

# HCV ADVOCATE WEEKLY NEWS REVIEW

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

*Alan Franciscus  
Editor-in-Chief*

Week Ending: September 5, 2009

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August 30, 2009

### ***Blood racket: Contaminated blood could have caused Hepatitis***

<http://www.thaindian.com>

Lucknow, Aug 30 (IANS) More than a week after police busted a massive racket in adulterated blood in Uttar Pradesh, another report on the quality of blood seized reveals that it was infected with the highly contagious Hepatitis B and C virus - painting an alarming picture of the possibility of patients having contracted it.

The Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), in another report to the government Friday, said the Hepatitis virus strains were found in the adulterated blood. The

report was also submitted to the Food and Drug Administration (FDA), an FDA source said Sunday.

A detailed examination of the blood, seized by the authorities from a private nursing home run illegally by a government doctor had revealed that very poor quality blood with extremely low levels of haemoglobin was being supplied to patients in different hospitals.

Over a period of two years, 100,000 units of the contaminated blood were sold.

Uttar Pradesh Police arrested six people, including an anaesthetist from the state-run Balrampur Hospital, in connection with the racket on Aug 22. The racket was allegedly being run with the connivance of several well-known private blood banks and doctors.

“We have received the report but the details cannot be revealed now because it will be presented in the court as evidence against the accused on Monday,” FDA commissioner Lalit Verma told IANS.

The blood seized by the police with fake labels of the state’s largest blood bank at King George’s Medical College (KGMC) were sent for detailed examination to the SGPGIMS.

Earlier, a report by the SGPGIMS revealed that saline water was being mixed with the blood to increase its quantity, which led to further dilution of the already low haemoglobin level in the blood.

Lucknow Superintendent of Police (City) Paresh Pandey, who busted the racket, had initially said he suspected animal blood was being mixed with human blood. Later, it was found that the blood was being diluted with saline water.

Last week a joint team of the FDA and police raided a number of private hospitals and blood banks across the city and a show cause notice was served to three blood banks.

“Charak Pathology, Indira Diagnostic Centre and Kohli Blood Bank were found functioning without proper facilities of blood extraction and storage. They were also not having proper certificates,” an FDA official said.

The gang used to buy blood from professional donors like drug addicts, rickshaw pullers and beggars and would mix it with saline water to make three units from one unit of blood, police said. This was sold at Rs.1,000-1,500 per unit.

### ***Race not a factor in liver transplantation***

<http://www.reuters.com>

NEW YORK (Reuters Health) - Racial disparities exist in many areas of health care, from heart disease treatment to rates of surviving cancer. And studies have suggested that white patients do better than African Americans following liver transplants. But race may not play a role in survival after liver transplants for hepatitis B infection, nor while waiting for one, according to a new study.

But an expert in the field who was not involved in the study cautions that the number of African-Americans included in the study -- just 23, 17 of whom underwent transplantation -- is too small to conclude that there are no racial disparities in survival on the "wait list" or after transplant.

Up to 2 million Americans are infected with the hepatitis B virus (HBV), and liver disease due to HBV infection accounts for up to 10 percent of liver transplants.

Several studies found that Asians who underwent transplantation for HBV infection fared worse than whites, but there is little information available on how African-Americans do after transplant for HBV, or on wait list outcomes for Asians or African-Americans, Dr. Natalie Bzowej of California Pacific Medical Center in San Francisco and her colleagues note.

To investigate, Bzowej and her team looked at 274 patients awaiting liver transplants for HBV infection at 15 different US centers, including 116 whites, 135 Asians, and 23 African-Americans. All had gone on the United Network of Organ Sharing wait list between 1996 and 2005.

The researchers found no racial disparities in the probability that a patient would receive a transplant, or survive on the wait list. Five years after the transplant, 94 percent of African-Americans were alive, compared to 85 percent of Asian Americans and 89 percent of whites, they report in the journal *Liver Transplantation*.

