

# HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Editor-in-Chief*

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## **Beefing up drug security at BCH**

<http://www.dailycamera.com>

John Aguilar

### *Hospital secures narcotics delivery system in wake of nurse scandal*

BOULDER, Colo. — As tales of yet another Colorado medical worker who allegedly tampered with painkillers made headlines last week, Boulder Community Hospital has been busy trying to ensure that its staff never again puts its patients at risk.

The hospital, still recovering from a narcotics scandal that threatened the health of nearly 300 patients last fall, says it has plugged many of the holes in its drug dispensary system that allowed a nurse to steal a powerful painkiller for his own use.

It plans to put into place a powerful new software system by the end of the summer that will provide even more rigorous accounting for narcotics dispensing at the hospital, in addition to installing surveillance cameras in the surgery suite to enhance security.

"One of the things we didn't do before is a good job of educating our employees about drug diversion," said Mike Moran, Boulder Community Hospital's vice president of quality and safety. "We've made sure there is now no opportunity for tampering in the way Ashton Daigle did."

Daigle, a former nurse, pleaded guilty last month in U.S. District Court to six felony counts of stealing Fentanyl -- a painkiller far more potent than morphine -- and replacing it with tap water and saline solution to be administered to surgery patients.

He is scheduled to be sentenced in the case Oct. 26 and will likely face at least 4 1/2 years in prison.

The improvements at Boulder Community Hospital come just as a Colorado surgical tech was charged last week with injecting herself with Fentanyl meant for patients, then filling the used syringes with saline solution.

The case of Kristen Diane Parker, who worked at Rose Medical Center in Denver and Colorado Springs' Audubon Ambulatory Surgery Center, has gained more attention because she has hepatitis C and may have infected others with the liver-crippling disease. She also may have affected far more people -- up to 6,000 patients.

Daigle, who was caught last fall after doctors discovered that their patients were experiencing pain and discomfort during and after surgery, has so far tested negative for HIV and hepatitis.

Bill Scanlon, a Louisville resident who had an appendectomy in September at Boulder Community Hospital and experienced post-operative pain, got tested for HIV and hepatitis C in the wake of the scandal.

He told the Camera earlier this year that he was frustrated it took the hospital so long to inform

him and other former patients about Daigle's misdeeds.

Neither Scanlon nor a couple other victims could be reached for comment last week.

Boulder Community Hospital officials said they had begun to make upgrades last year to their automated Pyxis medication dispensing system, which Daigle was able to manipulate before the most recent security measures were installed.

Prosecutors say Daigle, 27, got away with stealing medications for months by ordering vials of Fentanyl through Pyxis and then canceling those orders, fooling the machine into thinking he had put the drug back into the system's drawer when he had actually removed it, injected himself and replaced it with an inert solution.

Now the upgraded Pyxis system doesn't allow anyone to cancel a narcotics order.

"If it's removed from here," Karen Monserud, the hospital's director of pharmacy, said pointing to a row of secured drawers, "we're never going to give it to a patient."

She said any removed drugs have to be signed off by a witness, dropped into a locked return box and accounted for in a separate department of the hospital.

Pyxis has also been upgraded with a fingerprint identification component to limit access to authorized personnel. Narcotics are kept in dose-regulated drawers specific to each patient. The drawers only open when an authorized user punches in a code and it makes available only the amount of medication assigned to that patient.

The system also lets pharmacy staff run detailed reports on average medication usage, allowing them to identify staff members who withdraw abnormal amounts of narcotics, over-using certain functions on the machine and not accounting for drugs properly.

"That gives you a documentation of what the patient receives and it gives an inventory and keeps track of what narcotics are removed," Monserud said. "The tracking is pretty intensive on this system."

The new software component -- dubbed Pandora -- should be operational at the hospital by the end of next month. It will make tracking narcotics usage in the Pyxis system even more foolproof.

"You won't have to know something is going wrong -- it can show you something that is out of the norm," Monserud said.

Hospital officials acknowledge that there may be weaknesses they haven't foreseen through which a drug abuser or addict could strike again. That's why they have formed a 10-member Diversion Prevention Task Force to bounce around ideas for making drug dispensing at the hospital even more secure and safe for patients.

The hospital has also begun providing training to its staff on how to recognize addictive behavior patterns and suspicious behaviors among their colleagues. Drug screening for new employees at

Boulder Community Hospital has been expanded to test for more substances, including amphetamines, cocaine, methadone and PCP.

"The biggest opportunity to prevent this from happening again is to be open about it," said Moran, the hospital vice president.

**July 13, 2009**

## ***Philippine HBV Isolate May Be a New Subgenotype C6***

[www.medscape.com](http://www.medscape.com)

NEW YORK (Reuters Health) Jul 10 - A new isolate of hepatitis B virus (HBV) from the Philippines fulfills all criteria for a new subgenotype C6, researchers report in the June issue of the Journal of Medical Virology.

Dr. Stephan Schaefer of the University of Rostock, Germany, and colleagues observe that HBV genotypes and subgenotypes show distinct geographical prevalence, and introduction of a virus into new genetic environments leads to adaptation causing genetic segregation.

The researchers analyzed 28 serum samples from asymptomatic HBV carriers from the Philippines. Fifteen patients had genotype B, 5 had genotype C2, 4 had genotype D, 2 had A1 and 2 patients were infected dually with HBV genotypes B and D.

The distribution was similar to that observed in a previous study. However, further analysis showed that 1 of the isolates (Ph105) formed a separate clade in genotype C. It did not belong to one of the known subgenotypes.

The team notes that a threshold of 4% is usually used to differentiate subgenotypes from each other. The proposed new subgenotype was closest to subgenotype C2, with a 4.1% difference in nucleotide substitutions over the whole genome.

"We assume," the authors conclude, "that the proposed Philippine C6 isolate evolved from C2 after being brought into a new genetic environment."

