

HCV ADVOCATE WEEKLY NEWS REVIEW

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

*Alan Franciscus
Editor-in-Chief*

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October 11, 2009

AIDS, Hepatitis C Cases Increasing in Montana

<http://www.missoulia.com>

By TRISTAN SCOTT of the *Missoulia*

As H1N1 grabs headlines and dominates all things public health, state officials and local advocates remain focused on a "forgotten epidemic" they say has fallen under the radar in Montana.

Even without the glare of publicity, positive diagnoses of AIDS, HIV and hepatitis C have trended steadily upward for more than two decades in the Treasure State. Now, HIV testing becomes routine with a state law that went into effect on Oct. 1. Physicians and health care professionals must offer the blood draws (people can decline) in their battery of tests - a move that public health authorities say could help drive the number of cases down.

With more individuals getting tested, experts say, the new standard could potentially decrease transmission rates from people who don't know they are positive, or who don't want to know because of the stigma.

"It has been a stigmatized disease, and people who usually make the decision to get tested have put themselves at risk," said Laurie Kops, supervisor of the state Department of Health's HIV/STD programs. "Men who have sex with men and people who inject drugs have a lot of labels attached to them, and for that population, walking into a physician's office to get tested is difficult. But if everybody is being tested, whether they had high-risk sex or were shooting up or just want to be safe, more people will know their status and have a baseline."

If the law results in more people getting tested, as Kops hopes it will, she expects to see a slight initial increase in the number of cases recorded in the state health department's books, but says the rates will eventually taper off. An estimated 21 percent of people living with HIV and AIDS in the United States are unaware of their infection, she said, and it's been shown that people who are not aware of their HIV-positive status are more likely to transmit the disease.

"I do think we are going to find a few surprises. I do think we will see an increase," she said. "People need to not think it can't happen to you, because it does, and we've had new positives lately where they were just absolutely astounded when they found out they were positive, and at very young ages."

At the end of September, there were 27 new cases of HIV reported in Montana, compared with

22 in all of last year. Meanwhile, a total of 943 new cases of hepatitis C cropped up last year, with the reported rate for American Indians nearly six times higher than that for whites.

Of the HIV numbers, Jessie Frazier, an epidemiologist at Montana's Department of Health and Human Services, said, "That's not a huge increase, but in terms of raw numbers it's higher."

At the end of December 2008, a total of 895 HIV/AIDS cases had been reported in Montana since 1985, when reporting began; of those, 575 were first diagnosed in Montana, and 65 percent were living in the seven most populated counties, with Missoula and Yellowstone leading the pack.

The most frequent mode of exposure to AIDS and HIV is men who have sex with men, Frazier said, accounting for 53 percent of all diagnoses. Injection drug use accounts for 12 percent of those diagnosed.

And while state health officials do not have the data to determine principal modes of exposure for hepatitis C, experts say the spike in cases is almost certainly due to the rising numbers of people abusing prescription drugs, which are often injected to obtain a high.

"Active injection drug users are mostly shooting pain pills," said Casey Rudd, an outreach worker who targets drug users and educates them on their risk behaviors. "For a while it was a big meth thing, but that's pretty much done. We don't see much meth on the streets anymore. People have switched to OxyContin and other opiates."

Rudd, 60, a former addict who spent time in prison, has been doing "street outreach" for the past decade. Her method of ground-level outreach work allows Rudd to interact directly with addicts who are at risk to contract diseases, and who might not otherwise ask for help. Rudd, of Bozeman, is one of 14 outreach workers statewide who target high-risk populations.

"We help them make a plan for getting clean and moving forward with their lives, but we're also giving them resources to help them cut down on high-risk behaviors," Rudd said. "We're testing them for HIV and hep C because they're at huge risk for both of those."

Because Rudd targets injection drug users, she said between 85 percent and 90 percent of the people she tests are positive for hepatitis C. In its later stages, hepatitis C can lead to liver cirrhosis and cancer.

Other outreach workers focus on men who have sex with men, educating them on prevention measures and offering free testing.

The outreach positions exist through a program called Montana Targeted AIDS Prevention, a program within the Missoula AIDS Council that is funded by the federal Centers for Disease Control and Prevention.

Liz Murphy, executive director of the Missoula AIDS Council, said the positions are a critical component to AIDS prevention and risk reduction. Although her office offers free anonymous testing on a daily basis and provides risk reduction and counseling, the outreach workers tap into an otherwise invisible and unreachable group.

"In Montana, it's not very safe to be gay and out. Or to be bisexual or transgendered," she said. "We don't have sex clinics [where people can get tested] on every corner. We don't have gay bars. So these workers do outreach on the streets, at dealers' homes, out of their own homes, on street corners where people are shooting up, and they provide testing, referral services, and counseling. They create a safe place for high-risk populations to go. A lot of these folks do not want to step through the doors of a health clinic because of the stigma. Stigma makes people afraid to ask their doctor of 20 years for a test. That's part of what makes outreach so crucial."

Murphy, who is currently working to renew the CDC grant, said Montana's outreach workers provide about 1,000 tests a year and have built up trust and credibility within their communities.

"For a while, Montana was a low-incident state for AIDS," she said. "But with people increasing their travel, it's not staying in the hubs as it once did. It's not just a disease of the gay or the poor or the prostitutes. It doesn't discriminate. It affects everyone."

Perhaps no one understands that better than Kris FourStar, the communicable disease officer for the Fort Peck Tribal Health Department. In Roosevelt County, which is home to the Fort Peck Indian Reservation and has a population of less than 11,000, the state health department has documented nearly 500 cases of hepatitis C - more than anywhere else in Montana. In Glacier County, where the Blackfeet Indian Reservation is located, there are 396 cases.

"We've always known that there have been high hep C rates, but we just started addressing it in the last year and a half," said FourStar, who launched Montana's only needle-exchange program about four months ago. "The program is primarily in response to our rising numbers of hepatitis C, which is only spread blood to blood. And injection drug use is the culprit."

Since 1988, the U.S. government has prevented local and state public health authorities from using federal funds for needle-exchange programs, which studies have shown to be effective in reducing infection rates among injection drug users.

But Fort Peck is sovereign and has its own health code, under which it is recognized as a public health authority. FourStar says it took about a year of meetings and research - including interviews with 51 injection drug users - before the program was launched. The initial funding for the research came from Montana State University's Center for Native Health Partnership. The New York-based Syringe Access Fund then provided a \$70,000 grant to purchase supplies. No tribal dollars are being used to pay for the program, he said.

"Since then, it's been fueled by word of mouth," FourStar said. "They are starting to trust that we're not law enforcement, that we're trying to make them safe and clean. The networks of users are really tight. It's such a small community here and everyone knows everyone, so people are really wary of getting tested or reaching out for help."

Addicts contact the exchange program by calling or text-messaging a cell phone number printed on business cards advertising the program. The addicts are then given a hard plastic container containing a clean syringe, which is called a "rig" on the street, and a separate compartment in which to discard the needle. They also receive a "cooker," or a spoon, cotton balls, sterile water, alcohol wipes, tie-offs or tourniquets and gauze pads.

"It's a one-for-one program," FourStar said. "We give them 10 rigs, and when we get them back, they can get 10 more. The clients are very responsible, because they know it would reflect poorly on them. Whatever rigs we give them, they bring them back."

During every interaction with the addicts, FourStar said department officials discuss abstinence and safer injecting practices, such as cleaning the wound site and never sharing rigs.

"There's an enormous lack of knowledge about the spread of communicable disease," FourStar said. "The best course of action, obviously, is abstinence, but outside of that, it is using a new syringe every time they shoot up."

Kops, of the state health department, said the program is a positive step for the tribe, especially if it encourages more screenings for hepatitis C, which can go undetected for decades since it may not lead to illness in its early stages. Detection through a simple blood test is important, she said, because the disease can be treated and cured.

Kops said the prevalence of hepatitis C on reservations is a problem in Montana and across the country, particularly given the high rates of alcoholism.

"Because there are high rates of alcoholism, hepatitis C is even more likely to affect a person's health," she said. "Some people can fight it off, but when you already have liver disease it's more difficult."

"It's tragic. The hep C rates on reservations are unbelievable," she said.

Reporter Tristan Scott can be reached at 523-5264 or at tscott@missoulian.com.

October 12, 2009

B Here Raises Awareness for UCI

<http://www.newuniversity.org>

By Briana Kim

The Student Center was decorated with red balloons for the "B Here Campaign," to spread awareness of hepatitis B which was sponsored by the Chinese Association and Alpha Phi Omega. "B Here" kicked off last Monday, Oct. 5.

The "B Here Campaign" was composed of two parts: an art exhibit and a live performance. Admission to both parts was free; however, people had to attend the exhibit in order to get their tickets for the live performance.

Spirit Chair for Alpha Phi Omega, Michelle Fong, said that this co-ed fraternity "helps whenever it can to support important causes."

Alpha Phi Omega went to both the art exhibit and live performance as an organization.

This campaign was held on campus to support hepatitis B awareness. Many people, such as the dance crew Kaba Modern from "America's Best Dance Crew," and KevJumba, came to UC

Irvine to stand up for this cause.

