

## FDA Approves Pegasys plus Copegus for HIV/HCV Patients



Alan Franciscus, Editor-in-Chief

Roche announced on February 25th, 2005 that the U.S. Food and Drug Administration (FDA) approved Pegasys (peginterferon alfa-2A) and Copegus (ribavirin) for the treatment of chronic hepatitis C in people coinfecting with hepatitis C. The new indication is the first and only therapy approved by the FDA to treat hepatitis C in people coinfecting with HIV and hepatitis C. In addition, the study results based on the clinical trial data submitted to the FDA for approval reported a significant improvement in sustained virological response rates (SVR-undetectable HCV

RNA viral load during and six months following the completion of therapy) when compared to the combination of standard interferon plus ribavirin.

### WHY IS THIS APPROVAL IMPORTANT?

It is estimated that there are approximately 300,000 people in the United States who are coinfecting with HIV and hepatitis C. The need and urgency for treating HIV/HCV coinfecting people is greater than for those who are mono-infected with hepatitis C because HCV disease

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progression rate is much faster – the risk of progression to cirrhosis is doubled. In addition, successful treatment of hepatitis C improves liver health and functioning which should reduce the risk of potential liver toxicities caused by HIV medications.

FDA approval should also help with the comfort level of physicians treating hepatitis C in their coinfecting patients since there is now solid data and FDA approval for treatment of hepatitis C in the HIV/HCV coinfecting population.

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**Sustained Virologic Response in Patients with Chronic Hepatitis C Coinfecting with HIV**

	Roferon – A plus Copegus 800 mg 289 pts (SVR)	Pegasys plus Placebo 289 pts (SVR)	Pegasys plus Copegus 800 mg 290 pts (SVR)
All patients	33 pts (11%)	58 pts (20%)	116 pts (40%)
Genotype 1	12 out of 171 pts (7%)	24 out of 175 pts (14%)	51 out of 176 pts (29%)
Genotypes 2, 3	18 out of 89 pts (20%)	32 out of 90 pts (36%)	59 out of 95 pts (62%)

*Pegasys plus Copegus vs. Pegasys; Pegasys plus Copegus vs. Roferon-A plus Copegus p-value < 0.0001 (Cochran-Mantel-Haenszel).*

# Combating HCV Fatigue



Alan Franciscus, Editor-in-Chief  
and Fran Carey

**ONE OF THE MOST VIVID** memories I have from running a support group is of a woman who came to one of our support group meetings complaining of fatigue and depression. When we started our check-in, she expressed her frustration with the increased bouts of fatigue and the effect they were having on her life. This person's story is not that much different from others who suffer from fatigue, but I think that she was able to verbalize what many of us go through when we are fatigued. She is a single parent of two children. In order to put food on the table for her family and a roof over their heads, she is required to work long days and devote all of her precious energy to work. In the evening when she came home from work she would basically collapse in front of the TV and would be unable to perform many of the functions needed to care for herself and her children. She became isolated and started to become depressed. In addition, she was unable to spend the necessary time to cook nutritious meals for herself and her children. The thought of exercise never occurred to her because she was so tired all of the time. For this person, life became a downward spiral and she saw no way out. Luckily, she came to a support group. Throughout the evening we were able to give her words of encouragement – she was not alone. We were also able to help her develop strategies to combat her fatigue. It was one of those incredible support group moments when

you can start to see a ray of hope in someone's eye.

One of the most common symptoms that people with hepatitis C experience is fatigue. In fact, in one study 67% of people living with hepatitis C reported fatigue as a symptom. Fatigue can range from mild to severe and can affect every area of life. Fatigue is a difficult symptom to quantify since it affects everyone differently. Some people with hepatitis C have constant fatigue while others may have fatigue cycles – sometimes they feel energetic and at other times they may feel so tired that they might not be able to perform basic daily functions, such as going to work, cleaning the house or joining in on social events.

It is important to keep in mind that when living with a chronic illness such as hepatitis C, energy management should be a top priority. When we push ourselves beyond our physical capacity, good judgment declines and accidents occur more frequently. In addition, when fatigue sets in, it is easy to become depressed or anxious about the future.

One of the most important strategies HCV positive people can adopt is to pace themselves and focus on techniques that may decrease the time spent doing certain activities and increase the amount of rest. As well, activities should be prioritized according to their importance. If the house needs to be cleaned but you have a dinner date that evening, think about saving your energy for the evening and

doing the house cleaning later in the week. You don't want to sacrifice needless energy at the expense of more important areas that will provide more of a balance in your life.