"Currently," they add, "further efforts are being undertaken to identify other isolates of C6 in the Philippines."

*J Med Virol* 2009;81:983-987.

## ***Diet May Influence Liver Disease Progression***

<http://www.modernmedicine.com>

*Increased long-term risk of cirrhosis, liver cancer linked to diets high in protein and cholesterol*

MONDAY, July 13 (HealthDay News) -- Dietary nutrient composition may be associated with an increased or decreased long-term risk of developing cirrhosis or liver cancer, according to a study published in the July issue of *Hepatology*.

George N. Ioannou, M.D., of the Veterans Affairs Puget Sound Health Care System in Seattle, and colleagues studied 9,221 subjects ages 25 to 74 years who were enrolled in the first National Health and Nutrition Examination Survey and were cirrhosis-free at baseline and during the first five years of follow-up.

After a mean follow-up of 13.3 years, the researchers found that 118 subjects had developed cirrhosis and that five had developed liver cancer. After adjusting for potential confounders, the researchers found a high-protein diet was associated with an increased risk of hospitalization or death resulting from cirrhosis or liver cancer, while a high-carbohydrate diet was associated with a decreased risk. They also found that high cholesterol consumption -- but not serum cholesterol or total fat consumption -- was associated with an increased risk of cirrhosis or liver cancer.

"Many determinants of liver disease progression are currently unknown, as evidenced by the fact that we cannot predict accurately which patients with any of the major liver diseases (hepatitis C virus, hepatitis B virus, nonalcoholic fatty liver disease, and alcoholic liver disease) will progress to cirrhosis and which ones will have a relatively benign course," the authors conclude. "Our study raises the possibility that dietary factors may be important, modifiable, and hitherto unrecognized determinants of liver disease progression."

**July 14, 2009**

### ***FDA requires label change for some transplant drugs***

[www.reuters.com](http://www.reuters.com)

WASHINGTON (Reuters) - Novartis AG, Roche Holding AG and other makers of drugs to prevent rejection of transplanted organs will be required to note on their labels that patients are at risk for opportunistic infections when using the medicines, the U.S. Food and Drug Administration said.

The label changes are required for Wyeth's Rapamune; Novartis' Neoral and Myfortic; Roche's Cellcept and Sandimmune, the FDA said in a statement Tuesday posted on the agency's web site.

Organ transplant patients who take the drugs are at increased risk for infections such as BK virus-associated nephropathy, based on the FDA's analyses of its adverse event reporting system, the FDA said.

"BK virus-associated nephropathy can progress to renal allograft loss. Monitoring for this serious risk and early intervention by the health care provider is critical," the FDA said.

The FDA also said it was continuing to review the safety of immunosuppressant drugs used in kidney transplant patients.

The agency posted its announcement at: [here](#) .

(Reporting by Julie Vorman; Editing by Tim Dobbyn)

## **Can-Fite recruits patients for hepatitis C study**

<http://www.globes.co.il>

*Can-Fite is also recruiting patients for a Phase I/II clinical trial for CF102 for treating liver cancer.*

Can-Fite BioPharma Ltd. (TASE:CFBI) has obtained permission from the Ministry of Health to begin recruiting patients for the Phase I/II clinical trial of the company's drug CF102 for the treatment of type C hepatitis virus. The ethics committee of the Rabin Medical Center (Beilinson Hospital) in Petah Tikva also approved the trial.

The Phase I clinical trial of CF102, which was conducted in the US under US Food and Drug Administration (FDA) guidelines, found that drug had a high safety profile. The results made it possible to move onto the present trial, which will test the drug's safety and effectiveness in patients with hepatitis C.

The company said that the current size of the hepatitis C treatment market is \$3 billion, and that it is expected to growth to around \$8.3 billion in 2012.

CF102, like Can-Fite's other lead drug candidate, CF-101, was found to be effective when taken orally.

Can-Fite is simultaneously recruiting patients for a Phase I/II clinical trial for CF102 for treating liver cancer, which is frequent among patients with hepatitis.

Can-Fite is based on the scientific research of CEO Prof. Pnina Fishman.

Can-Fite's share rose 4.4% in morning trading to NIS 13.25

## **Hep C Doubles Risk for AIDS Illnesses**

<http://www.aidsmeds.com>

People coinfectd with both HIV and hepatitis C virus (HCV) have double the risk of developing an AIDS defining illness (ADI) as people infected with only HIV, according to a study published online July 10 in *Clinical Infectious Diseases*.

Numerous studies have demonstrated that HIV greatly accelerates HCV disease progression. It is a lot less clear, however, what impact HCV has on HIV disease progression. Studies have been mixed. Few studies have looked at the potential for an increased risk of developing an ADI in coinfectd people.

To determine the risk of ADIs in coinfectd individuals, Antonella d'Arminio, MD, at the University of Milan, and her colleagues examined the medical records of 5,397 HIV-positive patients in the ICONA Foundation Study Cohort. Most of the patients enrolled in the cohort in 1998, but some were enrolled as recently as 2008. Of those patients, 2,421 were also infected with HCV, and 2,976 were not. The average CD4 count was 418 in the coinfectd group and 458 in the group without HCV infection. Roughly one third were women.

There were 496 ADIs in the two groups. The rate of developing an ADI was two-fold higher in the coinfecting group, after adjusting for other risk factors. The rate of ADIs was three times as high for developing fungal infections, wasting, dementia and bacterial infections such as tuberculosis and Mycobacterium avium complex (MAC). People taking antiretroviral (ARV) therapy were less likely to develop an ADI than people not taking ARV therapy. People with more severely damaged livers (cirrhosis) were also more likely to have an ADI.

The authors conclude that coinfecting people should be more carefully monitored for AIDS defining illnesses.

