

June
2001

HCV Advocate

Volume 4
Issue 6

A monthly newsletter of the Hepatitis C Support Project
www.hcvadvocate.org

A Survey of Studies on Alcohol Use and Hepatitis C

By Norah Terrault, MD, MPH
Assistant Adjunct Professor
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Alcoholic liver disease is an important cause of cirrhosis in the United States. The Centers for Disease Control and Prevention (CDC) estimates that about 7500 deaths occur annually due to alcohol-induced liver disease. An estimated 7-10% of persons in the U.S. have met criteria for alcoholism at some time in their lives and approximately 10-25% of who drink alcohol regularly will develop alcoholic cirrhosis during their lifetime. Chronic liver disease secondary to alcohol is believed to be the most common preventable cause of liver-related deaths in the U.S.

Individuals with hepatitis C who drink a significant amount of alcohol are more likely to have abnormal liver enzymes and more severe liver disease than persons who do not drink alcohol. Reducing the amount of alcohol used can lead to improvement in liver enzymes (AST and ALT). In a study of 45 patients with chronic HCV who consumed an average of 3-10 drinks per day who decreased their intake to an average of 1-1.5 drinks per day, there was a significant decrease in liver enzymes. The effect of drinking lesser amounts of alcohol on the liver enzymes is less clear.

An increased risk of cirrhosis has been found in HCV-infected patients with "heavy" alcohol consumption compared to HCV-infected patients without "heavy" alcohol use. In a study of persons who acquire HCV infection by blood transfusion, the risk of developing of cirrhosis was increased 4-fold in those that were heavy users of alcohol compared to those who drank lesser amounts of alcohol. In untreated patients with chronic HCV infection and abnormal liver enzymes, "heavy" ingestion of alcohol (defined by

5 or more drinks per day) was among the most important predictors of a more advanced stage of liver disease. This study showed that the development of cirrhosis in HCV-infected patients was accelerated by 34% in those who drank more than 5 drinks of alcohol per day compared to patients who drank less than 5 drinks per day. Thus, available information strongly indicates that alcohol can have a detrimental effect on individuals with chronic HCV infection, but the focus of the studies to date has been on "heavy" consumers of alcohol. The effect of drinking lesser

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Pegasys Approval Delayed?

Swiss drugmaker Roche's plan to rollout their important new drug, Pegasys, by September has hit a snag, according to a Reuters report. An FDA review panel asked for more information on the clinical data, stalling its efforts to start selling the longer-lasting pegylated interferon in the fourth quarter of this year.

A Roche spokesman said that they would be able to respond to the FDA sometime this summer, and financial analysts speculated that Pegasys could still hit the market in late 2001 or by the second quarter of 2002 at the latest.

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Consumer Reports on Health: An Article Everyone With HCV Should Read

By Lucinda K. Porter, RN

HealthWise

I am a consumer health magazine junkie. I find this to be an essential part of my health toolkit. Having health-oriented literature stashed in my car, office, and home reminds me of my commitment to making healthy choices. Often a well-written article will provide the inspiration I need to keep on track.

This year I added Consumer Reports On Health to my subscription list. This twelve-page newsletter is packed with general articles on a variety of issues. I do think it is slightly on the pricey side. A subscription rate (\$24.00 annually) is twice that of The Advocate.

It is also costlier than Prevention magazine, which offers quite a bit more. However, the April 2001 issue had a fantastic article titled, "Why You Need to Protect Your Liver" (author unknown). I would like to summarize a few key points as well as provide information on how to send for a reprint.

This article offered a broad overview related to the liver. It began with a brief description of some of the liver's functions. The myth that the liver is a filter and detoxifying organ was addressed. Frequently patients report taking certain supplements to 'cleanse their livers.' "Modern science does not support the idea that the liver is a lint trap for toxins and requires cleaning.*

Ed Krenzelok, Pharm.D., director of the Pittsburgh Poison Center and past president of the American Academy of Clinical Toxicology pointed out that the liver is no more likely to retain toxins than any other body part.

Interpreting laboratory tests was also discussed. Although brief, the information was well presented and reassuring. It touched on liver biopsy as well. Naturally, an article about the liver would need to include something about viral hepatitis. I was not disappointed on this count either. This topic was covered in a sidebar as well as in the body of the article.

