

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Genetic Variant Predicts Success of Treatment in Chronic Hepatitis C

www.medscape.com

Jacquelyn K. Beals, PhD

Researchers have identified a genetic variant that predicts the difference between white and black patients' responses to treatment for hepatitis C. The favorable genotype, which is associated with a 2-fold better response to treatment, is more common in white populations and accounts for about half the difference between the 2 ethnic groups with respect to treatment efficacy.

The new study, published online August 16 in *Nature*, identified a single nucleotide polymorphism (SNP) in a genomewide association study of more than 1600 American patients with chronic hepatitis C infection. Most patients were drawn from a study that compared treatment regimens including peginterferon- α -2b (PegIFN- α -2b) or PegIFN- α -2a in combination with ribavirin.

The criterion for successful treatment was sustained virological response (SVR), defined as the absence of detectable virus at the end of follow-up evaluation. SVR was assessed by a real-time polymerase chain reaction assay 24 weeks after the end of treatment (or by undetectable viral levels after 12 weeks if follow-up was unavailable).

Genotyping identified rs12979860, a SNP on chromosome 19 near IL28B — the gene that codes for interferon- λ -3 — that is highly associated with SVR in each population group ($P = 1.06 \times 10^{-25}$ in white patients; $P = 2.06 \times 10^{-3}$ in black patients; P for combined populations = 1.37×10^{-28}). In each group, the highest percentage SVR occurred in patients with the CC genotype, response rates were intermediate in patients with the CT genotype, and patients with the TT genotype demonstrated the lowest percentage SVR.

"Eighty percent of those [patients] with the favorable response genotype eradicated the virus," senior author David Goldstein, PhD, director of the Center for Human Genome Variation, Institute for Genome Sciences & Policy, Duke University, Durham, North Carolina, said in a statement. "[O]nly about 30 percent with the less favorable response genotype did so. With differences of that magnitude, patients considering therapy may want to know what their genotype is before they start treatment," he suggested.

The findings gain further support from the observation that patients of East Asian ancestry show higher SVR rates than do whites, and the C-allele is more frequent in East Asian populations, the researchers comment. In fact, a nearly linear relationship exists between percentage SVR and the C-allele frequency for (in ascending order) blacks, Hispanics, whites, and East Asians.

"Because [the CC genotype] appears significantly more often among Caucasian populations than it does among African populations, we feel it explains much of the difference in response rates we see between African-Americans and those of European ancestry," observed Dr. Goldstein. "This tells us that individual genetic makeup is a much more important determinant of response to treatment than is race or ethnicity."

Treatment for chronic hepatitis C infection typically requires 48 weeks of PegIFN- α -2b or PegIFN- α -2a in combination with ribavirin. Many patients experience only mild reactions, but others are unable to complete the therapy. Among the side effects are flulike symptoms, depression, nausea and vomiting, dehydration, fatigue, anemia, neutropenia, loss of appetite, skin reactions, and diarrhea. "The side effects of hepatitis treatment can be brutal, and about half the time the treatment fails to eradicate the virus," said Dr. Goldstein.

However, Mary Carrington, PhD, director of SAIC's Basic Research Program, SAIC-Frederick, Inc, National Cancer Institute, Frederick, Maryland, commented on the importance of treatment in an email to Medscape Gastroenterology. "Permanent liver damage and liver cancer can be fatal, so treatment is generally a good option, especially since its success rate is about 40 to 80 percent, though [it is] more like 30 percent in African-Americans," she said.

"[T]reatment for HCV infection overall can be awfully difficult," said Dr. Carrington, but he added: "If I were infected, I would want treatment regardless of my genotype. If I had a very difficult time tolerating the drugs, I would feel more inclined to continue if I had the CC genotype. One of the beauties of this study is that it presents the possibility that interferon- λ -3 may provide an alternative treatment regimen that could be easier to tolerate and that may be more successful in clearing the virus." Dr. Carrington also mentioned that a recent phase 2 study with interferon- λ -1 suggests that this product may have fewer side effects.

The present study demonstrated that the effect of the polymorphism on the efficacy of hepatitis C treatment was consistent in the Hispanics, whites, and blacks studied, and the SVR rates correlated strongly with the C-allele frequency in these groups, as well as in East Asians, say the researchers. Although at least 2 other SNPs in IL28B were too closely correlated with rs12979860 to completely resolve their effects, it seems clear that a polymorphism in IL28B contributes significantly to the variation in SVR rates across multiple ethnic groups.

"This discovery enables us to give patients valuable information that will help them and their doctors decide what is best for them," concluded Dr. Goldstein. "This is what personalized medicine is all about."

Dr. Goldstein is a paid consultant for Schering-Plough, which markets the interferon treatment. He is also an inventor on a patent for the IL28B polymorphisms as a potential diagnostic for interferon treatment response and would receive royalties if such tests are marketed. Dr. Carrington has disclosed no relevant financial relationships.

August 17, 2009

Hepatitis C cases put focus on healthcare safety

<http://www.latimes.com>

By DeeDee Correll

A Denver hospital technician was arrested after allegedly exposing thousands of patients to the disease after stealing fentanyl and swapping out needles. Now administrators are reviewing their rules.

Reporting from Denver - By her own admission, Kristen Diane Parker cruised for empty

operating rooms at the Denver hospital where she worked.

The surgical technician would slip into the rooms and steal syringes of fentanyl, a powerful painkiller, replacing them with syringes she'd filled with saline, she later confessed to investigators.

Parker, who has hepatitis C, had allegedly used those decoy syringes -- the source of transmission, authorities believe, for at least 23 Coloradans now infected with the liver-damaging disease.

Parker's arrest this summer has reverberated through the state, prompting the testing of nearly 6,000 patients at a hospital and surgery center and focusing scrutiny on healthcare safety.

"The system is broken," said a 41-year-old Denver woman who contracted hepatitis C after a minor surgery at Rose Medical Center. She spoke on the condition of anonymity. "The system failed not only me, but Kristen. She has an addiction. It was too easy for her to get that drug." As Colorado wraps up its testing, with more than half of the exposed patients believed to be infection-free and results pending for about 2,100 people, two other states where Parker worked are probing the extent of damage she may have wrought.

Transmitted by blood, hepatitis C is treatable but incurable, and can cause lifelong health problems and death.

In Mount Kisco, N.Y., about 2,700 patients at Northern Westchester Hospital are being tested; the hospital has reported five cases, three of which it says are not linked to Parker. She worked there for about five months in 2007 and 2008. Further testing will determine whether the remaining two infections are linked to Parker, hospital spokesman Mark Vincent said.

In Nassau Bay, Texas, authorities are trying to determine when Parker contracted hepatitis before they order tests on patients at Christus St. John Hospital, where Parker worked from 2005 to 2006.

Though cases in which healthcare workers transmit their own diseases to patients are relatively rare, the effects are far-reaching. The Centers for Disease Control and Prevention have documented four such cases in which 70 patients were infected with hepatitis C between 1992 and 2003, the most recent years for which data were available.

Parker, 26, told police she believes she contracted hepatitis last year, when she became addicted to heroin and shared needles. Authorities say she learned of her illness in October, when she began work at Rose and a pre-employment test detected the disease.