## ***WHO says new flu "unstoppable", calls for vaccine***

[www.reuters.com](http://www.reuters.com)

WASHINGTON (Reuters) - Saying the new H1N1 virus is "unstoppable", the World Health Organization gave drug makers a full go-ahead to manufacture vaccines against the pandemic influenza strain on Monday and said healthcare workers should be the first to get one.

Every country will need to vaccinate citizens against the swine flu virus and must choose who else would get priority after nurses, doctors and technicians, said Dr. Marie-Paule Kieny, WHO director of the Initiative for Vaccine Research.

Several reports showed the new virus attacks people differently than seasonal flu -- affecting younger people, the severely obese and seemingly healthy adults, and causing disease deep in the lungs.

Kieny briefed reporters on the findings of the WHO's Strategic Advisory Group of Experts on Immunization, or SAGE. "The committee recognized that the H1N1 pandemic ... is unstoppable and therefore that all countries need access to vaccine," Kieny said.

"The SAGE recognized first that healthcare workers should be immunized in all countries in order to retain a functional health system as the virus evolves," she added.

After that, each country should decide who is next in line, based on the virus's unusual behavior.

Seasonal influenza is deadly enough -- each year it is involved in 250,000 to 500,000 deaths globally. But most are the elderly or those with some kind of chronic disease that makes them more vulnerable to flu, such as asthma.

### **Elderly Advantage**

The elderly seem to have some extra immunity to this new H1N1, which is a mixture of two swine viruses, one of which also contains genetic material from birds and humans. It is a very distant cousin of the H1N1 virus that caused the 1918 pandemic that killed 50 million to 100 million people.

A study published in the journal Nature on Monday confirmed that the blood of people born before 1920 carries antibodies to the 1918 strain, suggesting their immune systems remember a childhood infection.

The work by Dr. Yoshihiro Kawaoka also supports other studies that this new H1N1 strain does not stay in the nose and throat, as do most seasonal viruses.

"The H1N1 virus replicates significantly better in the lungs," Kawaoka said. Other studies have also shown it can cause gastrointestinal effects, and that it targets people not usually thought of as being at high risk.

"Obesity has been observed to be one of the risk factors for more severe reaction to H1N1" -- something never before seen, Kieny added. It is not clear if obese people may have undiagnosed health problems that make them susceptible, or if obesity in and of itself is a risk.

On Friday, a team at the U.S. Centers for Disease Control and Prevention and the University of Michigan reported that nine out of 10 patients treated in an intensive care unit there were obese. They also had unusual symptoms such as blood clots in the lungs and multiple organ failure.

None have recovered and three died.

The CDC estimates at least a million people are infected in the United States alone and clinics everywhere are advised not to test each and every patient, so keeping an accurate count of cases will be impossible. The United States has documented 211 deaths and WHO counted 429 early last week.

Kieny said WHO would also work to get better viruses for companies from which to make vaccines. She said the strains that had been distributed did not grow very well in chicken eggs -- used to make all flu vaccines.

One exception -- AstraZeneca's MedImmune unit makes a live virus vaccine that is squirted up the nose and it is easier to produce, Kieny said.

WHO said countries should continue with their normal vaccination programs against seasonal flu. Kieny said the seasonal H3N2 strain was also very active now in the southern hemisphere's winter.

Sanofi-Aventis, Novartis, Baxter, Schering-Plough's Nobilon, GlaxoSmithKline, Solvay, CSL and AstraZeneca's MedImmune are among those working on flu vaccines.

(Editing by Philip Barbara)

## ***Traits of Self-Discharged Cirrhotic Patients Identified***

<http://www.modernmedicine.com>

*Younger age, male sex, non-private insurance among independent predictors of self-discharge*

MONDAY, July 13 (HealthDay News) -- Nearly 3 percent of patients with cirrhosis leave the hospital against medical advice, with self-discharge being most common among patients with alcoholic cirrhosis or hepatitis B or C, according to a study published in the July issue of *Clinical*

Robert P. Myers, M.D., of the University of Calgary in Canada, and colleagues used the 1993 to 2005 U.S. Nationwide Inpatient Sample to identify 581,380 cirrhotic patients who were admitted to the hospital. The researchers analyzed the proportion of patients discharged against medical advice, as well as predictors of self-discharge.

The investigators found that 2.8 percent of the cirrhotic patients left the hospital against medical advice and that self-discharge was most common in patients with hepatitis B or C (3 percent) or those with alcoholic cirrhosis (4.2 percent). Admission to urban non-teaching hospitals, non-private insurance, younger age and male sex all independently predicted self-discharge.

"Self-discharge is most common among patients with alcoholic cirrhosis, lower socioeconomic status, psychiatric disorders, substance abuse, and less severe liver disease. These findings might assist in the prevention of self-discharge and, ultimately, improve health outcomes in patients with cirrhosis," the authors conclude.

**July 15, 2009**

## ***Focusing HIV Treatment Helps Control Concurrent Hepatitis B Infection***

<http://www.sciencedaily.com>

ScienceDaily (July 16, 2009) — Prolonged use of highly active antiretroviral therapy (HAART) to treat people infected with both HIV and hepatitis B (HBV) helps to better control the hepatitis B infection and could delay or prevent liver complications, according to a new study by researchers at Wake Forest University School of Medicine.

Researchers also found that patients who had higher levels of a common liver enzyme upon beginning treatment for HIV-HBV co-infection were at an increased risk of being diagnosed with cirrhosis within the first few years of follow-up. Cirrhosis is a disease that scars the liver, progressively shutting it down. The enzyme is one released into the bloodstream after liver damage.

"One of the most interesting findings was the confirmation that a simple marker, such as transaminase levels before treatment, is useful in identifying patients at higher risk of developing HBV-related complications in a few years," said lead researcher Marina Núñez, M.D., Ph.D., an assistant professor in the Section on Infectious Diseases, in the Department of Internal Medicine at the School of Medicine.

