

Canada's Hepatitis C News Bulleting

www.hepcbc.ca

FIRST-HAND VIEW OF AN INDIAN GENERIC DRUG COMPANY

by Cheryl Reitz, HepCBC Board Member and Volunteer

Before my visit to Lupin Limited in Pune, India, on November 20, 2015:

OK, this is to prepare you for what I learned about generic drugs on November 20th. Close vour eyes. What do you envision when I say: "Generic Drug Company in India"? If you're like me, you probably have viewed these companies as inferior to companies which research and develop new drugs, rightfully hold the patents, and make the big bucks. After all, generic companies simply copy what someone else has spent years—in many cases, decades-working on, discovering the uses and analyzing the structure of unique new Active Pharmaceutical Ingredient (API) molecules. They perfect the dosage and discover side-effects through clinical trials, while at the same time they've had to explore many research 'dead ends' which result in zero 'payback' before finally hitting on the 'pay dirt' of a commercially viable product.

As to the quality, while generic packaging always claims the contents to be equal to the patent version in efficacy and safety, I have commonly heard doubts about these claims, possibly because generics are often produced in countries such as India in which buyers fear quality standards may not be as strictly adhered to as in higher-income countries. Though the cheaper pricing is nice, it further adds to suspicions that generics may not be inspected as thoroughly by under-paid workers, that different standards might be applied, or that inferior APIs may have been used.

On the other hand, generic companies are often viewed more altruistically as suppliers of critical drugs to countries and peoples who simply cannot afford the patent versions. In some cases their products have resulted in saving thousands—possibly millions—of lives when the principle of "significant medical need" is deemed to overshadow the principle of "protecting intellectual property."

Though North Americans such as myself Coming Up



Cheryl with 4 top scientists at Lupin

may complain about our drug bills occasionally, we generally accept paying full price for the patented version of a prescription drug until the patent expires. After that, doctors will still often prescribe the patent version, and patients still purchase patent versions of over-the-counter medications, even when a generic version has become available at a lower price. North Americans seldom challenge drug makers claims that they must charge high prices during the period of the patent to recoup the significant research and development costs, assuming that once the patent expires, generic suppliers in countries with (Continued on page 2)

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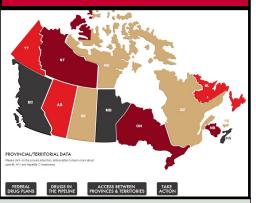
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ming Up

PROVINCE-SPECIFIC HCV TREATMENT ACCESS MAP NOW ONLINE!



The Canadian Treatment Action Council (CTAC) in Toronto has developed a great new free online tool for getting the most current HCV treatment news in Canada, province-by-province. It can be used by patients and medical care providers or anyone with an interest in HCV treatments. How to access:

- (1) Click on http://www.ctac.ca/resources/treatment-access-map
- (2) Click on the Province or Territory name
- (3) Click on "HCV Medications" tab
- (4) Click on the name of the drug and all the important information you need about the drug will pop up.

You can also watch an excellent video about this map and future goals for improving it further at:

https://goo.gl/FuP03U



Please let HepCBC (and the folks at CTAC as well!) know how you use this map, and if you have any suggestions. We at HepCBC are

very enthusiastic about this map and hope it will get lots of use.

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**Download the hepc.bull free (since 2001) at www.hepcbc.ca/hepc-bull-monthly-newsletter/

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LETTERS TO THE EDITOR

The hepc.bull welcomes and encourages letters to the editor. When writing to us, please let us know if you do not want your letter and/ or name to appear in the bulletin.

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NEW SUPPORT PHONE LINE NUM-BERS: VANCOUVER & LOWER MAIN-LAND: 1-604-259-0501

FOR THE REST OF BC: 1-778-655-8000

(INDIAN GENERIC DRUG CO.—Cont'd from page 1) lower production costs will start selling for much less, driving down the price globally.

This system is currently being challenged by some vocal advocates in the hepatitis C world, who see the pricing of HCV drugs as one of the greatest barriers to treatment in middle and even higher income countries such as our and how to participate in our annual general own. So...when given the opportunity to do a meeting, plus other ways to make your voice little research into the generic drug industry in India in person, I jumped at it, vowing to maintain an objective stance and open mind.

The November 20th Visit and 11 Inter-

The preconceptions I've outlined above have been significantly challenged, and I now see generic companies as important and complementary partners with patent companies, as part of the way towards the eventual eradication of this terrible virus, HCV, from the *planet.* Here's what changed my mind...

While visiting my son who works in Pune, India, I was given a remarkable opportunity to meet over one full day with eleven senior members of Lupin Limited's (http://www.lupin.com) management and research staff to interview them about the Indian generic industry. Lupin, founded in India in 1968, is now the tenthlargest generic pharmaceutical company in the world in terms of revenue, and the #6 supplier of generic drugs (in terms of prescriptions) in the USA. Lupin sells 19% of its market share to India and 45-50% to the USA. Lupin sells very little of its product line in Canada though the company recently opened an office here.

