

# 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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Dec 20, 2008

### ***Study Shows Dramatic Drop In Needlestick Risks For Healthcare Workers***

<http://www.emaxhealth.com>

When working with needles, healthcare workers always have to be concerned about contracting a life-altering or even life-threatening infection from HIV, hepatitis B or hepatitis C. But after 20 years of intense regulatory and legislative activity and innovative changes to the design and handling of needles, U.S. healthcare workers are now significantly safer from needlestick injuries, according to a new study from the University of Virginia International Healthcare Worker Safety Center.

"Since the U.S. Needlestick Safety and Prevention Act was passed in 2000, American healthcare

workers have benefited from an unprecedented level of protection from occupationally transmitted diseases," says Janine Jagger, M.P.H., Ph.D., director of the Center and co-author of the study published in the December 8 issue of the Journal of Infection and Public Health.

"This is a very significant advance and a remarkable public health success story," says Elayne Phillips, M.P.H., Ph.D., assistant professor in the UVA School of Medicine and director of research for the International Healthcare Worker Safety Center, who co-authored the study with Jagger.

Researchers analyzed 12 years of needlestick injury data (1993-2004) from a large network of U.S. hospitals and found a 34 percent decline in needlestick injury rates for U.S. healthcare workers overall and a 51 percent decline for nurses, who handle needles most frequently in healthcare settings. And while the needlestick law wasn't passed until 2000, Jagger and colleagues spent many years preceding its passage lobbying for stronger regulations.

For the last 20 years, Jagger has been a leading advocate not only for legislation but also for the development of safety-engineered medical devices to protect health workers. Such safety devices incorporate shielding, retracting or blunting features that protect workers from contaminated sharp devices.

In this study, researchers found that significant reductions in U.S. sharps injury rates were observed only after safety devices became the predominant technology. Furthermore, the passage of the law requiring the use of these safety devices was critical to their widespread adoption.

Exposure to patients' blood and body fluids through needlesticks and other sharp medical devices is the most potentially life-threatening risk healthcare workers face in the course of their work. Even the anxiety that follows such occupational injuries - as workers wait for HIV or hepatitis test results - can have an adverse impact on their professional and personal lives.

The study also found that the largest reductions in injury rates were for two devices with the highest risk of transmitting infections. These two high-risk devices, phlebotomy needles and I.V. catheter needles, showed reductions of 59 percent and 53 percent respectively.

The Centers for Disease Control and Prevention estimates that U.S. healthcare workers sustain an estimated 384,000 needlestick injuries each year. According to figures from the World Health Organization, nearly three million healthcare workers worldwide are exposed to bloodborne diseases in the course of their work every year, resulting in as many as 15,000 hepatitis C infections, 70,000 hepatitis B infections and 500 HIV infections annually. More than 90 percent of these occupational infections occur in developing countries - precisely where health workers are scarcest.

Jagger and Phillips strongly advocate that other countries adopt needlestick safety regulations. "Healthcare workers in the poorest countries, whose lives are at greatest risk, should be afforded the same level of protection as those in the U.S.," says Jagger

The UVA International Healthcare Worker Safety Center seeks to reduce life-threatening occupational infections from bloodborne diseases by working towards a global standard for healthcare worker protection. The Center has been a national and international advocate for

nearly two decades for safer medical devices, equipment and practices that protect healthcare workers from infectious diseases.

*By: University of Virginia Health System - Sat, 12/20/2008 - 16:42*

**Dec 21, 2008**

## ***Needle exchange program providing benefits***

<http://www.currentargus.com>

By Stella Davis

*Current-Argus Staff Writer*

CARLSBAD — Public health officials in Carlsbad believe a syringe (needle) program at the Eddy County Public Health Office is just a small tool, but a good tool in reducing the number of cases of Hepatitis C in drug addicts and the spreading of AIDS.

Anthony Landreth, a nurse and Eddy County Health Office manger representing the offices in Carlsbad and Artesia, said his office exchanges on average about 11,000 syringes a month.

Participants in the needle exchange program must sign up with the New Mexico Department of Health and are ensured confidentiality. They are given a card with a unique identification number that is good for one year. The card must be presented every time needles are exchanged.

Landreth said participants also complete a registration survey and must participate in an education session when they bring in their syringes for exchange.

