

HCV ADVOCATE WEEKLY NEWS REVIEW

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

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Week Ending: March 10th 2007

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March 3rd, 2007

SEBIVO(R) (Telbivudine) Approved in China as New Treatment Option for Patients with Chronic Hepatitis B

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

Idenix Pharmaceuticals, Inc. (Nasdaq: IDIX) announced today that SEBIVO(R) (telbivudine) has received approval from the Chinese State Food and Drug Administration (SFDA) as a once-a-day treatment, taken orally with or without food, for the treatment of chronic hepatitis B (CHB). CHB remains a significant global health care concern, particularly in China where it affects more than 100 million people(1-3) - representing about one-third of those infected worldwide.(2) SEBIVO is expected to be available in China in April.

"The Chinese approval of telbivudine is positive news for the many CHB patients in China," said Dr. Calvin Q. Pan, MD, Director, Clinical Research/Hepatology, Mount Sinai Services at Elmhurst Hospital in New York City. "As a physician who treats many CHB patients in the U.S., it is good to know that the patients in China will also have access to this new treatment option. Now, Chinese patients may also benefit from telbivudine's ability to provide early viral suppression, a primary goal of treatment."

Telbivudine received regulatory approval in the United States from the Food and Drug Administration (FDA) in October 2006 for the treatment of CHB in adult patients with evidence of viral replication and active liver disease. Telbivudine is called TYZEKA in the United States and is called SEBIVO in all other countries. The approval of SEBIVO in China follows earlier approvals in Canada, Australia, Switzerland and several countries in Asia and Latin America. SEBIVO also recently received a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommending approval by the European Commission.

Worldwide regulatory submissions have been based primarily on one-year data from the GLOBE study, the largest worldwide registration trial including hepatitis B e-antigen (HBeAg)-positive and HBeAg-negative patients with CHB, and the first to include patients from China. The study results demonstrated that telbivudine provided potent viral suppression and high rates of PCR-negativity after one year. An additional Chinese phase III trial, involving 332 adult Chinese patients with CHB, corroborated these findings and supplemented the filing in China.

About the GLOBE Study

Data from the worldwide phase III clinical trial, known as the GLOBE study, compared telbivudine to lamivudine, a commonly used antiviral therapy for the treatment of CHB, in 1,367 patients. In the GLOBE study, 60 and 40 percent of HBeAg-positive patients and 88 and 71 percent of HBeAg-negative patients achieved undetectable levels of HBV DNA (PCR-negativity) with telbivudine and lamivudine, respectively, at 52 weeks. Additionally, patients who achieved undetectable HBV DNA levels at 24 weeks were more likely to undergo e-antigen seroconversion, PCR-negativity, normalize ALT, and minimize resistance at one year.

The primary efficacy endpoint of the GLOBE study was therapeutic response at one year, a composite endpoint coupling viral suppression (serum HBV DNA suppression below 100,000 copies/mL) with either improved liver disease markers (ALT normalization) or loss of detectable HBeAg. In HBeAg-positive patients, therapeutic response was 75% (n=345/458) among patients treated with telbivudine and 67% (n=310/463) for those patients treated with lamivudine, while the response for HBeAg-negative patients was 75% (n=167/222) vs. 77% (n=173/224), respectively.

In the GLOBE study, telbivudine was generally well tolerated with most adverse experiences classified as mild or moderate in severity. Frequently occurring adverse events (> 5%) for telbivudine v. lamivudine, respectively, were upper respiratory tract infection (14% v. 13%), fatigue and malaise (12% v. 11%), abdominal pain (12% v. 13%), nasopharyngitis (11% v. 10%), headache (11% v. 14%), blood CPK increased (9% v. 7%), cough (7% v. 6%), nausea and vomiting (7% v. 6%), influenza and influenza-like symptoms (7% v. 8%), post-procedural pain (7% v. 6%), diarrhea and loose stools (7% v. 5%) and pharyngolaryngeal pain (5% v. 4%). Please see Important Safety Information.

Idenix/Novartis collaboration

Idenix and Novartis Pharma AG are co-promoting TYZEKA/SEBIVO, for the treatment of chronic hepatitis B, and co-developing valtorcitabine, a second hepatitis B compound, and valopicitabine, a hepatitis C compound, under a development and commercialization arrangement established in May 2003. Under this agreement, Novartis and Idenix will co-promote TYZEKA/SEBIVO and, if approved, valtorcitabine and valopicitabine in the United States, France, Germany, Italy, Spain and the UK. Novartis has the exclusive right to commercialize TYZEKA/SEBIVO, valtorcitabine and valopicitabine in the rest of the world.

Important Information about Telbivudine

The following information about telbivudine is adapted from the U.S. Food and Drug Administration's approved product label. It is anticipated that similar language related to the product's indication and important safety information will pertain to the product in global labeling.

Telbivudine is indicated for the treatment of chronic hepatitis B in adult patients with evidence of viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. This indication is based on virologic, serologic, biochemical and histologic responses after one year of treatment in nucleoside-treatment-naïve adult patients with HBeAg-positive and HBeAg-negative chronic hepatitis B with compensated liver disease. Full prescribing information is available at <http://www.tyzeka.com>.

Important Safety Information about Telbivudine

- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues alone or in combination with antiretrovirals.
- Severe acute exacerbations of hepatitis B have been reported in patients who have discontinued anti-hepatitis B therapy, including telbivudine. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy. If appropriate, resumption of anti-hepatitis B therapy may be warranted.
- Cases of myopathy have been reported with telbivudine use several weeks to months after starting therapy. Myopathy has also been reported with some other drugs in this class. Physicians considering concomitant treatment with these or other agents associated with myopathy should weigh carefully the potential benefits and risks and should monitor and advise patients to report any signs or symptoms of unexplained muscle pain, tenderness or weakness, particularly during periods of upward dosage titration. Telbivudine therapy should be interrupted if myopathy is suspected, and discontinued if myopathy is diagnosed.
- Because telbivudine is eliminated primarily by renal excretion, co-administration of telbivudine with drugs that affect renal function may alter plasma concentrations of telbivudine and/or the co-administered drug. Dose interval adjustment is recommended in patients with creatinine clearance < 50mL/min including those with ESRD on hemodialysis. For patients on hemodialysis, telbivudine should be administered after hemodialysis.
- The safety and efficacy of telbivudine in liver transplant recipients are unknown. If telbivudine treatment is determined to be necessary for a liver transplant recipient who has received or is receiving an immunosuppressant that may affect renal function, such as

cyclosporine or tacrolimus, renal function should be monitored both before and during treatment with telbivudine.

