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Report from DDW 2005 – Part 2



Alan Franciscus, Editor-in-Chief

Part 2 of our report from the Digestive Disease Weekly (DDW) Conference 2005 focuses on new clinical data about Pegasys, Peg-Intron and Infergen.

PEGASYS

“Real World Experience”

Treatment results from clinical trials can be somewhat misleading since patients enrolled in clinical trials are generally very motivated to do well; furthermore, clinical trial investigators might only enroll patients who will respond better to the particular medicine being studied. The larger question that needs to be answered is, how does this clinical data translate into everyday practice? E. Yoshida and colleagues examined the treatment response rates in a routine clinical setting in Canada and compared these results to data from previous phase III clinical trials of Pegasys plus ribavirin. In this study, 863 patients were enrolled in 18 centers throughout Canada. Study participants received either 48 weeks of Pegasys plus Ribavirin 800 mg/day (genotype 1 patients) or 24 weeks of Pegasys plus Ribavirin 800 mg/day (non-genotype 1 patients). It should be noted that 800 mg/day is now considered a sub-optimal dose for genotype 1 patients. Included in this study were previously untreated patients as well as previously treated patients (non-responders and

relapsers) and people with cirrhosis (F3/F4).

The overall sustained virological response rate (SVR) was 39% for genotype 1 and 72% for genotypes 2/3. In patients without cirrhosis the overall SVR rates were 56% compared to 41% in cirrhotic patients. As expected, patients who were previously treated but relapsed achieved better treatment results – 40% SVR compared to the 23% SVR for patients who failed to respond to a previous course of HCV treatment.

The authors concluded that “[t]hese real world results, obtained in a large cohort of non-responders and relapsers to conventional interferon-based therapy, demonstrated that such patients can be successfully treated with pegylated interferon alpha 2a (Pegasys) plus ribavirin.” It was also pointed out that nearly one-third of the patients who did not achieve an SVR with a previous course of therapy were able to achieve an SVR in this trial and that these results support a strong rationale for retreating prior non-responders and relapsers.

EFFECT OF FIBROSIS ON TREATMENT

People with HCV-related advanced scarring or compensated cirrhosis are at a greater risk for accelerated HCV



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disease progression than patients with little or no fibrosis. It is also known that people with advanced disease progression are less likely to respond to current HCV medications. Medical providers, in general, do not recommend the treatment of people with early disease because hepatitis C is a slowly progressive disease and treatment can be difficult for some people. However, this approach is being challenged as more information about the lower treatment response rates among people with advanced disease progression and the increased rate of disease progression in the later stages of HCV-related disease is coming to light.

Mitchell L. Schiffman and colleagues reviewed data from 569 genotype 1 patients treated with pegylated interferon alfa-2a plus ribavirin for 48 weeks, obtained from two of the registration trials of Pegasys plus ribavirin, to explore the relationship between the degree of liver damage and treatment response. It was found that those with early fibrosis achieved a higher sustained virological response rate (56%) compared to patients with

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Seafood Safety: Avoiding *Vibrio* and other Shellfish-Borne Infections



Liz Highleyman

With the coming of summer, many people's thoughts turn to fresh seafood. But eating raw or undercooked seafood is not without risk, especially for people with hepatitis C or other types of liver disease.

Seafood can be contaminated with a variety of disease-causing organisms, including viruses, bacteria, and parasites. Two-shelled (bivalve) mollusks such as oysters, clams, and mussels carry the greatest risk, since they are filter-feeders that concentrate pathogens and toxins in their flesh.

The most common consequence of seafood poisoning is gastroenteritis, or inflammation of the stomach and intestines (although some toxins can cause neurotoxic, paralytic, or amnesic shellfish poisoning). Most healthy people who eat tainted seafood only suffer abdominal cramps and diarrhea for a few days. But individuals with certain medical conditions – including chronic hepatitis B or C – and those with compromised immune systems – including people with HIV – are at much higher risk for serious illness and death.