The study is appears in the May/June issue of *HIV Clinical Trials*, published July 15.

HBV is a contagious liver disease, contracted in the same way as HIV – through intravenous drug use, sexual contact or mother-to-newborn transmission. Left untreated, it can lead to fatal liver disease or liver cancer.

HIV increases the activity of HBV, speeds the progression of related liver disease and might decrease the effectiveness of treatments for HBV.

But Núñez and Tsan Lee, a medical student at the School of Medicine, found that prolonged use of highly active antiretroviral therapy, including one or more drugs active against HBV, can lead to clearance of the HBV infection in co-infected patients. HAART is the treatment for HIV infection, consisting of a combination of drugs commonly known as the "cocktail."

For the study, researchers reviewed medical records of patients seen in an adult HIV clinic between 1990 and 2008. They included in the study all patients with positive HIV antibody, hepatitis B and at least three months of follow-up care on record.

Of the 72 patient charts reviewed – primarily black males with a median age of 39 and advanced HIV disease at the time of diagnosis – 64 of the patients received HAART that included drugs effective in treating HBV, for a median duration of one year. The researchers were looking for whether the patients were diagnosed with liver complications such as cirrhosis and liver cancer over the course of treatment, and whether the chronic HBV infection improved.

Analysis showed that receiving HAART combined with HBV treatment for a longer period of time was significantly associated with reduced and, in some cases cleared, chronic HBV infection.

Núñez said these findings "stress the importance of good control of the HIV and HBV infections through maintained compliance with HAART including drugs to treat HBV.

"In HBV-HIV patients with the elevated enzyme levels that signal liver damage, it is even more important to control the HBV infection in an attempt to decrease the risks of complications. Those patients should also be more closely screened for liver complications."

### ***Health summit scheduled***

<http://www.mercurynews.com>

The Associated Press

CARSON CITY, Nev.—Health professionals and state regulators plan to meet at a July 22-23 "summit" in Las Vegas to discuss new requirements for reporting on and responding to health care-associated infections.

Organizers of the event, sponsored by the state Health Division, say it's an opportunity to get ahead of the curve on important changes affecting hospitals, ambulatory surgical centers and other health care providers.

Preventing infection and controlling outbreaks are major concerns for health facilities. Southern Nevada Health District officials last year identified the potential exposure of over 40,000 patients to hepatitis C from unsafe injection practices at two ambulatory surgical centers in Las Vegas.

### ***Police issue warning regarding unlicensed tattoo operations***

<http://www.tonganoxiemirror.com>

By Shawn Linenberger

Leavenworth police have received several leads since warning the public about unlicensed tattoo artists operating in the city.

A Leavenworth youth, who allegedly received a tattoo from an unlicensed artist, tested positive for hepatitis C in preliminary tests. He was one of four high school-aged youths who visited the artist. On Friday, Police Chief Pat Kitchens said more testing revealed the youth had not contracted hepatitis C.

Regardless, the chief remains concerned about unlicensed artists operating in Leavenworth.

“Fortunately for the young man, it was just a scare,” Kitchens said.

Medical concerns prompted his department to issue a warning about unlicensed artists operating in Leavenworth, even before all testing was complete.

“There’s a reason why tattoo artists have to be licensed,” he said “When you get a tattoo, there’s an exchange of bodily fluids. And it is very, very important that this is done with the proper sanitation and proper care of the equipment and those kinds of things.

“If you get involved in something like this, the health risks are very substantial. So you want to be very careful about doing that.”

In addition, Kitchens stressed that HIV and a variety of other blood-borne conditions could also be contracted if proper sanitation and care were lacking.

Police have identified three suspects, but have made no arrests, Kitchens said. The four youths allegedly received the tattoos without parental consent, which is a state requirement for people under 18. The city of Leavenworth also requires tattoo parlors to be licensed. Prison City Tattoo is the only licensed parlor in Leavenworth.

Anyone with information about unlicensed tattoo artists is asked to call police Sgt. Jim Bridges at (913) 651-2260.

**July 16, 2009**

### ***NY hospital warns of possible hepatitis exposures***

<http://www.forbes.com>

Associated Press

DENVER -- A hospital in New York state is notifying about 2,800 patients of possible exposure to hepatitis C after learning that a former employee is suspected of exposing nearly 6,000 patients in Colorado to the disease.

The New York State Health Department said Wednesday that it's working with Northern Westchester Hospital after learning that Kristen Diane Parker once worked there.

Authorities say 26-year-old Parker may have exposed patients to hepatitis C when she was a surgery technician at a Denver hospital and Colorado Springs surgery center. She's accused of

exchanging her used syringes with saline solution for ones with a painkiller meant for patients even though she knew she was infected.

She faces federal charges of tampering with a consumer product, creating a counterfeit controlled substance, and obtaining a controlled substance by deception or subterfuge.

## ***Out of Control: Spiralling Number of Deadly Hepatitis C Infections As Government Strategy Fails. Urgent Call to Action to Halt Imminent Liver Crisis***

<http://www.responsesource.com>

16 July, 2009, London: New research demonstrates that a large majority (70%) of Strategic Health Authorities (SHAs) in England are failing to oversee the Government's strategy to tackle hepatitis C, leaving infection rates of this deadly virus to increase and causing the disease to spiral out of control – putting thousands of lives at risk. A further study shows SHAs ignoring NICE guidance with only 29% of diagnosed patients being treated across the country, less than half of the 60% that NICE recommends.

"We have to act now to stop this. It is not acceptable that people are dying when there are treatments available to save lives. The strategies that have been developed are simply not being implemented and there is no more time for excuses, we must act to ensure that the strategy is delivered. The time for paperwork is over, we need action not documents." says Graham Foster, Professor of Hepatology, Queen Mary, University of London.