However, Parker maintains that she didn't realize she had hepatitis, saying hospital staff told her only that her test results warranted follow-up, her attorney Gregory Graf said.

She didn't pursue it because she didn't have health insurance or a doctor, he said. "Obviously, she's upset she may have put other people at risk, something she never intended."

Parker aroused co-workers' suspicions in April when she was caught coming out of an operating

room to which she wasn't assigned. A drug screen tested positive for fentanyl, and she was fired.

She moved on to the Audubon Ambulatory Surgery Center in Colorado Springs, where she had applied and been accepted shortly before her firing.

As police began investigating the hospital's report of a potential fentanyl theft, health officials were trying to track the source of two recent hepatitis C infections. By the time they identified Parker as the suspected source, she'd been at her new job for more than a month -- a fact that has sparked criticism of health officials for not linking the cases more rapidly. Colorado's chief medical officer, Dr. Ned Calonge, defends the department, citing the difficulty of tracing the cases to an employee seemingly unassociated with some of the patients.

Parker, who is in custody, is charged federally with tampering with a consumer product and obtaining a controlled substance by deceit. If convicted of all 42 counts against her, she faces life in prison.

Her alleged victims are devastated, said Jim Leventhal, a Denver attorney representing seven patients.

"How do you go to a hospital and then walk out of the hospital with hepatitis C from a dirty needle?" said Leventhal, who faults Rose for not having "a system in place to make it impossible for someone like Kristen Parker to accomplish what she accomplished."

Rose spokeswoman Cara Harshberger declined to discuss Parker's alleged methods of obtaining drugs, but said the hospital has tightened access to drugs. It is also reviewing its hiring practices, although she noted that a criminal background check raised no red flags.

At Audubon, spokeswoman Amy Triandiflou said the surgery center was awaiting investigation results before making any changes. Health officials have connected one of the 18 cases to Audubon, but the center disputes a link.

Parker's case has prompted a number of proposed and planned changes. State officials are considering licensing medical assistants, a move that potentially could have barred Parker from obtaining a new job after Rose reported its suspicions.

Health officials will begin cross-referencing drug diversion reports they receive against infection reports, Calonge said. In this case, different divisions at the department had received reports about thefts and infections, but did not link the two. Calonge said they also will probe health facilities for more detail about people suspected of drug thefts.

Other measures, such as making syringes that can't be reused, are needed to prevent future outbreaks, said Evelyn McKnight, president of Hepatitis Outbreaks National Organization for Reform. The group also advocates greater oversight of outpatient facilities.

"Nineteen cases are 19 too many," said McKnight, who contracted hepatitis at her doctor's clinic in Nebraska.

That sentiment was echoed by the Denver patient, who said every report of a new infection

sickens her.

"Every day, the number grows, and there's more of us out there," she said. "If we don't learn from this tragedy, if we don't change the system, then this is going to continue."

Hepatitis C virus channels efforts into cell survival

<http://esciencenews.com>

Researchers at the University of Leeds have discovered a previously unknown mechanism that allows the hepatitis C virus (HCV) to remain in the body for decades. A study published in the *Proceedings of the National Academy of Sciences* (PNAS) shows that the virus blocks the actions of a specific ion channel in the cell membrane that would usually trigger apoptosis - the cell's self-destruct programme - and in doing so, has evolved another way of protecting itself from being eliminated from the body.

Apoptosis occurs naturally in the body to allow the removal of unhealthy cells or the replacement of worn-out cells. One of the ways in which apoptosis can be triggered in a cell is to reduce its potassium levels. This can happen when the cell is exposed to oxidative stress that activates a specific ion channel (which acts as a pore in the cell membrane) causing it to open and allow out potassium ions.

However, the research team has discovered that a protein made by HCV, known as NS5A, is able to block the activation of this ion channel in liver cells, enabling these cells to resist cell death for longer.

"For a virus to persist in the body over a long time, it has to find a way of manipulating the host cell so that it becomes resistant to apoptosis," says lead researcher Professor Mark Harris of the University's Faculty of Biological Sciences. "We know of many ways that viruses have evolved to do this, but this is the first observation of a virus preventing cell death by manipulating an ion channel."

HCV affects some 170 million people globally and only around half of these will respond to treatment. Many sufferers will be asymptomatic – some for twenty or even thirty years – but the virus remains in the liver, and its long-term damage can ultimately cause cirrhosis or cancer.

"Cells in the liver are often exposed to high levels of oxidative, and other, stresses as they work to detoxify the blood of foreign compounds such as drugs and alcohol, and to remove chemicals produced by our own bodies," says Professor Harris. "In addition, the virus itself causes oxidative stress as it replicates in the cells. The research shows that the virus has evolved another way of protecting itself from this natural process, and to avoid elimination from the body for longer."

The research team believes that continued research may offer a potential target for drug development, perhaps through combination therapy.

"We need to find out exactly how the blocking action works, but it's possible that two drugs could be coupled together, one to prevent the virus from blocking the ion channel and another to

induce stress to force apoptosis," says Professor Harris.

"It's a very exciting discovery, and ideally we'd like to expand our investigations to see whether other viruses that cause long term or chronic infections – such as HIV – have evolved the same ability."

Source: University of Leeds

Protein key to hepatitis C virus replication identified

<http://www.newkerala.com>

Washington, August 15 : Experts at Heidelberg University Hospital in Germany say that they have identified a protein in infected liver cells that is essential for the replication of the hepatitis C virus (HCV).

Writing about their work in the journal *Public Library of Science Pathogens*, they said that inhibiting the protein was highly efficient in blocking virus replication.

According to background information in the article, over 170 million people worldwide are affected by chronic hepatitis C, and, in up to 80 percent of infections, the virus can not be eliminated but persists in the infected individual.

The report further states that chronically infected persons have a high risk of developing serious liver inflammation, liver cirrhosis, and even a liver cell tumour.

An essential cell factor required for hepatitis C virus replication is cyclophilin, which promotes the proper folding of proteins and the formation of large protein assemblies, adds the report.

The researchers say that they analysed liver cells to determine which variant of cyclophilins is critical for hepatitis C virus replication, and found that blocking cyclophilin A leads complete inhibition of virus replication.

They have also found this cyclophilin to be the target of DEBIO-025, a derivative of the immunosuppressant cyclosporin, which is used primarily in the context of organ transplantation.

The researchers say that two complementary effects are responsible for the inhibition of hepatitis C virus replication: cyclophilin A is required both for the formation of the viral replication machinery and for the activity of a viral enzyme that is essential for the assembly of infectious virus particles.

According to them, inhibiting cyclophilin A with DEBIO-025 thus blocks hepatitis C virus replication from two different sides.

By contrast, blocking cyclophilin B had no effect.

The therapeutic potential of inhibiting cellular factors essential for virus replication has thus far hardly been tapped. But this approach has the major advantage that resistance arises less

frequently and to a lesser extent in comparison to therapies directly targeting viral factors,' says Professor Bartenschlager.

August 18, 2009

Discovery Of 'Marker' Molecule Offers Hope For Liver Cancer Test

<http://www.medicalnewstoday.com>

Cancer Research UK scientists have discovered a 'marker' molecule which could pinpoint when liver cells start to become cancerous, reveals research published in *Science**

Scientists at Cancer Research UK's London Research Institute Clare Hall Laboratories, investigated the behaviour of a new DNA damage repair enzyme called ALC1 (Amplified in Liver Cancer 1) which is found in excessive amounts in half of liver cancers.

