

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Week Ending: July 7th 2007

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June 30th, 2007

Hepatitis C: An epidemic bigger than HIV

<http://www.mckinnemessenger.com>

By Stefanie White, McKinney Courier-Gazette

Conditions such as HIV are known as epidemics worldwide, but Dr. Allen Reuben said there is another disease that's an even bigger problem in the United States.

Reuben, a consultant in infectious diseases for the Medical Center of McKinney, said about 2 percent of the population in the United States is infected with Hepatitis C.

“It’s a much bigger epidemic than HIV,” Reuben said. “It’s also a worldwide problem.”

Hepatitis C, like HIV, is a silent disease in which no symptoms are found in those affected. If there are symptoms, they are usually a flu-like illness with muscle aches and joint complaints.

“For the most part, most patients never know they have it,” Reuben said. “Acute disease and chronic disease are almost impossible to detect.”

Reuben said patients often discover they have Hepatitis C through blood donations and insurance physicals.

“On occasion, the liver-function test might be elevated, and that leads to screening for Hep C,” Reuben said.

Hepatitis C is most common in adults ages 40 to 49. Some people affected in this age range, Reuben said, were active in the drug era during the 1980s.

“The most common risk factors are obviously IV drug use and transfusions before 1990,” Reuben said.

Since 1990, all blood is screened for diseases such as Hepatitis C and HIV.

Other risk factors for Hepatitis C are body piercings, tattoos, incarceration and multiple sex partners.

There are several different genotypes for Hepatitis C. Reuben said Type 1 is the most common in the United States but the hardest to treat. Types 2 and 3 are less common but easier to treat with medicines.

Reuben said there is no immunization for Hepatitis C, but it is curable with medication.

“It’s a shot, once a week,” Reuben said. “Then you need to take a drug with that, Ribavirin, and it makes that a lot better.”

The treatment needs to be taken for about 48 weeks for Type 1; less for Types 2 and 3.

In some instances, Reuben said those infected with Hepatitis C don’t respond to treatment. While one out of five people get over the infection on their own, Reuben said the other 80 percent can’t get over it. For those who do test positive, there is an 80 percent chance that it is chronic.

Some long-term effects of Hepatitis C are the risk of developing cirrhosis of the liver. Reuben said drinking alcohol can increase that risk. Eventually, cirrhosis could lead to cancer of the liver.

“It [Hepatitis C] accounts for 8,000 to 13,000 deaths per year,” Reuben said. “A majority of liver transplants are for Hep C. It’s the most chronic liver disease.”

For anyone in one of the risk factors, Reuben said they should be screened for Hepatitis C by a physician. Those who test positive should seek the help of a specialist.

Contact staff writer Stefanie White at swhite@acnpapers.com . To post comments online, access this story at www.scntx.com .

July 1st, 2007

Sirius Satellite Radio Host Tawn Mastrey in Need of Life Saving Liver Transplant

<http://www.prweb.com/>

Legendary Radio Disc Jockey suffering from Hepatitis C and in need of liver transplant. Benefit concerts in the works.

(PRWEB) July 1, 2007 -- The name Tawn Mastrey is synonymous with the world of Hard Rock and Heavy Metal. The '70s, '80s and '90s rock scene would not be what it was and is today without this wonderful voice that uplifted so many major acts. Tawn is probably best known for her work at KNAC 105.5 in Los Angeles and her later work Scott Shannon's Pirate Radio, and with The Westwood One Radio Network and Sirius Satellite's Hair Nation channel.

It was announced recently that Tawn had to quit her job as the host on Hair Nation due to health reasons. Tawn, like so many others in today's world is suffering from Hepatitis C and is in dire need of a liver transplant. Further complicating this need is the fact that Tawn has no health insurance.

A major drive is now underway to get Tawn proper medical care and hopefully a transplant. This is going to cost money. Money that is needed not only for her care now, but for the actual transplant operation and follow up care.

Tawn was and always has been a spark of light and hope for the Rock world, and now she is in need of YOUR HELP!

There is now a Tawn Mastrey Transplant Fund where you can donate to the cause of helping save Tawn's life. Please find it in your heart to contribute whatever you can by visiting <http://www.tawnmastreybenefit.com/>

Your donation will go into the fund to help Tawn receive the best care and get the treatment she so desperately needs.

Events are being planned around the United States to bring some of the biggest names in the Hard Rock genre to perform benefit concerts to also help this fund. As well as a special "Tribute for Tawn" concert in the Los Angeles area with some of the best Tribute bands around with proceeds going to the Tawn Mastrey Transplant Fund. The first of these shows is set for July



28th at Martini Blues in Huntington Beach, Ca. (Ticket info call 714-840-2129)

Performing at this show will be local Tribute greats Metal Knights, Masters of Reality, Lights Out and Rude Awakening. At the end of the evening after the Metal Knights performance there will be an all star jam with members of DIO, Great White and other hard rock favorites in attendance.

Tawn, her family, friends and the rock community have enlisted the help of Donate Life America to raise awareness about the importance of organ, eye and tissue donation.

Donate life America representatives will be on hand at as many of these events as possible, but are always available online, via email and websites to answer any questions and to assist you in signing up to become an organ and tissue donor in your area.

To find out how to become an organ donor in your area, and to help save lives like that of Tawn Mastrey, and the other close to 100,000 currently awaiting a transplant in the United States, please visit www.donatelife.net

Former Rock Radio personality Robbie "Razor" Robfogel, a liver transplant recipient himself and friend of Tawn will be organizing the "Tribute for Tawn" shows, with his band Metal Knights performing. KNAC.com air personality Diana Deville will host the evening's event. Robfogel is also a spokesperson for Donate Life Rocks and has performed radio public service announcements for the organization.

Getting tattoos comes with risk of diseases

<http://www.kpcnews.com/>

Terry Gaff

In discussing our children, the subject of tattoos came up at a meeting I attended recently. I explained that my wife and I agreed to let our kids get their hair cut or colored any way they want (because hair will generally grow back) and get any body part pierced with sterile equipment if they want (because the holes generally grow shut).

However, we asked them to avoid tattoos because tattoos are so difficult (and expensive) to remove if you change your mind. Also, there is a small risk of "catching" hepatitis B or hepatitis C or HIV/AIDS or other diseases while being tattooed.

In this column, I want to tell you specifically about Hepatitis C Virus (HCV), even though the other diseases are important, too.

Hepatitis C is transmitted by injection, like hepatitis B rather than through food or water like hepatitis A. The most common risk factor for hepatitis C is intravenous (IV) drug use. Before 1992 (the introduction of blood donor screening and hepatitis tests), transfusion of blood or plasma-derived products was associated with significant risk of hepatitis C. Other potential risk factors for hepatitis C include nasal cocaine use, tattooing, body piercing, accidental needle-stick injury, and the sharing of household items.



Tattooing deserves special mention. The factors that may be associated with hepatitis C infection and tattoos include tattoo size, the number of tattoos, and obtaining a tattoo at a commercial tattoo parlor. These findings have led some governmental bodies to require parental consent for minors before commercial tattoo placement.

However, according to the Centers for Disease Control and Prevention (CDC), tattooing is not clearly considered a risk factor for HCV infection. They realize that some studies have shown a link between tattooing and the infection in certain groups of people, but the agency says there is not enough evidence to say the same is true for the general population.

The CDC does, however, advise people thinking about getting tattoos or body piercing to consider the health risks. It is possible to get infected with HCV, if the tools used have someone else's blood on them, or if the tattoo artist fails to use proper hygiene, such as washing hands, sterilizing tools, and using disposable gloves.

A reputable shop will look clean. If checked out before getting a tattoo done, you might be able to make certain that they use sterile needles and pigments from unopened packages and that the tattoo artist wears gloves at all times while working on you. Hepatitis C can be passed through tattooing by reusing needles or dye and insufficient sterilization of equipment between clients and it is almost impossible to sterilize the gun.