Landreth presented his data as a panel member in cooperation with the Eddy County Community Heath Council. Participating agencies presented recently countywide data on programs and services provided to the public in Eddy County.

Chris Minnick, New Mexico Department of Health regional public information officer, said the state implemented the program 1998. Since then, statewide, NMDH has exchanged 9 million syringes with a 97 percent return rate.

"The syringes are exchanged on a one-for-one basis with education and risk reduction services provided at each encounter," Landreth explained to the commission.

Minnick said that in order to get a new needle, participants must bring in a used one.

"Participants will not only bring in their own needles, but they will also go to places where they know there are used needles and bring those in for exchange," he added. "Since the needle exchange program began in 1998, newly diagnosed cases of AIDS have declined by approximately one-third each year, according to the data from the NMDH's Infectious Disease Bureau."

Landreth noted that the syringe exchange program in Eddy County was the first in New Mexico and it has been extremely successful.

He said the program has also helped reduce the number of discarded syringes found in parks and other areas where drug users shoot up and discard their needles, county leaders.

"The city's Public Works Department has said that they are seeing a significant reduction in the number of needles from what they were seeing in public places," Landreth said. "They said they very rarely find them now. They were also having a problem with people flushing the syringes down the toilet instead of putting them in a safe receptacle for disposal. By having people bring their used syringes to us, we know they are being disposed of properly and safely."

He said surprisingly, more methamphetamine users than opiate (heroin) users come in to exchange their needles.

Luis Camero, city public works director, said he was stunned after hearing the monthly syringe exchange numbers.

"Wow, that's a lot," he said. "But it appears to be helping. Two years ago, used syringes discarded in public places were a big problem for us. It (the problem) hasn't come up lately. It had come to the point that we provided all our sanitation drivers with rubber gloves and receptacles to put the syringes in so we could dispose of them properly."

On hearing Landreth's report, Commission Chairman Guy Lutman said the number of needles exchanged is "mind boggling."

Commissioner Janell Whitlock was also stunned on hearing the numbers and said, "Give me some good news. Are the syringes provided only to drug users?"

"The program is open to Type 1 diabetics. We do dispose of a lot of syringes for them. But we have less than 20 diabetics that come in for syringe exchanges."

Minnick said the program serves a dual purpose in the community. The first is to get possible infected needles out of the community, and the second it to develop trust with the participants so when they are ready to start fighting their addiction, they have a person to turn to whom they trust.

"Needle exchange is a unique safety line for the people in the program because everything is out in the open. When they are ready to get clean, they know they can turn to the Health Department for help," Minnick said.

To help stop the spread of infections diseases, the Department of Health offers screening for Hepatitis B and C, and for HIV. It also provides free immunizations for Hepatitis A and B. For more information about the department's harm reduction services, call (575) 528-5000 or visit the Department of Health online at [www.healthynm.org](http://www.healthynm.org).

**Dec 22, 2008**

### ***Study may predict if hepatitis C drugs will work***

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

By Julie Steenhuisen

CHICAGO (Reuters) - Doctors hope to be able to better predict which patients will respond to traditional treatment for the hepatitis C virus using a new method for identifying slight variances in the virus' genetic makeup.

U.S. researchers said on Monday that the technique may prove useful for other viruses such as HIV as well. The finding could be used to develop a test that would analyze a patient's specific virus strain before treatment was started.

A team at Saint Louis University in Missouri analyzed genetic patterns of the virus in patients infected with Hepatitis C to see if they could tell why many patients fail to respond to standard treatment with pegylated-interferon and ribavirin.

The year-long therapy activates the body's natural defenses against viruses, but patients often feel as though they have a bad case of influenza. Only about half of the people who suffer through the treatment actually respond.

"This is a very difficult therapy to take. It's really hard on the patient," said John Tavis, a professor of molecular and microbiology at Saint Louis University, whose study appears in the *Journal of Clinical Investigation*.

"If you can identify those patients who aren't going to respond anyways because they've got a strain that is highly resistant to the drug, then you just don't treat those patients and you save them \$20,000 to \$30,000 in medical bills just from drugs alone -- not to mention the side effects," Tavis said in a telephone interview.

He and colleagues studied the ribonucleic acid or RNA chains of the hepatitis C virus, looking for patterns that would explain why some people responded to the treatment while others did not.