- Patients should be advised that treatment with telbivudine has not been shown to reduce the risk of transmission of HBV to others through sexual contact or blood contamination.
- Safety and effectiveness of telbivudine in pediatric patients under the age of 16 years have not been established.
- Creatine kinase (CK) elevations were more frequent among subjects on telbivudine treatment. Grade 3/4 CK elevations occurred in 9% of telbivudine-treated patients and 3% of lamivudine-treated patients.
- The optimal duration of treatment with telbivudine has not been established. The relationship of initial treatment response to outcomes such as hepatocellular carcinoma and decompensated cirrhosis are unknown.

About Idenix

Idenix Pharmaceuticals, Inc., headquartered in Cambridge, MA, is a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral and other infectious diseases. Idenix's current focus is on the treatment of infections caused by hepatitis B virus, hepatitis C virus and human immunodeficiency virus (HIV). For further information about Idenix, please refer to <http://www.idenix.com>.

Forward-looking statements

This press release contains "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements can be identified by the use of forward-looking terminology such as "commitment," "may," "promising," "will," or similar expressions, or by express or implied discussions regarding potential approvals of telbivudine in additional markets or potential future revenues from telbivudine. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantees that telbivudine will be approved for sale in any additional markets or that revenues from the sale of telbivudine will reach any particular level. In particular, management's expectations could be affected by unexpected regulatory actions or delays, or government regulation generally; unexpected clinical trial results, including additional analysis of existing clinical data and new clinical data; the company's ability to obtain additional funding required to conduct its research, development and commercialization activities; the ability of the company to attract and retain qualified personnel; government, industry, and general public pricing pressures; competition in general; and the company's ability to obtain, maintain and enforce patent and other intellectual property protection for telbivudine, valopicitabine, its other product candidates and its discoveries. These and other risks which may impact management's expectations regarding telbivudine are described in greater detail under the caption "Risk Factors" in the company's most recent quarterly report on Form 10-Q filed with the Securities and Exchange Commission and other filings that the company makes with the Securities and Exchange Commission.

All forward-looking statements reflect the company's expectations only as of the date of this release and should not be relied upon as reflecting the company's views, expectations or beliefs at any date subsequent to the date of this release. Idenix anticipates that subsequent events and developments may cause these views, expectations and beliefs to change. However, while Idenix

may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so.

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Idenix Pharmaceuticals, Inc.

<http://www.idenix.com>

March 4th, 2007

Designer Genes

<http://www.phillyburbs.com>

By JOHN WILEN

It's not every day that you accidentally discover something that could end most disease.

But in the case of Catherine Pachuk and C. Satishchandran, founders of Horsham-based Nucleonics Inc., that's precisely what happened.

A decade ago, working for a different company, Pachuk and Satishchandran stumbled upon a method of silencing genes - the DNA "software" that tells human cells what to do and when to do it.

That gene-silencing technology, which spawned research that led to several patents, a Nobel prize and millions of dollars in venture capital, is now being developed by Nucleonics to fight hepatitis B, cancer and the common flu.

"We can make a product that will be effective every year versus every flu," said Nucleonics CEO Robert Towarnicki.

And it's a technology that can be applied to virtually any disease.

"All you need to know is the particular gene sequence that you want to get rid of," said Satishchandran.

Nucleonics hopes to begin a Phase I safety trial of its hepatitis B compound in the second quarter.

The accidental discovery

In the mid-1990s, Pachuk and Satishchandran worked together in Malvern at Apollon, which was experimenting with DNA vaccines and gene therapy, where they made an interesting discovery.

"Our cells have evolved not to accept DNA," Satishchandran said.

The scientists' attempts to get human cells to accept new DNA were consistently thwarted by compounds that came to be known as short-interfering RNA or RNAi (RNA stands for ribonucleic acid, a substance that takes the genetic code from DNA and turns it into a protein that actually performs a bodily function).

The RNAi were an impediment to the work Pachuk and Satishchandran were trying to do at Apollon, which was later acquired by Wyeth. But RNAi was, as it turns out, a key discovery and the foundation of everything they're trying to accomplish now at Nucleonics.

Wyeth was not interested in pursuing research in gene silencing, so Pachuk and Satishchandran, who had filed for a patent on gene silencing, negotiated an agreement to leave the pharmaceutical giant with a license to that technique.

In 2001, they founded Nucleonics, set up shop at the Hepatitis B Foundation, then located at Delaware Valley College, and raised \$1.6 million in seed capital.

"It sounded ridiculous," said Tim Block, director of the Hepatitis B Foundation and president of the Pennsylvania Biotechnology Center in Buckingham, of his initial reaction when approached by Pachuk and Satishchandran. "But they turned out to be right again and again."

Because Block helped nurture the company in its early years, it focused initially on treating hepatitis B.

But, Block notes, "This technology is applicable to any disease," even to afflictions such as high cholesterol.

Fixing the body's software

Pachuk and Satishchandran were "among the first" to have discovered gene-silencing RNAi, Block said. Researchers Craig Mello and Andrew Fire won a Nobel Prize last year for their work in the discovery of gene silencing, which they published in 1998.

Nucleonics has licensed the Mello and Fire-developed technology from the Carnegie Institution of Washington, and has licensed several other related patents from other institutions.