The only factor associated with survival after transplant was whether or not a patient had recurrence of liver cancer, and recurrence of the disease was the same in the three racial groups.

But within four years of undergoing transplant, 19 percent of white patients had a recurrence of HBV, compared to 7 percent of Asians and 6 percent of blacks. Whether or not a patient's HBV returned after transplant didn't influence their survival after the procedure.

In an editorial accompanying the study, Dr. Charles D. Howell of the University of Maryland School of Medicine in Baltimore points out that a study looking at liver transplantation for HBV between 1997 and 2001 found that while whites and Asians had similar survival rates, survival was less likely for African Americans.

The current study, he argues, included too few African-Americans for "dependable conclusions" to be drawn about whether African-Americans fare worse -- or the same -- after liver transplant for HBV compared to other ethnic groups.

*SOURCE: Liver Transplantation, September 2009.*

**September 1, 2009**

### ***Men experience sexual dysfunction during hepatitis C therapy***

<http://www.eurekalert.org/>

Bethesda, MD (Sept. 1, 2009) — Sexual impairment is common among men with chronic hepatitis C undergoing antiviral therapy, according to a new study in *Gastroenterology*, the official journal of the American Gastroenterological Association (AGA) Institute.

This is the first time a study evaluating the combination therapy, peginterferon and ribavirin, has identified sexual dysfunction as a side effect. Sexual dysfunction and impairment of desire should be considered common side effects of combination antiviral therapy in men with hepatitis C. It has the potential to affect all three components of sexual health: desire, function and satisfaction.

Before therapy, 37 percent of men reported at least some degree of impairment in sexual desire, while 44 percent reported dissatisfaction with their sexual life. In addition, 22 percent reported impairment in erectile and 26 percent in ejaculatory function. The average onset of sexual dysfunction appeared to be within four weeks of starting antiviral therapy, and many patients reported a gradual worsening over time. At the end of therapy (24 or 48 weeks), an estimated 38 percent to 48 percent of men reported that overall sexual function was worse than before treatment. African Americans reported less impairment in sexual desire and satisfaction than Caucasian Americans during therapy. While most components of sexual health evaluated in this study resolved within six months after the cessation of therapy, erectile and ejaculatory function remained slightly worse than before therapy in a proportion of men who received a full 48 weeks of treatment.

As part of the Study of Viral Resistance to Antiviral Therapy of Chronic Hepatitis C (VIRAHEP-C), 260 men treated with peginterferon alfa-2a and ribavirin completed self-administered questionnaires concerning sexual desire, sexual function — including erectile and ejaculatory function — and sexual satisfaction before, during and after treatment.

Chronic hepatitis C affects 1 percent to 2 percent of the American population and is more common among African Americans than Caucasian Americans and other racial and ethnic groups in the U.S. While current therapies for hepatitis C are evolving, at present they remain only partially effective.

Though sexual function and health are important elements of quality of life and overall well-being, they are infrequently mentioned in the discussion of complications of therapy with peginterferon and ribavirin. In fact, most review articles on hepatitis C treatment, summary publications on the side effects of therapy and the package inserts for peginterferon do not mention sexual dysfunction as a potential complication of therapy.

For more information on viral hepatitis, visit the AGA patient center at [www.gastro.org/patient](http://www.gastro.org/patient) .

## ***HepCAware.org Partners with Kelly's Lot, Scott Detweiler and LABlues.org to Raise Awareness of Hepatitis C***

<http://www.prweb.com>

Malibu, CA (PRWEB) September 1, 2009 -- HepCAware.org, Roadhouse Rock & Blues band Kelly's Lot and New Orleans blues guitarist Scott Detweiler are teaming to bring a little heat to Malibu when they perform Sunday, Sept 6 (2-4:30pm) at the 26th Annual Kiwanis Chili Cook-Off.