## CAUSES OF FATIGUE

Fatigue can be caused by many factors including depression, anemia, poor diet, and lack of exercise, or by more serious ailments. It is important to talk with your medical provider if you are constantly fatigued. If you feel too tired to get out of bed for more than 24 hours or if you feel confused, dizzy, or have a problem waking up you should notify your health care provider as soon as possible.

## MEDICAL TREATMENT FOR FATIGUE

There are no approved medications to treat HCV-related fatigue, but some physicians are experimenting with a variety of drugs including Ritalin and Provigil. However, there is concern about the potential for abuse of these drugs – especially Ritalin since it is known to exacerbate substance use disorders. Studies are needed to determine the safety and effectiveness of these drugs in HCV positive individuals before they are used to treat HCV-related fatigue.

## REST WHEN TIRED

It is important to rest when you get tired or when you have time. Taking short naps or rest

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# HealthWise:

## Oh Where, Oh Where Did I Leave My Whatcha-Ma-Callit?



Lucinda K. Porter, RN, CCRC

*Have you ever misplaced something, searched for the item and in the middle of the search, forgot what you are looking for? If so, welcome to the club. Misplacing objects, forgetting things, occasionally driving and realizing you forgot where you were headed, and putting the milk in the cupboard, are common and frustrating experiences. These occurrences become more frequent as we age.*

If you are the type of person who has been blessed with a good memory, this change can be extremely disconcerting. The “A” word leaps to mind (Alzheimer’s), followed by other worst fears, such as brain tumors, strokes, and various neurological impairments. For those with hepatitis C virus infection (HCV) memory changes can raise additional fears, specifically brain fog and hepatic encephalopathy (HE). Brain fog is a non-medical term commonly used to describe a feeling of foginess that some people who have HCV seem to experience. You won’t find the term in a medical reference book yet many HCV patients report having brain fog. The glossary on the Hepatitis C Support Project’s web site defines brain fog as “mild mental confusion, memory loss, and/or lack of concentration and alertness.” At this point we don’t know what causes brain fog, but we do know that people can still function and have meaningful lives in spite of it.

We do understand what causes hepatic encephalopathy. In advanced liver disease the liver cannot properly metabolize and detoxify everything that passes through it, so toxic substances can accumulate in the blood. Ammonia is the most common of these, although other substances can also build up. Ammonia is toxic to the brain and central nervous system, a buildup of which can lead to impaired brain function, including changes in behavior and consciousness. There are successful treatments for HE, so anyone with these symptoms needs to be under medical care.

**Note:** *Anyone with moderate to severe HE should not drive and needs support in order to get help and manage their lives until treatment restores their ability to think more clearly.*

What was I saying? Oh, yes, I was talking about memory loss. With age, forgetfulness generally increases, while ability to concentrate decreases. This is true for everyone, not just those with HCV. Pay attention to your peers and you will notice that others are experiencing memory loss, particularly with name recall. A typical conversation while discussing a movie with my friends goes something like this: “It was a great movie and it had So and So in it. I can’t remember his name, but I know you will know exactly who I mean. He’s been in a lot of movies, but I can’t think of a single title right now. He starred in that movie opposite What’s Her Name.” If I am lucky, the other person may be able to fill in the blanks, but usually my friends are just as forgetful as I am.

The average adult brain is actually smaller than the liver, and, unless you are in the field of hepatology, just as important. It is made up of over 100 billion nerve cells. We used to think that the brain stopped developing when we were young, but we now know that we can continue to develop our minds at least into our 70’s and that there is no age limit on learning new things. We learn more slowly as we age. Comprehension and reaction times slow. Multi-tasking becomes more difficult as we grow older. Short-term memory suffers far more quickly than long-term memory. Remembering who the U.S. President was in 1970 but not being able to recall what one had for lunch that day is common for the aging brain.

In spite of all this reassurance, we still wonder if something is wrong. How do we know when to be

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## HEALTHWISE

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concerned? Here are some possible early indications of Alzheimer's or other cognitive abnormalities:

- Repeatedly asking the same question after it has been answered.
- Inability to complete familiar tasks.
- Increasingly showing poor judgment.
- Decline in the ability to think abstractly.
- Changes in personality and mood with no apparent cause.