The art exhibit was held in Student Center Ballroom from 10 a.m. to 5 p.m. There were many student volunteers participating in this event as well as artwork all throughout the room and a photo booth area where students could take pictures with their friends.

In order to obtain the ticket for the live performance, each student needed to watch a five-minute video about hepatitis B awareness near the exit of the art exhibit.

In the video, Dr. Danny Chu defined hepatitis B as a “serious liver disease caused by the hepatitis B virus.” Chu also shared how hepatitis B can lead to “severe medical complications including liver failure, liver cancer and even pre-mature death.”

Arline Loh, a hepatitis B patient and advocate, was also on the video. She described hepatitis B as the “silent killer” because many people living with the disease do not know they are infected. Loh explained that she had chronic hepatitis B for nearly 40 years without knowing it.

The repeated quote in the video was that “one in 10 Asian Americans is living with chronic hepatitis B.” This quote was supported by the worldwide statistic that about 400 million people are living with hepatitis B and two-thirds are from Asian countries.

Kevin Wu, known to many as KevJumba, was the emcee for the night. He began by sharing how excited he was to be able to come to UC Irvine. KevJumba then introduced Jessica Sanchez.

Sanchez started her set off by singing Rihanna’s, “Please Don’t Stop the Music.” Afterward, she sang Beyonce’s “Smash Into You.” The last part of her set was a montage of Michael Jackson’s songs.

AJ Rafael was the next performer. He began his set by singing a Disney medley which consisted of everything from Hercules to Mulan. He also sang some of his own songs like “Showstopper” and “I Just Want You.”

Michelle Martinez, a northern California local, performed immediately after. She began to sing one of her songs “Euphoria” then sang a couple more acoustic covers as well as her own song, “Nobody but You.”

Paul Dateh then performed with Ken Belcher. Dateh played an electric violin and sang, while Belcher played the guitar.

Christine Gambito, also known as HappySlip, performed stand-up comedy. She shared many of her family gatherings and mimicked her relatives trying to speak English.

The last performance was done by Kaba Modern from “America’s Best Dance Crew.” Toward the end of the routine, a couple of the group members performed mini solo pieces. The audience was entertained by the group’s stage presence. Kaba Modern threw out t-shirts into the audience before leaving the stage.

Fong said that Alpha Phi Omega encouraged others to go to support the event as well. She felt

both the concert and gallery were “very effective.” Fong explained that the message of hepatitis B awareness was conveyed to the audience.

“[The concert was] pretty good in making people aware of hepatitis B,” third year Yesie Chang said. “It made my eyes open to Asian American YouTube stars pursuing their dreams.”

Alert Over Donor Organs Riddled with Cancer, Mad Cow Disease and Hepatitis

<http://www.telegraph.co.uk>

By Rebecca Smith, Medical Editor

Donor organs for transplant have been found to be infected with deadly diseases, carry cancerous tumours and have been too damaged to use, an alert to the health service has warned.

Doctors reported one instance where a kidney arrived for transplant in a poor state but the operation was carried out anyway only for a 'massive bleed' to occur from the organ meaning it had to be removed again. It was sent for testing and found to contain a cancerous tumour.

The incident prompted a search of the National Patient Safety Agency database which uncovered 11 similar reports of faulty organs.

An alert sent to the health service said other examples included ‘fatty’ organs, which can be caused by the donor patient being obese and fatty liver can also be caused by alcoholism and may lead to cirrhosis; the donor patient found to be infected with vCJD – the human form of mad cow disease and hepatitis B; and cuts and damage to an organ during the retrieval operation.

The report said there were also incidents relating to mismatching of tissue typing and patient identification errors.

It is not known if the transplant operations went ahead in all cases or if the recipients suffered any adverse effects.

The quality of transplant organs has been called into question before when it emerged that donations were being accepted from drug addicts due to the critical shortage.

There are around 10,000 people on the waiting list for an organ transplant and around 1,000 die each year waiting for a match.

The waiting list grows by around eight per cent each year and advances in intensive care medicine and surgery mean more patients who would become donors are surviving their injuries.

Representatives from the National Patient Safety Agency called an urgent meeting with NHS Blood and Transplant, the special trust which oversees transplants, after the incidents came to light.

The report added: "There was encouraging news on very recent changes where, for the first time, there will be a robust, secure and funded national system for organ retrieval, staffed by well-

trained surgeons and other healthcare professionals.

"NHS Blood and Transplant is setting up a system for monitoring the quality of organs and this will be supplemented by a photographic assessment of livers that is currently being evaluated.

"While these changes address many of our concerns, NHS Blood and Transplant strongly encourages staff to continue reporting all adverse events and any concerns about preventable harm to donated organs."

The National Patient Safety Agency database contains 3.5 million incident reports from England and Wales made by NHS staff since 2001 which can be analysed for patterns.

Keith Rigg, president of the British Transplant Society, said there has been a shift in donors with fewer young people dying of head injuries and more older people dying of brain haemorrhages which meant organs tended to be older.

But he added that all potential organs are inspected before the recipient is anaesthetised.

Mr Rigg, who is a transplant surgeon in Nottingham, added: "People are aware that quality and safety is an important issue and the cases highlighted here are a very small minority. Surgeons are careful about what they transplant and do not take unnecessary risks."

A Department of Health spokesman said: "We are committed to supporting new initiatives to optimise the number and quality of donor organs.

"Following the Organ Donation Taskforce recommendations, NHS Blood and Transplant are investing in the development a new national system for organ retrieval with a UK-wide network of highly trained organ retrieval teams, working to ensure high quality organ removal.

"This will be complemented by a new digital imaging service that allows surgeons to inspect livers online before accepting them."

In a separate case, it was disclosed yesterday that an Iraq war veteran died after a transplant in which he was given a pair of cancerous lungs donated by a smoker.

Haemophiliacs with HIV to Sue Firm that Sold Tainted Drug in Asia

<http://www.guardian.co.uk>

Bayer owned company to face victims in Taiwan and Hong Kong over its marketing of infectious blood products

Haemophiliacs in Taiwan and Hong Kong have been given permission to sue a multi-national drugs firm in the US over allegations that they contracted HIV from contaminated blood products that the company knowingly dumped in Asia.

The decision comes as US pharmaceutical firms meet UK victims of the scandal, which affected nearly 6,000 people with haemophilia in Britain during the 1970s and 1980s. Haemophiliacs in

the UK were refused permission to sue in the US courts by a judge who said the British courts were better placed to hear the evidence.

Nearly 2,000 of the UK victims have now died in what Lord (Robert) Winston has called "the worst treatment disaster in the history of the NHS".

One man, Haydn Lewis, who contracted HIV from contaminated blood he believed came from the US and then unwittingly passed the virus to his wife, said: "The main reason was to get a judgment in a court of law which suggests which of the two parties were at fault – the companies who provided the products or the Department of Health, which purchased them. For years we've had this denial of responsibility. We are still ... unaware of who is the guilty party."

The charges by the Taiwanese victims against the company, Cutter, which is now owned by Bayer, are particularly dramatic. The UK and other European authorities refused to buy blood products that had not been heat-treated in the 1980s, for fear of HIV contamination. Documents in the possession of US lawyers show, however, that Cutter did its utmost to continue marketing the products in Asia.

Cutter made a product called Koate, given to haemophiliacs to enable their blood to clot in the event of an injury. Documents in the court case brought on behalf of the Taiwanese haemophiliacs showed that some of the donated blood used to make the drug came from paid prisoners. Prisons had exceptionally high levels of inmates with HIV.

In the mid-1970s it was known that blood products carried a danger of infection from hepatitis, and that those coming from the US were particularly risky.

In the 1980s, once it was recognised that HIV was blood-borne, Cutter's market for non-heat-treated Koate began to dry up. Its executives, it is alleged, decided to carry on supplying the far east regardless. Baum, Hedlund, Aristei & Goldman, the US lawyers representing Taiwanese haemophiliacs who contracted HIV from blood transfusions, allege that Cutter put sales above lives. A copy of Cutter's 1985 far east region marketing plan suggests that the strategy was to offload stocks of Koate before the "hysteria over Aids" set in and caused a slump in sales. Sales in New Zealand had been hit as the US products were replaced by local and Commonwealth supplies, the document says. "What Koate business Cutter had left in New Zealand, as of 1982, was terminated when Aids became an issue there," it says. "Aids has not become a major issue in Asia. Perhaps it is because the region has so many other health hazards of greater, more common, concern."

The document says: "The hepatitis risk of American-made concentrates is not of such concern in a region where hepatitis B is so prevalent. If we see a need for a heat-treated product in the far east, we will react to the demand swiftly. Otherwise, we will try to continue to dominate the markets with low-cost ... Koate and Konyne."

Of 1,200 people in the UK with haemophilia who were infected with HIV, only about 300 are now alive. Of those, some 180 still have cases in the UK courts.

Lawyers for the US drug firms have offered compensation to those affected in the UK, and say the offer will be withdrawn unless 95% of claimants agree to it.

A spokesperson for Bayer said of the Taiwanese case: "Bayer is committed to the highest ethical standards, to promoting our medications responsibly and to providing life-saving therapies for the global haemophilia community."