To understand RNAi's influence on DNA, it's best to think of both substances as kinds of software. DNA is your body's operating system - it's what you come programmed to do, from growing lungs, feet and hands in utero to having brown or blue eyes to developing heart disease or losing your hair later in life.

When the DNA wants to do something, it makes a copy of a portion of itself on RNA. The body, following that snippet of software mapped out on the RNA, generates a protein that in turn performs the bodily function.

Most of these functions are things we want the body to do - we want lung cells to absorb oxygen, for instance, and we want liver cells to filter out toxins. But sometimes, DNA does things we don't want it to do, such as allow your body to develop heart disease. And other times, cells are infected with viruses, which themselves reprogram cell DNA to replicate themselves.

"When things go wrong in a body," Block explains, "it's because we've lost a gene or we make too much of a protein because of a gene."

Gene silencing, or RNA interference technology, is a means - as its name suggests - of interfering with or silencing those little snippets of "bad" software carried on RNA.

"You're putting a patch in, you're downloading an update," said Pachuk.

Following the map

Thanks to the mapping of the human genome, scientists know the software code needed to stop many diseases, Pachuk said.

"The science is solid, it works," said Christoph Seeger, a senior member of the basic science division at Fox Chase Cancer Center in Philadelphia. "The major challenge in RNA interference is delivery."

Nucleonics believes it has a solid delivery method.

"We will be injecting into someone's arm a product that is going to reside in the liver and treat a liver ailment," Towarnicki said.

But the company's competitive advantage is in the way in which that drug does its work once inside the body, he said. Where other companies plan to make their gene-silencing drug in a test tube, then inject it into a patient, Nucleonics' substance is similar to a virus in that it reprograms cells themselves to create multiple copies of itself.

"We deliver a factory that continues to replenish the supply of the active ingredient," Towarnicki said.

All gene-silencing technologies, Nucleonics' included, are in the early stages of development, Seeger said. That means it's too early to tell whether any will actually work, or which will work better.

"It is one of the most important discoveries in the last five or 10 years," Seeger said. "It has great potential."

End game

Nucleonics hired Towarnicki in 2003 in part because the founders wanted an experienced CEO at the helm - Towarnicki previously ran drug firm Cell Pathways out of the same Horsham building Nucleonics now occupies. He sold Cell Pathways to OSI Pharmaceutical, of Melville, N.Y., in 2003.

Towarnicki focused Nucleonics efforts on getting its first gene-silencing product to market, and in the process raised nearly \$50 million in venture capital. Towarnicki said the company's venture backers have pledged another \$15 million, which will be raised in the second quarter.

In December, the company filed an investigational new drug application with the Food and Drug Administration, starting the process under which it can begin testing its hepatitis B drug on humans.

Later trials and an actual application for government approval of the compound are years away.

In addition to hepatitis B, the company is working on drugs to silence the genetic coding behind the flu, hepatitis C, prostate and ovarian cancer.

Down the road, "we'll either be bought or go public," Towarnicki said.

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March 5th, 2007

Posters Focus on Hepatitis C

<http://www.oxfordmail.net>

By Victoria Owen

A former heroin addict has spoken of his life with hepatitis C as it was revealed that more than 3,000 people across Oxfordshire could be living with the infection.

Mark Lambert, 37, contracted the illness by sharing needles during his 15-year habit.

As part of a Department of Health campaign called FaCe It, he is urging others to be aware of the infection, which is usually spread by the transfer of blood and can lie undetected for years before leading to serious liver damage or cancer.

High-risk groups, like injecting drug users, are more likely to get the infection, but the virus can now be treated with anti-viral drugs.

Mr Lambert, of Burchester Avenue, Barton, Oxford, said: "The lifestyle I led made me completely ignorant to this sort of thing. I started to get worried as more people were diagnosed, so I decided to get checked out.

"When I found I was positive, I felt a bit wounded, because there's a stigma attached to the infection. But up until three and a half years ago, I was still taking drugs and didn't have my priorities right, so I didn't deal with the infection. Since then, I've been in rehab and started to get myself sorted out."

He has been lucky and not suffered any symptoms, allowing him to lead a normal life at college to train as a mentor helping other addicts get off drugs.

His anti-viral treatment is due to begin later this month.

He is featured as one of the giant portraits exhibited over the weekend at Gloucester Green, Oxford. They were taken by photographer and hepatitis C sufferer Michele Martinoli.

Mr Lambert said: "My treatment will not be a 100 per cent guaranteed, but I've got a 70-80 per cent chance the medication will clear up the infection and my liver will recover."

Clinicians hope the three-metre high portrait exhibition will prompt people in high risk groups to get tested.

Dr Eamonn O'Moore, communicable disease control consultant at the Thames Valley Health Protection Unit, said: "The problem with hepatitis C is that you can live with it for decades and it might not be obvious. You don't get the jaundice you get with other forms of hepatitis. About 3,000 people across Oxfordshire could have it without knowing."

Second Chances Are Worth Waiting For

<http://www.weatherforddemocrat.com>

Christina Childs

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John Blair is a survivor.

At 58, he has been there and back, overcoming not only liver disease and cancer, but also the stigma associated with the hepatitis C.

It wasn't irresponsible behavior or addiction that tainted Blair's blood, it was, ironically, a life line, a simple blood transfusion, that would terminally change his future, and show him the value in second chances, that for him were most definitely worth waiting for.

Born and raised in Texas, Blair was at ease with his life. He was happy being a father to his daughter Ashley and a husband to his wife Donna.

Things moved at a slower pace for the Blair family until a severe auto accident in 1997 would send the trio reeling, forcing John to require a blood transfusion, a medical treatment that would change his life forever.

He was diagnosed shortly after the transfusion with hepatitis C. Soon, he began to suffer from related complications, including liver disease, which would grow worse over time.

"The liver problems were caused by hepatitis C," John said. "The last couple of years were the worst. I was basically bedridden and that's when they found the cancer."