In short, it is normal to forget how to add, but abnormal to be confused about the concept of numbers. It is alright to forget where you put your keys; forgetting what your keys do is cause for concern.

There are many treatable conditions that can cause cognitive impairment, so it is important to obtain a good medical evaluation before jumping to conclusions. Hearing loss, sleep problems, thyroid disease, psychiatric disorders, stress, vitamin deficiency, alcohol, and drugs are just a few factors that can have an impact on our ability to think, communicate, and function effectively. Always talk to your medical provider about changes in your health.

Just because memory decline is natural does not mean we can't help slow down the process. The brain is like a muscle in that if you don't use it you lose it. An active brain can grow new cells and work more effectively. Here are some ways to keep your brain healthy:

- Be physically active on a daily basis. A combination of stretching, strength training,

and aerobic activity is an ideal approach.

- Eat a nutritious diet. Fruits and vegetables, along with other high-value nutritional foods can provide nourishment for our brains. Do not skip meals.
- Drink enough water.
- Manage stress. Meditation and relaxation techniques can help us to think more clearly.
- Avoid alcohol and unhealthy substance use.
- Get sufficient sleep. The average adult needs 7 to 9 hours of sleep a night.
- Breathe. Oxygen is essential to our brains.
- Stay mentally active.

How do we stay mentally active? Here are some tips:

- Read more or listen to audio books.
- Do puzzles and brainteasers.
- Learn new things, particularly drawing or painting.
- Go to lectures, plays, museums, or concerts.
- Cut down or eliminate T.V. watching.
- Take up a musical instrument.
- Maintain social and family connections.
- Study a new language.
- Find a hobby.
- Play games.
- Learn to juggle.
- Take adult education classes.
- Learn to dance.
- Deliberately shake up your routine. Rearrange your furniture, drive a different route to familiar places, or wear your watch on your other wrist.

As for forgetfulness, there are techniques that can be used to help us improve our memory. Libraries usually have books on memory improvement. A few suggestions:

- Organize yourself.
- Create habits and routines.
- Write things down and keep your lists in the same place.
- Do one task at a time, rather than multi-tasking.
- Pay attention to what you want to remember.
- Visualize what you want to recall.
- Use repetition to fasten something into your memory bank.
- To remember long lists, create a story or connections between items.

You can use memory devices, also called mnemonics to aid memory. A classic mnemonic is "My Very Educated Mother Just Served Us Nine Pickles" (the first letter of each word is also the first letter of the planets in our solar system – Mercury, Venus, Earth, etc) or "Thirty days has September, April, June, and November. When short February's done, all the rest have 31" (used to remember how many days are in each month).

Various supplements are being tested for memory enhancement capabilities. Ginkgo biloba, choline, lecithin and vitamins B, C, E are probably the most well-known; however, there is still nothing conclusive about choline, lecithin, or vitamins B and C. The research on vitamin E has only been conducted on dementia patients and more research needs to be done before coming to any conclusions. Lemon balm is being researched for a number of properties, including memory enhancement. This herb can be infused as a tea. Steep 3 teaspoons of dried lemon balm leaves in 2 cups of boiled water for about

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# Coinfection News from the 2005 Retrovirus Conference



Liz Highleyman

*HIV/HCV coinfection was one of the top stories at last year's Conference on Retroviruses and Opportunistic Infections, as researchers announced long-awaited results from three major studies of hepatitis C treatment in HIV positive individuals. While coinfection did not grab the headlines at this year's Retrovirus conference, held February 22-25 in Boston, a wealth of new data was presented.*

*For the complete program and abstracts of the 12th Retrovirus conference see [www.retroconference.org/2005/pages/frames/ProgGlance.htm](http://www.retroconference.org/2005/pages/frames/ProgGlance.htm).*

## LIVER DISEASE PROGRESSION

Mark Sulkowski and colleagues (abstract 121) presented some of the clearest evidence to date that liver damage can progress surprisingly fast in HIV/HCV coinfecting individuals. The researchers followed 67 coinfecting subjects who received paired liver biopsies an average of two years apart; 86% were on anti-HIV therapy and 79% had CD4 cell counts above 200. More than one-quarter (28%) had fibrosis scores that increased by at least two stages from one biopsy to the next. Patients who experienced a two-stage or greater increase in fibrosis score were more likely to have higher HIV viral loads, but there was no significant association between rapid progression and the use of anti-HIV therapy or CD4 count. The researchers suggested that their data "do not support the application of current HCV treatment guidelines" – which state that people with minimal fibro-

sis generally can defer therapy – to coinfecting individuals, and recommended that "such patients should be closely monitored for liver disease progression."