They'll be bringing the blues, but also free Hepatitis C testing sponsored by HepCAware.org. HepCAware.org has also teamed up with the Los Angeles Blues Society (LABLUES.org) to



offer information at their booth at The Long Beach Blues Festival on Saturday and Sunday, Labor Day weekend at Rainbow Lagoon Park in Long Beach. LABlues.org founder Phil Gates offered their support after hearing about Malibu.

**What:** HepCAware.org to offer Hep C Testing and Info At 26th Annual Kiwanis Chili Cook-Off. (PLUS Awareness at Long Beach Blues Festival)

**Where:** Malibu Civic Center Drive At Pacific Coast Highway and Webb Way, Malibu CA

**When:** Labor Day Weekend Sunday, Sept., 6, (Testing from 11 a.m. - 3 p.m.)

Local favorite Kelly's Lot, just completing their newest CD, "Pastrami and Jam," has been performing at the Chili Cook-Off for five years running. This year Kelly, also the founder of HepCAware.org, asked event booking agent Paul Gallo if she could bring Hep C Awareness and testing to the annual Malibu event. Paul was happy to hear the offer and as she's done at many music events in the last 10 years, Kelly made it happen. "A spoon full of music helps the awareness go down" she likes to say. "Maybe in this case a spoon full of blues and chili"

To add to the Malibu excitement, Kelly enlisted cohort composer and performer Scott Detweiler. The celebrated Southerner has himself been a long-time HepCAware.org supporter, manning the testing van before hitting the stage, just as he'll do again in Malibu. Kelly's Lot aims to hit the stage at 2 p.m. with Detweiler following at 3:30, though the duo will offer free Hep C testing and information throughout the day on Sunday.

By teaming with the 26th Annual Kiwanis Chili Cook-Off and The L.A. Blues Society, Kelly hopes to help HepCAware.org increase awareness that will lead to more intense research on curing the disease and also help those infected learn how to best live with Hepatitis C. Hepatitis C has infected the lives of millions of Americans including Naomi Judd, Natalie Cole, Steven Tyler, Pamela Anderson and Mickey Mantle.

There is no vaccine for Hepatitis C. It is a virus that attacks the liver and is spread by blood-to-blood contact. Although 1 in 50 Americans have the disease, 2 out of 3 do not know it. Persons who most at risk include those who have received blood, blood products or an organ transplant prior to 1992; those who have been involved with drug abuse (either injecting or snorting); those who have been patients of dialysis, those who have been tattooed or pierced, shared personal care items, been incarcerated or have been a war veteran (especially Vietnam).

## ***Women, Blacks, Medicare Recipients Less Likely to Be Evaluated for Liver Transplantation***

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

Patient race, gender and insurance status influence decisions about who will go on to receive liver transplants, according to a University of Pittsburgh School of Medicine study. Available online and published in the September issue of the *American Journal of Transplantation*, the study indicates that women, blacks and patients with Medicare who are in end-stage liver disease are less likely to be referred and evaluated for liver transplantation.

"There currently is no comprehensive oversight of liver disease patients as they go through evaluation, referral and are put on a waitlist for transplantation," said Cindy L. Bryce, Ph.D., study lead author and associate professor of medicine, University of Pittsburgh. "We know what happens once patients are selected for transplantation since they are closely monitored, but what happens prior to this point is fairly invisible. Ours is the first major study to look at whether everyone with liver-related conditions has a fair shot of being considered for transplantation, and points out that many patients are being excluded from this process."

The study, which followed 144,507 patients hospitalized in Pennsylvania with liver-related conditions, sought to determine whether any potential barriers exist at the referral and listing steps in the transplantation process. Dr. Bryce and colleagues found that 4,361 of these patients underwent transplant evaluation. Of these, 3,071 were waitlisted and 1,537 went on to transplantation. Patients were significantly less likely to undergo evaluation, waitlisting and eventual transplantation if they were women, black or covered by Medicare.

