

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Dec 13, 2008

DPP drops charges over Hep C scandal

<http://www.independent.ie>

Patricia McDonagh and Eilish O'Regan

A CASE against a leading doctor involved in the Hepatitis C scandal has been dropped by the Director of Public Prosecutions, it emerged last night.

The decision not to prosecute means that nobody has stood trial for the infection of more than 1,000 women with Hepatitis C from contaminated blood products -- a scandal that was one of the biggest health tragedies in the history of the State.

Seven charges had been brought against Dr Cecily Cunningham, a former biochemist at the Blood Transfusion Service Board, under Section 23 of the Offences Against the Person Act 1861. She was charged with unlawfully and maliciously causing a "noxious thing", namely infected Anti-D immunoglobulin, to be taken by seven people, thereby inflicting grievous bodily harm.

Failed

However, last night it emerged the prosecution had been dropped. In 1994, it was disclosed that the Blood Transfusion Service Board had failed in 1976 to prevent the use of blood donated by a woman who was known to have jaundice.

This was used to make the product Anti-D, despite there being a policy in 1968 that blood should not be accepted from anyone who had suffered jaundice or infectious hepatitis.

It was given to some women during childbirth in the late 1970s and early 1990s, and in 1997 the Finlay Tribunal was set up to examine the issue.

Dr Terry Walsh, a consultant haematologist and former assistant national director with the blood bank, had been charged along with Dr Cunningham over the Anti-D product.

However, he died as allegations relating to his involvement were before the court. The Hepatitis C support group, Positive Action, last night revealed the death of a key witness in the prosecution case, Dr H H Hoppe, had put an end to proceedings. A tribunal to compensate those affected has paid out more than €30m.

The DPP last night refused to comment when contacted by the Irish Independent. In a statement, Positive Action said it accepted the decision was due to circumstances "beyond the control of the investigating gardai team and the DPP".

Chairperson Detta Warnock said the decision had sparked anger amongst those affected.

Detectives from the National Bureau of Criminal Investigation will meet the group next Wednesday to formally outline why the decision was taken.

Roche Statement on Hepatitis C Maintenance Therapy Study

www.roche.com

Roche would like to provide comment on the "Prolonged Therapy of Advanced Chronic Hepatitis C with Low-Dose Peginterferon" (HALT-C) study published in *The New England Journal of Medicine* (NEJM). This study explored an experimental treatment regimen in a

difficult-to-treat hepatitis C patient population. Roche had no role in this study other than providing PEGASYS® (peginterferon alfa-2a) medication for clinical study purposes.

PEGASYS is not approved for the treatment protocol outlined in this study, which is known as “maintenance therapy.” As the results of HALT-C study clearly show, maintenance treatment failed to halt disease progression in these hepatitis C patients, and is not recommended.

PEGASYS is the most-studied pegylated interferon and has demonstrated efficacy in a broad range of patient types, even those with poor prognostic factors, including African Americans and patients co-infected with HIV.. This study in no way changes the known efficacy or safety profile of PEGASYS for its approved indication, which is for the treatment of adults with chronic hepatitis C virus (HCV) infection who have compensated liver disease and have not previously been treated with interferon alpha. PEGASYS plus COPEGUS is the current foundation of HCV treatment and the pegylated interferon therapy of choice for most HCV antiviral agents in development.

The current standard of care for HCV is comprised of pegylated interferon plus ribavirin, for a duration that is dependent upon factors such as genotype of the virus. A sustained virological response (SVR) is achieved in 76 percent of patients with genotype 2 or 3 who are treated with PEGASYS plus COPEGUS. For the most difficult to treat genotype 1 virus, a 48-week treatment course generally results in sustained viral response in about 50 percent of patients. The clinical benefits of achieving SVR in hepatitis C have been widely documented, dramatically reducing a patient’s chances of disease progression and associated life-threatening complications.

Dec 14, 2008

Six-year court battle over hepatitis C ends with settlement

<http://search.japantimes.co.jp>

Kyodo News

Hepatitis C patients and Nihon Pharmaceutical Co. reached a deal Sunday to end a series of damages suits over tainted blood products that infected the patients with a hepatitis virus.

Signing the agreement, Tsutomu Miura, Nihon Pharmaceutical president, told the patients, "I sincerely apologize to you that we could not prevent the outbreak and spread of damage. As a drug maker we are deeply reflecting on this in order to support patients and protect people's lives."

Three other defendants in the collective suits filed in 2002 — the state, Mitsubishi Tanabe Pharma Corp. and its subsidiary Benesis Corp. — have already reached out-of-court settlements with the hepatitis patients.

Under the agreement, Nihon Pharmaceutical recognizes its responsibility for failing to prevent the outbreak and spread of hepatitis C, and apologizes to the plaintiffs.

The company is also required to make utmost efforts to prevent any recurrence of medicine-induced health calamities and to take measures including the development of a new anti-hepatitis C drug.

