

# HCV ADVOCATE

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Hepatitis C Support Project

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## Treatment Advocate

*Joe Shaw*

One hundred and fifteen interferon injections, 690 ribavirin pills and there's still two-and-a-half months to go. It gets tedious day after day ingesting these drugs and I can hardly wait to stop. But the fact that my liver enzymes were normalized almost immediately and have remained normal since, has made it all worth it.

From my own personal experience, I can urge you to be screened for depression before you begin any treatment. I waited too long and was under dosed until only a month ago. Getting the right dose made all the difference in the world. Interferon treatment is a journey with ups and downs so it's important that you are fully prepared and you get the help you need.

This month's column features lots of interesting information in a wide variety of topics.

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## INFO UPDATES

### Ribavirin: Made To Order

*Lynn Shawn*

The Hepatitis Place

<http://www.hepplace.com>

In early July, a small specialty pharmacy in Pittsburgh began making its own version of ribavirin, the capsule currently bundled with injectible alpha-interferon in Schering Plough's combination therapy for hepatitis C. ribavirin, an antiviral developed by ICN Pharmaceuticals, has been the second drug to be used to combat the hepatitis C virus. Bundled with alpha interferon and sold under the trade name of Rebetron, ribavirin is unavailable for separate purchase in the United States, enabling Schering Plough to control its use and cost.

Until now.

Before Fisher's Specialty Pharmacy Services decided to compound its own version of ribavirin for physician-ordered prescriptions for hepatitis C patients, ribavirin capsules could only be obtained through PWA, an AIDS activist organization in New York, or through a very expensive prescription for Rebetrol (ribavirin). The typical cost for a one-year treatment with Rebetron is \$18,000.

As a compounding pharmacy, Fisher's Specialty Pharmacy Services has the legal right to compound, or mix, ingredients to recreate the prescription drug, ribavirin, by using a loophole in the patent and drug approval laws. Working with a European manufacturer and a U.S. importer, Fisher's is now compounding ribavirin for prescription orders.

Fisher's has spent many hours and dollars researching the legal aspects of compounding its own version of ribavirin after the patent expiration date of July 8.

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### **Blue-green Algae May Contain Toxins Harmful to the Liver**

On May 5, 1999, the Canadian Health Protection Branch warned: Products containing blue-green algae may contain toxins harmful to the liver and these products should not be given to children. Some species of blue-green algae produce toxins known as microcystins. As a result, these toxins may be present as contaminants in products made from blue-green algae. With lower body weights, children are at greater risk of developing serious liver damage should the blue-green algae product be contaminated with microcystins. A recent, independent sampling done by a researcher at the University of Alberta found several products containing natural-sourced blue-green algae with microcystin levels which exceed those considered safe for daily consumption by both Health Canada and the World Health Organization. Microcystins accumulate in the liver and can cause liver damage. Spirulina products contain no nutrients that are not readily available from food -- at a much lower price. They have no proven value for treating any medical problem, and some may contain potent toxins. For Additional Information: Health Canada Online, Information sheet on bluegreen algae: <http://www.hc-se.gc.ca/english/archives/warnings/9969ebk.htm>

### **Triple Antiviral Therapy Effective in Nonresponders, Pilot Study Reports**

Twenty consecutive adult patients with chronic hepatitis C who had failed to respond to a 6-month course of interferon alpha were randomly assigned to receive a combination of interferon alpha + oral ribavirin (double therapy), or the same combination + oral amantadine (triple therapy), for 6 months. By the end of therapy, normal alanine transaminase (biochemical response) was obtained in 2 out of 10 patients on double therapy but in 7 out of 10 on triple therapy, and negative serum hepatitis C virus (HCV) RNA (virological response) occurred in 1 out of 10 patients on double therapy but in 7 out of 10 patients on triple therapy. Six months after therapy, biochemical response was sustained in 1 (double therapy) and 4 patients (triple therapy), respectively, and the virological response was sustained in no patient on double therapy but in 3 patients on triple therapy. SOURCE: Italian Journal of Gastroenterology & Hepatology March 1999

### **Successful Delivery Of Interferon Without Injection**

Helix BioPharma Corp. announced Interferon-a has been successfully delivered both dermal and transdermal, without the need for an injection, utilizing the Biphasix(tm) delivery system in a study of seventeen healthy human volunteers. In a presentation to the Controlled Release Society in Boston, Professor Marianna Foldvari, of the College of Pharmacy and Nutrition at the University of Saskatchewan, presented the results of a study of the delivery of therapeutic proteins through human skin. The study showed a significant increase in anti-viral activity in the skin and in the blood following the application of an interferon-a-Biphasix(tm) patch when compared to a placebo.