Click here to download interactive map of SHA regions and view soundbites from key spokespeople: <http://www.hepcoutofcontrol.org.uk><http://www.hepcoutofcontrol.org.uk>

### **Five years wasted since Hepatitis C Action Plan for England launched**

In 2004 the Department of Health published the Hepatitis C Action Plan for England, which outlines specific actions to improve research, monitoring, awareness and prevention efforts and overall patient care. However, an audit in 2008 found that half of PCTs were only partially implementing the Action Plan and in 15% of PCTs there was minimal implementation or none at all. One year on, it is apparent that SHAs, which manage the NHS locally and are a key link between the Department of Health and the NHS, have not intervened to improve PCT implementation of the Action Plan, despite the fact that responsibility for oversight is placed with them. As the latest research shows, one SHA (South East) is not aware of any local arrangements in place to deliver the Plan, and in most areas of the country there is no plan in place to ensure improvements to hepatitis C services and treatment for patients.

Charles Gore, CEO of The Hepatitis C Trust, the charity that has published the research, says "Patients are dying and that is the Trust's concern. There is failure at every level in addressing hepatitis C. SHAs, PCTs and all relevant NHS bodies must be held accountable to avoid dire consequences. Time has run out and the Government need to show leadership and take control now. It is time to prioritise liver disease; it is time for a liver strategy; and it is time for a liver czar."

## **Liver deaths and new infections increasing in England compared to the rest of Europe**

Overall, mortality from liver disease is declining in Europe, in sharp contrast to the situation in England where deaths attributable to hepatitis C have doubled in the past decade. Furthermore, the number of people with hepatitis C cirrhosis is expected to double to 8,280 by 2015. Unless the Government responds now, poor treatment rates, coupled with an increase in incidence of around 12,995 infections per year (more than 1,000 per month)<sup>8</sup> mean that the hepatitis C epidemic will continue to soar in the UK.

Treating and curing so few patients means that deaths will continue to escalate, the demand for last ditch interventions such as liver transplants will rise and more people will become infected with the disease. This imminent crisis can be effectively managed and people's lives can be saved. It is time to prioritise liver disease; it is time for a liver strategy; and it is time for a liver czar.

### **The Hepatitis C Trust calls for:**

1. A national liver czar responsible for driving forward improvements in liver services, particularly hepatitis C.
2. A national liver strategy to address the growing crisis of liver disease, with clearly defined actions for addressing hepatitis C.
3. A robust governance structure for hepatitis C to oversee the monitoring, benchmarking and evaluation of actions by all levels of the NHS. These should be reported annually in the HPA report on hepatitis C.
4. A review of the implementation of NICE treatment and an audit of the barriers to achieving recommended treatment uptake levels.

## ***CALIFORNIA: "Open Door Clinics Drop Needle Exchange"***

<http://www.times-standard.com>

Times Standard (Eureka) (07.13.09):: Thadeus Greenson

Just as needle exchange programs in Humboldt County are hitting a major snag, the issue is coming up for what promises to be a raging debate on Capitol Hill.

This month, Open Door Community Health Centers' clinics in Arcata and Eureka quietly stopped administering the needle exchange program they have operated for almost a decade. It's not that the program wasn't successful -- quite the opposite, really.

"It's hard for anybody to imagine how big the program got," said Open Door Community Health Centers Chief Operating Officer Cheyenne Spetzler. "The footprint of the program just kept getting bigger."

The Humboldt County Board of Supervisors authorized the needle exchange program in 2000, but has never run or funded it. Instead, with the supervision of Humboldt County Health Officer Dr. Ann Lindsay, the program has been run by a number of providers, including the Open Door, Redwoods Rural and Mobile Medical clinics.

Susan Buckley, the director of the Public Health Branch of the Department of Health and Human Services, said the idea behind the needle exchange program is harm reduction, or reducing the

negative effects drug use has on individuals and communities.

”From a public health perspective, what needle exchange does is reduce the spread of blood-borne pathogens,” Buckley said, adding that those include Hepatitis and HIV. “It also helps get dirty needles off the streets in a safe manner.”

In most cases, the needle exchange program subsists on grant funding, but Spetzler said almost all the grants available for such programs only offer funding for the needles themselves, not for the costs of administering the programs.

In Humboldt County, the vast majority of the programs' clients are located in Eureka, which was only served by the Open Door and Mobile Medical clinics. Spetzler said the Open Door clinics in Arcata and Eureka combined to exchange more than 190,000 needles in 2008, with 150,000 of them being exchanged at the Eureka location.

Spetzler said administering the program in Arcata and Eureka simply became too much for Open Door Community Health Centers, both financially and practically.

First, with declining funding and the promise of another sizable reduction once the state budget is finalized, Spetzler said Open Door is struggling to get by, and is making cutbacks in a variety of areas: The Arcata dental office was closed, they've stopped medical outreach services and staff members have been asked to take pay cuts. It got to the point, Spetzler said, where it was hard to justify having a full-time staff person on hand solely to administer the needle exchange program.

Plus, as the program grew, there were additional problems. The centers were going through so many needles it necessitated massive deliveries, to the point that the clinics' storage space was filled with stacked palettes of needles, Spetzler said. Mothers, children and families that were comfortable coming into the clinics started feeling uneasy with what they were seeing.

It wasn't an easy decision, Spetzler said, but it was eventually concluded that the needle exchange program had outgrown Open Door.

”It doesn't feel good to have to do this,” Spetzler said. “(But) a lot of good was done. We really impacted the level of Hepatitis C in the community. And we haven't had those reports of needles in playgrounds and stuff like that in a long time.”

Humboldt County Department of Health and Human Services Programs Director Barbara LaHaie said that, with Open Door stepping away from the program, the county is currently weighing its options in finding another way to administer the program. Without a reliable funding stream, that may prove difficult.

But federal help may be on the way.

