

HCV ADVOCATE WEEKLY NEWS REVIEW

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

*Alan Franciscus
Editor-in-Chief*

Week Ending: May 23, 2009

In This Issue:

- [Open approach to HIV and Hep C](#)
- [Glucose abnormalities in non-alcoholic fatty liver disease and chronic hepatitis C virus infection: the role of iron overload.](#)
- [Three Primates, Antibodies and a Future for Hepatitis C](#)
- [Ensuring the Success of Future Generations Means Continuing the Fight to Eradicate Hepatitis B](#)
- [James Kreppner, 47 / Lawyer, Hemophiliac](#)
- [Camps to be set up for awareness raising, screening](#)
- [Hepatitis C: The silent killer among us](#)
- [Marijuana a cause for uprooting?](#)
- [An Overview of the HCV Drug Development Process](#)
- [Call to end hepatitis C ignorance](#)
- [World Health Assembly Forced to Postpone Decision on Viral Hepatitis](#)
- [Photo exhibit boosts Hep C awareness](#)
- [Soaring on Robin's Wings](#)
- [Congressional Briefing on Chronic Viral Hepatitis and Liver Cancer Highlights World Hepatitis Day](#)
- [Projected Surge in Liver Cancer Among Asian American and Pacific Islanders](#)
- [Villages couple's daughter writes book to promote understanding of hepatitis](#)
- [World Hepatitis Day: Prospects for the Future - Guest blog by Paul Klenerman and colleagues](#)
- [World Hepatitis Day Message from President Obama](#)

- [New Report Forecasts Hepatitis C Virus Epidemic Among Baby Boomers; Untreated HCV Progressing to Severe Liver Disease Seen Driving U.S. Costs to \\$85 Billion](#)
- [Nexavar Approved In Japan For The Treatment Of Advanced Liver Cancer](#)
- [This Is Your Government Making Sense on Drugs](#)
- [Tainted blood victims left angry](#)
- [Local liver specialists struggle to keep up with hep C influx](#)
- [World Hepatitis Day 2009: 5 Years For The EU To Rescue The Liver!](#)
- [Hepatitis C Virus Can Be Transmitted by Drug Use Through the Nose](#)
- [Doctor and Patient: Fear of Contagion](#)
- [ALT Level Increase Common During HCV Therapy](#)
- [Michigan Recognizes May As Hepatitis Awareness Month](#)

May 16, 2009

Open approach to HIV and Hep C

<http://nns1.com/>

Katherine Roth

Northern News Services

SOMBA K'E/YELLOWKNIFE - Focusing on lowering the spread of HIV and hepatitis C was the main topic of a seminar held in Ndilo this week. The NWT HIV and Hepatitis C Support Network held the workshop on Tuesday in an effort to better inform the community. Instead of trying to force people to quit habits that lead to the spread, the focus was on keeping drug abusers safe from harm.

Trevor Stratton, a Toronto-based aboriginal AIDS activist, spoke at the seminar and gave a personal account of being affected by HIV after his diagnosis in 1990.

"Aboriginal and gay men were forgotten back then, being about 10 years behind the mainstream HIV movement," he said.

After he was asked by a community health representative on his reserve to speak publicly about his condition, Stratton received a huge surprise regarding how well it was received.

"It really freaked me out how much support I got from sharing (my story)."

He now spends his time advocating for aboriginal people in Canada living with HIV and largely focuses on harm reduction and community readiness. These steps allow each community to acknowledge the presence of drug use and sexual activity that often leads to the spread of HIV and hepatitis C. Stratton said providing a non-judgemental atmosphere where people can talk and

build trust is important in allowing people to realize that they are not alone.

"I don't know if this program saves lives. I have no way of knowing that," he said.

"But people who are infected have received support, and that is so important."

The idea of support without judgement was music to the ears of April Manuel from the Deh Cho First Nations "Believing in Yourself" program.

"It really reflects onto the program that we are doing," she said.

"We have to get support to figure out who we are before we can go on in life, and (Stratton) made that a very strong point."

A growing need for help in Yellowknife is what inspired the NWT HIV and Hepatitis C Support Network to form in April 2008. In Canadian aboriginal communities, 32 per cent of people infected with HIV are youth, 50 per cent are women, and the risk of those in prison is 10 times higher than the general population. After receiving \$100,000 in funding from the Public Health Agency in February, the network now has the resources required to give people with chronic infectious diseases access to support programs and resources.

A meeting group is currently being developed by support network founder Debbie Russell and Irene Savoy for people in Yellowknife who are infected with HIV or hepatitis C. The goal for the future is to work together with the safe needle exchange program at the Jan Sterling building, said Russell.

"There has been a growing need, which is how the network started," she said.

"Now we are working on building a group where people can come who are directly affected."

Russell said although at points Stratton's message appeared to condone the use of drugs, that is not the message that the NWT HIV and Hepatitis C Support Network wants to send out.

"It is not about promoting drug use in any way shape or form," she said.

"Our perspective on harm reduction is exactly what it means: reducing harm. It isn't about counselling either, but reducing the transmission of HIV and hepatitis C."

City councillor Lydia Bardak has a different approach to the idea of harm reduction, and that is preventing the use of drugs before it becomes a problem. She was not present at the seminar, but said that the term "harm reduction" is one that seems to have different meanings.

"My own idea of reducing harm means starting very early in a person's life and continuously through life about the harm they do themselves when abusing substances," Bardak said. "There are lots of alternative activities encouraging people from a young age on to be involved in anything that is a healthier alternative to drugs."

Glucose abnormalities in non-alcoholic fatty liver disease and chronic hepatitis C virus infection: the role of iron overload.

<http://www.ncbi.nlm.nih.gov>

Non-alcoholic fatty liver disease (NAFLD) and chronic hepatitis C virus (HCV) infection are major causes of liver disease frequently described in outpatient patients with glucose abnormalities. Hyperferritinemia, which suggests that iron overload plays a decisive role in the pathophysiology of insulin resistance and hyperglycemia, is a common finding in both disorders. However, the role of the hepatic iron deposition differs from one to the other. In NAFLD, a moderate liver iron accumulation has been observed and molecular mechanisms, including the downregulation of the liver iron exporter ferroportin-1, have been described. Iron overload will enhance intrahepatic oxidative stress that promotes hepatic fibrosis, interfere with insulin signalling at various levels and may hamper hepatic insulin extraction. Therefore, liver fibrosis, hyperglycemia and hyperinsulinemia will lead to increased levels of insulin resistance and the development of glucose abnormalities. Furthermore, iron depletion by phlebotomy removes liver iron content and reduces serum glucose and insulin resistance in NAFLD patients. Therefore, it seems that iron overload participates in those glucose abnormalities associated with NAFLD. Concerning chronic HCV infection, it has been classically assumed that iron overload contributes to insulin resistance associated with virus infection. However, recent evidence argues against the presence of iron overload in these patients and points to inflammation associated with diabetes as the main contributor to the elevated ferritin levels. Therefore, glucose abnormalities, and specially type 2 diabetes, should be taken into account when evaluating serum ferritin levels in patients with HCV infection.

Diabetes Metab Res Rev. 2009 May 14. [Epub ahead of print]

Three Primates, Antibodies and a Future for Hepatitis C

<http://hepatitis.about.com>

Charles Daniel

Imagine a future when someone with a new hepatitis C infection could be treated with special hepatitis C antibodies that neutralize the virus. Gone would be chronic hepatitis C and many of its associated complications like cirrhosis and liver failure. It sounds too good to be true, but a team of scientists have done something very similar with animals. In due time, maybe this can be successful on people.

The scientists, associated with the University of Massachusetts Medical School, developed a novel antibody, called MBL-HCV1, that could tightly bind to the outer coat of a hepatitis C virus in an artificial environment (in vitro) and neutralize it. Since living systems are more complex, the next step was to see how the antibody acted in animals.

Three primates were exposed to hepatitis C viruses, but were studied under different conditions. One had previously received a low dose of the new antibody. Another had previously received a higher dose of the antibody. One received no antibody. Only the primate that received the higher

dose of antibody was protected. They other two developed hepatitis C infections. Furthermore, after the scientists gave the no-antibody primate a high dose, the hepatitis C infection disappeared.

This research is still a long way off from being available in the clinic, but it shows that scientists are hot on the trail of better treatments for hepatitis C. This could potentially be a wonderful therapy, both preventative and in newly diagnosed patients. According to the researchers, it could have a tremendous use in protecting liver transplant patients (due to chronic hepatitis C) from re-infection with the hepatitis C virus.

This research was presented in April 2009 at EASL, the 44th Annual Meeting of the European Association for the Study of the Liver.

Ensuring the Success of Future Generations Means Continuing the Fight to Eradicate Hepatitis B

<http://www.asianweek.com>

As we celebrate the accomplishments of Asian Americans, Native Hawaiians and Pacific Islanders throughout the month of May and reflect on how far we've come, it benefits us to also remember the obstacles and hindrances we still face as a community. One such health-related barrier that still prevents our community from achieving its full potential is hepatitis B.

Hepatitis B is a serious disease that affects some two billion people worldwide. Among the Asian American, Native Hawaiian and other Pacific Islander (AA and NHOPI) population, the disease has had an equally devastating impact, with AA and NHOPIs comprising more than half of the 1.5 million known hepatitis B carriers in the United States. Hepatitis B, which is caused by the hepatitis B virus (HBV), can lead to lifelong infection, cirrhosis (scarring) of the liver, liver cancer, liver failure and death. In the United States, it is estimated that one in 20 people will become infected with HBV, and one in four chronic hepatitis B carriers (25 percent) will die of liver cancer or liver failure. Roughly one in ten AA and NHOPI individuals are already infected with HBV, and AA and NHOPIs consequently maintain the highest rate of liver cancer among all ethnic groups.

The Association of Asian Pacific Community Health Organizations (AAPCHO) and its partners across the country are committed to altering the trajectory of this disease that has devastated the AA and NHOPI population. For its part, AAPCHO, a 20-year-old not-for-profit association of community-based organizations dedicated to improving health care and access to medically underserved Asian Americans, Native Hawaiians, and other Pacific Islanders, continues to diminish the impact of hepatitis B through both its programs and advocacy work.

At the most fundamental level, AAPCHO is attempting to raise awareness that hepatitis B is preventable. A hepatitis B vaccine does exist, and with proper screening and vaccination, we can prevent scores of AA and NHOPIs who are at risk for the disease from becoming infected.

And that is just the first step. If we're to eradicate this disease and its impact on our communities, there are a number of strategies that must be deployed in conjunction with screening and vaccination efforts. In addition to testing and vaccinating AA and NHOPIs for

hepatitis B, those individuals that are exposed to HBV should be encouraged to see a doctor. Moreover, the development of culturally and linguistically appropriate programs on screening and vaccination, prevention and management that addresses the diverse AA and NHOPi population must be made a priority. Education for doctors, nurses, health educators and policymakers that stresses the prevalence of hepatitis B between AA and NHOPis must continue. Lastly, financial resources must be consistently dedicated to programs at the national, state, and local level if we hope for our efforts to leave a great impact on generations to come.

AAPCHO calls on all individuals and advocates to vigilantly raise awareness of hepatitis B, on government agencies to continue to dedicate resources for programs targeting AA and NHOPis to acquire some level of sustainability, and on lawmakers to continue to craft legislation that, among other things, keeps hepatitis B at the forefront of health disparity areas that must be eliminated. Only if all of these measures are taken, do we stand a chance at ensuring that the AA and NHOPi community as a whole continues to thrive and make significant contributions to the fabric of this country.

Jeffrey B. Caballero, executive director, Association of Asian Pacific Community Health Organizations (AAPCHO)

James Kreppner, 47 / Lawyer, Hemophiliac

<http://www.theglobeandmail.com>

Sandra Martin

Blood activist used his legal skills to help others

He is described as the conscience of the Canadian Blood Services board

James Kreppner's life changed in the mid-1980s.

Before then, he had a medical condition - he suffered from a severe form of hemophilia-A, a genetic disorder that makes it difficult for blood to clot. He had to be prudent about the scrapes, bruises and cuts which most of us ignore after a yelp and a demand for a bandage, and he often had to be treated with transfusions and blood products for more serious bleeds.