Using a math formula, they zeroed in on a specific pattern of changes called "covariance networks" that differed depending on whether the drug worked. And these patterns proved to be a strong indicator of whether the virus was especially resistant to therapy.

"What we found will allow a doctor to predict whether or not a medication will work in a patient," Tavis said in a statement.

The finding also may have implications for other types of RNA viruses, such as human immunodeficiency virus or HIV or the influenza virus.

"It's a pretty easy process. The algorithm can be applied fairly quickly," he said. Whether or not it turns up a pattern that will be useful is less clear, he said.

Hepatitis C is a blood-borne liver disease that can lead to chronic liver disease, liver cancer, cirrhosis and death. The virus affects an estimated 3.2 million people in the United States alone and some 170 million worldwide.

Pegylated interferon brands include Roche Holding AG's Pegasys and Schering-Plough Corp's

Pegintron.

(Editing by Cynthia Osterman)

## ***State fines providers, says more to come***

<http://www.lasvegassun.com>

By Marshall Allen

*Health Division official hopes hefty penalties will ensure rules are followed*

Saying that the hepatitis outbreak at the beginning of the year taught them a painful lesson, officials are hitting Nevada health care providers with much larger fines for breaking rules intended to protect the public.

Fines in November and this month set records — and health officials say more hefty fines are coming.

They've come a long way since March, when the state fined a Las Vegas clinic a mere \$3,000 for causing a hepatitis C outbreak and endangering 50,000 patients with unsafe injection practices.

As a result of that scandal, state Health Division inspectors visited every outpatient surgery center in the state — the same type of facility as the colonoscopy center that caused the outbreak — and found several places that were also engaging in unsafe injection practices.

Richard Whitley, administrator of the Health Division, said the offenses by other surgery centers — even after the publicity caused by the hepatitis C outbreak — made it clear that imposing small fines and educating the facilities on proper safety standards were not changing behavior.

The hope is that bigger fines will get health providers' attention and spur compliance, Whitley said.

Another change: The Health Division sends out news releases to publicize the fines, an effort to address the public criticism of the inspection process that came after the hepatitis C outbreak. The public needs to understand that the health division takes enforcement seriously so people can have faith in the health care system, officials said.

So the division tried to spread the word that on Nov. 21, it fined Park Place, an assisted living facility in Reno, \$121,600 for poor record keeping and failing to give residents medications.

The fine was the largest ever levied by the state Health Division — until Dec. 10, when the state fined Desert Springs Hospital & Medical Center \$228,000 and required it to provide a year of donated services to select patients. Inspectors had cited Desert Springs' mammography program with 228 violations. They found the hospital had no records to assure that equipment used for mammograms had been maintained properly. Hospital officials told inspectors they performed the quality assurance tests, but those tests were not documented over a period when 92 patients had mammograms, said Ed Sweeten, radiation physicist for the Health Division.

The violations did not do any harm to patients, and the hospital had the patients come back and redid the tests, Sweeten said.

Assemblywoman Sheila Leslie, D-Reno, chairwoman of the interim legislative committee on health care, said she is glad to see what she calls a “turnaround” in Health Division regulation.

She credited many of the changes to Whitley, who took charge of the division in January.

The larger fines “give me more confidence in the Health Division, and prove that government can work and should work to protect its citizens,” Leslie said.

At a time when the state’s health budget is being chopped because of declining revenue, the fines can also help support the programs.

Whitley said the Desert Springs fine will go into the state’s general fund, and the fines against the Reno facility will go into the budget of the Health Division, where they’ll be used to improve the quality of care at the facility.

**Dec 23, 2008**

### ***Paladin Labs Inc. Acquired ViRexx Medical Corp.***

<http://www.foxbusiness.com>

SEND ComtexBuzz up!Digg It StumbleUpon Reddit MONTREAL, QUEBEC, Dec 23, 2008 (MARKET WIRE via COMTEX) ----Paladin Labs Inc. (TSX: PLB: undefined, undefined, undefined%), a leading Canadian specialty pharmaceutical company, announced today that it has acquired all the outstanding shares ViRexx Medical Corp. (TSX: VIR: 63.19, 2.08, 3.4%)(AMEX: REX: 63.19, 2.08, 3.4%).