Disparities were especially apparent in the early stages of the process when evaluation and listing occurs - 61 percent of men were evaluated for transplantation compared to 39 percent of women; 73.8 percent of whites were evaluated compared to 8.6 percent of blacks; and 62 percent of patients with commercial insurance were evaluated compared to 4.7 percent with Medicare only.

"While our study was not designed to identify causes for these disparities, current practices for identifying and referring liver disease patients for transplantation should be made more transparent," said Dr. Bryce. "Although we face a worsening gap in the supply and demand for organs for liver transplantation, race, gender and insurance status should not be factors that preclude patients from being evaluated for transplantation."

Co-authors of the study include Derek Angus, M.D., Robert Arnold, M.D., Chung-Chou Ho Chang, M.D., Max Farrell, B.S., and Mark S. Roberts, M.D., University of Pittsburgh School of Medicine; Cosme Manzarbeitia, M.D., and Ignazio Marino, M.D., Thomas Jefferson University.

The study was funded by the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health.

*Source: Clare Collins, University of Pittsburgh Schools of the Health Sciences*

**September 2, 2009**

## ***Mediterranean Diet Improves Glycemic Control in Patients with Type 2 Diabetes***

<http://firstwatch.jwatch.org>

A Mediterranean-style diet may be better than a low-fat diet for helping patients with type 2 diabetes delay treatment with antihyperglycemic drugs, reports *Annals of Internal Medicine*.

Italian researchers randomized some 200 overweight patients with newly diagnosed diabetes to either a Mediterranean-style diet (less than 50% of calories from carbohydrates) or a low-fat diet (less than 30% of calories from fat).

At 4 years, fewer patients on the Mediterranean diet than on the low-fat diet had HbA1c levels greater than 7%, thus requiring treatment with antihyperglycemic drugs (44% vs. 70%). The Mediterranean diet group also had a larger increase in insulin sensitivity, greater weight loss, and reduced coronary risk factors.

The authors say the Mediterranean diet's effects could be explained by the high consumption of monounsaturated fatty acids, which may increase insulin sensitivity. They conclude: "The findings reinforce the message that benefits of lifestyle interventions should not be overlooked."

## ***National Summit on Viral Hepatitis to be Held September 10-11 in Washington, D.C.***

<http://www.reuters.com>

*Politicians, Medical Experts and Community Advocates Will Gather for 2-Day Conference to Develop Action Plan to Combat Hepatitis B and C in the United States*

WHAT: Chronic viral hepatitis is a leading cause of liver cancer and cirrhosis that costs the nation's health system hundreds of millions of dollars each year, yet attracts little public attention. As many as 2 million people in the United States are living with chronic hepatitis B and an estimated 3.2 million are chronically infected with hepatitis C. However, most do not even know they are infected and miss out on getting early medical care, putting them at increased risk for developing serious liver disease.

To address this public health challenge, government, medical and community experts will meet September 10-11 in Washington, D.C. to plan an improved national response to viral hepatitis. The conference "The Dawn of a New Era: Transforming our Domestic Response to Hepatitis B & C" will feature keynote addresses, panel discussions and scientific poster sessions focused on enhancing the prevention and detection of viral hepatitis and improving care for people who are already living with the disease.

Journalists are encouraged to participate in all aspects of the summit, and will enjoy unprecedented access to leading experts on viral hepatitis. A press room will be available.

WHO: Speakers include:

- John W. Ward, MD, Director, U.S. Centers for Disease Control and Prevention (CDC) Division of Viral Hepatitis
- Congressman Mike Honda (D-CA), Chair, Congressional Asian Pacific American Caucus
- Congressman Bill Cassidy, MD (R-LA), Gastroenterologist and Associate Professor of Medicine, Louisiana State University Health Sciences Center
- Anna S.F. Lok, MD, Director of Clinical Hepatology, University of Michigan
- Eugene R. Schiff, MD, Director, Center for Liver Diseases, University of Miami School of Medicine
- Ronald O. Valdiserri, MD, MPH, U.S. Department of Veterans Affairs
- Jeff Caballero, Executive Director, Association of Asian Pacific Community Health Organizations

Sponsors and supporters of the summit meeting include the Centers for Disease Control and Prevention (CDC), the National Institute of Allergy and Infectious Diseases, the American Gastroenterological Association's AGA Institute, the U.S. Department of Veterans Affairs, Gilead Sciences, Bristol-Myers Squibb and Vertex Pharmaceuticals.