But, given the medical treatments and system of the day, he was able to live a reasonably normal life with the anticipation of a slighter shorter than average lifespan.

Those expectations were truncated when he became infected around 1985 with HIV and hepatitis C, two potentially life threatening diseases, through tainted blood products supplied by a blood system that we all trusted.

We now know that the system was more interested in cutting costs and saving money than in protecting people whose lives depended on blood products. Globe and Mail journalist André Picard, author of *The Gift of Death: Confronting Canada's Tainted Blood Tragedy*, called the infection of thousands of people between 1980 and 1985 our "worst-ever preventable public health disaster."

There were about 2,200 hemophiliacs in Canada in the 1980s, according to Mike McCarthy, a former vice-president of the Canadian Hemophilia Society. About 80 per cent of them became infected with HIV or hepatitis C or, in Mr. Kreppner's case, with both. By this year, half of them had died.

Mr. Kreppner was 25 and halfway through a law degree when he learned officially that he was a victim of the tainted blood scandal. Instead of collapsing from the enormity of the burden, he completed his studies, graduating with an LLB in 1989 and did his articles with the Toronto branch of the federal Department of Justice.

The lurking double whammy knocked him flat with AIDS-related pneumonia in August, 1991. He recovered, but he wasn't ever well enough again to work the treadmill hours of a newly qualified lawyer. Instead, he used his legal training and skills as an activist for people who had been harmed in the blood scandal, first within the Ontario and Canadian Hemophiliac Societies, and then as a representative on broader committees and associations.

He was a key strategist and lobbyist for a public inquiry, which led to the Krever Commission, before which he testified twice, and which resulted in myriad recommendations, in November, 1997, for overhauling the blood delivery system.

That wasn't the end of Mr. Kreppner's activism, however.

Despite increasing health problems - he almost died three times in the 1990s - he fought for expanded treatment opportunities on behalf of all people suffering from HIV and hepatitis C, no matter how they had contracted the diseases. His profession became his vocation as he honed his legal skills on the fight for social justice.

"I clicked with him right away. He was very calm, very dignified and very professional, no matter how upset or angry or wound up he felt," says activist Janet Connors, who contracted HIV through her late husband Randy, an infected hemophiliac. She and Mr. Kreppner met in the early 1990s when they were both on the board of directors of the Canadian Hemophiliac Society.

"I'm sure he had moments where he wished this had never happened - we all did - but he wanted to ensure it never happened again and he wanted to ensure that all people living with AIDS, not just within the blood community, had the best care that was available and everything that we would need in order to be able to live well."

Mr. Kreppner was one of her heroes. "I never expected that James of all people would die," she said. "He was such a magnificent fighter in every aspect of his life. He had such dignity and passion and I think what we will all remember about him is that right up to the last moment he never gave up and he never stopped."

It was a measure of Mr. Kreppner's integrity and his effectiveness that he also served for the last several years on the board of the Canadian Blood Services, the not-for-profit organization that took over the blood and blood products system for Canadians from the Red Cross. "He was a key element in the trust that we have established between the CBS and its stakeholders," said Verna Skanes, chair of the board of CBS.

"In a lot of ways he was the conscience of our board. He was a pretty eloquent reminder of what we are all there for, not just because of what had happened to him, but because he had a personality that allowed him to communicate what we were there for, and to remind us of Mr. Justice Krever's recommendations."

He was a hero to Ms. Skanes, for "the extraordinary grace and courage" with which he lived his life, a life that had been horribly compromised by the tainted blood products. As a gesture of respect, the CBS has lowered all of its flags across the country to half-mast.

James Kreppner was born in the Toronto-area in the expansive, optimistic 1960s, in a family that included several brothers and a sister. For a while, his father, who was originally from Germany, operated a small resort in the Haliburton area of Ontario, but by the time James was a teenager, the Kreppners lived in Aurora, Ont. That's where he went to high school at Dr. G.W. Williams School.

In his final year he became friendly with Antonia Swann and invited her to the high school prom. She remembers him telling her casually on the way to the dance that he was a hemophiliac, and that he was very matter of fact about his condition.

They both went to York University, where he lived in the Norman Bethune residence and she commuted from Aurora.

Then she was in an accident that totalled her car and so she needed a place to stay. He offered to share his minuscule room with her and slept on the floor for three months so that she could have the bed.

Gradually their friendship turned into a romance, a mutually supportive and loving relationship that lasted for the rest of his life. In an interview with *The Toronto Star* in August, 2006, he credited Ms. Swann with keeping him alive with her love and her daily insistence that he eat. Only two weeks ago she successfully defended her PhD thesis in economics.

"He was fighting until the last minute," she said yesterday, describing how in the hospital on Wednesday afternoon she and Mr. Kreppner, who was suffering from advanced liver disease, were looking at transplant lists in Canada and abroad to try to prolong his life. "But this time it was too much and he finally said to me, 'I'm tired, I don't want to be intubated,' " she said.

Paraphrasing her partner's final message, she said he was passionate about protecting the blood system, even if that meant restricting high risk donors, not because he wanted to discriminate against people, but because he was fearful of future and as yet unknown pathogens. "He wanted us to put safety above all else," she said.

JAMES KREPPNER

James Kreppner was born in Toronto on March 6, 1962. He died early in the morning of May 14, 2009 at Toronto Western Hospital of complications from organ failure. He was 47. Mr. Kreppner is survived by his partner Antonia (Smudge) Swann and his extended family.

Camps to be set up for awareness raising, screening

<http://www.thenews.com.pk>

By Muhammad Qasim

Rawalpindi

Pakistan Society of Hepatology, Rawalians Research Forum and Gastroenterology and Hepatology Division of Department of Medicine at Holy Family Hospital has launched an awareness campaign aimed at getting people talking about the fact that approximately 500 million people globally are living with either hepatitis B or C.

The campaign is being launched in connection with the World Hepatitis Day, which is going to be observed on Tuesday, May 19, around the globe. The day has been launched in response to the concern that the level of awareness and the political will to tackle chronic viral hepatitis is nowhere near to that of HIV/AIDS, TB and malaria despite the fact that the numbers chronically infected with, and annually killed by the diseases are equal to that of hepatitis B and C viruses.

“The day is being observed to increase awareness of the shocking statistic that one in 12 people on the planet are living with hepatitis B or hepatitis C and yet the majority of those infected are unaware,” said President (elect) Pakistan Society of Hepatology and President Rawalians Research Forum Professor Dr. Mohammad Umar. “We request media and public to show support for the campaign and be aware of the disease that kills some 1.5 million people a year.”

The camps for awareness and screening are being arranged in Holy Family Hospital on May 18 and 19 from 9 a.m. to 3 p.m. being a part of the ‘Am I Number 12?’ campaign that has already kicked off in 55 countries and high-profile campaigns are being coordinated. “The hepatitis’ campaigns and activities on May 19 aim to put hepatitis B and C firmly on the global healthcare agenda,” said Dr Umar.

He added that a comprehensive awareness campaign for education of general public is being launched regarding this dreadful disease and awareness banners are being put up in all teaching hospitals and important places of Rawalpindi City.

“Unlike other disease areas, awareness of hepatitis B and C remains inexplicably low,” he said and added that they believe that, unless awareness improves, they would not make any progress in reducing the enormous and largely preventable death toll. “Hepatitis B and hepatitis C should have the same profile as HIV/AIDS, malaria and TB and should really be up there alongside those diseases in the WHO’s millennium goals.”

In May, health ministers from around the world would be debating action to tackle viral hepatitis and deciding on support for World Hepatitis Day at the World Health Assembly. The resolution, which would be voted on by health ministers from around the world, calls for action to improve hepatitis awareness, prevention, treatment and support. It also calls for the World Health Organization (WHO) to support a World Hepatitis Day to increase awareness of the burden of viral hepatitis.

Dr Umar says that one of the main concerns of Pakistan Society of Hepatology is the lack of available data on chronic hepatitis B and C in Pakistan. “Even the most recent data from the World Health Organization date back to 1999 could not be termed authenticated as there is no

data registry system in Pakistan.” He said that without up-to-date statistics, government could not understand the depth of the problem or measure the effectiveness of public health campaigns.

He added that Pakistan Society of Hepatology with support from Pakistan Medical Research Council and National Programme for Control and Prevention of Hepatitis is working with the government to develop integrated programme for collection of statistics and treatment data. “The purpose of the data will be to provide the first truly local compendium of statistics and information relating to chronic viral hepatitis B and C - showcasing country statistics.”

Dr Umar added that in subsequent years, the Hepatitis Atlas would be designed to provide sophisticated data, information about services available to patients, vaccination statistics and best practice case studies demonstrating initiatives that really work in improving the experience of patients throughout Pakistan.

He added that they have set Gastroenterology and Hepatology division in Holy Family Hospital that provide not only diagnostic facilities but also therapeutic procedures and pre and post-liver transplant consultation are being done there. “We have planned to launch state of the art services for the patients of Hepatitis, de-compensated liver disease and Hepatocellular Carcinoma under one roof in Holy Family Hospital.”

Hepatitis C: The silent killer among us

<http://www.stuff.co.nz>

Mark Hotton

Hepatitis C's stigma as a "junkie disease" could be preventing thousands of New Zealanders from getting potentially life-saving treatment.

About 50,000 New Zealanders are infected with hepatitis C, with many infected through unscreened blood transfusions, experimentation with intravenous drugs or by just using a flatmate's razor.

Experts believe only about 20 per cent of those who have the disease are aware they are infected.

Treatment to potentially "cure" the disease is available suppression rates vary from 50 per cent to 80 per cent but access to specialised clinicians and adverse side-effects can deter people from seeking help.

World Hepatitis Day, tomorrow, aims to draw worldwide attention to the one in 12 people living with hepatitis B or C. Organisers hope the global event will target chronic viral hepatitis as an urgent public health issue.

Associate Professor of Medicine at the University of Auckland's School of Medicine, Ed Gane, said underdiagnosis meant many people were not identified early enough for treatment.

"People don't know they have hep C and they won't find out and get treated unless there is greater public awareness about getting screened."

The disease is also known as the "sleeping dragon" because it has a long dormancy.

It can take up to 15 years for symptoms to show, but by then irreparable damage can be done to the liver. It is that delay in obtaining the treatment that could be costing lives.

Gane said many people contracted the disease through experimental drug use in their teens or early 20s.

"But because they experimented [once or twice] and they shared injecting equipment, they're left with a lifelong infection," he said. "Most are in their 40s and 50s and don't realise their at-risk behaviour as teenagers exposed them to it."

Only about 2 per cent of those infected underwent treatment each year. Access to the treatment remained a barrier, particularly in smaller centres, and some people can be discouraged by the treatment's side-effects which are similar to those of chemotherapy treatment weight loss, diarrhoea, hair loss and general illness.

Treatment is based on a combination of interferon and ribavirin , taken for either 24 or 48 weeks.

Gane urged people that might have been put at risk to get tested.

Hepatitis C was the main reason people needed liver transplants in New Zealand and was rapidly replacing hepatitis B as the leading cause of liver cancer, he said.

HEPATITIS C

Hepatitis C is a blood-borne virus that infects liver cells.

It is estimated 50,000 New Zealanders have the disease about 25 new patients are diagnosed weekly.

Causes liver inflammation and liver disease, with unusual fatigue the most common symptom.

It can take up to 30 years to develop cirrhosis which can lead to liver failure and is the leading reason for liver transplants in New Zealand.

There is no vaccine, no immunity and no universal cure.

The non-screening of blood products before 1992 meant many people unwittingly contracted it.

As many as 10 per cent of those infected have no idea how they contracted it.

You should be tested if you:

- Received a blood transfusion or organ transplant before 1992.
- Spent time in prison - rates of infection can be 20 times higher than average.
- Lived in an area of high prevalence such as Egypt or South East Asia.
- Have ever injected street or recreational drugs.
- Have been exposed to acupuncture, tattooing or body-piercing equipment that may not have

been clean.

May 18, 2009

Marijuana a cause for uprooting?

<http://www.southbendtribune.com>

By Lou Mumford
Tribune Columnist

Niles man's marijuana use, while legal, may cost him his home.