Two aspects of the company were somewhat surprising to me: First, Lupin holds numerous

patents (both on drugs themselves, and on various processes they've developed to produce generic drugs). Consequently, they produce both generic and patent drugs. Second, its mission incorporates significant aspects of corporate social responsibility. Lupin was originally created to provide low cost treatment for tuberculosis in India, and continues to concentrate its new drug research and development on treatment of "unmet needs" such as rheumatoid arthritis pain management. And in 1988 the Lupin Human Welfare and Research Foundation (LHWRF) was founded; it works closely with the government to improve the lives of poor families in rural India.

While wages paid are significantly lower than in No. America, workers' living costs are proportionally lower as well. Their standard of living is comparable to ours.

I want to stress that everyone with whom I spoke at Lupin emphasized that the other large generic companies in India which sell to the No. American and European markets follow the same rules and adhere to the same high standards that Lupin does. While they provided examples from their own company, they assured me their answers were applicable to all mainstream generic drug companies in India, and, in many cases, to the industry worldwide.

O1: Do you use the exact same formulation and standards for the same product being sold in China or Nigeria as you do for that sold in Canada?

A1: No. We carefully customize product formulation and packaging according to the rules and standards of the country in which they will be sold. No batch will be sold to more than one country, except in the rare case they go by absolutely the same standards. While the international generic name must be included on all products, each country and company may have its own unique brand name for the same product. In some cases, a US and Canadian product may share the same generic brand name from the same company, but frequently they are different. In India, the pharma standards branch has been working closely with the USA's standards branch, the US Pharmacopeia (USP), with the goal of reaching equity, eventually. At present India has regional variations in standards. The Indian standard does not in any way affect the country-specific international standards used by India's generic compa-

Q2: How do you ensure that the active pharmaceutical ingredients (API) are as efficacious and of the same formulation

(Continued on page 3)

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(INDIAN GENERIC DRUG CO. —Continued from page 2) as the original?

A2: To quote Dr. Makarand K. Avachat, Senior Vice President of Lupin's Pharma Research and Development in Pune: "When doing generic product development, the sole aim is to make a product which is as pure and consistent as possible a copy of the original molecule, on a commercial scale." The generic company must submit to the government a very detailed plan of how they will ensure this; this plan, which must include the medical information insert and even the packaging materials, must be approved prior to starting commercial production.

Companies working under the auspices of the original manufacturer generally are able to make this plan quickly, getting the generic version to market much sooner as they are able to quickly access the original molecule(s') formulae, APIs and production processes for this. However, typically a company must independently develop its own version of the molecule and how to produce it. These must be evaluated through Bioequivalency Studies (BES), which take 2-3 years or more of research. The BES may involve clinical trials; sometimes these are required by the Indian or other government regulatory agencies. The need for BES helps explain why Lupin, like many other generics, spends at least 9% of its revenue on research, which can frequently result in development of production processes which are patentable.

Lupin produces approximately 60% of its own APIs, and the rest come primarily from China or elsewhere in India. Lupin communicates its high standards to each supplier, visits the supplier in person, and measures the purity, both in visits and delivery spot checks. If the APIs submitted to Lupin fail to meet the standard, defective batches are destroyed and another supplier, found. The US Food and Drug Administration (FDA) has inspectors in India who inspect APIs and generic products going to the USA; the European Medicines Agency (EMA) similarly inspects APIs ending up in European medications.

Q3: How do you ensure safety by removing dangerous impurities?

A3: This question was answered by Dr. Pritesh R. Upadhyay, Lupin's Senior Vice President of Analytical Research. The first question Lupin researchers ask about a new product is, "What is the 'total impurity' of this product?" If over 0.10%, the researchers must determine if any of those impurities are genotoxic, carcinogenic, or mutagenic. Lupin uses an Indonesian software program called DEREK to look for and analyze these particular impurities; about 80% of impurities are found to be benign or safe. If dangerous impurities are found, Lupin researchers develop a test that will cross-check the confirmation pre-

(Continued on page 6)



Victoria, December 1st, 2015

BEST OF THE UPCOMING FESTIVE SEASON TO ALL!

The holiday season gives us time to reflect on activities of the past year, savour our successes, and plan an even better future. Along with our warmest wishes, we would like to share with you some of HepCBC's many achievements and challenges, and request your continued support in 2016.

For over 15 years, HepCBC has consistently provided crucial support and information to the hepatitis C community. This last year, thanks to donations, we have been able to open an additional "Outreach" office in Vancouver. Because both the hepatitis C and broader communities recognize the high quality of our primarily volunteer-run, client-focused services, we are happy that we have been able to create two part-time project-management positions, while expanding our volunteer-run services. However, we still must watch our budget and limit our spending. If all our past donors simply gave again this year, we might not have to worry about fundraising for the rest of the year. Here is what we do now:

EDUCATION and OUTREACH

We have continued to publish the *hepc.bull*, Canada's leading hepatitis C newsletter, every month since March, 1996. Our website (<u>www.hepcbc.ca</u>), pamphlet series, and FAQ's provide relevant, up-to-date information for people infected or affected by hepatitis C—in both official languages and Spanish. We put up information tables at events like flea markets and shopping malls, immigrant health and wellness fairs, 55+ Lifestyle shows, First Nations health fairs, etc.