The most informative part of the article and the reason why I hope you consider getting a reprint is the sidebar on common drugs and herbs that may be harmful to the liver. Included in the sidebar are specific

comments, such as how often someone should have laboratory tests if they are taking a particular substance on a regular basis.

Some categories that were listed include common nonsteroidal anti-inflammatory drugs, cholesterol-lowering drugs, antidiabetic drugs, hormones, and nutritional supplements. There was even a sidebar on milk thistle that made some solid scientific recommendations.

Finally, the article discussed other factors that affect that liver, such as excessive alcohol intake, excess weight, and other medical conditions. There were also suggestions on how to get more information about the liver. I thought these four pages would be beneficial to all of us, whether we have hepatitis C virus infection or not. The cost of the reprint is a mere \$3.00, a true bargain in these days of high health care costs.

To send for a reprint of the April 2001 issue of Consumer Reports On Health, send \$3.00 to CRH, 101 Truman Avenue, Yonkers, New York 10703-1057

*Consumer Reports On Health, April 2001

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Lucinda K. Porter, RN is a research nurse and patient educator at Stanford in the area of hepatology. She co-facilitates a support group and is active in many aspects of hepatitis C education. In addition to being HCV positive, she has a life which include her husband and teenaged daughter.

Metabolife Energy Bars Recalled for Toxic Levels of Vitamin A

Metabolife is recalling 1.5 million Metabolife Diet & Energy Bars made December 25 through May 04, 2001 because they may contain toxic levels of vitamin A, which can cause severe liver damage.

No illnesses have been reported so far, but the bars pose potential health risks to people with liver disease, pregnant and nursing mothers. Recalled Metabolife bars include: Outrageous Oatmeal Raisin, Perfectly Peanut, Downright Chocolate and Lemony Lemon.

For more information call Metabolife at 1-800-540-7099 or visit their website: <http://metabolife.com>

Source: The Associated Press

Selected Studies From the 2001 Annual Meeting of the European Association for the Study of the Liver

By Alan Franciscus
Editor, HCV Advocate

On April 19, 2001 the European Association for the Study of the Liver held its 36th annual meeting in Prague, Czech Republic. This is the largest liver conference held in Europe and is the European equivalent to the annual AASLD held in the United States. The information presented at this conference deals with all liver disease, but a good portion is devoted to hepatitis C.

A word of caution – some of these reports are from small studies and point the way for further research to confirm or refute these findings.

These studies are just a sample of the information presented at EASL.

PEGASYS AND RIBAVIRIN

Probably the most encouraging data to emerge is the preliminary results of Pegasys (pegylated interferon 2a) in combination with ribavirin. NATAP reported on the preliminary results of Pegasys plus ribavirin presented by Di Bisceglie, MD. 1,143 treatment-naive patients (not previously treated) were randomized into three arms:

1. Rebetron -Intron A (3 mu injected thrice weekly, plus ribavirin 1,000-1,200 mg once daily;
2. Pegasys 180 micrograms injected once weekly plus oral placebo; and
3. Pegasys 180 micrograms injected once weekly plus oral ribavirin 1,000-2,000 mg once daily.

All 3-treatment arms were well balanced with genotype 1, viral load and cirrhosis.

Treatment was for 48 weeks.

Treatment Arm ETR* - 48 weeks

- | | |
|---------------------------|-----|
| 1. Rebetron | 51% |
| 2. Pegasys plus placebo | 58% |
| 3. Pegasys plus ribavirin | 68% |

*ETR or end of treatment response.

The true test of effectiveness of a drug is the sustained virologic response rates obtained 6 months after treatment stops and are always lower than ETR. Results of sustained virologic response from this trial will be presented in May 2001 at DDW.

Source: NATAP- <http://www.natap.org/>

PEGASYS WITH COMBINATIONS OF VARIOUS MEDICATIONS

Combination therapy with Amantadine is emerging as one of the most promising new therapies for treatment of chronic hepatitis C. The 24 week results of a clinical trial by Di Bisceglie and colleagues were reported. A total of 153 previously untreated patients were randomized into 4 treatment arms. 140 patients (87.5%) completed 24 weeks of treatment. The baseline patient characteristics were: mean age 45 y.o. (plus or minus 6.3 years), male 66%, mean ALT 109 (plus or minus 70.4), high viral load 67%, genotype 1 - 73%. Dosage of medications were not included in the abstract.