However, sociological studies of tattoo recipients have shown that few recipients compare tattoo parlors or watch a tattooing procedure before getting one, and few consider tattooing a future health risk. One study found that commercially acquired tattoos accounted for more than twice as many hepatitis C infections as injection-drug use. This means that tattoos may have been the largest single contributor to the nationwide epidemic of this form of hepatitis.

In the United States, almost every person knows someone with HCV. It is suspected that there are, at present, more than 5 million people in the United States who are infected with Hepatitis C, and perhaps as many as 200 million around the world.

This makes HCV one of the greatest public health threats faced in this century.

Hepatitis C attacks the liver and can lead to cirrhosis, liver failure, and liver cancer. However, it is a stealth virus that can be present in a healthy-looking person for decades and then strike without warning. It is the leading cause of liver failure resulting in the need for liver transplants. By 2010, it may strike down more Americans each year than AIDS, when the mortality rate is expected to increase from the current 15,000 to over 19,000 per year.

Since the pathogen was recognized in 1988, it has been shown to cause two types of problem. Acute hepatitis syndrome includes pain in the upper right side of the body, vomiting, and fever. Far more common is chronic, or silent, hepatitis C infection.

Of those initially infected, 15 percent mount a successful immune response and clear the virus from their bodies within the first year. The rest retain the virus, becoming chronic carriers. Eighty percent of the carriers suffer chronic liver inflammation and minor scarring of the organ. Twenty percent develop cirrhosis of the liver within 20 years.

Chronic liver disease is the tenth largest cause of death among U.S. adults with 40 percent to 60 percent apparently caused by hepatitis C.

As the disease progresses, healthy cells are replaced by scar tissue that can keep the organ from functioning properly. One quarter of those who develop cirrhosis develop end stage liver disease, which can involve cancer, require a transplant and result in death.

People with any of the risk factors for hepatitis C, including tattoos, should consider having a blood test, because treatments are now available to eradicate the virus in many before it causes permanent liver damage or cancer.

Dr. Terry Gaff practiced family medicine in Albion for 17 years and is now medical director of the emergency department at Parkview Noble Hospital in Kendallville and the Noble County EMS. He welcomes your questions. He can be reached at terrygaff@pol.net

July 2nd, 2007

Hep-Outbreak Probers Eye 'Double Dip' Syringes

<http://www.nypost.com/>

By SUSAN EDELMAN and LINDA STASI

July 1, 2007 -- Health investigators are looking into whether an anesthesiologist suspected of spreading hepatitis infections tainted batches of medication by "double dipping" syringes into vials used for multiple patients, *The Post* has learned.

In a widening probe, officials are also investigating whether other doctors may have used such sloppy methods - or cut corners on safety to lower costs, sources said.

Dr. Brian Goldweber is under investigation for lax practices that infected "a handful" of patients with hepatitis B and C, officials say.

Without naming him, the Health Department this month sent letters to 4,500 patients Goldweber had anesthetized since 2003, asking them to get tested for hepatitis and HIV.

Goldweber worked for Dr. Abbe Carni, of Teaneck, N.J.

Carni heads a group of anesthesiologists that serves outpatient-surgery centers and doctors across the city. He billed for some of Goldweber's work, records show.

Carni's name was added last week to a malpractice lawsuit by retired businessman Sam Bernard, who was hit with hepatitis B after an endoscopy in Manhattan, with Goldweber doing the anesthesia.

"We want to see if any other doctors used the same reckless practices to cut costs at the patients' expense," said Jude Avelino, Bernard's lawyer.

Avelino also questioned whether Carni knew that the state had suspended Goldweber's medical

license for three years in 1999 for negligence and fraud, and later fined him \$20,000 for lying about his record.

Carni did not return calls.

The city Health Department has confirmed transmission of hepatitis C, a liver disease, to three patients anesthetized by Goldweber last August. Two other patients got hepatitis C after colonoscopies in 2004 and 2005, *The Post* has reported.

Sources said one of the main theories under investigation is that he used the same syringe or tubing to give patients a "double dip" of anesthetic from a multi-dose vial.

"You can't double dip," a board-certified Manhattan anesthesiologist told *The Post*. "It's basic sterile technique."

A used syringe or tube can send a "back flow" of blood specks into the multi-dose vial – tainting a batch that can be used for up to six other patients.

"It's just sloppy, lazy, horrendous technique. It's also a way to save money," the anesthesiologist said.

"When I use a multi-dose vial, I use a different syringe every time – even for the same patient. Otherwise, you have to throw the vial out – it's contaminated."

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Stanford Free Clinic in San Jose Launches Hepatitis B Campaign

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

Students from the Stanford University School of Medicine will launch a new effort in San Jose to provide comprehensive hepatitis B medical services, targeting uninsured Asian and Pacific Islanders with low incomes.

The Hep B Free Campaign will provide free hepatitis B testing and low-cost vaccinations at the Pacific Free Clinic for high-risk Asians and Pacific Islanders in the San Jose community. For those already chronically infected with the hepatitis B virus, the clinic will provide appropriate monitoring with blood tests and liver ultrasounds, referrals and antiviral treatment.

The campaign launches July 7 at the Pacific Free Clinic, based at Overfelt High School at 1835 Cunningham Ave. in San Jose. The campaign's theme is, "Be Sure, Be Tested and Be Hep B Free." The campaign co-founders are Elizabeth Chao and Steven Chin, Stanford medical students who are recipients of a U.S. Albert Schweitzer fellowship.

Regardless of a patient's ability to pay or immigration status, the Pacific Free Clinic offers on-site medical interpretation services in Vietnamese and Chinese to help patients overcome cultural and language barriers to health care. In addition to the medical students who volunteer, the clinic



is staffed by physicians, including medical director Rex Chiu, MD, clinical assistant professor of medicine at Stanford. The clinic is open Saturdays from 10 a.m. to 2 p.m.

According to Stanford's Asian Liver Center, hepatitis B is the world's most common serious disease of the liver and can lead to premature death from liver cancer. The virus is endemic to Asia, and can be transmitted at birth from an infected mother to a newborn. Most children who become chronically infected have no symptoms for 20 to 40 years.

About one in 10 foreign-born Asians, particularly those from southeast Asia and China, have chronic hepatitis B infection -- a rate 100 times higher than that of Hispanic or white Americans. Many are unaware they are infected. The virus will eventually kill one in four people who are chronically infected, but this can be avoided with monitoring and treatment, according to Chiu.

"Most of the Asian and Pacific Islanders in San Jose are recent immigrants and their doctors have never tested them," said Samuel So, MD, the Lui Hac Minh Professor of Surgery and director of the Asian Liver Center.

Information about the clinic is available online at <http://pacific.stanford.edu/home.html> . For information about hepatitis B and liver cancer, visit <http://liver.stanford.edu> . For other questions, contact Steven Lin at linsteve@stanford.edu or (919) 452-8073.

Stanford University Medical Center integrates research, medical education and patient care at its three institutions -- Stanford University School of Medicine, Stanford Hospital & Clinics and Lucile Packard Children's Hospital at Stanford. For more information, please visit the Web site of the medical center's Office of Communication & Public Affairs at <http://mednews.stanford.edu> .

NOTE TO THE MEDIA: Reporters are invited to the news conference and ceremony launching the hepatitis B campaign at 11 a.m. July 7 at the Pacific Free Clinic, which is based at Overfelt High School, 1835 Cunningham Ave., San Jose.

When to Start and Stop Hepatitis B Treatment: Can One Set of Criteria Apply to All Patients Regardless of Age at Infection?