SUPPORT

HepCBC's Victoria Main office is our nerve centre, a safe place to meet, and home to our resource library. We regularly receive requests for information and support from all over North America and beyond, and still provide phone, email, or inperson peer support to anyone affected by this disease.

AWARENESS and PUBLICITY

elsewhere in India. Lupin communicates its high HepCBC works at local, provincial, federal, and international levels to combat standards to each supplier, visits the supplier in Liginorance and stigma about hepatitis C. Besides cooperating with local agencies, we person, and measures the purity, both in visits and Lactively participate in national and international hepatitis C organizations which delivery spot checks. If the APIs submitted to Linform decision-makers about hepatitis C needs, best-practices and current research.

TAX-DEDUCTIBLE DONATION: Your tax-deductible contribution will go directly to hepatitis C education, awareness and support. **Thank you for your generous support now and through the years.** We wish you all the best in 2016!

I want to help HepCBC!

Please donate via our website: http://hepcbc.ca/donate/ or mail your cheque and this form to:

HepCBC #20—1139 Yates Street Victoria, BC V8V 3N2



HepCBC Hepatitis C Education and Prevention Society is a Registered Canadian Charity: 86800-4979-RR0001 As a volunteer (we'll forward you information)
Here is my tax-deductible donation of \$30, \$50, \$100. Other

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U.S. FDA OKAYS GILEAD'S HCV DRUG FOR EXPANDED USE

On November 12, 2015, the U.S. Food and Drug Administration (FDA) "approved Harvoni® (ledipasvir/sofosbuvir) for expanded use in patients with genotype 4, 5 and 6 chronic hepatitis C virus (HCV) infection and in patients co-infected with HIV. In addition, Harvoni plus ribavirin (RBV) for 12 weeks was approved as an alternate therapy to 24 weeks of Harvoni for treatment-experienced, genotype 1 patients with cirrhosis."

Sadly we note that Genotype 3 has not been included in the above approval, but in any case the above is just a stopgap: Gilead expects the FDA to approve its newest pangenotypic treatment comprising a fixed dose of sofosbuvir and velpatasvir (SOF/VEL) sometime in 2016. This newer treatment is for all genotypes, and includes those with decompensated cirrhosis (Child-Pugh B).

More: http://wp.me/p6F7CY-1yU
http://wp.me/p6F7CY-1wH

(Additional article, bottom page 6)

Peppermint Patti's FAQs, Version 10.1!!

Do you have questions about Hep C or about treatment? Do you want to know how to make healthier choices for your liver?

Download for FREE:

http://hepcbc.ca/wp-content/
uploads/2015/04/
FAQ_v10_1.pdf

NEW INFO FROM CATIE CIRRHOSIS

http://www.catie.ca/en/practicalguides/understanding-cirrhosis

THANKS!!

HepCBC thanks the following institutions and individuals for their generosity: The late John Crooks, Allison Crowe, Billie Wood and Adrian, Victoria Positive Living Centre, Provincial Employees Community Services Fund, the Victoria Foundation, Dr. C. D. Mazoff, Judith Fry, and the newsletter team: Beverly Atlas, Diana Ludgate, Alp, Cheryl, Anamaria, and S.J.

Please patronize these businesses that have helped us: Top Shelf Bookkeeping, Merck Canada, Bristol-Myers Squibb, Roche Canada, Vertex, Gilead, Janssen, Boehringer-Ingelheim, AbbVie, Rx&D, VanCity, Country Grocer, and Thrifty Foods.

VANCOUVER HCV ERADICATION CONFERENCE 2015



On November 11-12, the second International Meeting on Hepatitis Cure and Eradication, sponsored by Virology Education, was held in Vancouver. HepCBC Project Managers, Shakuntala Soden and Catherine Luke, plus HepCBC volunteer Douglas Laird (who attended as a representative from Action Hepatitis Canada), were among the 88 attendees. The conference was organized around five topics: vaccines, testing, treatment, access to treatment and care, and how to prioritize HCV treatment from the perspectives of health economics, civil society, payers, and medical communities. Next issue we'll report more on this.

One interesting highlight was an Australian physician's description of plans to encourage general practitioners there to administer HCV treatment. This plan will involve much additional education for this large group of potential treaters; however, this has been done successfully with HIV treatment.

CONFERENCES

25th Conference of the APASL 20-24 February 2016 Tokyo, Japan

www.apasl2016.org/

Canadian Digestive Disease Week

Cdn. Assn. for the Study of the Liver and Cdn Assn. of Gastroenterologists 26-29 February 2016
Fairmont Queen Elizabeth, Montréal, QC. http://www.hepatology.ca/?page_id=51

5th Canadian Symposium on HCV 26 February 2016

Fairmont Queen Elizabeth, Montréal, QC.
Contact Norma Choucha: <u>ncrtp.hepc@gmail.com</u>
<u>https://event-wizard.com/Symposium2016/0/</u>
register/