Many of the sufferers contracted the disease from around 1970 to the early 1990s through tainted blood products during operations or when giving birth.

After more than 1,000 sufferers filed suits with courts across Japan in 2002, the government and the plaintiffs reached a compromise agreement to settle the court battles earlier this year.

Following the agreement, the Diet enacted a law in January to offer blanket relief to people who contracted hepatitis C, paying 12 million to 40 million yen per patient depending on the level of suffering. The funds paid under the law are financed by the state and the three firms.

Dec 15, 2008

Controversy of care

<http://www.corrections.com>

By Ann Coppola, News Reporter

A recent study, out of the University of California at Los Angeles offered a controversial, yet straightforward, answer to the legal and medical debate over standards of care for inmates with hepatitis C. The researchers concluded treating chronic hepatitis C in the prison population with interferon and antiviral drugs creates cost savings and improves the quality of life for all inmates, sick or not.

If the medical community is starting to move in this direction, they're not alone. An up-and-coming legal challenge is also looking to continue the momentum swing towards increased access to treatment.

The law firm of Khorrami, Pollard & Abir is currently filing hundreds of individual lawsuits on behalf of California inmates against the California Department of Corrections and Rehabilitation for failure to properly treat inmates with hepatitis C. The firm expects the total number of plaintiffs to grow into the thousands.

"This is an important problem nationally, it's not just a California problem," says Mark Ravis an attorney representing the inmates.

Hepatitis C is a blood-borne infectious disease that targets the liver. It can cause inflammation of the liver, which can progress to advanced scarring or cirrhosis. In some cases, cirrhosis can lead to liver failure or liver cancer.

Injection drug use, drug use by nasal inhalation, body piercings, tattoos, and blood transfusions are all risk factors for hepatitis C. The majority of patients with chronic hepatitis C will not clear the disease without treatment.

According to the National Institutes for Health and the Centers for Disease Control and Prevention, standards of care require that patients with Stage II hepatitis be offered treatment.

This year, CDCR changed its hepatitis C treatment protocols to meet the Stage II standard. However, lawyers representing the inmates say there are thousands in the California system who were excluded from liver biopsies and antiviral treatment under the previous protocol, which required inmates reach Stage III hepatitis before treatment could be administered.

“We’re suing on behalf of inmates who didn’t get treatment prior to the change in protocols,” Ravis says. “They’re the ones who have damaged livers.”

An estimated 150-200 million people worldwide are infected with the disease. The prevalence of chronic hepatitis C infection in U.S. prisons is 12 to 31 percent. California has some 190,000 inmates, and at least 40 percent have hepatitis C, according to Ravis.

“Despite an established standard of care, the California Department of Corrections and Rehabilitation has adopted protocols designed to exclude patients from diagnostic biopsies and treatment,” says Shawn Khorrami, the law firm’s founder. “This is in contrast to the care and treatment provided to the general population. This practice not only denies inmates proper care and allows their health to deteriorate, but also presents a health danger of further spreading the disease not only within the prison population but also in the general population once the infected inmates are release from prison.”

The state prison system has not yet commented on the lawsuit.

The firm continues to build its case against CDCR. For now, it remains to be seen if this suit will create a new statement for how corrections handles hepatitis C.

Concern as Hepatitis on rise in North West

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

NEARLY a quarter of confirmed cases of hepatitis C in England since 1995 were in the North West.

And the majority of these were associated with injecting drug use, the Health Protection Agency’s annual report on hepatitis C for 2008 has revealed.

The document discloses that 59,938 cases of hepatitis C have been confirmed in England since 1995 and 13,683 of these were recorded in the North West.

Dr Roberto Vivancos, a consultant with HPA North West, said: “This is a very worrying but timely report.

“We need to raise awareness of hepatitis C and the risk factors for it and encourage people at risk to be tested.”

Dec 16, 2008

1,000th Liver Transplant Celebrated at NewYork-Presbyterian Hospital

<http://www.healthnewsdigest.com>

By NewYork-Presbyterian Hospital

First Liver Transplant Recipient, Now 11 Years Old, Received Transplant on Her First Birthday, in 1998

Major Milestone Celebrated With Donors, Recipients and Their Families

(HealthNewsDigest.com) - NEW YORK -- More than 1,000 patients have received lifesaving liver transplants at the Center for Liver Disease and Transplantation (CLDT) at NewYork-Presbyterian Hospital. The Hospital's first liver transplant patient, now 11 years old, was transplanted with an organ donated by her father on the day of her first birthday, Jan. 20, 1998.

Today the Hospital celebrated this milestone together with more than 200 liver transplant donors, recipients and their families. The event took place at the Malcolm X & Dr. Betty Shabazz Memorial and Educational Center in Manhattan.

