

HCV ADVOCATE

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Hepatitis C Support Project

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HealthWise

Motivation

Lucinda Porter

This summer, the world witnessed a triumph of human spirit. Lance Armstrong, a cancer survivor, became the second American to win the Tour de France. Two years prior he had been barely able to walk, devastated from the effects of chemotherapy and surgery. He was told his survival chances were 50-50. Despite these odds, Lance Armstrong won this famous race, cycling 2,290 miles. The day after his victory, a chronic hepatitis C patient walked into the Stanford University Medical Clinic and said to her doctor, "If he could do this, surely I can make it through my treatment." Two winners, one made the newspapers, the other inspired this article.

It is interesting that some people are able to prevail despite hardships while others seem to crumble

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Texas probes marketing of Schering Drug Kit

10/17/99 - Newark Star-Ledger

Edward R. Silverman

The Texas Attorney General is investigating whether Schering-Plough Corp.'s controversial marketing of an expensive kit for Hepatitis C violates anti-trust laws.

The probe into the company's Rebetron product, which can cost up to \$18,000 annually, is in the "initial stages," according to a spokeswoman for the state agency. She declined to say what prompted the inquiry or discuss other aspects of the case.

However, two people who were recently questioned by an agency lawyer say the probe apparently reflects concern that other Texas agencies, which provide medicine to prisoners, state employees and Medicaid recipients, are paying unfair prices for the product.

"I was asked a lot of questions and was told they were looking at filing charges against Schering-Plough," said Don Kerrish of Fisher's Specialty Pharmacy Services in Pittsburgh, which makes and sells a rival medicine that is one of two products in the Rebetron kit.

A Schering-Plough spokesman declined to comment.

The inquiry is only the latest difficulty the Madison drug maker has encountered over

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HCV ADVOCATE

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under much lighter loads. A woman contacted me recently and poured her heart out about her fears that there would not be enough livers when she needed a transplant. She had been diagnosed with chronic hepatitis C and had felt paralyzed by fear for years. Although she was asymptomatic and had normal liver function tests, she had never had a viral load test done to confirm the presence of viremia. Following up on a suggestion to seek a more comprehensive medical evaluation, the test came back with no detectable HCV viral particles. Simply put, she had spent an enormous amount of effort worrying needlessly.

These two responses to life's challenges became the foundation for writing this month's newsletter article. My original hope was to analyze the elements of motivation. How do we keep ourselves going through the darker moments? What are the characteristics that impel some people to overcome major obstacles that may defeat others? Little did I know that I would be jolted from my rather smoothly running life, by a series of unexpected events that rendered me temporarily disabled and extraordinarily cranky. Fortunately the worst seems to be behind me now. However, I found it easy to invite self-pity and it became a struggle to maintain an optimistic attitude. In short, it was the perfect opportunity to gather research for this article.

No doubt about it, life can be hard. As someone once said, "Pain is inevitable. Suffering is optional". How we interpret these difficult times influences us. Believing that life will get better versus thinking it will never end can make a substantial difference in one's attitude. Looking back at other bleak times and seeing that it passed can inspire one to believe "this too will pass". In short, attitude can make or break a bad situation.

Here are some suggestions for how to survive challenging times:

- Try distraction: movies, comedy, music, friends, fantasy, audio books, do volunteer work
- Increase endorphin level: Try any form of exercise, humor, get a pet
- Use positive self-talk: Tell yourself, "this will get better." Ask yourself, "what do I have control over?" Instead of saying, "I can't", try saying, "I will", even if you don't know how you will. Do this even if you do not believe it.
- Employ self-soothing measures: candles, music, watching sports on TV, judicious use of favorite food, resting, soaking in the tub, playing video games, pray

- Practice visualization: Imagine yourself laughing, getting things done, feeling happy (If you have any doubts about the power of visualization, just imagine eating a lemon and notice what happens to your salivary glands.)
- Try to eliminate or reduce the amount of worry in your life. Worrying will not solve tomorrow's problems and depletes today's strength. If you find yourself worrying a great deal, try creating "worry-free" times. My goal is to not let worry interfere with sleep or driving. If I find myself worrying at those times, I tell myself I can worry all I want tomorrow. I go for a walk and allow myself to think as much as I want about the situation. This takes practice, but is very effective.
- Make emergency plans for difficult times: This is most effective when done while one is feeling in a good mood. Make a list of what would cheer you up if you were feeling lousy. Example: ask friends for help, read stories about those who have overcome major obstacles, take a day off work
- If you are depressed and/or having suicidal or other self-destructive thoughts, professional help is strongly advised. If you do not know how to find help, call your local mental health department or crisis hotline.
- When all else fails, try applying the acronym AFOG to the situation. It stands for "another opportunity for growth". I will let you figure out what the "F" means. One hint, it does not mean fine.