Results:

Therapy	24 Week Results/HCV RNA negative
1. INF a-2b + Ribavirin (RBV)	59.6%
2. Pegasys plus Cellcept	55.5%
3. Pegasys plus amantadine	76.4%
4. Pegasys, plus amantadine & ribavirin	64.7%

These are very preliminary results but the authors concluded: "These preliminary findings reveal a trend for the Week 24 antiviral effect of all 3 Pegasys combinations to be similar to or greater than that with conventional combination therapy."

CEPLENE STUDY (FORMERLY KNOWN AS MAXAMINE)

End of treatment results were presented on the study of 129 patients with chronic hepatitis C treated with the combination of INF alpha-2b (3 MIU, sc, TIW) and Histamine Dihydrochloride (Ceplene, by injection - Maxim Pharmaceuticals) randomized to one of four doses of histamine (3,5,6, or 10mg per week). The pretreatment patient population of this study included 68 patients (53%) with viral load equal to or more than 2 million copies, and 54 patients (42%) with genotype -1b (the most difficult to treat). Trial participants were treated for 12 weeks with 118 patients with a virological complete or partial response were treated for an additional 48 week and followed-up for 72 weeks. At 48 weeks, a virological complete response was achieved in 58% of all patients (range 55-65% across four arms). This

See Europe on page 7

Two Stiff Ones and a Wellbutrin, Please

By Joe Shaw
Contributing Editor

THOSE ON DEPRESSION MEDICATION, TAKE NOTE

When I started on anti-depression medication two years ago, my sex life went south, if you catch my drift. Nudge, nudge, wink, wink. Not being the shy and retiring type, I soon called it to the attention of my doctor and after several months of playing with dosage levels and trying a new medication, I am once again an upright citizen with a sex life.

If you are on anti-depressant medication please make sure that you speak to your doctor if you have any sexual dysfunction whatsoever.

This message goes for both men and women. You may not experience symptoms right away or they may appear to be mild, but there are anti-depressants on the market that do not cause sexual dysfunction at all. Sometimes adjusting the dosage may do the trick.

A recent study presented at the annual meeting of the American Psychiatric Association in May, found that 40 percent of people on anti-depressants reported sexual dysfunction, a rate nearly twice what their physicians predicted.

That means that patients are not communicating with their doctors about sexual dysfunction or that doctors aren't comfortable talking about it or both.

So TALK to your doctor if you have sexual dysfunction and if he or she doesn't want to talk about it, get a new doctor.

ALCOHOL AND HEP C

I will tell you right upfront, I have not had an alcoholic beverage in nearly twelve years. Although I had plenty before that. If that makes me prejudiced, then so be it.

But if you have Hepatitis C and you drink, you are hurting yourself. Just like the guy with lung cancer who still smokes, you are doing irreparable damage to your liver.

Lately, some have come to believe that since most studies linking increased liver damage for those with Hep C who drink heavily, that moderate or low alcohol use may be okay.

Sorry. Don't believe it. Just because smoking one cigarette a day may drastically reduce the chances of getting lung cancer, it's still a cigarette. Don't flirt with danger. The CDC still recommends abstinence from alcohol for those with Hep C and until they change their minds, I'm not going to either.

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Treatment Advocate

HCV Advocate

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The HCV Advocate offers information about various forms of intervention in order to serve our membership at large. By providing information about any form of medication, treatment, therapy or diet we are neither promoting nor recommending use, but simply offering information in the belief that the best decision is an educated one.

Hepatitis C Support Project - A Tides Center Project

UCSF Department of Medicine Plans Study On Alcohol Use and Hepatitis C

Dr. Marion Peters and Dr. Norah Terrault from the Department of Medicine at UCSF are conducting a long-term research study to find out more about the effects of drinking alcohol on chronic hepatitis C disease. They will be studying the effects different levels of alcohol use in the risk of progression of hepatitis C disease. Drs. Terrault and Peters are looking for hepatitis C infected individuals who have been diagnosed with hepatitis C within the last 24 months. Individuals who drink alcohol in any quantity (including those who do not drink) are needed for the study.

