

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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In This Issue:

- [Adiponectin: A New Independent Predictor of Liver Steatosis and Response to IFN-alpha Treatment in Chronic Hepatitis C.](#)
- [Task force recommends state collect more hepatitis data](#)
- [Scientists at University of Washington report research in acute hepatitis](#)
- [Individualized Treatment Duration for HCV Meets With Success](#)
- [Human Genome Sciences Modifies Dosing in Achieve Trials of Albuferon ®](#)
- [Vertex Pharmaceuticals to Begin Phase 3 Development of Telaprevir, Investigational Hepatitis C Protease Inhibitor](#)
- [Hepatitis C Top Illness to Sicken County](#)
- [San Antonio needle-swap activists facing charges](#)
- [Doctors Report Transplant Breakthrough](#)
- [Teen takes on donor's immune system](#)
- [Blood bank bias: whose blood is it, anyway?](#)
- [Too few patients receive antivirals for chronic hepatitis](#)
- [Body art draft ordinance draws public comments](#)
- [A Shot at Curbing the AIDS Epidemic](#)

January 21st, 2007

Adiponectin: A New Independent Predictor of Liver Steatosis and Response to IFN-alpha Treatment in Chronic Hepatitis C.

<http://www.docguide.com>

The objectives of this study were to compare serum adiponectin and tumor necrosis factor (TNF)-alpha among patients with viral liver diseases; to investigate associations of serum

adiponectin and TNF-alpha with histological or viral characteristics of chronic hepatitis C (CHC); to investigate adiponectin and TNF-alpha alterations during interferon (IFN)-alpha treatment; and to assess the relationship between serum adiponectin and TNF-alpha and response rates to treatment. The study, by TA Zografos, et al., is to be published in the *American Journal of Gastroenterology*, 2008 Jan 11.

The researchers analyzed Adiponectin (µg/mL) and TNF-alpha (pg/mL) determinations by enzyme-linked immunosorbent assay (ELISA) in serial samples (before, the middle, the end, and 6 months after the end of treatment) from 83 CHC and 59 chronic hepatitis B (CHB) patients. Forty-three blood donors served as healthy controls. Patients were treated with IFN-alpha (4.5 MU/t.i.w.) for 12 months in CHB cases, and IFN-alpha (3 MU/t.i.w.) plus ribavirin for 6-12 months according to hepatitis C virus (HCV) genotype in CHC cases.

After adjustment for gender and body mass index (BMI), HCV genotype 3 overweight patients (BMI > 25 kg/m²) had significantly lower adiponectin (7.3 +/- 2.7) at baseline compared with non-3 HCV genotype overweight patients (P < 0.05). Lower adiponectin (HCV genotype 3, P= 0.02 and HCV genotype 1, P= 0.025) and higher TNF-alpha (P= 0.025) at baseline were identified as independent predictors of liver steatosis in CHC patients. Lower adiponectin was also identified as an independent predictor of no virological response at the end of treatment (odds ratio [OR] 0.76, 95% confidence interval [CI] 0.66-0.87, P < 0.001). At the end of IFN-alpha therapy, only HCV genotype 3 patients had significantly higher serum adiponectin (10.4 +/- 6.3) compared with its levels before treatment (8.7 +/- 4.7, P < 0.05).

The researchers concluded that this study suggests that HCV genotype 3 may directly affect adiponectin. This is further supported by the significant increase in adiponectin at the end of treatment only in HCV genotype 3 patients. Serum adiponectin at baseline appears to be an independent predictor of liver steatosis and for the achievement of end-of-treatment virological response, while serum TNF-alpha at baseline was identified as an independent predictor only of liver steatosis.

January 22nd 2007

Task force recommends state collect more hepatitis data

<http://www.kptm.com>

LINCOLN, Neb. (AP) - A task force aimed at curbing the spread of hepatitis C is recommending the state collect more information on patients diagnosed in Nebraska.

The report released last month by the Hepatitis C Education and Prevention Task Force says state law requires all cases of hepatitis to be reported to the Health and Human Services Department, but some information about the patients is not being recorded.

The task force recommends a new system that includes a patient's age, gender, race and zip code, among other things.

The task force was created by the Legislature in response to an outbreak of hepatitis C in Fremont. Between March 2000 and December 2001, 99 patients of the Fremont Cancer Center

contracted the disease due to unsanitary conditions at the facility.

Scientists at University of Washington report research in acute hepatitis

<http://www.newsrx.com>

According to a study from the United States, "Acute hepatitis C virus (HCV) infection is often asymptomatic; thus, its epidemiology and natural history are difficult to define. Acute HCV infection was identified on the basis of HCV seroconversion within 1 year (n = 45), new anti-HCV seropositivity with clinical acute hepatitis (n = 21), or HCV strain sequencing after an iatrogenic exposure (n = 1)."

"Risk factors were assessed with a baseline questionnaire, and participants were followed up prospectively with serial measurement of viral loads. Of 67 persons with acute HCV infection, most were asymptomatic (64%) and injection drug users (66%). Thirteen had an unknown mode of transmission; of these, 11 reported high-risk sexual behavior. Ten acquired acute HCV infection within 3 months of an iatrogenic exposure; 3 had confirmed iatrogenic infection, and 4 had no other risk factors identified. The spontaneous viral clearance rate after 6 months of infection was 18% (95% confidence interval, 11%-31%). The rate of viral clearance varied significantly by sex (34% vs. 3% for women vs. men; $P < .001$). High-risk sexual or iatrogenic exposures may be important contemporary risk factors for HCV infection. The spontaneous viral clearance rate (18%) in this contemporary study was similar to that reported for past studies of transfusion-associated HCV infection," wrote C.C. Wang and colleagues, University of Washington.

The researchers concluded: "Women were more likely to clear acute HCV infection than men."

Wang and colleagues published the results of their research in the *Journal of Infectious Diseases* (Acute hepatitis c in a contemporary US cohort: Modes of acquisition and factors influencing viral clearance. *Journal of Infectious Diseases*, 2007;196(10):1474-1482).

For additional information, contact C.C. Wang, University of Washington, Dept. of Medical, Division Infectious Disease, 325 9th Avenue, Box 359908, Seattle, WA 98104, USA.

January 23rd, 2007

Individualized Treatment Duration for HCV Meets With Success

www.medscape.com

NEW YORK (Reuters Health) Jan 15 - In patients with hepatitis C virus (HCV), individualizing the duration of peginterferon/ribavirin treatment yields success rates similar to standard 48-week treatment, thus sparing unnecessary costs and side effects, according to results of two randomized controlled studies published in the January issue of *Hepatology*.

