

# Hepatitis Times

Volume No. 4 Issue No. 1 Spring 2003

## HIV Lessons Used in Hepatitis C Treatment

Drugs that interfere with HIV have had a major effect in reducing death and disability from AIDS. Now drug companies are beginning to test the first similar drugs for the hepatitis C virus, which can cause fatal liver disease and has infected far more people than HIV. "If they work, they could have the same impact on HCV that the HIV drugs do," said Dr. Frank Chisari, a professor of virology at the Scripps Research Institute in San Diego. Hepatitis C is now treated by the combination of alpha interferon, an immune system protein, and a pill called Ribavirin. The newest versions of the combination can virtually eliminate the virus in about half of the patients. But that leaves the other half at the mercy of the virus. Moreover, the treatment has severe side effects that include anemia, birth defects, and flu like symptoms, depression and even an urge to commit suicide.

"There's a huge need for better drugs, less toxic drugs," said Dr. Michael G. Katze, a professor of microbiology at the University of Washington. Neither interferon nor Ribavirin was specifically designed to attack hepatitis C. Each appears to give a general boost to the immune system to help it attack the virus, though scientists do not fully understand how they work. But the new hepatitis C drugs entering clinical trials are designed to interfere with enzymes that the hepatitis C virus needs to replicate, like protease and polymerase. Similarly, the AIDS drugs interfere with two enzymes used by HIV to replicate protease and reverse transcriptase. Some of the AIDS drugs can also be used for hepatitis B but not for hepatitis C, which operates differently. It will take years to know if the new drugs will work. But scientists are encouraged by a proof of principle reported by Boehringer Ingelheim, a German drug company, at the American Association for the Study of Liver Diseases conference in Boston in November. The company said its experimental protease inhibitor reduced viral levels by a range of a hundredfold to more than a thousandfold in a small number of patients who took the drug for only two days. "Sort of a hush went over the audience," Dr. Charles M. Rice, director of the Center for the Study of Hepatitis C at Rockefeller University in Manhattan, recalled. Others are now entering the race. ViroPharma, a biotech company in Exton, Pa., announced in January that it had begun a clinical trial of a polymerase inhibitor in partnership with the Wyeth Drug

Company. So did Idenix Pharmaceuticals, a biotech company based in Cambridge, Mass. Japan Tobacco reports having a polymerase inhibitor in Phase 2, the middle stage of clinical trials. Vertex Pharmaceuticals, also of Cambridge, has said it will start a trial later this year of a hepatitis C protease inhibitor and Rigel Pharmaceuticals of South San Francisco, Calif., plans to start a polymerase inhibitor trial this year. Isis Pharmaceuticals of Carlsbad, Calif., is in Phase 2 trials with a drug that tries to interfere with a different part of hepatitis C.

Hepatitis C has infected about four million Americans and 170 million people worldwide, about four times as many as HIV. Hepatitis C is spread mostly by needles or blood transfusions, rarely sexually. The rate of new infections in this country has dropped sharply to about 25,000 a year since a test to screen donated blood for the virus was approved in 1990. But there are still many people infected before the test was used that have yet to develop symptoms. The Centers for Disease Control and Prevention estimates that the number of deaths from hepatitis C, now 8,000 to 10,000 annually in the United States, could triple by 2010. But while there are now well over a dozen drugs that directly interfere with HIV enzymes, there are none that work that way for hepatitis C. Scientists say one reason for the discrepancy is that the hepatitis C virus was identified in 1988, four years after HIV. Still, numerous drugs for AIDS were approved within 15 years of its discovery. In contrast, 15 years after the hepatitis C discoveries, the first drugs are only entering clinical trials.

Another reason, some scientists say is that there has been much more federal financing for HIV, which has been considered more of a crisis than hepatitis C and has patients who have fought hard for money for research and treatments. Also, many people with the hepatitis C virus never get sick or do so only 10 or 20 years later. Yet another factor, some say, is that the Chiron Corporation, the biotech company in Emeryville, Calif., that first identified the hepatitis C virus, has demanded too much money for licenses to its patents, discouraging companies from entering the field "Chiron has been a little bit like a dog with a bone," said Dr. Donald G. Payan, executive vice president and chief scientific officer of Rigel. "I think they really slowed the field down. A lot of people just didn't want to get into it." Gilead Sciences, which has developed successful antiviral drugs for HIV V. and hepatitis B, dropped work on hepatitis C after being sued by Chiron. Vertex, which says it does not violate the patents, is in the midst of a lawsuit. Robert P. Blackburn, chief patent counsel for Chiron, said the company's patents were

