

# HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Editor-in-Chief*

Week Ending: August 30, 2008

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Aug 24, 2008

## ***Silymarin Prevents Antituberculosis Drug-Related Hepatotoxicity in Rats***

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

NEW YORK (Reuters Health) Aug 22 - Silymarin, an extract from milk thistle, protects rats from the hepatotoxic effects of antituberculosis drugs, according to a new report.

Several herbal drugs, including silymarin, have been shown to prevent or reduce the hepatotoxicity of individual antituberculosis drugs without interfering with their therapeutic actions, the authors explain.

Dr. Sude Eminzade from Marmara University, Istanbul, Turkey and colleagues investigated the hepatoprotective effects of silymarin in rats treated with two different combinations of antituberculosis drugs (isoniazid, rifampicin, and pyrazinamide). Treatment with combinations of these drugs caused a two-fold increase in serum ALT levels and a 75% increase in AST and ALP levels, the authors report.

These combinations also caused significant decreases in serum albumin and total protein concentrations and a two-fold increase in total bilirubin levels.

Simultaneous intra-gastric administration of silymarin with the antituberculosis drug combinations significantly decreased serum enzyme activities, increased the serum albumin and total protein concentrations, and decreased serum total bilirubin levels compared with the rats that received drugs only, the researchers note.

Silymarin administration was associated with a decreased frequency and severity of both steatosis and patchy necrosis, compared with the antituberculosis drug-only groups, the investigators report in the July issue of *Nutrition & Metabolism*.

"This study showed that silymarin has a significant protective action against the hepatotoxicity induced by the drugs used in the treatment of tuberculosis," the authors conclude. "High-quality, placebo-controlled randomized trials need to be conducted before silymarin or its constituents can be advocated as a medicine for use in humans."

*Nutr Metab* 2008;5:18.

Aug 25, 2008

## ***Delays, denials thwart patients hoping for help***

<http://toledoblade.com>

By STEVE EDER

BLADE STAFF WRITER

*Second of four parts*

OAK HARBOR, Ohio — Randy Steele was running out of options.

Mr. Steele, 64, of Oak Harbor shuffled back and forth between hospitals in northern Ohio last year as physicians scrambled to stay ahead of the hepatitis C virus invading his body and slowly threatening his liver and kidneys.

His prognosis seemed grim.

He was referred to the renowned specialists of the Cleveland Clinic to offer him a second opinion on a potentially life-saving kidney-liver transplant.

Cleveland Clinic quickly fit Mr. Steele onto its schedule. But instead, his appointment was canceled and he waited weeks to learn if his insurer would pay for his evaluation at the clinic, which was outside the network for his health plan.

“I truly believe that Randy could have been helped,” Mr. Steele’s wife, Pam, told The Blade.

Mr. Steele, like many patients across the country, was the victim of a complex health-care bureaucracy and an insurance industry that repeatedly denies doctors’ orders — leaving patients bewildered and suffering.

Others such as Bill Hodnik, 41, endured the same shortcomings.

He suffered months of pain while his insurer delayed and denied coverage for a surgery ordered by his physician.

A herniated disc in Mr. Hodnik’s neck sent numbing shivers down his left arm, rendering it useless. For years, back problems bothered Mr. Hodnik, a factory worker living in suburban Cleveland, but last year the pain intensified.

Mr. Hodnik’s physician told him the optimal solution to his problems would be cutting-edge artificial disc replacement surgery, rather than a more traditional spinal-fusion operation, which sometimes leads to additional operations.

“We don’t know how long we are going to live or what I am going to be like in 40 years, but he said the artificial disc was a much better choice than the fusion, and it would be a lot better for you in the long run,” Mr. Hodnik said. “I was all for it.”

The surgery was scheduled, but he never underwent the procedure. After months of repeated delays and denials from his insurer, and with his disability insurance running out, Mr. Hodnik needed to return to work, and so — against doctor’s orders — he settled on fusion surgery.

### **An emerging crisis**

A Blade investigation shows that doctors nationwide believe there is an emerging crisis in providing health care to their patients because insurers routinely challenge their orders.

The investigation included interviews with about 100 physicians and an online survey of members of the Ohio State Medical Association and American Medical Association.

The Blade prepared the survey questions, which the associations sent to their members.

Of the 920 respondents, more than 99 percent said insurers had interfered with their clinical decisions.

Doctors said patients usually receive the therapy, testing, medication, or procedure prescribed for them. But too often, physicians said, there's a lapse in time between the office visit and when the care or test is delivered because of interference by insurers.

And 14 percent of the respondents to the nonscientific survey said they have had a patient seriously injured or harmed because of interference with their clinical decisions.

### **A grim prognosis**

Randy and Pam Steele live on two acres in Ottawa County, a 45-minute drive from Toledo. Their home is brightened by four children and three dogs roaming about the house and yard.

The Steeles, who homeschool their children, have a classroom on the main floor of their home that converts into a hospital ward for Mr. Steele when he is too sick to walk upstairs.

The Steeles have a big family, with 11 children, all from past marriages or through adoptions. Of the 11, seven are grown — including adopted triplets and three sons who have served in the U.S. military in the Middle East, with two in Iraq.

Four of the children live at the Steeles' house in Oak Harbor, including Thomas and Brandon, who are foster children, and Celeste, an adopted child from Mexico.

A former Mormon minister in Lima, Ohio, Mr. Steele received his master's degree in engineering from Ohio State University in 1973. During his engineering career, Mr. Steele helped BP set its safety specifications.

Mr. Steele, later an engineer at the Sunoco Toledo Refinery, has battled illness since childhood. He suffered with rheumatic fever in his youth, and the fever affected his heart, requiring valve-replacement operations in the late 1960s and again in the 1980s.

In 2001, doctors diagnosed Mr. Steele with hepatitis C, an often-deadly disease that destroys the patient's liver. Mr. Steele likely contracted the virus through a tainted blood transfusion he received during his first heart-valve replacement operation, when blood wasn't routinely tested.

Under treatment for hepatitis C, Mr. Steele worked until September, 2006, when he became too ill to continue.

Mr. Steele has spent much of the past two years in hospitals or tethered to dialysis machines, defying predictions of his death, or prognoses that he would never walk again or would survive only in a vegetative state.

In July, 2007, Mr. Steele spent weeks in intensive care with his kidneys failing at the University of Toledo Medical Center, formerly known as the Medical College of Ohio hospital.

Mrs. Steele said a doctor and a social worker at the hospital told her that her husband's insurer, Medical Mutual of Ohio, was pressuring the hospital to discharge her husband as his medical bills mounted.

Paula Sauer, vice president of care management for Medical Mutual, said the entire stay at University of Toledo Medical was approved and she couldn't comment on what hospital personnel specifically told Mrs. Steele.

"There's no reason that anybody should be told that the insurer is kicking the [patient] out," Ms. Sauer said. "The physician needs to make his medical and legal, ethical, clinical decision and follow what he is liable for. I'm not sure why they felt this way."

Within a few days of Mr. Steele leaving the hospital, his kidneys shut down, indefinitely landing him on dialysis treatments three times each week.

He quickly returned to the University of Toledo Medical Center and later to University Hospitals Case Medical Center in Cleveland, where he was evaluated for a kidney-liver transplant.

If successful, a transplant could have extended Mr. Steele's life, but without the transplant, doctors told him he had weeks or months to live.

#### **A second opinion?**

After examining Mr. Steele, University Hospitals' transplant team reported that it couldn't offer him a kidney-liver transplant because of concerns that his damaged heart would diminish the likelihood he would survive the operation and thrive afterward, said Dr. Pierre Gholam, a transplant specialist.

