

# HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Editor-in-Chief*

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## **Bill provides funds to help hepatitis C investigation in LV**

<http://www.lvrj.com>

By Steve Tetreault

Stephens Washington Bureau

*Money also allocated to reduce medical errors*

WASHINGTON -- The spending bill passed by the Senate on Thursday contains \$5 million to assist investigators tracking the hepatitis C outbreak in Las Vegas, Sen. Harry Reid said.

The funding would go to the Southern Nevada Health District for expenses being incurred in responding to the health scare.

In another outbreak-related line item, the Centers for Disease Control and Prevention would be allocated \$21 million in the bill for programs to cut down on medical errors that could lead to infections.

The agency's request included funding for awareness campaigns, with pilot programs to be rolled out in Nevada where eight acute hepatitis C cases have been linked to clinics associated with the Endoscopy Center of Southern Nevada.

Part of the CDC funding also would go toward genetic mapping of unexplained hepatitis cases in Las Vegas, a Reid spokesman said.

The aim is to determine whether the infections might be traced to the clinics where investigators documented unsafe practices like the reuse of syringes and single-use medication vials.

The health district's request also included \$3 million for blood tests on 15,000 uninsured and underinsured patients and \$1.3 million for follow-up testing on persons found positive for HIV or hepatitis strains.

The request also included \$491,000 to organize medical records seized by the Metropolitan Police Department from endoscopy and gastroenterology clinics that have been closed.

Reid, D-Nev., had asked the Senate Appropriations Committee for \$5.25 million for the health district. His office on Thursday could not say immediately how or why the request was cut.

Meanwhile, Sen. John Ensign, R-Nev., said Thursday he continues to work on a separate track to seek assistance for Las Vegas health officials.

Ensign said he is working with officials in Nevada and at the Department of Health and Human Services "to identify how much is really needed and whether we can just reprogram this money" from elsewhere in the department to avoid new spending.

Ensign voted for the Iraq war funding bill that passed Thursday, but against a domestic spending package that may be combined with the bill, saying it contained "wasteful Washington

spending."

"This bill is going to be vetoed so we still have time" to obtain Nevada health funding from within the bureaucracy, Ensign said.

Contact Stephens Washington Bureau Chief Steve Tetreault at [stetreault@stephensmedia.com](mailto:stetreault@stephensmedia.com) or 202-783-1760.

## ***Hepatitis C Resource Centre England Urges The UK Parliament To Aggressively Tackle The Spread Of Hepatitis C In England***

<http://www.medicalnewstoday.com>

With the launch of the Hepatitis C Action Plan for Scotland Phase II, the Scottish Government has promised over £43 million to help tackle the spread of this virus. The plan will help to significantly improve testing, treatment, care and support services for Hepatitis C across Scotland. In addition, in order to increase prevention, national education and awareness initiatives will also be increased.

The British Government risks falling behind Scotland in its provision of Hepatitis C services. The Hepatitis C Resource Centre England encourages the Government to re-think its current approach, and to learn from the experiences of the Scottish process

At present, the Action Plan for England has several barriers to effective implementation;

- It was not financed as a 'whole intervention' hence large scale funding has therefore not been forthcoming to make implementation of the plan effective and immediate
- The Scottish Action Plan has clear lines of accountability, monitoring and communication, something which is sorely lacking in the English version
- The lack of stakeholder and patient consultation around both the implementation and drafting of the English Plan has become even more apparent. During the Scottish consultation, a variety of working groups were established followed by a national stakeholder event which utilized digital voting on actions and recommendations.
- The Scottish document is evidence based. 2 years were spent collating and reviewing all available evidence to determine the most effective interventions and approaches.

The result of this lacklustre plan has been the persistent spread of Hepatitis C coupled with continued lack of real public awareness about treatment, testing and support. It is estimated that 231,000 people in England have Hepatitis C, yet only an estimated 27% of these remain diagnosed.

Despite attempts to collate data by the Health Protection Agency (HPA) and the British Association for the Study of the Liver (BASL), a national picture of how many people who test positive for chronic Hepatitis C virus are referred, take up, and complete treatment in different

areas is not available

The image of people living with Hepatitis C is generally associated with injecting drug use and chaotic lifestyles which misrepresents many people living with the virus. This image and the fear of stigmatisation it evokes, can prevent people from seeking treatment and intervention.

On June 3rd and 4th, England will host the 10th International Conference on Hepatitis C through the charity Mainliners and its Hepatitis C Resource Centre. In light of this, we urge the Government to commit to an inclusive and extensive policy of prevention and treatment, which could ease the suffering of hundreds of thousands of people across the country.

" The Scottish Government is to be congratulated on recognising Hepatitis C as a major public health concern, providing the finance and interventions to tackle this disease. England must do likewise on an even larger scale and we would urge the Dept of Health to revise its 2004 Action Plan in light of the evidence base now available in order to move beyond tentative action if it is to prevent thousands of cases of Hepatitis C-related liver failure and death in coming years," said Dr Nicola Rowan, Director of Blood Borne Viruses for The Resource Centre.

### **Organisation Information**

Hepatitis C Resource Centre England is a project of Mainliners, a national blood borne virus and harm reduction charity. Mainliners continues its vision to reach those most vulnerable across the UK by its progressive and innovative work. We work under the core principles of harm reduction and blood borne virus prevention, as well as treating our clients with respect and dignity through the vital and active participation of service users.

Currently, Mainliners runs several projects which extend these principles both locally and nationally;

1. The Hepatitis C Research Centre - The Centre works to disseminate information, support and advice on all aspects of Hepatitis C. It does this through web-based resources, a telephone helpline, events, training and distribution of leaflets and posters which raise awareness of Hepatitis C. The Centre works in partnership with a variety of agencies to ensure that the vital messages about Hepatitis C are firmly in the public arena. The Centre is funded by the Scottish Government and Dept of Health, England.
2. C Plus - C Plus is a new, confidential information, advice and support service for individuals living with or affected by Hepatitis C. Its services are available for anyone in Edinburgh and the Lothians and are delivered in line with the values and aims of Mainliners. C Plus is funded by NHS Lothian and the City of Edinburgh Council, Drug and Alcohol Action Team.
3. SMART - SMART is the Streatham Mainliners Assessment Referral Team, established in 1999, as a direct-access service for the growing number of people with drug related issues in the South Lambeth area of London.
4. Outreach Service - Mainliners Outreach Team runs a mobile needle exchange in the London Boroughs of Lambeth and Southwark.

<http://mainliners.org.uk>

## ***The hepatitis C wedding***

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

David Hurst

*A couple in Cornwall married at a wedding with a hepatitis C theme. How a killer disease brought two people together*

Seventy guests file out from the wedding of Chrissy Davis and John Semple at Truro's register office, Cornwall. As they gather for photographs it is obvious that many of the guests are not a picture of health: some are gaunt; some have yellow complexions; and about a dozen have some hair missing. This is because 60 of them have hepatitis C. They have poorly functioning livers and are on treatments that can cause hair loss.

Chrissy and John got to know each other through an internet chat site for people with the condition. The wedding guests are also "heppers", members of the site. The best man, Clive Kirby, had a liver transplant seven weeks ago.

"As hep C brought John and I together, we thought what better day to get married than Hepatitis C World Awareness Day [last Monday]," says Chrissy, a 50-year-old mother of three. "On our wedding gift list we just asked everyone to tell at least one person about hep C; for us, that's the best wedding present ever." After the photographs, Chrissy and John, a 54-year-old antiques dealer, board a vintage bus with their family and friends and travel to the centre of Truro, where they hand out 1,000 hepatitis C awareness leaflets. "This is our honeymoon," says Chrissy.

