no relationship between gender and severity of DILI, but individuals with diabetes experienced more severe DILI.

This study is an initial analysis of an ongoing prospective study of DILI. Its primary aim is to develop well-characterized cases of medication-related liver injury on which to conduct hypothesis-driven research targeted at developing means to diagnose, prevent and treat DILI. DILI is the most frequent adverse drug-related event leading to abandonment of potentially promising new drug candidates during pre-clinical or clinical development, failure to achieve drug approval, and withdrawal or restriction of prescription drug use after approval.

The Drug-Induced Liver Injury Network is funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and was established in 2003 and will operate through 2013. It consists of eight clinical centers, one data coordinating center and NIDDK investigators. Visit <http://diln.dcri.duke.edu/> to learn more.

FibroScan vs. liver biopsy in patients with chronic C hepatitis

<http://www.eurekalert.org>

Liver biopsy (LB) was considered to be the best method to evaluate the severity of fibrosis in patients with chronic hepatitis. Over time, it was demonstrated that LB is not really a "gold standard" because of its intra- and interobserver variability, the sampling variability and, last, but not least, the fact that it is an invasive method, with morbidity and mortality greater than zero. Considering all these facts, noninvasive methods for the evaluation of liver fibrosis were developed in the last few years (especially transient elastography and FibroTest – ActiTest), in order to replace the LB.

The research team led by Prof. Sporea from The University of Medicine and Pharmacy Timisoara, Romania, Dept. of Gastroenterology and Hepatology, compared the noninvasive evaluation of patients with chronic viral C hepatitis by means of transient elastography to the "gold-standard" of evaluation—LB. This will be published on November 14, 2008 in the *World Journal of Gastroenterology*.

Transient elastography is an ultrasound-based, non-invasive method, which measures the liver stiffness by means of a FibroScan® device (EchoSens, Paris, France). By using an ultrasound transducer probe mounted on the axis of a vibrator, the transmission of low-frequency vibrations from the right intercostal space creates an elastic shear wave that propagates into the liver. A pulse-echo ultrasound acquisition is then used to detect the velocity of wave propagation. This velocity is proportional to the tissue stiffness, with faster wave progression occurring through stiffer material. Measurement of liver stiffness is then performed and measured in kPa.

Transient elastographic assessment of LS was validated as method of evaluation in chronic hepatitis C. Also, there are some articles that proved the value of this method in other chronic hepatopathies [like hepatitis B virus (HBV) infection, haemochromatosis, primary biliary cirrhosis or non-alcoholic steato-hepatitis], due to fibrosis, measured by transient elastography, was compared to the LB.

In patients with chronic hepatitis C virus (HCV) hepatitis, when compared to the LB, considered to be the "gold standard", transient elastography can differentiate between significant fibrosis and absent or mild fibrosis. According to international guidelines, only patients with significant fibrosis ($F \geq 2$ Metavir), should receive antiviral therapy. A cut-off value for liver stiffness, with a good positive predictive value, was established in order to differentiate patients with significant fibrosis (who should be treated) from those with absent or mild fibrosis (who do not need antiviral treatment), so that in patients with chronic HCV hepatitis, liver stiffness measurement could be used for the decision of therapy, in most patients, avoiding LB.

Similar to other anterior studies from different regions of the world, this study demonstrates the value of the non-invasive evaluation of liver stiffness for fibrosis assessment in chronic C viral hepatitis.

Reference:

Sporea I, Şirli R, Deleanu A, Tudora A, Curescu M, Cornianu M, Lazăr D. Comparison of the liver stiffness measurement by transient elastography with the liver biopsy. World J Gastroenterol 2008; 14(42): 6513-6517 <http://www.wjgnet.com/1007-9327/14/6513.asp>

ANA598 Receives Fast Track Designation From the FDA for the Treatment of Chronic Hepatitis C Infection

<http://biz.yahoo.com>

SAN DIEGO, Dec. 1 /PRNewswire-FirstCall/ -- Anadys Pharmaceuticals, Inc. (Nasdaq: ANDS - News) today announced that the U.S. Food and Drug Administration (FDA) has granted fast track designation to **ANA598** for the treatment of chronic hepatitis C virus (HCV) infection. ANA598 is Anadys' investigational hepatitis C non-nucleoside polymerase inhibitor. Anadys is currently enrolling patients in a Phase Ib study evaluating ANA598 for the treatment of patients chronically infected with HCV.