In 2005, John was in end stage liver disease, and waiting for a transplant to come through when doctors discovered the tumor, luckily for John, a second chance was about to surface.

"Once they found the cancer, it was three days and I was on the transplant table," John said.

After extensive post-op treatment, John began to live a normal life again.

"It was a remarkable turnaround," he said. "I'm a double survivor. This has changed my life enormously, to put it quite simply I have a whole new perspective on life."

“I see God’s hands in everything. It’s a miracle. It’s unbelievable how much things change. It gives you a whole new meaning and it’s unbelievable how much you look forward to and value your future.”

John said he is taking his second chance as an opportunity to help others who suffer from hepatitis C, offering them the hope he once lost, but found again through faith.

“This is a silent disease,” he said. “I know it. I have lived it. I feel blessed to be able to reach out and help others with the same condition.”

He hopes to one day form a support group for area residents.

Currently, John is in the rebuilding stage of life.

He works at the East Parker Center of Hope in Aledo, and said the organization has aided him in his recovery.

“I used to be a client here,” he said. “And now I work here and can return some of the same generosity these wonderful people gave to me.”

Now, with a tomorrow to look forward to and a future to treasure, John said his plans are simple.

“My life has been predetermined by God,” John said. “I don’t know how long it will be or what I’ll have to endure, it’s in someone else’s hands.

“I will follow my heart and my Lord and allow his advice to guide me.

“My faith and family play the biggest roles in my life today, tomorrow and forever.”

March 6th, 2007

PEGASYS(R) Gets European Approval for a Shorter Treatment Duration for Some Genotype 1 and 4 Hepatitis C Patients who Show a Rapid Response to Therapy

<http://www.prnewswire.co.uk>

- Shorter, Simplified Treatment Option May Encourage More Patients to Seek Treatment

Some hepatitis C patients with difficult-to-treat HCV genotype 1 who respond quickly to treatment with a combination of PEGASYS(R) (pegylated interferon alfa-2a (40KD)) plus COPEGUS(R) (ribavirin) can benefit from a shorter and simplified course of therapy, following Thursday's Commission decision. With the new approval, a subset of patients with genotypes 1 and 4 HCV who achieve rapid viral response can now receive a shortened, 24-week duration of treatment with Roche's PEGASYS plus COPEGUS. This is half the normal treatment duration.

Shorter, Simplified Treatment Shows Excellent Chance for a Cure

The EU approval is based on data from two pivotal clinical trials for PEGASYS plus COPEGUS.(1,2) Results from these trials show that among patients who achieved a rapid viral

response (undetectable viral load at week 4) in the first month of treatment up to 93 per cent of patients with genotype 1 HCV with a low pre-treatment viral load and 83 per cent of patients with genotype 4 were cured following only 24 weeks of therapy - a similar cure rate to that seen following 48 weeks of therapy.(3)

"This is excellent news for patients with hepatitis C," said Dr Peter Ferenci, Professor of the Department of Internal Medicine IV, Gastroenterology and Hepatology, at the University of Vienna, Austria. "This means that patients can find out within one month of starting therapy if they have an excellent chance of being cured and can benefit from a shortened treatment duration. This is likely to encourage patients to seek treatment and motivate them to stay on therapy."

New Recommendations for Treatment

A shorter, 24-week course with PEGASYS plus COPEGUS is now an option for the following patients:(4)

- Genotype 1 HCV with a low pre-treatment viral load (defined as <800,000 IU/mL) and an undetectable viral load at weeks 4 and 24;
- Genotype 4 HCV regardless of pre-treatment viral load and an undetectable viral load at weeks 4 and 24.

"This licence change reflects Roche's commitment to finding better treatment solutions for patients with HCV by improving treatment with existing therapies and developing new medicines to treat hepatitis C," said Claire Steers, PEGASYS Lifecycle Leader at Roche in Basel, Switzerland. "Roche is committed to finding solutions for a broad range of hepatitis C patients by continuing to simplify treatment with PEGASYS."

About Hepatitis C

Hepatitis C, the most common chronic blood-borne infection, is transmitted primarily through blood or blood products. Hepatitis C chronically infects 180 million people worldwide, with an additional three to four million people newly infected each year.(5,6) It is a leading cause of cirrhosis, liver cancer and liver failure.

About PEGASYS

PEGASYS, the market leader worldwide in hepatitis C therapy, provides significant benefit over conventional interferon therapy in HCV patients of all genotypes. The benefits of PEGASYS are derived from its large 40 kilodalton (KD) branched-chain polyethylene glycol (PEG) construction, which allows for sustained drug levels over the course of a full week. PEGASYS also distributes more readily to the liver (the primary site of infection) than conventional interferon. PEGASYS is the only pegylated interferon available as a ready-to-administer solution. Each weekly subcutaneous injection contains 180 microg of pegylated interferon alfa-2a (40KD), which is the approved dose for all patients, regardless of body weight.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation, and a market leader in virology. Roche employs roughly 70,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including

majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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Distributed by PR Newswire on behalf of Roche Pharmaceuticals

Legal Call for Hepatitis Inquiry

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

Lawyers acting for more than 100 people who were infected with Hepatitis C through blood transfusions have begun a legal battle for a public inquiry.

Previous calls for inquiries into how hundreds of people contracted Hepatitis C through transfusions have been rejected by Scottish ministers.

Now relatives are calling for a judicial review at the Court of Session into the deaths of two people.

Lawyers argue an inquiry must be held as they died in the care of the state.

Thousands of people in the UK were infected with HIV and Hepatitis C during the 1970s and 1980s after being given contaminated blood products.

Although the Hepatitis C virus was not identified until 1989, the NHS suspected a virus was present in the blood supply and some tests were available from the mid-1980s.

“What is being complained about is systematic failure, not individual negligence.” -- Aidan O'Neill QC

Counsel for the relatives, Aidan O'Neill QC, claimed that although the action had been raised by two individuals, they were "symptomatic of a whole number of other relatives".