House Democrats unveiled a \$160 billion measure Friday to fund the departments of Labor and Health and Human Services for the next fiscal year, and the measure contains a provision that would scrap the federal funding ban on needle exchange programs that has been in place for years.

North Coast Congressman Mike Thompson applauded the move.

”Sterile needle exchange programs are an important way to reduce the transmission of diseases,” Thompson said in a statement issued Saturday. “Studies show that syringe exchange programs don't encourage or increase the use of illegal drugs, and actually increase enrollment in drug treatment programs. I support lifting the ban on federal funding, and applaud my colleagues on the appropriations committee for taking the first step to do so.”

But, not everyone feels the same way, and the stage is being set for a battle over the merits and ethics of such programs.

Rep. Todd Tiahrt, the top Republican on the House Labor and Health and Human Services Appropriations subcommittee, wasted little time Friday in blasting the proposal.

”I am very concerned that we would use federal tax dollars to support the drug habits of people who desperately need help,” Tiahrt told Reuters news service Friday.

Many feel similarly, and argue that any program benefits would be eclipsed by the perception that the government is condoning drug use.

Statistics, however, suggest that the programs can have large impacts.

The U.S. Centers for Disease Control reports that 19 percent of the country's HIV cases can be attributed to injection drug use and the National Institutes of Health report that injection drug use is the primary cause of Hepatitis C. Needle exchange programs, proponents argue, simply ensure that injection drug users are shooting up with clean needles and are therefore less likely to contract a disease themselves or infect someone else with one. Some studies also have shown that injection drug users who utilize needle exchange programs are more likely to seek treatment.

Now that the funding measure has been introduced, it will be debated by the whole House Appropriations Committee before heading to the House floor for consideration. It's a safe bet Humboldt County health officials will be watching closely.

But whatever happens, Buckley said the county will work to ensure its needle exchange program continues.

”We're going to work in the community to make sure clean needles are available,” she said.

**July 17, 2009**

### ***Developing a Safer Form of Acetaminophen***

<http://www.sciencedaily.com>

ScienceDaily (July 16, 2009) — Scientists in Louisiana are reporting development of a process for producing large batches of a new and potentially safer form of acetaminophen, the widely used pain-reliever now the source of growing concern over its potentially toxic effects on the liver. Their study could speed development of a next-generation pain-reliever.

In June, an advisory panel of the U. S. Food and Drug Administration recommended banning certain prescription pain relievers containing acetaminophen because of the drug's potential to cause liver damage when used in high doses. Mark Trudell and colleagues note in the study that scientists recently discovered a new form of acetaminophen that has similar potency to the original drug with a lower risk of liver toxicity. But until now, scientists have had difficulty producing this substance in quantities suitable for industrial scale-up.

The researchers describe a simple, efficient method for producing the new pain-reliever using only a few starting materials and a short series of chemical reactions. In laboratory studies, they used the new method to produce multigram quantities of the substance with 99 percent purity. The scientists point out that the new process can be performed on a much larger production level if needed.

**Journal reference:**

Miao et al. First Multigram Preparation of SCP-123, A Novel Water-Soluble Analgesic. *Organic Process Research & Development*, 2009; 090625102714032 DOI: 10.1021/op900113b  
Adapted from materials provided by American Chemical Society.

## ***Early HIV Treatment Helps Acute Hep C Treatment Response***

<http://www.aidsmeds.com>

Starting early HIV therapy at the same time as hepatitis C virus (HCV) treatment—in people simultaneously infected with both HIV and HCV—yields universally good HCV treatment responses, according to a study published in the August 1 issue of *Clinical Infectious Diseases*.

HIV and HCV can be transmitted at the same time, and by the same risk factors, but there has not been much research attention paid to individuals who become infected with both viruses simultaneously. Moreover, it is not entirely clear whether starting HIV treatment at the same time as HCV therapy, when a person is caught in the acute phase of both infections, will have better treatment outcomes.

To examine this strategy, Julian Schulze zur Wiesch, MD, from the University Medical Center Hamburg Eppendorf, in Germany, and his colleagues gave early HIV and HCV treatment to three patients in their clinic. All three were infected simultaneously with both HIV and HCV. One of the patients was a gay man infected through unprotected sex; one patient was infected through an assault with an infected needle; and one was exposed to both viruses by a needle stick on the job. All were enrolled and initially treated with both HIV and HCV treatment in 2003. The gay male patient was infected with HCV genotype 1—a harder to treat strain of HCV—and the other two patients were infected with HCV genotype 3.

All three patients received triple combination HIV therapy that included efavirenz (found in Sustiva and Atripla). Two of the patients received 48 weeks of only pegylated interferon alpha for their HCV, and one person received 48 weeks of pegylated interferon plus ribavirin. Interferon plus ribavirin is standard therapy today for HCV. All three achieved undetectable HIV levels within three months of starting HIV treatment and undetectable HCV levels within four weeks of starting HCV treatment.

Six months after completing their HCV treatment, all three patients maintained undetectable HCV levels, which is generally considered to be a cure for HCV. An HIV treatment interruption was attempted on two of the patients, but both had an HIV viral rebound and needed to reinstate therapy.

The authors conclude that doctors should look for evidence of concomitant HCV and HIV infection whenever they suspect acute infection with one of the two viruses. Moreover, the authors state that early treatment of both viruses should be considered, though larger trials of this strategy will need to be conducted.

### ***19 Hepatitis A cases linked to a Milan, Illinois McDonalds - 13 are in Rock Island County, and 6 more are being reported in Henry, Mercer, Warren and Woodford Counties***

<http://www.marlerblog.com>

As of Thursday afternoon, there are 19 confirmed Hepatitis A cases. 13 are in Rock Island County, and six more are being reported in Henry, Mercer, Warren and Woodford Counties.

John David at WQAD has reported: that “Lunch customers coming to the Milan McDonalds on Thursday found the doors locked. Drive-up customers were being turned away. According to investigators, an outbreak of Hepatitis-A may be linked to employees or someone who ate there.”