In one study, Dr. Alessandra Mangia from "Casa Sollievo della Sofferenza" Hospital, San Giovanni Rotondo, Italy, and colleagues treated 696 patients with HCV genotype 1 with

peginterferon alfa-2a (180 g/week) or peginterferon alfa-2b (1.5 g/kg/week), plus ribavirin (1,000 to 1,200 mg/day). Patients were randomized to treatment for 48 weeks (the standard treatment group; n = 237) or for 24, 48 or 72 weeks if HCV-RNA was undetectable at 4, 8, or 12 weeks, respectively (the variable treatment group; n = 459).

According to the investigators, results showed "equivalent rates of lasting viral clearance after therapy administered for the standard 48-week length or a variable duration tailored on the first undetectable HCV RNA during the initial 12 weeks of therapy."

Nearly 49% of patients receiving variable treatment based on detectable HCV RNA achieved a sustained virologic response, compared with 45% of patients in the standard treatment group (p = 0.37), Dr. Mangia and colleagues report.

"This study shows that in HCV genotype 1, treatment duration should be tailored to the 12-week on-treatment virologic response," Dr. Mangia and colleagues write. "HCV RNA should be monitored qualitatively at week 4 to identify patients with the highest likelihood of response, and at weeks 8 and 12 to determine if extended duration may be required," they conclude.

Meanwhile, in a study of 428 patients with HCV genotype 2 or 3, researchers from Norway randomly assigned patients who achieved a virologic response after 4 weeks peginterferon alfa-2b (1.5 g/kg) weekly and ribavirin (800 to 1,400 mg/day) to complete either 14 weeks or 24 weeks of treatment.

In intention-to-treat analysis, Dr. Olav Dalgard from Ullevål University Hospital, Oslo and colleagues found that 81.1% of patients in the 14-week treatment arm and 90.7% in the 24-week arm achieved a sustained viral response.

Among patients with an HCV RNA test 24 weeks after the end of treatment, 86.3% of the 14-week treatment group and 93.2% of the 24-week treatment group had a sustained viral response.

"In conclusion, we cannot formally claim that 14 weeks treatment is non-inferior to 24 weeks treatment," Dr. Dalgard and colleagues write. "However, the sustained virologic response rate after 14 weeks treatment is high, and although longer treatment may give a slightly better sustained viral response rate, we believe considerable economical savings, good response to re-treatment, and less side effects make it rational to treat patients with genotype 2 or 3 and rapid viral response for only 14 weeks."

Hepatology 2008.

Human Genome Sciences Modifies Dosing in Achieve Trials of Albuferon®

http://www.hgsi.com/news/press/08-01-23_Albuferon_ACHIEVE.htm

ROCKVILLE, Maryland – January 23, 2008 – Human Genome Sciences Inc. (Nasdaq: HGSI) announced today that it will modify the dosing in one arm of each of its ACHIEVE clinical trials of Albuferon® (albinterferon alfa-2b) for chronic hepatitis C. Patients in the Phase 3 trials who



have been receiving the 1200-mcg dose will now receive a 900-mcg dose. The change is based on recommendations made by the studies' independent Data Monitoring Committee (DMC). HGS continues to expect to have all Phase 3 data available by spring 2009 to support the filing of global marketing authorization applications by fall 2009.

“For some time we have viewed the 900-mcg dose administered every two weeks as the most likely marketed dose of Albuferon,” said H. Thomas Watkins, President and Chief Executive Officer, HGS. “The 900-mcg dose demonstrated comparable efficacy and safety to Pegasys in Phase 2 – with half the injections, improvements in quality of life and fewer missed days of work during treatment. We continue to believe that Albuferon could become the market-leading interferon for the treatment of hepatitis C if Phase 2 900-mcg results are confirmed in Phase 3.”

Consistent with its charter, the DMC routinely reviews all adverse events for each treatment group. Serious pulmonary adverse events, while expected and rare during interferon therapy, were higher in the treatment group receiving 1200-mcg Albuferon administered every two weeks. The DMC did not express any safety concerns about the 900-mcg dose of Albuferon. Based on the DMC's review and conclusions, the patients receiving a 1200-mcg dose of Albuferon will be moved to the 900-mcg dose.

“The independent Data Monitoring Committee for these trials assessed risk/benefit based on review of unblinded safety and efficacy data for all doses, to which HGS remains blinded, and concluded that dosing should be modified for patients receiving the 1200-mcg dose of Albuferon every two weeks,” said David C. Stump, M.D., Executive Vice President, Research and Development, HGS. “HGS and Novartis have chosen to accept the Data Monitoring Committee's recommendation to modify dosing in the 1200-mcg arms in these studies. We are pleased that after careful review by the Data Monitoring Committee, the safety and continued dosing of 900-mcg Albuferon was affirmed. Thus, all Albuferon patients will now receive 900-mcg every two weeks.”

About Albuferon

Albuferon is a novel, longer-acting form of interferon alpha that was created using the proprietary HGS albumin-fusion technology. Recombinant interferon alpha is approved for the treatment of hepatitis C, hepatitis B and a broad range of cancers. HGS is currently conducting two pivotal Phase 3 clinical trials of Albuferon in combination with ribavirin: ACHIEVE 1 in treatment-naïve patients with genotype 1 chronic hepatitis C, and ACHIEVE 2/3 in treatment-naïve patients with genotype 2 or 3 chronic hepatitis C.

Albuferon requires half as many injections as Pegasys, and Phase 2 clinical results suggest that Albuferon could offer efficacy and safety comparable to Pegasys, in addition to the potential for improved quality of life and fewer lost days of work on treatment. Based on these data, HGS believes that Albuferon could become the market-leading interferon for the treatment of hepatitis C if Phase 2 results are confirmed in Phase 3 trials.

Albuferon is being developed by HGS and Novartis under a worldwide co-development and commercialization agreement entered into in June 2006. ACHIEVE 1 and ACHIEVE 2/3, assuming that they are successful, will provide the pivotal data to support global marketing authorization applications for Albuferon, which HGS and Novartis expect to file by fall 2009.