NILES — On a scale of 1 to 10, says Steve Allain, his pain is somewhere between 4 and 5.

On a good day.

"When my Crohn's flares up, it's like a saber-toothed badger trying to eat its way out," he said.

The 54-year-old Niles man, a victim not only of Crohn's disease but hepatitis C and acute depression, has run the gamut of medications. Just a few months ago, he hit upon a viable alternative: marijuana.

"I was approached by an MS patient. She finds relief by using marijuana medicinally," he said. "She thought it would help me, too. And it has."

Sure, he said, he could take other drugs that would provide the same benefit. But it wouldn't make good sense, or cents.

"With conventional medication, it's \$10,000 for one month's supply. So it's \$300 a month versus \$10,000 a month," he said. "You do the math."

Until now, Allain has obtained his marijuana from, as he puts it, street vendors. But soon he'll legally be growing his own, thanks to the Michigan Medical Marijuana Act.

For Allain, voter approval of the controversial legislation was a blessing and, potentially, a curse. The latter stems from his residence in one of Niles' scattered public housing sites, which fall under the guidelines of the U. S. Department of Housing and Urban Development.

So while Allain's cultivation and use of marijuana would not violate state law, it's likely to cost him his home if HUD takes the stance its housing is no place for what in most places would be an illegal drug.

The Rev. Bryant Bacon, interim executive director for the Niles Housing Commission, said he contacted a HUD official about a month ago regarding Allain's situation and has yet to receive an answer. Allain, a resident of public housing in Niles for eight years — he lived in the Hi Rise on Cass Street before he and his teenage son moved into their current home three years ago — is hoping for the best but said he'd understand if he's ousted.

"I can't fault what they're doing," he said.

He didn't fault either the Niles City Council after he approached the panel Monday night regarding the city's ordinance regulating aspects of the state Medical Marijuana Act. The ordinance requires that marijuana be grown inside and prohibits caregivers — those who provide marijuana to patients — from growing it within 1,000 feet of drug-free school zones.

Allain said he went to the meeting with bad information about the law's specifics.

"I was the south end of a horse facing north," he said.

As far as his illnesses, the former truck driver and Waste Management employee said he can only guess how he developed hepatitis C. All he knows for certain is that it and Crohn's disease cost him 18 inches of small intestine and resulted in a 30-pound weight loss.

"I've been dealing with those issues ever since," said Allain, who gets by on disability benefits.

With marijuana, he doesn't have side effects like the night sweats and night terrors — essentially, panic attacks while sleeping — he experienced with other anti-depressants, he said. So he'll continue to smoke pot and, once he receives the OK from the state, grow it as well.

He just hopes he's not uprooted in the process.

An Overview of the HCV Drug Development Process

<http://www.hepatitis-central.com>

Nicole Cutler, L.Ac.

Although often dismissed as non-crucial medical jargon, understanding the stages of development provides a more realistic appreciation of potential new Hepatitis C drugs.

Keeping current on the potential arrival of new, improved Hepatitis C drugs is a regular research venture for many who are living with the Hepatitis C virus (HCV). Because the current standard of care for HCV works for less than 50 percent of those infected, doctors, scientists and pharmaceutical companies are feverishly searching for a solution that is more effective and has fewer side effects than interferon combination therapy. However, keeping up with the seemingly endless announcements of discoveries and successes demands a layman's road map for deciphering what it all means.

The testing of new drugs is a long process that typically takes about 12 years from pre-clinical testing, through clinical trials, to U.S. Food and Drug Association (FDA) approval until it can finally reach the general public.

Pre-Clinical

Drug companies continuously analyze thousands of compounds, seeking ones of therapeutic value. During the average six to seven years of pre-clinical testing, the manufacturer completes synthesis and purification of the drug and conducts limited animal testing. Under FDA requirements, a drug company must first submit data showing that their drug is reasonably safe before it can be evaluated by humans in initial, small-scale clinical studies.

Only after proving its safety and efficacy in vitro (in a test tube) or in laboratory animal testing can a drug be administered to humans in clinical trials. During pre-clinical drug development, the following is evaluated:

1. Toxicity
2. Pharmacologic effects
3. Genotoxicity – genotoxic substances cause cancer, through genetic mutation or contribution to tumor development
4. Absorption and metabolism
5. Speed of excretion

If any evidence surfaces that it is unsafe or ineffective, the drug will likely never make it to human testing. Actually, only about 1 in 1,000 investigational compounds survives pre-clinical testing favorably and proceeds to clinical studies. Of those drugs that make it to human testing, approximately 1 in 5 will persevere through the many steps and receive FDA marketing approval. Therefore, a person living with HCV who hopes to find a new medicine may be disappointed if he/she gets too excited about drugs in the pre-clinical testing phase.

When a company is ready to proceed to clinical trials, it files an investigational new drug application with the FDA. Most clinical trials are designated as Phases I, II or III, and sometimes IV based on the type of questions that the study is seeking to answer. Although the phases of human clinical studies are generally conducted sequentially, there are cases when the phases overlap.

Clinical Trial: Phase I

Once granted approval by the FDA as an investigational new drug, testing can begin on humans. Phase I studies are typically conducted in healthy volunteer subjects, with the intent of determining:

- Metabolic and pharmacologic actions
- Side effects with increasing doses
- If possible, early insight into drug effectiveness

Typically considered to be smaller trials, Phase 1 studies generally recruit between 20 to 80 human subjects. Typically the drug remains in Phase I for one to two years.

Clinical Trial: Phase II

Instead of recruiting solely healthy people, Phase II clinical trials begin to evaluate the drug's effectiveness in the target population. This stage of testing is where the preliminary data on a potential drug's effectiveness for HCV emerges. Additionally, Phase II helps determine the common short-term side effects and risks associated with the drug. Several hundred people are usually enrolled in a Phase II clinical study. At the end of this round of studies, the manufacturer meets with FDA officials to discuss the development process, continued human testing, any concerns the FDA may have and the protocols for Phase III.

Clinical Trial: Phase III

Usually the most extensive and expensive part of drug development, Phase III studies are intended to evaluate the overall benefit-risk relationship of the drug. By gathering additional

information about the drug's effectiveness, safety, side effects and comparison to commonly used treatments, Phase III studies involve large groups of participants. Usually tested on several thousand people, Phase III studies also provide the basis for extrapolating results for physician labeling should the drug be granted FDA approval.

Once Phase III is complete, the manufacturer may file a new drug application. Review of the new drug application typically lasts one to two years, bringing drug development time after pre-clinical trials to approximately nine years. If the FDA approves the new drug, it may be marketed with FDA regulated labeling. The FDA also gathers safety information as the drug is used and adverse events are reported, and it will occasionally request changes in a labeling or will submit press releases as new contraindications arise. If adverse events appear to be systematic and serious, the FDA may withdraw a product from the market at any time.

Clinical Trial: Phase IV

In Phase IV studies, the drug is already on the market for a particular indication, but is now being tested for a different indication, use or disease.

Fast Track Status

During the phases of investigational drug development, the manufacturer can obtain accelerated development or review of its drug. If granted fast track status by the FDA, the timelines for clinical trials can take some shortcuts. Geared towards facilitating the development and expedition of new drugs that have the potential to address an unmet medical need for serious or life-threatening conditions, many HCV potential drugs are granted fast track status.

Once a drug receives fast track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

Having a general concept of the many steps and length of time involved in the approval of a new medication gives us a greater appreciation of what it takes to develop a drug. Patience is definitely required to see a potential cure come to fruition. While it may be premature to place all of your hope in a compound with promising pre-clinical trial results, go ahead and visualize how a drug emerging positively from Phase III will help you defeat HCV.

References:

- <http://en.wikipedia.org> , Genotoxicity, Wikimedia Foundation, Inc., 2007.
- www.fda.gov, Frequently Asked Questions on Drug Development and Investigational New Drug Applications, US Food and Drug Administration, 2007.
- www.fdareview.org , The Drug Development and Approval Process, The Independent Institute, 2007.
- www.hcvadvocate.org , Hepatitis C Treatments in Current Clinical Development, Alan Franciscus, Hepatitis C Support Project, October 2007.

Copyright ©1994-2009 Hepatitis Central. This work is reproduced with the permission of Hepatitis Central. www.hepatitis-central.com .

Call to end hepatitis C ignorance

<http://www.google.com>

Sufferers of hepatitis C are being stigmatised because of public ignorance about the condition in Ireland, it was claimed.

Support groups said up to 20,000 people affected by hepatitis C could be discriminated against and excluded due to inaccurate and poor knowledge. Three voluntary organisations - Positive Action, the Blood Borne Virus Forum and Community Response - have joined forces to educate people to reduce the stigma attached and mark World Hepatitis Day, which takes place on Tuesday.

June Colgan, of the Blood Borne Virus Forum, said: "Hepatitis C is not spread through day-to-day activities, and people living with it have the same right as everyone else to enjoy their home and work life without worrying that they will be judged. This is why we have come together to remind the general public and those working in the health services that anyone can be affected by hepatitis C and that everyone deserves to be treated as an individual with respect and dignity." Supporters said while successful treatments are available, support is also as important.

World Health Assembly Forced to Postpone Decision on Viral Hepatitis

<http://news.prnewswire.com>

GENEVA, Switzerland, May 18 /PRNewswire/ --

- Global Epidemic Kills One Person Every 30 Seconds and One Million People Will Die Before the World Health Assembly Meets Again in 2010

Ahead of the second annual World Hepatitis Day, the World Hepatitis Alliance today called on governments not to forget the plight of 500 million people living with hepatitis B and C, as the World Health Assembly postpones discussion of a World Health Organization (WHO) resolution on viral hepatitis - one of the biggest threats to global health.

The 62nd World Health Assembly, starting in Geneva on 18 May, has been shortened in response to the global efforts required to tackle H1N1 influenza. As a result a scheduled resolution on viral hepatitis, submitted by Brazil and entitled 'Proposal for the Establishment of a World Day for the Struggle against Viral Hepatitis and other issues relating to the Disease', which calls for action to improve hepatitis awareness, diagnosis, prevention, treatment and support will now not be discussed until 2010 at the earliest.

Charles Gore, President of the World Hepatitis Alliance explained that the hepatitis community recognised the need for a concerted effort to tackle H1N1 influenza, but stressed that global health leaders can no longer afford to ignore hepatitis B and C. "Viral hepatitis has never been properly addressed at a global level and the consequences have been disastrous," commented Mr Gore. "Despite this disappointing postponement, we look forward to working with both the WHO Executive Board and governments around the world to ensure that a resolution is passed in

2010 and that a comprehensive, coordinated approach is adopted before another million people die."

Chronic viral hepatitis B and C affects one in 12 people globally and approximately one person dies every 30 seconds, meaning that one million people will die before the World Health Assembly next meets in 2010. Since the hepatitis B and C viruses were first discovered in 1967 and 1988 respectively, there has not been a single WHO resolution that fully addresses the challenges of the global epidemic.

19 May marks the second World Hepatitis Day, and over 200 patient groups from more than 50 countries have been recognising the day by asking the question 'Am I Number 12?' - an awareness raising campaign aimed at highlighting the shocking statistic that one in 12 people worldwide are living with either chronic hepatitis B or chronic hepatitis C. While this is far higher than the prevalence of HIV or any cancer, awareness is inexplicably low and the majority of those infected are unaware.

Did You Know?

- Approximately 500 million people worldwide are currently infected with hepatitis B or C(1)
- This is over 10 times the number infected with HIV/AIDS(2)
- Between them, hepatitis B and C kill one million people a year(1)
- One in every three people on the planet has been exposed to either or both viruses
- Most of the 500 million infected do not know

Messages of Support for the World Hepatitis Alliance

The following people have provided quotes expressing their support to the World Hepatitis Alliance campaign for a WHO resolution on viral hepatitis. For further information please contact worldhepday@fleishman.com

- Dr. Michael Houghton, co-discoverer of the hepatitis C virus
- Prof. Baruch Blumberg, Nobel Laureate, co-discoverer of the hepatitis B virus and co-inventor of the hepatitis B vaccine
- Prof. Muhammad Yunus, Nobel Laureate and global Economist

World Hepatitis Alliance

The World Hepatitis Alliance provides global leadership and supports action that will halt the death toll and improve the lives of people living with chronic viral hepatitis B and C. Through better awareness, prevention, care, support and access to treatment, our ultimate goal is to work with governments to eradicate these diseases from the planet.