Hepatitis C, the condition contracted by the Body Shop founder Dame Anita Roddick, is a blood-borne virus that can cause significant damage to the liver, lymphatic system, immune system and brain. Half a million people carry the virus in the UK, yet only 50,000 have had their condition diagnosed because the symptoms of the disease, often dubbed the silent killer, can take up to 30 years to appear.

The virus can be caught through unscreened blood transfusions, medical treatment with unsterilised equipment, sexual contact, using infected needles, and any other means by which the blood of one person comes into contact with another.

"There's still a stigma attached to hep C, yet there shouldn't be," says Chrissy, who caught it in 1980 after she was given a blood transfusion following the birth of her third child, her daughter Tatum. She was living in Düsseldorf at the time and blood donations in most of Western Europe before the early 1990s were unchecked for the virus. She lived with the virus unknowingly for 20 years until she felt as though she was hungover for four days, so she went to see her GP.

"I'd been abroad to Cyprus a few weeks previously," says Chrissy. "So my GP ran hepatitis blood tests. A week later she told me that I had hepatitis C. I didn't know what it was. When she explained, I was shocked."

Chrissy learnt that although there are drugs that can cure the condition, they often have unpleasant side-effects, with four out of five experiencing fatigue, rashes, depression, hair loss and sight problems. Her GP gave her the details of a consultant to call, so that she could start her treatment. "But as I felt better the next day I kept putting off calling the number," says Chrissy.

“That was a massive mistake. I ended up with six years' worth of extra liver damage.”

There was a 50 per cent chance of success

In 2006 Chrissy had back pain caused by running. She went to hospital and ticked the hepatitis C box in a routine health questionnaire. Within an hour she was whisked off for a liver biopsy that showed that her organ was damaged by three on a scale of six. She started treatment a few weeks later, but was warned that she had only a 50 per cent chance of clearing her hepatitis C as she had what doctors call “geno 1b”, a mutation that was hard to clear.

“I was scared by now,” says Chrissy, “because I had contacted others on hep C chat-sites who were going through treatment and having appalling side-effects. I was convinced that life was going to come to a stop.” But she was fortunate in that she suffered only slight hair loss. After three months of treatment she found herself having regular online chats with another hepper called John, who lived about 35 miles away. “John had just been diagnosed and was about to start treatment,” says Chrissy. “He’s not sure how he got his virus although he has snorted cocaine with people; it can spread this way as users don’t notice traces of blood on the rolled banknotes they share. In effect, they can be snorting up the virus. He asked if we could meet as he wanted to see someone on treatment; some chat-up line I thought! We met for coffee, I talked him into coming to a hep C support group and everything progressed from there.”

John started his treatment in September 2006, but it failed. He is starting a 72-week treatment session next month. Chrissy has just learnt that she is cured of the virus. However, to prevent John reinfecting her, if he spills any blood, from shaving for instance, they bleach the area. “Other than that we’re a normal couple. It was just that hep C that brought us together; that’s our silver lining with this virus.”

Heppers chat-site: [www.hepcforum.co.uk](http://www.hepcforum.co.uk)

### **What is it?**

Hepatitis C was discovered in the 1980s, a new blood-borne virus affecting the liver that was not hepatitis A or B. A blood-screening test was developed in 1991. The virus damages the liver, causing cirrhosis, liver cancer or liver failure.

### **How is it spread?**

It can be passed on through sharing needles, toothbrushes, towels, razors and sometimes through sex, if blood is involved. Many doctors recommend condoms.

### **What are the symptoms?**

Fatigue, liver pain, digestive problems, concentration difficulties and flu-like feelings.

### **What's the cure?**

A combination of two drugs, interferon and ribavirin, taken for six or 12 months, clears the virus in half of those treated, and can slow the progression of liver damage.

### **Contact**

The Hepatitis C Trust, London SE1. Helpline: 0845 2234424; [www.hepctrust.org.uk](http://www.hepctrust.org.uk)

## ***New Hope for Liver Diseases***

<http://www.washingtonpost.com>

By Kathleen Doheny

HealthDay Reporter

FRIDAY, May 23 (HealthDay News) -- Human liver cells have been generated from embryonic stem cells using a new model, hopefully opening the door to help scientists screen for harmful side effects of new drugs before they are used in patients.

That was one of several reports on advances against liver diseases that were presented this week at Digestive Disease Week 2008 in San Diego.

Other presentations involved ways to predict which patients with hepatitis C might benefit from long-term antibiotic therapy and information about how monitoring the body's viral load in hepatitis B patients may help predict liver cancer.

Scientists from the University of Edinburgh, Scotland, reported they had efficiently generated human liver cells from embryonic stem cells without the problems that have plagued scientists in the past. The new model is unique, said Dr. David Hay, a senior fellow at the university's MRC Centre for Regenerative Medicine, who spoke at a press conference Tuesday.

His team developed a model that allows them to focus on key enzymes which are crucial in drug metabolism. Other clinical applications, he said, include the fact that the liver cells generated in vitro could be used in bioartificial devices, helping maintain normal function when the liver fails.

Down the road, said another investigator, Dr. Philip Newsome, the hope is that the cells could be used in liver transplantation.

The advance was praised by the press conference moderator, Dr. John M. Vierling, chief of hepatology at Baylor College of Medicine, in Houston.

The team produced "highly differentiated cells that maintain function," Vierling said, a feat that has thus far proved elusive to others working on the effort. "It is an extraordinarily rich advance to be exploited in many ways," he added.

Predicting which patients with chronic hepatitis C infection, another liver ailment, will respond to treatment may be done by monitoring the dendritic cells, the cells that are the most potent stimulator of the immune system's T-cells, said Dr. John Mengshol, a fellow in the department of gastroenterology and hepatology at the University of Colorado Health Sciences Center, in Denver.

Treatment for hepatitis C virus routinely involves 48 weeks of combination antiviral therapy. Side effects include flu-like symptoms, and treatment is successful in only half of patients.

So, predicting who will and won't respond would be helpful. Mengshol and his colleagues evaluated 64 patients with hepatitis C virus of the genotype 1, the most common strain and the most difficult to treat.

Researchers have found that therapy affects the dendritic cells differently. Mengshol's team studied blood samples from each patient before treatment and at 24 weeks after starting it. They looked at the population of two different types of dendritic cells, among other factors.

Levels of one type of dendrite cells normalized in those who responded to the treatment, while levels of those who did not respond did not.

Why some patients respond to therapy and others don't has been an ongoing mystery, Mengshol said. Monitoring the dendritic cells may help doctors determine who might respond to therapy.

In another study, Dr. Uchenna Iloeje, director of virology for Global Clinical Research at Bristol-Myers Squibb Co., reported that monitoring the viral load of hepatitis B virus in patients with that disease is a significant predictor of who will be likely to get liver cancer.

In the study, researchers followed more than 3,500 patients for 11.5 years, Iloeje said.

"Over time, those at highest risk of liver disease had a sustained hepatitis B load," he said.

The liver is the largest organ inside the body. It changes food into energy, cleans alcohol and poisons from the blood, and makes bile, a liquid that aids digestion.

### **More information**

For more on liver diseases, go to [Medline Plus](#).