In normal cells ALC1 acts as an important 'relaxant' which loosens tightly-packaged genetic information, called chromatin - made of DNA and 'packing proteins' - at the point of a DNA fault. The loosened chromatin enables exposure of the DNA damage to repair molecules, which can easily access and fix the fault.

But the scientists have discovered for the first time that when too much ALC1 is produced it excessively relaxes a cell's genetic material, which makes the DNA more vulnerable to mistakes and increases the chances of cancer developing.

The findings suggest the molecule could be developed as a test to detect pre-cancerous changes in liver cells, which could one day help monitor those at risk.

Lead author, Dr Simon Boulton, head of the DNA damage response laboratory at Cancer Research UK's London Research Institute, said: "When too much of the ALC1 molecule is produced, the genetic information inside cells unravels which makes it vulnerable to damage.

"We know that ALC1 is present in greater amounts in half of liver cancers and this research suggests it could be developed as a future test to detect pre-cancerous changes in liver cells."

He added: "So far ALC1 is known to be produced in greater amounts in liver cancer cells - so we need to carry out more experiments to see if this also happens in other cancers."

Around 3,000 people each year in the UK are diagnosed with primary liver cancer - cancer that starts in the liver. Unfortunately the disease is very difficult to treat successfully and fewer than six per cent of patients are still alive after five years.

Dr Lesley Walker, director of cancer information at Cancer Research UK said: "This research is particularly exciting.

"Liver cancer is difficult to treat so this makes it even more important to investigate ways to detect precancerous changes in cells in order to catch liver cancer before it has had a chance to fully develop.

"This research is a fantastic example of how science has the potential to have a direct impact in cancer diagnosis and treatment in the future."

Notes

*Poly(ADP-ribose)-Dependent Regulation of DNA Repair by the Chromatin Remodelling Enzyme ALC1. Ahel et al. Science. 6th August 2009.

Source: *Cancer Research UK*

4SC Commences Phase II Trial In Hepatocellular Carcinoma (HCC) With The HDAC Inhibitor 4SC-201

www.medicalnewstoday.com

4SC AG (Frankfurt, Prime Standard: VSC) the German drug discovery and development company, today announced the dosing of the first patient in its Phase II trial with **4SC-201** (resminostat), a pan-histone deacetylase (HDAC) inhibitor, as a new potential treatment option for patients with advanced hepatocellular carcinoma (HCC), the most frequent form of liver cancer. This proof-of-concept (POC) study will evaluate 4SC-201 as a second line therapy in this indication, for which only a single first line therapy drug is currently approved.

The 'Shelter' study, entitled 'A proof-of-concept Phase II study to evaluate efficacy, safety and pharmacokinetics of 4SC-201 and of the treatment combination of sorafenib plus 4SC-201 in patients with hepatocellular carcinoma exhibiting progressive disease under sorafenib treatment', will examine whether treatment with 4SC-201 alone or in combination with sorafenib (Nexavar(R), the current standard of care in advanced HCC), can induce progression free survival and tumour responses in HCC patients who display progressive disease under treatment with sorafenib. This two-arm, proof-of-concept study will be performed at oncology-experienced university hospitals in Germany.

In the first study arm 15 patients will be treated with the maximum tolerated dose of the combination therapy which will be determined through an initial dose-escalation part, testing sorafenib in combination with 200mg to 600mg of 4SC-201. In the second study arm 15 patients will discontinue sorafenib treatment prior to inclusion into the study and will receive 600mg of 4SC-201 as a monotherapy. In both arms 4SC-201 will be applied orally once daily over five consecutive days, followed by a nine day 4SC-201-treatment free period. In the combination arm sorafenib is additionally administered continuously every day. In both study arms, the resulting 14 day cycle for the treatment with 4SC-201 (a '5 + 9' dosing schedule) will be repeated until there is evidence of progressive disease. The first two radiological tumour stagings will be performed after six and 12 weeks. Patients who experience a clinical benefit, e.g., a stabilisation of their progressive disease or tumour regression, will be offered the opportunity to extend the study treatment until disease progression occurs or until the patient voluntarily withdraws. Based on the data of the first 15 patients treated in each study arm, an optional extension phase comprising ten additional patients may be included into each study arm. The primary endpoint of the study is to determine the progression free survival rate (PFSR) after twelve weeks of study treatment. The secondary endpoints include the analysis of time-to-progression (TTD), PFSR estimated at six weeks and PFSR estimated beyond twelve weeks of treatment, overall survival, analysis of drug safety, tolerability, pharmacokinetics and the investigation of biomarkers.

In preclinical studies 4SC-201 was shown to be very potent in inhibiting the growth of different liver cancer cells, and also displayed synergistic activity on liver cancer cell growth when combined with sorafenib.

Prof. Dr. Michael Bitzer, the coordinating investigator from the University Hospital Tübingen, Germany, commented, 'Advanced HCC is an aggressive form of cancer in which classical chemotherapy approaches fail, despite huge scientific efforts over decades. Only the recent approval of a targeted therapy sorafenib, the only approved therapy for the systemic treatment for advanced HCC, has offered an innovative approach to treat these patients. However, there is an unmet medical need for new therapeutic approaches for patients that do not tolerate, or have disease progression whilst under sorafenib treatment. Notably, this need is in the second line setting where there is currently no other approved treatment option. Based on preclinical and Phase I data generated by 4SC-201 (resminostat), we are hopeful that this HDAC inhibitor may offer considerable clinical benefit to HCC patients that are progressive under treatment with the only currently approved therapy.'

Dr Bernd Hentsch, Chief Development Officer at 4SC commented, 'We are very excited about commencing this proof-of-concept study for 4SC-201 (resminostat) in HCC, the first tumour disease to test the clinical efficacy of our lead oncology candidate. We have selected this indication as we believe that 4SC-201, based on our Phase I data, has the potential to stop tumour progression. We will investigate tumour responses in patients receiving monotherapy treatment with 4SC-201, and also after combination treatment, in which we will be able to additionally determine whether 4SC-201 can induce a re-sensitisation to treatment with sorafenib. Our new therapy option 4SC-201 could potentially offer tumour regression or a stabilised disease state, with the aim of moving these patients towards disease control.'

Additional information about the clinical trial can be found at <http://www.clinicaltrials.gov>.

About 4SC-201

4SC-201 is an oral, pan-isotope histone deacetylase (HDAC) inhibitor, for which recently the INN 'Resminostat' has been proposed by the WHO. HDAC inhibitors modify the DNA structure of tumour cells to cause their differentiation and programmed cell death (apoptosis) and are therefore considered to offer a mechanism of action that has the potential to halt tumour progression and induce tumor regression in order to move towards the therapeutic control of the cancer diseases. In a Phase I trial in multiple cancers, stable disease was achieved in over 50% of the patients, whilst the compound was well tolerated and showed a positive, differentiating pharmacological profile to other drugs in this class. This data were presented in a poster presentation (Abstract #3530 (Temp. Abst. ID: 33511) at ASCO in May 2009. A further Phase II trial with this compound is planned in Hodgkin's lymphoma this year.