Dr. Gholam referred Mr. Steele to the Cleveland Clinic for a second opinion with the hope that the clinic, with its expert cardiovascular care, could overcome the complications presented by his weakened heart and perform a transplant.

Dr. Gholam told The Blade that he recalled telling the Steeles that "even though our assessment here is that we don't feel we can do this in a way that's safe for him, the Cleveland Clinic has a pretty renowned cardiothoracic and cardiovascular program and perhaps they can offer him additional things that we may not be able to offer him."

He added, "I wasn't certain that was the case, but I thought he was someone that had a good quality of life who certainly had a family that wanted him to be around and have additional quantity of life."

Dr. Gholam wasn't overly optimistic the Cleveland Clinic would be able to offer Mr. Steele a transplant. "But for his peace of mind and for the peace of mind of his wife, I think he needed to hear that and he needed to have a second shot at this, which was legitimate," the transplant specialist said.

Cleveland Clinic placed Mr. Steele on its schedule to begin his evaluation for a kidney-liver transplant Sept. 27, 2007. But two days before the appointment, the Cleveland Clinic notified

Mr. Steele that Medical Mutual wouldn't cover his second opinion because the clinic isn't part of his health plan's network.

Mr. Steele's doctor quickly wrote a letter to Medical Mutual explaining why Mr. Steele should be covered for the consultation with Cleveland Clinic.

Medical Mutual's Ms. Sauer told The Blade that Mr. Steele's second opinion was approved for coverage the same day he was to meet with the transplant team at the Cleveland Clinic. The next day, she said, Medical Mutual mailed a letter to the Steeles notifying them of the decision.

But the letter states: "All services should be performed within the network."

The letter continued, "Please be advised that utilizing a provider outside of the network/first tier may result in additional financial liability and if you use a non-contracting provider, you may be financially responsible for the difference between the provider's charged amount and the contractual amount."

The letter, which was copied to the Cleveland Clinic and Mr. Steele's primary care physician, not Dr. Gholam, directed the patient to customer service for questions.

For Mrs. Steele, the letter raised more questions than answers, so she called Medical Mutual to find out more.

"When I called Medical Mutual, they said that Cleveland Clinic was not in the network for our policy. I did call to check it because it was so important," Mrs. Steele said, adding, "Knowing just a basic transplant for Randy would be \$500,000, there would be no way I could handle the liability."

Mrs. Steele, frustration growing, e-mailed friends and family.

"We still have not been able to go to Cleveland Clinic although they wanted to see us last week," Mrs. Steele wrote on Sept. 30. "We continue to pray that God opens a door. Our transplant team from [University Hospitals] has challenged the medical insurance company and only time will tell."

A week later, on Oct. 8, Mrs. Steele wrote again, enlisting friends and family members to seek intervention by state and federal lawmakers, including U.S. Rep. Marcy Kaptur (D., Toledo). A family friend scripted a template for a letter-writing campaign to officeholders and the media.

"The family is suffering a dangerous waiting game because of the bureaucracy of their HMO," the form letter stated. "This seems to be a case of bureaucrats [not his medical team] making a decision on whether to operate on a man when he has no time for games."

On Oct. 9, Cleveland Clinic learned by phone that Medical Mutual would cover Mr. Steele's second opinion, clinic spokesman Heather Phillips said. The clinic again fit Mr. Steele into its schedule, this time for the week of Oct. 22 — nearly a month after his original appointment.

### **A disappointing process**

As Dr. Gholam feared, Mr. Steele's visit to Cleveland Clinic yielded no life-saving answers.

After weeks of testing, a team of specialists determined Mr. Steele would not be a candidate for the transplant because he had too many factors working against him. The clinic's team didn't believe the lag between his initial appointment and his actual evaluation made a difference in Mr. Steele's final determination, Ms. Phillips said. But the Steeles still wonder if the results would have been different had her husband been able to keep his original appointment.

"I felt like I was being cheated an opportunity of being able to determine if I was going to be able to have a transplant or not," Mr. Steele said.

Mrs. Steele fears her husband's insurance plan worked against him when he needed it most.

"I truly believe the insurance companies have created a situation that has not been in Randy's best interest," she said.

### **A painful experience**

Like millions of Americans, Bill Hodnik is no stranger to back pain.

His father and sister both underwent lower back operations. In the late 1990s, a doctor diagnosed Mr. Hodnik with degenerative disc disease, which commonly causes neck and back pain.

By March, 2007, Mr. Hodnik's lower back condition worsened to the point that his left leg went numb and he was transported by ambulance to the hospital, where Dr. David Hart, the director of the Neurosurgery Spine Center of the Neurological Institute of University Hospitals Case Medical Center, performed surgery to clean up a herniated disc in his lower back in May.

"Over the course of my life, probably playing softball, bowling, working, I herniated a disc," Mr. Hodnik said.

A few months later, after returning to work, Mr. Hodnik began feeling numbness and slight pain in his neck and shoulder. He assumed he had pulled a muscle in his shoulder and treated his discomfort with over-the-counter pain medication.

"One day, the numbness just went right down my arm," said Mr. Hodnik, who returned to Dr. Hart's office, this time with neck pain and numbness. Magnetic resonance imaging soon showed that a herniated disc was pushing up against Mr. Hodnik's spinal cord, causing his arm to go numb.

In the past, Mr. Hodnik's condition would be addressed with a spinal fusion surgery, an operation in which two or more vertebrae are fused together. The operation has its drawbacks, especially for young patients, because it places pressure on surrounding discs, sometimes requiring follow-up procedures.

Considering his age and overall good health, Mr. Hodnik said Dr. Hart told him he would be an ideal candidate to have an operation to replace his herniated disc with an artificial cervical disc, approved by the Food and Drug Administration in July, 2007. The FDA began approving artificial discs for other parts of the back in 2004.

“This is a revolutionary kind of technology that allows a person to avoid having their spine fused, instead having essentially a mechanical disc placed,” Dr. Hart said.

“What we used to do ... [is] fuse the vertebrae together. That has significant consequences for the patient both in the long term and the short term.”

Mr. Hodnik was scheduled for artificial disc replacement surgery on Oct. 24, but the night before the operation, he heard from the hospital that the surgery couldn't be performed because his insurer wouldn't approve it.

A week later, Mr. Hodnik received a notice in the mail from his insurer, UnitedHealth Group Inc., stating that the surgery wasn't covered because of a lack of study to prove its merits.

### **'The jury is still out'**

UnitedHealth, the nation's largest insurer, declined to comment on why it rejected the doctor's recommendation for Mr. Hodnik's surgery, saying it does not comment on specific patient cases.

Generally, though, the company doesn't cover unproven services, such as disc replacement surgery, said Dr. Dick Justman, UnitedHealth's national medical director.

So far, studies comparing disc replacement and fusion surgeries have been among small groups of patients, and researchers have only looked at results after two years, Dr. Justman said. More evidence about disc replacement is needed to ensure it is a good alternative to fusion surgery, which does have drawbacks, he said.

“We will be very happy to see any alternative to [fusion] surgery come forward,” Dr. Justman said.

“In a situation such as this, the jury is still out,” he added. “The studies are simply too small, and they have not gone out far enough. We are eager to see this research go out a few more years.”

### **A denial of treatment**

In mid-November, Dr. Hart appealed UnitedHealth's initial decision with hopes of getting a prompt final resolution for Mr. Hodnik. But the process dragged on for two more months as Mr. Hodnik struggled to get a final answer from his insurer.

In the meantime, Mr. Hodnik's disability insurance was running out and the constant pain was taking a toll on his marriage and his family. Mr. Hodnik has two young children — a 4-year-old and a 2-year-old.