China to Stop Mandatory Hepatitis B Tests: State Media

<http://www.google.com>

(AFP)

BEIJING — China will stop mandatory hepatitis B tests for employees joining new companies and students enrolling in schools, state media said Sunday, after a court ruled the tests were illegal discrimination.

Deng Haihua, deputy director of the health ministry's general office, said the government would soon issue instructions to stop the practice, which is currently a requirement, the official Xinhua news agency reported.

"A hepatitis B disease carrier does no harm to others' health and the new practice will not increase the disease transmission," Deng was quoted as telling a news conference on Saturday.

A design company was ordered in May last year to pay a job applicant around 20,000 yuan (2,950 dollars) after it withdrew an offer because he had hepatitis B, according to the Hong Kong-based China Labour Bulletin's website.

The Beijing district court judgment was the first time a hepatitis case was successfully litigated in China, according to the group, which monitors mainland workers' rights.

Previous cases were settled through court-ordered mediation or private agreements, it added.

The judgment was seen as a sign the 2008 Employment Promotion Law, which specifically outlawed discrimination against people with an infectious disease, had teeth, according to the China Labour Bulletin.

DPP Refuses to Reveal Reason for Dropping Hep C Charges

<http://breakingnews.iol.ie>

The Director of Public Prosecutions has refused to say why charges relating to the infection of women with Hepatitis C were dropped against the former principal biochemist with the Blood Transfusion Service Board.

Ms Cecily Cunningham (aged 68) was charged with seven counts of unlawfully administering infected Anti-D medicine resulting in grievous bodily harm. All charges were dropped by the DPP last January because "changes in evidential subjects were such that a prosecution could not have been sustained".

Ms Cunningham, of Hollybrook Road, Clontarf had denied all charges and previously lost a challenge in the High Court to have the case thrown out. The case was under judicial review

when the decision was made not to proceed by the DPP.

A hearing at Dublin Circuit Criminal Court today to determine who was liable for costs heard that the DPP was under no legal obligation to disclose the specific reasons for dropping the case.

Mr Roderick Murphy SC, prosecuting, said there was no requirement for the court to know why charges were dropped, in the same way they did not have to know why a jury acquitted a defendant in a trial.

Mr Michael McDowell SC, for Ms Cunningham, read from an affidavit before the court that an expert witness for the State died in June 2004 but the gardaí said they did not learn of his death until three years later.

He submitted that his client should be entitled to the full costs of her defence because the evidence against her “barely came to knee height”.

He also said it was perfectly reasonable that she would incur “substantial” legal costs because “short of murder or treason, it is hard to think of more serious charges than deliberately setting out to ruin people’s lives.”

“Her reputation and liberty were on the line”, Mr McDowell said. “This case was life-threatening to her because it would have permanently altered her life.”

Mr Murphy said he was resisting the application because the case was brought in a fair manner and a high court judge had previously decided it was fit to go to trial. He said there was no evidence of misconduct by the gardaí or DPP and Ms Cunningham’s rights had never been violated.

He said the long delay in proceedings were mainly caused by Ms Cunningham’s legal team initiating a judicial review and was not the fault of the prosecution.

Judge Desmond Hogan said he intended to read though the book of evidence, which runs to 12 volumes, and decide if there was a case to answer and whether costs should be awarded. He adjourned the matter until December.

When Good Medical Care is All or Something

<http://www.psychologytoday.com>

Striving for understanding even when it is unobtainable

One of the greatest joys of practicing medicine is for me to understand where my patients are coming from, so I can best help them through their medical journey. I was reminded of this fact recently, when talking with a patient who had just come back to my primary care clinic after visiting the liver clinic to discuss his chronic Hepatitis C infection. His liver function was still quite good, but his blood tests and liver biopsy showed ongoing liver damage. If this continued, there was a good chance my patient would soon find himself with a failing liver.

At the liver clinic, he had met with a concerned and caring physician who talked to him about how serious his liver disease was, and who explained the pros and cons of treatment. When the patient returned to my office, it was clear that he had been well educated. He knew that treatment had about a 50% chance of curing him and that, for the majority of patients, the treatment was long and arduous, making them feel like they had an unending case of the flu. With this information in mind, and with vivid recollections of past bouts with the flu, my patient decided to forgo treatment.

His visit with the liver doctor was, by all measures, a paradigm of autonomous decision making. My patient was intelligent, informed and clear about his preferences, and yet I found myself unable to accept his decision at face value. I gently pushed back: "I've taken care of a number of patients this year who went through this same treatment who discovered that it wasn't nearly as bad as they thought it would be," I told him.

And that's when the two of us came up with a third alternative: a trial of treatment. My patient was understandably overwhelmed at the thought of months of flu-like symptoms. He didn't even know how severe these symptoms would feel, so it was difficult for him to commit himself to extended misery. But his decision didn't have to be all or nothing. What if he started treatment with the option of quitting if he found it intolerable? I laid the idea out for him: "You might find out that it is not so bad after all. But if it makes you miserable, and you don't want to go on, I will support you."

He returned to the liver clinic and told the specialist he was ready to start treatment.

Emboldened by my experience with this man and his hepatitis treatment, I have increasingly looked for third routes for patients who I fear might be making bad decisions because they haven't seen all the possibilities. I call it my "all or something" strategy.

So you won't be surprised at what I proposed to a patient I met one day who was reluctant to receive monthly shots to prevent recurrence of his prostate cancer. He was afraid that the monthly shots would be uncomfortable. It was our first visit together, and I was talking to him about his general medical history. He had already received treatment for prostate cancer, and his urologist had recommended that he receive a monthly injection of a medication that would reduce the chance of recurrence. But he was tremendously afraid of needles. Hated them in fact. And the thought of a monthly injection was simply too much for him to contemplate.

I talked to him at length about this decision, skeptical that fear of needles could dissuade him from a potentially life-changing treatment. Was he afraid of the side effects of the medications? No, he wasn't. The cost of the medication? Not at all. Did he trust his urologist? Had they had a bad interaction? No. In fact, he was delighted that the urologist happened to be African American, like he was. But that didn't mean he was going to put up with a monthly injection.

At this point I spun the discussion over to my "third way" approach. I suggested that he try a monthly injection once, to see what it felt like. Maybe it wouldn't be such a big deal. Then he could try it a second time, and continue the treatments only as long as he decided that they were worthwhile.

He rejected my idea. I honestly could not understand how any human being could be so afraid of

a little needle that he would turn down a treatment that might forestall the recurrence of a life-threatening cancer.

As I sat there, confused about this man's decision, he looked at me and said: "You're the first doctor who really understands me."

I neither comprehended this man's decision, nor understood what in the history of his life would have led him to make this decision. But I did understand one thing that day: that the proper practice of medicine is about striving for understanding even when we cannot obtain it.

October 13, 2009

Endoscopy Plaintiffs Target Drug Suppliers

<http://www.lasvegassun.com>

By Jeff German

Insurance thought not to be nearly enough to cover \$300 million in liability

Lawyers involved in the endoscopy center cases say the personal wealth of Dr. Dipak Desai could be as much as \$30 million.

Lawyers suing Dr. Dipak Desai and his clinics say it would take \$300 million on the table to negotiate a settlement for thousands of former patients whose lives were disrupted by last year's hepatitis outbreak.

The bulk of that money would not come from Desai and the other medical defendants, who have limited malpractice insurance, but rather from the wealthy medical suppliers that did business with Desai's clinics. The defendant with the deepest pockets is Israeli-based Teva Pharmaceutical Industries, which last year logged a record \$11.1 billion in sales.

To get Teva to the table, the lawyers believe they will have to obtain two or three multimillion-dollar jury verdicts holding the company's U.S. subsidiary liable for distributing products that led to the potentially deadly hepatitis C infections here.

"You have to have a knife to their throat in a back alley to get money out of them," lead plaintiffs lawyer Will Kemp said. "They never settle easy."

Looking to Teva for the pot of gold is crucial because the lawyers estimate the medical defendants' insurance proceeds — most, if not all of them, are covered by Nevada Mutual Insurance — would provide only \$54 million to \$60 million to the former patients. As many as 20 doctors and nurses are named as defendants, each with a maximum of \$3 million in insurance. The insurance policies are standard for the health profession, but do not take into account a medical calamity with large numbers of potential victims seeking financial damages, the lawyers said.

"What's available in insurance doesn't begin to scratch the surface of what's needed," said Robert Cottle, another lead plaintiffs attorney in the endoscopy litigation.

Of the nearly 5,000 former patients suing Desai and his clinics, about 300 are claiming they were infected with the hepatitis C virus. The average jury award in this kind of case ranges from \$2 million to \$5 million.

Cottle and Kemp expect that as many as 150 of the infected former patients will be able to prove they contracted the virus at Desai's clinics. Using the low-end \$2 million award figure, a settlement would total \$300 million.

Nevada's \$350,000 cap on noneconomic damages for plaintiffs does not apply to non-medical defendants such as Teva.

The other 4,500 noninfected plaintiffs in the endoscopy litigation would likely receive about \$5,000 each for the stress of having to get tested for hepatitis C, which throws another \$22.5 million into any settlement, Cottle said.