The intention of this essay is to stimulate thinking rather than to provide answers. I would like to hear from you on this issue. In planning for the new year, I would like to include the readers' responses. Please send me your suggestions for how you motivate yourself to meet your most difficult challenges. Depending on the response, some or all of these will appear in the January issue of the Advocate. Please send your thoughts to: "HCV Advocate - P.O. Box 427037 - San Francisco, CA 94142-7037 or by email to LPorterRN@Yahoo.com

Finally, I would like to pass on a favorite quote: "Defeat may serve as well as victory to shake the soul and let the glory out." Senator Sam Ervin, JR

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the kit, which contains an injectable medicine known as an interferon and a pill that was licensed exclusively from another company. The pill is called Ribavirin.

Since the kit was approved by regulators last year, patients, doctors and public officials have been critical of the marketing. Rebetron is the only available therapy that can beat the virus in some patients, but even some people with insurance can't afford the stiff price.

Moreover, some patients want to use the pill with interferons made by other companies. But despite a belated plea from the Food and Drug Administration to "unbundle," or sell the two products separately, Schering-Plough has refused.

Critics say the company puts profits ahead of patients. Certainly, Hepatitis C, a viral infection spread mainly by exposure to infected blood, is a big business. Schering-Plough's injectable drug, which is also used to treat cancer, is its second-biggest product. Last year, nearly 60 percent of \$719 million in sales stemmed from treating the virus.

In explaining its position, though, the drug maker cites concerns about liability for side effects the pill may cause. And Schering-Plough says other companies selling an interferon don't have evidence their products are effective when combined with the pill in the kit.

But researchers and other drug makers complain they're prevented from studying other interferons with the pill. And patient groups and doctors worry about setting precedents -- drugs needed to treat other illnesses may one day encounter similarly restrictive marketing.

To press their case, members of Hepatitis C Action & Advocacy Coalition, a patient group, last month met with several staff attorneys at the Federal Trade Commission in the hopes of convincing the agency to file an anti-trust lawsuit.

James Learned, an advocate who attended the Sept. 24 meeting at FTC offices in Washington, D.C., said the handful of FTC lawyers who listened to the group's presentation wouldn't say if they planned any action. An agency spokeswoman declined comment. Elsewhere, three members of Congress, including U.S. Rep. Christopher Smith (R-4th District) and U.S. Rep. Frank Pallone (D-6th District), sought a hearing on the marketing practices. To date, no hearing has been scheduled.

Shortly afterward, former U.S. Surgeon General C. Everett Koop told aides to the House Commerce committee, which oversees the subcommittee that has jurisdiction over the FDA, that Rebetron marketing is sound. The closed-door meeting took place last May.

However, one of Koop's nonprofit groups has also received a \$1 million grant by Schering-Plough, which is also a sponsor of his popular new Web site. Both Koop and a Schering-Plough spokesman have denied any link between Koop's activities and the grant.

Criticism has come from other corners. Last spring, the American Medical Association's Council on Ethics and Judicial Affairs rebuked the drug maker for refusing to unbundle the two products in the kit. The organization's main body, however, hasn't taken any action.

Meanwhile, Schering-Plough is unexpectedly fending off new competition from Fishers, the Pittsburgh pharmacy, which recently began making a version of the Ribavirin pill by compounding, or packing powder into capsules according to a doctor's prescription.

Fishers, which is also selling the pill at a lower price, caused an uproar because the FDA hasn't finished setting new rules about compounding. Even so, Schering-Plough complained bitterly to the agency that the pharmacy was skirting the law.

The FDA is still investigating the matter and hasn't taken any action, according to an agency spokeswoman. Meanwhile, other pharmacies have also begun compounding the Ribavirin pill, creating more unexpected competition for Schering-Plough.

Separately, the FDA recently chastised the drug maker for improperly promoting Rebetron. Promotional materials made misleading claims about the medicine's safety and effectiveness, according to a July 15 letter the agency sent to the company.

Ed Silverman covers the drug industry and can be reached at (973) 877-1542 or esilverman@starledger.com.

