

## July 2000's Advocate:

### [New Drugs and Combination Therapies for Hepatitis C Reported at European Meeting](#)

First Reports on Consensus Interferon Plus Ribavirin, And New Data on Pegylated Interferon

### [Treatment Advocate: How Herbal Supplements are Processed Plays a Big Role in Their Safety](#)

This month's article focuses on standards that should be used to ensure the safety of herbal supplements

### [Healthwise: Lucinda Takes a Look Inside The Hep C Files](#)

This month's healthwise features a little bit of this and a little of that

### [Canadian Activists Work on 'Unbundling' of Ribavirin and Interferon](#)

In Canada, Hep C advocates take steps to have government review the bundling of Rebetron

### [Harm Reduction Measures for IV Drug Users](#)

In the real world, getting information about healthy drug injection practices to users can help reduce hepatitis C infection.

Book Review: The Hepatitis C Help Book

## **July 2000's Advocate:**

### **New Drugs and Combination Therapies for Hepatitis C Reported at European Meeting**

#### **First Reports on Consensus Interferon Plus Ribavirin, And New Data on Pegylated Interferon**

Studies on a variety of new treatments for chronic hepatitis C disease highlighted the recent meeting of the European Association for the Study of the Liver. The meeting, held April 30 to May 3 in Rotterdam, featured clinical trials using today's drugs in new combinations, as well as some new compounds.

Paul Pockros, M.D. of Scripps Clinic in La Jolla, California presented data showing that consensus interferon (Infergen, Amgen) combined with ribavirin is a promising option for treating chronic hepatitis C infection. While ribavirin is normally dispensed only "bundled" with interferon alfa-2B, the researchers took the ribavirin out of the package and tested it with consensus interferon. Daily dosing of the combination was as safe and well tolerated as consensus interferon alone.

Further studies on pegylated interferons came out at the meeting. These modified, longer-acting interferons are administered once a week. Christian Trepo, M.D. of Hopital Hotel Dieu in Lyon, France reported that pegylated interferon alfa-2B alone (PEG-Intron, Schering-Plough) is superior to standard interferon alfa-2B (Intron A, Schering-Plough).

Once a week doses of 1.0 or 1.5 mcg/kg body weight resulted in two-fold greater sustained viral responses compared to standard interferon for patients who had not previously been treated.

Another new drug being tested for hepatitis C is histamine (Maxamine, Maxim Pharmaceuticals), used in conjunction with interferon alfa-2B.

Preliminary results of a multicenter, multinational trial on this combination showed that histamine may significantly improve the efficacy of interferon therapy. Yoav Lurie, M.D. of the Kaplan Medical Center in Rehovot, Israel reported that after 12 weeks of therapy, histamine plus interferon gave virologic response rates about twice those seen with interferon alone. While histamine is one of the substances implicated in allergic reactions, Dr. Lurie said patients tolerated it very well with only minor side effects.

Two studies on amantadine in combination with interferon showed no benefit of amantadine. Even when ribavirin was added to the combination, there was no additional effect from amantadine.

Reports of these studies and several others from the EASL meeting will be available in July at on Med On Scene at [www.medonscene.com](http://www.medonscene.com). The site offers health professionals the opportunity to earn continuing medical, nursing, or pharmacy education credits by completing the educational activity in liver disease.

Source: Patient Treatment News

## July 2000's Advocate:

### How Herbal Supplements are Processed Plays a Big Role in Their Safety

You'd have to be a hermit and live in a cave to not have noticed the exponential growth of the herbal and dietary supplement industry.

Surveys show that more than 50 percent of the U.S. adult population uses dietary supplements and herbal products. In 1996, consumers spent more than \$6.5 billion on dietary supplements, according to a market research firm. Many people are using supplements as a replacement for conventional medicine.

But even though consumers seem to be embracing these products, many people still have questions about dietary supplements: Can they trust them to have the results advertised? Are they safe? Who determines if they're safe?

In 1994, Congress passed the Dietary Supplement Health and Education Act, or DSHEA, which set up a framework but not authorization for FDA regulation of dietary supplements. Questions still remain.