<http://www.annals.org>

Bulent Degertekin, MD, and Anna S.F. Lok, MD
3 July 2007 | Volume 147 Issue 1 | Pages 62-64

Existing guidelines for the treatment of hepatitis B virus (HBV) infection recommend that only patients with active or advanced liver disease and high serum HBV DNA levels be treated and that, in patients who are initially seropositive for hepatitis B e antigen (HBeAg), treatment can be stopped 6 months after HBeAg seroconversion (1–3). In this issue, Lai and Yuen (4) raise concern that those recommendations are inappropriate for patients with perinatal HBV infection. They propose that patients with normal alanine aminotransferase (ALT) levels who acquire infection early in life should also be treated and that HBeAg-positive patients should continue treatment after HBeAg seroconversion. The 2007 update of the American Association of the Study of Liver Disease guidelines (5) address some of Lai and Yuen's concerns by



recommending that treatment also be considered for patients with intermittent or mildly elevated ALT levels; those who remain HBeAg- positive with high serum HBV DNA levels after 40 years of age; and HBeAg-negative patients with HBV DNA levels of 10 000 to 100 000 copies/mL (2000 to 20 000 IU/mL), particularly if liver histologic examination shows significant inflammation or fibrosis (5). Here, we put other aspects of their proposal in the context of existing evidence.

People with ALT values within the normal range are traditionally considered to have healthy livers. However, recent evidence suggests that the upper limits of normal in most diagnostic laboratories are erroneously high, owing to inclusion of patients with asymptomatic liver disease (6). Two studies reported that persons with ALT levels that are 0.5 to 1 times greater than the upper limit of normal had higher mortality from liver disease or cirrhosis complications than did persons with ALT levels less than 0.5 times the upper limit of normal (7, 8). Small studies have also found that up to one third of HBV carriers with normal ALT levels have moderate inflammation or advanced fibrosis (9, 10). However, the natural course of chronic HBV infection varies and may be punctuated by recurrent fluctuations in serum HBV DNA and ALT levels (11), and a study from Taiwan found that disease progressed slowly among HBeAg-positive patients with normal ALT levels: The cumulative probability of cirrhosis after 17 years was 12.6%, and none of the 240 patients developed hepatocellular carcinoma (12). These latter data suggest that treatment can be deferred in most patients with persistently normal ALT levels and that the presence of risk factors for progressive liver disease, such as older age, HBeAg positivity, high serum HBV DNA levels, and co-infection with hepatitis C or D virus, can be used to identify patients with normal ALT levels who warrant further evaluation and treatment.

Hepatitis B e antigen seroconversion was long thought to be associated with cessation of HBV replication and remission of liver disease. However, evidence from the past 2 decades shows that HBV DNA remains detectable in serum after HBeAg seroconversion, albeit at low levels (13). In some patients, high serum HBV DNA levels and active liver disease persist after HBeAg seroconversion (HBeAg-negative chronic hepatitis), a state frequently associated with precore HBV variant (14) and HBV genotype D (and less commonly genotype B and C) infection.

The recognition that HBV persists after HBeAg seroconversion has led to the term inactive carrier state, with the understanding that the virus is not eradicated and liver disease can become active again. Nevertheless, a study from Taiwan found that two thirds of patients with perinatal HBV infection had sustained remission and very low risk for cirrhosis and hepatocellular carcinoma up to 9 years after spontaneous HBeAg seroconversion (15). On the basis of these data, HBeAg seroconversion seems an appropriate treatment end point in most patients, provided that they continue to be monitored and treatment is reinitiated when hepatitis is reactivated. This is particularly true when a strict definition of HBeAg seroconversion—namely, HBeAg loss, HBe antibody detection, a nondetectable (or very low) serum HBV DNA level, and normalization of ALT values—is used as the treatment end point.

The major difference between perinatal and adult-acquired HBV infection is the presence of a long immune tolerance phase (10 to 40 years) in patients with perinatal HBV infection, during which patients are HBeAg-positive with a high serum HBV DNA level but a normal ALT level (11). Patients in this phase have a very low rate of spontaneous or treatment-related HBeAg seroconversion. Available data suggest that the next phases of immune clearance (HBeAg

positivity, high HBV DNA levels, and high ALT levels) and inactive carrier state (HBeAg negativity, low or undetectable HBV DNA levels, and persistently normal ALT levels) are similar for patients with perinatal or adult-acquired HBV infection. Some patients will progress from the inactive carrier state to HBeAg-negative chronic hepatitis. This transition is not unique to patients with perinatal HBV infection; in fact, it is most commonly associated with HBV genotype D, which is usually acquired during childhood or during adulthood. The basis for existing recommendations to defer treatment in HBeAg-positive patients with normal ALT levels is the low rate of HBeAg seroconversion with treatment and the generally slow rate of disease progression during the immune tolerance phase in patients with perinatal infection. Although HBV replication after HBeAg seroconversion can be reactivated in all patients independent of age at infection, an occurrence of 30% over 10 years (15) does not justify continuing treatment for all patients.

Beyond questions about when to start and stop treatment, Lai and Yuen's proposal reflects the conviction that the ideal treatment end point, permanent suppression of HBV DNA to undetectable levels on polymerase chain reaction, can be achieved with current therapies. Available data suggest that after a 1-year course of pegylated interferon therapy, sustained HBeAg seroconversion is achieved in only approximately 30% of HBeAg-positive patients and sustained suppression of serum HBV DNA to undetectable levels is achieved in approximately 20% of HBeAg-negative patients (5). A 1-year course of oral nucleoside therapy (lamivudine, adefovir, entecavir, or telbivudine) results in undetectable serum HBV DNA in 20% to 70% of HBeAg-positive patients and 50% to 90% of HBeAg-negative patients (5). However, viral relapse occurs in more than 90% of patients after treatment withdrawal, except in patients who have sustained HBeAg seroconversion or the rare patient who has cleared HBsAg (16). Extending treatment with lamivudine or telbivudine beyond 1 year is associated with a decreasing proportion of patients with undetectable serum HBV DNA because of selection of drug-resistant mutants. Continued treatment for HBeAg-negative patients with adefovir for up to 5 years has been reported to increase the proportion of patients with undetectable serum HBV DNA from 72% at the end of 1 year to 80% at the end of 2 years, with a subsequent decrease to 67% at the end of 5 years (17). Preliminary data indicate that treating HBeAg-positive patients with entecavir for up to 3 years resulted in undetectable serum HBV DNA in 87% of patients (18).

These long-term efficacy data are based on few patients: 70 for adefovir and 122 for entecavir. More important, viral suppression will not be permanent in all patients, given that the rate of drug resistance will increase with duration of treatment even with new drugs (such as entecavir) and nonadherence to therapy is more likely over time. Finally, most clinical trials enroll only patients with elevated pretreatment ALT levels; response rates may be lower in patients with normal ALT levels. A high pretreatment ALT level is the best predictor of interferon- and nucleoside treatment-related HBeAg seroconversion (19). Thus, although currently approved treatments can suppress serum HBV DNA to undetectable levels on polymerase chain reaction, no data show yet that any of these treatments can result in permanently undetectable virus in all patients.

Because HBV cannot be eradicated, many physicians have argued that patients with hepatitis B should receive lifelong treatment, as is given for other chronic medical illnesses. However, rates of drug resistance increase with duration of treatment (even with new therapies), long-term

safety data are lacking, and treatment is very expensive (approximately \$18 000 per year for pegylated interferon and \$2500 to \$9000 per year for nucleosides). Until treatments that are safe and affordable for long-term use can achieve permanent suppression of HBV replication in all or most patients, we recommend treatment only for patients who have high serum HBV DNA levels and active or advanced liver disease and deferral of treatment for patients with normal ALT levels who have a low likelihood of progressive liver disease (those who are young, are HBeAg-positive, and have persistently normal ALT levels) until it is indicated. Likewise, discontinuation of treatment in HBeAg-positive patients who have confirmed HBeAg seroconversion and have completed an additional 6 months of consolidation treatment is appropriate as long as they continue to be monitored and treatment is reinitiated if HBV is reactivated. We believe that these recommendations apply to all patients with hepatitis B regardless of their age at infection.