The lawyers acknowledge that these figures are early estimates for the massive litigation, which experts say could drag on for several years.

"It's an incredibly complex case," said Robert Correales, a UNLV Boyd Law School professor. "There is no blueprint for what could happen."

Attorneys on both sides prefer to settle large litigation cases like this because it saves everyone, including the courts, the time and cost of putting on a large number of hard-fought and often lengthy trials.

Correales, a torts expert, said the strategy of going after big-money manufacturers is common, but not always successful.

In this case, the plaintiffs will have a tough time proving that the products distributed to Desai's clinics led to the hepatitis C infections of the former patients, he said.

But Cottle, who expects to try the first case against Desai and Teva in April, disagrees.

Cottle's client, Henry Chanin, alleges he was infected with the hepatitis C virus June 26, 2006, when he was given the anesthetic propofol from a contaminated vial during a procedure at Desai's Desert Shadow Endoscopy Center, 4725 Burnham Ave.

Chanin and the other infected patients have charged that sloppy handling of propofol at Desai's clinics led to their medical problems.

Cottle contends that it takes only about 10 to 12 milliliters of propofol to put a patient under during a routine procedure, such as a colonoscopy.

Propofol is commonly sold in 10-milliliter vials, but from 2005 until January 2008, several manufacturers, including one of Teva's companies, Sicor Pharmaceuticals, were providing Desai's clinics with the anesthetic in 20-milliliter and 50-milliliter vials.

The 50-milliliter containers are meant for use on one patient who receives the sedative in drip

form over a long period of time. Desai's clinics, however, in an effort to boost profits, allegedly squeezed out doses for multiple procedures from the 50-milliliter vials, sometimes contaminating the vials in the process.

"These products were dangerous in the way that they were distributed," Cottle said. "They were shipping 50s when they knew it created an unreasonable risk to the patients."

As far back as July 1995, the New England Journal of Medicine cited the potential for contamination in an article warning against the use of 50-milliliter vials for multiple patients.

Las Vegas attorney Michael Stoberski, who represents Teva in the endoscopy litigation, declined to comment.

If the plaintiffs' lawyers are unable to prove Teva's liability in the hepatitis C infections, they would have the option of going after Desai's personal wealth, which the lawyers said could be as much as \$30 million, and that of some of the other physicians named as defendants.

A district judge had that possibility in mind in May 2008 when he barred Desai from conducting any personal financial transactions of \$50,000 or more without the court's permission. Plaintiffs' lawyers raised concerns that Desai might try to liquidate his assets.

Looking for compensation from Desai's three clinics — Desert Shadow Endoscopy Center, the Endoscopy Center of Southern Nevada and the Gastroenterology Center of Nevada — is another option. But that will be difficult.

All three clinics, which are now closed, have filed for Chapter 7 bankruptcy protection, and have reported having only a combined \$100,000 in cash on hand. The biggest current asset of the clinics is their insurance coverage with Nevada Mutual. But just how much money is available is unclear.

In Bankruptcy Court papers, attorneys for the insurance company said the Gastroenterology Center has a \$3 million policy limit, but the other two clinics share maximum coverage with Desai and the other medical defendants. The insurance attorneys did not put a dollar value on the shared coverage, but Bankruptcy Court officials believe it is included in the \$54 million to \$60 million the plaintiffs' lawyers estimated would be available for court settlements.

Chip Wallace, a Nevada Mutual Insurance director and spokesman, declined to discuss the insurance policies with the Sun, citing the ongoing litigation.

Despite the relatively minimal assets of the clinics, lawyers for Brian Shapiro, the bankruptcy trustee looking out for the interests of the creditors, are trying to engineer an overall settlement of the endoscopy lawsuits through Bankruptcy Court.

Shapiro's attorneys first disclosed their efforts in Bankruptcy Court papers last week. Shapiro wants Bankruptcy Judge Mike Nakagawa to order a settlement conference with all of the defendants and plaintiffs.

"All creditors of the bankruptcy estate, including the plaintiffs, need to be treated fairly," Shapiro

said. “Because there’s limited insurance coverage, no one should be able to settle with one party to the detriment of the others.”

Walter “Skip” Scott, a Dallas attorney representing Shapiro, added, “If we proceed on a piecemeal basis, the one thing I’m certain of is we will run out of coverage.”

Because of those fears, Shapiro and his lawyers want Nakagawa to block a confidential settlement that Nevada Mutual Insurance struck with one of the infected endoscopy plaintiffs, Michael Washington, on behalf of Desai.

But the plaintiffs’ lawyers say Shapiro’s efforts to have the matter resolved in Bankruptcy Court are a pipe dream.

“The party with all the money isn’t in Bankruptcy Court — the court has no authority over Teva,” Cottle said.

To the plaintiffs’ lawyers, the bankruptcy proceedings are a nuisance. They view the clinics as a minor player in any potential overall settlement.

Cottle said he’s considered dropping the clinics as defendants so he doesn’t have to deal with Bankruptcy Court, but he’s reluctant to because the public views the clinics as the “bad guys” in the litigation.

“At some point, if you’re going to have a global settlement, there will be some bankruptcy court settlement,” Kemp added. “But right now that’s premature until you get Teva’s liability resolved.”

Jeff German is the Sun’s senior investigative reporter.

UCSD Researchers Pave the Way for Effective Liver Treatments

www.medicalnewstoday.com

A combination of bioengineering and medical research at the University of California, San Diego has led to a new discovery that could pave the way for more effective treatments for liver disease.

In this work, the researchers have utilized an array system that can identify the biological components that can lead to or alleviate liver disease. The technology works by controlling the range of environments surrounding star-shaped liver cells called hepatic stellate cells (HSCs). HSCs are the major cell type involved in liver fibrosis, which is the formation of scar tissue in response to liver damage. The activated stellate cell is responsible for secreting collagen that produces a fibrous scar, which can lead to cirrhosis.

Current approaches to identify the factors affecting HSC biology typically focus on each factor individually, ignoring the complex cross-talk between the many components acting on the cells. The high-throughput cellular array technology developed by UCSD researchers systematically assesses and probes the complex relationships between hepatic stellate cells and components of

their microenvironment. By doing this, they found that certain proteins are critical in regulating HSC activation and that the proteins influence one another's actions on the cells. The findings were published in a paper entitled "Investigating the role of the extracellular environment in modulating hepatic stellate cell biology with array combinatorial microenvironments" in the September 2009 issue of *Integrative Biology*.

"We can spot hundreds of combinations of proteins in the matrix surrounding the cell such as different kinds of collagen - you can spot them individually and in combination, so you can get hundreds of combinations with several proteins," said Shu Chien, co-author of the paper and bioengineering professor and director of the Institute of Engineering Medicine at UCSD. "We used a spotting pin that's normally used for microarray DNA spotting. But we spot proteins instead of DNA on these slides.

"In one step we can look at the physical and chemical micro-environment of the cells," Chien added. "Now we can look at the optimum condition that is best for the cells to proliferate and differentiate."

The high-throughput cellular array technology used in this research was developed by Chien and his lab colleagues a few years ago mainly for stem cell research, but it has not been applied to this type of research before involving hepatic stellate cells.

"Our lab is interested in the cells that are responsible for laying down the fibrous scar in all types of chronic liver disease," said Dr. David Brenner, the dean of the UCSD School of Medicine and co-author of the paper. "In the course of 20 years, people have tried three or four matrixes to try to optimize their growth. Shu Chien mentioned this extracellular matrix array that his lab was using for stem cells, and I thought it would be an incredible opportunity to understand the effects of different matrixes in primary cell cultures.

"By looking at the array you get hundreds of different combinations of proteins and you can look at hundreds of cells at once," Brenner added. "This will give us new insights for the treatment for liver fibrosis, and it will give us the platform to test new treatments. This also allows us to do the critical experiments that will assess the ability of different drugs to work. There are really no effective therapies for liver fibrosis - there is only transplantation. Any less invasive therapy would be desirable. This is a big advance."

Chien said such medical advances are the result of the growing synergism between engineering and medicine. This study involves the dissertation work of David Brafman, who received his Ph.D. in bioengineering from UCSD under the joint advisorship of Chien and professor Karl Willert of the Department of Cellular and Molecular Medicine. Chien said the next step for this collaborative effort will be to develop a platform that allows scientists and researchers to differentiate cells into the kind they want. It's this type of work, Chien said, that gives the field of regenerative medicine a boost.

"Eventually we would like to help improve people's health," he said.

"Investigating the role of the extracellular environment in modulating hepatic stellate cell biology with array combinatorial microenvironments," *Integrative Biology*, September 2009. Authors: David A. Brafman, Samuele de Minicis, Ekihiro Seki, Kevan D. Shah, Dayu Teng,

David Brenner , Karl Willert and Shu Chien.

Source: Andrea Siedsma
University of California - San Diego

Report Calls for Global U.N. Pact to Ban Organ Sales

www.reuters.com

By Patrick Worsnip

UNITED NATIONS (Reuters) - A new international pact is needed to ban trafficking in human organs, tissues and cells, protect victims and punish offenders, says a report issued on Tuesday by the United Nations and Council of Europe.