ViRexx is a Canadian-based development-stage biotech company focused on developing innovative-targeted therapeutic products. ViRexx has three proprietary technology platforms - Chimigen(TM: 63.19, 2.08, 3.4%) Vaccine Platform, T-ACT(TM: 63.19, 2.08, 3.4%) Platform and the AIT(TM: 63.19, 2.08, 3.4%) Platform.

The Chimigen(TM: 63.19, 2.08, 3.4%) Platform is a versatile platform technology being used primarily to generate therapeutic vaccines for the treatment of Hepatitis B and Hepatitis C. Chimigen(TM: 63.19, 2.08, 3.4%) vaccines are designed to stimulate broad immune responses towards specifically targeted viral and foreign antigens. An early Chimigen(TM: 63.19, 2.08, 3.4%) Hepatitis B vaccine candidate completed a successful Phase I trial. Our goal will be to continue to develop the next generation Chimigen(TM: 63.19, 2.08, 3.4%) Hepatitis B vaccine towards completion of a Phase I trial in 2010.

The T-ACT(TM: 63.19, 2.08, 3.4%) Platform technology is deigned to interrupt blood supply to tumours, leading to tumour starvation and death. The lead product candidate of this platform is Occlusin(TM: 63.19, 2.08, 3.4%) 50 Injection, a treatment for primary cancer of the liver. This product has completed a Phase I trial in treating hepatocellular carcinoma as part of a transcatheter arterial chemoembolization. The second product candidate of the T-ACT(TM:

63.19, 2.08, 3.4%) Platform is Occulsin(TM: 63.19, 2.08, 3.4%) 500 AED, an embolic agent designed to treat hypervascular tumours including uterine fibroids. Our goal will be to seek partners for the future development of the T-ACT(TM: 35.51, -0.61, -1.69%) Platform.

The lead product candidates for the AIT(TM: 35.51, -0.61, -1.69%) Platform include OvaRex(R: 35.51, -0.61, -1.69%) MAb for ovarian cancer and BrevaRex(R: 35.51, -0.61, -1.69%) MAb for breast cancer. OvaRex(R: 63.19, 2.08, 3.4%) MAb was subject to one Phase II study examining combination chemo-immunotherapy in front-line treatment, and two randomized, double blind and placebo controlled Phase III clinical trials examining immunotherapy during remission. BrevaRex(R: 63.19, 2.08, 3.4%) MAb was shown to be safe in a Phase I clinical trial in patients with MUC-1 expressing tumours. Our goal will be to seek partners for the future development of the AIT(TM: 63.19, 2.08, 3.4%) Platform.

Paladin paid \$1,250,000 payable to existing ViRexx creditors. In addition, former ViRexx shareholders could receive a payment of up to \$2,500,000, if certain conditions are met before December 31, 2009

"ViRexx spent over \$30 million in developing its promising, innovative technology. Unfortunately, ViRexx got caught in this financial storm without the protection of cash. We intend to continue ViRexx's stated strategy of focusing resources on the Chimigen(TM: 63.19, 2.08, 3.4%) Platform while seeking outside partnerships for the T-ACT(TM: 63.19, 2.08, 3.4%) and AIT(TM: 63.19, 2.08, 3.4%) Platforms. We believe that our focused investment in Chimigen(TM) over the next 18 months may reward our shareholders through a lucrative partnering agreement," said Jonathan Ross Goodman, President and CEO.

As a result of this transaction, Paladin will be spending approximately \$2 - \$2.5 million in R&D in 2009 on the Chimigen(TM) platform and partnering activities. In addition, Paladin's non-capital losses and investment tax credits available to offset future taxable income has increased by a minimum of \$28 million.

#### **About Paladin Labs Inc.**

Paladin Labs Inc., headquartered in Montreal, Canada, is a specialty pharmaceutical company focused on acquiring or in-licensing innovative pharmaceutical products for the Canadian market. With this strategy, a focused national sales team and proven marketing expertise, Paladin has evolved into one of Canada's leading specialty pharmaceutical companies. For more information, please visit the Company's web site at [www.paladinlabs.com](http://www.paladinlabs.com).

#### ***Seattle biotech Kineta funds research step by step***

<http://seattletimes.nwsources.com>

By Ángel González

*Seattle Times* business reporter

A NEW Seattle biotech venture is seeking a piecemeal approach to growth to navigate the sector's troubled waters.