References <http://www.annals.org/cgi/content/full/147/1/62>

July 3rd, 2007

Comedian apologises for Hep C joke

<http://www.theage.com.au>

Rove comedian Peter Helliar has apologised to hepatitis sufferers for making light of the disease with a joke branded "cheap and cruel".

Hepatitis Australia said it was offended by an on-air witticism in which Helliar joked about giving hepatitis C to Pamela Anderson for her 40th birthday.

In a segment of the Sunday night comedy show Rove, the comedian asked what would be the best present for the former Baywatch star, who has everything.

"Hepatitis, oh wait, she already got that last year," Helliar said on the program.

Hepatitis Australia chief executive Helen Tyrrell said the "irresponsible" comment was a cruel and discriminatory attempt at humour.

"Many of the 260,000 Australians affected by hepatitis C already experience stigma and discrimination on a regular basis, and ignorant 'comedy' like this only adds to the pain," Ms Tyrrell said.

But Helliar today said he did not mean to cause offence.

"I realise hepatitis is a disease affecting many Australians," he said.

"The joke ... was not intended to offend those living with hepatitis and if any offence was caused, I sincerely apologise."

Hepatitis C is a blood-borne virus which newly infects about 10,000 Australians each year, causing liver failure and liver cancer in a small but significant number.

Ms Tyrrell said she did not understand why the illness was the target of jokes.

"We sincerely doubt Rove would have featured a similar joke about giving a celebrity a gift of HIV/AIDS," she said.

"But for some reason they think its acceptable to seek cheap laughs at the expense of people living with hepatitis C.

"The fact is it's not acceptable."

AAP

When the Surgeon Is Infected, How Safe Is the Surgery?

<http://www.nytimes.com>

By RONI CARYN RABIN

A few years ago, two Long Islanders with hepatitis C met in a support group and soon discovered they had something in common: both had become infected with the virus after open-heart surgery — by the same surgeon.

Public health investigators, who were looking into one of the two cases, had not asked members of the patient's surgical team whether one of them might be infected. Now they did. Eventually they determined that the surgeon, Dr. Michael Hall, was infected and that he was the inadvertent source of both patients' infections — and that of at least one other patient.

Dr. Hall was never found legally liable, and he continues to do hundreds of open-heart operations each year. His lawyer, Tony Sola, said last week that the doctor had tested negative for hepatitis C in recent years, that there were no restrictions on his practice and "that he did absolutely nothing wrong and operated in a perfectly reasonable manner."

Still, the episode was a window into a risk about which troublingly little is known: the possibility of getting a viral infection from a health care worker.

Viruses like hepatitis B, hepatitis C and H.I.V. are spread by blood-to-blood contact. Doctors, like cooks, often cut or nick themselves, and if it happens while a surgeon's hands are inside the patient's body cavity, the doctor is at risk of both picking up and passing on an infection. A survey in The New England Journal of Medicine last week reported that surgeons-in-training suffer an average of eight needle sticks in their first five years.

Despite the risk, however, there is no mandatory testing of surgeons for blood-borne viruses, and infected health care workers are not prohibited from practicing medicine or invasive surgery. Local expert panels are convened to review cases if they come up, but many surgeons simply refrain from being tested.

Where all of this leaves patients is a subject of fierce debate. Federal health officials say the risk of a health care worker's transmitting a blood-borne viral infection to a patient is insignificant.

But some critics say a double standard is in effect: While clear protocols are in place to protect health care workers exposed to a patient's blood, no such protections exist for patients undergoing invasive procedures.

"Patients don't know when they've been exposed to blood — they're under anesthesia when this happens," said Janine Jagger, an epidemiologist who is director of the International Health Care Worker Safety Center at the University of Virginia Health System. "If there's no report of it in the record, then nothing is done about it.

"Patients never suspect this could happen to them," Dr. Jagger went on. "It's really swept under the carpet."

Health care workers, on the other hand, are required to report any exposure to a patient's blood so they and the patient can be tested and monitored, and they can take advantage of protective treatments like antiviral medications against H.I.V., Dr. Jagger said.

In recent years, meanwhile, Lawrence O. Gostin, a prominent public health law expert who works with the federal Centers for Disease Control and Prevention, has been urging health authorities to drop any restrictions that pertain to infected health care workers. Such rules, he says, lead to discrimination and discourage testing.

C.D.C. officials insist they are not planning to change the current policy, but they note that relatively few such infections from doctor or nurse to patient have ever been identified, even when retrospective studies have been done on patients treated by physicians later found to have the AIDS virus.

"In general, the risk for a health care worker transmitting hepatitis B, C or H.I.V. to a patient is very, very remote," said Dr. Elise M. Beltrami, a medical epidemiologist at the disease centers' division of health care quality promotion. "If we look at transmission in the health care setting, the biggest risk is to health care workers themselves."

In addition, she said, hepatitis B vaccinations of health care workers have made that virus less widespread.

But hepatitis C is more easily transmitted than H.I.V., and Dr. Jagger says monitoring is so spotty that it is impossible to know the number of health care worker-to-patient transmissions. In a sharply worded commentary last year in *The American Journal of Infection Control*, she and co-authors said there were "cavernous gaps" in the identification of worker-to-patient infections in the United States, and characterized the review of infected doctors' practices as "a capricious process that is all too vulnerable to local interests and conflicts of interest."

To some extent, the belief that such transmissions are extremely rare reduces the chance they will be identified; in the Long Island case, for example, the surgeon might never have been tested for hepatitis C if not for the chance encounter between two of his patients.

Public health officials are now investigating suspicious hepatitis infections among patients treated by a New York City anesthesiologist. So far they have asked some 4,500 patients to come

in for testing, but have not publicly addressed whether the anesthesiologist has been tested.

Experts on both sides of the debate say adherence to strict infection-control and universal precautions — always wearing gloves when drawing blood, for example — are essential to protect both worker and patient. New technologies, like syringes with retractable needles, have drastically reduced needle-stick injuries in hospitals, though surgeons appear to be slower to adopt tools like blunt suture needles and scalpels with blade shields to prevent injuries.

Dr. Jagger and her colleagues have called for testing physicians for blood-borne pathogens before they start residencies in high-risk specialties, and for telling patients when they have been exposed to a health care worker's blood. Her group has also called for establishing a national reporting system for infection rates.

Health care officials urge patients not to postpone important medical procedures because they are worried about infections, since the risk is so remote. Patients may want to simply ask their surgeons in advance whether they are infected with hepatitis B or C or H.I.V., Dr. Jagger suggested.

But it is all too likely, she said, that the doctor has not been tested and will reply, in all truthfulness, "I don't know."

Most Surgical Residents Fail To Report Needle-Stick Injuries, Increasing Risk Of HIV, Other Bloodborne Diseases, Study Says

<http://www.medicalnewstoday.com>

Almost all surgical residents accidentally stick themselves with needles or other sharp medical instruments but most fail to report the injury, increasing their risk of contracting HIV, hepatitis or other bloodborne diseases from infected patients, according to a study published Thursday in the *New England Journal of Medicine*, the New York Times reports.

For the study, researchers at Georgetown University and Johns Hopkins University questioned 699 physicians who in 2003 were residents at 17 medical centers nationwide. They found that 99% of participants had experienced at least one needle-stick injury by the final year of residency, with an average of eight such injuries per resident. The study found that 51% of residents did not report the injuries to an employee health service, which is required at some hospitals. Of the residents who reported their injuries, 53% were stuck while working with a patient at high risk for common, potentially fatal bloodborne diseases, the *Times* reports (Altman, *New York Times*, 6/28).