SOURCES: John M. Vierling, M.D., professor, medicine and surgery, chief, hepatology, Baylor College of Medicine, Houston; John Mengshol, M.D., Ph.D., fellow, University of Colorado School of Medicine, Denver; Uchenna Iloeje, M.P.H, M.B.B.S., director, virology, Global Clinical Research, Bristol-Myers Squibb; May 20, 2008, presentations, Digestive Disease Week 2008, San Diego

### ***Overcoming virus early beats hepatitis***

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

Adam Cresswell, Health editor

DRIVING down the number of circulating copies of the hepatitis C virus to undetectable levels in the earliest stages of infection makes it highly likely that the patient will eventually be cured - even among patients who are also infected with HIV.

The findings, the interim results from an Australian study presented to a recent international conference in Italy, suggest that rapid virological response - or RVR, the term used to indicate successful suppression of viral load within four weeks of starting treatment - is just as good a predictor of eventual cure among patients suffering acute hepatitis C infection as it is already known to be among chronically infected individuals.

In addition, the trial - which is still continuing - suggests new treatment options for difficult-to-treat groups such as people with HIV and injecting drug users. Unlike most hepatitis C treatment

studies, this research included significant numbers of HIV patients and injecting drug users, and the findings showed RVR was just as good at predicting eventual cure in these as in other patients.

The Australian Trial in Acute Hepatitis C, known by its acronym ATAHC, was funded by the US National Institutes of Health. The interim findings were presented as a poster at the recent annual scientific meeting of the European Association for the Study of the Liver in Milan, where it was voted into the top 10 per cent of the more than 800 poster presentations at the meeting.

An estimated 264,000 Australians have been exposed to hepatitis C, a blood-borne virus that attacks the liver and left untreated can lead to liver inflammation, cirrhosis and eventually cancer.

Although 25 per cent of people clear the virus naturally, the prognosis for the remaining 75 per cent is more difficult as most will usually experience symptoms such as debilitating fatigue, pain and nausea.

While cure is possible with drug therapy, the drugs are quite toxic and hard to tolerate. Treatment also lasts a year and only works in fewer than 50 per cent of cases. Co-infection with HIV makes it even harder to eradicate hepatitis C.

Sydney-based hepatitis expert Greg Dore, a co-author of the study and who attended the Milan conference, said the message from the ATAHC findings was that if doctors could drive viral levels down to undetectable levels early "you can get incredibly good response rates".

While 107 patients in the study elected to have treatment for acute hepatitis C, 84 patients continued to the point where they had data on their progress after four weeks of treatment. Among the 26 patients infected with HIV as well as hepatitis C, RVR, or complete viral suppression, was observed in 10 people (45 per cent), and in 28 out of the 58 patients infected with hepatitis C alone (48 per cent).

Those with high hepatitis C viral loads at the start of treatment, with more than 400,000 international units per millilitre of blood, were less likely to achieve RVR.

Finally, 53 patients were assessed for both RVR and for sustained virological response, or SVR, a longer-term measure that is often taken to mean the patient has been cured. All the participants who achieved RVR went on to achieve SVR, and even 59 per cent of those who did not achieve RVR went on to be cured later.

The study's authors concluded that patients treated for acute hepatitis C infection and who achieved RVR "are highly likely to achieve SVR, irrespective of HIV status".

"This is the largest study ever of an injecting drug-user population with early infection," said professor Dore, who is head of the viral hepatitis clinical research program at the Sydney-based National Centre in HIV Epidemiology and Clinical Research.

"We have shown that it is feasible to treat this group, many of whom have been recent injecting drug users, and get remarkably good outcomes.

"What we are looking at now is to apply to the NIH for another five years' funding, to look at the different strategies to optimise treatment outcomes in this group."

Dore's colleague doctor Gail Matthews said the high proportion of HIV-positive cases in the study participants, about one-third, "probably reflects a current increase in acute HCV in this population - predominantly acquired through sexual transmission and mirroring what is being reported from many centres in Europe".

"This has potential implications for public health messages in this group," she said.

Adam Cresswell's trip to the EASL conference in Milan was organised as part of the prize for winning the Professor Geoff Farrell Medal, a journalism award organised by Hepatitis Australia for writing about hepatitis C. Funding for the award was provided by the drug company Schering-Plough.

**May 24<sup>th</sup>, 2008**

### ***Celebrity Health - David Marks***

<http://news.bbc.co.uk>

David Marks began playing music with his neighbours, the Wilson brothers, in 1958 when he was 10 years old and helped create the now famous California surf sound of the Beach Boys. He left the band - for the second time - in 1999 after being diagnosed with hepatitis C.

He finally beat the virus in 2004, but still remains the spokesman for a number of awareness campaigns.

#### **HOW DID YOU FIRST REALISE SOMETHING WAS WRONG?**

I didn't actually know I had anything wrong with me because I didn't have any obvious symptoms.

This is why hepatitis C is such an insidious disease.

People don't always have any symptoms until their livers are severely damaged.

I don't know exactly how I got hepatitis C.

I have been exposed to multiple risk factors, including indiscriminate experimentation with drugs in the early 1970s.

I really want to break the stereotype, though. Drug use is not the only way of getting hepatitis C. In most cases people can't pinpoint how they got it.

I know soccer mums who have hepatitis C, and can't remember ever being exposed to any risk factors.

#### **HOW DID YOU GET DIAGNOSED?**

I was diagnosed by accident, actually.

I went to the hospital because I had a pain in my side that turned out to be a cracked rib, but before the doctor figured out where the pain was coming from, he drew some blood that revealed my liver enzymes were elevated.

They did a test for hepatitis C that came back positive.

I tell people a broken rib saved my life, otherwise I might not have found out I had hepatitis C until it was too late.

#### WHAT WAS YOUR REACTION TO THE DIAGNOSIS?

My initial reaction was that I didn't even know what hepatitis C was, so I wasn't scared until my wife looked it up on the internet and read that I could die from this virus.

At that point, I immediately began to take it seriously, quit drinking alcohol and went on a strict regime of diet and herbs that would reduce inflammation in my liver and increase my immune system and energy.

#### WHAT WAS YOUR TREATMENT?

My treatment consisted of two antiviral drugs called Pegalayed Interferon and Riboviron.

I took six pills a day and injected the interferon once a week for a year.

I was virus-free after six months, but I continued for an additional six months just to make sure every last virus was killed.

#### HOW DID YOU FEEL DURING TREATMENT?

The treatment was not easy, but the side effects are manageable. I was still able to tour and record and I also travelled all over raising awareness for hepatitis C while on treatment.

Improvements in treatment keep happening.

For example, time released interferon means that you can now have an injection once a week, instead of once a day, which makes it easier.

With my own treatment, I didn't experience any excruciating discomfort. I was able to function in my daily life.

Side effects often include fatigue, nausea and sometimes flu-like symptoms. It's different for everyone though.

#### HOW DO YOU FEEL NOW?

Before I was diagnosed with hepatitis C my general health was OK.

I suppose I could have been taking better care of myself. I was drinking quite a lot of alcohol, not getting much sleep and sometimes forgetting to eat.

When I found out I had hepatitis C I started eating right, I quit smoking cigarettes and drinking alcohol completely.

I think that hepatitis C for me was almost a blessing in disguise.

I've cleared the virus and now lead a healthy lifestyle. It's become a habit for me.

I am healthier than I've been in 30 years. I feel really lucky that I was able to benefit from treatment and am now living a virus-free life. I'm a perfect example of how you can beat the virus, but you have to know you have it first.

If you think you might be affected, consult your doctor and get tested - it could save your life.

**WHAT IS YOUR MESSAGE TO OTHER PEOPLE WITH THE SAME CONDITION?**

My message to other people with hepatitis C is to take it seriously.