June McDermott, MS, Pharm and Thomas M. Motyka, DO, recently produced an in-depth report on the concerns about product quality and standardization of botanicals aimed at healthcare professionals. They also provide issues for healthcare providers to consider before recommending botanical products. Following is a paraphrased version of their report.

#### The Problem

The passage of DSHEA opened the floodgates to allow an array of herbal and nutritional supplements to enter the marketplace. These products do not require the approval of the Food and Drug Administration (FDA). Safety and efficacy prior to marketing are not guaranteed, and no outside monitoring of the identity or potency of the herbals is produced.

Reports of problems related to quality of herbal supplements can be found throughout the lay and professional literature. These reports fall into four categories:

- intentional addition of an active drug that is responsible for therapeutic or adverse effects;
- unintentional substitution of the herbal with a toxic species;
- environmental contamination of the herb with a chemical or pathogen;
- suboptimal or varying amounts of active ingredient within a formulation.

One final obvious problem, easily addressed, is labeling of botanical preparations. Labels often do not include proper dosing guidelines or warnings.

#### Factors Influencing the Pharmaceutical Quality of Botanical Preparations

##### Authenticity of Plant Species

The plant should be accurately identified using macroscopic and microscopic techniques. It should be referred to by its botanical Latin name. The use of common names can cause serious problems because the same name may be applied to several different plants.

##### Plant Part Used

The part of the plant (eg, flower, leaf, seeds, bark, root, rhizome) that is used for the preparation should be identified. Different plant parts contain different chemicals and concentrations of the chemicals leading to

varying pharmacological activities.

## Environmental Factors

Many factors play a role in the quality of chemicals found in the plant, including growing conditions such as soil, altitude, and climate.

## Harvesting and Storage Conditions

The level of chemical constituents in plant parts can vary during the growth cycle. The optimum harvest time must be determined individually. For example, ginsenosides from the root of the ginseng are concentrated in the fall, which is when harvesting occurs. Storage, temperature, light, and humidity will also influence the chemical profile.

## Contamination of Herbal Ingredients

Herbal products should be grown without exposure to pesticides, herbicides, toxic metals, and animal parts or excretions, fungi, and bacteria.

## Good Manufacturing Procedures

The quality of the final product is determined by the quality of the plant and the manufacturing procedures used in processing. Plant extracts are dependent on the solvent used, the extraction conditions, extraction time and temperature. Stability and expiration dating should be established. Lot numbers and test results should be logged.

## Standardization of Extracts

The pharmacologically active constituents have been identified and the manufacturer guarantees a specific quantity of these substances in the final product.

## Use of Whole Plants

Traditional medicine systems support the use of the whole plant or plant part and not just the extract of isolated chemicals. The use of products, containing whole plant parts instead of fillers and binders, and standardized to specific marker chemicals can guarantee quality from a traditional point of view.

## The Industry's Response

The nutritional supplement industry is responding to the need for standardized and safe products. The National Nutritional Foods Association (NNFA), the largest and oldest nonprofit trade association for the dietary supplement industry, has established a Good Manufacturing Practices (GMPs) Certification Program for its members. The program requires third-party inspections of the manufacturing facilities including specifications for testing raw and finished materials, equipment maintenance, recordkeeping, cleanliness and staff training. Meeting these standards will allow the manufacturer to use a seal on all product labels, ensuring the consumer of a quality product. Participation is required for all NNFA members supplying dietary supplements and will be phased in by the year 2002.

The Institute for Nutraceutical Advancement (INA) provides analytical services to the natural products industry. INA has developed a Methods Validation Program (MVP) designed to validate and distribute analytical methods for testing marker compounds in herbal products.

## Conclusions

Botanical products present challenges from a regulatory and safety perspective because plants contain a wide variety of potentially active constituents with synergistic potential and exhibit a broad range of chemical

profiles. There is potential for wide variations in quality and content.

In the absence of oversight from government, health professionals need to assess for themselves the quality of each botanical product before they can speak confidently about product quality and safety.

Unfortunately, despite recent industry attempts to self-regulate, there are no definitive standards by which to judge herbal supplements.