Conference Call

HGS management will hold a conference call to discuss this announcement today at 10 AM Eastern time. Participants may listen to the call by dialing 888-690-2876 or 913-981-5550, passcode 8463866, five to 10 minutes before the start of the call. A replay of the conference call will be available for several days by dialing 888-203-1112 or 719-457-0820, passcode 8463866. This conference call also will be webcast. Interested parties who wish to listen to the webcast should visit the Human Genome Sciences website at www.hgsi.com. The archive of the conference call will be made available within a few hours after the call and will remain available for several days.

About Human Genome Sciences

The mission of HGS is to apply great science and great medicine to bring innovative drugs to patients with unmet medical needs.

The HGS clinical development pipeline includes novel drugs to treat hepatitis C, lupus, anthrax disease, cancer and other immune-mediated diseases. The Company's primary focus is rapid progress toward the commercialization of its two key lead drugs, Albuferon for hepatitis C and LymphoStat-B® (belimumab) for lupus. Phase 3 clinical trials of both drugs are ongoing.

ABthrax™ (raxibacumab) is in late-stage development for the treatment of anthrax disease, and the Company is on track to begin the delivery in 2008 of 20,000 doses of ABthrax to the Strategic National Stockpile under a contract entered into with the U.S. Government in June 2006. Other HGS drugs in clinical development include two TRAIL receptor antibodies for the treatment of cancer. AEG40826, a small-molecule antagonist of IAP (inhibitor of apoptosis) proteins, is expected to enter Phase 1 clinical trials for the treatment of cancer in early 2008.

For more information about HGS, please visit the Company's web site at www.hgsi.com. Health professionals or patients interested in Albuferon clinical trials or other studies involving HGS products may inquire via the "Contact Us" section of the Company's web site, www.hgsi.com/products/request.html, or by calling (301) 610-5790, extension 3550.

HGS, Human Genome Sciences, ABthrax, Albuferon and LymphoStat-B are trademarks of Human Genome Sciences, Inc.

Safe Harbor Statement

This announcement contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements are based on Human Genome Sciences' current intent, belief and expectations. These statements are not guarantees of future performance and are subject to certain risks and uncertainties that are difficult to predict. Actual results may differ materially from these forward-looking statements because of the Company's unproven business model, its dependence on new technologies, the uncertainty and timing of clinical trials, the Company's ability to develop and commercialize products, its dependence on collaborators for services and revenue, its substantial indebtedness and lease obligations, its changing requirements and costs associated with facilities, intense competition, the uncertainty of patent and intellectual property protection, the Company's dependence on key management and key suppliers, the uncertainty of regulation of products, the impact of future alliances or transactions

and other risks described in the Company's filings with the Securities and Exchange Commission. In addition, the Company will continue to face risks related to animal and human testing, to the manufacture of ABthrax and to FDA concurrence that ABthrax meets the requirements of the ABthrax contract. If the Company is unable to meet the product requirements associated with the ABthrax contract, the U.S. government will not be required to reimburse the Company for the costs incurred or to purchase any ABthrax doses. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today's date. Human Genome Sciences undertakes no obligation to update or revise the information contained in this announcement whether as a result of new information, future events or circumstances or otherwise.

Vertex Pharmaceuticals to Begin Phase 3 Development of Telaprevir, Investigational Hepatitis C Protease Inhibitor

www.vrtx.com

-- Primary Phase 3 trial will focus on studying 24-week telaprevir-based regimens -- Vertex plans concurrent second study to support registration -- Final data from both trials anticipated in mid- 2010

CAMBRIDGE, Mass., Jan 23, 2008 (BUSINESS WIRE) -- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that it will begin Phase 3 evaluation of **telaprevir**, Vertex's lead investigational hepatitis C protease inhibitor. The primary focus will be a global, 3-arm pivotal controlled trial that will evaluate two 24-week telaprevir-based regimens in approximately 1050 treatment-naive genotype 1 HCV patients. In this study, rapid viral response (RVR) criteria will be used to determine which telaprevir patients can stop all treatment at 24 weeks. A second study of approximately 400-500 HCV patients is planned to evaluate a 48-week telaprevir-based regimen, to confirm the results from Phase 2 studies and provide additional evidence that supports the 24-week regimen that is being evaluated in the primary Phase 3 trial. The Company expects that both studies will run concurrently and that the first trial will begin enrolling patients in March 2008.

"Data presented in late 2007 from two large Phase 2b studies suggest that telaprevir, dosed in combination with pegylated interferon and ribavirin, may be able to meaningfully increase the proportion of treatment-naive genotype 1 HCV patients who achieve a sustained viral response, and also cut the current treatment duration in half, to 24 weeks," said John McHutchison, M.D., Principal Investigator for the primary telaprevir Phase 3 pivotal study and Associate Director of Duke Clinical Research Institute. "Telaprevir is the most advanced protease inhibitor in development for hepatitis C, and the initiation of Phase 3 clinical development for this investigational drug will begin the process of helping to further assess its potential efficacy and the safety in a larger number of patients."

Pivotal Trial to Evaluate 24-Week Telaprevir-Based Treatment Regimens

In accordance with the design and protocol Vertex submitted to the FDA, the primary pivotal trial will focus on evaluation of 24 weeks of telaprevir-based therapy and will enroll approximately 1050 treatment-naive, genotype 1 HCV patients, who will be randomized equally across three treatment arms (approximately 350 patients per arm).

The study will be conducted at approximately 100 centers in the U.S., E.U. and certain other countries. The study arms will include:

-- 24 weeks of therapy, with telaprevir dosed at 750 mg every eight hours (q8h) for 12 weeks in combination with standard doses of pegylated interferon alfa-2a (peg-IFN) and ribavirin (RBV) for 12 weeks, then continuing for another 12 weeks with peg-IFN and RBV alone;

-- 24 weeks of therapy, with telaprevir dosed at 750 mg every eight hours (q8h) for 8 weeks in combination with standard doses of peg-IFN and RBV for 8 weeks, then continuing for another 16 weeks with peg-IFN and RBV alone; and

-- A control arm with standard doses of peg-IFN and RBV dosed for 48 weeks.

Patients in both telaprevir arms who achieve rapid viral response (RVR), defined as undetectable (less than 10 IU/mL) viral levels by the end of week 4, and who stay undetectable at week 12 will receive 24 weeks of treatment. Patients in these treatment arms who do not meet the RVR criteria but are undetectable at week 24 will continue on peg-IFN and RBV for a total duration of 48 weeks.