Just because you don't feel sick doesn't mean you can ignore that you might have this virus eating away at your liver, and that you could be putting other people at risk. Anyone may have put themselves at risk and not realise it.

For those who have risk factors, I suggest getting tested...a simple blood test saved my life and it could save yours as well!

**May 26<sup>th</sup>, 2008**

### ***More people contracting infectious liver disease***

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

Derek Spalding, *Daily News*

An increased number of people are finding out they have Hepatitis C and they're turning to the Beaufort Communicable Disease Clinic for support and treatment.

Hep C support nurse Fran Falconer had treated 700 people since 2001 and has a treatment case load of about 30 to 50 patients on constant rotation.

She has dedicated her life to offering support to patients and spreading the word about the disease that has infected 170 million people around the world with 250,000 of those in Canada. Of those infected, only about 11% receive treatment, she said this week.

The statistics get even more severe in B.C. where 85 people for every 100,000 people are diagnosed with Hep C, twice the rate of the rest of the country. Hepatitis C is a blood-borne disease that primarily targets the liver, causing inflammation, which can lead to fibrosis -- scarring. Too much scar tissue can then lead to cirrhosis of the liver making people susceptible to liver cancer.

Not everyone will have Hep C symptoms, but people can carry the disease for decades before it attacks their system.

"People are becoming more and more aware of the disease so they're getting tested," Falconer said from her office.

"Hepatitis has taken liver disease from the large academic centres and brought it down to the community level because so many people are infected. We need to deal with this as a community."

In recent years, medical professionals have started to cure people of the disease through the use of harsh treatment involving weekly injections of pegylated interferon and twice daily injections of ribavirin. The regimen lasts for months depending on the strain of Hep C, but some patients tested six months later had no traces of the disease.

"At that point, we're starting to use the word 'cure,'" Falconer said.

More common risk factors for getting infected with Hepatitis C are intravenous drug use, blood transfusions, snorting cocaine, tattoos and body piercings, but lesser known means for spreading the disease are sharing of razors, toothbrushes, scissors and nail clippers, or any other equipment which could be contaminated with blood. Hepatitis C cannot be spread by hugging, kissing or shaking hands or by means of food or water.

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250-729-4231

## **8 million Pakistanis have hepatitis C**

<http://thepost.com.pk>

ISLAMABAD: The number of Hepatitis C patients has increased alarmingly during last five-years in Pakistan as liver dis-functioning has become the leading cause of deaths in Rawalpindi during this period.

According to data available here from various sources, the unstoppable deadly Hepatitis C virus has become a major cause of mortality in Pakistan, in the absence of any effective measure by the Ministry of Health and other authorities.

The experts of liver diseases believe that the re-use of syringes and contaminated surgical instruments in dental clinics and hospitals are two major reasons for the spread of Hepatitis B and C, media report said.

The estimates of Pakistan Society of Hepatology (PSH) suggest that there are 8 million patients of Hepatitis C in the country with a concentration of disease in some parts of central Punjab including Gujrawnwala and Mandi Bahauddin. As many as 6,000 patients of Hepatitis C and B are annually given medical advice at only one hospital of Rawalpindi.

"Every month around 500 Hepatitis B or C patients visit Gastroenterology and Liver (GIL) Clinic of Holy Family Hospital that works only for one day a week. This means 6,000 annual patients," said General Secretary of PSH Dr Umar, who is also in charge of GIL.

A study of Ravian Research Forum conducted at Rawalpindi hospitals, Holy Family Hospital, District Headquarters Hospital (DHQ) and Rawalpindi General Hospital (RGH) has shown that Hepatitis and other liver diseases are the most common causes of death in Rawalpindi along with cardiac diseases.

The study was conducted by doctors serving at these hospitals by collecting data in their respective wards. The researchers analysed the data of deaths during a period of five years after 1998, which showed 20 per cent to 25 per cent deaths with liver-related diseases. A random sample of 2,000 deaths was analysed, according to the president of Rawalian Research Foundation. The same data suggests 20 per cent deaths occurred due to cardio-vascular diseases during this period.

According to another research, around 8,500 patients visited the emergency department of Holy Family Hospital during the year 2000, out of which 20 per cent patients were suffering from liver diseases, while 27 per cent were had cardio-vascular diseases.

In Islamabad, the situation is not different, as a senior doctor of Pakistan Institute of Medical Sciences (PIMS), Dr Tashfeen Adam, is examining around 300 Hepatitis B and C patients per month alone. His other colleague, Dr Javed But and Dr Muzaffar Gul, two other senior hepatologists are also examining a large number of patients annually.

The experts have warned that Hepatitis C is the most dangerous liver disease as no vaccine is available to cure the disease and whatever treatment that is available is very costly.

The virus of Hepatitis C was discovered in 1989 while the Hepatitis B virus in 1965.

"Around Rs 60,000 to Rs 70,000 are required for a six month medical treatment of Hepatitis C" said Dr Tashfeen Adam. He said the cases of Hepatitis C have increased during the last 10 years due to better diagnoses and disease identification facilities. He predicted that Hepatitis C will increase further and the portion of population affected with the virus will rise to 20 per cent to 25 per cent. He said strict measures, legislation and awareness are required to check the spread of disease.

**May 27<sup>th</sup>, 2008**

## ***Hepatitis B and C Awareness Across Washington***

<http://www.kndo.com>

The State Health Department says people need to get checked for Hepatitis B and C.

[Hepatitis B and C Awareness Video](#)

They say in Washington more than 120,000 people have the virus, but only about half of the cases have been reported. Right now the health department is already working on how to prevent

more cases.

Starting in June, they'll offer free Hepatitis C testing across the state, and also free vaccines for Hepatitis A and B.

Doctors say one in 12 people in the world are living with Hepatitis. For this reason the World Hepatitis Alliance, has come up with a campaign called Am I number 12?. The Washington Health Department is also working with this campaign.

We've attached a [link to their web site](#) on the On-Air-Links Section of our web site.

## ***Boehringer unveils Laval research investment***

<http://www.canada.com>

*The Gazette*

*\$36-million centre will specialize in infectious diseases like Hepatitis C and HIV*

Boehringer Ingelheim, one of the world's 20 largest pharmaceutical research and development companies, yesterday unveiled a \$36-million research centre in Laval that will specialize in infectious diseases such as Hepatitis C and HIV.

The Laval facility will be one of four principal research centres around the world for Boehringer Ingelheim, a German-based company that has roots dating back more than century.

Jobs will be created for another 40 scientists, who will join the existing team of 150 researchers.

"We are drawing on talent here in Quebec and Canada to discover and develop medicines that will help in the fight against the growing problem of infectious virological diseases around the world," said Dr. Andreas Barner, head of corporate board division pharma research.

Ian Mills, president and chief executive of Boehringer Ingelheim (Canada), said the investment confirmed the company's "strong and sustained dedication to carrying out innovative research that supports products of high therapeutic value."

"For this to continue, we need federal legislative and regulatory action which ensures protection of intellectual property and encourages innovation," he said.

Mills made the comment at a ceremony attended by federal, provincial and municipal politicians.

Boehringer Ingelheim, which has been present in Canada since 1972, spent almost \$100 million on research and development in Canada last year, about half of it in Laval. Of its 39,800 employees in 47 countries, Canada accounts for more than 700.

Christian Boehringer, chairman of the company's shareholders' committee, said the Laval facility already has contributed to scientific discovery in the area of virology.

"This site is expected to make an even greater contribution to the translation of scientific

discoveries into drugs which help patients," he said.

"And that is what Boehringer Ingelheim stands for, research into health areas of unmet need."