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available for drug discovery to all comers for a modest upfront fee and royalties if a drug made it to market. He said Chiron took a significant risk in embarking on research to discover the virus and deserved to share in the proceeds from drugs developed by others. "Clearly companies like Vertex would not be working on an HCV drug today but for our inventions," Mr. Blackburn said. Still, most scientists agree, the biggest obstacle to the development of drugs for hepatitis C has been the inability to grow the virus in the test tube, a fact that makes it hard to study the virus or to test potential drugs. In addition, there are no animals that get hepatitis C except chimpanzees, which are expensive to use in testing. Scientists have started to circumvent those problems.

In 1999, Dr. Ralf Bartenschlager, then at the University of Mainz and now at Heidelberg University in Germany, developed an artificial viral system known as a replicon. Dr. Rice of Rockefeller University, who was then at Washington University in St. Louis, improved on it. The replicon consists of some of the RNA from hepatitis C, including that for the protease and polymerase enzymes. This RNA is put into liver tumor cells that can be grown in culture. The replicon does not produce complete new viruses. But it does reproduce itself using the protease and polymerase enzymes. So drug companies can use the replicon to test if their protease or polymerase inhibitors seem to interfere with replication of the replicon. "That's definitely a breakthrough that every group has used," said Dr. Marc Collett, vice president for discovery research at ViroPharma as with HIV, hepatitis C virus mutates rapidly and is likely to develop resistance to drugs, so combinations of drugs will probably be needed. "No one really knows what it's going to take for the antiviral effect to outrun the resistance effect," said Dr. Nathaniel Brown, vice president for hepatitis clinical research at Idenix Pharmaceuticals. But, he and others said, hepatitis C may be easier to treat in some ways than AIDS. That is because HIV turns its RNA into DNA, which is incorporated into the chromosomes of cells it infects, making it hard to totally eliminate the virus. But hepatitis C virus does not do that, and the experience with interferon has shown that if the virus can be eliminated, patients can be cured. Dr. Amy Weiner, director of hepatitis C research at Chiron, is optimistic. "It does appear with the data we have to date that it is possible to cure people with HCV, which has never been shown with HIV," she said.

*Source: The New York Times Company*

## Founder's Corner

By Howard Kindred Sr.

I guess all of you must have noticed it has been quite a while since our last newsletter, due to the fact that we had a shortage of volunteers to help with the typing of our newsletter. Also the fact that I was on therapy for my HCV, need I say more? It seems we are back to normal, a very nice lady volunteered to help type the *Hepatitis Times*. Being an all-volunteer organization has its drawbacks, but we feel it is worth it! What we are able to accomplish with the amount of contributions is very amazing when paying salaries are not in your budget.

On another very important note is the establishment of the **Eastern Pennsylvania Hepatitis C Coalition (EPHCC)**. This is a project we are working on and will report its progress in future newsletters. As we all know there is power in numbers, we need a strong voice the hepatitis community. I am very happy to report that our organization has been working with the Pennsylvania Department of Health, on tracking HCV infections since September of 2000. After receiving an e-mail from Mr. Joel H. Hersh, M.Ed., M.P.A. Director of Epidemiology of the PA. Health Department, they have implemented a new electronic reporting format recently that makes it easier to receive reports, do follow up where indicated and analyze data. Chronic HCV cases that were not previously reported. This will help the state get a better handle on how many residents in Pennsylvania counties are infected with HCV.

Our organization would like to thank State **Representative Kelly Lewis** for his assistance in his involvement with this project

## Hepatitis C Awareness Walk

As the writing of this newsletter we are planning to have our **1<sup>st</sup>. Hepatitis C Awareness walk on September 20 2003**. In this way bringing attention to the need to find a cure for this insidious disease and dispel the misconceptions about hepatitis C virus (HCV). We will notify everyone of the time of this event. The route will be from East Stroudsburg High School (South Campus) to Court House Square in Stroudsburg, where we will rally, enjoy refreshments and hear a guest speaker, very similar to our organ donor awareness walk our transplant division had in April this year.

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## Informational & Support Meetings

Looking to attend a meeting in your area? Here are some locations and phone numbers.