The World Hepatitis Alliance is a Non-Governmental Organisation representing more than 200 hepatitis B and C patient groups from around the world. The World Hepatitis Alliance is governed by a representative board elected by patient groups from seven world regions: Europe, Eastern Mediterranean, Africa, North America, South America, Australasia and Western Pacific. For further information visit: <http://www.worldhepatitisday.org>

World Hepatitis Alliance - Seeking a world without viral hepatitis B and C.

World Hepatitis Day



The second annual World Hepatitis Day will take place on Tuesday 19 May 2009, as part of an ongoing campaign launched by the World Hepatitis Alliance in 2008. An entirely patient-led initiative, World Hepatitis Day in 2009 aims to raise awareness of hepatitis B and C, as well as extend the political support for the diseases to levels seen in HIV / AIDS, TB and malaria. The long-term objective of the World Hepatitis Day Campaign is to prevent new infections and to deliver real improvements in health outcomes for people living with hepatitis B and C. The campaign theme for 2009 is 'Am I Number 12?' - designed to communicate the shocking statistic that one in 12 people worldwide are living with either hepatitis B or hepatitis C.

References

(1) World Health Organization. Viral hepatitis: Report by the Secretariat.
http://apps.who.int/gb/ebwha/pdf_files/A62/A62_22-en.pdf (accessed May 11, 2009)

(2) World Health Organization. Global summary of the AIDS epidemic.
http://www.who.int/hiv/data/2008_global_summary_AIDS_ep.png (accessed May 11, 2009)

SOURCE World Hepatitis Alliance

Photo exhibit boosts Hep C awareness

<http://www.abc.net.au>

By youth affairs reporter Michael Turtle

An art gallery in inner-city Sydney is trying to raise awareness about Hepatitis C, a disease that more than 10,000 Australians are diagnosed with every year.

The disease affects more than 200,000 Australians but is often not discussed.

There are fears most young people do not understand the disease, and public health experts are calling for a mass media campaign.

Young artists from at-risk backgrounds and who have very little experience in photography were given disposable cameras and asked to take pictures of their understanding of Hepatitis C.

The rough and raw photos now line the walls of the Sydney gallery.

"None of these young people were trained in photography of the arts at all," project manager Harpreet Kalsi said.

"It was just what they saw. It was their everyday lives or realities that they took images of."

The photos are varied - teenagers kissing, a syringe on a dashboard, a home-made tattoo, piercings, drugs, and even a barber shop.

But there are also images of clouds and of friends on a street.

Blood contact

Rachael Hundy, 19, took one of the photos with her friend. It shows an arm with a tattoo of the

word "sterile".

"Basically, if you don't have a sterile environment when you're getting a tattoo you're more likely to contract the virus, so that's why we have the word sterile as the tattoo," she said.

Through her involvement with the project Rachael learnt about Hepatitis C, a disease she previously knew little about.

"I knew there was a thing called Hepatitis C and basically that was it," she said.

"I didn't know it was blood contact. I thought it was everything like blood, saliva, everything like that."

She says it is not a topic which is often talked about with young people.

"Hep C is more to do with drugs and tattoos and that, and at our age you're not supposed to do drugs and have tattoos before you're 18," she said.

"So at high school you didn't really learn much about this."

Awareness

But the art exhibition and, more importantly, the creation of the art were designed to address that perceived lack of awareness.

Ms Kalsi says it targeted the kind of young people who would be vulnerable to contracting Hepatitis C.

"We're trying to make them think about anything that may put them at risk of Hepatitis C, so risky tattooing, unsterile piercing and drug use," she said.

"A lot of things that some young people engage in and they don't know that they could be placing themselves at risk of a blood-borne virus."

A series of photos from young people in Cowra, in rural New South Wales, has already made a practical difference.

The teenagers cannot afford to get piercings or tattoos professionally and do it themselves, and not always with clean equipment.

But the information they learnt while taking their photos means they are now prepared to change their behaviour.

Message

Hepatitis Australia vice-president Stuart Loveday is pleased these young people have got the message.

But he is now lobbying for a national public awareness campaign to reach more of the population.

"We need a widespread mass media public awareness campaign," he said.

"There was one in New South Wales in 2000 and that's been the only one so far in Australia.

"We need to raise community awareness about the basic facts of Hepatitis C transmission, the fact that there is a cure available through treatment, and the fact that very few people are accessing that treatment."

Tuesday, May 19, is World Hepatitis Day, and it will be a chance for public health experts to raise some of those issues around what has become Australia's most common notifiable health condition.

Soaring on Robin's Wings

<http://www.timesherald.com>

Melissa Brooks

Times Herald Staff

The loss of her older sister at too young an age was a tragedy Kim Hartline of Collegeville would not let go.

In her unwillingness to accept the cause of her only sister's death, the end of one woman's struggle became the beginning of another woman's fight for others to have it better.

"Liver disease kills more people every year than cancer and heart disease combined," Hartline said with such passion that suggests she's done her share of research and could recite the statistics in her sleep.

"It's so rampant. And people can go for years and never know their liver is slowly being killed, because they don't really have any symptoms until it's too late."

Hartline, a South Jersey native who moved to the area in 2000, serves on the American Liver Foundation's Mid-Atlantic Division Delaware Valley Region Board of Directors and is founder and president of Robin's Wings, a charitable foundation formed in 2006 to honor her late sister.

In 2004 Robin was diagnosed with cirrhosis of the liver, the result of a hepatitis C infection that likely came from emergency blood transfusions she received while giving birth to her twin daughters in 1980, according to Hartline.

For the next couple of years Robin would receive treatment from a doctor who Hartline said was "not really a liver specialist," but was the only person her sister, a waitress with no health benefits, could afford.

"We tried to help her where we could, Hartline said, "but her liver was so damaged, nothing could be done to salvage it at that point."

In 2005 Hartline got in touch with Albert Einstein Hospital in Philadelphia. Their live donor liver

transplant program seemed like the answer to her sister's problems.

"Einstein was willing to take her into their experimental program, willing to do more advanced treatment than what she could get — did get — at a local hospital in South Jersey," Hartline said. "But Medicaid wouldn't pay for her hospitalization expenses if she left the state."

Specialists Hartline contacted through the American Liver Foundation said her sister needed treatment at a medical facility specializing in liver disease.

But when they finally received approval for Robin's transfer, it was too late. She died Feb. 3, 2006 at age 47, leaving behind two daughters and a granddaughter "she idolized."

"I was appalled because she didn't have to die," Hartline said. "I think if she would've had proper care, she'd still be alive today."

"The whole thing sat badly with me. The care she got probably did her more harm than good."

Hartline felt "helpless" the entire duration of her sister's sickness. "I don't want other family members to feel that way; it's so frustrating," she said. "We fought so hard with people at Medicaid to get her transferred (to Einstein), but they wouldn't allow her to come and get treated at a Pennsylvania hospital."

"My sister was so ill she was unable to work, yet when she applied for Social Security, she was turned down."

After her sister's death, Hartline immediately contacted the American Liver Foundation. "I wanted to learn more, I wanted to do something," she said. "People should not have to die because they're poor in this country."

Hartline, who said she's been "very blessed" in life, is certain that if their situations were reversed, with her health insurance she would have received better care than her sister did. "I believe it would've made all the difference in the world."

Meanwhile, relatives and friends began sending condolences along with money for Hartline's nieces, who were 24 at the time. Together the family decided rather than keep the money, "let's do good with it," Hartline said.

Within a few weeks of her sister's death, Hartline had "decided to become an advocate for liver research" and with her nieces she founded Robin's Wings to help families of people suffering from liver disease.

"Because it's bad enough a person has to suffer," she said, "but when their children and families can't provide for them (it's worse)."

The foundation's logo is an outline of a robin with angel wings and a heart on its breast. Any money Robin's Wings raises is donated to the American Liver Foundation for research and education.

Robin's Wings sends food baskets to families of people affected by liver disease, and each year during the holiday season the foundation adopts a family in need and donates gifts.

"We just do what we can with the little bit of money we collect from relatives and friends," Hartline said. They also sell T-shirts and raise money for American Liver Foundation events.

This year Robin's Wings hopes to contribute \$10,000 toward the \$100,000 goal the local chapter of the American Liver Foundation set to raise for Liver Life Walk, a 3K walk along Boathouse Row in Philadelphia's Fairmount Park from 3:30 to 6 p.m. June 20.

Hartline, who is chairing this year's local walk, said she hopes that with the help of her nieces, Robin's Wings faces a bright future.

Because to her, a working mother, community service is so much more than just filling the day with good deeds.

"I think the true goal here is when you don't have enough hours in the day that you have to go above and beyond (to serve your community)," she said.

Hartline, whose father is a building contractor, said growing up "it was either feast or famine.

"If he had work, times were good. If not, we ate a lot of hotdogs," she said. "But we were the type of family who would share our hotdogs with people who didn't have any.

"My sister didn't have a lot of anything," she continued, "but what she had she would give you in a heartbeat. Even when she was sick she'd walk across the street to the elderly woman who didn't have family. It might take her a half hour to walk across the street, but she'd check on that woman because she was worried about her.

"That's why (the foundation) is an honor to her, because that was her philosophy. She liked taking care of people."

Hartline is corporate secretary for NOVA Savings Bank headquartered in Berwyn, which her husband, Brian, founded in 2002.

"Brian has always been big at giving back," she said, "he encourages everybody."

The bank's Community Outreach Program gets employees involved in donating to domestic violence shelters, adopting a family each year at the holidays and sending gifts and throwing parties for underprivileged children at Ludlow Community Center in Philadelphia.

"We participate where we can and do what we can, because life is short and nobody should have to suffer through it," Hartline said.

Her husband serves on the board of trustees for Immaculata University while she heads the fundraising committee that organizes golf outings to support the school's scholarship fund. This year the couple were honorary co-chairs for the university's art show, their largest fundraiser.

"In the banking world it's called CRA (Community Reinvestment Act)," Hartline said, referring to the federal law designed to encourage commercial banks to give back to their communities.

NOVA Bank supports senior housing and leads educational programs on saving money and avoiding debt at schools, recreation centers and churches. They send their mascot, Buddy, a dog, to appear at events like Special Olympics and community fairs.

"We always encourage our people," she said, "if they need to take off to go build for Habitat for Humanity, that's good."

But she and her husband do it, Hartline said, "not just because it's for CRA, but because it's the right thing to do."

For information about liver disease and the local ALF chapter, to volunteer or donate money to help fight liver disease or to register for Liver Life Walk, visit www.liverfoundation.org/chapters/delvalley.

May 19, 2009

Congressional Briefing on Chronic Viral Hepatitis and Liver Cancer Highlights World Hepatitis Day

<http://www.prlog.org>

Hepatitis B Foundation, AAPCHO and NVHR Work Together to Raise Awareness About 6 Million Americans Suffering from Chronic Hepatitis B and Hepatitis C

PRLog (Press Release) – May 19, 2009 – WASHINGTON, DC - In recognition of May 19th as World Hepatitis Day and May as National Hepatitis Awareness Month, the Hepatitis B Foundation (HBF), Association of Asian Pacific Community Health Organizations (AAPCHO) and the National Viral Hepatitis Roundtable (NVHR) have partnered to host a Congressional briefing titled "Chronic Viral Hepatitis: A Liver Cancer Story" on May 19, 8:30–10:00 am, at the Rayburn Building, Room B-340, in Washington, D.C. The briefing will call urgent attention to the millions of Americans suffering from chronic viral hepatitis infections. Congressmen Mike Honda (CA) and Charlie Dent (PA) will be special guests at the briefing. Through personal stories and expert testimony from the Centers for Disease Control and Prevention, National Cancer Institute, and Weill-Cornell Medical College, the burden of chronic viral hepatitis and its fatal link to primary liver cancer will be highlighted.

"Chronic viral hepatitis infections caused by the hepatitis B virus (HBV) and hepatitis C virus (HCV) represent a silent epidemic in the U.S. and affects an estimated 6 million Americans," says Dr. Timothy M. Block, Ph.D., HBF co-founder and president, and professor, Drexel University College of Medicine. "Chronic viral hepatitis is also the leading cause of liver cancer, which has a 5-year survival rate of only 10%."