"In a sense these are representative actions and the court should not close its eyes to the broader context of them," he said.

"What is being complained about is systematic failure, not individual negligence. We do not know, but it appears to be systematic failure."

An inquiry was needed to "raise real issues that will require to be investigated", added Mr O'Neill.

Heart treatment

The action has been raised by the relatives of Eileen O'Hara and the Reverend David Black, who both died in 2003.

Mrs O'Hara had received blood transfusions while having heart treatment.

Mr Black was a haemophiliac who had received treatment with blood products and was diagnosed with Hepatitis C in 1990.

Many patients received payments of between £20,000 and £45,000 under a scheme introduced by UK and Scottish ministers in 2003.

Ruled out

But repeated calls for a public inquiry have fallen on deaf ears.

In April 2006 the Scottish Parliament's health committee called on the Scottish Executive to hold a public inquiry into patients who had contracted the virus through blood products.

However, this was ruled out once again in February by Health Minister Andy Kerr.

The hearing will take four days, with Lord Mackay of Drumadoon expected to give a decision at a later date.

March 7th, 2007

Settlement Reached in Discrimination Suit against Brookshire's

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

By Lynn LaRowe
Texarkana Gazette

A federal lawsuit filed against Brookshire's Grocery Co., has been settled for \$50,000.

A former employee at the New Boston location was demoted after the company learned she was infected with Hepatitis C, a violation of federal law.

“The American with Disabilities Act (ADA) prohibits employers from making employment decisions based solely upon fears about their employees’ medical conditions,” said EEOC trial attorney Tisha Dominguez. “Hepatitis C is not transmitted through casual contact, or through food, therefore the employer’s myths, fears and stereotypes that this employee would transmit her medical condition to others were unreasonable.”

The suit, which was filed in the Eastern District of Texas in Texarkana on behalf of a Brookshire’s employee in New Boston, Texas, was settled Friday.

“The suit was settled to the satisfaction of all parties,” said Marshall Wood, of Norton and Wood of Texarkana, an attorney representing Brookshire’s. Wood was prevented from commenting further because of a confidentiality clause in the settlement, he said.

The case was presided over by federal magistrate Judge Caroline Craven.

When the company became aware the employee suffered from the Hepatitis C virus, Brookshires required the employee to provide medical confirmation of her diagnosis.

The employee’s position required contact with food and managers were concerned she could inadvertently infect consumers, court documents show.

After being demoted because of her condition the employee felt she had no alternative other than to resign, according to a press release issued by the EEOC.

As part of the settlement, the company will provide relevant training to managers within 180 days, post notices regarding the ADA, and consider the most current information available from public health authorities regarding an illness or disease before removing an employee from their position because of a medical condition. The company is also required to revise its policy regarding “sick partners” to accurately reflect illnesses which are communicable through food, court documents say.

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The EEOC publication, “How to comply with the ADA, a guide for restaurants and other food service employers,” must be included in training for managers. Brookshires will also submit written reports detailing the changes which have been made within the organization to comply with the settlement agreement.

“A look at the U.S. Centers for Disease Control Website would have shown this company that the CDC does not recommend that individuals with Hepatitis C be excluded from work, school, play, child-care or other settings,” said Toby Wosk Costas, supervisory trial attorney at the EEOC’s Dallas district office.

As part of the settlement agreement, Brookshire's is prohibited from mentioning the former employee's condition to anyone calling for an employment reference or from discussing it in general.

They must purge any reference to her condition or the EEOC case from her personnel file and provide documentation to the EEOC showing all of the requirements of the settlement agreement have been met.

For more information about Hepatitis C, contact your health care provider or visit the CDC's Website at www.cdc.gov. For information regarding the EEOC, visit them at www.eeoc.gov.

Fatigue and Illness

<http://www.ahfmr.ab.ca>

Why do we feel tired when we're ill?

In many illnesses—such as cancer, multiple sclerosis, rheumatoid arthritis, and liver disease—as well as infections, fatigue can be a major issue.

Brain function drives the fatigue in these diseases, even though all of them occur outside of the brain, AHFMR Senior Scholar and Calgary hepatologist Dr. Mark Swain points out.

“When we become sick with the flu or a bacterial infection, we feel tired, as well as losing our appetite and so on,” explains Dr. Swain. “The body signals the brain to produce these symptoms or behaviours. It's important for us to conserve energy and not move around and do things—so we'll get over the illness and get back to normal. Unfortunately, with a chronic disease, we don't get over the illness. The stimuli to the brain keep happening. Our bodies try to adapt but they never fully do so.”

Throughout his career as a physician and researcher, Dr. Swain has attempted to improve the quality of life and health outcomes for people suffering from liver disorders. More than 100 known forms of liver disease affect everyone from infants to older adults. Liver damage can result from viruses, cancer, autoimmune disorders, alcohol, drug use, toxins, and obesity.

Liver problems

Dr. Swain studies, diagnoses, and treats such liver problems as hepatitis, cirrhosis, fatty liver disease, and liver cancer. He investigates the basic mechanisms of liver inflammation and the changes in neurotransmission within the brain that occur in the context of liver disease. He is especially fascinated by the effects of liver damage on symptoms in liver disease, particularly fatigue. Dr. Swain studies how the liver might signal the brain, with the end result that the person feels tired.

Fatigue is the symptom most commonly mentioned by people with liver disease, but its cause is a puzzle. Since fatigue is an unspecific symptom (in other words, it can be caused by a variety of health problems), it is difficult to determine whether it is caused by the liver disease or by something else, or by a combination of factors. This is one reason why fatigue is difficult to study, understand, and treat.

Peripheral fatigue

Many people with very severe liver disease suffer what is called peripheral fatigue as a result of muscle atrophy. Patients with less severe disease often experience fatigue not related to muscle deterioration: that is, fatigue that comes from changes occurring within the brain. The severity of the fatigue in these individuals does not relate to their liver function. This means that some people who have severe liver damage may not feel tired at all, while others with minimal liver damage may feel totally exhausted.