Concurrent 48-Week Second Study to Support Registration

Vertex has agreed to conduct a second well-controlled clinical study as part of the registration program for a treatment-naïve indication. The objective of this second study would be to develop additional sustained viral response (SVR) and relapse rate data with 48-weeks treatment duration that confirm results from the Phase 2 studies, thereby providing additional evidence supporting the 24-week regimen in the Phase 3 trial. The design of this second study is being finalized, but at this time Vertex expects this study to enroll approximately 400-500 patients, including patients in the control arm.

The primary objective of the two studies will be to assess the proportion of patients in each study arm who achieve SVR, defined as undetectable (less than 10 IU/mL, as measured by the Roche TaqMan(R) assay) HCV RNA 24 weeks after the completion of dosing. Vertex expects to have SVR data from both studies by mid-2010.

Update on Meeting with FDA

Vertex and the FDA met in mid-January 2008 to discuss telaprevir's Phase 3 development program. This meeting included a review of available data from Phase 2b clinical trials of telaprevir, including newly available post-treatment data from the 48-week treatment arms in PROVE 1. In the control arm of PROVE 1, on an ITT basis, 37% of patients had undetectable HCV RNA at 12 weeks post-treatment follow-up. In the 48-week ("12+36") telaprevir-based treatment arm in PROVE 1, also on an ITT basis, 66% of patients had undetectable HCV RNA at 12 weeks post-treatment follow-up. The relapse rate in the 48-week telaprevir-based arm in PROVE 1 was 6%.

Additional HCV Studies

Vertex and Tibotec continue to conduct additional clinical studies to evaluate the potential role of telaprevir treatment for important HCV sub-populations as well as different dosing regimens for telaprevir.

-- The companies are conducting PROVE 3, a Phase 2b clinical trial of telaprevir-based combination therapy in patients with genotype-1 HCV who have not achieved SVR with a previous pegylated interferon-based treatment. Vertex plans to discuss with regulatory authorities in mid-2008 the next steps in the telaprevir development program for treatment-failure HCV patients after the first interim clinical data are available from the PROVE 3 clinical trial.

-- Tibotec is conducting a Phase 2 clinical study in Europe to evaluate 8-hourly and 12-hourly dosing of telaprevir in combination with pegylated interferon (Pegasys(R) or PegIntron(TM)) and ribavirin. Interim 12-week on-treatment data are expected to be available in the second half of 2008.

-- Tibotec is also conducting a Phase 2 viral kinetics study in Europe to evaluate telaprevir in patients infected with genotype 2/3 HCV. Interim on-treatment data are expected to be available in late 2008.

-- In addition, in December, Tibotec initiated a Phase 2 study in Europe to evaluate telaprevir in patients infected with genotype 4 HCV.

Updates on the status of Vertex and Tibotec's clinical trials of telaprevir are available at www.clinicaltrials.gov.

About Telaprevir

Telaprevir (VX-950) is an investigational oral inhibitor of HCV protease, an enzyme essential for viral replication, and is one of the most advanced investigational antiviral agents in development that specifically targets HCV. The types of adverse events that have been commonly observed with Peg-IFN and RBV were seen across all treatment arms in Phase 2b trials of telaprevir. The most common adverse events, regardless of treatment assignment, were fatigue, rash, headache and nausea. Gastrointestinal disorders, skin adverse events (rash, pruritus) and anemia were more common in the telaprevir arms compared to the control arm over the dosing period.

About Hepatitis C

Hepatitis C is a liver disease caused by the hepatitis C virus, which is found in the blood of people with the disease. HCV, a serious public health concern affecting 3.4 million individuals in the United States, is spread through direct contact with the blood of infected people. Though many people with hepatitis C may not experience symptoms, others may have symptoms such as jaundice, abdominal pain, fatigue and fever. Chronic hepatitis C significantly increases a person's risk for developing long-term infection, chronic liver disease, cirrhosis or death. The burden of liver disease associated with HCV infection is increasing, and current therapies typically provide sustained benefit in less than half of patients with genotype 1 HCV, the most common strain of the virus.

About Vertex

Vertex Pharmaceuticals Incorporated is a global biotechnology company committed to the discovery and development of breakthrough small molecule drugs for serious diseases. The Company's strategy is to commercialize its products both independently and in collaboration

with major pharmaceutical companies. Vertex's product pipeline is focused on viral diseases, inflammation, autoimmune diseases, cancer, pain and bacterial infection. Vertex co-discovered the HIV protease inhibitor, Lexiva, with GlaxoSmithKline.

Disclosure: Dr. McHutchison receives research support, as does the Duke Clinical Research Institute, from Vertex, and he has served in an advisory capacity for the company.

Lexiva is a registered trademark of the GlaxoSmithKline group of companies.

TaqMan(R) is a registered trademark of Hoffman-La Roche Inc.

Webcast and Conference Call on January 23

Vertex Pharmaceuticals will host a conference call on January 23, 2008 at 8:00 a.m. Eastern Time (ET) to review the Phase 3 trial announcement. This call will be broadcast via the Internet at www.vrtx.com from the 'Events & Presentations' page. To listen to the call live on the telephone, dial (800) 374-0296 (U.S. and Canada) or (706) 634-2224 (International). The call will be available for replay via telephone commencing January 23, 2008 at 11:00 a.m. ET running through 5:00 p.m. ET on February 6, 2008. The replay phone number for the US and Canada is (800) 642-1687. The international replay number is (706) 645-9291 and the conference ID number is 32008293. Following the live webcast, an archived version will also be available on Vertex's website until 5:00 p.m. ET on February 6, 2008.

Safe Harbor Statement

This press release contains forward-looking statements, including statements regarding (i) Vertex's plan to begin Phase 3 clinical development of telaprevir; (ii) the designs and protocols of the planned clinical trials, including the anticipated number of patients and the description of the anticipated treatment arms; (iii) Vertex's expectation that the two clinical trials will run concurrently and that the larger trial will begin enrolling patients in March 2008; (iv) the expectation that the second study will evaluate a 48-week telaprevir-based regimen, to confirm the results from Phase 2 studies and provide additional evidence that supports the 24-week regimen that is being evaluated in the primary Phase 3 trial; (v) Vertex's expectation that it will have SVR data for both clinical trials of telaprevir by mid-2010; (vi) Vertex's plan to discuss with regulatory authorities in mid-2008 the next steps in the telaprevir development program for patients with HCV who have failed to achieve sustained viral response with previous treatments; and (vii) the dates by which interim on-treatment data is expected for the Phase 2 clinical trials being conducted by Tibotec in Europe. While Vertex believes the forward-looking statements contained in this press release are accurate, there are a number of factors that could cause actual events or results to differ materially from those indicated by such forward-looking statements. These risks and uncertainties include, among other things, that Vertex's ongoing discussions with regulatory authorities may result in changes to the clinical trials described in this press release, that the outcomes for each of the planned clinical trials of telaprevir may not be favorable or may reflect unanticipated results which could impact the planned development path for telaprevir, that enrollment in the clinical trials may be more difficult or slower than Vertex currently anticipates or that the planned clinical trials may not start on the dates anticipated, and other risks listed under Risk Factors in Vertex's form 10-K filed with the Securities and Exchange Commission on March 1, 2007.