We recommend that all health professionals take some time to learn about the herbal products that their patients are taking. This may mean asking manufacturers about their quality control measures. Given the vast number of suppliers, this becomes difficult for busy clinicians. We look forward to progress toward better standards and a means of assuring safer use of botanical preparations.

## July 2000's Advocate:

### Lucinda Takes a Look Inside: The Hep C Files

A spectacular late spring day is just outside my window and my mind is distracted from writing. Some days I do not want to think about hepatitis C. It is evident to me that if I am going to meet my deadline for this article, I will have to get creative--in other words, cheat.

Every so often, I read a statistic or I hear something that inspires me. I make a note of these passing pieces of information and put them in a file for future articles I will write. This article is a collection of these odd notations, all thrown together into one pot.

#### Exercise

There are approximately 10,000 deaths annually due to complications from chronic hepatitis C infection. There are 250,000 number of deaths annually due to lack of exercise.

Are you among the 22 % of adults in the U.S. who exercises 30 minutes or more at least 5 times a week? If not, what are your obstacles? Many of us state we are too tired. However, we know that exercise promotes better sleep and can be a powerful remedy for fatigue. Not enough time? Did you know that 10 minutes of brisk walking or climbing stairs is nearly as beneficial as 30 minutes of continuous exercise?

Other helpful hints for the time-challenged include exercise first thing in the morning or schedule your exercise. If your major complaint about exercise is you find it boring, try the following: exercise with a friend, join a class, or find something you really like to do. Some suggestions are dancing, gardening, or walking in a scenic location. This is how I get myself to exercise: sheer courage to show up in spandex along with the gratitude for legs that move. (see last paragraph)

#### Herbs

Last month I wrote an article about supplements. Since that time, it came to my attention about products sold for treatment of diabetes under the labels of Sino America Health Products Inc. and Chinese Angel Health Products. These products are sold as Chinese herbal remedies, but were found to have dangerously high amounts of glyburide and phenformin (regulated substances).

The reason this caught my attention is because it is an example of why it is essential to buy your supplements from trustworthy sources. Chinese herbal recommendations should come from practitioners licensed by the state in which they practice. Their herbal recommendations should be U.S. pharmaceutical grade. Although alternatives are attractive, they are unregulated. Use good judgement before ingesting anything.

#### Organ Donation

There is a shortage of available livers needed for transplantation. This shortage is going to get worse as the need for organs increases. If we all start talking about this subject to our family, friends, co-workers, and community, perhaps we can make a difference.

Donation is as simple as making one's wishes known. It does not require any legal documentation. Basically it means breaking the silence that surrounds talking about death. Although currently those of us with hepatitis C cannot donate blood or body parts, I have told my family that if any part of me can be used in the future, this is my wish.

#### Courage

I did not write the following, but it holds concepts dear to my heart. It was written about physical disability.

"The battleground is one's own body, and the courage involved is what it takes to overcome self-pity, bitterness, pain, helplessness, when something traumatic occurs to it. It is a more difficult courage to come by than facing an adversary, because what must be overcome is within, and the struggle is a lifelong one."

The author also quotes a 13-year-old girl with polio who later became a talented cellist and teacher: "Maybe my legs were told to stop running me all over the place so that I could stop and find out who 'me' is." -George Plimpton Self magazine June 1993

## July 2000's Advocate:

### Canadian Activists Work on 'Unbundling' of Ribavirin and Interferon

By Darlene Morrow  
President, HepC VSG

Activists in Canada are attempting to get Rebetron (the combination of Schering's Intron A interferon and ribavirin) unbundled in an effort to reduce the cost and provide access to ribavirin for use with other interferons.

At issue is the cost of Rebetron - approximately \$1,700 a month (Canadian \$\$). If you deduct the cost of interferon - \$500, the ribavirin portion of the two-drug kit is approximately \$1,200/per month or about \$7.00 per capsule. Ribavirin is now off patent and available in the United States through compounding pharmacies for around \$1.25 (US \$\$) per 200mg capsule. The per capsule cost in Mexico is \$2.00 and Great Britain it is \$1.00. Canadian government funding for the drug is available, but people must fit into a narrow criteria to be accepted.