- NEPATSG HCV Support**                      **E. Stroudsburg, PA.**  
1<sup>st</sup>. Monday every Month, 7:00 PM. Call 866-869-1211
- Lehigh Valley HCV Support**                      **W. Allentown, PA.**  
2<sup>nd</sup>. & 4<sup>th</sup>. Thursday monthly, 7:30 PM. Call 610-776-5470
- Reading HCV Support**                      **Reading, PA.**  
2<sup>nd</sup>. Monday every Month, 7:00 PM Call 866-869-1211
- Lancaster HCV Support**                      **Lancaster, PA.**  
1<sup>st</sup>. Tuesday every Month. 7:00 PM Call 717-392-4813
- Warminster HCV Support**                      **Warminster, PA.**  
2<sup>nd</sup>. Monday every Month 7:00 PM. Call 215-682-9136
- Northeast HCV Support**                      **NE. Philadelphia, PA.**  
3<sup>rd</sup>. Wednesday every Month 7:00 PM. Call 215-682-9136
- Delco Hep C Connect**                      **Aston, PA.**  
1<sup>st</sup>. Tuesday every Month 7:00 PM. Call 866-739-1126

**If you know of a HCV group that would like to be listed above please call or write us:**

**NEPATSG Inc.**

**RD# 8 Box 8585M, E. Stroudsburg, PA. 18301  
1-866-869-1211 Toll Free**

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## FDA Approves Copegus for Use in Combination with Pegasys for Hepatitis C

Roche announced in December that the U.S. Food and Drug Administration had approved combination therapy with Pegasys® (peginterferon alfa-2a, a pegylated interferon) and Copegus™ (Ribavirin) for the treatment of adults with chronic hepatitis C who have compensated liver disease and have not previously been treated with interferon alpha. Pegasys alone was approved as monotherapy for chronic hepatitis C on Oct. 16, 2002, a month later, the FDA Advisory Panel recommended approval of the combination therapy. Pegasys is administered once weekly by subcutaneous injection, and Copegus tablets are taken twice daily. "Different genotypes of the hepatitis C virus need to be approached

differently. Certain genotypes of the hepatitis C virus are easier to treat while others are stubborn and more difficult to treat," said Pegasys investigator, David Bernstein, MD, Director of Hepatology at North Shore University Hospital, Manhasset, N.Y. "With Pegasys combination therapy, we can now tailor the dose and duration of a patient's therapy to the genotype of the virus."

Source: Hepatitis Magazine

## Artificial liver System Helps University of Michigan Patients live Until Transplant

Four-year-old Brandon Rice had a merry Christmas last year, but the Michigan boy's best present wasn't under the tree. Instead, it was already inside his body: a new liver that saved his life earlier in the year when his own liver mysteriously failed. He had help in waiting for that "gift of life" from a promising new technology that could someday help thousands of others. At the University of Michigan's C. S. Mott children's Hospital, the boy benefited from use of an "artificial liver" that the University of Michigan doctors are testing. This special machine can temporarily take over some of the functions of a failing liver, filtering toxic chemicals from the blood, acting as a "bridge" to transplant. The University of Michigan Health System was the first medical center in the United States to try the system invented in Germany. The machine uses a process called albumin dialysis, pumping the blood out of the body and into a plastic tube filled with hollow fibers made of a membrane that has been coated with albumin. On one side of the fiber's membrane is the blood; on the other, a dialysis solution containing more albumin.

Source: Hepatitis Magazine

**Don't let  
What you  
Cannot do  
Interfere  
With what  
You can do**

\_\_\_\_\_  
John Wooden

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## Predictors of Fibrosis Progression Identified in Chronic Hepatitis C Infection

The extent of serum aminotransferase elevations and the degree of hepatocellular necrosis and inflammation seen on liver biopsy are the best predictors of fibrosis progression in patients with chronic hepatitis C, according to a report in the January issue of *Gastroenterology* "Fibrosis is the hallmark of hepatic cirrhosis, worsening of which is probably the best surrogate marker for progression of chronic liver disease," Dr. Marc G. Ghany, of the National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, Maryland, and colleagues note. "They used liver histology to examine the rate and predictors of fibrosis progression in 123 patients with chronic hepatitis C" The patients underwent two liver biopsies a mean of 44 months apart with no intervening treatment.