(VRTX-GEN)

SOURCE: Vertex Pharmaceuticals Incorporated

Vertex Pharmaceuticals Incorporated Michael Partridge, 617-444-6108 Senior Director, Strategic Communications or Lora Pike, Manager, 617-444-6755 Investor Relations or Patricia Farrell, 617-444-6533 Director, Public Relations

Hepatitis C Top Illness to Sicken County

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

By Sarah Wienke, *Missourian* Staff Writer

Hepatitis C showed the biggest increase of all the diseases included in the Franklin County Health Department's 2007 report of confirmed communicable diseases in the county.

The health department reports that a total of 77 people had contracted the deadly liver disease during 2007, up from 52 confirmed cases in 2006.

"That number is way high," said County Epidemiologist David Noe. "The CDC (Centers for Disease Control and Prevention) would say it's going down, but we're seeing it go up here in Franklin County due to the intravenous drug use."

Hepatitis C is spread through blood to blood contact, most commonly through IV drug use. It also can be contracted through having sex with an infected person, and sharing personal items such as razors and toothbrushes.

Noe said Hepatitis C is popping up in people in their 40s and 50s who didn't know they had it, as well as a high number of younger people.

Hepatitis C is the leading cause of liver cancer, cirrhosis and liver transplants.

"I like to tell people if they change their lifestyle, they can die with Hep C instead of from it," Noe said.

There are four other Hepatitis strains that cause liver complications, but they are less prevalent in the county.

Hepatitis B is spread through unprotected sex, sharing needles and using personal items of someone with the disease.

In 2007, one case of prenatal Hepatitis B, two cases of acute Hepatitis B and two cases of chronic Hepatitis B were confirmed.

None of the other strains, A, D or E, were confirmed in the county in 2007.

San Antonio needle-swap activists facing charges

<http://www.chron.com>

Associated Press

SAN ANTONIO — Police said they will seek drug paraphernalia charges punishable by up to a year in jail for three activists who were caught handing out clean syringes in exchange for dirty ones.

The members of the nonprofit group Bexar Area Harm Reduction Coalition were cited Jan. 5 when a police officer saw them parked at a corner "with several known prostitutes and drug addicts next to the vehicle."

The police confiscated containers of clean syringe kits, while leaving them with the used syringes they'd collected.

An officer cited the three with possession of drug paraphernalia, a Class C misdemeanor punishable by a fine of up to \$500. But police now say they will refile the case this week with District Attorney Susan Reed as a Class A misdemeanor, distribution of paraphernalia, which carries a punishment of up to a year in jail and a \$4,000 fine.

The defendants are Bill Day, 73, a co-founder of the nonprofit group, and two board members, Mary Casey, 67, and Melissa Lujan, 39.

"These are enormously decent, charitable people, and what's happening with them smacks of persecution," said Neel Lane, an attorney with Akin Gump Strauss Hauer & Feld, which is representing the coalition at no cost.

The citations come as Bexar County health officials wait for a state attorney general's opinion on legislation passed last year authorizing the county to pilot a syringe exchange program.

Reed has warned local officials that the legislation doesn't shield participants from drug paraphernalia laws.

Texas is the only state that doesn't allow syringe exchange programs, which are meant to curb the spread of diseases through intravenous drug use by giving users clean hypodermic needles.

Assistant Police Chief David Head said if the pilot program moves forward, the law would allow only Bexar County's health authority to run a syringe exchange program, and not a private group such as Bexar Area Harm Reduction Coalition.

Head denied Day's claim that he had been given permission by police to exchange syringes.

Day has been open about his group's work. He said the dirty needles are disposed of with the Metropolitan Health District.

"Our volunteers regard their involvement as a Christian ministry work intended to elevate egregious suffering and improve the lives of the least among us," he said. "The statement and

actions of the district attorney have brought all needle exchange activities to a halt. As a result, we can expect transmission of hepatitis and HIV to increase."

January 24th, 2007

Doctors Report Transplant Breakthrough

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

LOS ANGELES_In what's being called a major advance in organ transplants, doctors say they have developed a technique that could free many patients from having to take anti-rejection drugs for the rest of their lives.

The treatment involved weakening the patient's immune system, then giving the recipient bone marrow from the person who donated the organ. In one experiment, four of five kidney recipients were off immune-suppressing medicines up to five years later.

"There's reason to hope these patients will be off drugs for the rest of their lives," said Dr. David Sachs of Massachusetts General Hospital in Boston, who led the research published in Thursday's *New England Journal of Medicine*.

Since the world's first transplant more than 50 years ago, scientists have searched for ways to trick the body to accept a foreign organ as its own. Immune-suppressing drugs that prevent organ rejection came into wide use in the 1980s. But they raise the risk of cancer, kidney failure and many other problems. And they have unpleasant side effects such as excessive hair growth, bloating and tremors.

Eliminating the need for anti-rejection drugs is "a huge advance," said Dr. Suzanne Ildstad, a University of Louisville immunology specialist who had no role in the work.

"It still needs some fine-tuning so that everyone who gets treated gets the same consistent outcome ... It's not the holy grail of tolerance yet," she cautioned.

The results do not mean that it is safe for current transplant patients to go off their medicines. Doing so could lead to organ rejection and even death, doctors warn. And Sachs said the treatment will not solve the country's organ shortage.

In the 1990s, Sachs showed the treatment could work in a kidney recipient who was a good genetic match. The woman, who had an organ and marrow transplant in 1998, has not needed anti-rejection drugs for a decade.

The new study involved five people who got kidneys from parents or siblings who had slightly different tissue types from the patients. Since many kidney transplants are similarly mismatched, there is hope more people might one day be spared immune-suppressing drugs.

The breakthrough has changed the life of a Los Angeles man who was one of Sachs' patients.