The National Institute for Occupational Safety and Health estimates that one in 300 health care workers who are stuck with a needle while working with an HIV-positive person will contract the virus. In addition, NIOSH estimates that two in 100 health care workers who are stuck while treating people with hepatitis C will develop the infection. The researchers noted that although the risk of disease is low, it would be virtually nonexistent if health care workers reported the injuries and sought treatment immediately, the *Baltimore Sun* reports.

According to the *Sun*, surgical residents are prone to needle sticks because they are inexperienced. In addition, residents often work with high-risk patients and conduct procedures in which needle sticks are common. About 800,000 needle sticks occur annually. CDC between 1985 and 1999 documented 55 cases of health care workers contracting HIV, the *Sun* reports (Emery, *Baltimore Sun*, 6/28).

According to the *Times*, being rushed at work was the No. 1 reason residents did not report needle-stick injuries. The study found that residents believed reporting their injuries would take too much time, could jeopardize career opportunities and might cause them to lose face among peers, the *Times* reports. In addition, some residents believed that timely medical treatment would not prevent them from contracting HIV or another illness.

The study's findings are "further evidence" that protection measures recommended by CDC to prevent such injuries and provide treatment should be strengthened, the *Times* reports. Researchers urged surgeons to provide residents with specific instruction on safe techniques and what to do if an injury occurs. Other preventive measures include wearing two sets of surgical gloves; using electric scalpels, clips and glue rather than sharp instruments; improving techniques for passing instruments between health care workers; using postoperative check lists; and increasing the use of nurse practitioners and physician assistants to reduce workloads. In addition, infection control experts are urging physicians to use the same precautions in treating all patients and not only those at high risk of HIV and other infections, according to the *Times*.

Reaction

Martin Makary, a surgeon at Johns Hopkins who led the survey, said that surgeons have made "little progress in the last 20 years" in preventing needle-stick injuries and that hospitals "are not doing what they should" to prevent such injuries (*New York Times*, 6/28). Makary added that attending physicians should insist that injuries be reported to the hospital, adding that if treatment is sought immediately, HIV is "almost 100% preventable" (*Baltimore Sun*, 6/28).

The study is available [online](#).

Drug fights obesity-linked liver disease

<http://www.upi.com>

MONTPELLIER, France, July 3 (UPI) -- A French-led study showed the anti-obesity drug rimonabant not only fights obesity-linked liver disease in obese rats but also improves lipid profiles.

Obesity has been found to be the main cause of several metabolic syndrome features, including hepatic steatosis -- an accumulation of fat in the liver. There are currently no drugs that have both anti-obesity effects and also reverse and prevent obesity-related steatosis, as well as a cluster of conditions such as high blood sugar and high triglycerides that can lead to cardiovascular disease.

The study was led by Mohammed Bensaid of Sanofi-Aventis in Montpellier, France -- the company that manufactures rimonabant. It showed treatment with rimonabant reduced liver

enlargement, eliminated hepatic steatosis and decreased blood levels of enzyme markers that indicate liver damage.

"These data reveal rimonabant possesses a hepato-protective activity and suggest a new therapeutic role of this CB1 receptor antagonist in hepatic diseases," the researchers said.

The study appears in the July issue of the journal *Hepatology*.

July 4th, 2007

Hep C scare for 2000

<http://www.news.com.au>

- *Almost 2000 put at risk of hepatitis C*
- *Clinic had 'inadequate infection controls'*
- *Patients to also be tested for Hep B and HIV*

ALMOST 2000 people who visited a Sydney medical clinic could be at risk of hepatitis C infection because of inadequate controls at the practice, NSW Health Minister Reba Meagher said.

At least three patients probably contracted hepatitis C because of inadequate infection control at Dr Daniel Hameiri's Double Bay clinic, an investigation has found.

Health Minister Reba Meagher said New South Wales Health had now notified almost 2000 patients who attended the clinic and who could be at risk of the blood-borne virus.

They are being advised to be tested for hepatitis C as well as hepatitis B and HIV.

The investigation found the spread of the highly infectious virus, detected in three patients in March, had probably occurred as a result of "inadequate infection control practices" at the clinic.

The disease, for which there is no vaccine, can cause liver damage including cirrhosis and liver failure, over a period of many years.

All three female patients who contracted the disease had visited the clinic for vitamin or mineral injections.

"Although the risk is low we also want to encourage anyone else who has received injections at this clinic to contact their doctor," Ms Meagher said.

Director of Public Health for South Eastern Sydney and Illawarra Health Service, Professor Mark Ferson, said during the investigation 300 patients had already been notified to be tested.

Of those, 160 people had been tested with two further patients having been found to have contracted hepatitis C, however Prof Ferson said this may be a coincidence.

He said the disease could have been spread at the clinic as easily as a drop of infected blood being on a tourniquet, used to make a vein stand out when giving injections.

"That tourniquet might have a drop of blood from someone on it that was infected and then placed over the wound of the next person, that's one of the theoretical possibilities," he said.

Prof Ferson said Dr Hameiri had cooperated fully with the investigation and had closed his clinic for a period of time to upgrade his infection control procedures.

His clinic was also inspected prior to re-opening, with infection control knowledge and practice of clinic staff being found to be up to standard.

Director of communicable diseases for NSW Health, Dr Jeremy McAnulty, said GPs had been written to as part of the investigation reminding them of the high importance of infection control.

Dr McAnulty said Dr Hameiri had now been referred to the Medical Board and Health Care Complaints Commission, with a further determination to be made by those two bodies.

The Epidemic You Don't Know About

<http://www.hyphenmagazine.com>

A press conference in New York City last month addressed an issue that often goes ignored but is already affecting many Asian Americans in the 21st century – Chronic Hepatitis B.

A study released by pharmaceutical giants Idenix and Novartis revealed some alarming figures. A survey of 301 CHB patients (55% of whom were Asian American) indicated that not enough CHB patients or the general population are properly informed about CHB and its causes, although the similarities to the HIV epidemic are obvious.

In the U.S. and estimated 1.25 million people are critically infected with HBV 2 -- Asian Americans make up more than half of this number.

- One in 10 Asian-Americans has CHB, compared with one in 1,000 for the general U.S. population:
- 1 in 10 Chinese Americans
- 1 in 12 Korean Americans
- 1 in 8 Vietnamese Americans

“The transmission of Hepatitis B usually is silent, that’s why we call it a ticking time bomb. Patients don’t usually have any symptoms when they’re very infected until a very late stage when the symptoms surface and the disease appears – in fact they (patients) may have normal results in a laboratory test,” said Dr. Calvin Pan, Director of Clinical Research / Hepatology for Amherst Hospital and Assistant Professor of Clinical Medicine for Mt. Sinai School of Medicine in New York.

Along with Dr. Albert Min, Associate Professor of Clinical Medicine and Director of Hepatitis



Research at Albert Einstein College of Medicine, the two medical professionals shared some vital information on Hepatitis B with a group of mostly Asian media in New York and outlined its impact on the community. Here's just a thought on how it was widely covered on TV across the globe, but I didn't see anything about it in the good old American press. After all this is Hyphen and we're one of a kind.

Like HIV, Hepatitis B can be transmitted in several ways. First is **vertical transmission**; the passage of a disease-causing agent vertically from mother directly to baby during the perinatal period (the period immediately before and after birth). The perinatal period starts between the 20th to 28th week of pregnancy and ends 1 to 4 weeks after birth.