The team used the histology activity index to grade liver histology and a scoring system of 0 to 6 to stage fibrosis" Forty-eight of the patients (39%) had worsening fibrosis scores, 46 (37%) exhibited no change, and 29 (24%) showed improvement. Of the 48 patients with worsening fibrosis, 36 (75%) had a 1-point increase and 12 (25%) had at least a 2-point increase in scores. Eleven of the subjects (10%) showed progression to cirrhosis. "The overall rate of progression was 0.12 fibrosis units per year, a rate that predicts progression to cirrhosis in 50 years if progression was linear,

Dr. Ghany and colleagues explain. "The rate of progression was variable. Older patients, patients with higher serum alanine and aspartate aminotransferase levels, and those with extensive degrees of periportal necrosis on initial liver biopsies had higher rate of progression"

"These findings," the investigators conclude, "support the recommendation that patients with normal aminotransferase levels and mild liver histology can safely defer treatment"

Source: *Gastroenterology* 2003.

## Ask The Doctor

### Diet in Hepatitis C

By Dr. Daniel Duprey MD.

Patients with Hepatitis C have at best a 50% response rate to standard therapy. Therefore most patients are interested in alternative therapies. In this article I will discuss diet and how it relates to Hepatitis C. In Hepatitis C the one thing that you can control is your diet. Therefore controlling your diet is one way to control your disease. The first part of diet I would like to discuss is iron. Hepatitis C is not cytotoxic (will not kill cells on its own) to hepatocytes it needs a cofactor. The question is what is the cofactor? Is it the immune system, iron, alcohol, smoking, or some other unknown dietary factor? It is well documented that in patients with elevated iron levels and Hepatitis Phlebotomy (removal of blood) will cause a decrease in transaminase levels (liver enzymes ). Patients are also found to have increased iron levels on liver biopsy. Therefore it is not a stretch to conclude that iron restriction may help patients. **Iron is found in red meat,** and green vegetables (example Spinach). The next part of diet I would like to address is total protein in the diet. In patients with cirrhosis protein restriction is an integral part of therapy. Protein is restricted to help prevent encephalopathy (change in mental status). A low protein diet has been clearly documented to prolong kidney function in Renal Failure and may have benefit in Hepatitis. Protein metabolism is very stressful for the liver. If there is less protein in the diet then the liver may be able to concentrate on keeping itself healthy. I believe that the kind of protein also makes a difference. Animal protein tends to concentrated and hard to metabolize. Therefore a vegetarian diet may give further benefit to the patient. A vegetarian diet tends to be low in saturated fat, low in calories, high in anti-oxidants, high in fiber, and promotes satiety

There have been other foods in the diet that have been used to help keep the liver healthy. Lemons are felt to cleanse the liver. Onions and Garlic are full of sulfhydryl groups, which help the liver metabolize drugs, poisons, and body waste products. Fresh fruits are loaded with antioxidants (example blueberries, strawberries, etc.). Nuts are loaded with good fat (unsaturated and polyunsaturated). In conclusion I would like to go back to what Andrew Weill is quoted as saying, "The only thing in life that we can control is what we put in our mouth."

*Note: Dr. Duprey is our facilitator at our support meetings at Pocono Medical Center in East Stroudsburg.*

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## Letters To The Editor

**Thanks Howard!** Hep. Div. God Bless you and the transplant support group of No. East Penn. you guy's are really great. Thanks for all your help. *Wayne B.*

**Dear Howard,** A Co-worker, Elaine wishes to get some info & join your Hepatitis C support group. Hope all is well with you. *Tony P.*

**Howard,** I hope all is well with you! I stayed on the Reg/Rib treatment for 7 months. However, I became very sick... passed out in Wal-Mart and spent 4 days at PMC for evaluation, etc. After getting off of treatment, I started feeling better. My platelets were in critical condition. I couldn't get my liver enzymes to the normal level. I've been on 5 treatments and I believe my system has gotten use to rejection. Best Wishes, *Bob I.*

**Hi Howard,** I just finished viewing the new HepC web site and had to let you know that you did a great job in putting it all together. **Thanks to you and Dr. Dan** for all you do for us in relaying information and helping us to deal with this insidious disease. Good luck to both of you. *Carolyn I.*

**Hi Howard,** This is Jim from this past Mondays meeting. I wanted to drop **both you and Dr. Dan a note of thanks. The support group is well run and very informative.** I will make an attempt to become a regular attendee. I have attached the study on Ceplene that I spoke about the other night. I had to find one in English!! OK guys, take care and thanks again for all you do. Peace, *Jim W.*

## HCV Informational Meetings

Every month (except July & September) at Pocono Medical Center we hold our meetings, 6-8 pm. in the Brodhead Room, these meetings are open to the public. If you have been diagnosed with hepatitis do yourself and your family a big favor and come to a meeting and learn your different options on what to do next! There are a lot of misconceptions about hepatitis out there!