Sherri Stuver and colleagues (abstract 947) looked at liver disease progression in a cohort of 231 HIV/HCV coinfecting injection drug users. About 10% (22 subjects) experienced "liver-related events," defined as clinical progression of, or death from, liver disease, at a rate of 5.1 per 100 person-years. In a multivariate analysis, having a nadir (lowest ever) CD4 count below 200 – and especially below 100 – was significantly associated with such events. However, subjects on highly active antiretroviral therapy (HAART) who achieved HIV viral loads below 75 copies had a decreased risk of liver disease progression or death.

It is not clear why coinfection is associated with more aggressive hepatitis C. Valerie Dutoit and colleagues from Switzerland (abstract 119) analyzed HCV-specific CD4 and CD8 T-cell activity in 28 coinfecting patients (most with early-stage HIV disease) and 47 subjects with hepatitis C alone. They found that while a similar proportion in both groups – about 40% – demonstrated HCV-specific T-cell responses, the range of T-cell activity against HCV antigens was narrower in the coinfecting subjects. In addition, while CD8 responses were predominant in the coinfecting patients, CD4 activity predominated in those with HCV alone.

## ADVANCED LIVER DISEASE

Having HIV also appears to have a negative impact on coinfecting individuals who have already progressed to advanced liver disease. Jose Garcia-Garcia and colleagues from Spain (abstract 948) compared the survival times of 180 HIV positive and 1,037 HIV negative hepatitis C patients with decompensated cirrhosis. During the follow-up period, 56% of the coinfecting subjects died, compared to 37% of those with HCV alone. The median survival times were 16 months for the coinfecting patients and 48 months for those with HCV alone. The authors concluded that coinfection "considerably reduces the survival of patients with HCV-related liver cirrhosis after the first hepatic decompensation," and suggested that this should be taken into account when considering coinfecting individuals for liver transplantation.

HIV also accelerates hepatitis B disease progression. Looking at data from 668 subjects with HBV, 196 of whom also had HIV, Yves Benhamou and colleagues (abstract 933) reported that decompensated cirrhosis was seen in 15.9% of the coinfecting patients, compared to 7.2% of those with hepatitis B alone. "HIV coinfection significantly increases the risk of liver decompensation among HBsAg carriers," the authors concluded, suggesting that HBV/HIV coinfecting patients should consider drugs with dual activity against both viruses.

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## FATIGUE

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periods during the day helps most people. Try not to sleep too much during the day because this could affect how well you sleep at night. Also, too much rest may make you even more tired so try to find a balance. Many people report that even just taking a few minutes to close down, meditate, pray, listen to music, reading or thinking about a happy or positive experience revitalizes them within a very short period of time. If you are having trouble sleeping or experience insomnia for more than a few days, talk to your medical provider about medicines to help you sleep.

## PLAN ACTIVITY AND REST

Make a plan for the day, week, and month. Try to alternate activities so that you can balance the more difficult activities with the lighter activities. People normally have certain times during the day or night when they have more energy. Save the more difficult tasks for when you are more likely to have the energy to perform them. Alternate the difficult with the easy tasks. Many people with hepatitis C and other chronic illnesses report that they have more energy in the evening. However, be careful that you don't overdo it or stay up too late since this can affect how well you sleep in the evening and how you will feel the next day.

## BREATHE

Incorrect breathing can lead to fatigue. When people are stressed out or fatigued they have a tendency to hold their breath. Try deep breathing exercises and concentrate on how the air goes in and out of your body.

## MASSAGE

People report that massage helps to improve their energy and general wellbeing. Try massage that uses techniques to encourage lymphatic flow and regain energy.

## ACUPUNCTURE

Acupuncture is based on the idea that "qi" flows through the body in channels called meridians; each organ system has a set of channels. Acupuncture has been found to be helpful in relieving pain, overcoming addictions and in decreasing fatigue.