COMMON CULPRITS

Vibrio bacteria are an important cause of seafood-related illness. The most familiar member of this family is *Vibrio cholerae*, which causes cholera. But other species – in particular, *Vibrio parahaemolyticus* and *Vibrio vulnificus* – are more likely to cause shellfish poisoning in the U.S. These bacteria live naturally in warm, brackish seawater, and are not necessarily associated with pollution. While they are found most often in

the Gulf of Mexico during the summer months, they have also been isolated up and down the Atlantic coast and in the Pacific. It is estimated that non-cholera *Vibrio* species cause several thousand cases of illness each year, and the rate appears to be increasing (perhaps due to warmer ocean temperatures, changing salinity levels, or better reporting).

V. parahaemolyticus is a more common cause of shellfish poisoning, but *V. vulnificus* is of greater concern because it is more likely to be fatal. People can acquire both species of bacteria by eating tainted shellfish (especially oysters, clams, and crabs), by swallowing seawater, by wading or swimming in contaminated water with cuts or sores on the skin, or by incurring injuries from stepping on seashells or preparing seafood. There is no evidence of person-to-person transmission.

Symptoms usually show up within 12-48 hours, and may include abdominal cramps, frequent watery (and sometimes bloody) diarrhea, nausea and vomiting, headache, and fever or chills. *V. parahaemolyticus* infection is usually self-limited; the same is true for *V. vulnificus* in healthy people. Symptoms usually resolve after about three days, and treatment with antibiotics generally is not necessary. Avoid anti-diarrhea medications, since these can interfere with the natural process of flushing bacteria out of the body. It is important to drink plenty of water or an electrolyte solution to prevent dehydration; if vomiting or diarrhea are prolonged, intravenous fluid replacement may be needed.

People with certain conditions, however, are at risk for more severe illness

related to *V. vulnificus*. These include liver damage (due to hepatitis B or C, heavy alcohol consumption, or some other cause), hemochromatosis (iron-overload disease), diabetes, certain types of cancer (e.g., lymphoma), reduced stomach acidity, and compromised immunity (due to HIV, use of steroids or immunosuppressive drugs, or other factors); interestingly, about 75% of serious cases are seen in men.

In susceptible individuals, the bacteria can enter the bloodstream from the intestines and cause septicemia (blood poisoning), resulting in high fever, pain (especially in the lower extremities), skin lesions, low blood pressure, and shock. *Vibrio* wound infections are characterized by swelling, pain, redness, numbness, and tissue death (necrosis). Once septicemia develops, it is fatal about half the time; people with cirrhosis are estimated to be 200 times more likely to die of *V. vulnificus* infection than those without liver damage. Systemic infection can be treated with antibiotics such as doxycycline. With prompt treatment, most patients recover fully with no long-term consequences. (In severe cases, however, *Vibrio* skin infections may require debridement – that is, surgical removal of the affected tissue – and reconstructive surgery.)

Vibrio bacteria are not the only disease-causing organisms found in seafood. Unlike hepatitis B and C, hepatitis A (and also hepatitis E, which is rare in the U.S. but endemic in some developing countries) can be transmitted through food and water that has been

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HealthWise:

Medication: Reading the Fine Print



Lucinda K. Porter, RN, CCRC

Your doctor hands you some information about medication for hepatitis C virus infection (HCV). The information could be simple or complex, depending on the level of printed material and your ability to understand medical language. Nevertheless, even the most basic material also includes a neatly folded copy of the professional information. This is often printed on white paper in very small print. It requires training and a magnifying glass to read it.

This piece of paper is the Package Insert (PI). It is also called product or prescribing information. The Food and Drug Administration (FDA) requires all manufacturers to include this with their drugs. This article offers tips on how to crack the medical code in the PI. It will tell you what to look for, what to avoid, what to fear, and what not to fear.

If you do not have the PI, you can get a copy from your pharmacy or the Internet. It can be found under “complete prescribing information” or “information for healthcare professionals.” Try to use the drug’s brand name rather than its generic name for your search. For instance, Copegus® and Rebetol® are the brand names for generic ribavirin. It’s like Coca Cola® and Pepsi® are the brand names for cola.

Most medications have information written specifically for patients. This will give you a broad overview of the most important information and is a good starting point. When a drug is advertised in a consumer magazine, this is what usually appears in small print on the backside of the advertisement. After you read the basic information, you may want to read the entire PI.