About Hepatocellular Carcinoma (HCC)

Hepatocellular carcinoma is the most prevalent form of liver cancer. HCC is the sixth most common cancer in the world and the third leading cause of cancer-related deaths globally (1).

HCC is most prevalent in Southeast Asia and is also very common in sub-Saharan Africa (an estimated 20 cases per 100,000 population by the World Health Organisation (WHO)). This is because in these geographies there is a high rate of hepatitis B virus (HBV) infection, which causes liver cancer as its genetic material disrupts the normal genetic material in the liver cells,

thereby causing the liver cells to become cancerous.

Historically, North America and Western Europe, has had less incidence (less than five per 100,000 population according to WHO), but is on the rise. A new study has shown that the incidence of liver cancer in the United States tripled between 1975 and 2005 and researchers believe that these trends may be partially due to an increase in chronic hepatitis C infections, which along with hepatitis B is a major risk factor for liver cancer. Other factors that may contribute to the increase in liver cancer include: heavy alcohol consumption, fatty liver disease, obesity, diabetes mellitus and iron storage diseases.(2)

References

(1) Ferlay J, et al., GLOBOCAN 2002. Cancer Incidence, Mortality and Prevalence Worldwide. IARC CancerBase No.5, Version 2.0. IARC Press, Lyon, 2004.

(2) Siegel A. B, et al. Risk of hepatocellular carcinoma (HCC) in patients with previous malignancy. Journal of Clinical Oncology 2009.

Source: ASC AG

Fight The Dreaded Hangover: Asparagus Extracts May Protect The Liver

www.medicalnewstoday.com

The amino acids and minerals found in asparagus extract may alleviate alcohol hangover and protect liver cells against toxins, according to a study in the *Journal of Food Science*, published by the Institute of Food Technologists.

Asparagus officinalis is a common vegetable that is widely consumed worldwide and has long been used as an herbal medicine due to its anticancer effects. It also has antifungal, anti-inflammatory and diuretic properties.

Researchers at the Institute of Medical Science and Jeju National University in Korea analyzed the components of young asparagus shoots and leaves to compare their biochemical effects on human and rat liver cells. "The amino acid and mineral contents were found to be much higher in the leaves than the shoots," says lead researcher B.Y. Kim.

Chronic alcohol use causes oxidative stress on the liver as well as unpleasant physical effects associated with a hangover. "Cellular toxicities were significantly alleviated in response to treatment with the extracts of asparagus leaves and shoots," says Kim. "These results provide evidence of how the biological functions of asparagus can help alleviate alcohol hangover and protect liver cells."

Source: Institute of Food Technologists

United States: FDA Finalizes Rules On Access To Investigational Drugs

<http://www.mondaq.com>

by Nathan A. Beaver, Judith Waltz, David L. Rosen and Joyce E. Gresko

On August 13, 2009, the U.S. Food and Drug Administration (FDA) published two final rules concerning access to investigational drugs and charging patients for investigational new drugs. The first rule, which addresses access to investigational drugs, does not change the methods by which seriously ill patients who are unable to participate in clinical trials can gain access to investigational therapies, but rather clarifies existing rules that have allowed some patients to access investigational drugs for several years and expands the class of patients that may have access. The second rule clarifies the conditions under which it is appropriate for drug sponsors to charge patients participating in clinical trials for investigational new drugs. Both rules take effect on October 13, 2009.

The first rule, entitled "Expanded Access to Investigational Drugs for Treatment Use," proposed at the end of 2006, clarifies the criteria for access to investigational drugs, enumerates the requirements for access submissions, establishes safeguards to protect patients from adverse side-effects, and implements mechanisms for maintaining meaningful data about treatment use and results. Per the rule, those who may be granted access to investigational drugs include individuals with a serious or immediately life-threatening disease and for whom there is no comparable satisfactory alternative therapy; intermediate-size patient populations comprising individuals who are ineligible to participate in clinical trials or whose disease is so rare that a drug is not being developed; and larger populations under a treatment protocol or in a trial conducted as part of an Investigational New Drug (IND) application.

The expanded access rule specifies that drug sponsors are responsible for submitting IND safety reports (and annual reports when the protocol continues for one year or more) and for providing treating physicians with necessary information to maximize the benefits and minimize the risks of treatment. Physicians who administer the treatments, who are considered "investigators" for purposes of this rule, must report adverse drug events to the sponsor, ensure that informed consent requirements are met, and maintain accurate case histories and drug disposition records. In support of the effort to help seriously ill patients gain access to these therapies, the FDA has launched a Web site (<http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/AccessToInvestigationalDrugs/ucm176098.htm>) where patients and their physicians can learn about options for access to investigational drugs.

The second rule, entitled "Charging for Investigational Drugs Under an Investigational New Drug Application," amends the existing rules concerning when drug sponsors may charge patients for investigational drugs. Though drug sponsors for years have been able to apply for permission to charge clinical trial participants for drugs, the rules were unclear about the circumstances under which it was appropriate and the types of costs that could be recovered. This rule specifies that a sponsor who wishes to charge a clinical trial participant for a drug must show that the drug may provide a significant advantage over other available treatments (as demonstrated by the trial), that the data from the trial is essential to demonstrating the drug's safety and efficacy, and that charging participants is essential because the cost of the drug is "extraordinary to the sponsor."

This second rule also specifies that sponsors may charge clinical trial participants to recover only the direct costs of making an investigational drug available, which include those costs per unit to manufacture the drug for the trial or to acquire the drug from another manufacturer and shipping and handling costs. If the investigational drug is used to treat intermediate-sized patient populations or large populations under a treatment protocol or IND, as authorized in the companion regulation, sponsors also may charge enough to recover the costs of monitoring the expanded-access protocol or IND. Finally, the rule also states that the FDA will withdraw authorization to charge for the investigational drug if the agency determines that charging is interfering with the development of the drug for marketing approval or if the criteria for the authorization are no longer being met.

In a press release issued by the FDA, Dr. Janet Woodcock, the director of the FDA's Center for Drug Evaluation and Research (CDER), said, "[T]he final rules balance access to promising new therapies against the need to protect patient safety and seek to ensure that expanded drug access does not discourage participation in clinical trials or otherwise interfere with the drug development process."

The final rules can be accessed at

<http://www.accessdata.fda.gov/scripts/oc/ohrms/dailylist.cfm?yr=2009&mn=8&dy=13>.

Foley will continue to provide updates on important FDA-related topics.

The content of this article is intended to provide a general guide to the subject matter. Specialist advice should be sought about your specific circumstances.

Judge to decide on prison liver transplant

<http://www.upi.com>

LOS ANGELES, Aug. 18 (UPI) -- The federal government has asked a judge to deny a liver transplant to an accused prison gang leader who could face the death penalty.

Ronald "Joey" Sellers, 41, is charged with racketeering for crimes allegedly committed as head of the Aryan Warriors, a white supremacist gang, the Las Vegas Sun reports. He is being held at Terminal Island in Southern California while federal prosecutors decide whether to seek the death penalty in his case.

In a brief filed with U.S. District Judge Kent Dawson, prosecutors say doctors at a Los Angeles hospital recently determined Sellers was not a good candidate for a transplant.

Sellers' lawyers say he is likely to die before he is tried unless he gets a transplant. He says he contracted hepatitis C while he was an inmate in state prisons in Nevada.