### **Herbs and Over-the-Counter or Prescription Drugs Don't Always Mix Well**

Dangerous cross-reactions between herbs and drugs: Researchers in alternative medicine, watching the mushrooming enthusiasm for nontraditional remedies, are becoming increasingly concerned. Among the little-known risky combinations listed in Duke's online database ([www.arsgrin.gov/duke/index.html](http://www.arsgrin.gov/duke/index.html)): Both grapefruit juice and the herb angelica (also called dang qui), with a long list of drugs such as antihistamines, anti-anxiety benzodiazepines, calcium channel blockers for blood pressure, and protease inhibitors for HIV; either the juice or the herb can triple the drugs' impact.

#### **Herb name: Echineacea**

Usual use: To boost the immune system in colds and flu; Not advised: In auto-immune diseases such as multiple sclerosis; may also interfere with drugs taken for HIV and TB.

#### **Herb name: Ginseng**

Usual use: Stimulant; Not advised: In hypertension; may diminish the effect of drugs to lower blood pressure.

#### **Herb name: Garlic**

Usual use: Reduce blood cholesterol ; Not advised: Can magnify the effect of blood-thinning medications such as Coumadin.

#### **Herb name: Cascara sagrada, Senna, Buckthron.**

Usual use: Stimulant Laxatives. Not advised: In cases of cardiac irregularity; may reduce blood levels of potassium and increase the effect of drugs to regulate heart rhythm such as Lanoxin.

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**Herb name: St. John's Wort.**

Usual use: Anti-depressant. Not advised: When taking a selective serotonin re-uptake inhibitor such as Prozac or a monoamine-oxidase inhibitor such as Nardil; the combination can cause serotonin intoxication, with fever, confusion and muscle spasms.

**Herb name: Ginger.**

Usual use: Calms nausea. Not advised: When taking blood-thinning medication such as Coumadin; ginger may amplify the drugs' action and cause bleeding disorders.

**Herb name: Valerian.**

Usual use: Mild sedative. Not advised: When already taking anti-depressants or sedatives; because it depresses the central nervous system, it can magnify the effect of those drugs.

**Herb name: Licorice.**

Usual use: Reduces cough and may help stomach ulcers Not advised: Reduces levels of potassium in the blood; when combined with diuretics such as Lasix or cardiac stimulants such as Lanoxin, can cause muscle weakness and irregular heartbeat. **Herb name: Kava kava** Usual use: Anti-anxiety. Not advised: increases the effectiveness of alcohol, barbiturates and psychoactive drugs.

*Sources: The American Botanical Council and the Herb Research Foundation*

Musculoskeletal Pain and Fatigue in Chronic Hepatitis C -The aim of this study was to identify the frequency of fatigue and musculoskeletal pain in hepatitis C compared with other liver diseases. Hepatology outpatients were evaluated by questionnaire for musculoskeletal pain and fatigue. Charts were reviewed for diagnoses, aminotransferases, histology, treatment, and presence of hepatitis C by second generation ELISA and/or polymerase chain reaction. The frequency of symptoms in patients with and without hepatitis C were compared. In 239 patients musculoskeletal pain was present in 70% and fatigue in 56%. Backache was the most common complaint (54%), followed by morning stiffness (45%), arthralgia (42%), myalgia (38%), neck pain (33%), pain "all over" (21%), and subjective joint swelling (20%). Diffuse body pain was present in 23% on a pain diagram and was strongly associated with fatigue. There was a significant association between hepatitis C positivity and the presence of musculoskeletal pain (81% of HCV-positive compared with 56% of HCVnegative patients) and fatigue (67% compared with 44%).