Using ribavirin (Copegus® and Rebetol®) as an example, let’s take a PI tour. The first things you will read are the drug’s trade name, generic name and manufacturer. What follows next in this case is a box with bold type. This is called black box information. This has to be predominately displayed and carries a serious message. In ribavirin’s case, there are warnings about pregnancy complications and cardiac disease. If you do nothing else, read and understand every word in the

black box. If any of it applies to you, do not take that drug unless your healthcare provider has adequately explained why you may take it. Not every drug has black box information.

Next is the description. This is the most complicated part and can be ignored until you are ready to tackle concepts that are more challenging. Clinical Pharmacology follows the description. This is also complicated and will be the subject of next month’s Healthwise.

Clinical study information is provided next. This is the data that proves why the drug works. It may be helpful to skip this for now and then return to it after you have read the rest of the PI. You can also ask your medical provider to summarize the parts that apply to you.

The indications and usage section lists the medical conditions the drug treats. It may surprise you to learn that interferon and ribavirin were originally used for other conditions. However, the indications for the pegylated (longer acting) alfa-interferons 2a and 2b are for HCV treatment. The indications may change per FDA approval. For instance, Pegasys® is approved for treatment of hepatitis B and HIV/HCV co-infection. The shorter acting interferon Intron-A® has indications other than for HCV. Sometimes physicians will use the pegylated interferon instead. This is called an off-label use and it is legal although insurance will not always cover the drug’s expense.

The contraindications and warnings sections are high priority. In contraindications, all the patients who should not take the drug are discussed. Also listed are situations in which patients can take the drug but need to be closely monitored. If the PI has a black box in the beginning, this information will be repeated in the warnings section along with additional cautions. Again, if you think information in this section applies to you, talk to your healthcare provider before you start taking the drug.

Precautions come next. This is important because

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HEALTHWISE

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it gives more information about the safety of the drug. In the PIs for Copegus® and Rebetol®, we are alerted to more possible risks. The black box information is restated and informs us about what lab tests medical providers should order before and during treatment. For example, an ECG (a simple and painless heart test) is recommended. Advice to patients is in this section, such as to drink lots of water and take medication with food.

The drug interactions section is included here. Read this section. Listed here are the drugs that are known to interact with the drug you are considering. If you are taking a drug that is on the list, tell your provider. Fortunately the list is very short for HCV drugs. Also included in the precautions section is information about special groups of people. This addresses pregnancy, nursing mothers, pediatric use (infants and children), geriatric use (older adults) and if the drug works differently between genders.

Try to read the adverse reactions section. When you want to know the drug's side effects, go to this section. The adverse reactions section may scare you but actually its bark is worse than its bite. This is where everything that is known to have happened is listed and informs patients about the drug's risks. Look for the most common adverse reactions. Ask yourself, how common are these?

Using Copegus® as an example, you will learn that in research studies, one or more serious adverse reactions occurred in about 10% of patients. The most common life-threatening or fatal events related to this drug (when used with Pega-

sys®) include depression, suicide, relapse of drug abuse/overdose, and bacterial infections. This may sound frightening. The good news is that each of these events occurred at a frequency of less than 1%.

Just about everyone reported one or more adverse event. The most common of these were depression, irritability, anxiety, fatigue, headache, muscle aches, fever and chills. Again, this sounds pretty awful. However, keep in mind that if a research patient was irritable for only one day that counts as an adverse event. Just because nearly everyone reported an adverse reaction does not mean that these reactions were constant or intolerable.

Sometimes information about adverse reactions includes numbers and percentages. Looking at Rebetol® (when used with PegIntron®), we find that 31% of patients reported depression. That means that roughly one-third of the study patients reported at least one episode of depression. That does not tell us for how long or how severe the depression was. However, we also learn that 14% of the study patients discontinued treatment for any number of reasons. This casts a more favorable light on the 31% depression figure because no more than 14% (and probably less) of patients had depression severe enough to cause them to stop treatment.

Although percentages can be reassuring, keep in mind that these numbers were derived from clinical trial patients. Research usually uses the healthiest patients. If you are already depressed, then your risk for increased depression could be higher than the percentages listed in the PI.

Probably the best way to find out about drug side effects is to talk to other patients who have experience with that medication. Support groups are great resources for this.

You can also talk to your medical provider or pharmacist and ask what sorts of feedback they are hearing from patients. Be cautious about relying on the Internet for patients' stories; negative experiences are more likely to appear than positive ones. It's important to get a full range of reports on which to base your decisions.