"The defendant is quite ill from his end-stage liver failure," the lawyer said in court papers. "He is severely bloated, has a massive hernia so large that a fist-size portion of his intestines are protruding from his muscular wall and he is in constant pain requiring medication in sufficient dosages that he risks addiction."

Roche, InterMune Commence Mid-Stage Trial of Hepatitis C Drug - Update

<http://www.rttnews.com>

(RTTNews) - Swiss drug giant Roche Holding AG (RHHBY.PK: News , RHHVF.PK) and InterMune Inc. (ITMN: News) Wednesday announced the start of a mid-stage trial to evaluate hepatitis C virus protease inhibitor, **RG7227/ ITMN-191**, in combination with Pegasys and Copegus.

The study is to be conducted at 45 sites globally, and will enroll about 300 patients. The study will further define the safety and efficacy profile of RG7227/ITMN-191 for a treatment duration of up to 24 weeks.

RG7227/ITMN-191 is being developed in partnership by Roche and InterMune. With the initiation of the phase 2b trial, InterMune will receive a \$20 million event payment from Roche under a collaboration agreement.

The objective of the Phase 2b randomized, double-blind, placebo-controlled study is to further characterize the safety, tolerability, and antiviral effects of RG7227/ITMN-191 in triple combination, compared with standard of care, PEGASYS plus COPEGUS.

Roche and InterMune also plan to initiate a phase 1 trial combining RG7227/ITMN-191 with low dose ritonavir to examine the virologic effect of ritonavir-boosted RG7227/ITMN-191 in once-daily and twice-daily regimens in combination with standard dosing of PEGASYS and COPEGUS in patients chronically infected with HCV genotype 1.

RG7227/ITMN-191 is also being investigated in combination with the NS5B polymerase inhibitor RG7128 in the INFORM-1 study.

ITMN closed Wednesday's regular trading session at \$14.49, up 58 cents or 4.17%. However, in the after-hours, the share lost 58 cents or 4.00%.

Cases of primary liver cancer rise

<http://www.google.com>

(UKPA)

Obesity and alcohol are fuelling cases of liver cancer, which have more than tripled in the past 30 years, according to new figures.

In 1975, there was just 865 cases of cancer that originated in the liver, but this rose to 3,108 in 2006, the latest UK figures show.

The rate of primary liver cancer almost tripled from 1.4 per 100,000 in 1975 to 3.9 in 2006.

Secondary or metastatic liver cancer - cancer that has spread to the liver from a tumour elsewhere in the body - is a relatively common disease but primary liver cancer has been rare until now.

Experts say the rise in drinking levels, obesity and hepatitis C is causing cirrhosis of the liver, which can develop into primary liver cancer.

Matt Seymour, Cancer Research UK's professor of gastrointestinal cancer medicine at the University of Leeds, said: "Three main risk factors for liver cirrhosis - alcohol, obesity and hepatitis C infection - are getting more common in the UK.

"So we are seeing more patients with cirrhosis and, in turn, more patients with primary liver cancer. This is likely to continue. There is a long delay between exposure to the risk factors and the onset of cancer. It might take between 20 and 40 years for liver cancer to develop after infection with hepatitis C.

"So even if new cases of infection stopped, the number of cases of cancer would continue to rise for some years."

Hepatitis C is commonly spread by drug users but in the 1960s and 1980s, people did catch it from contaminated blood transfusions.

Dr Lesley Walker, Cancer Research UK's director of cancer information, said: "While this increase is a concern, it is important for people to understand how their risk of liver cancer can be reduced by changes to lifestyle. Cutting down on alcohol and watching your weight will help to reduce the risk of a wide range of cancers including primary liver cancer. Taking plenty of exercise and eating a balanced diet high in fibre, fruit and vegetables and low in fatty foods, red and processed meat can all help towards keeping a healthy weight."

August 20, 2009

Pediatric HCV Infection May Lead to Liver Damage

www.medscape.com

By David Douglas

NEW YORK (Reuters Health) Aug 19 - Infection with hepatitis C virus (HCV) can cause a variety of symptoms and functional hepatic changes in children and adolescents, researchers report in the August issue of the *Pediatric Infectious Disease Journal*

"Our findings," lead investigator Dr. Wendy A. Henderson told Reuters Health, "indicate that pediatric patients with HCV have potentially significant symptoms and pathophysiologic liver changes related to HCV infection."

Dr. Henderson and colleagues, from the National Institutes of Health, Bethesda, Maryland, came to this conclusion after reviewing data on 62 HCV patients, 3 months to 19 years of age.

In all, 60% of these patients presented with symptoms including fatigue, joint and abdominal pain, and bruising and bleeding. In the 35 who underwent liver biopsy, 80% had evidence of

inflammation. Biopsy also showed that 57% had fibrosis and 9% had steatosis. Symptoms were universally present in patients with cirrhosis or steatosis.

Overall, males were significantly more likely to be symptomatic, as were older patients. In addition, patients with a viral load below 2 million copies were five times more likely to have symptoms than those with higher values ($p = 0.03$). The authors suggest that this inverse association is "possibly related to the presence of comorbid conditions in 74% of the cohort."

Given these findings, Dr. Henderson concluded: "It remains to be determined if children with HCV will have amelioration or complete resolution of symptoms following treatment."

Pediatr Infect Dis J 2009;28:724-727.

Losartan Lowers Diabetes Risk in Patients with Hypertension and HCV

www.medscape.com

NEW YORK (Reuters Health) Aug 20 - Treatment with losartan reduces the risk of type 2 diabetes in hypertensive Japanese patients with chronic hepatitis C, according to researchers.

"Data supporting a link between type 2 diabetes mellitus and chronic hepatitis C infection have been reported," Dr. Yasuji Arase at Toranomon Hospital in Tokyo and colleagues write in the September *Journal of Medical Virology*.

On the basis of earlier reports that angiotensin receptor antagonists can improve insulin sensitivity and glucose and lipid metabolism, the researchers analyzed the cumulative incidence and predictive factors for type 2 diabetes in 80 patients with hepatitis C virus (HCV) infection and hypertension who were treated with losartan. Another 160 patients treated with spironolactone and matched for age and gender served as controls.

At a mean follow-up of slightly more than 5 years, 3 losartan patients and 22 spironolactone patients had developed type 2 diabetes. The fifth-year cumulative appearance rate of type 2 diabetes was 5.9% in the losartan group and 14.0% in the spironolactone group, according to the authors.

On multivariate analysis, hazard ratios for development of type 2 diabetes were 6.10 with spironolactone, 4.31 when histological staging was advanced, 3.28 with steatosis, and 2.47 with pre-diabetes.

"Our results indicate losartan causes about 60% reduction of the risk of type 2 diabetes development compared to spironolactone," the authors said.

Vascular events occurred in 2 losartan-treated patients and 6 spironolactone-treated patients during the observation period.

J Med Virol 2009;81:1584-1590.

Hepatitis C Virus Impacts Survival after Liver Transplantation

www.medscape.com

NEW YORK (Reuters Health) Aug 20 - Liver transplant recipients whose indication for transplant was hepatitis C virus (HCV) cirrhosis have markedly poorer survival compared to patients transplanted for alcoholic liver disease (ALD), researchers have found.