The International Liver Congress 2016

13-17 April 2016 Barcelona, Spain http://ilc-congress.eu/

12th World Congress

20-23 April 2016 Sao Paulo, Brazil www.ihpba2016.com/

Digestive Disease Week

21-24 May 2016 San Diego, CA www.ddw.org/attendees/registration

2016 APASL Single Topic Conference on Hepatitis C

10-12 June 2016 Kaohsiung, Taiwan www.apasl-hcv-2016.org/

GEEW 2016

34th Gastroenterology and Endotherapy European Workshop 22 June 2016 Brussels, Belgium www.live-endoscopy.com/

EASL - AASLD

Roadmap for Cure
23-24 September 2016
Paris, France
Info: www.easl.eu/medias/PDFs/20151119%
20HCV%20special%20conference.pdf

WORLD HEPATITIS SUMMIT SLIDES

Now you can feel like you attended the World Hepatitis Summit Meeting held in Glasgow, September 2-5, 2015! See most of the slides from the presentations in your own home, free:

www.worldhepatitissummit.com/ presentations/

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WOULD YOU RESPOND TO **TREATMENT?**

WOULD YOU RESPOND TO TREATMENT? WHAT'S THE BEST ONE FOR YOU?

http://wp.me/p6F7CY-1yZ

"Very interesting, but I think the tool is way too simplified. For example simeprevir cannot be used if a person's IL28B genetic polymorphism is anything other than the CC allele; people with 1a generally have poorer results than people with 1b, and there are other predispositions (heart disease)..." C.D.M.

GENOTYPE 3?

Have you read about Dazlinka/Sovaldi and RBV? Check it out:

http://wp.me/p6F7CY-1z2

UPCOMING BUS AD **CAMPAIGN!**

In partnership with Positive Living Fraser Valley, HepCBC is running a bus campaign from December 14th for one month.

Look out for buses with our ad on them in and around the Fraser region (Burnaby, Port Coquitlam, Surrey, Chilliwack, Abbotsford and the surrounding areas), encouraging people to find out more about hepatitis C and to get tested for it.

Snap a picture of a bus with our ad on it and send it to us. We'll include some of them in a future issue of the Bulletin.

You can find out more about hepatitis C testing and treatment on our website (www.hepcbc.ca) and on Positive Living Fraser Valley's website (www.plfv.org). Drop us an email or give us a call and we will tell you

how to get tested and about the cures available.



Have you been undetectable for at least ner, RN, Vancouver Island. Now SVR24. others. Add your name! Congratulations to our friends:

- 1. GJ SVR Dec 1998 IFN/RBV 52 wks., Dr. Anderson / Natalie Rock, Vancouver, BC.
- 2. Jeanie Villeneuve Oct 2000 Schering IFN/RBV
- Amberose (GT2a/2c) SVR 2000 Schering IFN/RBV 24 wks.
- 4. **KG-**Transfused 1987 (treatment-naïve GT2A/2C) IFN/RBV 24 wks., 2003-2004, Toronto. SVR confirmed 2014
- 5.[NEW] Murray Palmer (GT1a) Transfused. SVR 2003 - Rebetron 48 wks (cleared at 24 wks.) SVR confirmed 2010.
- 6. Darlene Morrow (GT1 relapser) Mar 2004 - Hyperthermia/Induction + pegIFN/RBV.
- 7. Kirk Leavesley (GT1) 2004 Roche
- 8. Beverly Atlas (GT1a) 2005/2006 Albuferon/RBV 44 wks.
- 9. Steve Farmer (Transplant Vancouver 2005) IFN/RBV 72 weeks. SVR 2008
- 10. Gloria Adams† (GT1b relapser) Fall 2009 IFN/RBV/telaprevir 48 wks., Drs. Erb & Yoshida, Vancouver, BC)
- 11. Don Crocock (GT1 Stage II) Dec. 2010 IFN/RBV - 48 wks.
- 12. Daryl Luster (GT1a) Feb 2011 IFN/ RBV/RO5024048 48 wks.
- 13. Donna Krause (GT1 partial responder) SVR Nov 2011- Pegasys/Copegus, danoprevir/ ritonavir/R05024048 24 wks., Dr. Erb, Vancou-
- 14. Hermione Jefferis (GT1a) SVR 2011 PegIFN/RBV, 48 wks., Dr. Partlow, Victoria.
- 15. Cheryl Reitz (GT1b previous partial responder) SVR12 Mar 2013 - asunaprevir/daclatasvir 24 32. Wendy Mackay Transfused 1971 wks., Dr. Ghesquiere, Victoria, BC.
- 16. Anita Thompson (GT1a treated 3 times) rhosis. SVR24 Aug 2015, Harvoni 24 Cirrhosis - Apr 2013 - Pegasys/boceprevir 48 wks. Dr. M. Silverman, Whitby, ON.
- 17. Leon Anderson (GT2 partial responder) SVR24 May 8, 2013 - GS-7977/RBV 16 wks. Dr. Alenezi & Dr. Conway- VIDC - Vancou-
- 18. Joan King (GT1b treated 5 times) SVR24 June 2013 - asunaprevir/daclatasvir 24 wks., Dr. Ramji, Vancouver, BC
- 19. Jackie (GT1 relapser) SVR24 June 2013 - IFN/RBV/boceprevir 48 wks., Dr. Keith Boyell, Guelph, ON.
- 20. Sandy J. (GT1a treatment-naïve) Oct 31, 2013 - IFN/RBV/Victrellis 28 wks., Fran Faulk-