The National Cancer Institute reports that primary liver cancer continues to be one of three of the fastest growing cancers in the U.S. during a time when the overall incidence of cancer has stabilized, and in many cases declined. According to Jeffrey Caballero, AAPCHO executive director, "Primary liver cancer is the 8th leading cause of cancer death among Caucasians and

the 3rd leading cause of cancer death among Asians in the U.S.”

Despite the availability of a safe vaccine, there continue to be almost 50,000 new HBV infections each year in the U.S. Also alarming is the fact that up to 50% of Americans infected with HBV and 75% of Americans infected with HCV are unaware of their status. In addition, as many as 30% of HIV-positive Americans are co-infected with HCV, and up to 10% are co-infected with HBV. Most disturbing is that 15,000 or more Americans die each year from chronic viral hepatitis-related complications.

In a strong call to action, Chris Taylor, NVHR chair, and senior program manager, Viral Hepatitis, National Alliance of State and Territorial AIDS Directors, emphasizes, “Increased national attention and support is required for the care and treatment of the 6 million Americans living with chronic hepatitis B and hepatitis C who, without federal intervention, will die prematurely from either end-stage liver disease or liver cancer.”

The May 19 Congressional briefing will be moderated by Dr. Timothy Block, HBF co-founder and president; Jeffrey Caballero, AAPCHO executive director; and Chris Taylor, NVHR chair. Expert speakers include Dr. John Ward, director, Division of Viral Hepatitis, Centers for Disease Control and Prevention; Dr. Katherine McGlynn, senior investigator, National Cancer Institute; Dr. Ira Jacobson, chief, Gastroenterology and Hepatology, Weill-Cornell Medical College; and personal testimony from Shannon Morris whose 20 year old brother died tragically from liver cancer due to chronic hepatitis B.

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. Visit www.hepb.org.

Association of Asian Pacific Community Health Organizations

The Association of Asian Pacific Community Health Organizations is a national association representing community health organizations dedicated to promoting advocacy, collaboration and leadership that improves the health status and access of Asian Americans, Native Hawaiians, and Pacific Islanders within the United States, its territories, and freely associated states, primarily through our member community health centers. Visit www.aapcho.org.

National Viral Hepatitis Roundtable

The National Viral Hepatitis Roundtable is a coalition of public, private, and voluntary organizations dedicated to reducing the incidence of infection, morbidity, and mortality from viral hepatitis in the United States through strategic planning, leadership, coordination, advocacy, and research. Visit www.nvhr.org.

Projected Surge in Liver Cancer Among Asian American and Pacific Islanders

<http://www.healthnewsdigest.com>

By UC Davis Cancer Center

World Hepatitis Day brings awareness of liver cancer risk to carriers of hepatitis B virus

(HealthNewsDigest.com) - SACRAMENTO, Calif. — New liver cancer cases among Asian Americans and Pacific Islanders are expected to soar in coming years, the result of persistently higher rates of chronic hepatitis B, a leading cause of the disease, and population growth as projected by the US Census.

The UC Davis Cancer Center is working to address the disproportionate burden of liver cancer on Asian Americans and Pacific Islanders through research funded by the National Cancer Institute and the National Center on Minority Health and Health Disparities. Such research is expected to yield important findings to reduce the unnecessary death rates for liver cancer among all people of color.

UC Davis Cancer Center also houses the Asian American Network for Cancer Awareness, Research and Training (AANCART), which is dedicated to addressing the unique, unusual and unnecessary cancer burden among Asian Americans.

A recent report from the Journal of Clinical Oncology determined that by 2030, the number of new liver cancer cases among Asian and Pacific Islanders will increase by 134 percent compared to an increase of 28 percent among non-Hispanic whites. Asian Americans and Pacific Islanders most commonly get liver cancer through hepatitis B, which in these populations is typically passed from mother to baby during the birthing process. Symptoms do not typically appear until the infection becomes liver cancer, over a period of decades. The risk of liver cancer for those with hepatitis B is 100 times greater than it is for the general population. By contrast, liver cancer risk factors for non-Hispanic whites are attributable to other factors such as hepatitis C infections.

World Hepatitis Day (May 19) and Asian Pacific American Heritage Month (May) provide an opportunity to raise awareness of the projected rise in liver cancer cases among Asians and Pacific Islanders and to highlight important information about the control of hepatitis B.

Chronic hepatitis B can result in long-term health problems, including liver damage, liver failure and liver cancer. An estimated two million Americans are thought to be infected with hepatitis B. Liver cancer is a conspicuous cancer health disparity, being most common among Asian and Pacific Islanders and other people of color, and is least common among non-Hispanic whites.

About UC Davis Cancer Center:

Designated by the National Cancer Institute, UC Davis Cancer Center cares for 9,000 adults and children each year from throughout the Central Valley and inland Northern California. The center is dedicated to reducing cancer health disparities, enriching the lives of patients and their families, and supporting community members interested in learning more about cancer risks, prevention, early detection and research. For more information, visit www.ucdmc.ucdavis.edu/cancer.

About AANCART:

The Asian American Network for Cancer Awareness, Research and Training (AANCART) is a cooperative agreement between the National Cancer Institute (NCI) and the University of California, Davis. It is the first-ever national cancer awareness research and training infrastructure intended to address Asian American concerns. The overall mission of the Asian American Network for Cancer Awareness, Research and Training (AANCART) is to reduce

cancer health disparities by conducting community-based participatory education, training, and research by, for, and with Asian Americans.

UC Davis Cancer Center is a National Cancer Institute-designated cancer center that cares for 9,000 adults and children with cancer each year from throughout the Central Valley and inland Northern California. Its Outreach Research and Education Program works to eliminate ethnic disparities in cancer region-wide.

Villages couple's daughter writes book to promote understanding of hepatitis

<http://www.thevillagesdailysun.com>

By Caroline Klapper, *Daily Sun*

The Villages — Hepatitis isn't a subject people bring up frequently.

Most probably don't even think about it much, and for those who do, the topic is an uncomfortable one.

Hepatitis B and C carry the stigma of being contracted through unsafe sexual practices or drug abuse.

For those who are at risk for these types of hepatitis, it can be difficult to address the subject even with a doctor, either out of ignorance, embarrassment or fear.

In an effort to bring the topic of hepatitis to the forefront of public attention, the World Hepatitis Alliance is promoting World Hepatitis Day today.

It is a sobering fact that one in 12 people worldwide are living with either hepatitis B or C.

According to the WHA, this number is much higher than the prevalence of HIV or even cancer, yet awareness about these forms of hepatitis is extremely low.

For internist and addiction specialist Dr. Diana Sylvestre, founder of the Organization to Achieve Solutions in Substance Abuse and president of the California Hepatitis Alliance, it is imperative to spread awareness and advance sound viral hepatitis public policy and advocacy.

"It's something we don't think about; something we don't talk about," Sylvestre said.

One cause, two points of view

To get people thinking and learning the facts about hepatitis C, Sylvestre co-authored "Healing Hepatitis C" with Christopher Kennedy Lawford, son of actor Peter Lawford and nephew of former president John F. Kennedy.

Joining the campaign to help spread awareness are Village of Santiago residents Nick and Jan Jones, Sylvestre's parents.

Sylvestre's book addresses the topic of hepatitis C from the point of view of a doctor as well as that of a patient.

In her work with drug-addicted patients, Sylvestre has treated many people who have contracted hepatitis C and has devoted her career to treating those with the disease.

As a former drug user, Lawford talks about his personal struggle with hepatitis C, and his difficult road to recovery from the disease.

In "Healing Hepatitis C," they both address the stigmas and misinformation associated with the disease.

The book also serves as a guide to help readers recognize when they are at risk, and it gives information about how to talk to a doctor about hepatitis C.

"It's a different kind of book. It's coming to terms with this hepatitis C issue. Mine from a medical perspective, and his from a patient perspective," Sylvestre said. "Christopher Lawford and I wrote this book because we have a slightly different viewpoint of hepatitis C. The outlook for viral hepatitis is positive in so many ways, and we just have to get the word out."

Because of their daughter's work, the Joneses have become activists for the cause as well.

For Jan, the book was a fascinating read about a disease she never had considered to be a serious problem.

"I read it from cover to cover in no time, and I learned a lot," she said, adding she already has begun to share the book with her friends and neighbors.

Nick said he was most interested in learning about the real facts behind hepatitis.

"There's a stigma attached to it," he said. "People don't want to talk about it."

"There is a lot of misinformation about hep C," Jan added.

The facts about hepatitis C

Although hepatitis C is spread through contact with the blood of an infected person, sharing contaminated needles for drug use isn't the only way to contract the disease.

Before 1992, one of the most prevalent ways hepatitis C was spread was through blood transfusions and organ transplants.

Because blood screening tests for hepatitis C didn't exist before that year for donated blood and organs, many people unknowingly contracted the disease.

Both hepatitis B and C are known as silent viruses, which means a person can be infected for many years without symptoms.

“It’s not a disease of addiction. Of course, you can get it that way, but there are other risk factors,” Sylvestre said.

Additional risk factors include:

- Long-term kidney dialysis.
- Health-care workers with needle stick injuries.
- Children born to mothers with hepatitis C.
- People with HIV.
- Sexual exposure to someone who might have been infected.
- People who ever have injected drugs, including anabolic steroids and growth hormones.
- Intranasal cocaine use and use of crack cocaine pipes.
- Unsafe tattoos.
- Sharing of toothbrushes, razors or even nail clippers.

Fighting hepatitis C now and in the future

Sylvestre said with all of these risk factors, it is unfortunate that people tend to only associate hepatitis C with the use of injected drugs.

She added that it is even more unfortunate that for patients with a serious drug addiction, treatment for hepatitis C can be difficult to get.

Many people who are addicted to drugs cannot afford adequate health care, and because of the stigma of addiction, others avoid seeking treatment.

If left untreated, hepatitis C can lead to cirrhosis of the liver and possibly liver cancer, liver failure and death.

“In a health-care environment, no one wants to take care of those patients,” Sylvestre said. “It’s got this stigma behind it, and I think that’s ridiculous. It prevents people from getting the test.”

In her book, Sylvestre address the issue of drug addiction and hepatitis C.

In one excerpt from the book, Sylvestre writes, “The kinds of hep C patients I like to care for are rejected by society and the traditional medical system. They are poor, uninsured, mentally ill and homeless. Many have decades-long histories of drug use before they surface in my clinic. But inside those patients is the fundamental kind of warmth and gratitude and honesty that many people never see, because it is a challenge to bring them out.”

Such compassion and caring for others is something Sylvestre’s parents have come to expect from their daughter.

“I’m just very proud of her,” Jan said.

“Diana is the type of person who, if she hadn’t gone into medicine, she probably would have been in the Peace Corps because that’s the kind of person she is,” Nick said. “She’s a very giving person.”

The Joneses said they had no problem getting involved with their daughter’s cause.

“Even if you just saved one life ... well, that’s a good thing,” Jan said.

Aside from getting people to understand and be more aware of hepatitis, Sylvestre is concerned with getting testing and treatment for people at risk for the disease.

She said those who need to be tested include people with any of the risk factors and especially those who had a transfusion before 1992.

“If you are at risk, you need to go to your doctor for testing,” she said. “Viral hepatitis is a common disease. It can kill you, but it doesn’t have to.”

Although there is not yet a vaccine to prevent hepatitis C, as there is for hepatitis B, treatments have greatly improved.

Many people can be cured of the disease, and for others with chronic hepatitis C, new treatments and advancements are happening rapidly.

“The prognosis is actually excellent for most of those who have it,” Sylvestre said. “We’re curing about half and (have) good treatments for others. We’re looking at new medications in the pipeline coming through.”

For more information about World Hepatitis Day or hepatitis C, visit hepcentre.org.uk or cdc.gov/hepatitis.

“Healing Hepatitis C” is available online through harpercollins.com, barnesandnoble.com or amazon.com.