The second is **horizontal transmission**, which would come through contact with contaminated blood through unprotected sex or re-use/ sharing of needles

For vertical transmission, Pan recommended that all children from an infected mother should be screened for Hep B because 90% of the babies infected with Hepatitis B in the newborn or infant stage will become chronic. Pan stated that only about 50% of children infected between ages 1 and 5 will become chronic, so the disease should be caught in newborns.

Pan then identified a major at-risk group in the Asian community: Southeast Asians. He recommended that all immigrants from Southeast Asia should be screened for Hepatitis B because they averaged a 15-20% rate of Hep B infection.

“We need to encourage those immigrants or anyone from Southeast Asia to go for screening,” Pan said.

Asked to outline the common environmental factors that contribute to the Hepatitis B epidemic across regions of Asia, Dr. Pan said:

“One of the major factors in Southeast Asia causing a lot of cultures of Hepatitis B is the social setting. Many years ago in Southeast Asia a lot of countries were not using disposable needles or medical equipment in the hospital or they were in a remote area that was not well disinfected. The other cultural factor was the unconventional medical methods of treating disease / holistic medicine. Some disease can be transmitted by traditional ways to treat people. For example clubbing (the body) can cause some continuous bleeding, brutish as it being, and that's been proposed as a mode to transmit disease. Many of you are aware of the acupuncture part, and in Southeast Asia many countries are still practicing that. If you don't have very clean, disinfected needle that can lead to transmitting Hep B.”

Pan also pointed to environmental factors such as proper pre-natal and post-natal care as variables that can play a role. “The vaccination for the newborn baby and the infected mother is important and precautions may not be taken in those countries,” Pan said.

“They just came out with guidelines recommending vaccination of children under age 18 from high-risk groups that Dr. Pan pointed out,” added Min, recalling new guidelines from the Center for Disease Control and Authorized Committee on Immunization Practice, “In terms of transmitting a virus to newborn children, if they all get vaccinated and the mother has chronic

Hepatitis B, they also get opportunities of passage through prophylactics. New cases in newborn and young children would be 90-95% preventable.”

But why is Hep B more prevalent in some parts of Asia and not others?

“Theoretically, you have to look at the geographic distribution of Hep B, because we know that close contact is a mode of transmission,” Pan explained, “ You have to be aware of where those patients are coming from, whether they’re immigrants or you find any higher prevalence area. In general, Southeast Asia. Then China, especially, [is] the major country, out of Korea, China and Japan. And Taiwan. People from Taiwan have a high chance of contracting of Hep B. It’s not so much of an ethnic factor – I don’t believe that the data shows that Chinese are more easily infected with Hep B than Japanese or Koreans. It’s about the geographic distribution of the disease.”

In the U.S., social issues are the leading factors contributing to the transmission of Hepatitis B among members of the Asian community. “More likely we have to focus on behavioral modifications such as sexual contact, unprotected sex, needle use, men having sex with men, or any factors associated with HIV should be associated with Hepatitis B,” elaborated Pan.

Are those with Hep B aware of how it is transmitted?

The survey data shows that the majority of respondents correctly identify blood transfusion (78%) and sexual contact (68%) as the main sources of transmitting the virus. But, 36% of respondents believed that sharing utensils with an infected person would spread Hep B. And 23% said that living in the same household as an infected person could spread Hep B. Meanwhile, 9% believed that social contact such as a handshake could also lead to transmitting the virus. The parallels to misconceptions about HIV were obvious, and added to that Dr. Pan mentioned some of the same behavioral risks.

Singling-out lifestyles more at risk for contracting Hep B, Pan said, “I think certain communities, a) the Gay and Lesbian community -- probably they should screen everybody, b) those people known to use IV drugs should be screened, c) those people having unprotected sex with multiple partners they should be screened,” he said.

Then, Pan talked about something of a fad in our generation: tattooing. This hit home, for me, because I have several tats myself, though my artist used new needles. “A lot of people with different backgrounds, even in Southeast Asia like to get tattoos. In the United States some tattoo services might have a clean facility, but others are still practicing without disinfecting tattooing equipment. Sharing sharp objects is another factor. For example ladies who share earrings might have some risk for passing disease and infections,” Pan said.

With so little knowledge about Hep B, the message needs to be spread and precautions need to be taken. While the real reason Idenix and Novartis called this press conference was to promote their new drug, the recently FDA-approved TYZEKA (tebivudine 600mg), and compare its effect over two others: lamivudine and adefovir. The Asian American community should be able to find out more about this rarely mentioned affliction.

To learn more you can check out the Hepatitis B Foundation’s website at www.hepb.org/ and also see immunize.org .

Numerous Factors Affect Success Of Interferon Treatment For Hepatitis C

<http://www.sciencedaily.com>

Science Daily — A new study on predicting outcomes of standard treatment for hepatitis C virus (HCV) infection found that a number of factors impacted responses, including the form of the interferon given. However, for some genotypes of the disease, few of these factors play a role.

The results of this study appear in the July 2007 issue of *Hepatology*, the official journal of the American Association for the Study of Liver Diseases (AASLD), published by John Wiley & Sons, Inc.

Over three million people in the U.S. have chronic HCV infection, which accounts for approximately 40 percent of all chronic liver disease and is the most frequent indication for liver transplants. The current standard of care for HCV is the combination of pegylated interferon alfa (PEG-INF) and ribavirin, but this treatment can be difficult to tolerate. Many patients have side effects that include fatigue, flu-like symptoms, depression, fever and anemia. These can be severe enough to cause these patients to discontinue treatment.

Led by Lisa I. Backus, of the Center for Quality Management in Public Health located at the Veterans Affairs Palo Alto Health Care System in Palo Alto, CA, researchers conducted a large retrospective study to analyze predictors of sustained virologic response (SVR), or undetectable virus in the blood six months after finishing treatment. For this study, the researchers used a time frame of three months or later to determine an SVR, because a previous study showed that 98 percent of relapses occur within three months of stopping treatment. The study included 5,944 predominantly male patients receiving care at VA medical facilities.

The researchers were able to identify several independent predictors of achieving SVR after treatment. "In many of the previous trials only a few of these factors were identified," they state. "The expanded range of predictors may assist clinicians and patients in more accurately assessing the likelihood of an SVR and thus in making more informed treatment decisions." The results confirmed previous trials that identified low levels of HCV in the blood, absence of cirrhosis, genotype other than genotype 1, and elevated levels of the liver enzyme ALT as independent predictors of SVR.

They also confirmed significantly lower SVR rates among African-Americans compared with Caucasians and among patients who had not responded to prior non-pegylated interferon. The results provided new information indicating that the PEG-INF form may affect the likelihood of an SVR: Patients treated with PEG-INF 2A (as opposed to 2B) were 40% more likely to have an SVR. The two forms differ in pharmacokinetic properties, side effects, and method of determining dosage. In addition, the study identified low baseline cholesterol as a negative predictor of an SVR. "Low cholesterol may indicate more severe liver disease and subsequent reduced treatment response," the researchers note.

Patients included in the study were 80 percent genotype 1, but few of the significant SVR predictors for this genotype impact the rate for genotype 2 patients and even fewer do so for genotype 3 patients. The results suggest that genotype 2 patients are more likely to respond to



HCV treatment than genotype 3 patients, and that SVR predictors differed between these two genotypes, as well as from those for genotype 1.

"Our findings serve as a reminder that response rates in routine medical practice may be lower than those in clinical trials," the researchers state. This may be due to the fact that a substantial percentage of the study patients would have been excluded from clinical trials for factors that negatively predict an SVR, and the study showed higher treatment discontinuation rates than in clinical trials, possibly because patients in trials are generally extremely motivated and usually agree to continue treatment regardless of their response.