“Imagine taking care of those two with no use of your left arm, being in pain, and you can't sleep,” Mr. Hodnik said.

“Did it put a strain on the family? Yeah it did. It put a lot of strain between me and my wife. I don't mind taking care of the kids, but when you have no use of your left arm, you are taking pain medication just so you can move your arm a little bit, but you still can't play with your kids.”

By January, Mr. Hodnik said he called UnitedHealth about every other day to check on his appeal, often hearing contradicting reports on its status, including once mistakenly being told he was approved for surgery.

Finally, in mid-January, he received his last denial. Needing to return to work, he decided not to pursue his appeal further and opted for the fusion surgery.

### **‘It’s annoying’**

Dr. Hart, who performed the surgery, said he is frustrated that many insurers are blocking patients from undergoing newly conceived procedures, like disc replacements, that can help them.

“Every study has shown that these artificial discs are as good as or better than a fusion in terms of patient outcomes, patient satisfaction, return to work status, and all of these things that have big societal impact,” Dr. Hart said.

Mr. Hodnik’s fusion surgery went smoothly, he’s returned to work, and he can enjoy summertime activities with his family.

He doesn’t know what the future holds for his back, but Mr. Hodnik isn’t angry at his insurer.

“If they would have come out and said Dec. 1 it was denied [because of lack of study], we could have gone on and had the fusion done and I could have been back to work at the end of January,” Mr. Hodnik said.

Not being able to get what he wants for his patients is difficult for Dr. Hart to accept.

“For me, it’s an inconvenience, it’s a frustration, it’s annoying, it’s insulting, and as a doctor who has great concern and care for my patients, it upsets me. In the end, it doesn’t truly affect me personally ... But good lord, it has a huge impact on my patients,” Dr. Hart said.

### **Lost opportunities**

Nine months after his doctors said he was terminally ill with little time left, Randy Steele is still alive and savoring each moment with his family.

His health — bolstered by dialysis sessions every Tuesday, Thursday, and Saturday at Maumee Bay Dialysis Center in Oregon — is stable.

Last month Mr. Steele underwent surgery to replace his implanted defibrillator, a device that helps his heart beat properly.

In the months since doctors gave Mr. Steele little time to live, he celebrated his 16th wedding anniversary with his wife and his 64th birthday which coincided with Father’s Day, and he attended a Toledo Mud Hens baseball game on the Fourth of July.

“Each day is a gift and a miracle,” Mrs. Steele said.

The Steeles now say they are left to wonder if insurance delays squandered Mr. Steele's chance for more days.

But still, Mr. Steele says he holds no grudges against Medical Mutual, but his concerns about the role of insurers in health care linger.

"Sometimes it just interferes with patients' lives and that upsets me because it is interfering with my life," Mr. Steele said. "I had some opportunities, maybe for transplants, that are gone and they are not ever going to be able to be replaced."

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### ***Vaccine-denying couple still on run***

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

A Sydney couple - in hiding after refusing to have their newborn baby vaccinated against hepatitis B - also have a three-year-old child who could be carrying the virus.

The parents fled their Croydon Park home on Thursday to avoid police and Department of Community Services (DoCS) officials, after they refused to have their three-day-old son vaccinated at Royal Prince Alfred Hospital.

The baby's mother, who is from China, was diagnosed with hepatitis B several years ago.

On medical advice, DoCS took a recommendation to the NSW Supreme Court last week and ordered the parents to vaccinate the baby.

On Monday, the court made the decision to continue the orders, with the case due back in court Tuesday morning.

"This is a day by day proposition," DoCS spokeswoman Annette Gallard said.

The baby's parents, who have not been named, also have a three-year-old child, who DoCS believe has also not been vaccinated against hepatitis B.

"We understand that there is another child, but we were unaware at the birth of the child that there was an issue, so we did not have the opportunity to act," Ms Gallard said.

"We're very concerned that the health of both of these children is monitored and that the little baby in particular can be vaccinated."

Ms Gallard said the department was working with police to find the family and had spoken with the parents on a number of occasions.

"We've had some phone contact with them from time to time and obviously each time we're urging them to come forward," she said.

The parents believe the illness, which can cause liver cancer and cirrhosis, can be managed more effectively without vaccination.

They fear the vaccination could cause their child neurological damage.

Hepatitis Australia CEO Helen Tyrrell said the hepatitis B vaccination was extremely safe.

"The incidences of acute reactions to the hepatitis B vaccine are extremely rare ... and if they do occur, they are usually short-lived," she told AAP.

"So, if you're weighing up the risks of vaccination versus not vaccination, then we would certainly recommend vaccination."

Ms Tyrrell said mother-to-child transmission during the birth process and immediately after was common, with the chance of transmission between five and 40 per cent.

If a baby was vaccinated, the chances of infection were "very, very low", she said.

Vaccinations are not compulsory in Australia, but it's NSW health policy for babies born to hepatitis B mothers to be given the immunoglobulin injection within 12 hours of birth.

Ms Tyrrell said a baby who developed hepatitis B had a 95 per cent chance of developing the chronic form of the disease, which carried with it a "very high chance" of liver cancer among other problems which are difficult to reverse.

Ms Gallard refused to speculate on whether the parents would be charged, but said DoCs would be taking both medical and legal advice about what to do next.

"We will make a decision in the best interest of the family," she said.

"But at this stage, we just want to get the baby vaccinated."

### ***Uganda: Caught Flat-Footed By Hepatitis***

<http://allafrica.com>

*The East African* (Nairobi)

Eve Mashoo

Nairobi

The death toll from hepatitis E continues to rise in northern Uganda as the government struggles to come up with a coherent response 10 months after the outbreak was first reported.

The outbreak, which has killed more than 100 people, was first reported last October, but warnings from health experts that it could spread rapidly went largely unheeded until a feeble response earlier this month. Even now, some experts say the response by the Ministry of Health, falls short of addressing the underlying cause of the problem.

The experts say the response whose central strategy is behaviour change is unco-ordinated and lacks the means to adequately educate the public.

The Minister for Health, Dr Stephen Mallinga, announced an emergency plan to fight hepatitis E epidemic in the north after the death toll rose to 97. The latest update indicates that new infections over the past two weeks have risen to between 4,829 and 5,779. The government is launching a Ush10 billion (\$600,000) accelerated emergency response plan to contain the epidemic in the affected districts of Kitgum, Pader, Gulu and Yumbe.

Dr Mallinga said while the disease on its own was not as contagious, prevention was not being helped by the appalling state of hygiene in the affected districts where many people were displaced by the two-decade old insurgency.

The epidemic has spread in districts where the residents still live in congested camps. Northern Uganda suffers from an acute shortage of clean water and sanitation facilities. The disease is transmitted through contaminated food.

The government and non-governmental organisations have sunk more than 150 pit latrines and are encouraging residents to store water in plastic containers.

Dr William Mbabazi from the World Health Organisation (WHO), attributes the escalating rate of the epidemic to the poor hygiene behavior and unsafe water handling where local people use pots to carry water from the wells to their households and the non use of pit latrines.

"However, the focus on changing behavior as the main issue in controlling the epidemic has been ignored and is focusing on building more latrines than teaching people on how to use them.

The biggest issue is the need to build more latrines. Getting people to change behavior by using latrines requires a long-term educational effort, not short-term crisis management," said Dr Freddy Oyat, of the Gulu University, faculty of medicine.

Clay pots were identified as the leading cause of the disease outbreak especially in households. It has been said that treating the water with chlorine, which was later abandoned, was one way of controlling the epidemic, but was later stopped after complaints from the people that chlorine makes the water lose its natural taste.