"I want to congratulate the more than 1,000 patients who received liver transplants at NewYork-Presbyterian. It is a powerful testament to the success of our liver transplantation program that 10 years later, our first liver-transplant recipient has grown up and enjoys an active and healthful life," says Dr. Herbert Pardes, president and CEO of NewYork-Presbyterian Hospital. "This kind of success story is only possible in an academic medical center setting, where the experience and expertise of the nation's foremost specialists are focused on advancing new treatments to ensure the long-term health of patients."

Even though it treats some of the sickest patients, NewYork-Presbyterian's liver transplant outcomes are among the nation's best, with a five-year survival greater than 70 percent. The Hospital also offers transplants after a median wait time under 19 months, less than half that of other New York City area centers.

"This major milestone is the result of the tireless dedication of everyone on our liver transplant team -- including hepatologists, surgeons, our transplant psychiatrist, diagnostic and pathology experts, advanced-practice nurses, social workers, coordinators and others," says Dr. Jean Emond, chief of transplantation at NewYork-Presbyterian Hospital/Columbia University Medical Center and the Thomas S. Zimmer Professor of Surgery at Columbia University College of Physicians and Surgeons. "Together we have come a long way in the last 10 years, pursuing innovations to increase access to transplantation and improve quality of life for patients with end-stage liver disease."

NewYork-Presbyterian Hospital's liver transplant program is among the top 10 centers in the country for number of transplants performed annually, with 122 performed in 2007, up from 46 in 1999, the program's first full year.

One important way of increasing the number of available organs has been living-donor transplantation, a technique pioneered by Dr. Emond that enables the patient to obtain a transplant right away, skipping the waitlist. It's a significant advantage since research first described at NewYork-Presbyterian shows that early transplantation with a living donor means a better chance at survival. Today, the Hospital is one of only a few programs to offer the approach

and one of nine centers in the NIH-funded A2ALL consortium to study living donation. To date, the Hospital has transplanted more than 150 living-donor livers for both adults and children.

"A living donor can be a family member or friend," explains Dr. Emond. "In the procedure, a portion of the donor's liver is removed and implanted in the recipient. Both segments (the remaining section of the donor's liver, and the portion received by the patient) will regenerate and grow to fit the needs of each individual."

Another key innovation has been the Hospital's extended criteria donor (ECD) program, which uses advanced organ selection and preservation methods to make use of previously unused organs, such as those from older persons.

"With advanced techniques including improvements in anti-rejection medications, monitoring of organ rejection and organ preservation, we are able to use many more livers than we could 10 years ago," says Dr. Robert S. Brown Jr., director of the Center for Liver Disease and Transplantation at NewYork-Presbyterian Hospital, chief of the Division of Abdominal Organ Transplantation and the Frank Cardile Professor of Medicine and Pediatrics in Surgery at Columbia University College of Physicians and Surgeons. "The benefits are striking, with less than a quarter the number of waitlist deaths for ECD patients, compared to those on the regular waitlist."

Even more exciting innovations are on the horizon. "We are currently in the midst of a major initiative to expand our liver program," says Dr. Emond, citing new recruits including Dr. Tomoaki Kato, who adds expertise in multi-organ transplantation -- procedures that replace as many as six organs -- and a surgery called APOLT (auxiliary partial orthotopic liver transplantation) that resuscitates a failing liver by attaching a partial donor liver, making immunosuppressant drugs unnecessary.

The transplant initiative will also stress clinical research, says Dr. Emond. "Our patients have the opportunity to receive treatments available in only a few centers, or in no other centers." As one example, last year, NewYork-Presbyterian performed the first liver transplantation procedure in New York for a patient with bile duct cancer using an investigative technique that combines radiation and chemotherapy prior to surgery to improve outcomes, joining a select number of centers designing experimental approaches to treat this previously fatal disorder. Other ongoing research includes studies of specialized therapies for patients with hepatitis B and C, and blood-type-incompatible procedures.

Going forward, NewYork-Presbyterian will continue to give patients the kind of personalized care only possible through a multidisciplinary approach. "Our program stands out as one of the first built from its inception as a single unit, integrating medical, surgical and radiologic expertise," says Dr. Brown. "This means that the same team gets to know the patient and follows them from before transplant through to follow-up."

Liver disease describes any number of conditions affecting the liver, including hepatitis, cirrhosis, cancer and several hereditary diseases. Transplantation is offered to patients whose livers are no longer able to properly function, and will eventually shut down. At this time there are eight patients on the national waiting list for every available liver -- and many patients are considered too sick or too old to be placed on the list. Among those with end-stage liver disease,

more than 17,000 patients wait for a donated liver every year in the U.S., but fewer than 6,000 receive one, and about 1,800 people die while on the waiting list.

"In the coming years, we will continue to work toward improving these odds so every patient can enjoy long and productive lives," says Dr. Emond.