Musculoskeletal pain was more frequent among patients with isolated hepatitis C infection than among patients with isolated hepatitis B or alcoholic liver disease (91%, 59%, and 48%, respectively). Similarly, fatigue was more frequent among patients with isolated hepatitis C than among those with isolated alcoholic liver disease or hepatitis B (66%,30%, and 29%, respectively). SOURCE: American Journal of Gastroenterology 1999 May

Dubious Health Claims on Internet are Focus of FTC Crackdown- The Federal Trade Commission announced efforts to crack down on fraudulent health products and to encourage consumers to be careful when looking for medical advice on the Web. The commission has identified about 800 sites that contain questionable promotions for disease cures. More than a quarter of those sites targeted by the FTC in the past year have either removed their claims or have been taken down, Bernstein said. The Department of Health and Human Services is encouraging people to use the federal consumer health information gateway at <http://www.healthfinder.gov> as a reliable resource. The Food and Drug Administration has its own site <http://www.fda.gov> that consumers can search for additional information. Some of the common marketing techniques used to make false health claims about products: --The product is advertised as a quick and effective cure-all for a wide range of ailments. -- The promoters use words like "scientific breakthrough", "miraculous cure", "secret ingredient" or "ancient remedy". -- The text is written using impressive-sounding terminology. -- The promoter claims that the government, the medical profession or research scientists have conspired to suppress the product. -- The product is advertised as available from only one source.

## Blood Samples Reveal HCV Existed in 1948

### Study seeks clues to HCV behavior over 50-year period

Researchers at the National Institutes of Health (NIH) have discovered that the hepatitis C virus (HCV), first identified in 1989, has been present in the U.S. since at least 1948. The researchers found HCV in blood samples drawn from 8,500 Air Force servicemen stored since 1948. Leonard Seeff, MD, and colleagues at the NIH found that 0.4 percent of the blood samples contained antibodies to HCV. This infection rate is similar to the current HCV infection rate in the U.S.

The researchers have now turned their efforts towards examining the medical records of the HCV-positive servicemen to determine how the virus affected their health. They also want to know if the virus has changed in the men who are still alive. "As we find those men who harbor the virus, we will be able to tell how it behaves over a 50-year period," said Dr. Seeff.

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### Info Updates - continued from page 1

Even so, Fisher's is able to provide ribavirin at a price that is much less expensive than the hefty price tag that Schering Plough has assigned to ribavirin. In fact, Fisher's retail price of ribavirin is about 80% less than Schering Plough's ribavirin. By ordering ribavirin through Fisher's, patients pay \$225 for a one-month supply of ribavirin. This huge cost-savings has pleased many hepatitis C patients and activists.

Contact Information: Fisher's Specialty Pharmacy Services 3904 Perrysville Avenue, Pittsburgh, PA 15214  
Phone: (412) 231-3777 Toll Free Phone: (888) 347-3416 Toll Free Fax: (877) 231-8302 [www.spsdrug.com](http://www.spsdrug.com)

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## HAVE YOU BEEN VACCINATED AGAINST HEP A & HEP B?

*Bryan Makishi*

One more thing someone with hepatitis C (HCV) should consider is the threat of two other liver viruses, hepatitis A (HAV) and hepatitis B (HBV). Combined with HCV, HAV and HBV will probably be tougher to get rid of and will make you sicker, according to a spokesperson from the Centers for Disease Control and Prevention. If your liver has already been exposed to HAV or HBV, you've built up immunities, so vaccination is unnecessary. But, if you haven't been exposed, take advantage of these safe vaccines, which can be given together.

### **Hepatitis A (HAV)**

HAV is what most people think of when they think *hepatitis*. Most HAV is found in the stool of infected persons. Infected food handlers can infect others if they don't wash their hands with soap and water after defecating. Infected sex partners can pass it on via oral/anal sex. Consumers of raw or partially cooked shellfish from water containing HAV-contaminated sewage can get it. HAV is also found in blood and can be spread via infected blood, though it is rare.

Like HCV, someone with HAV may not know they're infected and can infect others. Vacationers, military personnel, missionaries and others that travel to foreign countries can bring back HAV unless they have been previously vaccinated. Even popular destinations like Mexico and the Caribbean are risk countries.

Most people (99%) infected with HAV recover without treatment and develop antibodies. According to the Center for Disease Control (CDC), 1 in 100 develops a sudden and severe liver infection (fulminant) that requires a liver transplant. Every year 100 people with underlying liver disease, including HCV and the elderly die from complications from HAV infection.