Under the FDA Modernization Act of 1997, fast track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions. Compounds selected must demonstrate the potential to address an unmet medical need for such a condition. Mechanisms intended to facilitate development include opportunities for frequent dialogue with FDA reviewers and for timely review of submitted protocols. However, the designation does not guarantee approval or expedited approval of any application for the product. The granting of fast track status for the ANA598 development program is consistent with the need for HCV treatments with novel mechanisms of action, oral administration, non-overlapping resistance profiles and improved safety and efficacy over the existing standard of care for both treatment-naïve and treatment-experienced patients.

"The FDA's fast track designation for ANA598 acknowledges the need for new HCV therapies to improve treatment outcomes," commented James Freddo, M.D., Anadys' Senior Vice President, Drug Development and Chief Medical Officer. "We anticipate continuing to work closely with the FDA on the development and regulatory review of ANA598, one of the few non-nucleoside polymerase inhibitors in clinical development for the treatment of HCV. We continue to believe this class of antivirals holds great promise as a component of future HCV treatment regimens."

About ANA598

Anadys recently initiated patient dosing in a Phase Ib study of ANA598 in HCV patients. In the Phase Ib study, naïve genotype 1a and 1b patients are to receive ANA598 over three days at doses of 200 mg bid (twice-a-day), 400 mg bid or 800 mg bid. Ten patients will be enrolled at each dose level, eight receiving active drug and two receiving placebo.

In a Phase I study in healthy volunteers, ANA598 was administered as capsules at single oral doses of 400 mg, 800 mg, 1400 mg, 2000 mg (fed and fasted) and 3000 mg. In addition, a

separate cohort received two 800 mg doses 12 hours apart. ANA598 was well tolerated at all doses and there were no serious adverse events or withdrawals from the study, although definitive conclusions regarding product safety and tolerability cannot be made until the results of future clinical trials of longer duration in more patients are known. All reported adverse events were classified as mild or moderate, with no apparent dose relationship. The pharmacokinetic profile demonstrated sustained plasma levels of ANA598 with a half-life of 24 to 30 hours in the fasted state and 22 hours in the fed state, consistent with the potential for once-daily or twice-daily oral dosing.

Preclinical evaluation of ANA598 was completed in the first quarter of 2008, leading to submission of an Investigational New Drug Application (IND) to the FDA, subsequent allowance of the IND by the FDA and initiation of clinical investigation in the second quarter of 2008. In the preclinical program, ANA598 was well tolerated at all doses tested in 28-day GLP toxicology studies. In September, Anadys initiated long-term, chronic toxicology studies of ANA598. If ANA598 is successful in early stage clinical trials, it is anticipated that the acceleration of these and other non-clinical activities into 2008 will enable a more rapid and continuous development path into Phase II studies during 2009.

About Anadys

Anadys Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company dedicated to improving patient care by developing novel medicines in the areas of hepatitis C and oncology. For the treatment of chronic hepatitis C, the Company is developing two potentially complementary agents, ANA598, a non-nucleoside polymerase inhibitor and ANA773, an oral TLR7 agonist prodrug. The Company is also developing ANA773 for the treatment of cancer.

Source: Anadys Pharmaceuticals, Inc.

Acupuncture beats aspirin for chronic headache

www.reuters.com

WASHINGTON (Reuters) - Acupuncture works better than drugs like aspirin to reduce the severity and frequency of chronic headaches, U.S. researchers reported on Monday.

A review of studies involving nearly 4,000 patients with migraine, tension headache and other forms of chronic headache showed that that 62 percent of the acupuncture patients reported headache relief compared to 45 percent of people taking medications, the team at Duke University found.

"Acupuncture is becoming a favorable option for a variety of purposes, ranging from enhancing fertility to decreasing post-operative pain, because people experience significantly fewer side effects and it can be less expensive than other options," Dr. Tong Joo Gan, who led the study, said in a statement.