People are attached to their water pots since they have been using them for ages and don't want to use the small bore cans commonly known as jerricans," said Dr Mbabazi.

The hepatitis outbreak came at a time when the government was preoccupied with outbreak of Ebola. This was made even worse by the fact that the government tends to bounce from crisis to crisis rather than address well-known underlying causes. The vast majority of epidemics stem from inadequate sanitation and hygiene, but the government doesn't have permanent policies in place to address these issues.

The hepatitis E epidemic death toll has been increasing by day and recent figures show that 106 people, majority of them in Kitgum have died. It took eight months to contain the outbreak when it broke out last year.

The onset of the heavy rains in Gulu district could worsen the epidemic because the water wells and springs are unprotected from run-off water, experts say.

Dr Mbabazi told The EastAfrican that most deaths reported were of pregnant women due to their low immunity. The disease has no specific medicine.

According to the reports from the center in Kitgum which is handling the epidemic, the first cases were reported in Madioppe sub-county, which was hard hit in the beginning of the outbreak.

Dr Freddy Oyat told The EastAfrican that priority should be given to the construction of latrines, education on the use of clean and safe water, enforcement of water purification and encouraging personal hygiene.

**Aug 26, 2008**

## ***Bayer and Onyx Begin Enrollment in STORM Trial Studying Nexavar as Adjuvant Therapy for Patients With Liver Cancer***

<http://www.therapeuticsdaily.com>

WAYNE, N.J. and EMERYVILLE, Calif., August 21, 2008 /PRNewswire-FirstCall/ -- Bayer HealthCare Pharmaceuticals, Inc. and Onyx Pharmaceuticals, Inc. today announced the companies have begun enrolling patients in the STORM Sorafenib as Adjuvant Treatment in the Prevention of Recurrence of Hepatocellular Carcinoma trial. The randomized, double-blind, placebo-controlled Phase 3 study is evaluating **Nexavar(R) (sorafenib)** tablets as adjuvant treatment, which is treatment following surgery or local radiation, for patients with hepatocellular carcinoma (HCC), or primary liver cancer.

"Nexavar is the only systemic therapy with proven efficacy and tolerability in HCC across multiple patient populations," said Dimitris Voliotis, MD, vice president, Nexavar Clinical Development, Bayer HealthCare Pharmaceuticals. "Liver cancer is the third largest global cancer killer worldwide and there is a significant need for new therapies that can be used at all stages in the course of the disease to delay disease progression and prolong life."

In addition, the U.S. Food and Drug Administration (FDA) has completed a Special Protocol Assessment (SPA) for the STORM trial. An SPA is a written agreement on the design and size of a clinical trial intended to form the basis for a new drug application.

### **Phase 3 Trial Design**

The international multicenter study is expected to enroll approximately 1,100 patients and will include patients who have received surgical resection or local ablation. The study will look at whether providing oral Nexavar in the adjuvant setting delays the time to recurrence and increases overall survival. The primary endpoint of the study is recurrence free survival. Secondary endpoints include overall survival, time to recurrence, patient-reported outcomes, plasma biomarkers, safety and tolerability.

The study is enrolling patients with all HCC histologies. Patients will be randomized to receive 400 mg of Nexavar twice daily or matching placebo for up to four years. The study will be conducted at more than 200 sites in North America, South America, Europe and the Asia-Pacific

region, including Japan. For information about enrolling in the study, please visit <http://www.clinicaltrials.gov> .

Hepatocellular carcinoma is the most common form of liver cancer and is responsible for about 90 percent of the primary malignant liver tumors in adults. Liver cancer is the sixth most common cancer in the world and the third leading cause of cancer-related deaths globally. More than 600,000 cases of liver cancer are diagnosed worldwide each year (more than 400,000 in China, South Korea, Japan and Taiwan, 54,000 in the European Union, and 15,000 in the United States) and the incidence is increasing. In 2002, approximately 600,000 people died of liver cancer including approximately 370,000 in China, South Korea and Japan, 57,000 in the European Union, and 13,000 in the United States.(1,2)

Currently there are no adjuvant treatments with proven benefit in HCC and half of the patients who have undergone surgical resection or local ablation will see their tumors return within three years and 70 percent will see their tumors return within five years.(3)

### **Nexavar's Differentiated Mechanism**

Nexavar targets both the tumor cell and tumor vasculature. In preclinical studies, Nexavar has been shown to target members of two classes of kinases known to be involved in both cell proliferation (growth) and angiogenesis (blood supply) -- two important processes that enable cancer growth. These kinases included Raf kinase, VEGFR-1, VEGFR-2, VEGFR-3, PDGFR-B, KIT, FLT-3 and RET.

Nexavar is currently approved in more than 40 countries for liver cancer and in more than 70 countries for the treatment of patients with advanced kidney cancer. Nexavar is also being evaluated by the companies, international study groups, government agencies and individual investigators as a single agent or combination treatment in a wide range of cancers, including metastatic melanoma, lung cancer, breast cancer and as an adjuvant therapy for kidney cancer.

### **Important Safety Considerations For Patients Taking Nexavar**

Based on the currently approved U.S. package insert for the treatment of patients with unresectable hepatocellular carcinoma, hypertension may occur early in the course of therapy and blood pressure should be monitored weekly during the first six weeks of therapy and treated as needed. Bleeding with a fatal outcome from any site was reported in 2.4% for Nexavar and 4% in placebo. The incidence of treatment-emergent cardiac ischemia/infarction was 2.7% for Nexavar vs. 1.3% for placebo. Most common adverse events reported with Nexavar in patients with unresectable HCC were diarrhea, fatigue, abdominal pain, weight loss, anorexia, nausea and hand-foot skin reaction. Grade 3/4 adverse events were 45% for Nexavar vs. 32% for placebo. Women of child-bearing potential should be advised to avoid becoming pregnant and advised against breast-feeding. In cases of any severe or persistent side effects, temporary treatment interruption, dose modification or permanent discontinuation should be considered.

For information about Nexavar including U.S. Nexavar prescribing information, visit <http://www.nexavar.com> or call 1.866.NEXAVAR (1.866.639.2827).

(1) Ferlay J, et al., GLOBOCAN 2002. Cancer Incidence, Mortality and Prevalence Worldwide. IARC CancerBase No.5, Version 2.0. IARC Press, Lyon, 2004. Available at: <http://www-dep.iarc.fr> . Accessed May 2008.

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**Aug 27, 2008**

## **High HBV Viral Load at Surgery Tied to Liver Cancer Return**

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

By David Douglas

NEW YORK (Reuters Health) Aug 14 - In patients undergoing liver resection for hepatocellular carcinoma related to hepatitis B virus (HBV) infection, viral load at the time of surgery is predictive of hepatoma recurrence, according to Chinese researchers.

"High hepatitis B viral load," senior investigator Dr. Man-Fung Yuen told Reuters Health, "is associated with a higher chance of HCC recurrence after surgical resection. Use of an antiviral agent after surgery may reduce this chance."

Dr. Yuen and colleagues at the University of Hong Kong followed 72 patients for a median of 18.9 months after surgery. Thirty patients developed tumor recurrence.

In the July issue of the *American Journal of Gastroenterology*, the researchers report that an HBV viral load of more than 2000 IU/mL at the time of surgery was "the most important correctable risk factor" for tumor recurrence on multivariate analysis (odds ratio, 22.3).

Other baseline factors that were independently associated with recurrence were tumor size greater than 5 cm, alpha fetoprotein level greater than 1,000 ng/mL, and age greater than 60.