## EXERCISE

It may seem counterintuitive, but regular exercise is one of the best strategies for combating fatigue. Try to stay as active as possible but don't overdo it. Exercise comes in many forms and walking is one of the best exercises for relieving fatigue. Other forms of exercise include Pilates, yoga, swimming, light weight resistance or any other activity that will reenergize, but do not exercise to the point of becoming overly fatigued. Listen to your body and let it guide you. Start slowly with a 2- or 3-minute walk and work your way up to 30 minutes of activity 5 days a week. It is also recommended that you check-in with your healthcare provider or an exercise physiologist to determine what level of activity is right for you.

## DIET

A healthy and nutritious diet based on the recommendations from health experts includes finding a balance between the quantities of food you eat with the amount of energy expended. Try to stay away from foods that are high in fat, sugar and sodium. Eat larger portions of fruits and vegetables and drink plenty of water. If

possible, consult with a registered dietician or nutritionist.

## VITAMINS & NUTRITIONAL SUPPLEMENT

A well-balanced diet should contain all the essential vitamins and minerals you need, but some people also take vitamin supplements. Taking a megavitamin supplement may be harmful to the liver. Instead choose a multi-vitamin supplement *without iron* that meets the daily requirements.

## IS IT IMPORTANT?

Ask yourself –is this task really necessary? Will the benefit outweigh the chance that you will become overly fatigued? There are many alternatives to common chores, such as to allow dishes to drip dry, to buy permanent press or fabrics that need little attention beyond laundering, and to use frozen or pre-cut vegetables instead of peeling and cutting.

## ASK FOR HELP

Don't be afraid to ask for help from family members or friends. Many times people are willing to help but may not want to interfere with your life. It never hurts to ask for help and you might be surprised to find that your family and friends will be more than happy to help you out. However, you may need to set limits so that it doesn't turn into a social exercise that could deplete your energy even more. If you have the resources available, it might be worth considering using a laundry or house cleaning service. *The key is to simplify when possible.*

## EDUCATE FAMILY AND FRIENDS

Talk to your friends about what it means for you to be fatigued.

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**HEALTHWISE**

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5 minutes. Strain the leaves out before drinking. Add honey if you like.

There is not much research on Ginkgo biloba, but what does exist is somewhat encouraging. If you want to try Ginkgo biloba, talk to your doctor. A typical adult dosage for memory enhancement is 80 mg 3 times daily of 50:1 standardized leaf extract. Ginkgo seeds are toxic and can be fatal if swallowed. Pregnant and nursing mothers and children should not take Ginkgo. Patients on current treatment for HCV or those with cirrhosis should also refrain from taking herbs. Common adverse reactions to Ginkgo are headache, dizziness, flatulence, upset stomach, heart palpitations, rash and allergic reactions. Seizures and bleeding problems have been reported but are rare. Discontinue Ginkgo and all supplements a week prior to any medical procedure. The following drug interactions have been noted: Trazodone, Monoamine oxidase inhibitors; Anticoagulants / Antiplatelets; Insulin; Antipsychotics / Prochlorperazine; Cytochrome P450. Ginkgo may alter coagulation lab tests.

If you are forgetful, go easy on yourself. However, if you forget an anniversary or a loved one's birthday they will probably scold you. Stay positive and maintain a sense of humor. Remember being happy is much more important than remembering where you put your keys.

In April I usually try to write a humorous column in honor of April Fool's Day. This year I will end with two jokes.

An old man visits his doctor and after a thorough examination, the doctor tells him, "I have good news and bad news, what would you like to hear first?"

Patient: Well, give me the bad news first.

Doctor: You have cancer; I estimate that you have about two years left.

Patient: OH NO! That's awful! In two years, my life will be over! What kind of good news could you probably tell me, after this???

Doctor: You also have Alzheimer's. In about three months you are going to forget everything I told you.

(From [http://www.angelfire.com/md3/medical\\_humor](http://www.angelfire.com/md3/medical_humor))

A distraught man ran into the doctor's office.

"Doc!" The man screamed, "I've lost my memory!"

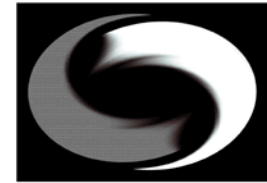
"When did this happen?" asked the doctor.

The man looked at him and said, "When did what happen?"

(From <http://swcbc.org/medical.html>)

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## FATIGUE

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Tell them that at times you may not be able to participate in social functions or that you may need to leave early because of fatigue. Learn to say “no” to family and friends who have unrealistic expectations of your energy level.