"This analysis reinforces that acupuncture also is a successful source of relief from chronic headaches."

Writing in *Anesthesia and Analgesia*, they said 53 percent of patients given true acupuncture were helped, compared to 45 percent receiving sham therapy involving needles inserted in non-medical positions.

"One of the barriers to treatment with acupuncture is getting people to understand that while needles are used, it is not a painful experience," Gan said. "It is a method for releasing your body's own natural painkillers."

They found it took on average five to six visits for patients to report headache relief.

Other studies have shown that acupuncture helped alleviate pain in patients who had surgery for head and neck cancer, can relieve hot flashes and other menopausal symptoms and can reduce chemotherapy-induced nausea.

(Reporting by Maggie Fox; Editing by Julie Steenhuysen)

Brand-name drugs no better than generics: study

www.reuters.com

By Will Dunham

WASHINGTON (Reuters) - There is no evidence that brand-name drugs given to treat heart and other cardiovascular conditions work any better than their cheaper generic counterparts, U.S. researchers said on Tuesday.

The findings run counter to the perception by some doctors and patients that pricier brand-name drugs are clinically superior, said Dr. Aaron Kesselheim of Brigham and Women's Hospital and Harvard Medical School in Boston, who led the study.

Kesselheim and colleagues combined the results of 30 studies done since 1984 comparing nine sub-classes of cardiovascular drugs to generic counterparts.

The brand-name drugs did not offer any advantage for patients' clinical outcomes in those studies, they wrote in the *Journal of the American Medical Association*.

"Brand-name drugs for cardiovascular disease can be as much as a few dollars a pill, whereas generic drugs might be as little as a few cents a pill," Kesselheim said.

"If a patient is prescribed a generic drug because that's what's appropriate for their condition, then they should feel confident taking that drug. And physicians themselves should also feel confident prescribing generic drugs where appropriate," Kesselheim said in a telephone interview.

He said rising costs of brand-name prescription drugs strain the budgets of patients as well as public and private health insurers. Overall U.S. prescription drug sales hit \$286.5 billion in 2007.

Exclusive Rights

Pharmaceutical companies retain exclusive rights to drugs they develop for a certain number of years, after which others can sell generic versions that are chemically equivalent. The active ingredient is the same, but the color and shape may differ and they may have different inert binders and fillers.

In the United States, the Food and Drug Administration must approve a generic version of a drug before it can be sold.

Kesselheim said cardiovascular drugs to treat conditions of the heart and blood vessels are the most commonly prescribed category.

The study covered beta-blockers, diuretics, calcium-channel blockers, statins, antiplatelet agents, ACE inhibitors, alpha-blockers, anti-arrhythmic agents and warfarin.

The researchers said brand-name manufacturers have suggested generic drugs may be less effective and less safe. They also found that many editorials in medical journals questioned whether generic drugs were as good.

Generic medications represent 66 percent of the total prescriptions in the United States, but less than 15 percent of the money spent on prescription drugs, according to the Generic Pharmaceutical Association industry group.

Kathleen Jaeger, who heads the pharmaceutical group, said the research reconfirms that FDA-approved generics provide the same medicine with the same clinical effects at a substantial cost savings.

"You have patients worrying about being able to receive and afford quality health care. As everyone is grappling with how to increase access and reduce costs, we know that generics are part of the solution," she said in a telephone interview.

Ken Johnson, senior vice president of the Pharmaceutical Research and Manufacturers of America, or PhRMA, said in a statement, "The contention that brand-name medicines drive up the cost of health care is fatally flawed.

"Without today's innovative brand-name drugs to legally copy, there would be no generic drug industry," he said.

(Editing by Maggie Fox)

Dec 2, 2008

How sweet it is

<http://blogs.denverpost.com>

by Joanne Davidson

The cakes and candies and cookies were enough, really, but when the name of your event is Desserts & Delights, it doesn't hurt to add a few more yummys to the mix.

To ward off a total sugar buzz — or not — sandwiches, chicken skewers and other more substantial fare was part of the buffet that preceded the auction and awards ceremony at the Hep C Connection's annual fundraiser. Katie Barton and Mike Grube were the chairmen; 7News anchor Mike Landess emceed the event held at the Colorado Convention Center.