The HAV vaccine is given in two doses made from killed viruses and is considered safe and effective. The CDC reports only minor adverse events have been attributed to the HAV vaccine. The vaccine offers protection for at least 20 years. Over 1 million people in Europe and Asia have been given this medicine.

The HAV vaccine is recommended by the American Liver Foundation (ALF), Hepatitis Foundation International (1-1171) and The Hepatitis C Support Project (HCSP). Furthermore, the CDC recommends that anyone awaiting a liver transplant, those already transplanted and those individuals with liver damage caused by HCV be vaccinated against HAV.

### **Hepatitis B (HBV)**

HBV is present in blood and body fluids and is spread when these fluids come into contact with breaks in the skin or other body surfaces. Sexual transmission is how most people become infected, but can also be transmitted by infected intravenous drug users who share dirty needles or other drug paraphernalia. Other transmission routes include sharing contaminated razors or toothbrushes. Nail salons, tattoo or body piercing shops can all pass HBV if they do not sterilize their instruments or if they reuse instruments contaminated by someone with HBV.

Like HCV and HAV, someone infected with HBV may not know it and easily infect others. Because the virus can survive outside the human body on even dry surfaces for a minimum of 7 days and up to 2 weeks, HBV is said to be 100 times more contagious than HIV, the virus that causes AIDS. 4,000 to 5,000 people die annually from HBV infections.

The HAV vaccine is made from killed or inactivated viruses and consists of 3 doses given over 12 months and is considered among the safest and most effective vaccines. The HFI estimates the HBV vaccine will provide life long immunity. HBV is also recommended by the HFI, ALF and HCSP for people infected with HCV.

Talk with your doctor about getting these vaccinations. It is vitally important that if you are infected with HCV that you are immunized against HAV and HBV. If your insurance company will not cover these vaccinations, inform them that the CDC recommends that anyone infected with HCV be vaccinated against HAV and HBV. It can literally be a matter of life and death.

For further information on the HAV and HBV vaccines, call or click... Centers for Disease Control & Prevention, (800) 232-2522 or [www. cdc.gov/hepatitis](http://www.cdc.gov/hepatitis)

*For more information about hepatitis C, please contact the following organizations:*

- *American Liver Foundation*                      800-223-0179                      <http://www.liverfoundation.org/>
- *Hepatitis Foundation International*                      800-891-0707                      <http://www.hepfi.org/>
- *Hep C Connection*                                      800-522-4372                      <http://www.hepc-connection.org>

## **"Hidden" HBV Infection May Affect Clinical Outcome of Chronic Hepatitis C**

HCV and HBV co-infection increases risk for liver cancer; PCR testing can reveal presence of HBV

Hepatitis B virus (HBV) infection that occurs in people who lack detectable hepatitis B surface antigen (HBsAg) is called occult ("hidden") HBV infection. Although researchers have identified occult HBV infection in people with chronic hepatitis C (HCV) liver disease, the number of people affected by occult HBV infection and its clinical significance is not known. Italian researchers recently published an analysis of the prevalence of occult HBV infection in persons with chronic hepatitis C. They conclude that occult hepatitis B infection occurs frequently in people with chronic HCV and further, that it may significantly affect the clinical course of HCV liver disease.

HBV and HCV are both transmitted through the blood and by sexual contact. Infection with both viruses is common. HCV infection is diagnosed by blood tests that detect specific antibodies and viral RNA. Usually, HBV infection is diagnosed by detection of circulating hepatitis B surface antigen (HBsAg). However, it is not uncommon for HBV infection to occur among HbsAg *negative* patients. It is not known why these patients do not have circulating HBsAg. These instances of occult HBV infection have frequently been identified in patients with HCV-related chronic hepatitis. Results of several studies suggest that occult HBV infection may contribute to chronic liver damage and the development of hepatocellular carcinoma (liver cancer).