Biotech startups are known for burning through huge piles of cash as they do expensive research

in hopes of one day hitting the jackpot with a miracle drug.

But in a troubled economy dominated by tightfisted investors, Kineta is trying a new approach. The Seattle-based company in South Lake Union plans to fund its research step by step, relying on revenue-generating deals to undertake the next step in research.

"Our fundraising strategy is to grow in an organic way," said CEO Charles Magness.

Kineta's formula underscores the biotechnology sector's struggle to survive the economic debacle.

Software and other sectors relying on venture capital are suffering from the drop in venture funds and the depressed market for equities.

Biotechnology firms are particularly in bad shape because they need more cash and longer lead times than other budding companies.

Local companies like Targeted Genetics, which has only enough cash to operate through the first quarter of next year, are caught in the crunch.

Magness and fellow Kineta founder Shawn Iadonato started the company last December but unveiled it publicly only this month.

Their new venture quickly came after the \$9 million sale of their previous company, Illumigen Biosciences, to Massachusetts-based Cubist Pharmaceuticals. If Illumigen's research and commercial potential fully pans out, its shareholders could get up to \$330 million in additional payments from Cubist.

Kineta — which has the scientific backing of University of Washington scientists Michael Gale and Michael Katze — focuses on therapies that could help the immune system fight diseases such as influenza or hepatitis C.

Kineta's strategy is to do early-stage research until it can prove a biotech compound works, then seek a bigger partner that will pay for an interest in the product and do the expensive clinical experimentation and commercialization efforts.

"We're looking for some return to the company in the three-year time frame," as opposed to the nearly decadelong wait many biotechs aim for, Magness said.

Kineta has so far partnered with Cubist for early-stage work on a hepatitis C drug, and has received funding from the National Institutes of Health. But it is also pitching itself to investors.

The company plans to host an investor open house Jan. 15, according to its Web site.

Ángel González: 206-515-5644 or [agonzalez@seattletimes.com](mailto:agonzalez@seattletimes.com)

## **Hep C payout tops €818m**

<http://www.independent.ie>

Eilish O'Regan Health Correspondent

A HANDFUL of solicitors' firms have earned most of the €103m paid out in legal fees by the Hepatitis C compensation tribunal.

The tribunal -- set up in the mid-1990s to compensate the victims of blood contamination -- has now paid out a massive €818m in damages and legal fees although no blood bank official has ever been held criminally accountable for any of the scandals.

Legal fees topped nearly €8m last year with most of the payout shared by firms such as Malcomson Law, Ivor Fitzpatrick, Lavelle Coleman and Arthur P McLean.

One of the highest awards in the history of the tribunal was made last year to a victim who received €5.2m.

The tribunal's annual report does not say the circumstances which merited such a high payout but it is believed the person had suffered severe loss of earnings because of their illness.

The tribunal was set up in 1996 and compensates victims of blood contamination including 1,000 mothers who received contaminated batches of the blood product Anti-D which was made by the Blood Transfusion Service Board (BTSB).

An inquiry tribunal found the BTSB -- since renamed the Irish Blood Transfusion Service -- negligent. It left women, who received the product to prevent them having blue babies, infected with the potentially lethal Hepatitis C in the late 1970s and 1990s.

Others included in the tribunal are people who received Hepatitis C through blood transfusion and haemophiliacs who were allowed additional compensation in 2002 after being infected with the virus as well as HIV.

It recently emerged that the last surviving big player in the contamination of the blood product Anti-D, former BTSB biochemist Cecily Cunningham, will not face prosecution due to lack of any living witnesses.

At least 42 mothers who received contaminated Anti-D have died. A significant number of these died from liver failure.

The death toll among people with haemophilia who were infected with HIV and Hepatitis C has reached 92. Four have undergone liver transplants.

The tribunal will have to sit for many more years because a substantial number of victims have deferred any major award until their condition deteriorates.

### **Assistance**

Detta Warnock, chairwoman of Positive Action, the organisation representing women infected through Anti-D, said it was important that claimants receive legal assistance.

Acknowledging the payout to solicitors was high she said, however, that she would "not say a word against" the legal teams involved.

Positive Action is continuing to advocate for about 30 women who received contaminated batches of Anti-D but who are excluded from the tribunal or the special packages of medical supports for victims.