The highlight of the evening came when Dr. Igal Kam, Dr. Greg Everson and their team from the Liver Transplant Center at the University of Colorado Denver were given an award for their pioneering work with liver disease, specifically on behalf of patients with hepatitis C.

Coincidentally, a Hep C Connection board member, volunteer and support group leader have all had liver transplants at the center.

The Denver-based Hep C Connection (1-800-522-4372 or hepc-connection.org) is a nationally recognized organization whose mission is to educate the public about hepatitis C and to provide resources and support for those affected by the virus. Nancy Steinfurth is the executive director.

Guests at Desserts & Delights included such board members as Tom Kim, Cheryl Anderson, Ann Eckman-McDougal, Mike Hofmann, Scott Meiklejohn and Brian Wilkerson. Also, Elsie Lacy, former chair of the state Joint Budget Committee; Sherry Jackson, executive director of the Colorado Democratic Party; her father, George Anderson; Lovey Cunningham; Christy Calvin; Sylvia Jackson; retiring board member Karen Robinson Rosenthal and her husband, Ed Rosenthal; and Rebecca Kim.

Pictures taken at Desserts & Delights can be viewed at www.denverpost.com/seengallery

Getting hepatitis C from needle stick unlikely

<http://www.phillyburbs.com>

By JO CIAVAGLIA

Bucks County Courier Times

Medical experts say it's unlikely that a Tullytown police officer would contract a highly infectious, potentially life-threatening virus spread primarily through blood after he was stuck with a hidden syringe during a routine traffic stop.

The risk of hepatitis C infection after a needle stick exposure to positive blood is roughly 2 percent, though the estimate is based on health care worker experiences, according to local epidemiologists and the Centers for Disease Control and Prevention statistics.

Last Tuesday Officer John Finby stopped a car with four people inside for allegedly speeding on Levittown Parkway. During the traffic stop, the officer said he noticed blood droplets between the two rear seat passengers, and asked all to get out of the vehicle.

While searching the rear seat, the cop's gloved hand hit an uncapped needle lodged in the seat. It pierced the glove and jabbed Finby's hand, according to police reports.

Finby said all four occupants of the car told him they are positive for hepatitis C and share needles while doing drugs. It's unknown if the four are being treated for the disease.

Finby underwent testing and antibiotic treatment at Lower Bucks Hospital. He is awaiting test results and taking medication as a precaution. There is no vaccine against hepatitis C, however.

Hepatitis C is transmitted primarily through blood or blood products contact and can cause major liver damage. The virus is responsible for 8,000 to 10,000 deaths in the U.S. annually, according to the CDC.

Unknown is whether police are testing the needle to see if it was used or exposed to hepatitis C. It is also unclear if the other passengers told police they had used the needle that stuck Finby.

The Courier Times was unsuccessful in reaching Tullytown police Chief Patrick Priore for comment Monday.

In 2006, 802 cases of newly confirmed hepatitis C were reported in the U.S., according to the CDC, but the agency estimates that about 19,000 new infections occurred that year. Most newly infected people are asymptomatic, so hepatitis C is rarely identified or reported in its early stage.

Since last December, two new hepatitis C cases were diagnosed in Bucks County and there were 343 chronic cases, according to the state health department. Montgomery County had no newly diagnosed cases, though there were 865 chronic cases.

Generally, a screening test can detect the virus four to 12 weeks after exposure. About 15 percent to 25 percent of people exposed to hepatitis C become clear of the virus without treatment, though scientists aren't sure why, according to the CDC.

Abington Memorial Hospital epidemiologist Dr. Geetika Sood said the risk of contracting a blood-borne virus through a needle stick is remote, but varies depending on factors such as if the needle was used, the width of the needle and the depth of the puncture wound.

She estimated the risk at 1 percent to 3 percent among health care workers tested after a needle stick. Not enough police officers are routinely tested after a needle stick incident to formulate their risk potential, she said.

A 2000 study in the *American Journal of Preventative Medicine* found that among 803 active duty metropolitan police officers surveyed anonymously, nearly 30 percent had at least one needle stick injury and 40 percent sought medical attention for it.