“Fatigue can be the main feature of many forms of liver disease, and can be anywhere from mild and trivial to completely incapacitating,” explains Dr. Swain. “The thing that’s most difficult is that there’s no correlation between the severity of the fatigue and the severity of the liver disease. Some people will say, ‘If I have cirrhosis, why do I feel so good?’ Others will say, ‘Why do I feel so bad?’ I think, inherently, some people are more tired than others because of the different ways individuals adapt to the signals which their bodies are sending to their brain.” Dr. Swain hopes that his research may someday allow physicians to better target the treatment of fatigue as a symptom, improving quality of life for patients with liver disease and possibly for those with other chronic diseases as well.

Dr. Mark Swain is an AHFMR Senior Scholar and a professor in the Department of Medicine at the University of Calgary. He receives funding from the Canadian Institutes of Health Research (CIHR).

Selected publications

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Learning from Experience

<http://society.guardian.co.uk/>

Sara Moralioglu

The Guardian

Ex-drug users are advising addicts how to tackle an overdose and how to treat their dependencies

There is a buzz of activity in the office of the Oxfordshire User Team (Out). Volunteers and the founder, Glenda Daniels, who are all former drug users, are preparing for the weekly overdose and hepatitis C workshops. "I remember at my worst waking up daily with a needle still in my arm and feeling pins and needles," says Daniels, who for eight years was addicted to crack and heroin. "That is the first symptom of an OD [overdose]. Most drug users think it's because you've had 'good gear', but it's not at all, and we explain these kinds of facts at the workshops from first hand experiences."

Daniels' life as an addict was a downward spiral that included having her daughter taken away to be looked after by other family members, shoplifting, drug dealing, and time in prison.

Daniels has been taking prescription Subutex, an alternative to methadone treatment, for the past four years. She founded Out in 2002 after being approached by a drug action team worker, Rowan Williams - another former drug user - to help set up a project in response to the high overdose rate in Oxfordshire. Together, they organised a workshop out of which grew the charity that last year taught some 180 drug users what to do if they, or another user, had an overdose.

Controversially, the 15-20 workshop attendees receive a £20 reward for turning up. Richard Huggins, Out chair and assistant dean of social studies at Oxford Brookes University, argues that the payments are a necessary response to the problem of hepatitis C among injecting drug users, they make up 70% of the estimated 200,000 people infected with the condition in the UK. "This [payment] hardly stimulates the drug market," he says. "It is a pragmatic and progressive approach that gets people to attend programmes and reduce the transmission of hepatitis C, and overdoses. It's a small price to pay. This will reduce overall harm in communities, and this is of prime concern where there is a lot of drug use."

His views, it appears, are shared by the National Institute for Clinical Excellence, which in January issued guidance for consultation that recommends shopping vouchers be given to drug users as an incentive to stay clean.

In Slough, Out is working alongside needle exchange centres to ensure drug users are offered clean needle kits tailored to their needs. Such a kit for homeless drug users, for example, includes clean water, filters and a clean spoon, explains Daniels, so puddles or water from toilets is not used, and old cigarette butts or pieces of metal from drink cans.

In 2003, Out helped to change legislation to allow intravenous drug users to have clean needle kits when leaving custody, after an outcry in the community because clinical waste bins in public toilets were being broken into for their needles.

In addition to harm minimisation programmes, Out is one of the few drug advocacy groups in the UK that provides job training for ex-drug addicts who are still on prescription. David Drough, one of six Out volunteers, is completing an NVQ in health and social care. He still takes methadone. "With 20 years of drug experience and all the detox theory I know, I can thankfully train at Out and use this knowledge to help others," he says.

Daniels says employment is crucial to help former drug users reassimilate into society. Drug users also respond particularly well to being taught by former users, who can communicate their experiences.

Research throughout Buckinghamshire by the Out team found that many drug users are unaware of residential rehabilitation and certain detox programmes. The charity focuses its efforts to change this by ensuring that drug users are fully informed of treatments available to get off drugs.

But Out not only works with drug users. The team has advised Thames Valley police on how to deal with an overdose situation and plastic breathing masks are now installed in its vehicles.

The charity, which is funded partially from the National Treatment Agency and the Oxfordshire drug action team, is heavily reliant on donations. Daniels, however, is concerned that, with the

ending of the government's 10-year drug strategy in 2008, the money may run out. "We barely have enough to cover our running costs at the moment," she says. "The future is very worrying."

For now, she must put those worries aside and instead prepare for two workshops and a speech to the Royal College of GPs on the management of drug users in primary care - before rushing to pick up her 11- and 16-year-old daughters.

March 8th, 2007

Outcomes for Patients with Hepatitis B Who Need Liver Transplants

<http://www.eurekalert.org>

Survival rates are similar among patients with hepatitis B who are listed for liver transplantation, whether or not they have hepatocellular carcinoma (HCC), according to a new study in the March 2007 issue of *Liver Transplantation*. An accompanying editorial suggests that these results affirm the current policy on the allocation of donor livers.

The study and the editorial appear in the March 2007 issue of *Liver Transplantation*, the official journal of the American Association for the Study of Liver Diseases (AASLD) and the International Liver Transplantation Society (ILTS). The journal is published on behalf of the societies by John Wiley & Sons, Inc. and is available online via Wiley InterScience at <http://www.interscience.wiley.com/journal/livertransplantation>.

The United Network for Organ Sharing (UNOS) utilizes the Model for End-Stage Liver Disease (MELD) to determine allocation of available organs. Patients with hepatocellular carcinoma have higher MELD scores, and may be more likely to receive transplants quickly compared to patients with other types of liver disease. Without transplant, many HCC patients die or become unsuitable for transplantation because of tumor progression.