I guess lightning does strike at least twice. In March of 1998, the Skagit County Health Department (SCHD ) in Washington State received a number of reports that residents had been diagnosed with hepatitis A and began an investigation into what appeared to be a hepatitis A outbreak. During its investigation into the outbreak’s source, SCHD determined that the outbreak had occurred among patrons of the McDonald’s restaurant located on Riverside Drive in Mt. Vernon, Washington, who had eaten at the restaurant in mid-February, 1998. Through its investigation, SCHD learned that an assistant manager at the McDonald’s had worked while infected with hepatitis A and had contaminated food.

Hepatitis A is one of five human hepatitis viruses (hepatitis A, B, C, D, and E) that primarily infect the liver and cause illness. An estimated 80,000 cases occur each year in the U.S., although much higher estimates have been proposed based on mathematical modeling of the past incidence of infection. Each year, an estimated 100 persons die as a result of acute liver failure in the U.S. due to hepatitis A, but the rate of infection has dramatically decreased since the hepatitis A vaccine was licensed and became available in the U.S. in 1995.

Hepatitis A is a communicable (or contagious) disease that spreads from person-to-person. It is spread almost exclusively through fecal-oral contact, generally from person-to-person, or via contaminated food or water. Food contaminated with the virus is the most common vehicle transmitting hepatitis A. The food preparer or cook is the individual most often contaminating the food, although he or she is generally not ill at the time of food preparation. The peak time of infectivity, when the most viruses are present in the stool of an infectious individual, is during the two weeks before illness begins. Although only a small percentage of hepatitis A infections are associated with foodborne transmission, foodborne outbreaks have been increasingly

implicated as a significant source of hepatitis A infection.

In the last ten years we have been involved in a dozen Hepatitis A cases around the country. Most, if not all could have been prevented if restaurant or field workers had received a Hepatitis A shot BEFORE serving the customer.

- Carl's Jr. Hepatitis A Outbreak - Washington
- Chi-Chi's Hepatitis A Outbreak - Pennsylvania
- Chipotle Grill Hepatitis A - San Diego, California
- D'Angelo's Deli Hepatitis A Outbreak - Massachusetts
- Friendly's Hepatitis A Exposure - Massachusetts
- Houlihan's Hepatitis A Exposure - Illinois
- Maple Lawn Dairy Hepatitis A Outbreak - New York
- McDonald's Hepatitis A Outbreak - Washington
- Quizno's Hepatitis A Exposure - Massachusetts
- Soleil Produce Hepatitis A Outbreak - California
- Subway Hepatitis A Outbreak - Washington
- Taco Bell Hepatitis A Outbreak - Florida

Hepatitis A can be severe. In one case, in late October 2003, Beaver County ER doctors reported an alarming number of Hepatitis A cases. Investigators from the Pennsylvania Department of Health initiated an investigation immediately and discovered that many, if not all, cases had eaten at Chi Chi's restaurant in Monaca, Pennsylvania's Beaver Valley Mall. Along with the health department, the federal Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) conducted further studies of the outbreak. Preliminary analysis of a case-control study suggested that green onions were the probable source of the outbreak. The onions had been shipped to the restaurant in boxes and were stored and refrigerated in buckets of ice. They were eventually chopped up and served in various dishes at the restaurant, often uncooked, as in the preparation of mild salsa. "Preliminary trace-back information indicated that the green onions supplied to Chi Chi's had been grown in Mexico." Ultimately, over 650 people were sickened in the outbreak. The victims included at least thirteen Chi Chi's employees and numerous residents of six other states. Four people died from their injuries, and more than 9,000 people obtained immune globulin shots as protection against the virus.

### ***Liver Transplant Outcomes for HIV-Positive Patients Similar to Those of the General Population***

[www.medscape.com](http://www.medscape.com)

Laura Newman, MA

July 17, 2009 (New York, New York) — HIV-positive patients who undergo cadaveric liver transplantation have graft and survival rates equal to those of HIV-negative patients, but those co-infected with hepatitis C virus or who are HCV positive alone have suboptimal outcomes, according to new research presented here at the International Liver Transplantation Society 15th Annual International Congress.

The study involved liver transplants performed at 1 of 7 liver-transplant centers in the United Kingdom between March 1994 and April 2008: 33 patients were HIV positive (16 of whom were HIV/HCV co-infected), 5435 were HIV negative, and 847 were HCV positive.

One- and 5-year survival rates, respectively, were as follows: HIV positive/HCV negative (100%, 100%), HIV positive/HCV positive (73%, 53%), and HCV positive (87%, 69%) ( $P < .04$ ).

Infection was the leading cause of mortality, followed by HCV recurrence. One patient had a cholestatic recurrence of HCV. Pegylated interferon and ribavirin were poorly tolerated.

Kosh Agarwal, MD, consultant hepatologist and transplant physician at the Institute of Liver Studies at King's College Hospital, United Kingdom, and the study's senior investigator, told Medscape Transplantation that with the widespread use of highly active antiretroviral therapy (HAART), "you expect to treat HIV as a chronic disease and see good long-term function and survival."

"The availability of HAART since 1997 has really helped us improve outcomes. In the [United Kingdom], the number of patients with HIV that we see for transplant has placed an additional burden on [organ] allocation," Dr. Agarwal pointed out. "It is a learning curve for us on how to handle these patients, and there are ethical and practical issues that we are trying to address."

Another issue is liver-disease awareness. "We are very much involved in it, in prevention, and in educating patients to get in early because they may not have time to wait," said Dr. Agarwal.

"How we treat co-infected patients is very much an evolving field," he added.

"A study like this pushes so many hot buttons," noted Peter Stock, MD, professor of surgery at the University of California at San Francisco Medical Center in an interview with Medscape Transplantation.