**May 28<sup>th</sup>, 2008**

## **Former Medical Technician Gets Gallbladder Surgery in Mexico; WorldMed Assist Saves Him 70%**

<http://news.yahoo.com>

*WorldMed Assist, a medical tourism company, found an affordable solution when Washington coast resident Allen Miller learned he needed his gallbladder removed. Because Miller had Hepatitis C, he'd been uninsurable for the past six years. WorldMed Assist hooked him up with Dr. Jorge Zavala Ruiz at Hospital Angeles in Mexico, which saved Miller 70% of what he'd have likely spent in the US.*

Seaview, WA (PRWEB) May 28, 2008 -- WorldMed Assist, a medical tourism company, found an affordable solution when Washington coast resident Allen Miller learned he needed his gallbladder removed.

When Allen Miller heard that gallbladder surgery was the solution to the abdominal pain he'd endured for two months, his resentment at being classified as uninsurable took on new life. Six years earlier, he'd quit a job with employer-provided health insurance, and discovered when trying to get his own private-pay plan, no one would cover him because he had Hepatitis C. When he learned his surgery, a cholecystectomy, would run at least \$20,000, he hit the Internet to learn how to become a medical tourist.

"I had friends who'd gone abroad for dental work, so I thought, 'Why not see something of the world while having this surgery!' I could afford to have the surgery in the U.S., but I knew I could get it done elsewhere for a lot less. I got on the computer, and right away found WorldMed Assist. I contacted them, and two weeks later, I was on a plane with my wife, headed for gallbladder surgery at Hospital Angeles in Tijuana, Mexico." Miller had looked at options for the surgery in Belgium, Turkey and India, but because he and his wife run a Bed and Breakfast, they needed the shortest trip possible.

Both Miller and his wife recently retired from dual careers as medical technicians, so when WorldMed Assist set them up on a conference call with his surgeon, Dr. Jorge Zavala Ruiz, they knew what questions to ask. "That call was very helpful," he said. "We got all the answers we needed and felt this was the right decision. The total cost for all my medical bill plus travel and hotel for my wife and me was around \$6,000--a savings of 70%. The price included a liver biopsy to get the latest information on my Hepatitis C situation.

"Not only was the cost of my surgery significantly lower, WorldMed Assist got us great rates on travel and lodging. When my wife researched plane tickets, the best deal she could find was \$1000 for two. WorldMed Assist got us both tickets for \$400," said Miller.

On May 5, the Millers flew to San Diego. A driver from Hospital Angeles picked them up at the airport and drove them across the border. "He spoke English well, and told us all about his

family," said Miller.

Miller was impressed with the hospital. Built just two years ago, everything was state of the art, and scrubbed and polished. He liked that every patient had a private luxury room.

The morning after his arrival, he was wheeled away for his gallbladder surgery and discharged two days later. "We were driven back across the border to check into a San Diego resort for three relaxing days before heading home," he said.

Just two weeks after surgery, he reported in to WorldMed Assist, "I'm off to our cabin by Ranier National Park to go hiking. Boy, do I feel good about the experience." His wife is now looking to have WorldMed Assist arrange cosmetic surgery in Mexico, again at Hospital Angeles. "Medical tourism is a good option for anyone who can't get insurance," Miller said. "Thanks to WorldMed Assist, I rolled the dice and got a seven."

### **About WorldMed Assist**

Experts in medical tourism, WorldMed Assist's mission is to improve lives by helping patients receive high quality medical treatment abroad at affordable prices. WorldMed Assist (<http://www.worldmedassist.com>) coordinates and simplifies every aspect of medical care and travel. Waiting times are virtually eliminated, track records are proven, and facilities are state-of-the-art.

###

WorldMed Assist  
Robbie Neely  
510 530-4286  
<http://www.worldmedassist.com>

### ***Santaris Pharma Begins Human Clinical Testing of the World's First Medicine Targeted at a Human microRNA***

<http://www.businesswire.com>

*SPC3649 (LNA-antimiR-122) being developed as a potential new therapy for Hepatitis C virus (HCV) infection*

*Ground-breaking Phase I volunteer study made possible through the success of Locked Nucleic Acid (LNA) chemistry*

COPENHAGEN, Denmark--(BUSINESS WIRE)--Santaris Pharma, the Danish biopharmaceutical company, announced today that it has commenced a Phase I human volunteer trial of the world's first microRNA medicine to be tested in man - SPC3649 (LNA-antimiRTM-122). The study is being conducted by PhaseOneTrials A/S, Copenhagen, and will include a maximum of 48 healthy male volunteers. The Company also announced that the first cohort of healthy volunteers in the study have completed treatment satisfactorily. SPC3649 is being developed by Santaris Pharma as a potential new approach to the treatment for Hepatitis C infection. Phase II studies in hepatitis patients will follow.

SPC3649 specifically targets microRNA-122, a small, liver-expressed, regulatory ribonucleic acid (RNA) that has recently been shown to facilitate human Hepatitis C virus replication in liver cells. Keith McCullagh, President & CEO, Santaris Pharma, said:

“The mechanism of action of this drug represents a potential breakthrough in medical science. The ability to switch off the functions of particular microRNAs may enable clinicians to modulate entire networks of genes associated with disease or ill-health. Santaris Pharma scientists recently published the results of successful microRNA silencing with SPC3649 in non-human primates.<sup>1</sup> We are excited now to be able to evaluate the drug’s efficacy and safety in human subjects. If successful, such trials may lead to the development of a new approach to the treatment of Hepatitis C and more generally, contribute to the development of a major new class of therapeutic agents.”

The Phase I “First-In-Man” clinical trial is a placebo-controlled, double-blind, randomised, single dose, dose-escalating safety study of SPC3649 in a total of 48 healthy male volunteers. The volunteers are divided into six groups with eight persons in each. In each group six persons will receive SPC3649 and two will receive placebo (non-effective substance). Each volunteer will receive a single two hour intravenously infusion with either SPC3649 or placebo. SPC3649 will be administered at six escalating dose levels and each volunteer will be followed for three months.

### **About Santaris Pharma**

Santaris Pharma is a Danish clinical stage biopharmaceutical company. The Company was formed in 2003 and has the exclusive rights to LNA technology, a 3rd generation antisense chemistry used to develop new classes of RNA medicines, called RNA antagonists. Santaris Pharma’s messengerRNA antagonists and microRNA antagonists are being developed to silence mRNAs and microRNAs associated with various diseases, including cancer, metabolic disorders and viral infections. Santaris Pharma completed a Euro 40m second round of equity financing in May 2006 and a Euro 20m third round of equity financing in December 2007. Santaris Pharma has a global alliance with Enzon Pharmaceuticals of New Jersey to develop and co-commercialise a series of Santaris Pharma RNA antagonists for the treatment of cancer and a worldwide strategic alliance with GlaxoSmithKline for the discovery, development and commercialization of novel medicines against viral diseases.

### **About Santaris Pharma’s Locked Nucleic Acid technology**

LNA is the first true conformational analogue of RNA (ribonucleic acid). The ribose sugar in LNA is ‘locked’ in the three-dimensional shape of RNA by virtue of its rigid bicyclic structure. The result is that when incorporated into oligonucleotides, LNA conveys dramatically enhanced binding affinity to complementary RNA sequences. Drug molecules with multiple LNA substitutions therefore have truly unprecedented potencies. The greater potency of LNA in binding complementary RNA sequences means that LNA oligonucleotide drugs can be made significantly shorter than previous antisense or siRNA drugs. These shorter RNA antagonist drugs are taken up efficiently by cells and tissues, thereby overcoming many of the delivery problems of RNAi to date. As LNA drugs are resistant to degradation when given systemically, have long tissue half lives, and are taken up readily by many tissues they have greater potency than other oligonucleotide chemistries.