"Initiation of antiviral therapy for patients with HBV DNA levels above 2,000 IU/mL...at the time of tumor resection and close monitoring of the subsequent HBV viral load may be able to decrease tumor recurrence in these patients," the investigators conclude.

*Am J Gastroenterol* 2008;103:1663-1673.

## **Study Supports Prompt HCV Therapy in HIV/HCV-Coinfected Patients**

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

NEW YORK (Reuters Health) Aug 26 - Patients coinfecting with hepatitis C virus (HCV) and HIV often exhibit low levels of HCV neutralizing antibodies, which could contribute to a poorer outcome of HCV infection, a French study indicates.

"These results favor starting HCV therapy as soon as possible in coinfecting patients," Dr. Gilles Duverlie from Hopital Sud, Amiens, and colleagues conclude in the August 1st issue of *The Journal of Infectious Diseases*.

Dr. Duverlie and colleagues retrospectively determined HCV neutralizing antibody titers in 37 HIV/HCV-coinfecting patients and compared these values with those found in 37 patients with HCV monoinfection. The patients were matched on the basis of sex, age, and HCV genotype.

"A group of patients with well-controlled HIV infection was selected," the researchers explain, "and HIV disease in all was at a stage at which HCV therapy could either be started or, if hepatitis C has not progressed, delayed. In this context, the potential role of HCV neutralizing antibodies was evaluated by measuring HCV viremia in both groups of patients."

According to the researchers, a third-generation HCV neutralization assay showed a significantly lower mean HCV neutralizing antibody level among HIV/HCV-coinfecting patients than among HCV monoinfecting patients ( $p = 0.013$ ).

The coinfecting population also had a greater prevalence of undetectable HCV neutralizing antibody levels.

In this study, "anti-HCV antibodies production seemed already impaired by HIV infection, even in coinfecting patients for whom HIV infection was well controlled by HAART and HIV viremia was not present," Dr. Duverlie and colleagues point out.

"In the context of HIV coinfection, our results highlight the weakness or even the absence of an HCV neutralizing antibody response during chronic HCV infection," they add.

These results, the investigators conclude, "provide an additional argument that efficient HCV antiviral therapy should be started as soon as possible in HIV-infected patients in order to improve the chance of eradicating HCV."

*J Infect Dis* 2008;198:332-335.

### ***Some Ayurvedic medicines have harmful metals: study***

<http://www.reuters.com>

By Andrew Stern

CHICAGO (Reuters) - One in five Ayurvedic medicines commonly used by followers of the ancient Indian health philosophy were found to contain the metallic poisons lead, mercury or arsenic, researchers said on Tuesday.

Ayurveda is an ancient system that includes medicines, meditation, exercise and dietary guidelines practiced by millions of adherents on the Indian subcontinent and increasingly in the West.

Ayurvedic medicines made in the United States and India were ordered from 25 Web sites and tested for the metallic poisons by a team from Boston University School of Medicine and Boston Medical Center.

Nearly 21 percent of 193 Ayurvedic medicines analyzed had detectable levels of one or more of the metals, and at least half of those exceeded established standards for unhealthy exposure levels, Dr. Robert Saper and colleagues reported in the *Journal of the American Medical Association*.

Saper said the findings raise concerns about the ingredients found in the lightly regulated dietary supplement market that includes vitamins and traditional Chinese medicines.

He said the U.S. Food and Drug Administration relies on manufacturers to report ingredients accurately and then investigates complaints.

"We suggest strictly enforced, government-mandated daily dose limits for toxic metals in all dietary supplements and requirements that all manufacturers demonstrate compliance through independent third-party testing," he wrote.

"There's some studies that show that some herbs have a very promising anti-diabetic effect, anti-high blood pressure effect, a cholesterol-lowering (effect)," Saper said in a telephone interview.

#### ORIGINS UNCLEAR

"In Ayurveda and all those traditional systems there certainly are some promising wisdom and heritage that we need to harvest. But the key thing is we need to separate out what's helpful and ... what needs to be looked at and perhaps set aside."

The report follows up the team's study published in the same journal in 2004 when they purchased Ayurvedic medicines produced in South Asia from Boston-area stores and found similar contaminants.

How the metals get into the medicines is unclear, Saper said. He agreed with Wynn Werner of the Ayurvedic Institute in Albuquerque, New Mexico, that there could be several sources.

Some metals occur naturally in soil, and plants and herbs used to make Ayurvedic medicines may concentrate the contaminants. The metals may come from human-made pollutants and industrial sources, particularly in India where lead pollution is widespread.

The metals also may be introduced during the manufacturing process, accidentally or intentionally.

One class of Ayurvedic medicines, called rasa shastra, contained very high levels of lead or mercury, as well as precious metals and processed gemstones. Indian practitioners say extensive preparation of the metals elicits the benefits while rendering them harmless, but Saper called this doubtful.

Werner also warned against the use of rasa shastra medicines until more research can be done and said few if any manufacturers outside of India produce them.

In the study, about half the Ayurvedic medicines found to be contaminated with lead would exceed the daily dose limit of 20 micrograms set by the American National Standards Institute. But Saper said ingestion of even small amounts of lead may harm the brain and the kidneys and could raise blood pressure.

(Editing by Maggie Fox and Eric Walsh)

### ***Infected reveller's bite threat to cop***

<http://www.sunderlandecho.com>

By Jane O'Neill

A police officer faces an anxious wait to discover if he has been infected by a hepatitis sufferer who attacked him after getting drunk at a stag do.

Richard Kulla, who had travelled all the way from New Zealand to attend his sister's wedding, screamed: "I've got hepatitis C, I'll bite you", as the brave Wearside officer tried to arrest him.

The policeman was forced to subdue Kulla with CS gas before calling for backup.

He now faces an agonising wait to see if he has the blood-borne infection because he was scratched by Kulla.

Kulla, 42, admitted a charge of assaulting a police officer. Sunderland Magistrates' Court heard he was arrested after an argument after the stag party.

Police were called to his sister's home and Kulla at first offered himself up for arrest, but when the officer entered the property he lunged at him.

Kulla was jailed for six weeks and as a result missed his sister's wedding.

Prosecutor Helen Wareham said: "Kulla grabbed him by his stab vest in the upper chest area and was making threats to kill him.

"They both fell to the floor. He attempted to headbutt the officer, who activated his panic button to call for assistance.

"Kulla shouted, 'I've got hepatitis C and I'm going to bite you.'"

The police officer was left with scratches and bruises from his ordeal.

In a victim personal statement, he said: "This incident has left me extremely concerned about contracting hepatitis C. I feared for my safety while struggling with Kulla and now have to have tests which will leave me with a period of uncertainty for a couple of months.

"I know as a police officer I will come into contact with situations where I face violence, but Kulla trying to bite me deliberately knowing he had hepatitis C was deplorable."

Mitigating, James Palmer, said Kulla had not touched alcohol for 14 years prior to the stag party, saying it had a dramatic effect on him.

Kulla denied there was any dispute before police arrived, and reacted after the officer grabbed him by the shoulders and tried to force his arms up behind his back.

"He did not think that was very fair as he had offered himself for arrest, but in the struggle that took place does accept that he assaulted the officer.

"He did threaten to bite the officer, but only to get him off, and did not actually bite him."

## ***Early Trigger for Type-1 Diabetes Found in Mice, Stanford Scientists Report***

<http://www.marketwatch.com>

STANFORD, Calif., Aug 26, 2008 (BUSINESS WIRE) -- Scientists at the Stanford University School of Medicine are shedding light on how type-1 diabetes begins.

Doctors have known the disease is caused by an autoimmune attack on the pancreas, but the exact trigger of the attack has been unclear. Now, a new study in mice implicates the immune signal interferon-alpha as an early culprit in a chain of events that upend sugar metabolism and make patients dependent on lifelong insulin injections.