The final portion of the PI supplies information about overdose, discusses Dosage and Administration, states how the medication is supplied and how it should be stored. This is important to know. Peginterferons are injectable drugs that have special storage requirements. Knowledge about dosages gives you guidelines for how much medication is recommended and for how long. However, patients are unique and medications are not "one size fits all." Physicians and mid-level practitioners may prescribe different doses to different people for different reasons. If your dose differs from the printed guidelines, ask your provider to explain the reason for this.

Taking a new medication can be both frightening and exciting. Fear can be reduced when sound judgment is applied to solid information. The exciting part is that, in general, medications work well. When medications work for people living with hepatitis C, this can be good news indeed.

Further reading:

HCSP's booklet: *A Guide to Understanding Clinical Research in Hepatitis C*.

HCSP Fact Sheet: *A Simple Guide to Reading an Abstract*.



DDW

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advanced fibrosis (43%). As expected the incidence of neutropenia, anemia and thrombocytopenia was greater in the group of patients with advanced liver disease. The authors concluded that “[t]hese findings support earlier reports of higher fibrosis scores predicting a lack of virologic response.” The authors also noted that this study suggests that genotype 1 patients with no fibrosis or a low fibrosis score may benefit from early treatment with Pegasys plus ribavirin. However, this recommendation will remain controversial until larger prospective studies are undertaken to establish the risk versus benefit of treating people with little or no HCV-related liver disease.

PEG-INTRON

Genotype 1, Low Viral Load

HCV RNA (viral load) is well-known as a predictor of treatment response. The established duration of treatment for people with genotype 1 is 48 weeks. However, it has been speculated that people infected with genotype 1 who have a low viral load may only need to be treated for 24 weeks instead of the standard 48 weeks. S. Zeuzem and colleagues conducted a study to find out if a shorter duration of treatment (24 weeks) for people with genotype 1, low viral load is as effective as the standard duration of therapy (48 weeks). In this study, 235 patients with low viral load (less than or equal to 2 million copies/mL) were treated with pegylated interferon alpha 2b (Peg-Intron) 1.5 µg/kg/week plus ribavirin (800-1400 mg/day based on bodyweight). It was found that genotype 1, low viral load patients who were treated for 24 weeks achieved a 50% SVR compared to 71% of the historical control arm of patients with genotype 1, low viral load treated for 48 weeks. As a result, the authors

concluded that patients with genotype 1, low viral load should be treated for 48 weeks. However, the authors stated that the subset of patients who had undetectable virus at week 4 of therapy achieved a similar treatment response rate as those who were treated for 48 weeks.

African Americans

African Americans typically have a lower treatment response than other populations with hepatitis C. It is also well known that people who are retreated are less likely to achieve an SVR than people that have never been treated (treatment naïve). Schering’s RENEW clinical trial is looking at retreating people that did not achieve an SVR with a previous course of interferon plus ribavirin therapy. A subset of this study is evaluating the retreatment of African Americans who did not respond to previous course of HCV treatment. In this study, a total of 963 patients have been enrolled of whom 152 are African Americans. The participants received a weight based dose of ribavirin (12-15 mg/kg day) and either Peg-Intron dosed at 1.5 µg/kg once a week or 3.0 µg/kg once a week. One hundred thirteen African American patients were confirmed to have started treatment. The patient characteristics were similar between both study groups except for weight – the group that received the higher dose of Peg-Intron included more overweight patients – 96 kg compared to 88 kg for the group that received the lower dose of Peg-Intron. No growth factors were used in this study. The sustained virological response rate was 16% for the 3.0 µg/kg once a week plus ribavirin group compared to 4% for the group that received the 1.5 µg/kg once a week plus ribavirin. The side effect profile was similar between both study groups.

The authors noted that neither body weight nor degree of liver damage influenced treatment response and

that their trial has shown that, even in patients that are known to have lower response rates, aggressive re-treatment can be achieved with higher dose of Peg-Intron. “[T]he combination of high-dose PEG alfa-2b plus weight based ribavirin should be investigated in other hard-to-treat patient populations.

INFERGEN PACT-trial

Interim results from the PACT-trial (PegIntron-Against-Consensus-Trial) on treating previously untreated HCV genotype (serotype) 2 and 3 patients were released at the recent DDW conference. W.O. Bocher and colleagues looked at the safety and efficacy (sustained virological response rate) of daily Infergen (CIFN) plus ribavirin compared to Peg-Intron plus ribavirin.