Derek Besenfelder was born with a genetic kidney disease. After a year on dialysis, he decided to

enroll in the experiment and received a kidney and marrow transplant from his mother in 2005. He took anti-rejection pills for eight months, but then was weaned from them. He has been drug-free for two years.

"I wanted to be off the drugs as soon as possible. I had this huge bloated face and didn't feel comfortable going out in public," said Besenfelder, 28, who works as a communications director for a Beverly Hills plastic surgeon.

Doctors have experimented with giving marrow before, during or after organ transplants, while also tinkering with patients' immune systems to prime them to accept the new organs.

Sachs' treatment involved weakening each kidney patient's immune system with intravenous drugs several days before the transplant. After the transplant, the patient got an infusion of marrow from the donor to create a new immune system.

The stem cells from the marrow reprogram the body by allowing new immune cells to grow that don't try to attack the donated organ.

The patients took anti-rejection drugs but were weaned several months later.

Four of the five patients developed a hybrid immune system – where recipient and donor cells live together in the body – for a short time. They were able to stop taking anti-rejection drugs and had healthy kidney function two to five years later.

In the one case that failed, the patient had a second kidney transplant and has been on medications since.

Some researchers such as Ildstad believe the "home run" breakthrough will come when more people respond to the treatment and keep the mixed immune system permanently.

Transplant pioneer Dr. Thomas Starzl of the University of Pittsburgh said donor cells appeared to persist in the bodies of the successful transplant recipients even if those cells were not readily detected.

As promising as the treatment is, Sachs said it won't solve the country's organ shortage problem. Nearly 98,000 people are on the waiting list, according to the United Network for Organ Sharing.

The study was funded by the Immune Tolerance Network, an international consortium of federal and advocacy groups. Sachs plans a follow-up study involving 15 to 20 patients at Massachusetts General and other hospitals.

In the same issue of the *New England Journal*, Stanford University doctors reported successfully inducing tolerance to a donor organ in a man who was born with one kidney.

Larry Kowalski, now 50, received a matching kidney and marrow from his brother in 2005 and was weaned off drugs six months later. He has been off medications for two years.

Unlike the Massachusetts General cases, doctors said Kowalski has maintained an immune system from his own cells and his brother's. The research was funded by the National Heart, Lung and Blood Institute.

On the Net: *New England Journal of Medicine*: <http://www.nejm.org>

Teen takes on donor's immune system

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

By medical reporter Sophie Scott and staff reporters

A 15-year-old Australian liver transplant patient has defied modern medicine by taking on her donor's immune system.

Demi-Lee Brennan had a liver transplant after she suffered liver failure. Nine months later, doctors at Sydney's Westmead Children's Hospital were amazed to find the teenager's blood group had changed to the donor's blood type.

Further tests revealed the stem cells from the donor liver had penetrated her bone marrow.

Dr Michael Stormon says he and his colleagues were even more surprised when they found the girl's immune system had almost totally been replaced by that of the donor, meaning she no longer had to take anti-rejection drugs.

"We consulted widely throughout the hospital and then looked at the medical literature and consulted colleagues around the world to see if anyone had seen this kind of thing before," he said.

"No-one had, so we were stunned and amazed."

Dr Stormon says his team is now trying to identify how the phenomenon happened and whether it can be replicated.

"That's probably easier said than done... I think it's a long shot," he said. "I think it's a unique system of events whereby this happened.

"We postulate there's a number of different issues - the type of liver failure that she had, some of the drugs that we use early on to suppress the immune system and also that she suffered an infection with a virus called CMV, or cytomegalovirus, which can also suppress the immune system."

Anti-rejection drugs, known as immunosuppressants, have significant side effects, including serious infections and toxic effects on organs.

Dr Stormon says doctors are trying to identify which patients could come off the treatment.

"They may not, like Demi, change their blood group and change their whole immune system and

their bone marrow but there are a small percentage of patients who seem to get away with not needing immunosuppression," he said.

"But the difficulty is trying to identify which ones you should stop immunosuppression on because there's always that fear and risk that over many months or years, rejection can still occur."

The case has been published in the *New England Journal of Medicine*.

Blood bank bias: whose blood is it, anyway?

<http://www.bloggernews.net>

by Nancy Reyes

Sometimes political correctness seems to lack common sense, but reading this [article in the Seattle Post Intelligencer](#) has so many cliches and exaggerations it makes me think of one of the "drinking game" stories: Take a drink at every cliché, and see who gets drunk first.

The story is about screening donors for blood banks.

Certain diseases can be spread via blood transfusion, but since some of those diseases get missed on the tests, and some diseases are not tested for, and sometimes labs make errors, the rule is to screen out those who are at high risk at spreading disease via giving blood.

So since I lived for awhile in West Africa, I am ineligible to give blood. And since I had malaria, I have a second reason that I would not be allowed to give blood.

Diseases that can be spread via blood include HIV, Hepatitis C, Hepatitis B, Syphilis, CMV, HTLV I and II (which can cause leukemia), Chagas disease, Epstein Barr virus, West Nile Virus, acute bacterial infections, and some rare prion diseases.

Most of these diseases can only be spread during the acute infectious stage of the disease (such as West Nile Virus). But some of the diseases remain latent (hiding and not making the person sick) yet the virus will be present in the body. Examples of this are syphilis, some types of Malaria, HIV, and some Hepatitis B cases.

So, since I lived in West Africa, I'm on the "no donor" list. Smart move. I not only had Malaria (and hepatitis) but I did a lot of surgery and deliveries where my gloves broke.

Ah, but the article mentions but doesn't discuss me. Instead the article is framed to make donating blood a civil rights issue.

If I decide to have a risky behavior with someone who also has risky behavior, it doesn't matter: I have the right to donate blood, and how dare you be judgmental:

"It upsets me when I see signs that say, 'We need blood, give now,' but they don't want my blood," said Pete, 26, an office supervisor who lives in North Seattle. He was put on the deferral

list three years ago because he had sex with a man one time.

Ah yes. He only had sex with a man one time. Sounds like all the pregnant teenagers I see in my office who “only” had sex once...but can’t identify the father of their kid.

Even if this was true (and it could be...many heterosexual/bisexual men have had only one or two homosexual encounters, often when intoxicated), this allows one to overlook that the man he had sex with might have had sex with six men, or six hundred men and infected him...and it only takes one time...