Persons wishing to participate in this study will be asked to:

1. Complete an interview in-person or by telephone.
2. Provide a blood sample.
3. Undergo a physical examination.
4. Have a liver biopsy (if one has not been done already).

Participants will be followed by 4 years and visit UCSF every year for an interview, blood draw, and physical examination. In return for the time, effort, and travel related to participating in the study, each person will be reimbursed up to \$50.00 for each visit. In addition, free parking is available. Persons with HCV infection who are interested in finding out more

about the study are asked to call the toll-free phone number 1-888-286-1821, or the study coordinator Karly at 415-514-2861.

Alcohol and Hep C Continued from page 1

amounts of alcohol has not been well studied.

Alcohol and hepatitis C are the commonest etiologies of liver disease in the U.S. A national health objective is to reduce the number of deaths due to cirrhosis from 10.4 per 100,000 persons (incidence in 1989) to 6 or less per 100,000 persons. If this goal is to be achieved, an increased understanding of the effects of alcohol on HCV-associated liver disease is needed to allow for specific interventions to be undertaken. The CDC recommends abstinence from alcohol for all persons infected with HCV regardless of previous or current alcohol intake. The NIH consensus panel from 1997 advised that alcohol use should be limited to "one drink or less" per day. These recommendations are appropriate based upon the data that are available. However, more information is clearly needed on the effects of "light" or "occasional" use of alcohol. This information is vitally important to those affected by HCV disease and to doctors who care for HCV-infected patients.

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First Canadian Conference on Hep C

By Joan King
President, HEPCBC
Editor, hepc.bull

Can you imagine being completely overwhelmed by information on hepatitis C? That's what happened to me when I attended the 1st Canadian Conference on Hepatitis C, from May 1st - 4th in Montreal. I wish I could convey the bustle and excitement of the event: Opening ceremonies... a candlelight memorial... May 1st declared Hepatitis C Day in Canada - lots of great things to talk about, but unfortunately no room here. These will live in my memory for a long, long time. What I can share with you here are the highpoints.

Some of the highlights:

“The Natural History of Hepatitis C Virus Infection,” by Harvey Alter, MD, presented statistics on disease progression, noting that one quasispecies of the virus can become more dominant than the original strain. There was a chart of one patient with 20 different quasispecies! Alter believes host response is very important. He also mentioned that some people clear both the virus and the antibodies.

“Manage the Disease, or It's Going to Manage You,” by Mary Giudici, Colina Yim and Vikki Boddy, was geared toward patients. Giudici, a nutritionist, focussed on balancing proteins and calories, and on keeping the immune system strong through proper nourishment. She discussed brain fog and good bowel functioning. She reminded us that obesity may be related to fibrosis, of the dangers of alcohol, raw seafood, and aflatoxins, and stressed the importance of Vitamin E, snacking, and consulting with a dietician.

Colina Yim focused on fatigue-management: getting out more, getting enough sleep, and using a daily journal to record when we feel good, to take advantage of those hours. She stressed that exercise is important, and more beneficial if done in a natural setting.

“Transmission of Hepatitis C,” with Patty Daly, MD, and Bernard Willems, MD, focused on how and where the disease is spread, needle-sharing

being the principal culprit. According to both doctors, surprisingly, infection rates are rising in spite of needle exchange programs. The solutions suggested were: i) use of substance alternatives, ii) making people feel responsible, iii) targeting youth, iv) distribution of cotton and spoons, and v) a vaccine. Other routes of infection were examined, as was prevention.

“Living with Hepatitis C: Legal and Ethical Issues Affecting Human Rights,” by Ralph Jurgens, discussed prison issues, access to care, treatment and support, discrimination, drug laws, testing and confidentiality, poverty, income benefits, immigration issues, legal and ethical issues, informed consent for clinical trials, drug approvals, “off label” use of drugs, income maintenance, insurance, PharmaCare and medical marijuana.

“Treatment Options and Issues,” by Jenny Heathcote, MD, extolled the future virtues of pegylated interferon combined with ribavirin, reminding us that we have three options: Prevent progression, treat, and/or wait.