Transplantation at NewYork-Presbyterian Hospital

NewYork-Presbyterian Hospital's organ transplantation program -- which includes NewYork-Presbyterian Hospital/Weill Cornell Medical Center, NewYork-Presbyterian Hospital/Columbia University Medical Center and the Rogosin Institute -- performed more transplants in 2007 than any other center in the nation. It offers comprehensive and personalized care for the heart, liver, pancreas, kidney and lung. With outcomes ranked among the nation's best, the Hospital is dedicated to improving quality of life for its patients. NewYork-Presbyterian's dedicated teams of surgeons and physicians are responsible for many significant advances made over the past several decades in transplant surgery and the maintenance of healthy organs. The Hospital has been on the forefront of developing and improving anti-rejection medications (immunosuppressants), minimally invasive surgery for living donors, genetic methods to detect transplant rejection, strategies to increase opportunities for donor matching, islet cell transplantation, and the FDA-approved left ventricle assist device (LVAD), which functions as a bridge to transplantation for those waiting for a new heart.

For more information, visit www.nyp.org

Fear of Deportation Makes Many Nurses Hide Infectious Diseases

<http://www.khaleejtimes.com>

Martin Croucher

DUBAI - Healthcare workers who are likely to have contracted HIV or Hepatitis B from hospital needles and scalpels are often not reporting the injuries for fear of losing their jobs.

A survey of 1,420 nurses and doctors in Dubai and Sharjah revealed that one in five was injured by sharp objects and 55 per cent of those injuries were from contaminated objects.

However, under-reporting was six fold in a study group of 752 workers and non-existent in a further study group of 668 workers.

"People are often scared of reporting these injuries because they could be socially excluded or isolated," said Dr Ana Jacob, Specialist Physician at Welcare Hospital in Dubai.

"Especially in the UAE, they could lose their jobs if they are found with these diseases."

"There is a three-month incubation period from the point of injury until the disease becomes apparent," said Jacob. "There is a high degree of anxiety during this period for healthcare workers."

The study has not been published but findings were revealed at the International Risk Management Conference on Tuesday.

It is the first of its kind in the UAE and fills a gap in World Health Organisation statistics.

Bins overflowing with hypodermic needles can cause accidental injury and over half of the injuries reported in the survey were from objects which had been inadequately disposed of.

Immediately after injury, the healthcare worker should be given medication to be taken an hour after the injury to prevent contraction of HIV.

While this is available in the government hospitals, private hospitals do not similarly protect staff. Jacob said the same protection should be offered at private hospitals.

Moreover, she added that where such treatment was available, it was important that nurses be able to report injuries anonymously rather than having to put their careers on the line.

The two healthcare organisations surveyed in Jacob's report had previously made employees pay for their own Hepatitis B vaccinations soon after joining the company.

This meant that many had opted out and were not protected against the disease. However, after hospital bosses were notified of the survey both organisations began to offer free vaccinations to new employees.

Dec 17, 2008

How to throw it all away

<http://www.southbergenite.com>

by Michael Lamendola

'You never replicate your first high. That's the hitch.'

For years, Dan Davis knew what it meant to be down and out, literally to the extreme. He stole, betrayed the trust of friends and loved ones and even jeopardized his own human health. He missed out on a chance to make it big playing professional football. The benefit at the time was his ability to score drugs and then use them to get as high as possible. He liked to drink, so much that he's injured numerous people drunk driving. At the time he was using or drinking his life away, it was the only thing that mattered to him.

That was over 20 years ago however. Now Davis, a formidable, muscular man sporting a thick goatee and long golden ponytail, looks back and laments his past, but in the process, he finds his recollections to be beneficial to the youth of today. Last week, Davis used his life experiences to urge students at Lyndhurst High School to not repeat his mistakes of the past. It was a talk that brought a stark reality to most of the students, some drawn to clenching their friends' hands, some to tears.

Dan Davis, a former aspiring pro football player ruined his potential career by heavily abusing alcohol and drugs. He now speaks to communities nationwide on the effects a potent addiction can have. Below, he spoke last week to parents and students in Lyndhurst.

"It was really powerful, I think everyone had some type of reaction to it," said junior Gabriela Mendoza who in just weeks will be eligible for her license when she turns 17, the same critical stage in life when Davis began to see his greatest demise.

Davis started drinking when he was only 14. By high school, the upstate New York all-state football offensive back had a dream, to play professional football. By the time he was given a scholarship to play at the University of Missouri however, he had already clipped a man while driving drunk at the age of 16. Soon after the scholarship, he cruised through a red light drunk, hitting a family of four, sending to twin babies to the hospital, one with a fractured leg, the other with a broken arm. The problem is, Davis never learned from his mistakes. In each incident, his father arrived at the police station and convinced the police to not tarnish the name of a rising star, a proven hometown hero. He was set free with no charges.

"You inherit the gene of addiction. In my family, you deal with success the same way you mourn something, you drink." said Davis, of the cycle of addicts in his family and father's enabling of his alcohol inducement. "What was strange about me, I could out-drink everybody and I was so proud of that."