### **About microRNAs**

MicroRNAs are a newly discovered class of small regulatory molecules which control many biological processes in cells. In addition, microRNAs are implicated in many diseases, such as cancer, viral infections, cardiovascular disease and neurological disorders and, therefore, represent a new class of targets for therapeutic intervention. Santaris Pharma's unique LNA technology enables development of short, synthetic RNA-binding molecules that can effectively antagonize disease-causing microRNAs and, thus may yield patient benefits unobtainable by other therapeutic approaches.

**About SPC3649:**

SPC3649 is the first of the new class of microRNA antagonists based on Santaris Pharma's proprietary LNA technology. SPC3649 targets the liver specific microRNA122. SPC3649 works by blocking microRNA-122 in liver cells leading to a rapid loss of Hepatitis C virus replication. Another effect of the drug is to enhance the metabolism of cholesterol and fats.

**About Hepatitis C (HCV):**

There is a huge need to develop effective therapeutics for the treatment of HCV. 170 million people world-wide are chronically infected with the disease. 75-80% of newly infected patients develop chronically HCV infection which leads to severe morbidity and mortality caused by cirrhosis, cancer and liver failure. Six different types (genotypes) of HCV have so far been identified. The standard therapy, which is a combination therapy (pegylated interferon and ribavirin) is often poorly tolerated by the patients. This treatment is furthermore only efficient in 50 % of the cases against the most frequent HCV genotype (1).

**About PhaseOneTrials**

PhaseOneTrials A/S is a Danish Contract Research Organization (CRO) that conducts highly specialized clinical phase I trials and early phase II trials of new drug candidates. PhaseOneTrials has extensive experience planning and conducting "First-in-Man" trials for both classical pharmaceutical and new biological drugs having worked with recombinant peptide hormones, enzymes and growth factors. The location at a university hospital, proximity to their intensive care unit and collaboration with distinguished specialists all mean that the Company easily meet the increasing government safety requirements for such trials.

1 See reference: Elmen, J, Lindow, M. et al., (2008) "LNA-mediated microRNA silencing in non-human primates." Nature, VOL 452, April 17, pages 896-899, 2008

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**May 29<sup>th</sup>, 2008**

***Diabetes doubles liver cancer risk for patients with advanced hepatitis C***

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

Patients who have chronic hepatitis C with advanced fibrosis have twice the risk of developing liver cancer if they also have diabetes. These findings are published in the June issue of *Hepatology*, a journal published by John Wiley & Sons on behalf of the American Association for the Study of Liver Diseases (AASLD).

Recent studies have suggested that diabetes increases one's risk for hepatocellular carcinoma (HCC), also known as liver cancer, possibly because diabetes often occurs as part of the metabolic syndrome, which increases the risk of non-alcoholic steatohepatitis (NASH), which can lead to liver cancer. Chronic hepatitis C also increases the risk of liver cancer, so patients who have both diabetes and hepatitis C have two pathways through which HCC might develop.

Researchers led by Bart Veldt and Harry Janssen of the Erasmus MC University Medical Center in the Netherlands, aimed to quantify the liver cancer risk of patients who have both diabetes mellitus and advanced hepatitis C. They used data from five large hepatology units in Europe and Canada and included 541 consecutive patients between 1990 and 2003 who had chronic hepatitis C and advanced liver fibrosis or cirrhosis as shown by liver biopsy. For each patient, they gathered demographic, clinical, biochemical and virological data, along with fibrosis assessment and details of hepatitis C treatment.

Eighty-five of the 541 patients included in the study had diabetes. Patients with more severe fibrosis were more likely to be diabetic. "The prevalence of diabetes mellitus was 10.5 percent for patients with Ishak fibrosis score 4, 12.5 percent for Ishak-score 5 and 19.1 percent for Ishak-score 6," the authors report.

During the median follow-up time of four years, 11 patients (13 percent) with diabetes vs. 27 patients (5.9 percent) without diabetes developed hepatocellular carcinoma. The 5-year occurrence was 11.4 percent and 5.0 percent, respectively. Male gender and older age were significantly associated with elevated HCC risk. "In addition, there was a strong trend towards a higher incidence of HCC among patients with diabetes mellitus," the authors report. Multivariate Cox regression analysis of patients with Ishak 6 cirrhosis showed that diabetes was independently associated with the development of HCC.

Interestingly, among patients with diabetes, there was a trend towards higher risk of HCC as fasting glucose levels increased. The authors hypothesize that resulting hyperinsulinemia might help explain the increased risk of HCC among diabetic patients.

Whatever the mechanism, the risk is clear. "For patients with chronic hepatitis C and advanced cirrhosis, diabetes mellitus increases the risk of developing HCC," the authors conclude.

*Source: Wiley*

## ***InterMune Announces Start of 14-Day Triple Combination Study of ITMN-191 in Patients With Chronic Hepatitis C***

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

*- Fifth cohort of MAD study supports continued development in treatment-experienced patients -*

BRISBANE, Calif., May 29 /PRNewswire-FirstCall/ -- InterMune, Inc. (Nasdaq: ITMN - News) today announced that it has begun dosing in its Phase 1b clinical trial evaluating **ITMN-191, designated R7227 at Roche** (SWX: ROG - News), in combination with Pegasys® (pegylated interferon alpha-2a) and Copegus® (ribavirin) in treatment-naïve patients infected with chronic hepatitis C virus (HCV) genotype 1 infection.

InterMune also reported that results from the only cohort of treatment-experienced patients in its Phase 1b multiple-ascending-dose (MAD) clinical trial of ITMN-191 given as monotherapy support continued development of the compound in treatment-experienced patients. InterMune expects to submit results from all dose cohorts in the MAD study for possible presentation at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD).

Dan Welch, Chairman and Chief Executive Officer of InterMune, said, "After having recently announced excellent safety and very competitive reductions in serum HCV RNA levels following monotherapy of ITMN-191 in treatment-naïve chronic hepatitis C patients, we are pleased to announce the start of our very important 14-day triple combination study of ITMN-191 plus Pegasys and ribavirin, also in treatment-naïve patients." He continued, "We are also pleased to report that ITMN-191 given as monotherapy to treatment-experienced patients demonstrated a safety profile and viral kinetic performance that support the continued development of ITMN-191 in this patient population. Based on the monotherapy results to date, we and our partner Roche are planning the development of ITMN-191 in combination with various antiviral compounds, including other small molecule direct antivirals, in both treatment-naïve and treatment-experienced patients."

### **Phase 1b Triple Combination Trial Design**

The Phase 1b placebo-controlled, triple combination study is anticipated to enroll up to approximately 50 treatment-naïve patients chronically infected with HCV genotype 1. The study will assess the effects of multiple doses and regimens of ITMN-191 given in combination with pegylated interferon alpha-2a (Pegasys®) and ribavirin on safety, efficacy, pharmacokinetics and viral kinetics compared to the effects in patients treated only with pegylated interferon alpha-2a and ribavirin.

All patients will receive standard treatment with pegylated interferon alfa-2a and ribavirin. In addition to this standard treatment, patients will be randomized to receive either ITMN-191 or placebo, administered with a meal for a period of 14 days, and a single dose on Study Day 15.

Up to five cohorts of patients will be enrolled, exploring total daily doses starting at 300mg. Both twice daily and three-times-daily regimens will be studied to collect data on the safety, pharmacokinetic and viral kinetic effects of ITMN-191 when given with Pegasys and ribavirin.