Selling body parts was not just unethical, it also led to greater health risks for both donor and recipient than free, voluntary transplants, the 98-page report said.

"We affirm as a primary principle no financial gain should be coincident with obtaining organs and tissues for transplant," University of Pennsylvania academic Arthur Caplan, one of the report's authors, told a news conference.

Despite proposals to create a legal market in commercial transplants, "it seems to us that money-for-parts is still a situation that exploits the poor, that people do not have choices in nearly all parts of the world when they sell an organ," Caplan said.

Although data on the scale of organ trafficking was scarce, the report quoted estimates that 5 percent to 10 percent of an estimated 68,000 annual kidney transplants around the world resulted from the practice.

The report highlighted what it called "transplant tourism," in which people from rich countries in western Europe, North America and parts of Asia went to poorer ones in Africa, Asia, eastern Europe and South America to obtain organs.

A "package" that included the travel and the transplantation procedure could cost from \$70,000 to \$160,000, it said, with most of that going to professionals and intermediaries involved rather than to the donor.

"Impoverished and vulnerable people sell organs to solve their desperate economic needs," said the report, presented to U.N. delegates at a meeting earlier on Tuesday. "Abuse, fraud and coercion are common."

Health Risks

The health of organ-sellers declined in 58 to 86 percent of cases, according to various studies, the report said. As for recipients, a study of Canadians who bought organs abroad found a 60 percent three-year survival rate of the grafted part, "significantly lower" than in altruistic donations.

The Council of Europe, a 47-nation pan-European human rights body, already has a convention against organ trafficking, but there is no U.N. treaty, although the world body has outlawed

trafficking in people for the purpose of transplants.

A 2004 General Assembly resolution urged member states to adopt laws against organ trafficking, but the report said these still did not exist or were ignored in many countries, although Caplan said the situation was improving.

The report called for "an international legal instrument" to define trafficking and set out "the measures to prevent such trafficking and protect and assist the victims, as well as the criminal-law measures to punish the crime."

Carmen Prior, an Austrian public prosecutor who was also a co-author of the report, told the news conference punishments should aim primarily at intermediaries and medical staff involved.

Rachel Mayanja, a senior U.N. official on women's issues, said she would like to see the General Assembly start work on a binding convention as soon as possible, but declined to say how long it might take for one to be developed.

October 14, 2009

Liver Stiffness Scan Shows Cirrhosis

<http://www.6minutes.com.au>

by Jared Reed

Liver fibrosis can be easily identified with a non-invasive ultrasound scanning device for liver stiffness, researchers at a Melbourne teaching hospital say.

The Fibroscan device is proving particularly useful in patients with hepatitis C, say gastroenterologists from The Alfred Hospital in Melbourne.

Reporting their experience with the scanner in 1300 procedures, they found that the four minute scan obtained valid readings in 95% of cases.

About half the indications were hepatitis C, and the remainder were hepatitis B, steatohepatitis, alcoholism and HIV, they will tell the annual Australian Gastrointestinal Week conference in Sydney next week.

"Fibroscan is a quick and reliable noninvasive technique that can be applied successfully in the vast majority of patients to estimate liver fibrosis. The commonest indication for Fibroscan is chronic hepatitis C consistent with the substantial data validating the technique in this condition," they write.

"While this technique looks promising in the evaluation of patients with liver disease, further studies are needed to determine its impact on clinical management," they conclude.

Other researchers say the scan may be an alternative to a liver biopsy for fibrosis assessment, but it is unable to determine the cause of a liver disease or to distinguish subtle diagnostic differences such as NASH from nonalcoholic fatty liver disease (NAFLD), or measure disease activity.

Hospital in Milan, Illinois to Help Pay for Hepatitis-A Shots

<http://www.foodpoisonjournal.com>

by David Babcock

WQAD reports that Trinity Regional Health System is making an \$80,000 "contribution" toward the cost of Rock Island County's vaccination expenses arising out of this summer's Hepatitis-A outbreak. The outbreak, which sickened more than 30 people, was traced to an ill worker at the Milan, Illinois McDonald's. In an effort to limit illness, the County provided more than 5,000 vaccinations to people exposed at the restaurant. WQAD reports that:

Rock Island officials asked Trinity to pay for expenses after an investigation into the outbreak concluded that Trinity and a metro lab failed to report the first case of Hepatitis A in June. The county determined the outbreak originated from a sick worker at the McDonald's restaurant in Milan, Illinois and eventually spread to more than 30 people.

Keep Body's 'Chemical Plant' in Good Working Order

<http://www.chron.com>

By Kim Morgan for *The Chronicle*

Dr. Joseph Galati, a liver specialist, says people taking statins for cholesterol control should get regular check-ups.

Hepatologists like to say you can't spell "liver" without "live," and Dr. Joseph Galati, medical director of the Center for Liver Disease and Transplantation at Methodist Hospital, is no different.

"Think of the liver as a chemical plant," Galati said. "It's the largest organ in the body and performs more than 200 functions ranging from forming cholesterol to detoxifying the blood. It's the only major organ that cannot be artificially reproduced. It's impossible due to the complexity of it."

That's why you've got to be careful with it.

The importance of your liver was in the news this summer when the FDA reviewed painkillers Vicodin and Percocet because of the dangers to the liver when too much acetaminophen is consumed. Vicodin alone is prescribed 100 million times a year. Countless more take over-the-counter painkillers containing acetaminophen.

Then there are statins, drugs that help lower cholesterol. Among the most commonly prescribed drugs in the U.S., they come with a warning about liver damage. Most patients taking statins must undergo routine bloodwork every six months to be sure the drugs are not harming the liver.

You may remember from Anatomy 101 that the liver can regenerate, but if it's chronically inflamed, irritated or injured, it will begin making scar tissue instead of new liver cells.

That's called cirrhosis, and once that happens, the risk of liver cancer increases by 50 percent to 70 percent.

“Scar tissue has no function,” Galati said. “Over time, as you get more cirrhosis, you go into progressive liver failure.”

Only 50 percent of cirrhosis is caused by alcohol abuse, which means 50 percent of cases are caused by conditions ranging from hepatitis to a genetic overload of copper or iron in the body.

But when it comes to managing pain and cholesterol, are consumers swapping a heart attack for liver failure?

Not likely, Galati said.

“It's estimated that 0.5 percent to 3 percent of people on statins will develop some elevation of their liver chemistry, which would be an indicator there is some unrest in the liver,” Galati said. “In most cases when you stop the statin, the liver chemistries go back towards normal.”

Galati said patients, and even some doctors, are almost hypersensitive to statins and their relationship to the liver.

Dr. John Walker, a family medicine practitioner with Village Medical Centers in The Woodlands, said there is no question statins work.

“We don't have near the number of heart attacks we used to,” Walker said. “I've been practicing for 20 years, and the frequency is much lower. Not just from statins, but that is one of the reasons. Statins are a good tool.”

Walker said he has his patients return for lab work six weeks after beginning statins, and then every three to six months.

“First to make sure it's working, and also to make sure they're not one of the few people who have elevation of their liver enzymes,” Walker said. “Although it's something you look for, the guidelines will tell you that you don't have to discontinue the medication until the liver enzymes are three times the normal level. But most doctors aren't comfortable letting it get that high.”

Dr. John Vierling, professor of medicine and surgery at Baylor College of Medicine, director of Baylor Liver Health and director of advanced liver therapies at St. Luke's Episcopal Hospital, said the enzyme in question is called ALT, short for alanine aminotransferase.

ALT is measured to indicate liver injury, he said, and while some people who start statins may show an elevation of the enzyme, a substantial number of them will normalize the enzyme as they continue the statin.

“In other words, it's not necessarily an indication you should stop the drug,” Vierling said. “Does this elevation of ALT lead to liver failure? The answer is no. So the drug can induce ALT elevation, but those elevations do not pose a serious risk to your health or your life.”

However, Vierling said, there are a handful of reports that suggest statins may cause a small, benign liver injury, and then those injured cells have to be removed as debris by the body's scavenger cells in a way that may lead to auto-immune liver disease.

“It was noted just a few years ago for the first time,” Vierling said. “Most hepatologists have been on the lookout for that, looking very hard for it actually, and we have not seen additional cases. But we are aware of those reports in the literature.”

The Liver

- Where your liver lives: Upper right quadrant of the abdomen
- Why you should love your liver: It performs more than 200 functions
- It's the only major organ whose function cannot be reproduced.

Three Ways to Love Your Liver:

1. *Ask for a hepatitis C test:* Hepatitis C afflicts one in every 50 adults although most are not aware of it. Risk factors include blood transfusions before 1992, tattoos, body piercings, intravenous drug use, intranasal cocaine use or if you were born to a hepatitis C-positive mother.
2. *Reduce the booze:* Women should have no more than one alcoholic drink a day. For men, it's two. It doesn't matter if your choice of drink is beer, wine or spirits — all are equally toxic to the liver.
3. *Chill on the pills:* Too much Tylenol can be lethal. Products containing acetaminophen are the leading cause of drug-induced liver failure, Galati said. People get too much by combining Tylenol with other acetaminophen products, including cold and flu medicines or prescription pain meds. The FDA has suggested manufacturers lower the maximum daily limit from 4,000 mg to 3,250 mg.