Led by Anna S. Lok, M.D. of the Division of Gastroenterology at the University of Michigan, researchers set out to compare clinical outcomes for hepatitis B patients awaiting a liver transplant, whether or not they had HCC. They enrolled 279 patients from the National Institutes of Health-sponsored HBV-OLT study between November 2001 and June 2005. Of these patients 183 had HBV with cirrhosis, and 96 had HBV with HCC. Most were receiving antiviral therapy. The researchers collected demographic and laboratory data for all participants, and computed a MELD score for each. They then followed the patients for a median of 30.2 months.

The patients with HBV-HCC were older, more likely to be Asian and had less severe liver impairment than patients with HBV-cirrhosis; 78 percent underwent liver transplantation, compared to 51 percent of patients with HBV-cirrhosis. Despite this difference, 5-year survival rates were similar: 73 percent of the HBV-HCC group, compared to 78 percent of the HBV-cirrhosis group. The 5-year survival rates for patients who did not receive a transplant were also very similar: 82 percent of the HBV-HCC group versus 79 percent of the HBV-cirrhosis group. It should be noted that 71% of the patients in the HBV-HCC group who had not been transplanted had received some form of HCC treatment including surgical resection and the number of patients alive without transplant 5 years after listing was very small (n=6).

"Despite more advanced liver disease and a lower rate of transplantation, intention-to-treat survival of patients listed for HBV-cirrhosis was comparable to those with HBV-HCC, possibly related to beneficial effects of antiviral therapy. However, these data may not apply to patients with liver disease due to other etiologies for which safe and effective therapies that can improve or stabilize liver disease in those with decompensated cirrhosis are not available" the authors conclude.

In an accompanying editorial, Myron Schwartz and colleagues from the Mount Sinai Liver Cancer Program at the Mount Sinai School of Medicine in New York say the study vindicates UNOS policy while reporting a surprising finding: survival without transplantation was excellent and equal between the two groups, with 5-year survival in patients not transplanted actually better than the survival for the entire cohort.

"This figure calls into question the basis for placing these patients on the waiting list in the first place," the authors write. Furthermore, since previous studies have shown that 5-year survival for HCC patients without treatment is unusual, "the accuracy of the diagnosis of HCC in these is questionable," they say.

The Wong study does show that UNOS policy helps patients with high MELD scores get a liver transplant, and that their prioritization does not affect outcomes for non-HCC patients with HBV. "The refinement of the UNOS algorithm to optimally balance the risks for HCC and non-HCC liver transplant candidates remains a work in progress," conclude the authors.

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Article: "Comparison of Clinical Outcomes in Chronic Hepatitis B Liver Transplant Candidates With and Without Hepatocellular Carcinoma," Stephen N. Wong, K. Rajender Reddy, Emmet B. Keeffe, Steven-Huy Han, Paul J. Gaglio, Robert P. Perrillo, Tram T. Tran, Timothy L. Pruett, Anna S.F. Lok, and the NIH HBV-OLT Study Group, *Liver Transplantation*; March 2007 (DOI: 10.1002/lt.20959).

Editorial: "Outcomes in Hepatitis B Transplant Candidates With or Without Hepatocellular Carcinoma: UNOS Policy Vindicated!" Myron Schwartz, Ana Carolina del Pozo, Patricia Lopez, *Liver Transplantation*; March 2007 (DOI: 10.1002/lt.20991).

March 9th, 2007

Drug Improves Quality of Life for Patients with Cirrhosis

<http://www.docguide.com>

ALEXANDRIA, VA -- March 1, 2007 -- A study of patients with cirrhosis who had minimal hepatic encephalopathy (MHE) found that cognitive function and health related quality-of-life improved when they took lactulose.

The results of this study appear in the March 2007 issue of *Hepatology*, the official journal of the American Association for the Study of Liver Diseases (AASLD).

Led by Radha K. Dhiman, MD, DM, MNAMS, FACG, of the Department of Hepatology, Postgraduate Institute of Medical Education and Research in Chandigarh, India, researchers

conducted a study involving 61 patients who had MHE. The patients were diagnosed with MHE if they had abnormal scores on two or more neuropsychological tests that were used to assess their mental state. The patients were also given a Sickness Impact Profile (SIP) questionnaire to determine the impact of the disease on daily activities such as sleep/rest, eating, work, home management, mobility, social interaction and emotional behavior and communication. They were then divided into two groups: 31 patients received lactulose treatment for 3 months, while 30 patients received no treatment.

The results showed that the number of abnormal neuropsychological tests decreased among patients who took lactulose compared to those who did not. Changes in these tests indicating significant improvement in cognitive function were also seen in the lactulose group. In addition, the lactulose group also showed improvement in their quality of life as measured by SIP scores, with significant improvement in emotional behavior, movement, mobility, sleep/rest, and recreational activities.

The study also confirms the negative impact of MHE on HRQOL: patients showed impairment in perception, memory, learning, expression, mental activity and executive function. Other studies have shown that half of MHE patients do not have regular employment and that it has a negative effect on the ability to drive. "These observations strongly suggest that MHE should be considered a medical condition that might warrant treatment in order to improve psychomotor impairment and HRQOL," the authors state.

Ammonia is the key factor in HE and although the study did not measure ammonia levels, the authors believe that this is also the case with MHE. They chose lactulose since it is inexpensive, easily available and is effective at reducing ammonia levels in the blood. The authors conclude that cirrhosis patients with MHE may benefit from treatment with lactulose, adding: "Whether treatment also prevents or delays progression to overt HE and improves prognosis, remains to be determined in prospective studies."

In an accompanying editorial in the same issue, Asif Qadri and colleagues from MetroHealth Medical Center affiliated with Case Western Reserve University in Cleveland, OH, state that the current study "may potentially change the overall management of hepatic encephalopathy (HE)," adding that the results strongly suggest that MHE is the cause of reduced quality-of-life in patients with cirrhosis.