"In the 1990s, nobody thought that we could put HIV-infected patients on immunosuppressants. It seemed counterintuitive," Dr. Stock said. But in San Francisco, AIDS activists fought hard for access to transplantation.

"We have all gotten better at improving our outcomes," Dr. Stock said of the British study, "but the punch line is still that HIV/HCV co-infected patients still do about 10% to 15% worse than HIV positive/hepatitis B-positive or HIV-negative patients."

"That being said, some [HCV positive] patients do extraordinarily well and we have seen people clear their HCV." He also acknowledged that there is "a subgroup that won't tolerate it all."

Dr. Stock confirmed that results in co-infected patients in the British series are consistent with those seen in other studies done in the United States. José M. Miró, MD, PhD, consultant to the infectious diseases service and associate professor of medicine at Hospital Clinic Universitari in Barcelona, Spain, added that the results are parallel to outcomes in France and Spain.

Dr. Miró, who was not involved in the study, noted 1 drawback: "The number of liver transplant

patients in this study is small — only 33 patients, of whom 16 were co-infected."

Dr. Miró told Medscape Transplantation that "the next step in this field is to try to identify the predictors of survival among HIV/HCV co-infected patients."

To identify the best candidates for liver transplantation among HIV/HCV co-infected patients with end-stage liver disease, HCV genotype, Model for End-Stage Liver Disease (MELD) score when placed on the waiting list, CD4 cell count threshold, and donor age must be considered, he said.

"The other important issue is treatment of HCV recurrence after orthotopic liver transplantation," Dr. Miró said. "If we were able to clear HCV because the patient has a sustained virological response, the survival would be the same as in [HCV negative/HIV positive] recipients." Dr. Miró has received a grant from FIPSE (the Spanish Foundation for AIDS Research and Prevention) to examine these issues.

Dr. Stock is the lead investigator on a multicenter National Institutes of Health trial, currently underway, that is examining the effect of HIV on graft survival, the effect of immunosuppression on the immune response against HIV and copathogens (hepatitis B virus, human papillomavirus, cytomegalovirus, Epstein-Barr Virus), and the pharmacokinetic interactions of immunosuppressive agents and HAART.

Dr. Agarwal, Dr. Stock, and Dr. Miró have disclosed no relevant financial relationships. They are each investigators in publicly funded research.

*International Liver Transplantation Society (ILTS) 15th Annual International Congress: Abstract 0-11. Presented July 9, 2009.*

## **Firefighter case could cost Orlando \$1 million or more**

<http://www.orlandosentinel.com>

Orlando could be on the hook for as much as \$1 million in legal fees after losing an eight-year legal battle that the opposing attorney said could have been settled relatively cheaply without ever going to court.

That's on top of the \$159,933 the city has paid an outside law firm to contest the case of retired firefighter Bob Flamily, who in 2001 accused city officials of hiding years of medical results that showed he'd contracted hepatitis. It also doesn't include the medical expenses for a separate heart problem the city will now have to pay his widow.

Flamily died in 2007 — two weeks before his case went to the Florida Supreme Court. That court sided with Flamily and sent the case back to the appeals court, which on Thursday ruled in part in his favor, effectively ending a lengthy legal battle that gained national attention.

"In 2001, I invited the city to simply pay this guy's claim, to do the right thing and acknowledge responsibility for his hepatitis. There was no litigation at that point and that would have been it,"

said Geoff Bichler, Flamily's lawyer. "They could have paid Bob Flamily and probably saved \$1 million."

Even so, Orlando officials argue that the consequences for the city could have been much more damaging had they not gone to court.

Flamily retired with a heart ailment in 1996 after 23 years with the Fire Department. Under Florida law, heart problems are presumed to be job-related for emergency workers, so Flamily received a worker's compensation settlement of about \$100,000 to cover his medical costs. But his heart problem turned out to be more severe than he'd been led to believe.

Later, Flamily discovered he also had hepatitis C — another condition that's presumed to be job-related, because firefighters are apt to come in contact with patients who have the blood-borne disease. But by then, the disease was in its final, terminal stage.

That's what started the legal battle.

Test results from his annual physicals at the medical clinic for city employees showed elevated liver-enzyme levels, a possible sign of hepatitis, as far back as 1978. But Flamily said city doctors never told him about the results or ordered further tests or treatment.

In addition, the city refused to pay the higher-than-expected medical costs for his heart problem or for the hepatitis, saying he'd waived that right when he received a settlement at retirement.

Other firefighters began checking their own clinic files and making similar allegations — which the city denied — that they had not been told they were suffering from a variety of ailments. A class-action suit failed, but the city reached a \$600,000 settlement with 28 firefighters in 2004.

But Flamily's lawsuit over both his heart condition and hepatitis dragged on, even after he succumbed to hepatitis-related liver disease.

Thursday's decision found that the city was wrong to deny Flamily further coverage for his heart problem because he'd been misled about its severity before he signed away his right to further claims.

"He would be so happy," his widow, Ramona, said Friday. "It didn't have to go on this long. But he was so bound and determined not to let this happen again."

Still, the ruling was mixed; the city won on the hepatitis claim. City lawyers argued that they shouldn't be liable for Flamily's hepatitis care because they hadn't kept all of his medical records, and the court agreed.

"That was really our big issue, based on the potential economic harm to the city," said City Attorney Mayanne Downs., who said a loss would have allowed other workers to press claims without complete medical records. "The city has always had a great sadness that this battle about the hepatitis issue went on for an extended period of time, so we're really glad to address the primary issue and let the family move on."

The ruling means the city will have to pay the legal fees and costs of Family's attorney. That could total \$500,000 to \$1 million, Bichler said.

"It's certainly true there will be substantial hours and rates claimed," Downs said. "But I'd be shocked if we're talking about those kinds of dollars."

The total will be the decided either through negotiation or by a judge.