One night after partying at a bar celebrating a tryout and letter of intent with the Kansas City Chiefs he jumped on the hood of his car while his friend was driving it. The friend, a former pro-catcher for the Montreal Expos, hit the brakes. Davis split his head open and was in a coma for seven days. His football career was over.

Then came the drugs. After landing a teaching and coaching job, his downfall got even greater. It started with coke, progressed to acid, mushrooms, steroids and more cocaine. He'd wake up to four lines every morning, losing jobs here, lying to get them there. However, no matter how high he was, he always wanted to see his son Jason who lived with his ex-wife. Every time he had him, he screwed up, got high, got drunk and further distanced himself from Jason.

"You can never, never replicate your first high," said Davis. "You do more and more and more. That's the hitch."

After hitting near rock bottom after his home was raided by the State Police and his \$10,000 worth of cocaine was never found, he did a stint in rehab, but as soon as he got out, the enabling of his addictive lifestyle persisted.

"Who's out front? Mom and dad with a brand new sports car, how sick is that?," said Davis.

Then came Oct. 6, 1986...the last day he would pick up a drink, eat a mushroom or snort a line. His parents finally turned their backs on him by this point after he robbed nearly everything of value from their home. But it was that October, when he brought Jason to a bowling alley where all the other little boys and fathers were having fun. But Davis was "wasted" on mushrooms and Jack Daniels. He never brought Jason home that night because he fell on the alley, splitting his head open once again. Reality of who he had become finally set in.

Davis' most shocking reality to drug use however is where he and his family stand today, even after all the success of sobriety. He's slowly dying from the effects of Hepatitis C, a disease contracted from his use of shared, dirty needles and drug paraphernalia from his days gone awry.

The doctors originally told him they thought he had AIDS after battling a deep spell of convulsive sweats following one of his 17 knee surgeries. He later found out it was Hepatitis C. He now has 50-percent liver capacity, the doctors are ready to take out his dysfunctional spleen and his Hepatitis C count numbers over two million.

He was remarried after he got his life back on track, even had a little daughter named Serenity. He has made amends with Jason. Jason has pledged to break the cycle of addiction. He graduated as an engineer from the University of Buffalo. Serenity and his wife however still live with Davis' past addiction. They both have tested positive for Hepatitis C.

"I had stolen her choice," said Davis said of his daughter. "If you choose to use, it will come back to get you."

As students left Davis' talk, his message sent shock waves through the halls. Junior Katelyn Cunniff said she could see the emotion on most people's faces as they made their way to their last class of the day, many walking silently, and if any were talking, they were talking about the message Davis sent to them.

"I think it will have some people re-thinking what they might do or maybe what they have already done," said Cunniff, who sees peer pressure, as Davis was heavily influenced by, as a main attribute to drug or alcohol use in Lyndhurst. "He wasn't preaching to us, he wasn't telling us to not do this or not do that, he was just being honest about what happens."

Fresno Co. approves needle exchange pilot program

<http://www.fresnobee.com>

By Barbara Anderson / *The Fresno Bee*

Intravenous drug users can legally receive clean hypodermic needles in exchange for dirty ones in a pilot program approved Tuesday by the Fresno County Board of Supervisors.

The one-year program, which includes substance-abuse counseling, will allow members of the Fresno Needle Exchange to move off the street and into a building where they can dispense clean needles without fear of arrest.

"We can reach so many more people," said Dallas Blanchard, who has been dispensing clean needles to injection drug users for 13 years.

Volunteers have been illegally handing out 6,000 to 8,000 clean needles each Saturday and receive that many dirty ones for safe disposal, he said.

The illegal exchange has never been a secret. It occurs in Fresno down the street from the California Highway Patrol offices at West and Hedges avenues. Police look the other way.

But while the underground exchange has been tolerated, it's never been endorsed by the Board of Supervisors, who repeatedly refused to approve requests for a legal program.

Supervisors voted against creating a program the last time in 2006. At that time, Supervisor Susan Anderson was the lone dissenting vote for a legal exchange.

On Tuesday, supervisors voted 3-2 for the needle-exchange plan proposed by Dr. Edward Moreno, the county's public health officer. Supervisors Anderson and Bob Waterston and Board President Henry Perea voted for approval.

In their support, supervisors said they were sensitive to law enforcement concerns about illegal drug use, but the county needs to reduce the spread of disease. Among intravenous drug users, needle-exchange programs have been shown to decrease hepatitis C and HIV, the virus that causes AIDS.

A 2005 study estimated 15,169 injection drug users in Fresno County, with 11,377 most likely infected with hepatitis C, a liver disease that can be deadly.

Under the program proposed by Moreno, hypodermic needles will be exchanged once a week at The Living Room, a support center for people with HIV and AIDS and operated by WestCare, a nonprofit health and human-services agency.

County substance-abuse staff will provide information about drug-treatment options and referrals.