The tribunal report showed that the average payout to claimants last year was €287,128.

Some 15 victims appealed the tribunal's payout to the High Court and received increases of €3.2m.

**Dec 24, 2008**

### ***Needle/Syringe Programmes And Opioid Substitution Therapy Should Be Widely Available In Prisons To Help Prevent HIV Transmission***

<http://www.medicalnewstoday.com>

Prisons should have needle and syringe programmes (NSPs), opioid substitution therapy (OST) and other preventive measures in place to prevent HIV transmission between inmates. These are the conclusions of a Review published in the January edition of *Lancet Infectious Diseases*, written by Dr Ralf Jürgens, a consultant for HIV/AIDS based in Quebec, Canada, and colleagues on behalf of WHO.

The high prevalence of HIV infection and drug dependence among prisoners, combined with the sharing of injecting-drug equipment, make prisons high-risk environments for the transmission of HIV and also hepatitis C. The authors reviewed the effectiveness of interventions to reduce risky behaviour in this context. This Review forms part of a broader review of interventions to address HIV in prisons commissioned by WHO, together with the UN Office on Drugs and Crime, and UNAIDS, to guide countries in their efforts to scale-up towards universal access to HIV prevention, treatment and care by 2010.

Drug dependence in male prisoners is estimated at 10-48%, and in female prisoners 30-60%. The first needle and syringe programme (NSP) was introduced in Switzerland in 1992, and NSPs have since been implemented over 40 prison in 12 countries in western and eastern Europe and central Asia. In some countries, only a few prisons have NSPs but in Spain and Kyrgyzstan NSPs have been rapidly scaled-up and operate in a high number of prisons. All the available studies show that implementation of an NSP results in needle/syringe sharing declining or stopping altogether, and in these studies no new HIV cases were reported where NSPs were implemented. Other benefits include a reduction in overdoses and deaths, more contact between prisoners and drug-treatment programmes, improved relationships between prisoners and staff, and better awareness of risky behaviours. Needles were not used as weapons, and needle-stick injuries to staff during searches have decreased. The authors say: "The availability of sterile injecting equipment has not resulted in an increased number of prisoners injecting drugs, an increase in overall drug use, or an increase in the amount of drugs in prisons. Once in place, acceptance of NSPs is generally high among staff and prisoners." Furthermore, ensuring that prisoners have easy and confidential access to NSPs has been shown to be a key factor in guaranteeing their

success. The Review also discusses use of bleaching to disinfect injecting equipment, but points out that the effectiveness of bleach to kill HIV and hepatitis C is limited outside of the prison context. In prison facilities it is even more difficult to follow the recommended disinfecting procedure properly. The authors say that "because prisoners can be accosted at any moment by prison officers, injecting and cleaning is a hurried affair."

Evaluations of prison-based methadone maintenance therapy (MMT) have shown many positive results for prisoners, prison systems, and for the communities to which most prisoners eventually return. In particular, all studies found that prisoners who receive this therapy inject substantially less frequently than those not receiving the therapy. Evaluations have also found reduced mortality among prisoners retained in MMT. Maintenance treatment with methadone also has a positive effect on institutional behaviour, thus improving prison safety, and makes prisoners less likely to re-offend and return to prison. This is particularly the case if methadone is provided for longer, uninterrupted periods, if moderate-to-high doses of methadone are provided, and if provision of methadone is accompanied by support.

The authors say: "Far from condoning drug use in prisons, making available to prisoners the means that are necessary to protect them from HIV (and hepatitis C) transmission acknowledges that protection of prisoners' health needs to be the primary objective of drug policy in prisons. As the Scottish report\* on drug use and prisons pointed out, 'the idea of a drug free prison does not seem to be any more realistic than the idea of a drug free society' and 'stability may actually be better achieved by moving beyond this concept.'" Importantly, promoting and protecting the health of prisoners, through measures like NSPs and MMT programmes has been shown to benefit not only prisoners, but also prison staff and the communities outside prison.

The authors conclude: "The renewed emphasis on HIV and broader health issues in prisons represents a recognition that public health can no longer afford to ignore prison health."

"Interventions to reduce HIV transmission related to injecting drug use in prison."