Four hundred patients with chronic hepatitis C, genotype 2 and 3 were randomized to receive Infergen (9 mcg qd) daily or Peg-Intron (1.5 mcg/kg body weight) once weekly. Both groups received the same dose of ribavirin (greater than 10.6 mg/kg body weight). Treatment duration was 24 weeks with a 24 week follow-up period.

One hundred forty-eight patients out of the 237 patients enrolled prior to April 2005 reached treatment week 12, which is the basis for the interim results. The patient population was similar between the study arms for age, gender, genotype and viral load.

In the patients that reached the end of the 12 weeks the response rate was 94.8% for the Infergen group and 98.8% for the Peg-Intron group. Eighty-eight patients (Infergen 41 patients, Peg-Intron 47 patients) reached the 24 week post treatment period and the SVR rate was similar between the treatment arms (90.2% in the Infergen group compared to 93.6% in the Peg-Intron group).

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Treatment was well-tolerated in both treatment groups with no significant difference in the numbers of serious adverse events or treatment discontinuations.

The authors concluded that “[i]n treatment-naïve patients with chronic hepatitis C and serotype-2 or -3, daily treatment with CIFN combined with ribavirin has the same antiviral efficacy and safety profile as weight adjusted peg-IFN α 2b” (and ribavirin).

RETREATMENT

Retreatment of previous interferon plus ribavirin treatment non-responders and relapsers has shown lackluster results in most studies. In a study conducted by K.D. Rothstein and colleagues, the interim results of a small study using high daily dosing of Infergen in HCV positive individuals who did not respond to a previous course of pegylated interferon and ribavirin

treatment was presented. To date, 33 patients have been enrolled – 76% males, 94% genotype 1, 39% cirrhotic, 70% non-responders. The study participants were given 27 mcg/day Infergen plus ribavirin (400 mg BID – twice a day) for the first 4 weeks; 18 mcg/day Infergen plus ribavirin (400 mg BID) for weeks 5 to 12, followed by 15 mcg/day Infergen plus ribavirin (increased to 1000-1200 mg daily) for 36 weeks.

The results of this study showed that 52% (16 patients) achieved an end-of-treatment response. The authors noted that the medications were well-tolerated with dose reduction and discontinuation rates similar between other non-responder clinical trials using pegylated interferon plus ribavirin. Sustained virological response rates for this trial are expected at the end of 2005.



ANNOUNCING WEB BASED CME ACCREDITATION COURSE

The HCV Advocate Online Education Center CME Courses are intended for physicians specializing in gastroenterology, internal medicine, and hepatology, as well as other healthcare professionals conducting research and/or providing care for individuals with diseases of the liver.

Overview

This CME course, Diagnosing HCV, is an interactive web course that provides comprehensive information on the diagnosis of HCV infection. Participants can test their knowledge of the material through study questions at the end of each section. By combining up-to-date clinical and epidemiological information this web-based training program provides a valuable educational tool to assist health professionals in the complex task of diagnosing HCV infection.

Course: Diagnosing HCV

Visit <http://www.hepeducate.org> for more information.

ORGAN DONOR REGISTRY: FLORIDA

Sixteen people die every day because they did not receive a needed organ transplant. The state of Florida makes it easy for those who want to donate their organs upon death. Florida has a donor registry. Anyone can sign up. Whether or not an organ can be used is determined at the time of death. HCV infected organs are sometimes used. Minors need to have parental or guardian permission and signature.

In addition to joining the registry, tell your close relatives, friends and medical providers if you wish to be an organ donor. The web address for the Florida registry is: www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Organ_Donors

For further information, contact:
Florida Organ & Tissue Donor Education Program
Agency for Health Care Administration
Division of Health Quality Assurance
2727 Mahan Drive
Tallahassee, FL 32308
Phone: (850) 414-0359
Fax: (850) 410-1511
otdonors@ahca.myflorida.com

VIBRIO

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contaminated with feces. Filter-feeding mollusks living in sewage-contaminated water are particularly risky. The hepatitis A virus (HAV) prefers colder water than *Vibrio*, and outbreaks are most frequent in the late fall and early winter. Usually hepatitis A is an acute self-limited illness, and the immune system spontaneously clears the virus after several weeks. But HAV (and HEV) can cause serious liver problems – including fulminant liver failure – in people with pre-existing liver disease. For this reason, people with chronic hepatitis B or C are advised to get vaccinated against hepatitis A; exposed but unvaccinated individuals may receive prophylactic treatment with HAV immune globulin.