- 12 weeks after treatment? Encourage 21. Andrew P. (GT 1a many prev treatment attempts over 10+ years, including Incivek Jan 2014) sofosbuvir/ledipasvir + RBV 24
 - 22. **Peter A Walker** (GT1a, treatment-naïve) SVR Jan 2014 - PegIFN/RBV +boceprevir (Eprex–for low RBC count from RBV.)
 - 23. Diane Stoney Transfused 3/21/79 (GT 1a treatment-naïve) Feb 4 2014 - 12 wks. placebo, then 12 wks. on ABT-450/r+ABT-267+ABT-33+RBV. Dr. Tam, Vancouver, BC
 - 24. Coreen Kendrick (GT1a treatmentnaïve) Mar 10, 2014 MK5172/MK8742 12 wks., Dr. Ramji, Vancouver, BC.
 - 25. Jack Swartz (Treated 3 times) Apr 2014 IFN/RBV/Victrelis, Dr. S. Wong, WHSC.
 - 26. **Del Grimstad** July 2014, 12 weeks simeprevir/Sovaldi
 - 27. Linda May (GT1b transfused, treatment-naïve) asunaprevir/daclatasvir 12 wks., Dr. Tam, LAIR Centre.
 - 28. Robin Tomlin (GT1 treatment-naïve) SVR12 May 4, 2014 - Harvoni 12 wks., Dr. Yoshida VGH.
 - 29. Bob (GT1a/HIV relapser) SVR24 Nov 2014 pegIFN/RBV/Incivek 24 wks., Dr. Montaner, Salt Spring Island, BC.
 - 30. Nancy Neel (GT1a previous relapse IFN/RBV 48 wks.) SVR24 Mar 2015 MK-5172/MK 8742 12 wks., Dr. Ramji, Richmond, BC.
 - 31. Sandra Newton (GT1a treatmentnaïve, infected 1984) SVR12 Aug 2015. Harvoni 8 wks., Dr. David Pearson, Victoria. BC
 - (GT1a prev. 48 wks., Victrelis Triple) Cirwks., Dr. Tam, LAIR Centre
 - 33. Wendy L (GT1b pegIFN/RBV intolerant) SVR12 Sep 15, 2015, Harvoni 8 wks. Dr. Steve Brien, Peterborough ON.
 - 34. Nancy Dunham [NEW] Transplant patient, SVR 2015, Harvoni Toronto, ON.

Please send your name and info to Joan at info@hepcbc.ca

You Can Have Hepatitis C and Not Know it.





ere is a Cu

Find out more at HEPCBC.ca



HEPC.BULL DECEMBER 2015 ISSUE NO. 194 Page 5 (INDIAN GENERIC DRUG CO.—Cont'd from p. 3) dicted by DEREK. Then they inform the company that a particular impurity is toxic, and that it must improve the process to remove the toxic substance below a certain (safe) limit. Once production starts, the inspection process will include stringent monitoring for any toxic impurities."

Q4: How does India's generic drug industry respect international Intellectual Property laws?

Generic drugs are produced following the expiry of the patent, or in a cooperative sub- the AASLD Conference this month in San contract with the patent-owner, or in a patent Francisco. They looked at the records of -superseding agreement with an official body such as the government of India, Medicines Patent Pool, UNAIDS, or the World Health those, 100 developed HCC after being Organization. There is also a precedent for superseding patents in India through granting an Indian generic company a Voluntary License (VL). In these cases, the price of a vital drug in India is thought to be unaffordable to India's citizens, so the patent holder is first asked to lower its price, or to share its Intellectual Property license with the generic company and mutually negotiate royalties. At this point, if the patent holder agrees to the proposal, a VL is issued to the generic company. If the patent holder refuses, the generic company can then ask the government for a Compulsory License (CL). The likelihood of the CL being approved depends on the severity of the disease, the drug's benefit to the public health, and the price. In all cases, these VL and CL drugs cannot be exported to countries which have granted sole market to the patent holder; however, patients from any country may come to India and be treated by Indian doctors with the drug through recognized procedures developed by India's Dept. of Medical Tourism.

That's it! With the understanding gained through this experience, I have much more confidence in the quality of generic drugs, and tons more respect for this industry and the people who work in it. I hope you will join me in gratitude to these eleven researchers who so willingly shared their extensive knowledge and experience with this nonmedical Canadian grandmother, and that you have enjoyed and learned something new during this armchair journey with me.

SVR? YOU CAN STILL **GET LIVER CANCER**

Hepatocellular carcinoma (HCC) is the most common liver cancer suffered by those with hepatitis C; it is often found in those who have not been treated whose disease has progressed. The new treatments, direct-acting antivirals (DAAs) are curing almost everyone, but researchers in Houston. TX wanted to know if the risk of HCC goes away. They presented their findings at 10,738 patients who had been cured (SVR), all with no history of HCC. Of cured. Scary... That means that if you're cured, you have 0.33% per year chance of getting HCC. You are more likely to be among that unlucky bunch if you had cirrhosis, are over 65, if you have diabetes or if you have GT3 (0.9-1.55% per year). These results came mostly from male veterans, who took IFN-based treatments. More data is needed. In the meantime, the researchers suggest earlier treatment is necessary, before the patient is older and develops cirrhosis.