Ralf Jürgens, Andrew Ball, Annette Verster

[The Lancet Infection](#) Vol 9 January 2009

**Dec 25, 2008**

## ***Silibinin Infusion Has Antiviral Effect Against HCV in Nonresponders***

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

By Megan Rauscher

NEW YORK (Reuters Health) Dec 25 - Intravenous silibinin, a flavanone derived from milk thistle, provides a "substantial" antiviral effect in patients with chronic hepatitis C (HCV) who have not responded to standard full-dose pegylated interferon plus ribavirin (PegIFN/RBV), clinicians from Austria report.

In comments to Reuters Health, lead investigator Dr. Peter Ferenci said: "Milk thistle preparations (have been) used for treatment of liver diseases for centuries. A final proof of efficacy is missing. This study shows for the first time in humans that silibinin given intravenously is a potent antiviral in patients with chronic hepatitis C, thus linking 'folk medicine' to evidence-based medicine."

Dr. Ferenci and colleagues from Medical University of Vienna treated 16 HCV patients who failed to respond to full-dose PegIFN/RBV combination therapy with IV silibinin 10 mg/kg/day for 7 days. On day 8, PegIFN/RBV was started.

They report in the November issue of *Gastroenterology* that serum HCV RNA declined in all patients on IV silibinin monotherapy, with a mean log decline of 1.32 within 1 week ( $p < 0.001$ ). "Unexpectedly," however, HCV RNA levels increased again after the infusion period in spite of PegIFN/RBV therapy.

IV silibinin "failed to improve the outcome of nonresponders by augmenting the response to interferon, which was the primary hypothesis of the study," the investigators note. This clinical trial was then discontinued.

However, in a subsequent dose-finding study, 6 of 14 patients achieved HCV RNA levels of less than 15 IU/mL after a 14-day infusion of 15 or 20 mg/kg/day silibinin, Dr. Ferenci and colleagues report. As in the first study, PegIFN/RBV combination therapy was started on day 8. "These patients are still on treatment," the authors note.

At week 12, HCV RNA became undetectable in 7 patients who received the 14-day infusion of IV silibinin at the 15- or 20-mg dose.

Intravenous silibinin was well tolerated with no serious adverse effects. The most common side effect was a transient sensation of heat.

Summing up, Dr. Ferenci noted that there currently is no available treatment for nonresponders to PegIFN/RBV therapy. "There is unmet medical need for new treatment strategies like the one described in my paper," he said.

While further study is needed, the current observations suggest that silibinin "may be a very useful drug treatment of PegIFN/RBV nonresponders or in future combinations with HCV protease or polymerase inhibitors," Dr. Ferenci and colleagues conclude.

*Gastroenterology* 2008;135:1561-1567.

**Dec 26, 2008**

## ***Liver disease may resolve with weight loss surgery***

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

By Megan Rauscher

NEW YORK (Reuters Health) - Obesity surgery, also known as bariatric surgery, not only helps obese individuals shed a significant amount of weight, it also significantly improves or completely resolves a common obesity-related liver problem known as non-alcoholic fatty liver disease, a review of published studies shows.

So-called "non-alcoholic fatty liver disease" is an emerging problem related to the obesity epidemic. The prevalence of the condition is estimated to be around 70 percent in obese

individuals and 85 percent to 95 percent in those who are morbidly obese.

Studies have shown that weight loss achieved through bariatric surgery improves diabetes and lowers high blood pressure in obese individuals. However, the overall effect of weight loss on fatty liver disease remains unclear.

To investigate, Dr. Gagan K. Sood from the University of Texas Medical Branch in Galveston and colleagues pooled data from 15 studies that looked at the impact of bariatric surgery on the liver.

"Overall results are encouraging for improvement in liver disease associated with obesity," Sood told Reuters Health.

As expected, liver biopsies showed that the vast majority of obese individuals had clear signs of fatty liver disease. Obesity surgery-induced weight loss improved or completely resolved fatty liver disease in most of the study subjects, Sood and colleagues report.

For example, one severe, progressive form of non-alcoholic fatty liver disease that can lead to cirrhosis and even liver cancer called "steatohepatitis" was present in 299 of 555 liver biopsies (53.8 percent) initially and the pooled proportion of patients with improvement or resolution of this problem was 81.3 percent, the team reports.