October 15, 2009

Cyplasin Biomedical Ltd., Announces Hepatitis C Product Licensing Deal

<http://www.tradingmarkets.com>

EDMONTON, Oct. 15, 2009 (Canada NewsWire via COMTEX)

Cyplasin Biomedical is pleased to announce it has entered into an agreement for a worldwide, exclusive licensing agreement with Arizona-based C-Pharma, Inc. The license gives Cyplasin the rights to the manufacture and commercialization of certain antiviral drugs for the treatment of hepatitis C virus-infected patients. The agreement also licenses the rights for the development of a prophylactic vaccine (called **C-Vaxin**) for the prevention of chronic hepatitis C disease. While the financial terms of the license have not been disclosed, the agreement calls for standard upfront licensing fees with a low digit royalty. Cyplasin will also fund an R&D contract to develop the C-Vaxin product line.

The antiviral drugs will initially consist of ribavirin in combination with pegylated interferon and with the brand names of C-Virin and C-Pegferon respectively. "We expect to be able to complete the required studies prior to regulatory approval during 2010, with a target of first sales in mid 2011," stated Garth Likes, President and CEO of Cyplasin. He went on to further state, "these two important Hepatitis C therapies are the current standard of care for chronically infected Hepatitis C patients worldwide and will be offered to these patients at generic price points. The market for these two hepatitis C therapies is estimated at over \$2 billion per year. As these two products meet their developmental and commercialization milestones, we will look at new

product formulations for C- Virin and C-Pegferon as well".

Dr. Joseph Sinkule, President and CEO of C-Pharma stated, "under the terms of the R&D license, we look forward in not only creating revenue generating products in the near term, but also in developing C-Vaxin for the prevention of hepatitis C infection."

The patented C-Vaxin technology was initially developed at the NIH and has undergone several years of development. The vaccine completed successful and important proof of concept in studies with rodents, baboons, and chimpanzees. "C-Vaxin has been one of the only HCV vaccine candidates to protect against HCV infection in the important chimpanzee hepatitis C viral challenge model, and the next step is to complete the preclinical toxicology studies and then rapidly move into human phase I clinical studies," says Dr. Sinkule.

Mr. Likes added, "we are very excited about the license agreement with C-Pharma as it adds to our mission to generate revenues in the near term while at the same time being able to develop novel and patented technologies which address unmet needs.

Schering-Plough Highlights Boceprevir, Narlaprevir (SCH 900518) and PEGINTRON(R) Data at the American Association for the Study of Liver Diseases (AASLD) 2009 Annual Meeting

<http://www.schering-plough.com>

KENILWORTH, N.J., Oct 15, 2009 /PRNewswire-FirstCall via COMTEX/ -- Schering-Plough (NYSE: SGP) today announced that data on boceprevir, an investigational hepatitis C virus (HCV) protease inhibitor, will be reported in an oral presentation at the American Association for the Study of Liver Diseases (AASLD) Annual Meeting in Boston, Oct. 30-Nov. 3. Researchers will present sustained virologic response (SVR) data on boceprevir triple combination therapy in treatment-naïve HCV genotype 1 patients who had a null response to peginterferon and ribavirin (defined as <1 log decrease in HCV viral load) in the 4-week lead-in arms of the Phase II SPRINT-1 study. Patients with null response to peginterferon and ribavirin are considered to be among the most difficult to treat successfully.

Phase III registration studies with boceprevir in treatment-naïve HCV patients and those who failed prior treatment have been fully enrolled and are expected to be completed in mid-2010.

In addition, a late-breaker oral presentation on narlaprevir (SCH 900518), a next-generation once-daily HCV protease inhibitor, will report week-4 rapid virologic response (RVR) and week-12 early virologic response (EVR) data in treatment-naïve HCV genotype 1 patients from the ongoing NEXT-1 study. Narlaprevir is currently in Phase II clinical development.

Several presentations will report results with PEGINTRON(R) (peginterferon alfa-2b) and REBETOL(R) (ribavirin, USP) combination therapy, an approved treatment regimen for chronic hepatitis C. These include a late-breaker oral presentation on a genome-wide analysis of patients from the IDEAL study that identified the first genetic marker that may predict a patient's response to peginterferon and ribavirin combination therapy for hepatitis C. Peginterferon and ribavirin are expected to remain the backbone of HCV treatment regimens for the next several

years. Schering-Plough is in the process of analyzing options for the development of a genetic test based on this marker and for making it widely accessible to providers, patients and diagnostic companies for the advancement of science and for helping physicians and patients make more informed treatment decisions.

Hepatitis C is the most common blood-borne infection in America and the most common form of liver disease, affecting nearly 5 million people in the United States and 200 million people worldwide. It is the leading cause of cirrhosis and liver cancer, and the number one reason for liver transplants in the United States and Europe.

For program information, please visit the AASLD Web site at www.aasld.org.

This document is intended for trade media attending AASLD for their planning purposes.

Key Data Presentations at AASLD 2009

Boceprevir Oral Presentation

- High Sustained Virologic Response (SVR) in Genotype 1 (G1) Null Responders to Peg-Interferon alfa-2b plus Ribavirin When Treated with Boceprevir Combination Therapy; P.Y. Kwo et al. Abstract 62. Sunday, Nov. 1, 5:00 pm to 5:15 pm, Hynes Auditorium

Boceprevir Poster Presentations

- Response-Guided Therapy (RGT) for Boceprevir Combination Treatment - Results from HCV SPRINT-1; P.Y. Kwo et al. Abstract 1582. Tuesday, Nov. 3, 8:00 am to 1:00 pm, Hynes Exhibit Hall C
- Clonal analysis of mutations selected in the HCV NS3 protease domain of genotype 1 non-responders sequentially treated with boceprevir and/or pegylated interferon alfa-2b; J. Vermehren et al. Abstract 1592. Tuesday, Nov. 3, 8:00 am to 1:00 pm, Hynes Exhibit Hall C
- Narlaprevir (SCH 900518) Late-Breaker Oral Presentation Once-Daily Narlaprevir (SCH 900518) in Combination with PEGINTRON (Peginterferon alfa-2b)/ Ribavirin for Treatment-Naive Subjects with Genotype-1 CHC: Interim Results from NEXT-1, a Phase 2a Study; J.M. Vierling et al. Abstract LB4. Monday, Nov. 2, 5:30 pm to 5:45 pm, Hynes Auditorium

Narlaprevir (SCH 900518) Poster Presentation

- SVR Results in Chronic Hepatitis C Genotype 1 Patients Dosed with SCH 900518 and Peginterferon Alfa-2b for 2 Weeks, Followed by Peginterferon Alfa-2b and Ribavirin for 24/48 Weeks: An Interim Analysis; J. de Bruijne et al. Abstract 1555. Tuesday, Nov. 3, 8:00 am to 1:00 pm, Hynes Exhibit Hall C

IDEAL Study Late-Breaker Oral Presentation

- Genome-wide analysis of patients from the IDEAL study identifies a polymorphism upstream of the IL28B gene that is strongly associated with SVR in patients with HCV-1; A.J. Thompson et al. Abstract LB5. Monday, Nov. 2, 5:45 pm to 6:00 pm, Hynes Auditorium

IDEAL Study Oral Presentation

- Relationship of the Use of Statins and Elevated Low-Density Lipoprotein (LDL) or Total Cholesterol (TC) to Virologic Response in Patients Treated for Hepatitis C Virus (HCV) in

the IDEAL Study; S.A. Harrison et al. Abstract 120. Monday, Nov. 2, 4:15 pm to 4:30 pm, Hynes Ballroom B

IDEAL Study Poster Presentation

- Analysis of Reasons for Treatment Ineligibility in the IDEAL study: African Americans (AA) vs. non-African Americans (non-AA); M. Melia et al. Abstract 848. Sunday, Nov. 1, 8:00 am to 5:30 pm, Hynes Exhibit Hall C

PEGINTRON Oral Presentation

- Interim analysis of a controlled trial of pre-transplant peginterferon alfa-2b/ribavirin (PEG/RBV) to prevent recurrent hepatitis C virus (HCV) infection after liver transplantation (LT) in the Adult-to-Adult Liver Transplantation (A2ALL) Study; G.T. Everson et al. Abstract 1. Sunday, Nov 1, 8:00 am to 8:15 am, Hynes Auditorium

SOURCE Schering-Plough <http://www.schering-plough.com>

Aethlon Medical to Present Data on HVC Patients Treated with its Hemopurifier at the 42nd ASN Meeting

<http://www.news-medical.net>

Aethlon Medical, Inc. (OTC Bulletin Board: AEMD) disclosed today that clinical data resulting from the treatment of Hepatitis-C (HCV) infected patients with the Aethlon Hemopurifier® will be presented at the 42nd Annual Meeting & Scientific Exposition of the American Society of Nephrology (ASN). Dr. Vijay Kher, principal investigator of the Hemopurifier® studies and Director of Nephrology at the Fortis Hospital in New Delhi, India will present and discuss Hemopurifier® treatment results from 10am-12pm pacific time on October 30th, 2009. The event is being held at The San Diego Convention Center in San Diego, California.