WHEN: September 10-11, 2009

(Opening Keynote Address begins at 8 A.M. on Thursday, September 10)

WHERE: Washington Marriott Wardman Park Hotel 2660 Woodley Road NW (between 27th St. and Connecticut Ave) Washington, DC 20008

RSVP: Registration is free for media. To register for the conference, to schedule interviews or for more information please contact:

Lauren Graham

(212) 584-5015

[lgraham@corkerygroup.com](mailto:lgraham@corkerygroup.com)

*SOURCE The Dawn of a New Era: Transforming our Domestic Response to Hepatitis B & C*

## **Medtronic Initiates Phase II Hepatitis C Clinical Study "COPE-HCV" to Determine Tolerability and Safety of Continuous Interferon Infusion for Patients with HCV**

<http://www.marketwatch.com>

*Medtronic Paradigm(R) Pump Infusion System and CareLink(TM) Clinical Monitoring System Used to Study the Continuous Delivery of INTRON A in Previously Untreated Genotype 1 Patients*

MINNEAPOLIS, Sep 02, 2009 (BUSINESS WIRE) -- Medtronic, Inc., today reported the initiation and first enrollments of patients in COPE-HCV (CONTinuous Interferon Delivery via the Medtronic Paradigm Pump Infusion System Clinical Evaluation for Chronic HCV), the company's first-ever clinical study using an external pump infusion system to treat patients with the hepatitis C virus (HCV). The COPE-HCV trial is being conducted under an Investigational New Drug Application (IND).

COPE-HCV is a Phase II, 250-plus patient study designed to gather clinical data on the tolerability, safety and efficacy associated with continuous subcutaneous interferon infusion compared with the current standard-of-care in patients with HCV genotype 1 infection not previously treated. In the first month of the U.S. study, 20 patients have been enrolled at six clinical sites in Nashville, Minneapolis, Atlanta, San Antonio, and Sarasota, Fla. Stage 1 of this randomized controlled study will include 124 patients at up to 30 sites.

"For years Medtronic has developed drug-delivery systems to bypass traditional but less effective routes of administration and to help patients with chronic diseases better manage their conditions," said Bill Hawkins, Medtronic chairman and CEO. "With this trial now underway,

we have the potential to extend our pump technologies and develop yet another drug-delivery option for a chronic disease that impacts millions of lives. If successful, this novel therapy will open new doors to treating other advanced diseases more safely and effectively than currently available approaches."

The World Health Organization has estimated that three to four million people become infected by HCV each year and 70 percent of those infected will develop chronic hepatitis. Standard-of-care for HCV is weekly injections of pegylated interferon in combination with oral ribavirin medication for up to 48 weeks. This therapy is only effective in treating approximately 43 percent of all genotype 1 patients, who represent the overwhelming majority of U.S. hepatitis C cases. In addition, many patients develop serious side effects from weekly injections, including chronic fatigue, depression, blood disorders, and flu-like symptoms.

"There are a host of challenges related to the treatment of HCV that, to this point, have resulted in less than optimal outcomes and therefore patients are at a greater risk for developing progressive liver disease," said Dr. John McHutchison, associate director of the Duke Clinical University Research Institute (DCRI) and lead investigator of the Medtronic-sponsored study. "However, the innovative strategy that will be studied in the COPE HCV study may ultimately be shown to improve both efficacy and tolerability over currently available drug formulations."