## ORGANIZE

Staying organized is sometimes difficult, but it is the key for putting to use the limited energy one has. Have organized work centers, with all supplies for each task stored together:

- Keep all of the dry ingredients together including the mixing bowls; keep measuring tools together.
- Put all of the cleaning supplies in a pail.
- Store the can opener in the cupboard with the canned goods.
- Store pots & pans near the stove.
- Keep items within easy reach.
- Avoid bending & reaching.
- Eliminate unnecessary clutter.
- Utilize organizing equipment such as revolving shelves, stacking bins, lazy-susans, etc.
- Use wheels to transport: laundry cart, grocery basket, kitchen cart – to convey equipment & supplies in one trip. Load the cart with all the goods needed to set the table in one trip rather than several.
- Use a wagon to transport groceries from car to the house, a cart to transport the laundry, foods from the fridge to the counter, etc.

There are a lot of strategies that can help conserve energy and reduce the likelihood of fatigue induced injuries.

### Try some of these simple tips:

- Sit whenever possible. Use a tall stool at the sink to wash & prepare food, use an adjustable ironing board as a work surface to sit at, wipe down the bathtub while still sitting in it, or use a shower stool and hand held shower for bathing.
- Bathe before going to bed rather than in the morning. It takes less energy to put on nightwear since there is much less of it and you will have less to attend to in the morning. Always sit down while dressing and undressing.
- Use good posture and comfortable work heights. While standing, the working surface should be between waist & hips, while sitting, the surface should be no more than 3 inches below your elbows. Don't work at a low counter that causes you to bend over it. If the kitchen sink is low, place a pan under the dishpan to raise it closer to you.
- Stand & sit with spine erect.
- While you are working avoid stretching & bending. Keep most commonly used items within easy reach. Have long handles on the dustpan, bath brush, and use tongs to reach for something on the floor.
- Work in a well-lighted environment that is at a comfortable temperature and has good ventilation. Wear supportive and comfortable shoes.
- Use both hands for activities: setting the table, dusting, holding pots.
- Avoid stress and rushing. Frustration and irritation increase fatigue. Pace yourself; rushing leads to mistakes and accidents which then require extra energy to clean up or resolve, not to mention the potential for injury.

Flare-ups of symptoms including fatigue are a common experience for people with HCV, which

can drastically reduce your energy level and quality of life. Prepare for these times by storing dried, canned and frozen foods/meals available for the times when you are not able to get to the store. Keep healthy snacks around the house and remember to eat small frequent healthy meals. Skip unimportant tasks until a better time.

One of the most important strategies is to listen to your body. It is important that you allow yourself to rest – pushing yourself unnecessarily could prolong your “flare-up” and make you feel worse. We all know that fatigue can cause depression and anxiety. Be prepared to indulge yourself in enjoyable activities that require little energy, such as meditating, reading, watching a video, knitting, etc.

It is ‘ok’ to recognize that you are depressed. It is not healthy to put a positive spin on everything. Talk to family and friends – a friendly ear can help with anxiety and depression. Talk to professionals and seek guidance. Consider antidepressants – they can help with depression and energy. One of the most important strategies people living with hepatitis C can adopt for themselves is to join a support group.

Everyone experiences physical, mental and emotional changes throughout their lives and must adapt accordingly in order to safely maintain their ability to function. By practicing some of the above techniques you will reduce your risk for injuries and conserve your energy for the things in life that are most important to you.

### Sources:

- Arthritis Foundation website:  
<http://www.arthritis.org>
- American Occupational Therapy Association – website:  
<http://www.aota.org>



## FDA APPROVAL

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### PEGASYS MEDICATION GUIDE

The FDA approval of Pegasys plus Copegus is based on the results from the APRICOT trial that was conducted in over 19 countries including the United States. The study was a randomized, partially blinded study with three arms or study groups. This article will report on the information obtained from the FDA approved Pegasys plus Copegus medication guide.

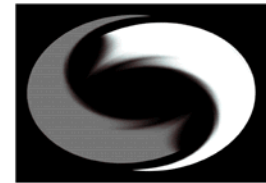
The patients in this trial were randomized to receive standard interferon (interferon alfa-2a-Roferon-A) three times a week plus ribavirin 800 mg/day, or 180 mcg of Pegasys once weekly plus placebo, or 180 mcg of Pegasys once weekly with 800 mg/day of Copegus (ribavirin). It is important to note that the dose of ribavirin in both combination arms was 800 mg/day which is lower than the usual or standard dose used to treat people monoinfected with hepatitis C, genotype 1. This was due to concerns of possible increased anemia in HIV patients. Hopefully, future clinical trials will focus on increasing the ribavirin dose since it is widely believed that by increasing the ribavirin dose (to that of the standard dose used to treat HCV mono-infected patients) the SVR will be higher in the coinfection population when treated with pegylated interferon plus ribavirin.