According to Dr. Michael R. Lucey of the University of Wisconsin, Madison, and colleagues: "Except in patients with very low or very high Model for End-Stage Liver Disease (MELD) scores, HCV status has a significant negative impact on the survival benefit of liver transplantation. In contrast, the presence of ALD does not influence liver transplant survival benefit."

In their study, the researchers considered the effect of etiology and severity of underlying liver disease (HCV infection and ALD) on the transplant survival benefit, which encompasses both pre- and post-transplant events -- something that has not been done previously, they note.

They analyzed data from the Scientific Registry of Transplant Recipients on 38,899 adults placed on the U.S. transplant waiting list for deceased donor liver transplantation between September 2001 and December 2006. Subjects were classified into one of four cells of an HCV x ALD 2x2 table according to their status with regard to these conditions.

Overall, 27.8% of the study cohort had ALD and 42.5% were HCV positive.

According to a report in the August issue of *Hepatology*, patients with HCV infection had increased waiting list mortality (HR, 1.19) and post-transplant mortality (HR, 1.26) compared to HCV-negative patients, and this effect was greater in patients with both HCV infection and ALD.

The survival benefit of liver transplantation for patients with HCV was decreased at intermediate MELD scores of 9-29 (15% to 33% increased hazard of death) but increased at MELD scores greater than 30 (41% survival benefit).

In contrast, ALD had no effect on mortality for patients on the waiting list or who had undergone a liver transplant, and having ALD did not influence the survival benefit of transplantation at any MELD score, the researchers found.

In an editorial published with the study, Dr. Sumeet K. Asrani and colleagues from the Mayo Clinic College of Medicine, Rochester, Minnesota, discuss the implications of these findings if a "benefit-based transplant policy" were to be adopted in the face of an organ shortage that mandates rationing of a scarce resource.

The data, they write, suggest that "compared to patients with ALD who have comparable MELD score, patients with HCV should be given a lower priority when their MELD is intermediate (score of 9 to 29), whereas patients with HCV who have higher MELD score should be given an even higher priority than candidates at the same MELD score with another diagnosis."

For such a benefit-based transplant policy to be implemented, Dr. Asrani and colleagues note,

the transplant community "must be willing to accept this departure from the traditional thinking: because some patients with hepatitis C will experience poor outcome, they will be placed at lower priority than patients without HCV who are faced with the same (or even lower) risk of death while waiting."

Summing up, Dr. Asrani and co-authors say this study is "an important step" in the continued debate on which variables matter in predicting survival benefit of liver transplantation and whether an organ allocation system based on predicted survival benefit can be equitably implemented.

Hepatology 2009;50:352-354,400-406.

Rare flesh-eating bacteria kills man after fishing trip

<http://www.chron.com>

By Mike Tolson

A Baytown man has died from illness caused by exposure to a rare pathogen often referred to as flesh-eating bacteria.

Thomas Jesse Shurley, 52, died Tuesday night of multiple organ failure following a three-week battle against the infection. He had suffered a scrape on his knee while fishing in Galveston Bay on July 26, family members said. The bacteria, most often encountered in seawater, rapidly spread throughout his body, and even the amputation of his leg could not stop it.

"It's really a shock to the entire family," said his daughter, Shaunte Angelo. "He was young and full of life. We never saw this coming."

The incident occurred when Shurley was fishing alone close to shore in a small jon boat. The boat tipped over and he scraped his left knee while righting it. Shurley felt sick the next day but thought little of it. By Tuesday evening, his knee was so swollen and he felt so bad that friends took him to Baytown Methodist Hospital, fearing he had broken it.

"The doctors ran some tests and figured out what it was," Angelo said. "They asked him if he wanted to lose his leg or his life. Of course, he chose his leg."

The next day Shurley was taken by Life Flight to St. Luke's Episcopal Hospital in the Texas Medical Center. He was placed on a ventilator and never regained full consciousness, his daughter said. Infected tissue was surgically removed, and later most of his leg. But there was little hope once the infection spread through his blood and most of his organs, she said.

He was taken off life support at 6:30 p.m. Tuesday and died about five hours later.

"If he had gone to the hospital Monday morning, the day after he hurt his knee, he might have been fine," Angelo said. "But who would have thought to do that for a scrape?"

The medical name for Shurley's illness is necrotizing fasciitis. It is caused by several kinds of bacteria, the most common of which is *Streptococcus pyogenes*, the same thing that causes strep

throat and impetigo. Another bacterium sometimes involved — as in Shurley's case — is *Vibrio vulnificus*.

Such infections, often mild, can become life-threatening for people with underlying medical conditions such as diabetes or hepatitis. Shurley suffered from hepatitis C, Angelo said.

Shurley was a sales manager at Gyro Chemical and Equipment Company in Deer Park, which specializes in industrial cleaning supplies.

Hepatitis C linked to illegal blood donation in China

<http://cultureeconomy.thetkr.com>

Research in a rural province of central China has documented that illegal blood donation practices led to high hepatitis C virus (HCV) infection rates in blood and plasma donors during the 1980s and early 1990s, and that deficiency to screen for HCV in transfusion recipients increased their risk of infection as well, according to an article in the November 15 issue of *The Journal of Infectious Diseases*, now available online.

Some blood donation facilities in rural China illegally pooled blood and reinfused compatible red blood cells to permit more frequent donations. Although government action has markedly curtailed such practices since the late 1990s, blood collection and banking methods in such settings still need to be monitored and improved, the article noted.

Researchers from the United States and China, including Han-zhu Qian, MD, PhD, of the University of Alabama at Birmingham, conducted a survey in 2003 among a random sample of 538 adult residents from 12 former commercial plasma-donating villages in Shanxi Province. Structured questionnaires were administered and blood samples tested for HCV antibodies. HCV rates were 8% in all participants, 28% in former plasma/blood donors, and about 3% in non-donors. Selling blood or plasma was the strongest independent predictor for HCV-positive findings. Receiving a blood transfusion was also independently associated with HCV; villagers who received blood transfusion had about 8 times the risk of HCV infection than those who had no history of blood transfusion.

Among the 538 villagers, 22 percent had a history of selling blood or plasma; from village to village, the rates ranged from 9 percent to 49 percent. The most common reasons for the practice were a need for money and being talked into it by other people. Villagers began to sell blood as early as in 1973 and as late as 1998; the main reasons for stopping were improved economic status, concern about health effects of blood drawing, abnormal liver function tests or hepatitis, and shut-down of the illegal blood center.

The investigators concluded that unhygienic plasma donation and receipt of blood transfusion are strong risk factors for HCV infection in rural central China, and that improved blood collection and blood banking practices remain an urgent health priority. “Technical support and drugs are needed to assist these central Chinese provinces cope with the care and treatment needs of HCV patients,” the investigators added.

In an accompanying editorial, Roger Y. Dodd, PhD, of the American Red Cross noted that the

study is “a snapshot of past events and should not be taken to define the present circumstances.” Nevertheless, it illustrates that “short cuts, shoddy practice, pursuit of the bottom line, and lack of oversight can have devastating outcomes, not only for patients but also for donors.”

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

Herbs, vitamins that can hurt you

www.cnn.com

By Elizabeth Cohen

CNN Senior Medical Correspondent

(CNN) -- Carole Grant doesn't really trust medical doctors. She never has. Whenever she has had a health issue, she has headed straight for an herbalist, acupuncturist or other "natural" healer.