Fresno County health workers, who have been offering free HIV and hepatitis C screenings at the illegal exchange, will continue to provide the tests at The Living Room, said Jena Adams, a communicable-disease specialist with the county's Department of Public Health.

Dr. Marc Lasher has agreed to provide free medical care. Lasher has offered the care to drug users who come to the illegal exchange.

"I'm ecstatic," Lasher said from his office after the board meeting. "We've worked so hard for it over the years."

Lasher credited Moreno for proposing a treatment-based program that got the needle-exchange program approved.

State law allows California counties and cities to operate needle-exchange programs. Seventeen counties and three cities have such programs, said Alessandra Ross of the state Office of AIDS. Ross offered her assistance to Fresno County health officials in proposing the pilot program and was in Fresno on Tuesday to offer support.

Blanchard said he would like to hand out more clean needles.

"The main point is there is a cure for HIV and hepatitis C," he said before the board meeting. "The cure is prevention, and syringe exchange is prevention."

Bee staff writer Brad Branan contributed to this report. The reporter can be reached at banderson@fresnobee.com or (559) 441-6310.

Judge: Vegas clinics must show financial records

<http://www.sfgate.com>

A judge has ruled that Las Vegas medical clinics linked to a hepatitis C outbreak have to turn over financial records to lawyers representing infected patients.

Clark County District Court Judge Allan Earl on Tuesday ordered the two sides to hammer out a confidentiality agreement and complete the records transfer by the end of the year.

Earl originally ordered the records to be turned over last May.

But lawyers for the Endoscopy Center of Southern Nevada and the Gastroenterology Center of Nevada have failed to persuade the Nevada Supreme Court to intervene.

The clinics closed early last year, after health officials linked hepatitis C infections to improper injection practices.

Since then, the Southern Nevada Health District has traced nine cases of hepatitis C to the two clinics, and said another 105 cases might stem from procedures at the clinics.

Information from: Las Vegas Review-Journal, www.lvrj.com

Drug Helps Asians Battling Liver Cancer

<http://www.healthcentral.com>

TUESDAY, Dec. 16 (HealthDay News) -- The drug sorafenib increased overall survival in Asian-Pacific patients with advanced liver cancer, according to the results of a study that included 226 patients in China, South Korea and Taiwan.

The 150 patients in the treatment group received 400 milligrams of **sorafenib (Nexavar)** twice a day in six-week cycles, while those in the control group received a placebo.

Median overall survival was 6.5 months for those in the treatment group and 4.2 months for those in the control group. The study also found that sorafenib prolonged the time to progression and disease control rate.

Side effects among those taking the drug included skin reactions on the hands and feet, diarrhea and fatigue. The findings appear online and in the January print issue of *The Lancet Oncology*.

Sorafenib has been approved in Europe and the United States for treatment of advanced liver cancer, but approval in China was dependent on results from a study in Asian-Pacific patients, who account for 75 percent of liver cancer cases worldwide, according to background information in the study. Liver cancer is associated with chronic infection with hepatitis B (HBV), which is common in the Asian-Pacific region. Many patients are diagnosed when they have advanced liver cancer, which means that surgery is an option for only 20 percent of patients.

"Although other studies suggest that sorafenib might be less efficacious in patients with HBV, we do not agree with these conclusions, and believe that the large proportion of patients with HBV enrolled in our study supports the efficacy of sorafenib in this important patient population," wrote Dr. Ann-Lii Cheng, of the National Taiwan University Hospital, and colleagues.

Obese patients wait longer for liver transplant

www.reuters.com

By Will Boggs, MD

NEW YORK (Reuters Health) - People hoping for a liver transplant and who are obese face prolonged waiting times, reflecting a possible "reluctance to transplant obese patients," according to a new report.

"In transplantation, outcomes are available online to the general public, and compared from hospital to hospital," Dr. Dorry L. Segev explained to Reuters Health.

While this transparency may be welcome, "the side effect is that centers might become too reluctant to take on challenging cases, in fear that a bad outcome would be misinterpreted as poor quality of care."

Segev, from Johns Hopkins University School of Medicine, Baltimore, and colleagues looked into the relationship between body weight and access to transplantation in more than 25,000 consecutive patients.

After adjusting for other factors, severely obese patients had 30 percent lower odds and morbidly obese patients had 38 percent lower odds of getting a priority classification than did non-obese patients, the researchers report in the November issue of the *Annals of Surgery*.

Similarly, severely obese patients had 10 percent higher likelihood and morbidly obese patients had 16 percent higher likelihood of being turned down for an organ offer.

Among centers posting their waiting lists during this study period, 11 percent listed no patients who were severely obese and 19 percent listed none who were morbidly obese, the investigators report.

"Our findings suggest a reluctance to perform liver transplantation on obese patients," the authors conclude.

"I believe that liver (grafts) should be allocated fairly to patients who are determined by their providers to be good candidates," Segev said. "Many obese patients are predicted to derive a significant survival benefit from liver transplantation."