InterMune expects to announce top-line results from the triple combination study during the fourth quarter of this year.

### **Publication Plans for ITMN-191**

InterMune intends to submit several abstracts regarding ITMN-191 for possible presentation at the 59th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), scheduled for October 31 - November 4, 2008 in San Francisco. Among the abstracts submitted will be the clinical experience with ITMN-191 to date including, but not limited to, the results of

the single-ascending-dose (SAD) study, the multiple-ascending-dose (MAD) monotherapy study of ITMN-191 as well as in-vitro results of ITMN-191 in combination with various direct antiviral compounds.

### **About InterMune**

InterMune is a biotechnology company focused on the research, development and commercialization of innovative therapies in pulmonology and hepatology. InterMune has a pipeline portfolio addressing idiopathic pulmonary fibrosis (IPF) and hepatitis C virus (HCV) infections. The pulmonology portfolio includes the Phase 3 program, CAPACITY, which is evaluating pirfenidone as a possible therapeutic candidate for the treatment of patients with IPF and a research program focused on small molecules for pulmonary disease. The hepatology portfolio includes the HCV protease inhibitor compound ITMN-191 (referred to as R7227 at Roche) in Phase 1b, a second-generation HCV protease inhibitor research program, and a research program evaluating a new target in hepatology. For additional information about InterMune and its R&D pipeline, please visit <http://www.intermune.com>.

*Source: InterMune, Inc.*

**May 30<sup>th</sup>, 2008**

### **EMA Provides Guidance on Chronic Hepatitis C Trials**

<http://fdanews.com/>

Sponsors of initial clinical trials of treatments for chronic hepatitis C (CHC) are advised to enroll subjects who have not received standard-of-care treatment, have hepatitis C virus (HCV) genotype 1 infections and are not infected with advanced fibrosis or HIV, according to a draft guideline from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use.

### **After Las Vegas Hepatitis Scare, ECRI Institute Provides Guidance About Device Reuse**

<http://www.dotmed.com>

by Barbara Kram, Editor

PLYMOUTH MEETING, PA--ECRI Institute, an independent, nonprofit organization that researches the best approaches to improving patient care, has created a new online resource devoted to medical device reuse issues. The free site, [www.ecri.org/device\\_reuse/Pages/infection.aspx](http://www.ecri.org/device_reuse/Pages/infection.aspx), provides access to a select number of guidance articles from ECRI Institute's research library. The site includes recommended practices, as well as policy and procedure development tools on patient communication and device reuse issues.

"The recent situation in Las Vegas, where nearly 40,000 people were potentially exposed to hepatitis B and C viruses and HIV has renewed public concerns about patient infection from inappropriate reuse of medical devices," says Mark Bruley, Vice President for Accident and Forensic Investigation at ECRI Institute. "We've brought together a number of our resources on one site to help physicians understand the current issues and risks of reuse and to assist them in

the proper management of medical device reuse."

In the news recently was a hepatitis scare among some former patients of the Endoscopy Center of Southern Nevada who tested positive for Hepatitis C. According to Edward M. Bernstein & Associates, a personal injury law firm, blood borne diseases may possibly threaten thousands of people who received treatment in Las Vegas since March 2004. These may include approximately 40,000 patients who received injections of anesthesia at the clinic. The law firm has been retained by former patients who received routine check-ups and colonoscopies. Apparently, the clinic was reusing syringes, according to Ed Bernstein, Managing Partner, who is looking into the allegations.

The ECRI Institute is addressing public concerns via the website, which also features new guidance on recommended practices for multiuse vials from ECRI Institute's recently published Physician Office Fundamentals in Risk Management and Patient Safety, a 250-page guide with information and tools for complex safety and risk issues in physician offices.

ECRI Institute has published hundreds of guidance articles, evidence reviews, medical product alert reports, and practical toolkits around the reuse of medical devices. Its range of expertise also includes participation in the U.S. Food and Drug Administration's round table discussion about their proposed regulations on reuse.

For more information about ECRI Institute's resources on device reuse and patient communications, please e-mail [communications\(at\)ecri.org](mailto:communications(at)ecri.org), call +1 (610) 825-6000, or mail to ECRI Institute, 5200 Butler Pike, Plymouth Meeting, PA 19462.

### **About ECRI Institute**

ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research to healthcare to uncover the best approaches to improving patient care. As pioneers in this science for 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. ECRI Institute is designated a Collaborating Center of the World Health Organization and an Evidence-based Practice Center by the U.S. Agency for Healthcare Research and Quality. For more information, please visit [www.ecri.org](http://www.ecri.org).

### ***Four Japanese gang figures got liver transplants at UCLA***

<http://www.latimes.com>

UCLA Medical Center and its most accomplished liver surgeon provided a life-saving transplant to one of Japan's most powerful gang bosses, law enforcement sources told *The Times*.

In addition, the surgeon performed liver transplants at UCLA on three other men who are now barred from entering the United States because of their criminal records or suspected affiliation with Japanese organized crime groups, said a knowledgeable law enforcement official who spoke on condition of anonymity.

The four surgeries were done between 2000 and 2004 at a time of pronounced organ scarcity. In each of those years, more than 100 patients died awaiting liver transplants in the Greater Los Angeles region.

The surgeon in each case was Dr. Ronald W. Busuttil, executive chairman of UCLA's surgery department, according to another person familiar with the matter who also spoke on condition of anonymity. Busuttil is a world-renowned liver surgeon who co-edited a leading text on liver transplantation and is one of the highest-paid employees in the University of California system.

There is no evidence that UCLA or Busuttil knew at the time of the transplants that any of the patients had ties to Japanese gangs, commonly called yakuza. Both said in statements that they do not make moral judgments about patients and treat them based on their medical need.

U.S. transplant rules do not prohibit hospitals from performing transplants on either foreign patients or those with criminal histories.

The most prominent transplant recipient, Tadamasu Goto, had been barred from entering the U.S. because of his criminal history, several current and former law enforcement officials said. Goto leads a gang called the Goto-gumi, which experts describe as vindictive and at times brutal.

The FBI helped Goto obtain a visa to enter the United States in 2001 in exchange for leads on potentially illegal activity in this country by Japanese criminal gangs, said Jim Stern, retired chief of the FBI's Asian criminal enterprise unit in Washington.

Goto got his liver, Stern said, but provided the bureau with little useful information on Japanese gangs.

"I don't think Goto gave the bureau anything of significance," Stern said. Goto "came to the States and got a liver and was laughing back to where he came from. . . . It defies logic."

Although Stern was not involved with the deal, he said he learned the details when he became unit chief in 2004 and continues to be troubled by what happened.

After the transplant, Goto was again barred from reentering the U.S., said the first law enforcement official, who was not authorized to discuss the matter publicly and therefore requested anonymity.

But Goto continued to receive medical care from Busuttil in Japan. The doctor traveled there and examined Goto on more than one occasion, said Goto's Tokyo-based lawyer, Yoshiyuki Maki -- and evaluated Goto while he was in custody in 2006.

Busuttil's medical opinion was cited in a successful court petition to have Goto released for medical care at a Tokyo hospital, Maki said.

*The Times* is not naming the other three transplant recipients in this article because neither they nor their lawyers could be reached.

Several transplant experts and bioethicists contacted by *The Times* said they were troubled by the transplants, especially because organs are in such short supply in this country. In the year of Goto's surgery, 186 people in the Los Angeles region died waiting for a liver, U.S. transplant statistics show.