Eight hundred and sixty-eight adults were enrolled in this clinical trial. All trial participants had compensated liver disease, detectable hepatitis C virus, liver biopsy diagnosis of chronic hepatitis C and were previously untreated with interferon. In addition, patients also had a CD4 +

cell count of greater than or equal to 200 cells/ $\mu$ L or a CD4 + cell count of greater than or equal to 100 cells/ $\mu$ L but less than 200 cells/ $\mu$ L and HIV-1-RNA less than 5000 copies/mL, and stable status of HIV. Approximately 15% of patients in the study had cirrhosis.

The side effect profile in this study and listed in the indication was generally similar to that shown for HCV monoinfected patients in clinical trials of Pegasys plus Copegus. The side effects occurring more frequently in the coinfection study were neutropenia (40%), anemia (14%) thrombocytopenia (8%), weight decrease (16%), and mood alteration (9%).

One aspect of treating hepatitis C in someone with HIV/HCV is the potential for drug interactions between the HCV medications and the HIV medications, and a couple of warnings are listed in the medication guide. It is **not** recommended that didanosine (ddI) be taken at the same time as Pegasys plus Copegus. It was also noted that zidovudine (AZT) when taken with Pegasys plus Copegus could produce severe neutropenia and severe anemia more frequently than in similar patients not receiving zidovudine (neutropenia 15% vs. 9%), (anemia 5% vs. 1%). There did not appear to be any pharmacokinetic or pharmacodynamic interactions (how a drug is processed by the body, with emphasis on the time required for absorption, duration of action, distribution in the body and method of excretion) when ribavirin was taken with lamivudine, stavudine, and/or zidovudine.



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The HCV Advocate offers information about various forms of intervention in order to serve our community. 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.

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## RETRO CONFERENCE

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### LIVER TRANSPLANTATION

Fortunately for those with advanced disease, research increasingly shows that HIV positive patients can achieve liver transplant outcomes nearly as good as those seen in their HIV negative counterparts. Researchers from Bonn, Germany (abstract 931) reported that six out of seven HIV positive patients with either HBV or HCV were still alive a median of 432 days after liver transplantation. Post-operative complications were generally similar to those seen in HIV negative transplant recipients, but dose adjustment of cyclosporine (an immunosuppressive drug used to prevent rejection) was needed due to interaction with anti-HIV protease inhibitors. HCV recurred in all patients with preexisting hepatitis C. Similarly, Michele Roland and colleagues (abstract 953) reported on 1-3 year liver and kidney transplant outcomes in HIV positive recipients. From March 2000 through November 2003, 11 patients received livers and 18 received kidneys; six liver and five kidney recipients had hepatitis C. Three deaths occurred, two due to recurrent HCV and one due to heart failure. The estimated 1-year survival rates were 94% for kidney and 91% for liver recipients, with 2-year survival decreasing to 80% for liver recipients. CD4 cell counts did not change significantly, and all but one surviving patient had undetectable HIV viral loads after their transplant.

### STEATOSIS, INSULIN RESISTANCE, AND DIABETES

Research continues to accumulate on the link between hepatitis C and metabolic problems including steatosis (fatty liver), insulin

resistance, and diabetes. Patients with HIV are likely at greater risk because HAART can contribute to these conditions. Alison Uriel and colleagues (abstract 925) looked at 96 HIV/HCV coinfecting subjects (83% on HAART, 70% with undetectable HIV viral load) being retreated with pegylated interferon plus ribavirin. They found that 55% had hepatic steatosis (24% moderate to severe). About half (52%) had insulin resistance, and this was associated with steatosis and more advanced fibrosis. However, use of specific anti-HIV drugs (protease inhibitors or d4T) did not predict steatosis. Furthermore, insulin resistance was associated with a lower early virological response rate. The authors recommended further study to determine whether correction of insulin resistance and steatosis might improve treatment response. In another study (abstract 952), Shruti Mehta and colleagues found “a strong relationship” between steatosis, fibrosis, and hyperglycemia (high blood sugar).