In fact, Segev concluded, "All patients in our study were already on the waiting list -- in other words, already determined to be good candidates. I believe that there should be no disparities past that hurdle."

SOURCE: *Annals of Surgery*, November 2008.

Dec 18, 2008

More than 54 million disabled in U.S., census says

www.reuters.com

WASHINGTON (Reuters) - More than 54 million U.S. residents, or about 19 percent of the population, have some sort of disability, the U.S. Census Bureau reported on Thursday.

The numbers, based on 2005 data, are up slightly from the 2002 survey when 51.2 million people or 18 percent reported a disability, the census found.

About 46 percent of adults aged 21 to 64 with a disability were employed, compared with 84 percent of adults without disabilities, the survey found.

It also found that:

- 7.8 percent of people aged 15 and older had difficulty hearing a normal conversation, including 1 million completely deaf people.
- 3.3 million people, or 1 percent of those aged 15 and older, used a wheelchair or a similar device.
- Nearly 7.8 million people aged 15 and older had difficulty seeing words or letters, including 1.8 million who were completely blind.
- More than 16 million people had difficulty with cognitive, mental or emotional functioning.
- People with a severe disability earned \$1,458 a month on average compared to \$2,539 for those with no disability.
- 4.7 million children aged 6 to 14, or 13 percent, had a disability, mostly a problem doing regular schoolwork.

(Reporting by Maggie Fox; Editing by Xavier Briand)

Dec 19, 2008

The Office Of Minority Health Releases Strategies To Address Chronic Hepatitis B In Asian American, Native Hawaiian And Other Pacific Islander

<http://www.medicalnewstoday.com>

More health education, awareness and screenings, improved access to care and treatment, and increased research are needed to reduce and eventually eliminate chronic hepatitis B among Asian-Americans, Native Hawaiians and Other Pacific Islander communities (AAs/NHOPIs), a federal report recommends.

The report was created by members of The National Task Force on Hepatitis B Expert Panel, and staff members of HHS' Centers for Disease Control and Prevention, and Office of Minority Health.

Hepatitis B, the world's most common serious viral infection of the liver, can cause premature death from liver disease or liver cancer. Chronic hepatitis B and liver cancer caused by hepatitis B in AAs/NHOPIs comprise one of the most serious but frequently neglected racial and ethnic health disparities in the United States.

"We must find more effective and far-reaching strategies if we are to succeed in reducing the toll hepatitis B takes on our health, well-being and productivity," said Garth Graham, M.D., M.P.H., deputy assistant secretary for minority health. "By calling attention to hepatitis B and creating strategies to fight it, we can take the steps necessary to make a difference in communities that are impacted by this deadly disease."

The Centers for Disease Control and Prevention estimates that as many as two million people in the country are living with chronic hepatitis B, and over half are AAs/NHOPIs. These groups have the highest rates of chronic hepatitis B among all racial/ethnic groups in the United States, and they are at a disproportionately high risk of liver cancer, which is the third leading cause of cancer death among these populations.

"The fight against hepatitis B and associated liver cancer is critical to protect the health of Asian Americans and Pacific Islanders, who bear the brunt of the disease burden," said John W. Ward, M.D. director of CDC's division of viral hepatitis. "With a new strategic plan developed directly in partnership with communities most affected, we all now have a clear roadmap to move forward in recognizing hepatitis B prevention as a national priority and protecting Asian Americans from the ravages of the disease."

Although the incidence of acute hepatitis B across the United States has declined substantially in recent years, the high prevalence of chronic hepatitis B among AAs/NHOPIs, particularly the foreign-born, appears to have remained relatively constant.

For more information on the report, Goals and Strategies to Address Chronic Hepatitis B, visit here. <http://www.omhrc.gov/templates/browse.aspx?lvl=2&lvlid=190>

The Office of Minority Health

Dynavax Announces Termination of Partnership With Merck for HEPLISAV Hepatitis B Vaccine

<http://biz.yahoo.com/>

BERKELEY, Calif.--(BUSINESS WIRE)--Dynavax Technologies Corporation (Nasdaq:DVAX - News) today announced the termination of a global license and development collaboration agreement with Merck & Co., Inc. for HEPLISAVTM, a Phase 3 hepatitis B virus (HBV) vaccine. All rights to develop and commercialize HEPLISAV revert to Dynavax.

Dynavax will continue to evaluate regulatory options for the development of HEPLISAV indicated for adults outside of the United States and for the global end-stage renal disease markets, which the Company estimates represent approximately 70% of the total market opportunity for this vaccine. If the regulatory feedback is favorable, Dynavax plans to pursue a

new partner or financing arrangement to support the completion of HEPLISAV's development for these markets.