World Hepatitis Day: Prospects for the Future - Guest blog by Paul Klenerman and colleagues

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

Submitted by Andrew Hyde

"World Hepatitis Day...does not usually make the headlines in the same way that World AIDS day does, but viral hepatitis affects about half a billion people globally (perhaps 1 in 12 of the global population) and so the relative publicity associated with World Hepatitis Day does not accurately reflect the importance of hepatitis as a public-health problem."

In this World Hepatitis Day blog ahead of the formal publication of their Perspective article in *PLoS Medicine*, Paul Klenerman, Vicki Fleming and Ellie Barnes of the University of Oxford describe research by Christian Drosten and colleagues about a new low-cost diagnostic test for Hepatitis C for use in developing countries. The research was recently published in *PLoS Medicine*.

The Perspective article by Paul Klenerman and colleagues will be formally published in *PLoS Medicine* on 16th June 2009.

What Are the Prospects for Controlling Hepatitis C?

May 19 this year marked World Hepatitis Day [1]. This event does not usually make the headlines in the same way that World AIDS Day does, but viral hepatitis affects about half a billion people globally (perhaps one in 12 of the global population), and so the relative publicity associated with World Hepatitis Day does not accurately reflect the importance of hepatitis as a public health problem.

The two major hepatitis viruses—hepatitis C virus (HCV) and hepatitis B virus (HBV)—share a number of features. Both viruses are readily spread through the transfer of infected blood or blood products. Both cause persistent infections and share an insidious progression after decades of asymptomatic carriage that creates a huge burden of end-stage liver disease and liver cancer. Thus, both viruses are major public health problems across the globe. However, there are substantial differences between these infections in terms of the risk groups affected, the geographical distribution of the viruses, and the tools at our disposal to deal with them.

Prospects for Controlling HBV and HCV

For HBV we have a well-established vaccine and an emerging panel of well-tolerated oral agents for the treatment of chronic infection. Although there is still a massive burden of complex and severe infection to tackle, the pathway towards effective combination therapy has already been trodden in HIV, and careful clinical trials in this area for HBV should bring some clarity. Delivery of such drug combinations in resource-poor settings where the prevalence of carriage is high will create its own significant challenges.

For HCV we have no current vaccine, and current therapies are toxic, complex, and expensive, as well as only partially effective. Treatment is further complicated by HIV coinfection, which is increasingly encountered in some risk groups [2]. So why is the prevention and treatment of HCV infections apparently so far behind that of HBV infections? One reason is that HCV was only identified in 1989, and only successfully cultured in 2005 [3,4]. However, the major biological hurdle to controlling HCV is the huge diversity of the virus, both within patients and among populations [5].

HCV is an RNA-based virus with a variable genome and the capacity to evolve over time to evade drug and immunologic pressure. HCV has coevolved with human populations for centuries, if not millennia [6], and has diversified widely over this period (Figure 1). By comparison, the phylogenetic tree of HIV is much more compact because this virus has had less than a century in which to diversify in humans.

The net result of this diversification is the existence of seven major genotypes of HCV (the last added very recently) that share less than 80% sequence homology with one another, and more than 50 HCV subtypes [7]. Although these genotypes may have arisen over long periods as endemic strains in geographically distinct regions (e.g., genotype 6 in southeast Asia [8]), most have now spread globally. Genotype 1 is particularly common in western Europe and the United States, although genotype 3 is also now very common in the United Kingdom as a result of its spread through intravenous drug-using populations and through immigration from the Indian subcontinent.

Multiple genotypes occur in many other viruses, including HBV, but their importance in HCV is

particularly high because both the duration and success rate of current treatments for HCV infection (pegylated interferon-alpha and ribavirin) are highly genotype dependent. Thus, genotypes 2 and 3 are typically associated with much greater response rates than genotypes 1 and 4 (70%–80% long-term clearance versus 40%–50%) and require shorter treatment periods (six months versus one year) [9]. The biological basis for these differences is unclear—the genomes of these genotypes are so diverse that such differences could result from multiple complex changes. Even within a single genotype (e.g., genotype 1), the fundamental mechanisms behind relative resistance to treatment of different HCV subtypes are not fully defined, although an interferon-sensitivity determining region has been described [10].

The Role of Nucleic Acid Tests for HCV

Given these important clinical and virologic differences between HCV genotypes, robust and sensitive nucleic acid tests for HCV have a major role to play in virus detection and in guiding treatment and thus are at the core of current clinical practice in developed countries. However, these tests are relatively complex molecular tests and are therefore not universally available. Additionally, they may not be equally sensitive at detection of all genotypes. In a recent article in PLoS Medicine, however, Christian Drosten and colleagues described a new approach to nucleic acid testing in HCV [11].

The authors generated a test based on a highly conserved region in the 3' end of the virus (most current tests are based on the 5' end) and validated their assay to show that it was sensitive in detection of a wide range of genotypes from geographically diverse populations. They also attempted to reduce the overall cost of their approach and have thus provided a novel system that uses an open (i.e., nonproprietary) protocol that might be particularly appropriate for resource-poor settings. This new assay is potentially an important step forward for laboratories in such regions and, if rolled out effectively, could provide novel information relevant to the prevalence, clinical impact, and treatment response of HCV genotypes that are currently poorly studied—most clinical analyses, and vaccine and treatment trials have focused on genotype 1.

Although very simple and cost-effective tests to detect, quantify, or genotype HCV in resource-poor areas could be of great value in future, the overall costs and usefulness of any such test in comparison to other methods and in relation to other public health priorities in such regions will need to be considered carefully. Thus, although conventional PCR methods as used by Drosten and colleagues look promising, non-PCR-based methods such as loop-mediated isothermal amplification (LAMP) also need to be considered, since little specialist equipment is required for LAMP and the sensitivity appears to be high [12]. In the end, however, the definitive test for any new method of HCV analysis will be clinical utility in the field.

The Extreme Viral Diversity of HCV

As we mark World Hepatitis Day, the recent paper by Drosten and colleagues once more draws our attention to one of the key features of HCV: its extreme viral diversity, which brings enormous challenges for the future. The capacity for HCV to evolve creates a complex target for both vaccine and drug development. Nevertheless, recent advances in both these areas provide some cautious hope for the future—at least in the case of genotype 1 infection [13,14]. Key to successful vaccine development will be the generation of effective, sustained, and broad anti-HCV immune responses. However, the immune responses to non-genotype 1 viruses are very poorly described, and recent data suggest that there is relatively little overlap between immune responses to genotypes 1 and 3. Thus, at present it is unclear whether HCV vaccines against

specific genotypes will provide any cross-protection against other genotypes [15]. The situation with drugs may be even more complex, with pre-existing diversity even within genotype 1 already providing some level of drug resistance [16].

Future studies of the diverse HCV genotypes that exist globally—hopefully facilitated by the recently published methods—will, therefore, help us understand the overall clinical impact of HCV in affected populations and will determine our potential to intervene. Since HCV emerged from the shadows 20 years ago, it has shown itself to be “smarter than the average virus.” Thus, it may take longer than 20 years for us to put it back into the shadows, and it will probably take all our efforts to do so.

References

1. World Hepatitis Alliance (2009) World Hepatitis Day. Available: <http://www.worldhepatitisday.org/>. Accessed 11 May 2009.
2. Klenerman P, Kim A (2007) HCV–HIV coinfection: Simple messages from a complex disease. *PLoS Med* 4: e240. doi:10.1371/journal.pmed.0040240
3. Houghton M (2009) Discovery of the hepatitis C virus. *Liver Int* 29 (Suppl 1): 82- 88.
4. Wakita T, Pietschmann T, Kato T, Date T, Miyamoto M, et al. (2005) Production of infectious hepatitis C virus in tissue culture from a cloned viral genome. *Nat Med* 11: 791-796.
5. Simmonds P (2004) Genetic diversity and evolution of hepatitis C virus—15 years on. *J Gen Virol* 85: 3173-3188.
6. Pybus OG, Charleston MA, Gupta S, Rambaut A, Holmes EC, et al. (2001) The epidemic behavior of the hepatitis C virus. *Science* 292: 2323-2325.
7. Kuiken C, Simmonds P (2009) Nomenclature and numbering of the hepatitis C virus. *Methods Mol Biol* 510: 33-53.
8. Pybus OG, Barnes E, Taggart R, Lemey P, Markov PV, et al. (2009) Genetic history of hepatitis C virus in East Asia. *J Virol* 83: 1071-1082.
9. Zeuzem S, Berg T, Moeller B, Hinrichsen H, Mauss S, et al. (2009) Expert opinion on the treatment of patients with chronic hepatitis C. *J Viral Hepat* 16: 75-90.
10. Torres-Puente M, Cuevas JM, Jimenez-Hernandez N, Bracho MA, Garcia-Robles I, et al. (2008) Genetic variability in hepatitis C virus and its role in antiviral treatment response. *J Viral Hepat* 15: 188-199.
11. Drexler JF, Kupfer B, Petersen N, Grotto RMT, Rodrigues SMC, et al. (2009) A novel diagnostic target in the hepatitis C virus genome. *PLoS Med* 6: e1000031. doi:10.1371/journal.pmed.1000031
12. Nagamine K, Hase T, Notomi T (2002) Accelerated reaction by loop-mediated isothermal amplification using loop primers. *Mol Cell Probes* 16: 223-229.
13. Thompson AJ, McHutchison JG (2009) Review article: Investigational agents for chronic hepatitis C. *Aliment Pharmacol Ther* 29: 689-705.
14. Thimme R, Neumann-Haefelin C, Boettler T, Blum HE (2008) Adaptive immune responses to hepatitis C virus: From viral immunobiology to a vaccine. *Biol Chem* 389: 457-467.
15. Schulze Zur Wiesch J, Lauer GM, Timm J, Kuntzen T, Neukamm M, et al. (2007) Immunologic evidence for lack of heterologous protection following resolution of HCV in patients with non-genotype 1 infection. *Blood* 110: 1559-1569.
16. Gaudieri S, Rauch A, Pfafferott K, Barnes E, Cheng W, et al. (2009) Hepatitis C virus drug resistance and immune-driven adaptations: Relevance to new antiviral therapy. *Hepatology* 49: 1069-1082.

17. Bao Y, Bolotov P, Dernovoy D, Kiryutin B, Zaslavsky L, et al. (2008) The influenza virus resource at the National Center for Biotechnology Information. *J Virol* 82: 596-601.
18. Combet C, Penin F, Geourjon C, Deleage G (2004) HCVDB: Hepatitis C virus sequences database. *Appl Bioinformatics* 3: 237-240.
19. Division of AIDS, National Institute of Allergy and Infectious Diseases (2009) HIV databases. Available: <http://www.hiv.lanl.gov/> . Accessed 11 May 2009.

Figure 1 Legend

Complete genome trees of the hepatitis C virus, HIV-1 (M-group), and the hemagglutinin region of influenza A. Nucleotide sequences were randomly selected from their respective databases representing each of the major subtypes from each virus [17–19]. Only non-recombinant genomes were included. Maximum likelihood trees were built using GARLI (Genetic Algorithm for Rapid Likelihood Inference, available at <http://www.nescent.org/>). Trees have been drawn to the same scale.

Trackback URL for this post: <http://www.plos.org/cms/trackback/470>

May 20, 2009

Nexavar Approved In Japan For The Treatment Of Advanced Liver Cancer

<http://www.medicalnewstoday.com>

Bayer HealthCare Pharmaceuticals and Onyx Pharmaceuticals, Inc. (Nasdaq: ONXX) announced that the Ministry of Health, Labour and Welfare (MHLW) in Japan has approved Nexavar(R) (sorafenib) tablets for the treatment of patients with unresectable hepatocellular carcinoma (HCC), a type of liver cancer that accounts for 95 percent of all liver cancer cases in Japan(1). Nexavar is also currently available in Japan as an approved treatment for unresectable or metastatic renal cell carcinoma (RCC).

The approval in Japan was based on the international, Phase 3 double-blind, placebo-controlled Sorafenib HCC Assessment Randomized Protocol (SHARP) study that evaluated more than 800 patients who received no prior systemic therapy. The study found that Nexavar improved overall survival in patients with HCC by 44 percent (HR=0.69; p=0.0006) versus placebo. Based on SHARP results, Nexavar is currently approved in more than 70 countries for liver cancer, including the U.S. and countries in Europe.