Regular ultrasounds and alpha-fetoprotein (AFP) tests are necessary to screen for HCC, even after you are cured.

Source: AASLD's Liver Meeting®, San Francisco, CA, November 14-17: "Incidence and predictors of hepatocellular carcinoma following sustained virological response."

Press releases and all abstracts are available online at www.aasld.org.



HAVE YOU HAD YOUR

FLU SHOT? PNEUMONIA SHOT? ULTRASOUND? **AFP TEST?**

VIRUSES THAT AFFECT THE LIVER

Those of us who have or have had hepatitis C must take extra care so as to not get other infections, since many if not most of us still have scarring, even if the virus is gone. This means taking care, as before, not to expose our bodies to toxins or anything that can cause liver inflammation (such as tobacco. alcohol and fast foods).

As you may have heard, "hepato" refers to the liver, and "itis" means inflammation, so "hepatitis" is inflammation of the liver. A very interesting article at inpractice.com. called "Viruses that Affect the Liver," shows that some forms of viral hepatitis may be caused by a broad range of pathogens. Viruses that affect the liver are called hepatotropic. and there are three main families: Primary, secondary and exotic.

Hepatitis A, B, C, D and E, the ones we are most familiar with, are primary hepatotropic viruses. But there are other things, including other viruses, that can damage the liver. Sometimes the damage is mild. Sometimes it can be life-threatening, especially in people with prior liver damage, altered immune systems and/or transplants.

Secondary hepatotropic viruses include herpes-viruses (cytomegalovirus, Epstein-Barr, herpes viruses, varicella, adenoviruses [colds], enteroviruses [stomach infections] paramyxovirus. The third group, exotic hepatotropic viruses, consists of dengue virus, yellow fever, Ebola, Marburg, Bunya, Rift Valley fever, Crimea Congo hemorrhagic fever, and Lassa fever viruses. These can all cause hepatitis. This interesting article deals with the secondary and exotic hepatotropic viruses.

How can we avoid these viruses? Get your Hep A/B vaccines. Avoid contact with bodily fluids of others. Make sure your medical caretakers use universal precautions. If you are travelling to exotic places, tell your doctor before you go, and get any recommended vaccines. Take insect repellant. Sleep under a mosquito net. Do you have any other ideas of how to avoid further damage to your liver? Write to us at info@hepcbc.ca

Source: http://goo.gl/vSsI9G

SOFOSBUVIR/VELPATASVIR SUBMITTED TO US FDA

On October 28, Gilead submitted a drug application to the US FDA for approval of the combination of two DAA's (direct-acting antivirals) sofosbuvir (SOF) and velpatasvir (VEL). The combo has been granted "Breakthrough Therapy" status, with the idea that it could offer better treatment than those available. SOF is a polymerase inhibitor and VEL is an NS5A inhibitor, targeting all genotypes. The intention is to get approval for genotypes 1-6. The combo is a once-a-day pill. Treatment will be 12 weeks for patients with no cirrhosis and 24 weeks with patients with Child-Pugh Class B cirrhosis. SVR in clinical trials has been 83-98%, depending on liver damage. Side effects included headache, fatigue and nausea. (See additional article mentioning this drug on page 4)

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ABBVIE CARE

With the approval of HOLKIRA PAKTM, AbbVie is launching AbbVie Care, which is a program that will provide best-in-class solutions to improve outcomes for people living with hepatitis C.

Canadians prescribed HOLKIRA PAKTM will have the opportunity to request to be enrolled in AbbVie Care. The signature care program is designed to provide a wide range of customized services including reimbursement assistance, education and ongoing disease management support. AbbVie Care will not only support health care professionals but people living with genotype 1 hepatitis C throughout their treatment journey to achieve high cure rates in the real world.

For enquiries: 1-844-471-2273.

CLAIRE

Bristol-Myers Squibb Canada has created Claire, a patient support program designed to provide patient health information and reimbursement assistance for patients who have been prescribed DAKLINZATM (daclatasvir). This personalized patient support program represents a service offered at no cost to the patient and is fully confidential. It will be available to patients once the product is commercially available, which is expected before the end of September. Once it is available, you can call the information line for more details at: 1-844-428-2559. Should you have medical enquiries regarding DAKLIN-ZATM, please contact our Medical Information Department at 1-866-463-6267.

MOMENTUMTM SUPPORT

To learn more about SOVALDITM, HAR-VONITM or the Momentum ProgramTM in Canada, the patient should speak to his/her doctor or nurse or call the Gilead Sciences Canada medical information line at 1 855 447 7977. Eligible patients may receive an integrated offering of support services for patients and healthcare providers throughout the entire treatment journey, including:

·Access to dedicated case managers/ reimbursement navigators to help patients and their providers with insurance-related needs, including identifying alternative coverage options through private, federal and provincially-insured programs.

- •The SOVALDITM/HARVONITM Co-pay assistance program, which will provide financial assistance for eligible patients who need help paying for out-of-pocket medication costs.
- •Medication delivery services.
- •Compliance and adherence programs.