Editor's Note: For more information on compounding, contact the International Academy of Compounding Pharmacists at 1-800-927-4227 or <http://www.IACPRX.ORG>. You can also contact Fisher's Pharmacy Services at 1-888-347-3416 / 3900 Perrysville Ave., Pittsburgh, PA 15214

Treatment Advocate

Joe Shaw

Hello again. I'm happy to report I'm one month post-treatment. Not missing the fatigue and headaches of the combo at all. No not at all. Still don't feel like my old self. Still don't know what my PCR level is but my liver enzymes are still normal. So that's a good thing. I just hope this treatment works for awhile and I don't backslide.

This month I'm giving you a big list of sites on the internet where you can get information on drugs, treatments, applying for social security disability, etc. etc. etc. Here goes:

Info on Drugs and Treatments

FDA Drug Approval List: <http://www.fda.gov/cder/da/da.htm>

New Drug Development in the U. S., the process(FDA): http://www.fda.gov/fdac/special/newdrug/ndd_toc.html

Internet Drug Index: <http://www.rxlist.com/>

Drug Info Net: <http://www.druginfonet.com/>

Pharmaceutical Companies: <http://www.cbc.med.umn.edu/~jhan/cp.html>

Drug Industry Index: <http://www.bbi.co.uk/pharm/alphalist/index.html>

Amgen: <http://wwwext.amgen.com/patient/patientCenter.html>

Roche: <http://www.rocheusa.com/products/roferon/pi.html>

Schering-Plough: http://www.hep-help.com/site_map.htm

Complementary & Alternative Medicine(CAM-NIH): <http://altmed.od.nih.gov/nccam/what-is-cm/fields/pharm.shtml>

Quack Watch: <http://www.quackwatch.com/>

Herbs, Traditional Chinese Medicine (TCM):

The Hong Kong University of Science and Technology (HKUST): <http://www.ust.hk/~bri/tcm.html>

Natural Interferon Boosters (HCF): http://www.hepcfoundation.org/disi_natinterferon.html

American Academy of Medical Acupuncture (AAMA): <http://www.medicalacupuncture.org/>

Botanical Links: <http://www.botanical.com/botanical/links.html>

Taoist Sanctuary, San Diego: <http://www.taoistsanctuary.org/>

"Natural healing...extraordinary remedies": <http://www.healingedge.com/hepatitiscde.html>

Hepatitis A Virus (HAV):

CDC, National Center for Infectious Disease (NCID): <http://www.cdc.gov/ncidod/diseases/hepatitis/a/fact.htm>

Johns Hopkins University: http://www.hopkins-id.edu/diseases/hepatitis/hav_faq.html

Hepatitis B Virus (HBV):

World Health Organization (WHO): <http://www.who.int/inf-fs/en/fact204.html>

CDC: National Center for Infectious Disease (NCID): <http://www.cdc.gov/ncidod/diseases/hepatitis/b/fact.htm>

HBV: Dr. H. J. Worman, M.D. of Columbia University: <http://www.comeunity.com/adoption/health/hepatitis/worman.html>

Johns Hopkins University: http://www.hopkins-id.edu/diseases/hepatitis/hbv_faq.html

Hepatitis B (Duke): <http://h-devil-www.mc.duke.edu/h-devil/stds/htitis.htm>

Hepatitis C virus (HCV):

World Health Organization (WHO): <http://www.who.int/inf-fs/en/fact164.html>

Hepatitis C, The Virus and the Disease (ALF): <http://gi.ucsf.edu/alf/infohepc.html>

Natural History of Acute HCV Infection, Excellent Graph: http://www.hopkins-id.edu/diseases/hepatitis/hep_fig8.html

CDC, Hepatitis Branch: <http://www.cdc.gov/ncidod/diseases/hepatitis/c/fact.htm>

Chronic Management of Hepatitis C (NIH): <http://www.niddk.nih.gov/health/digest/pubs/chnhepc/chnhepc.htm>

National Kidney Foundation (NKF): <http://www.kidney.org/general/aboutdisease/index.cfm>

Definitions, Glossary: <http://www.hepnet.com/liver/glossary.html>

Other Liver Related Web Sites (Columbia): <http://cpmcnet.columbia.edu/dept/gi/other.html>

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Fibrosis as an Endpoint for Treatment of Hepatitis C

Kip D. Lyche, M.D.