"Liver cancer is one of the leading causes of cancer-related deaths in Japan, and the incidence is continuing to rise," said Gunnar Riemann, member of the Executive Committee of Bayer HealthCare. "We are pleased with today's approval and what it may mean for liver cancer patients in Japan and their families who now have a therapy like Nexavar that has the potential to extend their lives."

In Japan, approximately 40,000 people are diagnosed with liver cancer each year and approximately 36,000 die from the disease, making primary liver cancer the third leading cause of cancer-related death in Japan.(2)

Hepatitis B viral infection (HBV) and hepatitis C viral infection (HCV) are leading risk factors

for developing primary liver cancer worldwide, with HCV being the primary risk factor in Japan. An estimated 80 to 90 percent of Japanese patients diagnosed with liver cancer have HCV.(3)

"This is a significant milestone in the Japanese region where patients, who have high rates of liver cancer, are truly in need of a treatment option that improves survival," said Laura Brege, executive vice president and chief operating officer at Onyx Pharmaceuticals, Inc. "This latest approval provides further evidence that Nexavar is an important therapy for patients with liver cancer as well as kidney cancer, an indication for which Nexavar was first approved in Japan."

Hepatocellular carcinoma is the most common form of liver cancer(4) and is responsible for about 90 percent of the primary malignant liver tumors in adults(5). Liver cancer is the sixth most common cancer in the world(6) and the third leading cause of cancer-related deaths globally(7). 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(4). 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(4).

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. Preclinical models have also demonstrated that Raf/MEK/ERK has a role in HCC; therefore blocking signaling through Raf-1 may offer therapeutic benefits in HCC.

Nexavar is currently approved in more than 70 countries for liver cancer and in more than 80 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, lung cancer, breast cancer, colorectal cancer, lung cancer, ovarian cancer, and as an adjuvant therapy for kidney and liver cancer.

This Is Your Government Making Sense on Drugs

<http://blogs.tnr.com>

Harold Pollack

Harold Pollack is a public health policy researcher at the University of Chicago's School of Social Service Administration, where he is faculty chair of the Center for Health Administration Studies. He is a regular contributor to The Treatment.

Last week, I chided the Obama Administration for its tepid approach to HIV prevention policy. No doubt responding to my broadside, incoming Drug Czar Gil Kerlikowske granted his first official interview to the Wall Street Journal. The piece was a disorienting read. For the first time in years, we have a Drug Czar making sensible and informed points rather than invoking the tired tropes of past culture wars.

Mark Kleiman has already put up a nice posting. In addition to his web journalism, Mark is one of the nation's leading drug policy experts. His book *Against Excess* remains an essential reference. So he ought to know. The title of his latest column, "The drug war is over," says it all.

Kerlikowske was specifically asked about needle exchanges. Here is what he said:

I think needle exchange programs are part of a complete public-health model for dealing with addiction. Some people get the impression folks just walk in and exchange needles or get clean needles and you do want to reduce HIV and Hepatitis C and other transmittable diseases but you also would like to see, which those in Buffalo and Seattle do, access to treatment, access to counseling.

Not an elaborate policy treatise, but he got the high points quite right. Two things I especially liked about this statement:

First, Kerlikowske noted that Americans have an oversimplified idea of what needle exchanges are, and what they try to do. Yes, exchanges provide sterile syringes (and collect used ones) to injection drug users (IDUs) to prevent HIV infection. Yet they do other things, too. Needle exchanges provide a way to engage street users. Once these human relationships are created, you can address other serious problems in users' lives, help link people into methadone treatment and into other needed services.

Needle exchanges are--or should be--part of a continuum of care. If the ban on federal funding were lifted, these programs could operate much more effectively. We could also do much better health services research to explore new strategies to improve these services, not only to make them more effective in reducing HIV, but also in achieving other goals such as reducing drug use and criminal offending among the men and women who use these services.

Second, Kerlikowske noted the incredibly serious challenge of hepatitis C (HCV). This damn disease is rampant in pretty much every population of street IDUs. Around the world--even in places that achieve very low HIV prevalence and do everything right from treatment-on-demand to widespread needle exchange services--users generally become infected if they inject for more than a few years.

We seem unable to reliably protect street users against HCV. We also struggle to address another serious challenge: Fatal overdose. HIV provides one reason not to become an injection drug user. There are lots of other good reasons, too.

In addressing such daunting problems, an appropriate seriousness and humanity is beginning to intrude. This new mood didn't start with the Obama administration. Many Democrats and Republicans have been backing away from the drug war for awhile now. The comments of our new Drug Czar suggest that it's become official.

Tainted blood victims left angry

<http://news.bbc.co.uk>

By Nick Triggle

Health reporter, BBC News

Victims of the contaminated blood scandal have accused the government of treating them with contempt.

Thousands of UK people - mainly those with haemophilia - were infected with HIV and hepatitis C during the 1970s and 1980s after using blood products.

An inquiry had called for an overhaul of the victim pay-out system, but ministers refused, promising only extra funds for those with HIV.

Campaign groups condemned the response as "unacceptable".

They were joined in criticising the announcement by the head of the inquiry, Lord Archer of Sandwell.

His two-year investigation was privately-funded as the government has always rejected demands for a full public inquiry - although officials in Scotland have agreed to one.

Instead of agreeing to a full reform of the pay-outs system, which victims have said is demeaning because parts of it is means-tested, ministers promised to pump extra money in for people with HIV to double average annual payments to £12,800.

The fund for people with hepatitis C, which works through a series of lump sum payments and was set up much more recently, has funding available until 2014 after which it will be reviewed, the government said.

Public health minister Dawn Primarolo said: "I would like to offer my deepest sympathy to all those who suffered in this tragic episode.

"Sadly, it was not possible to effectively test for these viruses in the 1970s and early 80s and we deeply regret that these events occurred following NHS treatment."

But the Tainted Blood campaign group described the changes as "insulting and degrading".

And Chris James, chief executive of the Haemophilia Society, said the response showed "contempt" towards the victims.

"The government talks of moral responsibility but has seen fit to try to ignore or water-down Lord Archer's recommendations. It is simply unacceptable for ministers to propose such a collection of half measures."

'Tragedy'

Lord Archer's report, which was published in February, called the contaminated blood scandal an "horrific human tragedy".

Nearly 5,000 people were exposed to hepatitis C before the heat treating of blood products began in the mid 1980s.

Of these, more than 1,200 were also infected with HIV.

Almost 2,000 of those people have since died as a result.

Much of the contaminated blood is thought to have come from the US where it was taken from "skid row" donors, such as prison inmates, whose risk of infections was much higher than the general population.

Lord Archer said commercial interests appeared to have been given a higher priority than patient safety.

However, he added the UK was slow to react in everything from becoming self-sufficient in blood products to recognising the scale of the problem.

Lord Archer called for a government-backed payment scheme to replace the ones that are administered by charitable trusts, which victims have complained can be hard to access.

He also wanted to see a committee of specialists be established to act as official advisers to ministers over on-going compensation claims and the treatment of victims.

This was again rejected by the government, which would only commit to meeting an official group of doctors and patients twice a year.

Lord Archer said the government response was a "faltering step that only compounds the anguish of the afflicted and bereaved".

Meanwhile, the government has also revealed more than 800 people have a heightened risk of vCJD.

The group, again mostly people with haemophilia, received blood products from a donor who went on to develop the brain disease.

It comes after a man in his seventies died with traces of vCJD in his spleen. His death was due to an unrelated cause, but he was thought to have been the first person to have got the brain disease from contaminated blood.

Local liver specialists struggle to keep up with hep C influx

<http://www.winnipegfreepress.com>

By: Jen Skerritt

LOCAL liver specialists are struggling to keep up with the constant influx of hepatitis C patients, as the number of Manitobans who test positive for the virus climbs every month.

Dr. Kelly Kaita, director of the viral hepatitis investigative unit at Health Sciences Centre and one of three liver specialists in Manitoba, said his clinic sees about 8,000 hepatitis C patients -- about 10 times more than a decade ago.

Despite the increase, Kaita said too few family doctors test for hepatitis C and many Manitobans infected with the virus don't know it. He said many of his patients are diagnosed with the virus

by sheer accident or when symptoms surface and their livers have already suffered damage.

Kaita said tattoo enthusiasts, blood transfusion patients and anyone who has ever experimented with drugs should ask to be tested for hepatitis C since drug treatment can often cure the infection and prevent complications.

About 20 per cent of patients with hepatitis C will develop end-stage liver disease or liver cancer, including many who will need a liver transplant. Hepatitis C is the number one reason Manitoba patients end up on the transplant list, Kaita said.

"It's just the sheer volume of patients that makes it difficult to see everyone," he said. "A lot of these patients are people who acquired their infection years ago, if not decades ago."

Tuesday was World Hepatitis Day, and a group of health-care workers and volunteers canvassed city streets to raise awareness of the virus that affects one in 12 worldwide.

Hepatitis C can be transmitted through contact with blood. Left untreated, it can scar the liver, cause inflammation and eventually result in liver cancer.

Between January and October 2008, the latest data available, 291 Manitobans tested positive for the viral infection.

The bulk of Kaita's patients are between the ages of 30 and 50, many infected in the 1960s and 1970s, either through a blood transfusion or dabbling in drug use.

Kirk Leavesley, a counselor with a local hepatitis C support group, said many patients are afraid to ask their doctors about hepatitis C because of the stigma associated with the disease. Leavesley, who was diagnosed with the virus in 2000, said many people falsely believe they can easily contract the infection from a person who tests positive.

"The biggest problem we still have is stigma," he said. "A lot of people who have hep C don't want to tell people because there's a real fear of being shunned."

That's why Jack, a lanky grey-haired professional, prefers to keep his last name anonymous when discussing how his hepatitis C diagnosis caught him off guard 10 years ago. A test uncovered he had hepatitis C and that more than half of his liver was damaged. While two rounds of intense chemotherapy drugs helped restore part of his liver, Jack said he has developed an extreme sensitivity to sunlight and has chronic fatigue.

The former martial arts and hunting enthusiast said he doesn't discuss his health with his peers or colleagues. He worries they'll treat him differently.

"I have a lot of symptoms," he said. "I'm not healthy at all."

May 20, 2009

World Hepatitis Day 2009: 5 Years For The EU To Rescue The Liver!

<http://www.medicalnewstoday.com>

On the occasion of World Hepatitis Day and on the eve of the European Parliament elections, healthcare professionals and patients call on EU decision-makers to make the next 5 years about protecting the liver!

Dr. Heiner Wedemeyer, Secretary General of the European Association for the Study of the Liver (EASL) and Nadine Piorkowsky, President of the European Liver Patients' Association (ELPA) urged EU decision-makers to save the lives of millions of Europeans and make liver diseases an EU health priority over the next five years: 'We are witnessing an alarming trend in the number of people affected by liver diseases in the EU: every year, liver cancer causes approximately 700,000 deaths. Hepatitis B and C alone are estimated to affect more than 20 million people in the wider WHO European region and are on the rise in many EU countries' - said Dr. Heiner Wedemeyer, Secretary General of EASL.

'A strong EU voice on liver disease is particularly needed because liver disease is often killing patients "silently": for years, and sometimes decades, patients do not feel the symptoms of their illness and therefore remain undiagnosed until it is too late. Targeted screening of those at risk of catching viral Hepatitis will contribute to defusing this "viral time bomb" and reducing Hepatitis-related morbidity and mortality in Europe' - added Nadine Piorkowsky, President of ELPA and a former Hepatitis C patient herself.

EASL and ELPA call for four key EU measures that should be achieved over the next five years:

- To adopt an EU Council Recommendation on viral Hepatitis Screening to further hepatitis prevention, surveillance, screening and care in Europe, promote cooperation among Member States and encourage the adoption and implementation of best practices in the area of liver diseases.
- To increase EU research funding for liver diseases by including adequate calls for proposals on liver diseases, such as viral hepatitis, liver cancer, cirrhosis, fatty liver and others, in the European Commission's Research Framework Programme
- To develop and promote independent public awareness campaigns aimed at informing citizens about liver disease and how it can be prevented and treated
- To improve monitoring and surveillance of liver diseases in the EU by stepping up the work of the European Centre for Disease prevention and Control (ECDC)

About liver disease

The liver is the body's largest internal organ and is essential to life. It performs over 500 different functions for the body including processing digested food from the intestine and controlling levels of fats, amino acids and glucose in the blood.