A few years ago, her alternative practitioner of choice was a self-described "intuitive healer" in New York, where she lives. The healer put Grant on a regimen of herbs, supplements and vitamins to help her lose weight.

A few weeks later, Grant, a geriatric care manager, was closing up an apartment for an elderly client who'd died when she started feeling strange sensations in her toes.

"They were tingling like crazy," Grant said. "I thought it was the carpet in the apartment, because it was old and dirty, and I'd taken my shoes off."

When the tingling in her toes spread to her feet, Grant knew that it was more than just the dingy carpet. When it spread to her legs, she knew that she was really in trouble.

"Both legs went numb up to my knees," she remembers.

Grant sought help from a podiatrist, who insisted that she get care from a medical doctor. Grant chose Dr. Roberta Lee, vice chairwoman of the Department of Integrative Medicine at the Beth Israel Medical Center in Manhattan.

After some testing, Lee discovered the reason for Grant's numbness: She had sky-high amounts of vitamin B6 in her blood, which can interfere with circulation.

"The intuitive healer had told me to double my dose of vitamin B6," Grant said. "She never told me when to stop the double dose, and I never checked with her."

It turned out the healer was having Grant take about 100 times the normal dose of B6, according to Lee. The healer had intended for Grant to take this high dose for a few weeks. Instead, she took it for more than four months.

"It blew my mind to think this could happen to someone like me," Grant said. "I'm so careful. I'll use every natural modality I can before taking medicine."

Lee says that although it's unusual, she's seen other patients get into trouble with herbs,

supplements and vitamins precisely because they're less cautious with something that's natural than they would be with a drug.

"A lot of people think herbs are safe because they come from nature, and they are safe if used properly," Lee said. "But you can still get into trouble with them."

"I don't think any herb is good or bad. It's how we use it," said Dr. Brent Bauer, director of the Complementary and Integrative Medicine Program at the Mayo Clinic. "Sometimes people take too much. They think, if two is good, then 20 must be better."

Here's a list of herbs and supplements that can be dangerous if taken the wrong way: either in high doses, in combination with certain drugs or before surgery.

1. St. John's wort

This herb, often taken to relieve depression, is always at the top of the list of potentially problematic natural remedies because it can cause serious side effects and increase or decrease the potency of many medications. The Mayo Clinic recommends that many people should avoid it, including those taking antidepressants, anti-blood-clotting drugs, certain asthma drugs, immune-suppressing medications or steroids.

2. Kava

A sedative herb, kava is associated with serious liver problems, even when taken for a very short time, according to the Mayo Clinic. It's especially risky if you're taking drugs to lower cholesterol.

3. Fish oil

Though it's a very safe supplement to increase your intake of heart-healthy fat, Lee says she's seen patients have excessive bleeding when taking high doses of fish oil. "It's not life-threatening, but for example, I've seen where people are taking too much fish oil, and they'll have prolonged bleeding from acupuncture needles."

How much fish oil is too much? More than 5 grams -- or 5,000 milligrams -- a day, according to Bauer.

4. Artemisinin

Last week's *Morbidity and Mortality Weekly Report*, put out by the Centers for Disease Control and Prevention, details the case of a man who developed hepatitis after taking the herb artemisinin for stomach problems. There was no other reason for his hepatitis, and the disease went away when he stopped taking the herb, and the authors suggested that doctors be aware of a possible relationship between the artemisinin and hepatitis.

5. Various herbs when taken before surgery

Dr. David Rowe, a plastic surgeon, was operating on a patient when he noticed an unusual amount of bleeding.

"The tissue was just oozing, and we couldn't figure out why," he remembered, noting that the patient had told him he wasn't taking any supplements. "After the surgery I asked the patient, 'Are you sure you're not taking anything?' and he said, 'Oh, yes, I'm taking this, this and this.' "

In a paper published this year in the *Aesthetic Surgery Journal*, Rowe listed about a dozen herbs that should be avoided within two weeks of surgery, including common ones such as garlic, ginseng and echinacea. Some increase bleeding and some affect the heart, and others interfere with anesthesia or other drugs.

It's imperative that you tell your surgeon absolutely every natural remedy you're taking, says Rowe, an assistant professor of plastic surgery at University Hospitals Case Medical Center in Cleveland. Studies have shown that 60 to 70 percent of patients don't tell their physicians about supplements.

He tells his patients to read their supplement labels carefully.

"One supplement can have 10 or 15 things in it, so you may not know what you're on, which is really scary for us surgeons," he said.

As for Grant, she's still feeling tingling and numbness in her legs and feet even three years later.

"I still need to lose weight, but I'm not taking any supplements," she said. "I'm just too gun-shy at this point."

For more information about herbs, vitamins and supplements, visit the Web sites for the **National Institutes of Health**, the **Food and Drug Administration** and the **Alternative Medicine Foundation**.

Hepatitis B Foundation STEERS Students through Summer Enrichment Programs

<http://www.prlog.org>

8th annual Research Internship Program. Internships include a High School Enrichment Program, offered to students in area school districts, and a College Internship Program that is highly competitive and attracts students from top tier colleges.

PRLog (Press Release) – Aug 20, 2009 – DOYLESTOWN, PA – The Hepatitis B Foundation graduated 16 students from their 8th annual Summer Research Internship Program designed to steer them into exploring potential careers in the fast-growing areas of biomedical research, biotechnology, and public health research. The summer internships include a High School Enrichment Program, offered to students selected by the area school districts, and a College Internship Program that is highly competitive and attracts students from top tier colleges. This year the Foundation received more than 100 applications for eight college internships, which are funded in part by a grant from Merck's West Point Charitable Contributions Committee and the Charles Sigety Family Foundation.

"Our research training programs enhance the students' research abilities while providing them an awareness and appreciation of the importance of research, public health, and patient advocacy within the context of hepatitis B," said Peggy Farley, Director of Programs at the Hepatitis B Foundation. "The participating students are mentored by our dedicated research and public health professionals in state of the art research labs."

The College Summer Internship Program offers junior and senior year college students a 10-week paid summer research experience where they work on individual projects with professional scientists from the Hepatitis B Foundation. Students participate in the intellectual life of the Foundation's research institute that includes daily lab meetings, and journal clubs and research seminars. At the conclusion of the 10 weeks, each student presents their project to the Foundation and its research faculty in a special ceremony that includes a presentation of certificates from the Foundation president. This program has been supported for many years by the Charles Sigety Family Foundation and Merck & Co. West Point Charitable Contributions Committee. This year's Sigety Fellow was Lisa Faber and the two Merck Scholars were Daniela Hess and Tim Humpton. College interns for 2009 included Beth Clearfield (Lafayette College), Lisa Faber (Delaware Valley College), Daniela Hess (Fordham University), Tim Humpton (MIT), Andrew Klein (Notre Dame), Amy Dunaway-Knight (University of Oklahoma), Matthew O'Donnell (Penn State University), Mark Pinkerton (Delaware Valley College), Ken Moritz (Penn State University), and Crystal Leonard (Bryn Mawr College).