In contrast to Uriel’s team, Barbara McGovern and colleagues (abstract 950) found that patients who had been exposed to nucleoside reverse transcriptase inhibitor (NRTI) drugs, and in particular those who used dideoxynucleosides – d4T (stavudine, Zerit), ddI (didanosine, Videx), and ddC (zalcitabine, Hivid) – were at higher risk for steatosis. They suggested that this effect might be due to the NRTIs’ “deleterious effects on mitochondria and oxidative phosphorylation.”

### RIBAVIRIN LEVELS

Some past research, including study ACTG 5071 reported at last year’s Retrovirus conference, has suggested that ribavirin helps improve response rates and prevent HCV relapse following interferon-based therapy. Dominique Breilh

from Bordeaux, France and colleagues (abstract 928) looked at the relationship between plasma ribavirin concentration and sustained response in 30 HIV/HCV coinfecting subjects receiving Pegasys plus 800-1200 mg daily ribavirin for 48 weeks. They found that the chances of sustained virological response (SVR) improved significantly with higher steady-state ribavirin levels (above 1.0 mcg/mL). Likewise, Ana Rendón and colleagues from Madrid (abstract 929) studied 98 coinfecting subjects treated with the same regimen. Although all subjects received similar ribavirin doses, plasma concentrations varied widely from person to person. However, plasma levels remained steady over time in a given patient. Early virological response (at least a 2 log drop in HCV viral load by week 12) was associated with higher than average ribavirin levels (above 2.70 mcg/mL). Not surprisingly, higher ribavirin doses were also associated with worse anemia. Data from these two studies confirm ribavirin’s importance in HCV therapy, and suggest that drug-level monitoring and aggressive management of anemia might help patients achieve optimal ribavirin dosing. In a related study, Daniel Alvarez and colleagues (abstract 927) found that coinfecting patients taking AZT (zidovudine, Retrovir) experienced worse ribavirin-related anemia (greater drops in hemoglobin level) and were more likely to need erythropoietin (EPO) compared to patients not on AZT.

### SEXUAL TRANSMISSION OF HCV

While most studies show very low rates of sexual transmission of HCV within monogamous heterosexual couples, the picture remains less clear for men who have sex

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with men. Over the past year several new HCV infections among gay and bisexual men in the U.K. and France have been potentially linked to sex. Marie-Laure Claire and colleagues from Necker Hospital in Paris presented data on a cluster of 12 HIV positive men diagnosed with acute hepatitis C, indicating recent infection (abstract 122). In this cohort, male-to-male sex was “the only significant risk factor” reported. A cluster of 10 out of the 12 had genotype 4d (which is unusual France, as it is in the U.S.), suggesting a common source of infection. In a related study, A. Rauch and colleagues (abstract 943) studied 1,347 heterosexual subjects and 1,542 gay/bisexual men in the Swiss HIV Cohort; these initially

HCV negative participants, none of whom reported injection drug use, received HCV testing every two years. Fourteen gay/bisexual men seroconverted, compared with eight heterosexuals. The HCV incidence rate was 0.2 per 100 person-years in the heterosexual group and the same for gay/bisexuals who did not report unprotected sex. Among gay/bisexual men who did report unprotected sex, however, the rate was 0.7 per 100 person-years. The researchers concluded that while the overall incidence of HCV infection is low among HIV positive persons who do not inject drugs, there appears to be an association between unsafe sex and HCV transmission among men who have sex with men.



The Hepatitis C Support Project has launched a new campaign to help bring about more awareness of hepatitis C with a red awareness bracelet. Embossed on the bracelet is “for living positively. being well.” To receive a bracelet just make a donation of \$10.00 or more. Proceeds from the bracelet will be used to develop a new web-based patient learning center. You can make a donation to the Hepatitis C Support Project by going to our web site [www.hcvadvocate.org](http://www.hcvadvocate.org) or you can use the form below.



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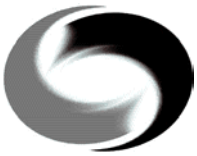
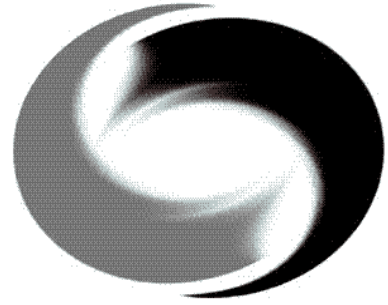
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