**If you are looking for a support group in your area, they are listed on page 3 of this newsletter.**

We now have a Toll Free Hot Line for members outside the local area code 1-866-869-1211 where members can call to receive educational information on their particular questions on HCV.

Our Web Site is up and running, come and visit our pages for educational information on this site!

[www.nepatsg.org/hepatitis/index.htm](http://www.nepatsg.org/hepatitis/index.htm)

The Hepatitis Times is published 3 times a year by NEPATSG Inc. Information in this newsletter is not intended to replace, the medical advice you receive from your healthcare providers. If you have any questions regarding any information in this publication, consult your physician. Please share your stories, questions and thoughts with us, send your submissions to the address below ” C/o NEPATSG Editor” or e-mail us at [office@nepatsg.org](mailto:office@nepatsg.org).

### **Northeastern Pennsylvania Transplant Support Group Inc. (NEPATSG)**

#### **Hepatitis Division**

**(570) 223-2833 Local**

**866-869-1211 Toll Free**

**[www.nepatsg.org/hepatitis/index.htm](http://www.nepatsg.org/hepatitis/index.htm)**



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## Livers Not At Risk With HIV Drug Treatment

HIV patients coinfecting with hepatitis C had similar clinical outcomes when treated for HIV in comparison to those who are HCV-negative in a study presented July 6 at the XIV International AIDS Conference in Barcelona, Spain. For two years, Johns Hopkins University School of Medicine scientists observed 1,955 HIV patients, 873 of whom were coinfecting with hepatitis C. A percentage of each group was treated with antiretroviral therapy

At the AIDS conference, Mark S. Sulkowski, head of the Hopkins team, said physicians may be less likely to prescribe aggressive antiretroviral therapy to hepatitis C and HIV coinfecting patients because they are thought to be more likely to develop liver complications, the National Institutes of Health reported. However, the outcome of their study revealed otherwise. "Among patients in this urban U.S. cohort, we did not detect evidence that HCV infection substantially alters the risk of dying, developing AIDS, or responding immunologically to highly active antiretroviral therapy (HAART), especially after accounting for differences in its administration and effectiveness," the researchers reported in the study; which was published in the July 10 issue of the *Journal of the American Medical Association*.

Source: Hepatitis Magazine

## Protease Inhibitors: Restoring Immune Response in Hepatitis Patients

A new generation of drugs may be the key to restoring immune response blocked by the hepatitis C virus, reducing the virus to what researchers describe as nearly undetectable levels in a matter of days. The finding could lead to additional effective treatments for liver disease caused by HCV, they say. **A Dual Efficacy** "We found that the new protease inhibitors could actually prevent the virus from blocking this immune response and basically restore the innate antiviral response in human cells," said Michael Gale, Ph.D., an assistant professor of microbiology at the University of Texas Southwestern Medical Center at Dallas, and senior author of the study. "Our conclusion is that these new drugs will have a dual efficacy," he said. The immune system has many ways to detect and fight off invading microbes, and microbes have just as many ways

to elude and disarm immune system components. Through a series of experiments on cells grown in a laboratory, Gale and co-researchers Stanley Lemon, MD., of the University of Texas Medical Branch at Galveston, defined the strategy that HCV uses to evade the immune response. As HCV begins to replicate in the body, it manufactures enzymes, called *proteases* (PRO-tee-ayz-ez), which it needs to transform viral proteins into their functional forms. Protease inhibitors, which are being scrutinized in clinical trials as therapies to treat chronic hepatitis C infections, target the enzyme activity of the viral protease. "If you block the protease, it neutralizes the virus, and restores the host response to infection, allowing the cell to clear the virus naturally," Gale explained. "That type of mechanism of the drug was completely unexpected."