Another pathogen found in shellfish, the Norwalk virus, is also a common cause of gastroenteritis. Symptoms are similar to those of *Vibrio parahaemolyticus*; the infection usually resolves in about 48 hours and treatment is not necessary.

KEEPING IT SAFE

Although people with advanced liver damage are at highest risk for severe seafood-related illness, anyone with liver disease should take precautions. While it's certainly wise to avoid seafood from known contaminated areas, *Vibrio* naturally live in clean seawater. Since the bacteria thrive in warm water, seafood-borne illness is most common in the summer (thus the folk adage to avoid eating raw oysters in months that do not contain an "R"), but it can occur year-round. It's impossible to tell whether seafood is tainted with *Vibrio* or HAV by appearance, smell, or taste. So, the best way to prevent infection is by always avoiding raw or undercooked seafood, including fresh sushi, sashimi, and marinated preparations such as ceviche or gravlax.

Fortunately, there are many delicious

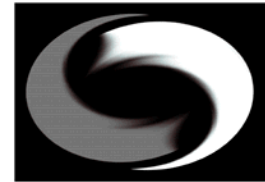
ways to enjoy seafood without putting your health in peril. Preparations such as cioppino, scampi, bouillabaisse, and seafood stews and chowders are safe. Cooked crab, shrimp, and lobster can be chilled and served cold in cocktails and salads.

Seafood should be cooked to an internal temperature of 150 F (65 C) to kill pathogens. Live shellfish such as oysters and clams should be boiled for 3-5 more minutes or steamed for 8-10 more minutes after the shells have opened (which takes about one minute). **Do not** eat shellfish that either open before cooking or fail to open during cooking (suggesting the animal is dead). Shrimp, lobster, crabs, and fish should be cooked until shells are pink or red and the center of the meat is opaque (no longer translucent). Baking (for about 10 minutes at 450 F) and frying also kill disease-causing organisms, but many experts recommend that people with liver disease should avoid fried food.

While preparing and serving, make sure that juices from raw seafood do not contaminate cooked seafood or serving plates or utensils. Carefully wash preparation surfaces and tools. Wear rubber gloves when preparing shellfish, especially if you have cuts on your hands. Thaw frozen seafood and marinate fresh seafood in the refrigerator, not at room temperature. After cooking, seafood should not be left unrefrigerated for more than two hours. Home freezing of seafood does not kill all pathogens – and folk myths about reducing the risk by eating raw shellfish with hot sauce or alcohol are not credible!

Information about the risks of raw oysters is available from the FDA's 24-hour Seafood Hotline at 800-332-4010 (specialists are available during business hours).

For more information, see <http://seafood.ucdavis.edu/consumer/safety.htm>.



**HEPATITIS C
SUPPORT PROJECT**

**Executive Director
Editor-in-Chief,
HCSP Publications**

Alan Franciscus
alanfranciscus@hcvadvocate.org

Managing Editor, Webmaster

C.D. Mazoff, PhD
cdmazoff@hcvadvocate.org

Contributing Authors

Liz Highleyman
Lucinda K. Porter, RN, CCRC

Design and Production

Paula Fener
Blue Kangaroo Design
blueroodesign@aol.com

Contact information:

Hepatitis C Support Project
PO Box 427037
San Francisco, CA 94142-7037

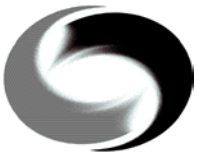
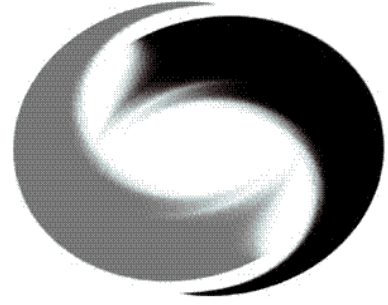
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HCSP

P.O. Box 427037
San Francisco, CA
94142-7037