The researchers conclude that "with the demonstrated efficacy of PEG-INF/ribavarin against HCV, it is increasingly important to understand the predictors of response to this treatment. Just as SVR rates differ substantially by genotype, so too do the significant SVR predictors."

The research was supported by the U.S. Department of Veterans Affairs.

Article: "Predictors of Response of U.S. Veterans to Treatment for the Hepatitis C Virus," Lisa I. Backus, Derek B. Boothroyd, Barbara R. Phillips, Larry A. Mole, *Hepatology*; July 2007; (DOI: 10.1002/hep.21662).

Note: This story has been adapted from a news release issued by John Wiley & Sons, Inc..

July 5th, 2007

Why Liver Cancer Is More Prevalent In Males Than In Females

<http://www.sciencedaily.com>

Science Daily — Production of a protein that promotes inflammation appears to be linked to the higher incidence of liver cancer in men than in women, researchers at the University of California, San Diego (UCSD) School of Medicine have determined in mouse studies. Their discovery that female mice produce far less of the protein called interleukin-6 (IL-6) in response to liver injury than males do, and that production of this protein is suppressed by estrogen, may point the way to therapies to reduce the incidence of liver cancer in males. IL-6 contributes to the chronic liver inflammation that leads to cancer.

The research team was led by Michael Karin, Ph.D., professor of pharmacology in UCSD's Laboratory of Gene Regulation and Signal Transduction. The findings will be published in the July 6 issue of the journal *Science*.

"Males show a higher rate of inflammation than females in the same diseases, including cancer," said Willscott Naugler, M.D., clinical instructor in UCSD's Department of Medicine and first author of the paper. "We wondered if increased inflammation was behind the higher incidence of liver cancer in males and, if so, how and why?"

Heptocellular carcinoma (HCC) -- a devastating complication of chronic liver disease and inflammation caused by risk factors such as hepatitis B and C viruses, or alcoholic liver disease - makes up the majority of liver cancers in humans. Overall, men are three to five times more

likely to develop HCC than women; however, in individuals who are under 50, HCC is seen seven to 10 times more frequently in men. A similar or even more pronounced gender disparity is seen in mice.

In order to understand the mechanisms underlying gender disparity in HCC, the UCSD researchers used a chemical carcinogen, DEN, to induce cancer in mice. This resulted in HCC in 100 percent of male mice, but only in 10 to 20 percent of their female littermates.

The researchers discovered that normal female mice given DEN produced far less IL-6 than the males. Comparing the normal mice to knockout mice missing the IL-6 cytokine, the scientists found that when knockout mice were given DEN, both males and females developed liver cancer at the same, lower, rates.

"By eliminating IL-6, we reduced the incidence of liver cancer in the males by close to 90%," Karin said. "However, the missing IL-6 made no further difference in female mice."

The researchers then treated normal male mice with estrogen, and exposed them to DEN. The IL-6 level in those males was reduced to the same level as in female mice, as was the degree of liver injury. Experiments on specialized cells in the liver that produce IL-6 showed that estrogen acts on these cells to suppress IL-6 production.

A similar mechanism may account for the gender bias in liver cancer in humans, according to the researchers. Their discovery could lead to development of therapies to reduce development of liver cancer in males by either decreasing the levels IL-6 in males, interfering with IL-6 action or by administering estrogen-like compounds to males in order to inhibit production of IL-6.

"While some organs, such as breasts, are clearly influenced by gender, others -- like the liver -- are not," said Naugler. "So it's quite interesting that liver inflammation is so markedly suppressed by estrogens. It raises the possibility that organs not usually associated with gender differences may be governed by the same principle. Bladder cancer, for example, occurs more frequently in males than females, and the differences may be a result of higher IL-6 levels and inflammation in male bladders."

Additional contributors to the paper include Toshiharu Sakurai, Sunhwa Kim, KyoungHyun Kim and Ahmed M. Elsharkawy of UCSD's Laboratory of Gene Regulation and Signal Transduction, Department of Pharmacology and Cancer Center; and Shin Maeda, Division of Gastroenterology, Asahi Life Foundation, Toyko. The study was funded in part by the National Institute of Diabetes and Digestive and Kidney Diseases, the Japan Society for the Promotion of Science, the Human Frontier Science Program, the National Institutes of Health and National Cancer Institute. Michael Karin is an American Cancer Society Research Professor.

Note: This story has been adapted from a news release issued by University of California - San Diego.

ViroPharma Initiates Phase 3 Study of CAMVIA(TM) (maribavir) in Liver Transplant Patients

<http://money.cnn.com>

EXTON, Pa., July 5 /PRNewswire-FirstCall/ -- ViroPharma Incorporated today announced that the recently initiated second Phase 3 clinical study of **CAMVIA(TM) (maribavir)** in transplant patients is now open to patient recruitment. This study will evaluate the prophylactic use of CAMVIA in patients undergoing a liver transplant procedure, and will be conducted in up to 60 U.S. transplant centers. The first Phase 3 study of CAMVIA was initiated in September 2006 in patients undergoing a stem cell transplant.

ViroPharma's Phase 3 liver transplant study will compare the efficacy, safety and tolerability of prophylactic use of CAMVIA versus oral ganciclovir when administered for up to 14 weeks for the prevention of cytomegalovirus disease in recipients of orthotopic liver transplants at high risk of developing CMV disease. The study also will evaluate the pharmacokinetics of CAMVIA in this subject population.

"We have made great progress with CAMVIA in the last 12 months; the initiation of this second Phase 3 study is our latest milestone as we work towards our goal of making this important drug available for the more than 120,000 transplant patients throughout the world who are at risk of deadly CMV disease," commented Colin Broom, M.D., ViroPharma's chief scientific officer. "The excellent CAMVIA Phase 2 data presented at the 2006 ASH meeting encourage us as we execute on our comprehensive Phase 3 program in transplant patients."

Phase 3 Liver Transplant Study Design

This Phase 3 study is a randomized, double-blind, multicenter study intended to enroll over 300 subjects who have undergone liver transplantation and are at high-risk of developing CMV disease (i.e., donor CMV seropositive / recipient CMV seronegative). Following transplantation, eligible subjects will be randomized to receive CAMVIA 100mg BID or oral ganciclovir 1,000mg TID in a 1:1 allocation ratio for up to 14 weeks. If CMV disease, defined as symptomatic CMV infection or CMV organ disease, occurs during the study drug administration period, study drug will be discontinued and the subject will be managed according to standard CMV treatment practices at the transplant center.

The primary efficacy endpoint is the incidence of CMV disease (either symptomatic CMV infection or CMV organ disease) within 6 months post transplantation, which is expected to be approximately 12 percent in the oral ganciclovir arm of the study, based on data from published literature. A number of key secondary endpoints have been identified and assessment of these endpoints will play an important part in assessing the clinical benefit of CAMVIA. These secondary endpoints include time to onset of CMV infection and disease; the incidence and time to onset of anti-CMV therapy; and survival without CMV infection or disease; in addition to the incidence of adverse effects that limit the use of current therapies, including suppression of bone marrow function.

CAMVIA's antiviral activity and tolerability were elucidated in a Phase 2 study designed to assess the rate of CMV reactivation in patients undergoing allogeneic stem cell transplantation. The press release announcing the presentation of the data at the 2006 American Society of



Hematology meeting can be found at the following URL: <http://phx.corporate-ir.net/phoenix.zhtml?c=92320&p=irol-researchNewsArticle&ID=941183&highlight=> (to ensure proper link, please copy and paste full address into browser)

About CAMVIA

CAMVIA(TM) (maribavir) is a potent and selective, orally bioavailable Phase 3 antiviral drug with a unique mechanism of action against cytomegalovirus and a favorable early clinical safety profile. It is a potent member of a new class of drugs called benzimidazole ribosides. Unlike currently available anti-CMV agents that inhibit CMV DNA polymerase, CAMVIA inhibits viral DNA assembly and inhibits egress of viral capsids from the nucleus of infected cells. CAMVIA is active in vitro against strains of CMV that are resistant to commonly used anti-CMV drugs.