**Hepatitis C Affects 3.9 Million People** Hepatitis C virus, which is primarily transmitted by intravenous drug use, blood transfusions or blood products, affects approximately 3.9 million Americans. About 2.7 million are chronically infected, and the number of new infections has declined from approximately 240,000 in the 1980s to about 25,000 in 2001. Hepatitis C virus is also the leading cause of liver cirrhosis and liver cancer. Treatment for the disease includes interferon and the anti-viral medicine, ribavirin. Pegylated, or longer-lasting, interferon combined with ribavirin is the current main line of treatment for HCV. Combination therapy can clear the virus in 5 out of 10 people with the genotype 1 strain, and 8 out of 10 persons with genotypes 2 and 3.

**HCV Persistence** The aim of the study was to determine why hepatitis C virus is so persistent in human cells. Some 85 percent of individuals exposed to the virus develop chronic infections that are non-responsive to therapy. Seventy percent of those with chronic infections develop chronic liver disease, and nearly 3 percent with long-term infections die of related illnesses. Gale and his team of investigators discovered that the virus persists, in part, because it blocks the innate immune response in infected cells. "We believe that is a major reason why hepatitis C virus causes chronic infection," Gale explained. The identification of this viral protease, Gale explained, opens new avenues in both clinical and basic research on hepatitis C. Until now, scientists had not considered the possibility that inhibiting the protease enzyme did anything more than halt viral replication. "Now that we know [protease] inhibition essentially restores the hosts immune response to the virus, we can assess hepatitis drug candidates for this ability as well," he said.

**Scrutinizing Protease Inhibitors** Two different protease inhibitor drugs are currently in different stages of clinical trials. These medications will likely be evaluated relative to the latest findings, Gale said. "As opposed to just studying

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how much the drug knocks down the virus, now we will evaluate how the drug impacts the host cells response to the infection," he explained. Protease inhibitors are already well known as effective drugs against HIV, the virus that causes AIDS. They work by interfering with the protease enzyme that HIV uses to make infectious viral particles. Some experts believe protease inhibitors may now have a new role, based on the findings of studies like this one.

**"These new findings with hepatitis C virus** suggest that protease inhibitors will become an important addition to existing interferon treatments for hepatitis C, and that they will have equal if not greater impact on the treatment of this important form of liver disease," said Stanley Lemon, MD., dean of medicine at the University of Texas Medical Branch at Galveston, whose researchers also took part in the study.

Source: [Hepatitisneighborhood.com](http://Hepatitisneighborhood.com)

## **CDC Warns Doctors About HCV Transmission in Antibody Negative Donors**

The Centers for Disease Control and Prevention is issuing a warning to doctors to be aware of the possibility organ and tissue donors who test negative for antibodies associated with hepatitis C infection can still transmit the virus to other patients after transplantation, although it may be rare. In its April 4 Morbidity and Mortality Weekly Report (MMWR), CDC cited the case of an Oregon patient whom had contracted HCV approximately six weeks after receiving a tendon and bone transplant from a donor. At the time of the donor's death, subsequent blood tests revealed he was "anti-HCV"; that is, there were no detectable levels of antibodies related to the virus in his bloodstream. However, further investigation by the CDC and the Oregon Department of Human Services revealed that the donor was *HCV RNA* positive, and that the donor had likely infected eight transplant recipients. In HCV RNA tests, clinicians are searching for viral genetic material in the patient's cells. If that material is found, it is a clear indication of infection. **Rare Transmission Risk** Based on this case report, the CDC advises that "although transmission from anti-HCV-negative tissue donors probably is rare, determining the frequency of transplantation from such donors, and the risk for transmitting HCV to recipients, is important in evaluating whether additional prevention measures are warranted." The donor had died of an intracranial hemorrhage with no signs or symptoms of hepatitis at the time of death. The CDC reports the mans liver enzyme levels were normal, and physical examination revealed no skin markings that might have suggested he was an injection drug user, or that hinted at liver disease. A questionnaire subsequently

delivered to the donors family revealed no history of injection-drug use nor blood transfusion. A range of tests for both hepatitis Band C, as well as other possible viruses, were all negative.