The COPE-HCV study uses the Medtronic Paradigm Infusion System, a device currently approved by the U.S. Food and Drug Administration for delivering insulin in patients with diabetes. It also incorporates the use of Medtronic's CareLink remote data management system to ensure patients enrolled in the study are compliant to study protocol for the trial period. The COPE-HCV study will deliver INTRON(R) A, via the Paradigm pump in combination with oral REBETOL(R). The comparison group in the study will use PegIntron(TM) and REBETOL. All drugs in the trial are manufactured and marketed by Schering-Plough.

**About Medtronic Drug-Device Delivery Innovations** A pioneer of drug delivery systems, Medtronic recently announced new developments in its long-standing goal to create a "closed-loop" diabetes management system designed to closely mimic the insulin delivery of a normal pancreas. In addition, the company provides its SynchroMed(R) II implantable, drug infusion system for the treatment of chronic, intractable pain, or to deliver ITB Therapy(SM) (Intrathecal Baclofen Therapy) to treat severe spasticity related to brain injury, cerebral palsy, multiple sclerosis, spinal cord injury, or stroke.

**About Hepatitis C** 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.

### **About Medtronic**

Medtronic, Inc. ([www.medtronic.com](http://www.medtronic.com)), headquartered in Minneapolis, is the global leader in medical technology -- alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's Annual Report on Form 10-K for the year ended April 24, 2009. Actual results may differ materially from anticipated results.

September 3, 2009

## **SSD Disability: Applying for Social Security Disability and Hepatitis**

<http://www.disabilitysecrets.com>

Here's an excerpt from the page on Disability Secrets that discusses the disability approval criteria established in the blue book (the social security manual that provides specific criteria for a number of medical impairments, though certainly not all impairments) for hepatitis. As always, of course, it should be noted that most applicants for SSD and SSI benefits who are approved are not approved on the basis of a listing. Most approved applicants are actually awarded benefits after an evaluation of their medical history and work history demonstrates that they do not have the capacity to work and earn what is considered by the social security administration to be a substantial and gainful income.

Now, here that's excerpt of the hepatitis page and the link that leads to the full page.

*You could be awarded Social Security Disability (SSD) or SSI on the basis of hepatitis by meeting the listing for hepatitis in the official Social Security disability list of impairments. Hepatitis is listed in the blue book under the section dealing with the digestive system.*

The rest of the page can be viewed at this link: [Social Security Disability and hepatitis](#)

### **Other pages that discuss hepatitis:**

#### 1. [Is hepatitis C a disability?](#)

**Excerpt:** "Hepatitis C is a disease caused by the Hepatitis C Virus (HCV), which can lead to severe liver damage. Often people with hepatitis C are not aware that they have the disease, as it typically operates silently in the body for some time without manifesting any particular symptoms"

#### 2. [Disability and hepatitis](#)

**Excerpt:** "Chronic hepatitis C may lead to cirrhosis of the liver or cancer of the liver. Left untreated, two-thirds of those with hepatitis C will develop cirrhosis"

#### 3. [Hepatitis Information](#)

**Excerpt:** "Hepatitis is caused by bacterial or viral infection, drugs (including alcohol), toxins, or parasites. It is most commonly caused by one of three viruses: the hepatitis A virus (HAV), the hepatitis B virus (HBV), or the hepatitis C virus (HCV)"

#### 4. [What Causes Cirrhosis?](#)

**Excerpt:** "Cirrhosis of the liver can also be caused by hepatitis B and C, and nonalcoholic fatty liver disease (NAFLD). Twenty percent of the 4 million Americans with hepatitis C develop cirrhosis of the liver"

See also

[A Guide to Hepatitis and Disability, by Jacques Chambers, CLU](#)

## ***NY may tighten review of inmate HIV/hepatitis care***

<http://www.newsday.com>

Jessica M. Pasko (Associated Press Writer)

ALBANY, N.Y. (AP) — A bill pending before Gov. David Paterson would direct the New York State Health Department to monitor the care of state and local prisoners with the AIDS virus or hepatitis C, a move supporters say is long overdue.