MERCK CARETM

MerckCareTM is a program to help people who have been prescribed PEGETRONTM, VICTRELISTM or VICTRELIS TRIPLETM. The program provides:

- ·assistance with reimbursement and/or insurance claims.
 - •financial assistance for co-pay/ deductible for people who qualify.
 - •24/7 nursing support by phone. •multilingual assistance.

 - •home delivery of medication.

MerckCareTM provides all of these services free of charge.

To enroll in MerckCareTM, you can call 1-866-872-5773 or your doctor or nurse can submit an enrollment form for you. Reimbursement specialists are available from 8:00 a.m. to 8:00 p.m. EST Monday to Friday, excluding statutory holidays.

PEGASSIST

The PegAssist Reimbursement Assistance Program provides reimbursement coordination assistance for patients who have been prescribed Pegasys or Pegasys RBV. The program will assist in securing funding for patients to ensure that they can start, stay on, and complete their treatment successfully. PegAssist Reimbursement Specialists are available (Monday to Friday, 10 AM - 6 PM EST) by calling: 1-877-PEGASYS or 1 -877-734-2797. Patients can also obtain a program enrollment form from their nurse/physician to gain access to the pro-

The program provides financial aid to qualified patients, alleviating financial barriers which may prevent patients from starting treatment, i.e., deductibles and/or copayments. In partnership with CALEA Pharmacy, the program can conveniently deliver the medication directly to patients' homes or to the clinics.

INCIVEK CARE

Vertex's INCIVEKTM Care Patient Assistance Program supports patients with the reimbursement process for INCIVIKTM (telaprevir) treatment (INCIVIKTM, pegIFN, ribavirin). It will give you an efficient assessment of your options and eligibility. You may qualify to receive co-payment and other financial assistance to supplement vour private and provincial drug program coverage. The program also provides dispensing and home delivery options, and expert treatment advice. Call the Support Line at 1-877-574-4298. (Select option 2 for English, then 2 for INCIVIKTM Care.)

IBAVYRTM

Pendopharm has established the IBAVYRTM Patient Support Program. The program will assist patients who have been prescribed IBAVYR™ (ribavirin tablets) with reimbursement navigation, financial assistance and pharmacy services. Case managers will support patients with insurance-related matters and assess eligibility for financial support. Pharmacy services include adherence support, medication delivery and counselling.

To enquire or to enroll, you may call 1-844-602-6858 Monday-Friday 7am to 11pm

BIOADVANCE®

JANSSEN's GALEXOSTM (simeprevir) BioAdvance® program can assist you in many ways during your treatment. This includes compiling and submitting, on your behalf, all the forms and documents required by your insurance company to request coverage of GALEXOSTM, and following up with your insurer to get you the best coverage possible. If you don't have private insurance, the GALEXOSTM: BioAdvance® program will investigate public assistance programs that can help pay for your treatment. Whichever type of coverage you have, if your insurance does not fully cover the cost of treatment, the GALEXOSTM: BioAdvance® program can usually coordinate and provide financial assistance to help you get treated. Finally, the program can offer many other types of support and your doctor and members of your healthcare team will work with the GALEXOSTM: BioAdvance® Program to develop a customized approach to best support you throughout the course of your treatment. Contact: 1-855-512-3740.

COMPENSATION

Class Action Suit Hotline: 1-800-229-5323 ext. 8296 Health Canada Compensation Line: 1-888-434-0944 Red Cross Compensation pre-86/post-90 Registration: 1-888-840-5764 <u>HepatitisC@kpmg.ca</u>

Ontario Compensation: 1-877-222-4977 Quebec Compensation: 1-888-840-5764

CLAIMS ADMINISTRATOR 1986-1990

Claimants may be reimbursed for costs of treatments and accepted hepatitis C medications not covered by public or private healthcare plan while they wait for reimbursement from the 1986-1990 plan.

Administrator 1-877-434-0944 www.hepc8690.com info@hepc8690.com

Pre-86/Post-90

Administrator 1-866-334-3361 preposthepc@crawco.ca www.pre86post90settlement.ca

Settlement Agreement:

www.pre86post90settlement.ca/PDFs/SA/

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SUPPORT BC/YUKON

Armstrong HepCURE Phone support 1-888-437-

AIDS Vancouver Island The following groups provide info, harm reduction, support, education and more:

· Campbell River: Drop in, harm reduction, needle exchange, advocacy. 1371 C - Cedar St.