Ah, but the article doesn’t stop whining there. It then goes on to another case: you need my blood because I have a rare blood type:

Kyros Starr, 38, called the ban “flat-out discrimination.” His blood type, O negative, is the universal donor — found in less than 5 percent of the population.”It frustrates me that I’m a universal donor and I can’t give,” said Starr, a former EMT and the son of a nurse. “They won’t take our blood. They think we’re disease carriers.”

Why, yes. I think you might be a disease carrier. You are a former EMT. Would you consider it discrimination to wear gloves to stop a person’s bleeding at a car wreck? Of course not. It’s common sense.

Let’s get sensible.

The US blood banks have saved thousands of lives.

But in the past, failure to screen behavior, and because they allowed buying blood from dubious sources, thousands have been infected not only with HIV but with hepatitis C.

Even before an HIV test was found, it was known that hepatitis B was widespread in some populations.

I’m old enough to remember when they stopped buying blood from anyone in the slums. Lots of drug addicts would give blood when they ran out of money, and we saw lots of hepatitis B cases...indeed, when I trained, hepatitis was considered an occupational hazard for surgeons. Then in the early 1970’s they stopped buying blood from prisons and high risk groups.

Later, there were Hepatitis B epidemics reported in sections of the gay community (indeed, the Hepatitis B vaccine was developed with the assistance of that community). Yet the US Red Cross didn’t bother to screen for such behavior until 1983...even though by the late 1970’s, it was suspected that this new disease in the gay community and another outbreak among IV drug abusers made epidemiologists suspect it could also be spread in the same way that Hepatitis B was spread: Via certain forms of sex and via IV drug use.

By 1983, the connection between HIV and gay sex was known even by the public, and many cases of HIV had already been spread via blood transfusions, and even more via contaminated plasma products, such as factor VIII given to hemophiliacs...

Tardiness in implementing these screening tests caused thousands of lives, not only from HIV but from Hepatitis C, which is found in IV drug abusers.

Canada, whose Hepatitis C scandal from contaminated plasma collected in [Arkansas prisons](#) made headlines, has a full time line [HERE](#) and [HERE](#). This scandal never got much attention in the US, probably because the then governor of Arkansas had become president of the US when the scandal broke out in Canada, but those of us who lived along the border were aware of the problem.

Finally, one important reason that the screening cannot be replaced by testing of blood is that HIV can remain undetectable in the blood, yet infectious for others, for several months.

So as a physician I find this statement ludicrous:

“Given modern testing and the fact that anyone can be vulnerable to infection, there is no medical or scientific rationale for this discriminatory policy,” said Joe Solmonese, president of the Human Rights Campaign.

Yes, given the fact that modern testing fails to detect the infection in many people, there is a very good medical and scientific rationale for this discriminatory policy, sir. It is a lie that “anyone can catch HIV”. No, you catch HIV in certain ways, and if you avoid these behaviors, you just don’t catch HIV.

So you can catch HIV without having sex or without injecting drugs, especially if you are a doctor or nurse or EMT treating an HIV positive person. But the rate of HIV among monogamous non drug using people is quite low statistically, and to pretend a promiscuous gay male is at the same risk of catching HIV as a lesbian or monogamous person is scientific nonsense.

But you are right: anyone can be vulnerable to infection. That’s why we screen blood: So that a four year old after a car wreck or a 72 year old monogamous grandmother can receive a blood transfusion without a high risk of infection.

Nancy Reyes is a retired physician living in the rural Philippines. Her website is [Finest Kind Clinic and Fishmarket](#).

Too few patients receive antivirals for chronic hepatitis

<http://www.bmj.com>

Antiviral therapy is approved by NICE but too few patients receive it

Editorials: Chronic hepatitis C

Hepatitis C infection is a treatable disease.¹ Generally, people with chronic hepatitis C are relatively asymptomatic but risk progression over time to cirrhosis and its complications. Combination antiviral therapy with pegylated interferon and ribavirin achieves sustained virological response rates of 42-80% depending on genotype.² In August 2006 the National

Institute for Health and Clinical Excellence (NICE) published updated guidelines for the management of patients with this infection.³ The guidance allows antiviral therapy for patients with hepatitis C viral RNA without the need for liver biopsy. This is a major change to the traditional practice of restricting treatment to patients with moderate or severe disease on liver biopsy.

Specialists in the field, who are keen to increase the uptake of treatment in eligible patients, will welcome the new guidance. However, they together with people infected with the virus and those who seek to deliver appropriate medical care will remain frustrated. Although the new guidelines will increase the number of people eligible for antiviral therapy, the broader public health and service provision issues associated with viral hepatitis have still not been recognised and tackled adequately.

Between 200 000 to 400 000 people are infected with hepatitis C virus in England and Wales.^{4 5} Lack of education in primary care physicians has meant that fewer than half of patients with antibodies to the virus are referred for specialist care.⁶ Even if patients are referred, specialist clinics are overburdened and antiviral therapy is often unavailable. In 2005 the Department of Health estimated that just 47 000 people had been diagnosed and only 7000 had been treated successfully.

What has been done so far to remedy this situation? In recognition of the importance of this virus as a public health issue the Department of Health released a hepatitis C strategy document for England in 2002.⁷ It recommended strategies to prevent and minimise harm, along with the implementation of clinical managed networks and specialist treatment centres. In 2004 an "action plan for hepatitis C" set out required actions for primary care trusts and National Health Service hospital trusts.⁴

In 2006 concern about the slow implementation of this action plan prompted the All Party Parliamentary Hepatology Group to audit hepatitis C healthcare provision in England.⁸ It found that only 8% of primary care trusts were approaching full implementation of the recommendations: only 33% had tried to estimate the number of cases in their area, 34% had a protocol for testing and screening, and 26% had protocols for monitoring treatment. In secondary care, 46% of clinics and hospitals reported considerable delays in starting antiviral therapy; the time to starting treatment varied from one week to one year. Reasons for delay included staff shortages, budget or contractual problems, and delays in accessing liver biopsy.

In a healthcare environment where financial pressures and short term targets are paramount, antiviral therapy (pegylated interferon and ribavirin) for hepatitis C virus might seem relatively expensive. The cost of treating one patient varies from £6000 to £8000 (9-12 000; \$12-16 000) per course in the United Kingdom. However, cases of compensated cirrhosis, decompensated cirrhosis, and hepatocellular cancer related to the virus more than doubled between 1995 and 2005 and are predicted to more than double again by 2015.⁵ Deaths from hepatitis C almost tripled from 1997/8 to 2004/5⁵ and hepatitis C is one of the most common indications for liver transplantation (UK Transplant, personal communication, 2006). Hepatitis C thus already places an important and increasing clinical and financial burden on the NHS.