Sustained loss of hepatitis C virus is the goal and ultimate endpoint of trials for patients infected with hepatitis C. This lofty goal is important to both the patient and the community because the patient is no longer infectious and is no longer at risk of developing end stage liver disease. Other important goals of therapy should include:

1. Improvement in symptoms associated with the disease.
2. Improvement in survival.
3. Decrease in the progression to cirrhosis.
4. Decrease in the development of liver cancer (hepatocellular carcinoma).

Interferon Alfa-2B Alone or in Combination with Ribavirin for the Treatment of Relapse of Chronic Hepatitis C. Davis, GL., et al. New England Journal of Medicine, 1998.

- Histological improvement occurred in both treatment groups.
- 63% of combination treated patients had improvement in biopsies.
- 41% of interferon monotherapy patients had improvement.
- Patients with loss of virus were more likely to have improvement.
- Some patients without loss of virus did have improvement on their liver biopsies!

Interferon Alfa-2b Alone or in Combination with Ribavirin as Initial Treatment for Chronic Hepatitis C. McHutchison JG, et al. New England Journal of Medicine, 1998.

Histological improvement occurred in all groups treated (short or long term, mono- or combination therapy). Improvement was greatest in the groups given combination treatment for the full year. 86% of patients who cleared the virus had improved liver biopsies regardless of what type of what type of therapy they received. 39% of patients without virus eradication (that is, these patients did not clear the virus from their blood) had significant improvement in their liver biopsies.

These data are the good news. For patients with a sustained loss of hepatitis C virus, the liver biopsy will become normal over the next few years. In general, this does not pertain to patients with cirrhosis on a pretreatment liver biopsy.

The bad news is that when biopsies are done before and just after treatment, the fibrosis scores do not change. That is the degree of scar tissue present on the biopsy did not improve. The improvement in biopsies is due to a decrease in the amount of inflammation. No studies have been done to see if some "nonresponders" (those with persistently positive virus tests) would have a decrease in their fibrosis scores if they were treated with longer courses of therapy.

Future studies will look into some of these issues. It is my personal bias that patients with advanced fibrosis (bridging fibrosis or cirrhosis) on biopsy should be treated differently than patients with less advanced fibrosis. We should look for evidence of response by virology (Hepatitis C RNA tests), biochemistry (ALT), and perhaps even by biopsy. We should perhaps continue treatment in patients who fail to clear the virus but have normalization of their ALT on therapy. This decision must be made jointly between the patient and physician. Side effects from therapy must always be considered in the decision of whether to continue treatment.

Please Note:

If you experience any unexpected, serious, or not previously reported adverse events to Rebetron or interferon, please ask your doctor to report this to the FDA. This information could benefit us all. Thank you.

First Annual Hep C Picnic

Alan Franciscus

Under the beautiful sky of an autumn afternoon in San Mateo, the Hepatitis C Support Project held its first annual Hep C Picnic.

It was great to meet so many family and friends of people with Hep C - over 80 people from young (2 years old) to older (70 years old) and just about every profession. It was a great microcosm of people with Hep C.

Highlights of the picnic included the "Whining Contest"! Judged to be the best Whiner of 1999, Linda Sweeney whined and complained so much we had to tell her to stop. Linda vows to keep practicing and prepare for next year's contest where we expect competition to be intense.

The highlight of the picnic was the presentation of 'Volunteer of the Year' award to Barry Howe. Barry's commitment of time and energy has been instrumental in our success. Currently, Barry manages the helpline, newsletter distribution and runs a support group in Marin. Additionally, Barry has just been named Co-Director of the Hepatitis C Support Project. Congratulations Barry - you deserve it!!

We would also like to thank the following organizations for donating prizes - San Francisco Chronicle, Amgen, Roche, Schering and an autographed T-shirt by Phil Lesh!!

A big "Thanks" to Craig Miller and Debra Magnum who worked so tirelessly to make this event so enjoyable. Deb made a great liver mascot!!

Please stay tuned - we will announce the dates for next year's "Second Annual Hep C Picnic and hope that you will be able to join us for another day of celebration.

Subscription rates: \$12.00 / year – 12 issues – back issues available at \$1.00 each. Please fill out the form below and send to:

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*Scholarships are available for \$6.00. Please fill out the above information and write 'Scholarship' on the form.