“Co-infections: Which One To Treat First,” comprised a panel of four speakers, who compared the HCV and HIV and their individual treatments, and came to the conclusion that, since HIV patients are living longer, the more severe cases need treatment for hepatitis C. According to Dr. Walmsley, if the immune system is restored, HIV viral load is good and it can't be treated, then hepatitis C should be treated first. However, if CD4 levels are low, it's best to treat the HIV first. “We NEVER start by treating both infections simultaneously,” she stated. While some of the drugs help each other, others are antagonistic, and the Hep C drugs may harm the immune system, while the HIV drugs can hurt the liver. In the question period, Dr. Peltekian recommended that those who relapse get a repeat biopsy in 1-2 years, and that should the grading/staging be the same, these persons should consider more treatment. If the grading/staging has improved, he recommends waiting for a better treatment to come along.

In her talk, subtitled **“Guinea Pigs Unite,”**

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Canada

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which I could definitely relate to, Robyn Sussel from the HIV Clinical Trials Network discussed all aspects of clinical trials and informed consent, and urged us to request more research (Activist materials: www.hivnet.ubc.ca/ctn.html). At the same time, a talk was being given on pediatric issues, the first of its kind at a hepatitis conference. Fibrosis occurs in 50-70% of infected children 8 to 15 years old, and children have a better response rate and less side effects to treatment than adults.

“Prevention,” by Eugene Oscapella, LL.B., focussed on both the decriminalization of drugs, and the lack of prevention in prisons, asking, “Could we have designed a better way to spread infection?” His policy is “Legalize, control, discourage.”

“Future Therapies and Vaccine Development,” by Dr. Frank Anderson, was a very technical talk on patient and disease variables involved in treatment, and on current and future treatments, such as the protein-based inhibitors, ribozyme and anti-sense-based therapies, and inhibitory cytokine therapies.

“Liver Transplant” made it very clear that we must take care of our livers rather than depend on future transplantation. Waiting times are increasing. (If we doubled organ donations, there would be no wait.) The outcomes for people with hepatitis C are

similar, but not quite so good as for other liver-transplant patients in Canada. Treatment post-transplant was discussed, and the use of older organs, live donors, and splitting livers was mentioned. All HCV+ transplant patients remain infected. Many progress more rapidly than before. The normal 5-year survival rate is acceptable, and post-transplant treatment is “sub-optimal.”

“Canadian Viral Hepatitis Network,” by Dr. Morris Sherman, outlined the new non-profit organization funded and set up by Health Canada, whose projects include a national database, serum and tissue bank, a physician-mentoring program, a nurse/practitioner program, and a virtual research center. It hopes to include a role for community groups in the near future

Finally, in **“Extra-Hepatic Manifestations,”** Dr. Kelly Kaita gave us a long list of diseases outside the liver triggered by HCV. She focussed primarily on cryoglobulinemia (MEC) and its symptoms and treatments (mostly interferon). She also touched on diabetes type 2.

I am truly grateful for the opportunity that I had to attend this conference. Let us hope that something good will come out of it.

Conference reports will soon be available.

Website: www.hepcbc.org

Europe

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study was designed to examine the efficacy, safety and optimal dose of histamine in combination with interferon. The authors noted that this study suggests that Ceplene may improve the efficacy of interferon therapy for chronic hepatitis C. Only end of treatment response rates were reported. The sustained response rates will be released soon.

GENOTYPE AND DISEASE PROGRESSION

It has been well documented that genotype 1 is the most difficult to treat with medications currently available. However, two small studies presented at EASL reported that genotype 1 may have less aggressive disease progression than genotypes 2 and 3.

In a study by I.K Delladetsima, et al., the relation-

ship of HCV genotypes and viral load with hepatitis severity and liver tissue damage were studied.

406 patients were biopsied - 243 males, 163 females, median age 42.4 (13.8). Adjusting for age the authors reported that genotypes 2 and 3 are associated with more severe hepatitis activity.

P. Marcellin et. al, reported on a study of 110 patients with mild fibrosis reported on the first liver biopsy. A second liver biopsy was performed 3 years after the first biopsy. Progression of fibrosis was analyzed according to gender, age, alcohol consumption, duration of disease and grade of activity. The authors concluded that patients with chronic hepatitis C with mild or absent fibrosis on first liver biopsy, progression to fibrosis is more rapid in patients with genotype 2 or 3 than in patients with genotype 1.

The Importance of Drinking Water

By Alan Franciscus
Editor, HCV Advocate

We've all been told that it is essential for proper health maintenance to drink at least 8 glasses of water (8 oz. each glass) every day.