"The most encouraging finding," the team concludes, "is that a majority of patients experience complete resolution of non-alcoholic fatty liver disease after bariatric surgery, and the risk of progression...seems to be minimal."

*SOURCE: Clinical Gastroenterology and Hepatology, December 2008.*

**Dec 27, 2008**

## ***You Feel Like You're Talking to an Angel'***

<http://www.nytimes.com>

Thomas McDonald for The New York Times

AS a nurse who deals with liver disease — a particularly trying medical field with a steady drumbeat of dispiriting news — Martha Shea does everything but get away from it after hours.

"I'm just passionate about what I do," said Ms. Shea, 57, on a recent weekend in a moment of rare repose at her home in Wallingford.

Ms. Shea is described as tough but compassionate by patients she has seen over the years at the Veterans Affairs hospital in West Haven. She has worked there since 1979, first running a hepatology research lab and since 1987, as a nurse — now the nurse-manager of the hepatitis C resource center.

After 25 years in the Air Force Reserve, Ms. Shea retired in 2001 and has been a diligent volunteer with the American Liver Foundation's Connecticut chapter in North Haven ever since.

“She’s sort of a whirling dervish,” said JoAnn Thompson, the chapter’s executive director. As chairwoman of the chapter’s annual Liver Life Walk the last two years, Ms. Shea raised record amounts of money: \$110,000 in 2007, then \$142,000 in 2008.

But there’s more. “Whatever we need her for, she finds time to come in and help us out,” Ms. Thompson said.

That can mean stuffing envelopes or decorating the office for the holidays, as Ms. Shea recently did. But more often, she uses the medical skills honed on the front lines of liver disease research and care, volunteering at a half-dozen health fairs a year — usually opting to work a whole day rather than a single shift. And she volunteers with the foundation’s treatment choices initiative — an educational program aimed at those at high risk for contracting hepatitis C.

“I just saw the need and how important it was and how it helped the patients,” Ms. Shea said, explaining why she volunteers on top of her regular job, which includes a hepatitis support group at the V.A. hospital that she runs on her own time. “My feeling for my patients — it’s not just sitting there at the V.A. I advocate for them. I’ll go to congresspeople. I’ll help them write letters. I’ll help them find a place at the shelter. It’s not just ‘come into the clinic, get your shot, here’s your pill.’ ”

Hepatitis C is a chief scourge in the world of liver disease, coming from an infectious blood-transmitted virus that has proved tricky to treat, let alone cure. There are some 5 million people in the United States with hepatitis C, and about 19,000 new cases every year. The disease can cause severe liver damage, cancer and death. Transplants are possible, but there are far more people who need new livers than there are available livers.

Many people contracted the disease through blood transfusions before the nation’s blood supply was screened, but many contract it through risky behavior like intravenous drug use. So, to work in the field means not only confronting the frequent specter of death but also potentially problematic patients who still engage in the practices that got them sick in the first place.

“Patients love her,” said Dr. Roberto J. Groszmann, a hepatologist who recently retired from the V.A. hospital. He said Ms. Shea was critical in his clinical research because she made sure the patients came in. “Martha calls them at home, talks to them, talks to the patients’ wives. That’s very important.”

Philip Scarfo said he doubted he would have made it through a transplant for his nonhepatitis liver disease without Ms. Shea. Mr. Scarfo, 59, of Meriden, now works at the foundation’s Connecticut chapter.

“With the number of nurses and professionals I’ve dealt with, I could count on one hand the ones that stand out, and Martha is right on the top of that list,” he said. “I went through procedures and tests that were absolutely horrible. I can’t tell you how many times Martha came into the room and literally held my hand.”

Gail Brown, 55, of Preston, a former intravenous drug user who contracted hepatitis C, said that Ms. Shea was a big part of her survival through a transplant and subsequent treatment when her disease returned.

“When you talk to her,” Ms. Brown said, “you feel like you’re talking to an angel.”

Ms. Shea — who says she does take vacations and has been known to give herself a “spa day” when things get tough — said her dedication came from her Catholic faith, her brush with breast cancer five years ago and the memory of what people did for her and her husband, Jim, years ago when they were struggling.

“You know you’ve got to give back,” she said, still expressing concern that she would never be able to give enough. “There’s always tomorrow. There’ll be somebody who needs some help.”