The High School Science Enrichment Program provides high school students with hands-on research experience and exposure to the different career opportunities in biomedical research, biotechnology and public health. In addition to working in the lab on specific projects, students enjoy guest lectures; attend scientific seminars, and much more. This year's participants were Victoria Avanzato (William Tennent High School), Julia Brokaw (Palisades High School), John Holby (Palisades High School), Jennifer Jang (Central Bucks South High School), Casey McGinley (Central Bucks East High School), Rachel Shulman (Central Bucks East High School), and April Wangment Zhang (Central Bucks South High School).

About the Hepatitis B Foundation

The Hepatitis B Foundation is the only national nonprofit organization solely dedicated to finding a cure and improving the quality of life for those affected with hepatitis B worldwide through research, education and patient advocacy. For more information, visit www.hepb.org or call 215-489-4900Bi

Aspen resident to compete in World Transplant Games

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

Jon Maletz

The Aspen Times

ASPEN — The scar on his torso, one shaped like a Mercedes Benz emblem, is a constant reminder of Michael Wells' unsavory past.

It is also a reminder of his good fortune.

Less than 10 years ago, the 58-year-old Aspen resident was wondering if he would get his call. Stricken with hepatitis C and cirrhosis of the liver, Wells was in rapidly declining health. A transplant was the only thing that could save his life, doctors said.

“I might have had anywhere from one to 10 years [to live],” Wells said Tuesday. “At the time this was all happening, I could tell things were not going well.

“Now, I can live without fear, or worrying about dying.”

Wells received that call — and a new lease on life. He's taking full advantage.

He recently applied for his first passport. And earlier this week, he took a trip across the world.

Wells is slated to compete in the 20 km. bike race and 5 km. time trial at the World Transplant Games, which begin Saturday on Australia's Gold Coast.

“If I never got the transplant, I probably never would have gone to Australia,” he said. “It's kind of weird ... but it'll be a great experience.

“I'm just happy to be alive.”

Wells was living in Bellingham, Wash., 80 miles north of Seattle, when, in 1994, he mysteriously gained about 55 pounds of water weight in little more than a month.

“I was a walking water balloon,” he recalled.

Wells later learned he had hepatitis C and cirrhosis, which resulted in incurable end-stage liver disease.

Wells determined he had been infected with hepatitis, which causes scarring of the liver and is spread by blood-to-blood contact, when he was a teenager growing up in Colorado Springs. In subsequent years, the infection was exacerbated by his drinking.

“I did some stuff with friends, some needle stuff,” Wells said. “It was just an eight- or nine-time thing. After that month, I realized it was a pretty stupid thing to do and I never did it again.

“At that time we didn't know. It was 1967 or '68 and no one had heard about this.”

After following suggested medical protocols for a few years, Wells' doctor sent his records to the University of Washington in January 1998 to see if he would be a candidate for any hepatitis studies or treatments.

He was told a transplant was his only option. Wells was put on the waiting list in October.

One year later, his health took a turn for the worse.

“I was driving to the store one day and I felt like I was drunk — I hadn't had a drink at all at the time,” he remembered. “I was weaving all over the road, and I said, ‘What's the matter with me?’ I went home and called my doctor, and he told me to come down and get more tests.”

Soon after, Wells went from transplant list 3B, the longest wait, to list 1, he said. His life-saving call came Dec. 2, 1999.

That week, Wells was twice called to be a backup patient in case things went wrong with the original recipient. On one such occasion, he returned home after an eight-hour wait in the UW

Medical Center waiting room to find the phone ringing.

“My first thought was, ‘Why are sales people calling me at 11 at night?’” Wells said. “The transplant center said they had a liver for me.

“I jumped in the shower, washed my face and called my brother and told him, ‘Be at the hospital at 6:30 p.m. They're going to put me under.’”

He was on the operating table for 13 hours, and in the hospital for 26 days. Doctors would later tell him he received the liver of a 19-year-old man, who was most likely killed in a car accident.

“I was just happy to wake up. I remember thinking, ‘Wow, I'm back alive,’” Wells said.

“They told me I had a good heart, so take care of it. I have.”

An active outdoor enthusiast before the operation who enjoyed hiking and biking, Wells took things slow for the first few years.

Upon moving to Aspen six years ago, a decision prompted by a desire to return to Colorado and to be close to a brother who lives in the area, Wells got back in the saddle and joined a gym.

“I was thinking about other things I could do physically, and thought that if I was working out I might as well have a goal,” Wells said. “I'm no elite athlete or anything.”

He started riding to work at Ace Hardware from his home in Aspen Village. He started signing up for local races in an attempt to raise awareness about organ donation. He participated in the first Summit for Life in 2006 — “I finished dead last two years in a row,” he joked — and has taken part in the annual uphill race on Aspen Mountain, which was created by Olympic bronze medalist and fellow liver transplant recipient Chris Klug, ever since.

In Aug. 2008, he took part in the U.S. Transplant Games in Pittsburgh. He rode in the 20 km. bike race.

“It's interesting being around a couple thousand people who are happy to be alive,” Wells said. “It's hard to explain in words sometimes how it feels, but it's a good thing.”

This year, with the support of the Chris Klug Foundation, the National Kidney Foundation of Colorado, Montana and Wyoming plus Ute Mountaineer owner Bob Wade and his wife Ruth, Wells will represent the U.S. at the world games, which take place every two years.

His goals are modest: To finish the 20 km. ride in less than 45 minutes and the 3.1-mile time trial in about 12.

“If I actually get a podium finish in my age group, that would be totally amazing,” Wells said. “We'll see how it goes. I'm in so-so shape, not the best shape.”

Podium finishes will not define Wells' first trip to Australia. After years spent living with uncertainty, he said he is content to live freely and without reservation.

What a gift.

“After a while you get used to it and get back to your normal life. Then there are moments when you look at something as say, ‘Wow, I wouldn't have seen that,’” Wells said. “I'm not anyone famous. I'm just someone doing what they want to do.

“I'm lucky to be alive.”

Up to 11,000 U.S. veterans may have been mistakenly infected with HIV

<http://www.tajikistannews.net>

Tajikistan News.Net

11,000 veterans who had colonoscopies at U.S. Veterans Affairs hospitals may have been exposed to hepatitis B, hepatitis C and HIV.

The veterans were advised equipment used during their treatment was not sterilized. Of those so far that responded by having follow-up blood checks, 8 have tested positive for HIV. Twelve of the veterans have tested positive for hepatitis B, and 37 have tested positive for hepatitis C.

This week it was learned a 55-year-old North Miami man, Juan Rivera, a thirteen-year Army veteran with a wife and 5 children, filed notice last month that he will sue the Federal Government claiming he was infected with HIV during a colonoscopy at the Miami Veterans Administration hospital. He had a colonoscopy at the hospital in May last year.

Rivera is suing the government for \$20 million.

On March 28, the VA department wrote to more than 3,000 veterans who had colonoscopies at the Miami VA hospital advising them that improperly cleaned equipment might have exposed them to hepatitis B, hepatitis C and HIV.

VA officials say endoscopy equipment was rinsed instead of being sterilizing as was required by the manufacturer's directions.

Similar problems were uncovered at VA hospitals in Murfreesboro, Tenn., and Augusta, Ga. The total number of veterans subsequently blew out to more than 11,000.

Following congressional inquiries, Miami VA hospital director Mary Berrocal disciplined up to 10 employees.