"We never considered that interferon-alpha could be a major player in early type-1 diabetes," said Qing Li, MD, PhD, a postdoctoral scholar in microbiology and immunology who was the primary author of a paper describing the new result. The study is published in today's issue of *Proceedings of the National Academy of Sciences*. "This was a pretty surprising finding."

Interferon-alpha normally helps the body fight viruses. Synthetic interferon-alpha is injected as a drug for treating hepatitis C and some forms of cancer, Li noted.

"Everybody's been wondering what process initiates type-1 diabetes," said Hugh McDevitt, MD, professor of microbiology and immunology and the study's senior author.

Type-1 diabetes is caused by complete deficiency of insulin, a hormone that helps the body store and burn sugar. About 1 million Americans have the disease, also known as juvenile diabetes because it tends to be diagnosed in children and young adults, for which there is no effective prevention or cure. Diabetes is a leading cause of heart disease, blindness, limb amputations and kidney failure.

The early pathology of type-1 diabetes is hard to study in humans, McDevitt said, because it's almost impossible to predict who will get the disease and when it will develop. Scientists have relied on animal models, such as diabetic mice, because they predictably develop high blood sugar and other features of the human disease.

To pinpoint interferon-alpha, Li and McDevitt worked backwards from what they knew about how type-1 diabetes starts. Prior studies in diabetic mice showed a pathogenic role for immune

cells called CD4+ T cells. These cells are an early player in the immune attack on the body's insulin factories, pancreatic beta cells. The scientists used silicon gene-chip technology to measure which genes are revved up in the CD4+ T cells just before they assault the pancreas. The measurements fell into a pattern: many of the upregulated genes were known to be controlled by interferon-alpha.

To confirm the signal's nefarious role, the researchers gave mice an antibody that blocks interferon-alpha activity several weeks before the animals were expected to develop diabetes. Thwarting interferon-alpha delayed the start of the disease by an average of four weeks, and, in 60 percent of treated mice, it prevented diabetes entirely.

The finding confirmed the importance of interferon-alpha and helped the scientists connect the dots between normal mouse physiology and early diabetes. Mice are born with more pancreatic beta cells than they need, Li noted. The extras soon undergo programmed cell death, leaving plenty of working beta cells to pump out insulin. However, in mice that develop diabetes, debris left behind by the dying cells triggers an inappropriate immune response, with lots of interferon-alpha. The interferon-alpha cues immune destruction of more and more beta cells, causing insulin deficiency and diabetes.

The mechanism may be more complex in humans, the scientists cautioned, explaining that while their new finding goes a long way toward explaining the beginnings of diabetes in the mice, additional genetic and environmental factors influence the human disease. But the basic principle of disease is likely the same in diabetic mice and humans, they said.

"A normal process -- programmed cell death -- causes a normal response," McDevitt said. "But it does this in such a way that, in a small subset of the population, it starts them on the road to type-1 diabetes."

Li and McDevitt collaborated with Stanford colleagues Baohui Xu, PhD, senior research scientist in pathology; Sara Michie, MD, professor of pathology; and Kathleen Rubins, PhD, a former postdoctoral scholar at Stanford who is now a research fellow at the Massachusetts Institute of Technology; and with Robert Schreiber, a professor at the Washington University School of Medicine in St. Louis.

The research was funded by grants from the Juvenile Diabetes Research Foundation, the American Diabetes Association Mentor-Based Postdoctoral Fellowship and the National Institutes of Health.

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

*SOURCE: Stanford University Medical Center*

## ***Newest disease-spreading fear: Handcuffs***

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

MONTREAL, Aug. 27 (UPI) -- A Canadian company warned a national police conference in Montreal that dirty handcuffs can transmit herpes, HIV, influenza and hepatitis B.

Among the exhibitors at the annual conference of the Canadian Association of Chiefs of Police this week was the Cuff Cleaner company, based in Edmonton, Alberta, *The Gazette* newspaper reported.

The company markets a device and chemicals that disinfect handcuffs in ways they claim manual cleaning can't accomplish.

"If you go around here and ask any police officer how often they clean their cuffs, they'll probably say never," said company spokesman Kevin Berg.

The company claims in random checks of police and corrections officials handcuffs, they found viruses and bacteria along with dried blood and skin particles in the hinges.

The company Web site says that's not only dangerous for the next person to be cuffed but for the officers.

The cleaning device creates ultra-high frequency sound waves, which are passed through a cleaning solution in a process that takes 10 minutes, the site said.

**Aug 28, 2008**

## ***WHO study backs universal health care***

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

By Stephanie Nebehay

GENEVA (Reuters) - Major inequalities in health and life expectancy persist worldwide, according to an independent World Health Organization commission which on Thursday called for all countries to offer universal health care.

Huge discrepancies also exist within countries, including Scotland where a boy born in the poor Glasgow suburb of Calton can expect to live to 54, 28 years less than one born in affluent Lenzie, just across town, it said.

"The health inequities we see in the world are absolutely dramatic in their scale," Michael Marmot, a WHO health researcher, who chaired the commission, told reporters.

"Between countries we have life expectancy differences of more than 40 years. A woman in Botswana can expect to live 43 years, in Japan 86 years."

The Commission on Social Determinants of Health, composed of 19 independent experts, handed over its three-year study to the World Health Organization, a United Nations agency.

"Social injustice is killing people on a grand scale," it declared.

Marmot, head of the epidemiology and public health department at University College London, said the report recommended universal health care systems should be available to people regardless of their ability to pay.

"Virtually all advanced countries have universal health care systems but we don't think that should be limited to high-income countries," he added.

#### INABILITY TO PAY

The sustainability of health care systems is a concern for all countries, amid growing "commercialization" of services, according to the commission. It favored financing health care through general taxation and/or mandatory universal insurance.

Each year, more than 100 million people worldwide are pushed into poverty due to catastrophic health care costs, it said.

"We are distressed by the reports of health care simply being unavailable to people because of inability to pay. We see that throughout low- and middle-income countries," Marmot said.

Health care is also a key issue in the U.S. presidential campaign, with both Democrat Barack Obama and Republican John McCain proposing to fix what they call a broken system.

Some 15.3 percent of Americans had no public or private health insurance in 2007, down from 15.8 percent in 2006, according to the latest U.S. figures released on Monday. A total of 45.7 million people were uninsured, down from 47 million.

In the United States, minorities are more likely to be diagnosed with late-stage breast cancer and colorectal cancer than whites, the report said. In Indonesia, maternal mortality is three to four times higher among the poor than the rich.

Margaret Chan, WHO director-general, said WHO's Executive Board would examine the report at its January meeting and submit proposals to the annual meeting of its 193 member states in May.

"The importance of prevention continues to grow, partly because of escalating health care costs. We simply cannot afford the way we go about doing health care nowadays without tackling and doing more prevention," she said.

Nobel laureate Amartya Sen, former U.S. Surgeon General David Satcher, former Chilean president Ricardo Lagos Escobar and former Mozambique health minister Pascoal Mocumbi served on the commission.

(Editing by Richard Balmforth and Dina Kyriakidou)

### ***Clovis patients possibly exposed to hepatitis, HIV***

<http://www.fresnobee.com>

By Barbara Anderson / *The Fresno Bee*

*Some instruments used last week may not have been fully sterilized.*

Fourteen Clovis Community Medical Center patients -- some of whom were on the maternity ward -- may have been exposed to hepatitis and HIV last week when doctors used instruments that may not have been fully sterilized.

Although hospital officials say the risk of infection is remote, they have offered to test all the patients and doctors.