The Italian researchers studied 200 HbsAg negative patients with HCV-related liver disease. Using PCR testing, they found that one-third of the patients with HCV-related chronic hepatitis had detectable HBV genomes, despite having undetectable HBsAg. This prevalence was significantly higher than that among HCV-negative patients with chronic liver disease. The prevalence of occult HBV infection was especially high among patients with anti-HBV antibodies. The patients with occult HBV infection had very low levels of HBV, as measured by PCR testing, leading the investigators to conclude that occult HBV infection is usually due to a strong suppression of HBV replication. The reasons for the strong inhibition of HBV replication are unknown. The researchers suggest that the immune system may be responsible for suppression of the virus. In patients with HCV co-infection, it could be due to the suppressive activity of HCV.

Other study results indicate that persistent HBV infection may play an important role in the development of liver cancer among HbsAg negative patients. The Italian study shows that occult HBV infection correlates significantly with cirrhosis among HCV-infected individuals. "This suggests that a masked [occult] HBV infection may interfere with the clinical outcome of chronic hepatitis C and favor or accelerate the evolution to cirrhosis," write the investigators. Cirrhosis is regarded as the most significant risk factor for the development of liver cancer. The researchers found no significant association between occult HBV infection and chronic hepatitis. However, the investigators did find a trend toward an association between occult HBV infection and a lack of response to interferon therapy in patients with chronic hepatitis, but not in those with, cirrhosis.

Reference: I Cacciola and others. Occult hepatitis B virus infection in patients with chronic hepatitis C liver disease. *The New England Journal of Medicine* 341(1): 22-26. July 1, 1999.

From: [WWW.HIVANDHEPATITIS.COM](http://WWW.HIVANDHEPATITIS.COM)

## NOT WITH A BANG, BUT A VIRUS

*Maxine Haytin*

In the Summer of 1997, life as I had known it collapsed around me. I had just undergone two surgeries for breast cancer and was facing eight weeks of radiation therapy when a routine blood test revealed the unthinkable -- I had Hepatitis C! I had faced the cancer treatment with confidence that I would return to health, but the news of this second threat was unbearable. The fragile structure of illusions and willful ignorance which often sustains us in times of good fortune simply disappeared. I was plunged into a state of mind alternating among despair, terror and panic. I felt as though I were living a nightmare from which there was no hope of awakening. I tried to cope, but each day was a struggle just to get through to the next. In the mornings, I awoke feeling as if the weight of some malevolent beast were sitting on my chest, wondering how I could find the strength to get up and go through the motions of daily living.

Over the course of the next year, I was plagued by a variety of symptoms associated with HCV. Feeling exhausted and very ill, my life became increasingly constricted. I stopped working and communicating with many of my friends. I was often on the verge of panic attacks. All of the activities which I had previously found pleasurable and rewarding seemed lost to me forever. Since I already felt so sick and had recently completed treatment for the cancer, I was unwilling to begin another course of conventional medical treatment whose efficacy was doubtful and which would most likely weaken me even further. I began trying a variety of alternative approaches, including meditation, yoga, acupuncture and herbs. Some were more helpful than others, but the simple act of doing each of them gave me a sense that I still had some control over my life.

At the same time, I made contact with Alan Franciscus and Barry Howe, two dedicated activist members of the HCV support community. I admit I had some initial resistance to attending a support group. On a primitive level, I must have believed that if I didn't acknowledge the virus, it would finally get discouraged and go away!

(There's nothing quite so sad as a virus that's been rejected.)

Ultimately, however, I started attending Barry's Marin support group. It was a revelation and a comfort to be in the company of people facing circumstances similar to mine. Even more encouraging was the fact that we actually spent more time laughing and exchanging information, than we did bemoaning our unfortunate fates. And, I made some wonderful friends who have enriched my life greatly.

As the burden of hopelessness and helplessness lifted, I began to feel better and my energy level improved. I was able to work again and resume some social activities. It was such a relief to be able to think beyond myself, and I started wanting to give something back to the community which had given me so much. When the opportunity presented itself, I volunteered to work on the HCV Helpline. One day a week, I return calls from those who are reaching out for information and support. Many of these callers are newly diagnosed or are friends and relatives of such people. Most are confused, anxious and seeking some perspective on their predicaments. Many of those I have spoken with have shared their situations with me and, thus, given me a more balanced view of my own condition. As anyone who has ever done volunteer work learns, one invariably receives much more than one bestows. Working on the Helpline has been and continues to be a rewarding experience and an important step in my own spiritual healing process.