At present service provision for viral hepatitis is piecemeal, disjointed, and poorly resourced.⁹

Knowledge within healthcare professionals remains suboptimal: 42% of primary care providers in East London were unaware that treatment for hepatitis C has good treatment outcomes.¹⁰ To change this will require a coordinated approach by primary care commissioners, primary care providers, and hepatology specialist services and must be based on an accurate assessment of local disease burden. In practice, this means improved knowledge at the primary care level and improved case ascertainment across a range of settings, including prisons.

Integrated primary and secondary care networks that provide counselling, appropriate testing, and seamless care pathways to specialist assessment and treatment should be established. Furthermore, innovative strategies and environments for service provision need to be examined for a population that does not always interface well with traditional models of health care. Incentives may need to be considered, given the considerable public health problems and disease burden surrounding viral hepatitis.

Hepatitis C is currently underdiagnosed and undertreated. Antiviral treatment is cost effective—it decreases the risk of progression and liver related complications.¹¹ Provision of adequate resources to fund NICE approved therapy, as well as the infrastructure to deliver it, merits a higher priority.

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Source: *BMJ* 2007;334:54-55 (13 January), doi:10.1136/bmj.39050.576644.80

January 25th, 2007

Body art draft ordinance draws public comments

<http://www.insidebayarea.com>

By Rachel Cohen , STAFF WRITER

Hepatitis C, unsterile equipment top list of concerns

SAN LORENZO — Proper sterilization and hepatitis C were among residents' top concerns about a draft ordinance on body art establishments at Wednesday's unincorporated services meeting.

The ordinance lays out physical, hygiene and health standards for tattooing and piercing businesses, said William Pitcher, Alameda County's environmental protection chief. It also specifies that clients of the businesses be required to give written consent.

The draft ordinance is modeled after Santa Clara County's because the state has lagged in setting regulations for the businesses.

"There's basically no oversight," Pitcher said. "We're bringing these businesses under county scrutiny and starting from scratch."

Practitioners now must prove they have tested negative for the blood-borne disease hepatitis B.

Jorge Goitia, senior environmental health specialist, told Wednesday's group, "Some of the practitioners will test the needle on themselves before they do it on you."

Under state confidentiality laws, the practitioner does not have to prove he or she does not have HIV/AIDS. Several audience members suggested the ordinance also require practitioners to prove they do not have hepatitis C.

Pitcher said the public health department was nervous about adding hepatitis C without proof it has been transferred with a tattoo needle.

"That may change tomorrow," he said.

The county's health officer, Dr. Anthony Iton, will be at the unincorporated services meeting next month to discuss hepatitis C.

San Lorenzo resident Kathy Martins questioned the sterilization procedures and businesses' sharing of body jewelry.

"I think these county ordinances can't be comprehensive enough," she said. "Because, you know, if you give someone an inch. ..."

Concerns such as these also will be revisited at next month's meeting.

"There are different ways of sterilization. It is kind of a technical problem for non-medical professionals," Pitcher added.

He later explained that the county's public health department is organized by funded programs. Once the ordinance passes and receives funding, then the department will investigate more how different facilities operate. Unincorporated Alameda County has eight tattoo businesses, and there are 60 to 70 countywide. Beauty parlors that apply permanent makeup likely will be added to the regulated businesses.

Pitcher said a full draft of the ordinance will be available on the county's environmental health Web site within a few days. The county plans to discuss the ordinance with all of the local city councils and bring it to the Board of Supervisors by April.

Reach Rachel Cohen at rcohen@bayareanewsgroup.com or 510-293-2463.

January 26th, 2007

A Shot at Curbing the AIDS Epidemic

By Julia Ewan -- *The Washington Post*
<http://www.washingtonpost.com>

Del. Eleanor Holmes Norton (D-D.C.) and Rep. Jose E. Serrano (D-N.Y.) should be congratulated for accomplishing last year what many said was impossible, repealing the federal ban prohibiting the District from spending its own money on syringe exchange programs to

reduce the spread of HIV-AIDS, hepatitis C and other infectious diseases. Because of their leadership, thousands of lives will be saved. If Congress takes the next step and repeals the national syringe ban, hundreds of thousands of lives could be saved.

Lifting the local funding ban could not have come at a more critical time. A D.C. government report released in November showed that Washington still has the highest HIV-AIDS rate in the nation. Nearly 21 percent of all cases of HIV transmission in the District are attributable to injection drug use.

The D.C. government recently announced that it will invest \$650,000 in needle exchange programs to combat the spread of HIV-AIDS [Metro, Jan. 3]. The city should be applauded for this move. It is a major investment toward the creation of a comprehensive continuum of care for drug users that includes getting people into drug treatment and linking them to medical care, rapid HIV counseling and testing, and a comprehensive medication adherence program.

Still, more needs to be done.

The District should amend its paraphernalia laws to make clean syringes more accessible through pharmacies, increase the number of beds in local detox centers, and increase the length of stay for drug treatment clients. District officials should also make good on their promise to improve HIV testing practices, counseling and comprehensive treatment for people in the D.C. jail.

As part of the national fight against AIDS, Congress should repeal the national funding ban that prohibits cities from using their share of federal AIDS prevention money on syringe exchange programs. According to the Centers for Disease Control and Prevention (CDC), of the 415,193 people reported to be living with AIDS in the United States at the end of 2004, about 30 percent of cases were related to injection drug use, either directly (sharing contaminated syringes) or indirectly (having sex with someone who used a contaminated syringe or being born to a mother who used a contaminated syringe).

The CDC, along with the American Medical Association and numerous other scientific bodies, contends that syringe exchange programs are highly effective at preventing the spread of HIV-AIDS and other infectious diseases. Moreover, seven federal reports have found that increasing access to sterile syringes saves lives without increasing drug use.

As many as 300,000 Americans could contract HIV-AIDS or hepatitis C over the next decade because of a lack of access to sterile syringes. This essentially makes the national syringe ban a death sentence for drug users, their partners and children. Members of Congress could spare their lives by repealing the ban. The question is, will they?

-- Naomi Long -- Bill Piper
Washington

The writers are, respectively, director of the Washington office and director of national affairs for the Drug Policy Alliance.