So far, no infections have been found, said Michelle Van Valkenburg, director of communications for Community Medical Centers, which operates Clovis Community. She said she didn't know how many remain to be tested or how many test results are pending.

The instruments in question were used in delivery rooms and for laparoscopic -- or minimally invasive -- surgery Aug. 16. They had been cleaned and sanitized, but officials suspect that a final sterilization procedure may not have been completed, Van Valkenburg said. That last step involves intense heating.

Usually, two tags on instruments will change color once the sterilization process is complete, Van Valkenburg said. In this case, she said, one of the tags completely changed color, and the other did not.

The Fresno County Department of Public Health was not required to be notified, because it was not considered an outbreak, said David Luchini, the department's division manager for communicable disease.

Luchini said the risk of getting HIV -- the virus that causes AIDS -- from unsterilized instruments is remote.

"HIV is very unstable once it hits air," he said.

But the risk of getting hepatitis B and C is greater, Luchini said.

"The hepatitis virus tends to stay alive for many more hours," he said. "That's usually the main concern, and why you would notify people to be tested."

Hepatitis viruses attack the liver. About 1.25 million people in the United States are infected with hepatitis B, and about 3.2 million have hepatitis C, which kills as many as 10,000 people a year, according to the federal Centers for Disease Control and Prevention.

Despite the low infection risk, Van Valkenburg said, "We just felt we wanted to take an additional step to inform the patients and really guarantee their safety and offer to do a lab check."

She said the hospital is educating staff and has stepped up its regimen for ensuring that instruments are sterile -- and that the intense heating process is completed.

The state Department of Public Health generally investigates such incidents, but late Wednesday, a department spokesman said he could not comment.

The reporter can be reached at [banderson@fresnobee.com](mailto:banderson@fresnobee.com) or (559)441-6310.

## ***Nurse charged with infecting patients***

<http://www.bradenton.com>

BY JOHN DORSCHNER

[jdorschner@MiamiHerald.com](mailto:jdorschner@MiamiHerald.com)

Jon Dale Jones, a nurse anesthesiologist working in a Miami area hospital, has been arrested in Miami, suspected of intentionally infecting 15 patients with potentially deadly hepatitis C at an army hospital in Texas.

The federal indictment accuses Jones of assaulting six patients in 2004 and illegally acquiring a controlled substance, a strong pain killer called fentanyl, which is often used in surgery and is reported to be 80 times more powerful than morphine.

Clark Harmonson, an El Paso attorney who has filed a civil lawsuit, said Jones contracted hepatitis C while working at the Beaumont Army Medical Center.

The disease is spread through blood-to-blood contact. The lawyer alleges that Jones injected himself with the painkiller before injecting patients with the same needles. "Basically, there's no other way it could have happened," Harmonson said.

Hepatitis C can destroy the liver. An investigation by the Centers for Disease Control found that 15 patients were infected from July 31 through Oct. 12, 2004. Jones was the only staff member with hepatitis C known to be in the operating room with all 15 patients, Harmonson said.

Jones' attorney, Ed O'Donnell, said his client "absolutely" maintains his innocence. Since the allegations came to light, Jones has informed the state boards that govern health practitioners about them, O'Donnell said.

Jones has been working through a staffing agency for hospitals in Virginia, the District of Columbia, Hawaii and Miami, O'Donnell said. He wasn't certain where Jones worked in Miami.

Jones was arrested at 6 a.m. March 6, by an FBI agent, court records show. Earlier this week, he was released on a \$200,000 bond, \$20,000 of which was paid, cosigned by his wife, on condition that he not work as a nurse anesthetist and not have access to or possess narcotics.

## ***Brain dysfunction may explain fibromyalgia symptoms***

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

NEW YORK (Reuters Health) - Dysfunction in a portion of the brain may explain some of the symptoms of fibromyalgia syndrome, researchers suggest in a paper published in the *Journal of Rheumatology*

Dr. Yasser Emad, of Cairo University, Egypt, and colleagues used proton magnetic resonance spectroscopy to examine the function of the hippocampus in 15 patients with fibromyalgia syndrome and in 10 healthy women who were the same age as the other patients.

The hippocampus is located deep in the front portion of the brain involved in regulating emotions and memory. Functionally, the hippocampus is part of the olfactory cortex, which is important to the sense of smell. The name is from the Greek hippos (horse) = kampos (a sea monster), based on its shape, which resembles a seahorse.

Using spectroscopy, the researchers calculated levels of hippocampus levels of the brain chemicals N-acetyl aspartate (NAA), choline, creatine, along with their ratios, and compared the findings between the two groups. All study participants also underwent assessments of sleep patterns, cognitive function, and symptoms of depression. The number of tender points on the body was assessed in all patients and a visual analog scale was used to measure pain.

Patient age averaged 35.7 years, and their average disease duration was 18.1 months. All of the patients had cognitive functional impairments on the Mini-Mental State Examination, eight (35.5 percent) were depressed according to the Hamilton Depression Scale, and nine (60 percent) had sleep disturbances. None of the control subjects had any problems in these areas.

"NAA levels of the right and left hippocampi were lower in the patients compared to controls," Emad's team explains. "Another statistically significant difference was observed in choline levels in the right hippocampus, which were higher in the patient group." The fibromyalgia patients also had significantly lower NAA to choline and NAA to creatine ratios compared with the control subjects.

There were no differences between the groups in other metabolites measured or in the choline to creatine ratio.

In the patient group, language scores were significantly correlated with choline and creatine levels, but there was no significant correlation between the levels of the metabolites or their ratios and the number of tender points.

"The hippocampus was dysfunctional in patients with fibromyalgia, as shown by lower NAA levels," the investigators conclude.

Because the hippocampus has a critical role in maintaining cognitive functions, sleep regulation, and pain perception, the researchers suggest that metabolic dysfunction of hippocampus may be implicated in the symptoms of this puzzling syndrome.

**Aug 29, 2008**

## ***State urges clinic's patients to be tested for hepatitis C***

<http://www.fayobserver.com>

By Jennifer Calhoun

Staff writer

LAURINBURG — The state Department of Public Health is asking people who received a nuclear stress test at Scotland Cardiology in Laurinburg between June 25, 2007, and Aug. 26, 2008, to get tested for the hepatitis C virus and other infectious agents that may be transmitted through unsafe injection practices.

A nuclear stress test involves injecting a radioactive substance into the bloodstream as a way to check for inadequate blood flow in the heart.

A recent investigation of the clinic revealed that unsafe medical practices could have been used during the nuclear stress tests, possibly causing seven patients to acquire the disease.

Dr. Matthew Block, a cardiologist at Scotland Cardiology and the city's mayor, agreed to quit performing the procedure, which could have infected seven of his patients with hepatitis C, according to an Aug. 27 disciplinary order from the state medical board.

Hepatitis C is a liver disease caused by the hepatitis C virus, according to the Centers for Disease Control Web site. The disease can sometimes cause acute illness, but most often becomes a chronic condition that can lead to cirrhosis of the liver and liver cancer, the Web site said.

The virus is transmitted through contact with the blood of an infected person. There is no vaccine for the virus, the Web site said.

Block said in a release Friday that he was devastated by the news.

“I will work hard with the Department of Health to ensure that everything possible is done to ensure the health and safety of my patients,” Block said. “I have run my nuclear laboratory to conform with the highest national standards and find it just simply unbelievable that something like this may have occurred.”

A release from the Department of Public Health said there was only a small chance that those who received the nuclear stress test at the clinic would have acquired the infection.