About Cytomegalovirus

CMV is a member of the herpes virus group, which includes the viruses that cause chicken pox, mononucleosis, herpes labialis (cold sores), and herpes genitalis (genital herpes). Like other herpes viruses, CMV has the ability to remain dormant in the body for long periods of time. Human CMV infection rates average between 50 percent and 85 percent of adults in the U.S. by 40 years of age, but in healthy adults causes little to no apparent illness. However, in immunocompromised individuals including cancer patients, HIV patients, and transplant patients, and in children born with primary CMV infection, CMV can lead to serious disease or death. Patients who are immunosuppressed following hematopoietic stem cell (bone marrow) or solid organ transplantation are at high risk of CMV infection. In these patients, CMV can lead to severe conditions such as pneumonitis or hepatitis, or to complications such as acute or chronic rejection of a transplanted organ. While currently available systemic anti-CMV agents are effective against the virus, their use is limited by toxicities, most notably bone marrow suppression and renal impairment.

About ViroPharma Incorporated

ViroPharma Incorporated is a biopharmaceutical company dedicated to the development and commercialization of products that address serious diseases treated by physician specialists and in hospital settings. ViroPharma commercializes Vancocin(R), approved for oral administration for treatment of antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* and enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains (for prescribing information, please download the package insert at http://www.viropharma.com/docs/Vancocin_pi_2007.htm). ViroPharma currently focuses its drug development activities in viral diseases including cytomegalovirus (CMV) and hepatitis C (HCV). For more information on ViroPharma, visit the company's website at <http://www.viropharma.com> .

Certain statements in this press release may contain forward-looking statements that involve a number of risks and uncertainties, including those relating to our hope that CAMVIA could be a very important drug to market for the 120,000-plus transplant patients throughout the world at risk of deadly CMV disease and the expected incidence of CMV disease within 6 months post-transplant the oral ganciclovir arm of the study. Our actual results could differ materially from those results expressed in, or implied by, these forward-looking statements. The development and commercialization of pharmaceutical products is subject to risks and uncertainties. Further testing such as the planned Phase 3 clinical trials, may not support any or all of the statements in

this press release. The antiviral and tolerability data that were elucidated in our Phase 2 study designed to assess the rate of CMV reactivation in patients undergoing allogeneic stem cell transplantation may not be predictive of the results of our Phase 3 programs in allogeneic stem cell transplantation or liver transplant patients and further testing such as the ongoing Phase 3 clinical studies may not support any or all of the statements in this press release. There can be no assurance that that our Phase 3 programs will yield positive results, that the FDA or other regulatory authorities will not require additional or unanticipated studies or clinical trial outcomes before granting regulatory approval, or that ViroPharma will be successful in gaining regulatory approval of CAMVIA in the US or other jurisdictions. These factors, and other factors, including, but not limited to those described in ViroPharma's quarterly report on Form 10-Q for the quarter ended March 31, 2007 filed with the Securities and Exchange Commission, could cause future results to differ materially from the expectations expressed in this press release. The forward-looking statements contained in this press release may become outdated over time. ViroPharma does not assume any responsibility for updating any forward-looking statements.

Free Vaccinations Offered at Jail

<http://www.wtap.com>

WTAP News

Andrea Wilcox

Email Address: andrea.wilcox@wtap.com

Inmates in the Washington County Jail are lining up for a free vaccination. It's an effort to eliminate the spread of Hepatitis B in the United States and the Ohio Health Department is on board.

This is the first time local health departments have received adult Hepatitis A and B vaccine to administer at no charge. It's free, but clients have to meet certain requirements. This allows at-risk clients protection where they may not normally be able to afford it.

The director of nursing at the Marietta Health Department said, "The Ohio Health Department decided to give us these vaccines so we might reach people who may not have the money."

Hepatitis B is a sexually transmitted disease that attacks the liver.

Kelly says it's a virus that's spreading. That's one reason the vaccine is being administered to at-risk clients.

"It can be people presenting at STD clinics or HIV testing sites. One of the big ones was to be in correctional facilities or for people who were entering correctional facilities."

At the Washington County Jail on Tuesday, nurses from the health department administered 28 vaccinations to inmates.

Captain Dean Ketelsen says its one way to protect not only the inmates, but also his staff.

"There's a lot of health issues in the jail, TB, Hepatitis B, staph infections. It's fortunate they got this opportunity. A lot of people can't afford it."

Normally, the vaccine is \$35 a dose. There are three doses administered over a six-month period.

Eligibility for the Hepatitis B Vaccine:

- Inmates at/or entering correctional facilities
- Persons at drug abuse and prevention settings
- Persons known or suspected to be injection drug users
- Person infected with Hepatitis C Virus
- HIV positive persons
- Persons with multiple sexual partners
- Sexual contacts of sexually transmitted diseases
- Men who have sex with men
- Homeless persons
- Persons presenting at sexually transmitted disease clinics, whether or not they have a sexually transmitted disease
- Person presenting at HIV counseling and testing sites, whether or not they have HIV
- Person in group homes

Hepatitis A Vaccine or Twinrix (A and B) Vaccine Eligibility:

- Persons with chronic Hepatitis B Virus
- Persons with chronic Hepatitis C Virus
- Persons with HIV

For more information you can call your local city or county health department.

The number for the Marietta City Health Department is 740-373-0611, ext. 186.

Hepatitis C scandal: trial of biochemist can go ahead

<http://www.examiner.ie/>

By Vivion Kilfeather and Claire O'Sullivan

A LEADING biochemist in the Blood Transfusion Service Board could become the first person to stand trial on charges relating to the infection of women with hepatitis C from contaminated blood products.

Former BTSB head biochemist Cecily Cunningham yesterday lost a High Court bid to stop her trial, which could lead to a prison sentence of up to 10 years.

The affected women's support group, Positive Action, welcomed yesterday's ruling, saying it was "a good day" for them.

Mr Justice Liam McKechnie, in the High Court, found that there had been an "inordinate and inexcusable" delay by the DPP in bringing about the prosecution, which breached Cunningham's constitutional right to a speedy trial.

He ruled, however, that in the “exceptional circumstances”, there was a “far superior” and “paramount” public right to have the charges prosecuted. Mr Justice McKechnie found the case was exceptional because of its serious and tragic consequences, and its impact on so many people.

Cunningham was charged four years ago relating to the infection of seven named women, between 1977 and 1992.

Under the Offences Against the Person Act, she is accused of administering, or causing to be administered, a “destructive or noxious thing”, thereby causing grievous bodily harm.

No date has been set for her trial. Cunningham has leave yet to appeal Mr Justice McKechnie’s decision.

Cunningham was charged following a two-and-a-half-year Garda investigation, following the findings of the Finlay Tribunal’s 1997 report, and a lengthy consideration of the case by the DPP

The tribunal inquired into how 1,200 women, who received the blood product anti-D from the BTSB during their pregnancies, were infected with hepatitis C.

Last night, Positive Action chairwoman Eleanor O’Mahony said: “Today is a good day for our members, who have travelled a long road. There are people getting sicker and some of us have died, but we continue to fight for justice.”

The only other person charged in connection with the hep C saga was Dr Terry Walsh, formerly assistant national director with the BTSB. He died and the proceedings against him collapsed.

In his lengthy reserved judgment, Mr Justice McKechnie said the infection of hundreds of people with hepatitis C from infected blood products had severely traumatised the lives of multiple families.

He detailed the steps taken to investigate the matter following publication of the Finlay report and complaints by members of the family of the late Brigid McCole and Positive Action.