A complaint was filed in June 1999 with the Canadian Medicine Price Review Board claiming that Schering Plough is guilty of exorbitant pricing. It is currently under review but is not considered a high priority by the board. A similar lawsuit was filed in Canada against ICN, the company that makes ribavirin and was fined 1.6 million dollars and forced to drop the price. Canadian activists hope that history will repeat itself.

In an effort to force the unbundling of the two-drug kit, a complaint was filed in June 1999 with Industry Canada charging Schering Plough with Tied Sales. Tied Sales are a civil reviewable offense in Canada and are defined as a sale that forces a consumer to buy one brand of a product when a second product is purchased. Industry Canada has reviewed the complaint and moved it into the Enforcement and Compliance Division.

The wheels of government will never move fast enough for people denied access to life saving drugs. The energy required to continue this fight is demanding, but necessary for people affected by HCV.

## July 2000's Advocate:

### Harm Reduction Measures for IV Drug Users

#### In the real world, getting information about healthy drug injection practices to users can help reduce hepatitis C infection

By Allan Clear  
Executive Director  
Harm Reduction Coalition

The impact of AIDS on the drug injecting community has been profound. But drug injectors have forestalled a more terrible tragedy by reducing the syringes they share, buying and possessing their own syringes, and by using syringe exchange programs where and when available. Drug users have shown that they are invested in their own health. When they have access to sterile injection equipment, drug users show us that an unused, sharp syringe is preferable to a barbed, clogged and potentially contaminated one. Legal restrictions have not provided drug users with the luxury of choice.

Despite gains in HIV prevention, 80% of injectors contract HCV; most within two years and many within six months of injecting. Holly Hagan's research in Seattle and Tacoma with injectors who use the syringe exchange programs, clearly shows that the message and practice of not sharing syringes is an ineffective strategy when it comes to HCV. At the recent "Bringing it all Together" conference in Baltimore, Steve Koester of Denver suggested placing a greater emphasis on drug sharing/dividing messages and Don Des Jarlais suggested that the message is "avoid blood".

Both Steve and Don are correct and we are beginning to build a picture of HCV prevention for injectors. However, we need to talk less in terms of disease prevention and more about healthy injection practices. If we respond only to specific viral infections, one by one, we fail to normalize the acceptance of basic injection hygiene as common sense. Blood and bleeding are a normal part of injection, and injection is a normal practice for many users. "Avoid blood" means a simple, day-to-day consciousness of how blood is present during injection, and simple day-to-day habits that respond to this reality. Conditions are seldom going to be perfect for injection, but drug users need to think of injecting along the same lines as preparing to eat dinner. Wash your hands and arms. Clear a space that is yours. Use clean surfaces. Make sure your injecting space is clean by wiping it down or spreading out a sheet of newspaper. (Hey, I always do that before sitting a meal).

Remember when you are getting off with other people, syringes look alike. Be sure you know which syringes are yours by marking them before you get off. Keep track of how you marked yours, and remember markings can wipe off. Knowing which are yours is important if you recap your syringes.

Splitting drugs is an economic necessity for users, but also creates risks for viral transmission. Best practice: each person has their own syringe, and an extra sterile syringe for actually splitting the drugs, if possible. When preparing your shot use your own cooker. Clean out the cooker with an alcohol pad to be sure it's sterile. If you're sharing a cooker, try to use only new syringes. It's a bad idea to draw up from a cooker if someone else stuck a used syringe in it.

Always clean your injection site by using an alcohol pad or soap and water.

During the whole process of injection, be aware of what you touch or handle. After you've shot your drugs, apply gentle pressure to the injection site using tissue or cotton to stop the bleeding. Alcohol pads don't stop bleeding, the alcohol stops your blood from clotting. Dispose of the used cotton or tissue, and dispose of the syringe in a sharps container (or a hard, puncture proof container). Be aware that you've been handling syringes, cotton, tissues and other materials that have probably contacted your blood. Wash your hands and arms. Re-wipe your surface, check your tie and remember how your blood could have ended up on anything

you might touch or use.