"We believe the economics for HEPLISAV, which has been shown to be clinically superior in our trials, favor identifying an appropriate regulatory path in the U.S. and Europe," commented Dino Dina, M.D., President and Chief Executive Officer of Dynavax. "In the first quarter of 2009, we expect to gain additional insight into the regulatory path for HEPLISAV that will enable us to evaluate further development and pursue partnering agreements with potential collaborators or investors. Independently of HEPLISAV, with our current cash position and strong pharmaceutical partnerships, we have the ability to continue to advance our diversified, well-funded pipeline of products to position Dynavax for future success."

Update to 2008 Cash Outlook

Dynavax's consolidated cash, cash equivalents, marketable securities and investments held by Symphony Dynamo, Inc., or total cash, is projected to be over \$65 million at December 31, 2008, an increase from the previous guidance of over \$50 million. This increase is due to the \$10 million initial payment under Dynavax's worldwide strategic alliance with GlaxoSmithKline as well as the Company's conservatively managed cash burn rate. Due to the termination of the Merck partnership, Dynavax anticipates that it will accelerate the recognition of approximately \$31 million of non-cash revenue previously reported as deferred revenue.

About HEPLISAV

HEPLISAV is a Phase 3 hepatitis B vaccine that combines HBV surface antigen (HBsAg) with Dynavax's proprietary immunostimulatory sequences (ISS), which specifically target Toll-Like Receptor 9 (TLR9) to stimulate an innate immune response. Clinical data demonstrate HEPLISAV's highly effective protection against HBV with a more rapid onset of protection, superior 2-dose regimen, and longer lasting seroprotection compared to current vaccines. In a recent Phase 3 trial, 95% of subjects receiving 2 doses of HEPLISAV were seroprotected compared to 81% of subjects receiving 3 doses of Engerix-B. In 9 clinical trials conducted over a period of nearly 10 years, a total of approximately 2,500 individuals have been vaccinated with more than 5,000 doses of HEPLISAV.

In October 2008, the U.S. Food and Drug Administration (FDA) requested additional information prior to considering further development of HEPLISAV in end-stage renal disease patients but advised that the balance of risk versus potential benefit no longer favors continued clinical evaluation of HEPLISAV in healthy adults and children. The clinical hold on the two U.S. IND Applications for HEPLISAV has been in effect since March 2008 following the FDA's request for a complete review of safety data, including all available information about a single case of Wegener's granulomatosis reported in a Phase 3 clinical trial.

HEPLISAV is not on clinical hold in any market outside of the U.S.

About Dynavax

Dynavax Technologies Corporation, a clinical-stage biopharmaceutical company, discovers and develops a diversified, well-funded pipeline of novel Toll-like Receptor (TLR) product candidates. Based on Dynavax's proprietary technology platform, these products specifically modify the innate immune response to infectious, respiratory, autoimmune, and inflammatory diseases. Dynavax's product programs are supported by global partnerships with leading

pharmaceutical companies such as GlaxoSmithKline, AstraZeneca AB, and Novartis as well as funding from Symphony Dynamo, Inc. and the National Institutes of Health. For more information visit www.dynavax.com.

'Gross' Messaging Used To Increases Handwashing, Fight Norovirus

<http://www.sciencedaily.com>

ScienceDaily (Dec. 19, 2008) — Research conducted by University of Denver (DU) Associate Professor Renée Botta suggests that it takes "gross" messaging to get undergraduate students to wash their hands more frequently after going to the bathroom.

In fall quarter 2007, researchers posted messages in the bathrooms of two DU undergraduate residence halls. The messages said things like, "Poo on you, wash your hands" or "You just peed, wash your hands," and contained vivid graphics and photos. The messages resulted in increased handwashing among females by 26 percent and among males by 8 percent.

"Fear of spreading germs or getting sick by not washing didn't mean much to students," says Botta, the lead author of the study and an associate professor in the Department of Mass Communications and Journalism Studies. "What got their attention was the knowledge that they might be walking around with "gross things" on their hands if they didn't wash."

Observations in two control dorms over the same four-week period showed handwashing decreased 2 percentage points among females and 21.5 percentage points among males.

"We tried gross messages, germ messages and you'll-get-sick messages. And the only ones that stuck was gross," says Assistant Director of Health Promotions Katie Dunker, one of a team of five who conducted the pilot study. "We found that the 'gross factor' is what works, and we were able to increase hand washing behavior by a lot."

The findings are generating interest. Universities including UC Santa Barbara, Wyoming, Colorado State and CU–Colorado Springs want to borrow DU's techniques in hopes of improving student handwashing behavior on their campuses.

"The relevance of the message is really, really important," she says. "You can threaten that they'll get the flu or promise a flu-free winter, but if they don't really care about that, your message is going to fall flat," Botta says.

What was clear, she adds, was that the grossness campaign brought positive results not only in the study but also in a campus emergency that broke out last April. A week before the study was to be expanded to the entire University, a Norovirus outbreak made 63 students ill over a four-day period. Handwashing was identified as an important way to prevent the disease from spreading.

The study appears in the October edition of the *Journal of Communication in Healthcare*.