Your tax-deductible donations will also be greatly appreciated. Please indicate your preference:

_____ Hepatitis C Support Project _____ Back to Life - Santa Barbara _____ Back to Life - Orange County

Treatment Advocate - continued from page 4 -

World Map of Hepatitis C Virus around the Globe:

http://www.epidemic.org/theFacts/theEpidemic/hepC_worldPrevalence.html

Governing Health Bodies

World Health Organization (WHO): <http://www.who.int/>

United Nations (UN): http://www.un.org/site_index/

Other Health Ministries, Health Statistics, etc: <http://www.who.int/whosis/countrysites/>

International, Non-Government, Health-related Organizations: <http://www.who.int/ina-ngo/>

Surgeon General of the US: <http://www.surgeongeneral.gov/>

The Office of Public Health and Science (OPHS): <http://www.surgeongeneral.gov/ophs/default.htm>

CDC, National Center for Infectious Disease (NCID): <http://www.cdc.gov/ncidod/diseases/hepatitis/index.htm>

Health and Human Services (HHS): <http://www.os.dhhs.gov/>

National Institute of Health (NIH): <http://www.nih.gov/health/>

Food and Drug Administration (FDA), Website Index: <http://www.fda.gov/opacom/index/index4.html>

National Academy of Sciences (NAS): <http://www.nas.edu/>

Indian Health Services (IHS): <http://www.tucson.ihs.gov/>

National Institute for Biological Standards (England): <http://www.nibsc.ac.uk/links.html>

United Nations Children's Fund (UNICEF) <http://www.unicef.org/>

Health Canada, online: <http://www.hc-sc.gc.ca/english/>

Disability:

Things to know before you file SSDI: <http://members.aol.com/pbcers/ssd.htm>

How to apply for Soc. Sec. Benefits (SSA): <http://www.ssa.gov/disability.html>

Estimates your future Social Security benefits (PEBES): <https://s3abaca.ssa.gov/pro/batch-pebes/bp-7004home.shtml>

Nat. Org. of Social Security Claimants' Reps (NOSSCR): <http://www.nosscr.org/hallfaq.html>

Independent Living: <http://www.ilusa.com/>

Other Internet Disability Sites in General: <http://janweb.icdi.wvu.edu/kinder/linkframe.htm>

ADA, Department of Justice (DOJ): <http://www.usdoj.gov/crt/ada/adahom1.htm>

DOJ's ADA Info Line, 1-800-514-0301

Disability Discrimination in the Workplace: <http://www.cyberscribe.com/talklaw/disabil.shtml>

ADA in Layman's Language: <http://www.swiftsite.com/adaman/aboutada.html>

The Commission on Mental and Physical disability Law (ABA): <http://www.abanet.org/disability/referral.html>

National Alliance for the Mentally Ill (NAMI): <http://www.nami.org/toc.htm> - 1-800-950-NAMI

Wellness for Caregivers of an Aging Relative, Friend or Neighbor: <http://www.caregiving.com/index.html>

Chart Book on Disability: <http://www.infouse.com/disabilitydata/chartbook.choices.html>

Disability Statistics Center (DSC): <http://dsc.ucsf.edu/links.html>

National Organization on Disability (NOD): <http://www.nod.org/>

Nat. Info Center for Youth and Children's Disabilities(NICHCY): <http://www.nichcy.org/index.html>

Federal Programs to Help the Homeless (HUD): <http://www.hud.gov/homeles2.html>

Federal Government:

Federal Government Agencies Directory:

<http://www.lib.lsu.edu/gov/fedgov.html>

Federal Web Locator: <http://www.law.vill.edu/fed-agency/fedwebloc.html>

Federal Government Information Locator Service (GILS): http://www.access.gpo.gov/su_docs/gils/gils.html

Dept. of Commerce, National Technical Info Service (NTIS): <http://www.fedworld.gov/#usgovt>

Harden Political System: <http://hpi.www.com/us50/map.html>

Legislative, (House and Senate E-mails) (LOC): <http://lcweb.loc.gov/global/legislative/email.html>

Social Security On-line (SSA): http://www.ssa.gov/SSA_Home.html

The Government Manual, Nat. Archives and Records Admin(NARA): <http://www.access.gpo.gov/nara/nara001.html>

Catalog of Federal Domestic Assistance Programs (CFDA): <http://aspe.os.dhhs.gov/cfda/index.htm>

Links to Government Servers and Information: <http://www.eff.org/govt.html>

Canadian Government, Federal Organizations: http://canada.gc.ca/depts/major/depind_e.html

Note: If you do not have access to a home or work computer, check with your local library - many have computers to use free of charge.