"We are honored that Dr. Kher has been invited to travel from India to present our clinical data at the largest annual gathering of Nephrologists," stated Aethlon Chairman and CEO, Jim Joyce. The Aethlon Hemopurifier® is the first-in-class medical device able to selectively remove viruses and immunosuppressive proteins from the bloodstream. In HCV care, the device targets to improve patient cure rates as an adjunct to accelerate and enhance the performance of current and future iterations of standard of care drug therapy.

SOURCE Aethlon Medical, Inc.

Women with HIV Co-Infected with Hepatitis B or C Have Increased Risk of Bone Problems

www.aidsmap.com

Michael Carter

HIV-positive women who are co-infected with hepatitis B or hepatitis C have lower bone mineral density than HIV-positive women who do not have these co-infections, Italian investigators report in the October edition of AIDS.

This difference was not, however, present in men, with bone mineral density being broadly comparable between HIV and hepatitis co-infected men and HIV mono-infected men.

The investigators are calling for further studies to “elucidate the mechanism for low bone mineral density in coinfecting women.”

Antiretroviral therapy has brought about significant improvements in the prognosis of HIV-infected individuals and there is now optimism that such treatment will provide patients with HIV with the opportunity to live a normal life-span.

However, studies have consistently shown that co-infection with hepatitis B, hepatitis C, is associated with higher rates of serious illness and death in patients with HIV.

Unsurprisingly, most of the research into the impact of hepatitis co-infection in individuals with HIV has focused on liver disease. However, both hepatitis B and C can cause other serious health complications, one of which is reduced bone mineral density.

Investigators from Modena, Italy, therefore conducted a cross-sectional (or “snap-shot”) study to determine the prevalence and risk factors for reduced bone mineral density in patients with HIV who also had cop-infection with hepatitis B or C.

Bone mineral density was assessed using DEXA scans of two sites, the lumbar spine and the femoral neck. The investigators calculated the age and sex-specific Z score – the difference in bone mineral density from that expected for an individual's age and sex - and a Z score of at least – 2.0 was taken as indicating significantly lower than expected bone density.

Blood samples were also obtained to assess HIV viral load, CD4 cell count and to measure metabolic parameters that can affect bone mineral density.

Conducted between 2004 and 2007, the study involved 1237 patients. Antibodies to hepatitis B were detected in 85 (9%) individuals and antibodies to hepatitis C in 572 (47%).

A significant relationship was found between hepatitis co-infected, sex and bone mineral density in both the lumbar spine ($p = 0.002$) and femoral neck ($p = 0.04$). Therefore, the investigators analysed all their results according to sex.

Men had generally lower Z scores than women for the lumbar spine (- 0.5 vs. + 0.06, $p < 0.001$). However, women co-infected with hepatitis C had lower Z scores than HIV mono-infected women for bone mineral density in this region (- 0.15 vs. + 0.29, $p < 0.001$). This difference persisted after controlling for other factors that could affect bone mineral density ($p < 0.001$).

By contrast, there were no significant differences in bone mineral density in the lumbar spine region between co-infected and mono-infected men.

Next the investigators looked differences in femoral neck bone mineral density Z scores. Once again, co-infected women had lower Z scores than mono-infected women, even after adjusting for possible confounding factors (difference, - 0.26, $p = 0.02$).

However, femoral neck bone density Z scores were comparable for co-infected and mono-infected men.

The investigators also conducted analyses to see if the risk of low bone mineral density differed for individuals co-infected with HIV and hepatitis C and those only infected with HIV.

Twice as many women as men (8% vs. 4%, $p < 0.001$) had a lumbar spine Z score of -0.2 or less.

Furthermore, low lumbar spine bone mineral density was more common in co-infected patients than mono-infected individuals (9% vs. 6%).

After adjustment for factors such as use of antiretroviral therapy, smoking, and levels of physical activity, the investigators found that the risk of low bone mineral density in this region was higher for co-infected women than co-infected men.

Low bone mineral density in the femoral neck was slightly more prevalent amongst women than men (8% vs. 7%). Z scores of -0.2 or less were also more common in co-infected patients (9% vs. 7%), but this difference was not significant.

After adjustment for confounding factors, the investigators once again found that the risk of reduced bone mineral density in this region was increased for co-infected women but not co-infected men. But the association was weak and did not achieve significance.

Finally, the investigators looked at lumbar spine and femoral neck scores together. This showed that low Z scores in these sites were more common in women than men (14% vs. 9%, $p < 0.001$). After controlling for confounding factors, the association between hepatitis co-infection and low Z scores in these regions persisted for women (adjusted OR, 2.89, 95% CI, 1.31 – 6.29), but not for co-infected men.

Focusing on individuals co-infected with hepatitis C, they found that bone mineral density Z scores were significantly lower in both sites for co-infected women (adjusted OR, 2.99; 95% CI, 1.33-6.74), but once again this was not the case for co-infected men.

“We found that viral hepatitis increased the risk of low bone mineral density among HIV-infected patients”, comment the investigators. They note that the reasons why this association was significant in co-infected women “remain unclear”, but they state that much is still unclear about the impact of hepatitis B or C co-infection on bone metabolism.

“Future studies should evaluate fracture rates and examine risk factors and potential mechanisms for low bone mass among HIV/viral hepatitis-coinfected patients”, conclude the authors.

Reference

Lo Re V et al. Viral hepatitis is associated with reduced bone mineral density in HIV-infected women but not men. AIDS 23: 2191-98, 2009.

Former Drug Addict Urges More to Take Hepatitis Test

<http://www.stroudnewsandjournal.co.uk>

By Nick Wakefield »

A FORMER drug addict from Stroud is encouraging more people to get tested for hepatitis C.

Nigel Calvert was 19-years-old when he contracted the virus through intravenous drug use in 2002.

He has lived drug-free since 2004 and now works as an NHS drug and alcohol advocacy worker.

Nigel's plea is part of the Department of Health's Get Tested Get Treated campaign for hepatitis C, which launches across the UK this week.

Experts estimate that only half of the 200,000 people in the UK infected with the virus have actually been diagnosed, as it can often lie undetected and symptomless for 20 years or more.

Currently the most common cause of transmission is through the shared use of drug-taking equipment, although the Government is warning that you may also be at risk if you have had a blood transfusion before September 1991 or received blood products before 1986 in the UK.

Other less common ways of contracting the virus is through unprotected sex, tattooing or body piercing and medical or dental treatment abroad where unsterile equipment may have been used.

Another cause of infection is through the shared use of razors or toothbrushes that may have been contaminated with blood from someone who is infected.

Before visiting their GP, people concerned that they may have hepatitis C are advised to self-assess themselves using the NHS Choices website www.nhs.uk/hepc or by calling a free and confidential information line on 0800 181 4114.

October 16, 2009

Subaru Donates 'Hep B Hero Mobile' to Support Campaign

www.reuters.com

- Company Supports Asian/Pacific Islander Community in Promoting Hep B Awareness -

SAN FRANCISCO, Oct. 15 /PRNewswire/ -- Subaru of America is joining the San Francisco Hep B Free campaign as the official vehicle and partner by donating the use of a 2010 Subaru Legacy detailed with full color artwork promoting the campaign theme which calls on everyone to "B a Hero" in preventing liver cancer and the hepatitis B disease.

Hepatitis B causes up to 80 percent of all liver cancers, and disproportionately affects 1 in 10 Asian and Pacific Islanders. A safe and effective vaccine prevents infection and liver cancer caused by hepatitis B. The most important step towards eliminating hepatitis B disease is by being tested for infection in your doctor's office.

The new model 2010 Subaru Legacy Sedan is black with a cape design and features the "B" emblem of the campaign along with the Subaru logo. It will debut at the 2nd annual B a Hero Gala -- a benefit fundraiser for SF Hep B Free, the citywide campaign to screen and vaccinate all Asian and Pacific Islanders for hepatitis B. The car will be on display in front of the Empress of China on Oct 15 from 5:30 to 9pm and will be featured in prominent Bay Area Asian American oriented events including the Northern California Cherry Blossom Festival, Pistahan Parade and Festival and Autumn Moon Festival. The car will make its traveling road show debut on November 4 at the San Mateo Hep B Free launch.

"Subaru is committed to helping educate the community and increase awareness through the Hep B Free movement," said Todd Lawrence, promotions and sponsorship manager, Subaru of America, Inc. "The Asian American/Pacific Islander community is one of the most vibrant and fastest growing in America. We are proud to be part of the community's good health initiatives and continued development."

HBV is the greatest health disparity between Asians and non-Asians. One in 10 Asians are chronically infected with Hep B and are four times more likely to die from liver cancer compared with the general population. 80 percent of liver cancer worldwide is caused by chronic HBV infection. Early detection of HBV will benefit the carrier as well as prevent the infection from spreading. Hepatitis B is not only vaccine preventable, but it also has effective treatments that can slow or prevent liver damage caused by the disease.