Some, but not all, of the experts said a transplant center has an obligation to determine whether a patient would be a worthy custodian of an organ and to protect potential donors' faith in the system.

"If you want to destroy public support for organ donation on the part of Americans, you'd be hard pressed to think of a practice that would be better suited," said Arthur Caplan, a bioethicist at the University of Pennsylvania.

In a statement, the UCLA Health System said it could not comment on specific cases because of federal patient privacy laws. Generally, it said it complies with all the rules and regulations of the United Network for Organ Sharing, the federal contractor charged with ensuring the safety and fairness of the U.S. transplant system. Last year, UCLA performed more liver transplants than any other U.S. hospital.

"UCLA's processes for evaluating a patient -- both for mental and physical suitability for organ transplants -- are the same regardless of whether the individual is a U.S. citizen or a foreign national," the statement said.

Hospitals and doctors in the U.S. have the final say on which patients get added to their waiting lists and have the discretion to refuse patients with unhealthy lifestyles that could compromise the transplant's success. Patients may be refused on other grounds as well, including an inability to pay.

At the time of Goto's 2001 transplant, liver allocations were made based on both a patient's medical status and waiting time. Since 2002, livers have been allocated to patients based almost entirely on how sick they are.

It is unclear when Goto joined UCLA's waiting list. He had been in the United States two months when he received a new liver. Overall, 34% of the patients added to UCLA's liver waiting list between January 1999 and December 2001 received a new liver within three years of being listed, national transplant statistics show.

Busuttil, a former president of the American Society of Transplant Surgeons who has testified before Congress on who should receive priority for transplants, released his own statement this week. He did not directly address the transplants of the Japanese patients but said in part:

"As a surgeon, it is not my role to pass moral judgment on the patients who seek my care. . . . If one of my patients, domestic or international, were in a situation that could be life-threatening, of course I would do everything in my power to assure that they would receive proper care.

"I consider that to be part of my responsibility and obligation as a physician."

### **'A serious player'**

On May 18, 2001, Tadamasu Goto boarded Japan Airlines Flight 0062 at Narita International Airport, bound for Los Angeles with his son Masato.

Goto, now 65, had hepatitis C and was worried it would develop into cancer, Maki, Goto's lawyer, said in an interview last week in his Tokyo office. Because Japan has an extreme

shortage of organ donors, many sick patients feel they need to go abroad to seek treatment.

The FBI did not help Goto arrange his surgery with UCLA but did help him gain entry to this country, Stern said. The agency had long been frustrated by the reluctance of Japanese law enforcement to share information on yakuza members in the United States.

"For American law enforcement, it's been like pulling teeth to get criminal intelligence from Japanese authorities," said David Kaplan, a journalist who co-wrote the book "Yakuza: Japan's Criminal Underworld," published in 2003 by the University of California Press.

In his book, Kaplan describes Goto's gang, the Goto-gumi, as an offshoot of the largest Japanese organized crime group, the Yamaguchi-gumi. In an interview, Kaplan said Goto is "a serious player in the yakuza. His gang is known for being particularly ruthless and violent."

A senior member of the group and an affiliated gang member were sentenced to prison for the 1992 slashing of a Japanese director whose film portrayed the yakuza as violent thugs, according to a story in the Japan Times. Goto was not personally implicated in the case.

Goto underwent a successful transplant in July 2001. He received the liver of a young man who died in a traffic accident, Maki said. "Goto is over 60 now, but his liver is young," he said.

Several years after the transplant, in May 2006, Goto was arrested in Japan on suspicion of real estate fraud.

Maki said he and other lawyers worried that their client was not well enough to be interrogated. In addition to his liver problem, Goto was suffering from heart disease, high blood pressure and diabetes.

The lawyers asked that Goto be released immediately, but authorities rejected the request, Maki said. He said the lawyers asked that Goto be given his medication at precise times, but that did not happen either. "Goto lost his appetite, had a terrible headache, scratched his arm until it started to get infected, and he was throwing up," Maki said.

Maki used the interview to vent against Japanese prosecutors, saying he believes they were attempting to exploit his client's poor health to obtain a conviction on what Maki considered groundless charges.

He said Busuttil, along with doctors from Tokyo University Hospital and Showa University Hospital in Tokyo, examined Goto and recommended that he be released for outside medical treatment.

On May 24, 2006, some 16 days after he was arrested, the court temporarily released Goto and he entered the hospital.

Goto was acquitted of the charges in March of this year.

"The UCLA doctor [Busuttil] examined Goto during his detention and again one week after he received his not-guilty ruling," Maki said.

The law enforcement official who spoke on condition of anonymity said Goto's criminal history includes prison time. But Maki said that his client's last conviction was three decades ago, for assault, and that his previous convictions were as a youth.

Court records in Japan are kept by prosecutors who generally do not share them with anyone not party to a case.

Jake Adelstein, a former reporter at Japan's largest daily newspaper, Yomiuri Shimbun, said he received a tip about the circumstances surrounding Goto's liver transplant in 2005. Within days of making inquiries, however, Adelstein was visited by men who told him: "Erase the story or be erased," he said in an interview.

Adelstein did not pursue the story but mentioned the incident in a recent opinion piece in the Washington Post. He said he would elaborate on it in a forthcoming book.

### **Dealing with scandals**

Word of the surgeries at UCLA comes as the U.S. transplant system is slowly recovering from scandals that forced the closure of three transplant programs in California. In one of those, St. Vincent Medical Center in Los Angeles moved a Saudi national up a liver waiting list, bypassing dozens of others, and then covered it up by falsifying paperwork, officials there have acknowledged.

Overseers of the U.S. transplant system say they are unaware of other cases in which hospitals have provided organs to foreign criminals. But some hospitals, including Stanford University Medical Center, have performed transplants on U.S. prisoners -- often controversial because taxpayers foot the bill.

According to the ethics committee of the United Network for Organ Sharing, "one's status as a prisoner should not preclude them from consideration for a transplant."

The network encourages transplant programs to give foreign recipients less than 5% of organs from deceased donors each year, but that is not a hard-and-fast rule. At one point, in the 1980s, the threshold was 10%, but it was lowered after Congress considered banning transplants for foreign nationals entirely.

Centers that exceed the 5% guideline are asked for an explanation in writing, but none has been sanctioned publicly. In 2001, the year Goto received his transplant, UCLA slightly exceeded the guideline.

Typically, transplant experts say, foreigners cannot receive transplants at U.S. centers unless they are willing to pay the full cost of the procedure out of pocket -- without the substantial discounts given to insurers. Charges for a liver transplant and immediate follow-up care generally exceed \$523,000, according to an April report by Milliman Inc., an actuarial firm.

It could not be determined how much UCLA and Busuttil were paid for the Japanese transplants.

Tom Mone, chief executive of OneLegacy, the group responsible for procuring and distributing organs in much of Southern California, said transplants for foreign criminals are "an unfortunate

result of a system that's magnanimous to the world."

Mone also said hospitals do not have the resources to investigate their patients. "The enforcement should be at the borders, not at the hospital," he said.

In recent years, nonresident foreign nationals have accounted for less than 1% of all transplant recipients nationwide, transplant statistics show.

Dr. Mark Fox, associate director of the Oklahoma Bioethics Center, said the UCLA transplants may create pressure to eliminate transplants for foreign nationals entirely, which Fox said he does not support.

"For some people, there are misgivings for transplanting foreign nationals at all. For some people, there are misgivings about transplanting criminals at all," he said. "When you put those two together, it is certainly reasonable to expect that a certain portion of the population would say, 'This is not what I expected when I signed my donor card.' "

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