The measure would require the department to conduct annual reviews of the treatment of HIV and hepatitis C in state and local correctional facilities. The agency also would mandate necessary changes and release annual reports on its findings.

If Paterson signs the bill, monitoring state prisons would begin immediately, with oversight of local jails starting in two years.

Currently, the state Department of Correctional Services monitors the health care it provides inmates, conducts audits and assesses each prison's compliance with treatment guidelines. Local jails are governed at the local level with little state oversight.

Morgan Hook, a spokesman for the governor, said Paterson would review the bill and seek information from the agencies before making a decision.

U.S. Department of Justice statistics show that New York has had one of the highest populations of HIV-positive inmates for the past several years. About 3,100 inmates in New York are HIV positive and roughly 7,000 have hepatitis C. The state's total prison population is around 59,400.

Advocates say that although state prison officials have significantly improved care in recent years, widespread inconsistencies in the quality of treatment at the different prisons and jails still exist. They say the care of inmates with these illnesses becomes a health issue that goes beyond prison walls when these prisoners are released back into their communities.

Sen. Thomas Duane of Manhattan, the bill sponsor, said that if the bill becomes law, it would make New York a leader in addressing the spread of HIV and hepatitis C.

"This is not meant to be punitive, but if there are problems, let's make sure we know in a timely manner so we can rectify it," Duane said.

Legislated oversight of such care in prisons is rare. Neither the National Commission on Correctional Health Care nor the American Civil Liberties Union National Prison Project could recall any other state that has legislated monitoring and oversight by a health department. In response to a lawsuit over problems in California prisons, a nonprofit organization — California Prison Health Care Receivership Corp. — was created in 2005 to monitor and oversee the medical system in that state.

Corrections department spokesman Erik Kriss said the department wouldn't comment on the measure while the governor is reviewing it. The health department also declined to comment.

Kriss noted that the rate of HIV and hepatitis infection is higher in the prison system than in the general population largely because drug offenders and users tend to have higher rates of both diseases. He said the death rate for prisoners with HIV has fallen dramatically — 95 percent — since 1996, with about 60 deaths in 2008.

## ***More drug firms doing follow-ups than thought—FDA***

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

WASHINGTON (Reuters) - More pharmaceutical companies have completed studies required by U.S. health regulators after their products were allowed on the market than previously thought, according to an analysis released on Thursday.

But the study found that FDA database errors had obscured the issue, and critics said the post-approval studies, even when completed, still did not necessarily provide useful long-term information about the safety and effectiveness of the drugs.

Often, the Food and Drug Administration approves drugs and devices for sale on condition that companies keep studying the products for possible additional side effects or other issues.

For years, critics lamented such approvals because the FDA could only request more studies, but could not order them. The critics say companies had little incentive to do the studies once they won approval.

A 2007 law gave the agency more power to require the follow-up studies and ordered the analysis, which found more drug companies than previously thought had completed their studies. Results of the audit by Booz Allen Hamilton Inc were given to the FDA.

"Most companies are doing these studies and they are submitting the reports," said Dr. John Jenkins, director of the FDA's Office of New Drugs.

The audit found that of the backlog of 1,531 pending studies, about one-third, or 501, were actually completed, Jenkins told reporters in a conference call. The rest are in various stages of completion.

Still, Jenkins said that while 6 percent of the studies previously were considered delayed, the review found 15 percent were actually delayed.

Jenkins said the review, which did not look at devices, found that the agency had a number of problems in the database it uses to track such studies.

The report also found that while FDA is supposed to review submitted studies within a year, it only met that goal 23 percent of the time.

A recent infusion of funding from Congress should help alleviate that problem with extra staff, Jenkins said.