### **Testing HCV RNA Positive**

However, after a physician alerted the Oregon Department of Human Services about the incident, doctors tested the donor's blood, which had been frozen and stored. It tested negative for HCV antibodies, but positive for hepatitis C RNA. Investigators subsequently identified a possible recipient of the HCV infection who had the same genotype as the donor, and was not known to have been infected before the transplant procedure. Once health investigators obtained information on the recipients who had been transplanted with the donor's organs and tissue, health care providers were contacted to obtain clinical information, and to arrange for testing of recipients. Blood tests taken from each recipient both prior and subsequent to transplantation were compared for both the presences of hepatitis C antibodies and HCV RNA. Among 40 recipients who had been transplanted with the donors organs or tissues, eight positive cases of hepatitis C were confirmed, all with a strain of the virus known as *genotype 1a*. Three of the recipients had received organs, and it was determined that another five tissue allograft recipients were probable cases because their blood samples had not been made available prior to surgery. Additionally, one cornea recipient had tested negative for HCV antibodies, but HCV RNA tests had not been conducted prior to the publishing of the MMWR report. An allograft is a graft, or unattached organ, transplanted between two genetically non-identical patients.

### **Infection Speculation**

Why did the donor test negative for the presence of hepatitis C antibodies yet still infect eight organ and tissue recipients? The CDC speculates that the donor's time of death was likely in the 8 to 10 week window period between hepatitis C infection and the development of detectable antibodies. "Although available data are limited, HCV transmission by organ and tissue donors during this period appears to be uncommon," the CDC stated. "Only one previous report describes HCV transmission from a tissue donor in whom anti-HCV testing was negative."(2) The CDC stated that the frequency of hepatitis C transmission from previously negative donors is not known, however data have shown that among voluntary blood donors, approximately 4 in 1 million blood donations are from people who test antibody negative and HCV RNA positive. It noted that donor screening is the primary means to prevent donor hepatitis transmission, with oversight provided by both the FDA and Health Resources and Services Administration. While nucleic acid testing to

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detect HCV RNA is effective, the CDC noted that the tests are not routinely performed among organ and tissue donors because organ viability declines rapidly after death, and nucleic acid testing is lengthy and not immediately accessible in organ donation settings.

## Officials Urge Better Awareness

The CDC stresses that the way to effectively curb this risk is to ensure that health care providers notify authorities promptly in the event an infected donor is discovered so that an investigation can be initiated, and tissues recalled to prevent further transmission. "Centers performing transplantation should maintain adequate records of graft recipients to facilitate investigations of allograft-associated infections," the CDC added. The agency also plans to investigate whether changes are needed in donor screening guidelines. "Although transmission from anti-HCV negative tissue donors probably is rare, determining the frequency of transplantation from such donors and the risk for transmitting HCV to recipients will be useful for evaluating the benefits and limitations of additional prevention measures," it said.

Source: Hepatitisneighborhood.com

## Breaking Down Interferons

Here's a quick breakdown of each interferon, their generic name, brand name and manufacturer.

<u>Generic Name</u>	<u>Brand Name</u>	<u>Manufacturer</u>
Interferon Alfacon-1	Infergen	Intermune
Interferon Alpha2a	Roferon-A	Hoffman-La Roche
Peginterferon alpha-2a	Pegasys	Hoffman-La Roche
Interferon alpha2b	Intron-A	Schering-Plough
Combination therapy	Rebetron	Schering-Plough
Peginterferon alpha-2b	Peg-intron	Schering-Plough

## In Remembrance

**Mr. Robert Charles Mulcahy**, who passed away on February 10 2001, we would again like to give his family our deepest condolences. Also our First hepatitis C awareness walk that will be held September 20 2003 in Monroe County will be dedicated in his honor.

*Editor's note:* The Mulcahy family has been very supportive of our organization, they helped in making hepatitis educational literature is made more available to the public.

*It's not important what we accomplished in life,  
But what we have overcome!*

Cut out and mail below

### GETTING THE MESSAGE OUT

#### IS COSTLY....

Besides holding educational meetings for Hepatitis patients, we are educating the public about Hepatitis C awareness and prevention. We are looking for Individuals to sponsor our Newsletter, to assist with the printing, etc. Donations will help us with the operating costs associated with getting out the much needed communication that will make people become aware of Hepatitis C Virus (HCV).

**All donations are tax deductible. We are registered with the PA Department of State Bureau of Charitable Organizations. Certificate #22479**

The official registration and financial information of Northeastern Pennsylvania Transplant Support Group Inc. (NEPATSG ) may be obtained from the Pennsylvania Department of State by calling toll-free within Pennsylvania, 1-800-732-0999. Registration does not imply endorsement.

**Please give a gift to help others:**

**Name:** \_\_\_\_\_

**Address:** \_\_\_\_\_  
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