People who received the test may contact the N.C. Department of Health and Human Services care line at 1-800-662-7030 (TTY 1-877-452-7030) for more information

### ***Bristol-Myers Squibb Welcomes NICE Guidance Recommending Baraclude(R) (entecavir) as a Treatment Option for Chronic Hepatitis B***

<http://biz.yahoo.com>

UXBRIDGE, England, August 29 /PRNewswire/ -- NICE (National Institute for Health and Clinical Excellence) has published guidance that recommends Baraclude® (entecavir) as an option for treatment of eligible patients with chronic hepatitis B (CHB). Entecavir is a potent anti-viral treatment for chronic Hepatitis B that has been shown to be more effective at suppressing the virus than the most widely used anti-viral treatment (lamivudine)(1) and has

shown minimal emergence of resistance in new patients treated with it (entecavir) for up to 5 years.(2)

Richard Marsh, Director of External Affairs and Market Access, Bristol-Myers Squibb said, "This is good news for patients with chronic Hepatitis B. We welcome the publication of NICE's final guidance on Baraclude, recommending it as a treatment option for chronic Hepatitis B in line with its licence. PCTs are now required to make funding available for Baraclude for patients prescribed it by their specialist. Bristol-Myers Squibb will continue to work proactively with clinicians and PCTs to enable access to Baraclude for those patients who will benefit from it.

"Chronic Hepatitis B is a leading cause of liver cirrhosis and liver cancer. It is highly infectious, growing in prevalence in the UK and an increasing cost to NHS resources. Baraclude is a clinically effective and cost effective treatment for all eligible patients with chronic Hepatitis B. Its favourable resistance profile, in particular, makes it a very valuable treatment option for patients and for the NHS. NICE's new guidance endorses this view."

### **NICE Final Guidance**

- Entecavir, within its marketing authorisation, is recommended as an option for the treatment of people with chronic HBeAg-positive or HBeAg-negative hepatitis B in whom antiviral treatment is indicated.(10) This guidance does not apply to people with chronic hepatitis B who also have hepatitis C, hepatitis D or HIV. Further information can be found at <http://www.nice.org.uk/Guidance/TA153>

### **Treatment of Chronic Hepatitis B (CHB)**

- CHB is a highly infectious and potentially fatal disease which is effectively treated with anti-viral drugs that reduce the amount of virus (viral load) in the blood to an undetectable level
- Over 60%(4) of patients treated with the most widely-used (over 5 years) anti-viral (lamivudine)(1) develop resistance(4) This identifies the need to access treatment options to which patients do not develop resistance
- The aims of CHB treatment with antivirals are to achieve sustained suppression of the virus, avoid treatment resistance and prevent serious liver disease. The preferred anti-viral therapy should combine superior efficacy (compared to other antiviral treatments) with low resistance rates
- It is estimated that management of CHB could cost the NHS from GBP26m to GBP375m annually(5). The total cost to the economy, including time lost at work, is likely to be substantially higher

### **Background on CHB**

- Hepatitis B is the most serious type of viral hepatitis(6)
- HBV is 100 times more infectious than HIV(5) and is the 10th most common cause of death worldwide(9)
- 325,000 people in the UK suffer from chronic HBV(6) which is the leading cause of liver cancer and cirrhosis of the liver(8)
- There is an estimated 7,700 new cases of CHB each year(5) 15 to 25 percent of chronic hepatitis B patients will die of liver-related diseases(8)
- The cost of treating CHB is less than one third of the cost of caring for patients whose disease becomes too far advanced to treat effectively with anti-virals(7)

## **Baraclude (Entecavir)**

- Entecavir is an oral antiviral therapy specifically designed to provide rapid and sustained suppression of viral replication with minimal development of resistance, reducing viral load to undetectable levels in the majority of new patients with CHB. It is available as 0.5mg and 1mg tablets and is prescribed for once a day use(3)
- Entecavir is generally well tolerated(3)
- There is minimal emergence of resistance in new patients treated with entecavir for up to 5 years(2)
- Entecavir is approved for use in more than 60 countries/regions around the world

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## ***interTrend Partners With The San Francisco Hep B Free Campaign to Increase Awareness and Understanding of Hepatitis B***

<http://biz.yahoo.com>

*- The 'B a Hero' Campaign Will Be Launched in August -*

LONG BEACH, Calif., Aug. 28 /PRNewswire/ -- interTrend Communications, a full-service Asian American marketing communications agency, joined forces with The SF Hep B Free Campaign (The SF Hep B Free) in creating the "B a Hero" advertising campaign to increase the public's understanding of hepatitis B disease. The "B a Hero" campaign is scheduled to launch in the San Francisco Bay area this August.

Although the "B a Hero" campaign is aimed to raise awareness of hepatitis B across all markets, it especially tries to reach out to Asian Americans, who are ten times more likely to have hepatitis B disease than other Americans. The campaign encourages patients to have open discussions about testing, screening and treatment with their doctor.

Hepatitis B is a deadly disease that causes up to 80% of all liver cancers. However, it can be prevented with a simple vaccine and treated with effective medications. Because of reticence

among Asians and Pacific Islanders to talk about illness, the campaign emphasizes a positive approach with the slogan: "Be Tested. Be Vaccinated. Be Treated. B a Hep B Hero!"

"This is the best example of how to do Asian marketing. The message reaches both Asian-language and English-language speakers, both immigrant Asians and those born in America," said Ted Fang, Publisher of AsianWeek and Steering Committee Member of The San Francisco hep B Free Campaign. "We haven't even launched the major advertising campaign yet, but are already receiving national interest in the SF hep B Free 'B a Hero' icon."

interTrend has been volunteering to take the lead to develop the campaign creative strategy, concept, and the tactical ideas since November 2007. The "B a Hero" campaign was born in April 2008.

"interTrend enjoys working with our community partners to create and design social marketing campaigns that are important to our society," said Jon Yokogawa, managing director of interTrend communications. "Partnering with The SF Hep B Free and creating an influential campaign such as 'B a Hero' campaign gives the public, especially Asian Americans, the option for a healthy and hep B free life."

The "B a Hero" teaser campaign is being launched during May in celebration of Asian Heritage Month; moreover, Hep B Free organized free public screening at the Asian Heritage Street Celebration, which is the largest gathering of Asians in America.

The formal launch of "B a Hero" advertising campaign, including billboards, bus posters, and banners will start in late August. The SF Hep B Free is seen as a national model in efforts to raise awareness in the fight against hepatitis B. To view "B a Hero" creative, please log in to <http://www.intertrend.com>. For more information on hepatitis B, please visit <http://www.sfhepbfree.org>

### **About interTrend Communications**

interTrend Communications, Inc. is a leading full-service marketing agency targeting the Asian American segments such as Chinese, Japanese, Korean, Vietnamese and Filipino. With a proven track record, interTrend has successfully helped Fortune 1000 clients nurture and establish brand leadership positions in this emerging market through an integrated mix of advertising, public relations, promotions, events and interactive strategies via various in-language media outlets.

interTrend delivers excellence to clients, working as marketing partners. Today, long-term partnerships have been established with Toyota Motor Company, JCPenney, State Farm Insurance, Pala Casino, Western Union, Verizon, Northwest Airlines, Southern California Gas Company, San Diego Gas & Electric and Santa Anita Park.

### **About Hep B Free Organization**

The San Francisco Hep B Free Coordinating Council is a first-in-nation effort calling on the collaboration of a wide spectrum of organizations for testing and vaccinating all Asian and Pacific Islander residents, with the goal of making San Francisco free of hepatitis B.

The San Francisco Hep B Free Steering Committee consists of the San Francisco Department of Public Health, Asian Liver Center at Stanford University, and AsianWeek Foundation.