The audit found that most companies "take their obligations to conduct and complete ... (studies)

in a timely matter very seriously," Jenkins said. "That fact was obscured in the past by inaccuracies in the FDA database, which led to criticisms that both industry and FDA and were not doing enough to ensure these studies were completed in a timely manner."

But Diana Zuckerman, president of the advocacy group National Research Center for Women & Families, said even if companies finish such studies, the results don't necessarily provide useful information. She said patients are not necessarily tracked as well as in trials done before approval.

"I've repeatedly seen longitudinal studies where more than half the patients have dropped out and nobody knows if they are alive or dead, healthy or sick," she said. "So, the studies might be completed, and might be on time, but might not provide useful information on safety or effectiveness -- which is what post-market studies are supposed to do."

Peter Lurie, Public Citizen's Health Research Group deputy director, said the FDA's database is scrubbed each year, making it impossible to do any long-term analysis on how companies and the FDA are faring over time.

The Pharmaceutical Research & Manufacturers of America and the Biotechnology Industry Organization, industry groups that represent drugmakers, both welcomed the findings, which were posted on the FDA's website here

(Reporting by Susan Heavey; Editing by Gary Hill)

## ***Antioxidant pills do not prevent metabolic syndrome***

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

By Amy Norton

NEW YORK (Reuters Health) - People who want to forestall heart disease and diabetes may do better by choosing antioxidant-rich foods instead of antioxidant supplements, a new study suggests.

Researchers found that among more than 5,200 middle-aged adults, antioxidant supplements had no effect on the risk of developing metabolic syndrome over seven-plus years.

Metabolic syndrome refers to a collection of risk factors for type 2 diabetes, heart disease and stroke -- including high blood pressure, abdominal obesity, low levels of "good" HDL cholesterol, elevated triglycerides and high blood sugar. The condition is diagnosed when a person has at least three of those risk factors.

The current findings, reported in the American Journal of Clinical Nutrition, suggest that taking antioxidants in capsule form may not thwart metabolic syndrome.

On the other hand, men and women who began the study with relatively high blood levels of certain antioxidants -- particularly vitamin C and beta-carotene -- were less likely than those with lower levels to develop metabolic syndrome.

The implication is that even though antioxidant supplements might not cut the risk of metabolic syndrome, antioxidant-rich foods just might, according to the researchers, led by Dr. Sebastien Czernichow of the French national research institute INSERM, in Paris.

Blood levels of vitamin C and beta-carotene are "rather good surrogate markers" of people's fruit and vegetable intake, Czernichow told Reuters Health in an email.

"This reinforces the guidelines for an adequate intake of this food group and goes against the regular use of antioxidant pills," he said.

The study included 5,220 adults with an average age of 49 who were randomly assigned to take either a mix of vitamins C and E, beta-carotene, selenium and zinc in capsule form or inactive placebo capsules.

After an average of 7.5 years, 263 study participants had been diagnosed with metabolic syndrome. There was no significant difference in risk between the supplement and placebo groups.

There were differences, though, when the researchers looked at participants' antioxidant blood levels at the study's outset. The one-third with the highest vitamin C levels had about half the risk of metabolic syndrome as those with the lowest levels.

Similarly, the third with the highest beta-carotene levels had only one-third of the risk of metabolic syndrome as those with the lowest beta-carotene concentrations.

In contrast, higher zinc levels in the blood were linked to an increased risk of metabolic syndrome. It's not clear why this is, but the researchers speculate that high zinc levels might, in some people, reflect heavy consumption of red meat -- one of the prime food sources of the mineral.

Good food sources of vitamin C include citrus fruits, strawberries and cantaloupe, and vegetables such as red peppers, broccoli and tomatoes.

Beta-carotene, which is converted in the body into vitamin A, is found in foods such as carrots and sweet potatoes, and leafy greens like spinach and kale.

*SOURCE: American Journal of Clinical Nutrition, August 2009.*