This is especially true for those of us with hepatitis C and, if you are on treatment with interferon and ribavirin, it is even more important to drink plenty of water.

In fact, you should try to drink as much water as possible even if you are not thirsty. This will help with the many potentially nasty side effects that may be experienced while on treatment.

The exception to this rule is the person who has ascites (accumulation of fluid in the abdominal cavity) in which case a medical professional will instruct you on the correct diet and fluid intake.

Drinking at least 8 glasses of water can be a problem, but it is not as hard as it appears. Many people fill containers with filtered water so they can track the exact amount of water they drink daily.

Frequently, I buy bottled water to take with me when I am on the go. I refill these bottles with filtered water every morning to keep track of the amount I consume daily.

Remember, you are going to have to urinate much more frequently and want to make sure you are near a restroom. If you know that you will not have easy access to a bathroom, you may want to stop drinking an hour or so before an outing.

Even with these obstacles, you will find that the health benefits of drinking large amounts of water greatly outweigh the inconvenience and the frequent runs to the restroom.

Some of the health benefits of drinking adequate amounts of water include:

- * **Weight loss - suppresses appetite and metabolizes stored fat.**
- * **Digestion - improves the digestive process and can relieve or prevent constipation**
- * **Dry Skin - moisturizes the skin**
- * **Body wastes and toxins - rids the body of wastes and toxins**
- * **Body temperature - regulates body tempera-**

ture to keep you cool in hot temperatures

* **Nutrients - water contains many essential nutrients**

* **Joints - lubricates and cushions joints**

* **Cancer - helps with preventing some cancers, such as colon and liver cancer**

Remember to consume water instead of coffee or colas that contains caffeine. Beverages that contain caffeine deplete body fluids. In order to replace these lost fluids, you must drink two glasses (16 oz) of water for every glass (8 oz) of a beverage that contains caffeine. Additionally, make sure you check the content of the water - you should stay away from any water that contains sodium.

So take that plunge - drink WATER!

Treatment Advocate

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I'VE TESTED HCV-RNA NEGATIVE FOR MORE THAN A YEAR, WHY AM I STILL DOING THIS?

Treatment worked for me. I had the right genotype and I've been HCV-RNA negative for a while now. Does that mean I still don't have Hep C? I don't think so. Who knows? All of this is too new for us to know what will happen to me next. I believe that I'll always have Hep C and I'll always need to keep up with the latest medical knowledge about Hep C. Are you negative? What do you think? Please drop me a line, negative or not and let me know what you think.

E-mail me at joesha@yahoo.com or write to the PO Box on page 4. I'd like to hear from you.

Joe Shaw was diagnosed with HCV in January 1998 and lives with his partner and his two pugs, Willie and Sammie in Long Beach, CA.

Support Groups

Northern California

San Rafael

Paul Coss (415) 883-8193

Redwood City

For Info Call: (650) 367-5998

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For Info Call: CHRC (415) 923-3155

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Santa Maria

Kathy Lustig (805) 692-2860

Ojai

Kathy Lustig (805) 692-2860

Pegasys

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“We hope that (a delay) is not going to happen. This depends on the quality of the questions. Our experts are looking into this now,” a Roche spokesman said.

“I would not say there is an immediate delay to the whole thing. This cannot be completely ruled out, but there is not an immediate indication for that,” he added.

Financial analysts say Roche’s biggest challenge is gaining approval for Pegasys in combination with ribavirin, because pegylated interferon with ribavirin will soon be the standard treatment for HCV. Roche rival in the pegylated interferon market, Schering Plough, is on fast track approval for their combination treatment.

Schering is also been rumored to be an acquisition target for the much bigger Roche.

SOURCE: Reuters

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California Pacific Medical Center
Linda Brooks (415) 202-1504 or (415) 202-1506
San Francisco General Hospital
Athiana (415) 206-3725
Stanford University Hospital
Stanford Liver Research Clinic (650) 724-7057
Quest Medical Research
Dr. Jay Lalezari (HIV/HCV Co-infection trials)
(415) 353-0800
East Bay Liver Clinic
Oakland, CA 94609
Contact: Grant Young - 510/208-1777

Dr. John J. Jolley - San Rafael
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