"The Asian community draws its heritage from some of the oldest cultures in the world. Today Subaru is starting a new "legacy" with the donation of this Subaru Legacy and becoming the first car company to become a major player in the health and well-being of the growing Asian/Pacific Islander community," said Ted Fang, AsianWeek Foundation Director and SF Hep B Free Steering Committee Member.

"Thanks to Subaru's generosity, SF Hep B Free is delighted to have the hepatitis B awareness message displayed in such an innovative and fun manner," said Janet Zola, Health Prevention Specialist with the SF Dept. of Public Health and SF Hep B Free Steering Committee Member. "We are on the right path to eliminating the transmission of this very serious disease as we encourage everyone to be screened and vaccinated if they have not yet done so."

San Francisco Hep B Free

www.sfhepbfree.org

San Francisco Hep B Free is a first-of-its-kind collaboration between city government, private healthcare and community organizations. The program's goal is to make San Francisco a hepatitis B-free city by

- (1) creating public and healthcare provider awareness about the importance of testing & vaccinating APIS for hepatitis B;
- (2) promoting routine HBV screenings and vaccinations within the primary care medical community; and
- (3) facilitating access to treatment for chronically infected individuals.

SF Hep B Free is a project of Community Initiatives, a 501(c)(3) tax-exempt organization.

The AsianWeek Foundation

www.asianweek.com

The AsianWeek Foundation is a founding Steering Committee member of the Hep B Free campaign and focuses on community organizing and strategic partnerships. AsianWeek Foundation's purpose is to bring together the diverse segments, organizations and individuals of the Asian Pacific/Islander community. AsianWeek Foundation also organizes the Asian Heritage Street Celebration, a celebration of traditional and contemporary culture in Asian Pacific America. It is the largest one-day gathering of Asians in America. www.asianfairsf.com

Subaru of America, Inc.

Subaru of America, Inc. is a wholly owned subsidiary of Fuji Heavy Industries Ltd. of Japan. Headquartered in Cherry Hill, N.J., the company markets and distributes Subaru Symmetrical All-Wheel Drive vehicles, parts and accessories through a network of approximately 600 dealers across the United States. Subaru boasts the most fuel efficient line-up of all-wheel drive products sold in the market today based on Environmental Protection Agency (EPA) fuel economy standards. All Subaru products are manufactured in zero-landfill production plants and Subaru of Indiana Automotive Inc. is the only U.S. automobile production plant to be designated a backyard wildlife habitat by the National Wildlife Federation. For additional information visit www.subaru.com

SOURCE Subaru of America, Inc.

Florida Hospital Confirms Patients Infected by Reused IV Bags

<http://www.newsinferno.com>

Earlier this month we wrote about yet another case of potential hospital-spread hepatitis that was discovered in Fort Lauderdale, Florida. Now, NBC Miami says that some Broward General Medical Center patients received reused IV bags and have tested positive for some infectious diseases.

Nurse Qui Lan violated infection-control protocols that, according to the Sun Sentinel previously, her staff said occurred with Lan's full knowledge. Lan put over 1,800 patients at risk with her shoddy infection practices when administering saline solution to patients who were at Broward undergoing cardiac chemical stress tests. Broward said it is not clear how those who have tested positive for infectious diseases originally became infected.

"Based on the current Broward County disease prevalence data, we expect some of the screening results to be positive for infection exposure and we will need to conduct an individual evaluation to help determine the origin," said Dr. David Droller, head of Epidemiology and Infectious Diseases at Broward, in a statement, quoted NBC Miami. "At this time, we will make certain the individual receives appropriate care and follow-up," added Dr. Droller.

Broward is offering free testing for HIV/AIDS and Hepatitis B and C to those patients who underwent stress tests at its facility, reported NBC Miami; to date, preliminary results have been received back on testing conducted on 254 former patients. All three pathogens are blood borne in nature.

Police spokesman Sgt. Frank Sousa said the hospital requested the investigation of Qui Lan, 59,

said the Sun Sentinel previously. Officials at the hospital said they learned that Lan was reusing catheter tubing and saline bags on multiple patients, said the Sun Sentinel. The tubing and bags were meant for one-time patient use during the cardiac chemical stress tests. NBC Miami said Lan handled IVs during cardiac stress testing since 2004.

Lan has an active Florida nursing license and a clean record, said the Sun Sentinel last week. She was suspended on September 8 and resigned on the 9th; the hospital reported her to the Florida Board of Nursing, said the Sun Sentinel, which added that authorities believe Lan has left the United States. James Thaw, Broward's CEO, told the Sun Sentinel that the hospital notified patients and arranged for off-site testing in the month before it notified the police.

This is the most recent in a string of similar incidents in which medical supplies have been tampered with or used in ways that expose countless patients to disease. We have been following the scandals with the Department of Veterans Affairs' centers in three cities in which colonoscopy and endoscopy equipment were reused without being properly sanitized. To date, noted the Sun Sentinel some 50 veterans have tested positive for blood borne pathogens.

Most recently, a surgical tech who worked out of two Colorado hospitals and hospitals in New York and Texas was charged and sentenced after it was discovered she was swapping syringes containing the narcotic pain reliever Fentanyl with saline after injecting herself. She has tested positive for hepatitis.

Website Warns Asian Community of Hepatitis C Dangers

<http://world-countries.net>

THE Department of Health has launched a new hepatitis C information website aimed at the South Asian community.

The new site, which is part of the Department's national hepatitis C awareness campaign, provides specific advice and information relevant to South Asian communities. Emerging evidence suggests they may be at a greater risk of contracting the virus compared to the general population in England.

The site provides the key facts about hepatitis C and includes a simple online questionnaire for people to assess whether they may have been at risk of infection.

*Visitors to the site will also be able to watch the latest television adverts for the campaign and download an information leaflet in several South Asian languages, including **Urdu, Gujarati and Punjabi.***

Hepatitis C is a blood-borne virus that can cause chronic infection and lead to serious liver damage.

It is mainly spread by contact with the blood of someone who has the infection. Many people are unaware that they have hepatitis C, as symptoms often do not occur for many years. If left untreated, it can lead to cirrhosis, liver cancer or liver failure. Although there is yet no vaccine for hepatitis C, there is treatment available which is effective for many patients.

Dr Jahangir Rehman, a hepatitis C specialist at Bradford Royal Infirmary, whose specialist interest is hepatitis C in South Asian patients, said: “The new hepatitis C site is a great resource and shows that the Department of Health is committed to raising awareness and tackling this disease amongst South Asian communities.

"People who think they or a member of their family may have been at risk or have the disease can visit the site and get the key information they need. The site is a very useful tool in helping people to avoid the risk of acquiring the infection and tackling misconceptions the South Asian community still associate with hepatitis C – especially when it comes to how easy it is to test for the disease and the effective treatment that exists for the virus.”

A confidential and free phone hepatitis C helpline is available for people who want to talk to someone in their own language on 0800 181 4774.

You can visit the website at www.nhs.uk/hepc/southasian

Source: The Asian Today Online – Asian News

CAMP Rehoboth to Offer Free Hepatitis Vaccinations

<http://www.capegazette.com>

Rehoboth Beach, Delaware – CAMP Rehoboth and the Department of Public Health are offering free hepatitis A and hepatitis B vaccinations.

The vaccine being used is the Twinrix vaccine. Twinrix is a vaccine that provides protection from hepatitis A and hepatitis B. The routine schedule for Twinrix is three doses. These doses are given over a six-month period.

Hepatitis A is the most common form of viral hepatitis and is transmitted through ingestion of infected fecal matter in food and water and through close personal contact, including oral and anal sex, a Health Department fact sheet states. People traveling through countries where hepatitis A is common are also at risk.

Hepatitis B is a very contagious virus that is transmitted through body fluids and is considered a sexually transmitted disease, because the transmission fluids include blood, semen and vaginal secretions.

Due to the limited number of vaccinations available on the day of the clinic, an RSVP is required to receive the free vaccination.

To sign up for shots, call 302-227-5620.

Race for a Cause: Hepatitis C

<http://emmanow.wordpress.com/>

Troy, NY – Emma Willard School students, alumnae, faculty, administrators, and parents, as



well as runners from throughout the Capital District, will gather on campus, at 9:30 a.m. on **November 1** for Chasing the Cure for Hepatitis C. The 5k race will traverse the Emma Willard School campus and venture into the surrounding neighborhood, returning to campus for the finish.

This race is being coordinated by Race for a Cause, a school community service group that sponsors and supports races, games, and other activities to raise funds for local and national charities. Proceeds from the November 1 race will benefit the Massachusetts General Hospital Hepatitis Research Center. The race is being held in honor of Betsy Lamoureux, director of student activities, who was diagnosed with Hepatitis C in 2000.

Competition categories will be divided by gender and age, and prize money will be donated to the Massachusetts General Hospital Hepatitis Research Center. There is an after party starting at 10:30 a.m. Preregistration fee is \$20, due by October 28. The entry fee on race day is \$25. The first 100 entrants will receive a long-sleeved t-shirt. Listen to Julia's announcement at today's Morning Reports here, then register here.

For more information about Race for a Cause, contact Judith Curry at jcurry@emmawillard.org, (518) 833-1316.