It is important to take control of your own injection. Having another person inject you significantly increases your chance of getting infected. But even when someone else injects you, basic hygiene can prevent most infections. If someone injects you after they have gotten themselves off, they should wash their hands, and use a sterile syringe, cooker and tie for you.

HCV is easy to acquire and transmit and it seems that very small amounts of blood will do the trick. Injecting drugs is the riskiest way to use, due to the variety of complications that can occur. But while some risks may be unavoidable, others can be reduced or eliminated through awareness and planning. Above all, it is time to recognize that hygiene can be a normal part of injection, just like it's a normal part of eating.

To learn more about the Harm Reduction Coalition and their annual conference, visit their website at: [www.harmreduction.org](http://www.harmreduction.org)

## Book Review

The Hepatitis C Help Book is a collaboration between two of the best known and most knowledgeable practitioners working in the hepatitis field today - Misha Cohen O.M.D., L.AC. and Robert Gish, MD. This is a well rounded and comprehensive guide that should be in the personal library of anyone dealing with hepatitis C, and can easily be used by both patients and health care providers. Highly Recommended.

### [The Hepatitis C Help Book : Combining Western and Eastern Medicines for the Most Effective Therapy Yet Against a Devastating New Epidemic](#)

by Robert G. Gish, Misha Ruth Cohen, Kaha Doner, Kalia Doner (Contributor)

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For many of us, hepatitis C is a chronic life altering illness, not a life threatening one. We need ways to remain as symptom free as possible and to maintain the highest possible level of health.

Western medicine is not offering us much at this point in that area. It currently offers a course of treatment with interferon and ribavirin (a kill-the-virus approach) and a constant monitoring of our liver function through blood tests & biopsies. But when it comes to living with HCV on a day-to-day basis there really isn't much medical help beyond anti-depressants and some form of pain medication.

The Hepatitis C Help Book is a collaboration between two of the best known and most knowledgeable practitioners working in the hepatitis C field today. Misha Cohen O.M.D., L.AC. is a pioneer in the use of Chinese Medicine for treating hepatitis C.

Robert Gish, M.D. is an internationally recognized liver specialist currently at California Pacific Medical Center. Together they have given us a wealth of insight and information into hepatitis C, from diagnosis to treatment, and a model for living well day to day.

The book is divided into three easy to understand sections and is followed by comprehensive appendixes that offer numerous resources and information on

herbal formulas and liver toxic substances. There is also a glossary of the terms and abbreviations used throughout the book.

The first section, "The Silent Epidemic," is basic information on all types of hepatitis, with an emphasis on hepatitis C, as well as an in-depth explanation of how the liver works and the role it plays in body functions. It becomes clear that Eastern medicine treats in a more holistic way, calling the liver "The Liver Organ System," while Western medicine simply looks at the liver as an individual organ.

We also see that Western medicine offers us analysis of the liver's biochemical functions, through blood tests and biopsies, that Eastern medicine cannot. This is indicative of the entire theme of this book. Combining the two approaches is truly the best of both worlds.

The second section "Treatment Choices" goes into extensive detail on the available options. It covers Western Medicine, Chinese Medicine and Herbal Therapy, Chinese Nutritional Therapy and Recipes, Acupuncture, Moxibustion and Acupressure, and Qi Gong Exercise and Meditation.

The third section "Integrated Treatment Programs" is a hands-on guide to choosing or developing a program combining Chinese and Western medicine. There is a basic hepatitis C program as well as specific plans for digestive dysfunction, dispelling fatigue, immune strengthening, relieving depression and fuzzy thinking, easing aches and pains, addiction management, harm reduction and withdrawal.

The Hepatitis C Help Book is a well rounded and comprehensive guide that should be in the personal library of anyone dealing with hepatitis C, and can easily be used by both patients and health care providers. It is currently available and if your local bookstore doesn't have it, ask them to order it for you from St. Martin's Press. It is also available at Amazon.com.

Misha Cohen has a web site that contains information on hepatitis C and Chinese Medicine: [www.docmisha.com](http://www.docmisha.com)