The study concluded that needle stick injuries occur with considerable frequency in this group of law enforcement personnel, suggesting an increased risk of becoming infected with blood borne pathogens, including hepatitis C.

Did You Know?

Most recent Centers for Disease Control and Prevention surveys indicate that one-third of active injection drug users between the ages of 18 and 30 are infected with hepatitis C. The infection rate among older injection drug users is 70 percent to 90 percent.

Jo Ciavaglia can be reached at 215 949-4181 or jciavaglia@phillyBurbs.com.

Third doctor faces state action over hepatitis C

<http://www.mercurynews.com>

The Associated Press

LAS VEGAS—The Nevada Board of Medical Examiners has filed a malpractice complaint against a third physician affiliated with a Las Vegas outpatient clinic at the center of a hepatitis C outbreak.

Dr. Clifford Carrol is accused in the complaint filed Nov. 24 of failing to exercise proper skill and diligence during his work at the Endoscopy Center of Southern Nevada, among other allegations. The complaint was made public on Tuesday.

The board also has complaints pending against the clinic's majority owner, Dr. Dipak Desai, and Dr. Eladio Carrera. Both have had their licenses suspended pending hearings early next year.

Louis Ling, the medical board's executive director and special counsel, said no decision had been made whether to suspend Carrol's medical license.

Carrol is identified in his complaint as the gastroenterologist who treated a colonoscopy patient whose hepatitis C was spread to other patients on Sept. 21, 2007. Carrol faces a medical board hearing June 22.

"The allegation is that he was the physician treating the source patient that led to other patients acquiring hepatitis C later that day," Ling said.

Authorities allege that unsafe injection practices including reusing syringes and contaminated vials of anesthesia led to transmission of the incurable liver disease.

The Southern Nevada Health District has linked 114 cases of hepatitis C to the Endoscopy Center of Southern Nevada and an affiliated clinic, the Desert Shadow Endoscopy Center.

But the public agency says only nine of those cases can be directly linked to treatment at the clinics, which have been closed. It says the other 105 people could have contracted the disease in other ways.

The health district has not attributed any deaths to the outbreak. But the widow of one former patient has filed a lawsuit blaming her 60-year-old husband's hepatitis C diagnosis and death in 2006 on unsafe medical practices at one of the clinics.

More than 100 other former patients have filed civil lawsuits against the clinics and physicians.

The outbreak is the largest ever in Nevada, and it led to the nation's largest patient notification, with some 50,000 former Endoscopy Center of Southern Nevada patients and 13,000 former Desert Shadow Endoscopy Center patients notified to get tested for hepatitis B, C and HIV, the virus that causes AIDS. Officials say no cases of hepatitis B or HIV have been linked to the outbreak.

Roche's Pegasys Fails to Curb Hepatitis C Progression in Study

<http://www.bloomberg.com>

By Dermot Doherty

Dec. 3 (Bloomberg) -- Roche Holding AG's Pegasys drug for hepatitis C didn't keep liver disease at bay when given in smaller doses over a longer period of time, a study found.

The medicine failed to slow disease progression in patients who hadn't responded to initial treatment, according to the study in the *New England Journal of Medicine*. The research, which focused on 1,050 patients with advanced hepatitis on so-called maintenance therapy, also found the patients' health declined over a four-year period.

Pegasys won approval as a treatment for hepatitis C in 2001 and last year generated 1.6 billion Swiss francs (\$1.3 billion) in sales for Basel, Switzerland-based Roche. Hepatitis C, the main cause of liver cancer, is a blood-borne infection that affects as many as 200 million people worldwide. Patients on Pegasys are typically given 16 to 48 weeks of therapy. Hepatitis C causes no symptoms in 80 percent of cases and is responsible for about two-thirds of all liver transplants.

"This course of treatment had been adopted by a number of doctors in the U.S. and in other countries, though it had yet to be proven to work. That practice should be stopped based on the results of this trial," researcher Adrian Di Bisceglie, a professor of internal medicine and co-director of the Liver Center at Saint Louis University, said in a statement.

Half of the patients in the study were given 90 micrograms of Pegasys, also known as peginterferon, a week for 3 1/2 years. The rest made up a control group. About 30 percent of the patients in both groups went on to develop liver failure or cancer, or else died. About 10 percent to 12 percent of patients with milder cirrhosis developed severe liver disease, the study found.