The liver's complexity makes it susceptible to many different diseases, including among others:

- Hepatitis - the most common liver disease which causes inflammation of the liver. It can occur in both viral (e.g. Hepatitis A, B, C, D, E) and non-viral forms (e.g. alcoholic and autoimmune hepatitis) and may result in an acute or chronic condition.
- Cirrhosis - the excessive development of scar tissue within the liver which can lead to complete liver failure. This is the result of long-term, continuous damage to the organ.
- Fatty liver - covers a range of conditions where there is a build-up of fat in the liver cells. It is caused by certain chemical compounds (particularly alcohol) and by nutritional and

endocrine disorders.

- Liver cancer - may occur as both primary (cancer that starts in the liver) and secondary (cancer that first develops elsewhere in the body and then spreads to the liver)
- Genetic diseases - includes conditions such as Haemochromatosis, Wilson's Disease and Glibert's Syndrome. Most (but not all) of these diseases are rare (with a prevalence of less than 50 per 100,000 people).

Although the liver is unique in its ability to regenerate it cannot survive continuous damage.

About EASL

EASL is the leading pan-European association of medical professionals dedicated to promoting liver research and care. Through its work, EASL aims to promote the education of physicians and scientists as well as to improve public awareness on liver diseases and their management. For more information on EASL, see <http://www.easl.ch>.

Source: ELPA

Hepatitis C Virus Can Be Transmitted by Drug Use Through the Nose

<http://www.drugabuse.gov>

In most cases of hepatitis C virus (HCV), the virus is transmitted through contact with infected blood, usually through the sharing of needles and other drug injection instruments. However, for up to 20 percent of HCV infections, the method of transmission is unknown.

Researchers have suggested that for some of these cases, HCV may be transmitted through the nose via the use of contaminated drug-sniffing implements.

To test this hypothesis, investigators funded in part by NIDA tested mucus samples from 38 intranasal drug users with chronic, active HCV infection for the presence of blood and HCV.

They also asked participants to snort air through a straw in a way that would mimic their normal drug-sniffing behavior to determine whether sniffing implements became contaminated. The straws were then tested for blood and HCV.

The investigators found trace amounts of blood in 74 percent of mucus samples and on 8 percent of the straws used for sniffing. In addition, they detected HCV in 13 percent of mucus samples and on 5 percent of the straws. Only 8 percent of the samples contained both HCV and trace amounts of blood.

Participants had a high rate of nasal inflammation and other nasal problems, including nosebleeds and damage to the inside of the nose from drug use, which may have contributed to the passage of blood and HCV from the nose.

These results lend support to the hypothesis that HCV can be transmitted through shared use of contaminated sniffing implements, stated the authors.

Aaron S, McMahon JM, Milano D, Torres L, Clatts M, Tortu S, Mildvan D, Simm M. Intranasal

transmission of hepatitis C virus: Virological and clinical evidence. Clin Infect Dis. 2008;47(7):931–934.

Doctor and Patient: Fear of Contagion

<http://www.nytimes.com>

By Pauline W. Chen, M.D.

Early on in my internship, a senior doctor pulled me aside after hearing a couple of other interns grouse with me about our workload. “Caring for patients is a privilege, a calling,” he said. “Remember, no one forced you to sign your contract.”

For years those words came to mind whenever I cared for patients who had lethal, and potentially contagious, infections, patients like Jean (not her real name), who was in her 50s when I met her. She had contracted hepatitis C from receiving a vaccination with a contaminated needle years before, and the symptoms of her end-stage liver failure had become increasingly difficult to tolerate over the last year. She itched constantly from jaundice; her memory had deteriorated; and she had had episodes of life-threatening bleeding that had landed her in the intensive care unit on two separate occasions. According to the nurses, Jean had walked into the hospital on the night she was to receive a liver transplant, bubbling over about the new start on life she would have with the new organ.

Despite Jean’s optimism, she ended up suffering from a series of devastating postoperative complications and infections. By the time I came onto her surgical team as one of the interns, she had spent three months in the hospital.

One morning soon after I began taking care of her, one of the nurses noticed that Jean had become short of breath. A chest X-ray showed fluid in her lungs, fluid that I could drain to help her breathe. The drainage procedure wouldn’t take long once the needle was in her chest; but because everything would be done using sterile technique, once the procedure started, I could not leave Jean’s side or touch anything other than the instruments I was using.

My beeper went off the moment I slipped on the sterile gloves. I tried to ignore it, forging ahead with the procedure. I disinfected Jean’s skin, laid down sterile drapes and began numbing her skin with a syringe filled with anesthetic solution.

Over and over again, my beeper went off. And I continued ignoring it until the fifth page, when I began to worry that there might be an emergency elsewhere in the hospital. I wriggled my hips against Jean’s nightstand, trying to dislodge the beeper from my waist without touching it or contaminating the sterile field. I shouted for help, but no one answered my calls.

Finally, when my pager went off for the sixth time, I pulled off my left glove and reached down, groping for the beeper hanging on my right hip while walking toward the door to find a phone.

I felt a sharp sting. Looking down, I saw a small scarlet drop emerging from the tip of my left index finger. I had stabbed my finger against the needle I had just used to anesthetize Jean’s skin, a needle I still held in my right hand.

I stared at the tiny red bloom on my fingertip. And for a moment, I felt the floor beneath my feet give way, pulling everything — Jean, my heart, my work, my life — down with it. I stood there paralyzed, staring at the puncture wound on my fingertip and unable to stop the movie playing in my mind's eye, a movie of a future like Jean's. Jean would never leave the hospital and, a few months later, would die in the I.C.U., succumbing to a final, massive infection.

Over the years, I have been stuck, cut, coughed on, scratched and splashed several more times. Each time, I feel the floor and my life fall away. I have never contracted a life-threatening infectious disease; but sometimes I catch myself wondering if it's only a matter of time. During the SARS epidemic a few years back, for example, health care workers were disproportionately affected; certain hospitals in affected areas reported that over half their workers contracted the disease.

And then every day there is news that swine flu may still reach pandemic proportions.

When I think about the possibility of becoming infected with a potentially deadly disease during the course of my work — when I allow myself to think about it — I struggle to reconcile my beliefs about a doctor's responsibilities and my fears about my own safety.

But, always, I arrive at the same conclusion. Like that senior doctor, I believe it's a privilege, a calling, to take care of patients. And I believe that in deciding to practice medicine, I have consented to an unspoken contract with the public, one that requires that I take care of those who are sick.

Lately, however, I have also begun to think that there is another side to that contract. Maybe there are obligations that the general public has to its health care workers.

Four years ago, Dr. Kent A. Sepkowitz from Memorial Sloan-Kettering Cancer Center in New York and Dr. Leon Eisenberg from Harvard Medical School published a study on occupational deaths among health care workers. They estimated that anywhere from 17 to 57 deaths per million workers occur annually in the United States as a result of occupational exposures. When placed in the context of other occupations, this calculated death rate was more than the national average, less than that of policemen and firefighters, and much less than that of the most dangerous occupations like fishing, construction, flying and being a part of the military. (Lawyers and waiters, interestingly enough, came at the bottom of the entire list with some of the safest jobs.)

But with some nine million people working in the health care industry, health care workers end up with one of the highest numbers of total deaths, upwards of more than 300 per year.

There is a flaw, however, in all of these comparisons. And it is that the estimated annual death rate for health care workers is, well, just that — a calculated guess that is an underestimate at best. Despite the very real risk that exists for all health care workers, the actual number of deaths from occupational injuries or infections is unknown. Unlike policemen and firefighters and other high-risk occupations, health care workers have no national registry to track deaths caused by infections or injuries acquired on the job. As Drs. Sepkowitz and Eisenberg are quick to point out, the figure they use is based on their best educated guess regarding occupational deaths from only four infectious diseases: hepatitis B, hepatitis C, H.I.V. and tuberculosis.

In a recent e-mail, Dr. Sepkowitz confirmed that four years after the publication of their paper, we still do not know what the actual occupational death rate is for health care workers. No federal or national organizations have stepped up to the plate and taken on the task of tracking these deaths. Without those numbers, without a clear idea of just how many people are affected, there is no way any of us can come up with better ways to protect those workers who put themselves at risk to care for others.

I recently spoke to Gerald M. Oppenheimer, a historian who has written extensively about the doctors who chose to care for AIDS patients just as the disease was emerging in the 1980s. It was a frightening period; no one understood how the illness was transmitted or infected.

“We are so used to seeing heroes as different, as people who are larger than life and who prepare all their lives for this event. But it’s not that at all,” Dr. Oppenheimer said. “[These doctors] were ordinary people who were responding to something that appeared to be very dangerous. And they were willing to take that risk because of their beliefs.”

Supporting a national registry of occupational deaths in health care workers would go a long way toward recognizing and supporting some of the extraordinary decisions of ordinary individuals. And that registry, I believe, should be part of the agreement between health care workers and those they serve.

May 22, 2009

ALT Level Increase Common During HCV Therapy

www.medscape.com

NEW YORK (Reuters Health) May 21 - Elevations in alanine aminotransferase (ALT) levels late in the course of antiviral therapy of hepatitis C virus (HCV) RNA-negative patients are not unusual and may be associated with virological relapse in some cases, Italian researchers report in the May issue of *Hepatology*.

However, senior investigator Dr. Antonino Picciotto told Reuters Health: "Elevated ALT in HCV RNA-negative patients during pegylated interferon and ribavirin therapy should not be a reason for treatment discontinuation."

Dr. Picciotto of the University of Genoa and colleagues studied 173 chronic hepatitis C patients who achieved viral clearance during combination therapy.

Overall, 33% of the patients with undetectable HCV RNA had elevated ALT in at least one scheduled visit during a 24-week follow-up period; included were patients with HCV genotype 1 or 4 who alone were followed for 48 weeks.

The distribution of these findings did not differ between sustained responders and those who responded and then relapsed. The researchers found no association with pretreatment demographic features, such as age and gender, or with clinical or viral parameters.

However, at 12 weeks until the end of treatment, elevated ALT was more common in relapsed responders (90%) than in those who maintained a sustained response (9%).

Dr. Picciotto concludes that elevated ALT "during the late phase of therapy may suggest a higher risk of relapse."

Hepatology 2009;49:1442-1448.

Michigan Recognizes May As Hepatitis Awareness Month

<http://www.emaxhealth.com>

As May is observed as Hepatitis Awareness Month, the Michigan Department of Community Health (MDCH) is encouraging families to protect themselves from hepatitis virus disease. Also, the Centers for Disease Control and Prevention (CDC) and the National Viral Hepatitis Roundtable Coalition recognize the importance of addressing viral hepatitis.

This month is aimed at raising awareness of hepatitis. There are three main types of hepatitis caused by viruses that attack the liver.

Hepatitis A disease is spread by persons who have the virus or by eating food or drinking water with the hepatitis A virus in it. Hepatitis B disease is spread through unprotected sex, blood-to-blood contact with someone who has the virus, or at birth. Hepatitis C disease is spread by coming into contact with blood or by sharing dirty needles with someone who has the virus. People may already have hepatitis C virus if they received blood, blood products or organs before 1992 or clotting factor before 1987.

Some people infected with viral hepatitis may never show any symptoms of having the disease and without a blood test to confirm they are infected may be spreading the disease unknowingly to others. Some people with viral hepatitis may become extremely ill and those with hepatitis B or C may also develop long-term infection that can cause liver damage, cancer, or even death.

Each year, hundreds of people in Michigan become ill from viral hepatitis. Hepatitis A and B can be prevented by getting immunizations. All three types of viral hepatitis can be addressed through other prevention methods. Prevention, vaccination and testing are the best ways to protect your family against hepatitis disease.

Hepatitis vaccines are safe and effective. These vaccines are thoroughly tested before being approved for public use and monitored carefully by doctors, researchers, and public health officials. Make sure your family is protected from viral hepatitis disease.

Source: Michigan Department Of Community Health