While studies need to be done to confirm these findings, Dhiman et al. also note that the study highlights some interesting questions that could be answered in future studies, such as whether early treatment of HE can postpone worsening symptoms for longer periods of time, and whether it impacts survival. Although the results support the ability of lactulose as a treatment for HE, there are significant barriers to widespread diagnosis of MHE, the authors point out. They suggest that measures need to be taken to simplify the diagnosis of MHE, or alternatively, it may emerge that all cirrhotic patients will eventually develop MHE, making its treatment the standard of care and eliminating the need to determine if it is actually present. "In any event," they conclude, "it appears that we cannot ignore minimal hepatic encephalopathy any longer."

SOURCE: American Association for the Study of Liver Diseases

Mayo Clinic Tests New Drug to Prevent Hepatitis C Recurrence after Liver Transplant

<http://www.allamericanpatriots.com>

March 08, 2007 -- ROCHESTER, Minn. -- The Mayo Clinic Transplant Center is studying whether Hepatitis C Immune Globulin (Human), an investigational drug candidate known as **Civacir**, prevents the recurrence of hepatitis C-related liver disease in liver transplant patients.

Mayo Clinic sites in Arizona, Florida and Minnesota are looking for adults to participate in this study. Eligible participants must have hepatitis C and need a liver transplant. Individuals who have liver cancer may participate.

Hepatitis C is a liver infection caused by the hepatitis C virus (HCV). Each year approximately 6,000 liver transplants are performed in the United States, and more than 2,000 of those are due to HCV. There are no approved or effective treatments for HCV-positive liver transplant patients or patients who receive HCV-positive livers.

"The clinical need for hepatitis C prevention in liver transplant patients is great," says Michael Charlton, M.D., medical director of the liver transplant program at Mayo Clinic's campus in Rochester, Minn. "HCV recurrence for liver transplant patients is nearly 100 percent. Five years after transplantation, one-third of re-infected patients either pass away, get re-transplanted or experience cirrhosis from HCV."

Civacir is a human-pooled antibody product created from blood and serum donated by individuals who have HCV antibodies. The idea for this potential therapy for hepatitis C came from an unexpected result of a similar human antibody drug for hepatitis B, known as HBIG.

"Prior to the discovery of hepatitis C in 1988, HBIG unknowingly included hepatitis C antibodies," says Dr. Charlton. "A retrospective study of approximately 200 patients who received HBIG found that in addition to preventing hepatitis B, it also prevented hepatitis C in about half of the cases."

The Mayo Clinic study will test whether Civacir can prevent HCV recurrence after liver transplant.

More than 400 patients receive liver transplants at Mayo Clinic's three sites each year. Mayo Clinic is the most experienced liver transplant center in the nation, with some of the highest survival rates in the world.

For more information on eligibility requirements and the screening process for this study, contact Kristin Eggebraaten, Mayo Clinic liver transplant referral coordinator at 1-888-227-7501 (toll-free).

Civacir is a product of NABI Biopharmaceuticals and Kedrion S.p.A.

Source: Mayo Clinic

Hospital Seeks Patients of Surgeon with Hepatitis C

<http://calsun.canoe.ca>

By CP

CHARLOTTETOWN -- Island health officials are contacting hundreds of former patients of a general surgeon now that tests have confirmed the doctor has hepatitis C.

Dr. David Ashby is well with no symptoms, Dr. Lamont Sweet, chief health officer for the Department of Health, said yesterday.

Ashby had worked for years as a surgeon at the Queen Elizabeth Hospital in Charlottetown.

Sweet said Ashby has seen about 6,000 patients during the past three years.

Sweet said only 400 are considered in the high-risk category and letters will recommend they be screened for hepatitis C.

Hep C Policies Failing as Drug Users Fall Ill

<http://www.theaustralian.news.com.au>

John Stapleton

DESPITE more than two decades of harm minimisation policies and the ready availability of free syringes, Australia's heroin addicts have some of the highest hepatitis C rates in the world and one-third of prisoners have the potentially deadly virus, according to two new studies.

Sydney has outstripped London's alarming rates of infection, with a NSW research team warning that half of all new users contract the virus within three years and the "extremely high" numbers need the urgent attention of Australian policy makers.

"We had no idea it was going to be this high," said professor Lisa Maher from the National Centre in HIV Epidemiology and Clinical Research based at the University of NSW. The team studied more than 200 addicts who were either younger than 30 or who had been injecting for fewer than three years, in Sydney's south-west. They found that for every 100 new users followed for a year, 46 became infected with hepatitis C.

Rates were highest among women, those under 20, people originally from South East Asia, cocaine injectors and those using for less than a year.

Maher says the statistics, published in the February issue of the Australian and New Zealand Journal of Public Health, paint a grim picture of rates in NSW. They exceed London, which recently recorded a rate of 42 per 100 new users.

"This one of the highest, if not the highest, documented rate of hep C infection in injecting-drug users in the world," Maher said. She says it shows prevention strategies implemented in the late 1980s don't appear to be working. New users appear to pick up the blood-borne disease almost immediately after they start injecting, making the window to help protect them "very, very small", she said.

Another study shows that one in three inmates of Australian prisons has hepatitis C. A sample of prisoners from NSW, Queensland, Tasmania and Western Australia returned rates of 34 per cent, with infection numbers almost double this among inmates who regularly injected drugs before being jailed.

That study, led by the University of NSW Centre of Health Research in Criminal Justice, tested almost 500 volunteers from a cross-section of Australia's 25,000-strong prison population.

Results showed NSW inmates were "significantly more likely" to test positive to hepatitis C than prisoners in other states. Most sufferers were aged over 30 and had been in prison before.

Lead researcher Tony Butler says the findings show the need for better harm minimisation practices in prisons. Authorities should also consider routinely including prisoners in the national surveillance of hepatitis and HIV, he says.

"That would provide a more complete picture of blood-borne virus epidemiology in Australia."
Additional reporting: AAP