The U.S. National Institutes of Health funded the research.

Dec 4, 2008

Children do well 5 years after liver transplant

www.reuters.com

NEW YORK (Reuters Health) - New research indicates that most children who are 5-year survivors of liver transplantation have good graft function; however, chronic medical conditions and complications affecting other organs are common in this patient population.

"The success of liver transplantation in children is defined by more than just excellent survival rates. Better understanding of the long-term medical considerations is of critical importance in pediatric liver transplant recipients, who by nature of their young age face a greater cumulative burden of life-long immunosuppression," Dr. Vicky Lee Ng and co-researchers emphasize in their report in the journal *Pediatrics*.

Liver transplantation has been the standard of care for life-threatening liver diseases for more than two decades, yet multicenter data regarding the long-term outcomes have been lacking, Ng, from the University of Toronto, and associates point out.

The current investigation included 461 patients who survived longer than 5 years after undergoing a liver transplant at 1 of 45 pediatric centers across North America between 1996 and 2001.

Overall, 88 percent of the patients survived with their first liver transplant, while 12 percent required one or two additional attempts.

Most patients had a functional liver at their 5-year clinic assessment, the report indicates. For immunosuppressive therapy, given to prevent organ rejection, most patients - 97 percent - received a calcineurin inhibitor and 25 percent were prescribed prednisone.

The risk of having an episode of sudden cellular rejection within 5 years was 60 percent. Gradual continuous, or chronic, rejection also occurred in 5 percent of the patients, the authors note.

Six percent of the children developed posttransplant lymphoproliferative disease, an increased production of lymphocytes, which is normally seen as a response to infection. Thirteen percent of the subjects had signs of possible kidney disease.

After accounting for the effects of age and gender, 12 percent of the subjects had a weight that was above the 95th percentile and 29 percent had a height below the 10th percentile.

"This study emphasizes the need for a collaborative partnership between primary care practitioners and pediatric healthcare providers both beyond and within transplant centers to further improve outcomes for pediatric liver transplant recipients," the researchers conclude.

SOURCE: Pediatrics, December 2008.

Roche's Pegasys approved for new indication in EU

www.reuters.com

ZURICH, Dec 4 (Reuters) - Swiss drugmaker Roche Holding AG (ROG.VX: Quote, Profile, Research, Stock Buzz) said on Thursday the European Commission had approved its hepatitis C drug Pegasys for patients whose first round of treatment had not been successful.

"A significant number of patients do not achieve treatment success with their first treatment. This results in a large and growing population of patients who urgently need alternative treatment solutions," Roche said in a statement.

"Today's approval provides a significantly broader indication for Pegasys and establishes a new standard of care for treatment-experienced patients with the most difficult-to-treat virus," it said.

But a study in *New England Journal of Medicine* found that long-term therapy with Pegasys did not reduce the rate of disease progression in patients with chronic hepatitis C and advanced

fibrosis who had not had a response to initial treatment. (Reporting by Katie Reid; Editing by Jon Loades-Carter)

End of P.E.I. needle exchange worries health officer

<http://www.cbc.ca/>

Without new funding the needle exchange will not reopen. (CBC)

The planned shutdown of P.E.I.'s needle exchange has the province's deputy chief health officer worried about the spread of hepatitis C and AIDS.

For the last five years the program, run by AIDS PEI in Charlottetown, has handed out about 500 syringes a week. But a lack of funding is forcing the program to shut down, at least for January. If no new funding is found the program may be finished for good.

AIDS PEI is the only provincial AIDS organization in Atlantic Canada that doesn't get money from a provincial government.

Dr. Lamont Sweet, P.E.I.'s deputy chief health officer, told CBC News Wednesday there are 550 cases of hepatitis C on P.E.I., with about 40 new cases every year. He worries that number will climb if the needle exchange program ends.

"It would really be a big step backwards if the program could not be maintained," said Sweet.

"With all of the hepatitis C that we have here, of course, that would be the major fear that we'd have. But we've also got AIDS and hepatitis B about which we'd have concerns."

A difficult job

Staff at AIDS PEI say it's emotionally draining to run the program, and to see the drug users struggling, but say things would be worse without a needle exchange.

"Once this service is no longer available to them, they're going to go out on the street," said Mark Hanlon, executive director of AIDS PEI.

"They're going to start purchasing their needles from people who have already used that syringe. They're going to be finding syringes, they're going to reuse them. They might start using syringes that they've found on the ground, anything to get the drug into their system."

"It's really hard to watch sometimes," added Troy Perrot, client liaison co-ordinator.

"It's one of the hardest parts of the job, but on the other side of the coin you know you're really helping someone."

The City of Charlottetown provided \$5,000 for the program this year, but those funds are almost gone and the group is hoping the province will step up.

"We would prefer that the province get involved and be a little more proactive in helping us reach that population," said Hanlon.

Health Minister Doug Currie won't talk about what the province might offer, but said he plans to meet with the group later this week.

"We're looking forward to looking at what their needs are and ask them to present us to what they see as their priorities as we work at enhancing the partnership," said Currie.

Hanlon said it's a stressful time for AIDS PEI and for the people it helps. The group hopes some kind of new funding can be found, but until that happens clients are being told the needle exchange program won't be available in January, and there is no schedule for when it might reopen.

Dec 5, 2008

Medical records seized during hepatitis probe to be released

<http://www.lasvegassun.com>

By Amanda Finnegan

Medical documents seized by authorities earlier this year from the Gastroenterology Center of Nevada following a major hepatitis scare in Las Vegas will soon be returned, authorities announced today.

Work will begin Saturday to package all impounded patient files so they may be released back to the medical center's various locations from which they originated, according to the Las Vegas Metropolitan Police Department. Metro anticipates that the files will be released to patients by January 2009.

On Feb. 29, 2008, members of Metro Police, the FBI and investigators from the Nevada State Attorney General's Office and the Department of Health and Human Services served multiple search warrants at six of the center's locations.

Patients' medical records were seized in connection with the criminal investigations against the center and its founder, Dr. Dipak Desai. Desai also owned the majority of The Endoscopy Clinic of Southern Nevada where 40,000 patients were potentially exposed to hepatitis C and HIV through contaminated needles.

Desai has since been barred from practicing medicine in Nevada and faces disciplinary hearings by the medical board.

The City of Henderson suspended the Gastroenterology Center of Nevada on March 4, 2008.

Dec 6, 2008

Glaxo says oral drug raises blood platelet counts

www.reuters.com

By Deena Beasley

LOS ANGELES (Reuters) - Patients treated with GlaxoSmithKline PLC's Promacta rather than a placebo were eight times more likely to have sustained increases in platelet counts, according to pivotal trial results announced by the company on Saturday.

Promacta, also known as eltrombopag, was approved by the U.S. Food and Drug Administration last month for the treatment of patients with chronic immune thrombocytopenic purpura (ITP) who have had an insufficient response to steroids, immune-suppressing drugs or surgery to remove the spleen.

ITP is an autoimmune disease which results in low blood platelet counts. Because platelets contribute to blood clotting, patients with low counts bleed more easily than others, heal more slowly and bruise more often.

Promacta, a pill discovered in a collaboration between Glaxo and Ligand Pharmaceuticals Inc, is seen as a competitor to Amgen Inc's Nplate, an injectable drug approved by the FDA in August for the same patient group.

Glaxo said the six-month, Phase III trial involving 197 patients with chronic ITP also showed that Promacta reduced bleeding. But the drug raised the risk of liver problems -- although there were no serious, drug-induced liver injuries.

The company said hepatobiliary laboratory abnormalities were reported in 13 percent of patients taking Promacta, compared with 7 percent of patients on placebo.

Glaxo also said the trial showed no clinical or laboratory symptoms of bone marrow fibrosis in patients taking Promacta.

The trial results were unveiled in San Francisco at a meeting of the American Society of Hematology.

Amgen and Glaxo are slated to announce at the conference on Monday additional trial results for the platelet drugs.

About 60,000 U.S. adults have chronic ITP, according to the companies.

(Reporting by Deena Beasley, editing by Matthew Lewis)