Contact leanne.wingert@avi.org 250-830-0787

- Comox Valley Harm reduction, counselling, advocacy. 355 6th St., Courtenay. Contact Sarah sarah.sullivan@avi.org 250-338-7400
- Nanaimo AVI Health Centre. Counseling, advocacy. NEW: 102-55 Victoria Rd Contact Anita for details. 250-753-2437

anital.rosewall@avi.org

- Port Hardy (Port McNeil, Alert Bay, Port Hardy Sayward, Sointula and Woss) Drop-in kitchen. 7070 Shorncliffe Rd. Contact Shane, 250-949-0432 shane.thomas@avi.org
- •Victoria Access Health Centre, drop in, disability applications, peer training. Support group Tues 12:30 PM, 713 Johnson St., 3rd floor, 250-384-2366 Hermione.jefferis@avi.org

ANKORS Hepatitis C Project

Hep C Info, support for prevention, testing, treatment and living well with Hep C

- .Boundary, Nelson, West Kootenay Women's gathering monthly. 101 Baker St, Nelson. Contact Laura 1-800-421-2437 250-505-5506 <u>ankorshepc@ankors.bc.ca</u> **◆East Kootney** 209 16th Ave N, Cranbrook,
- Contact Michelle 250-426-3383 1-800-421-2437 ankorshev@gmail.com

Castlegar Contact Robin 250-365-6137 eor@shaw.ca

Chilliwack PCRS Hep C Prevention, harm reduction. 45904 Victoria Avenue, Chilliwack. Contact Kim Lloyd 604-798-1416. lbirdsall@pcrs.ca www.pcrs.ca

Comox Valley Positive Wellness North Island Treatment/Pre & Post-treatment Support Group 2nd & 4th Wed., 615-10th St, Courtenav. Lunch. Contact Cheryl 250-331-8524. Cheryl.taylor@viha.ca

CoolAid Community Health Centre, Victoria. Meetings each Wed 10 AM and Thu 1:30 PM. 713 Johnson St. Support for all stages of treatment (deciding, during, after). Contact Roz rmilne@coolaid.org for treatment or group info.

Courtenay HCV Peer Support and Education Contact Del 250-703-0231 dggrimstad@shaw.ca

Cowichan Valley HCV Support Contact Leah 250-748-3432 *r-l-attig@shaw.ca*

Haida Gwaii support. Contact Wendy wendy@wendyswellness.ca www.wendyswellness.ca

HepCBC info@hepcbc.ca, www.hepcbc.ca Call for office hours. Email support through website form. Peer phone support through:

- Lower Mainland: 1-604-259-0501 Fraser Valley Support/Info: 604-576-2022 (9 am-10 pm)
- **The rest of BC:** 1-778-655-8000

Kamloops ASK Wellness Centre. Chronic illness health navigation/support.

info@askwellness.ca 250-376-7558 1-800-661-7541 ext 232 or Merritt health housing & counseling 250-315-0098 www.askwellness.ca

Kamloops Hep C support group, 2nd and 4th Wed monthly, 10-1 PM, Interior Indian Friendship Society, 125 Palm St. Kamloops. Contact Cherri 250-376-1296 Fax 250-376-2275

Kelowna Hepkop: Phone support, meeting info. Contact Lisa 1-866-637-5144 ljmortell@shaw.ca

Nanaimo - Central Island Hepatitis Service: Nurses & doctors available for info, support, treatment. Clinic located in Nanaimo. Doctor or self-referral. Contact 1-855-740-2607, sarah.hughes@viha.ca or shelby.munk@viha.ca

Westminster Stride with Purpose "HepC" Support Group 1st & 3rd Fri monthly 10:30-11:30. BBP Nursing Team, refreshments/ lunch. Contact: Stride Workers 604-526-2522. mail@murnosesociety.org

Positive Wellness North Island-North Island Liver Service Info, support, treatment/pre-post treatment groups. Doctor or self-referral. 1-877 -215-7005 250-850-2605.

- •Courtenay: 2nd Fri monthly 1PM, Drop-in, Comox Valley Nursing Centre (nurse)
- •Campbell River: Treatment/pre&posttreatment support group 1st&3rd Thu monthly 10-12 noon, Discovery Room, Sunshine Wellness Centre, Campbell River Hospital. Jody Crombie at 850-2620, jody.crombie@viha.ca

Penticton & District Community Resources Society, Harm Reduction Program, Meetings every 2nd Tues, 12:30-1:30 PM. 330 Ellis Street, Contact Melanie: 250-488-1376 or 250 -492-5814

Positive Haven Info, harm reduction, support, drop in, clinic. 10697 135A St. Surrey. Contact Monika 604-589-9004.

Positive Living Fraser Valley (Abbotsford) Hep C support, Drop-in centre #108-32883 S. Fraser Way, M-F 10:30 AM-4:30PM. Info, support worker, rides to appointments in surrounding areas. Contact 604-854-1101 or plfvcentre@plfv.org

Powell River Hepatology Service Powell River Community Health, 3rd Floor-5000 Joyce Ave. Contact Melinda 604-485-3310 Melinda.herceg@ych.ca

Prince George Hep C Support Contact ilse.kuepper@northernhealth.ca

Sunshine Coast-Sechelt Healthy Livers Support Group Information/resources Contact Catriona 604-886-5613 catriona.hardwick@vch.ca or Brent 604-740-9042 <u>brent.fitzsimmons@vch.ca</u>

VANDU The Vancouver Area Network of Drug Users. 380 E Hastings St. M-F 10-4 Contact 604-683-6061

vandu@vandu.org www.vandu.org

Vancouver HCV Support Contact Beverly 604-435-3717 batlas@telus.net

Vancouver Hepatitis C Support Group Contact 604-454-1347 or 778-898-7211, or call 604 -454-1347 (Terry), to talk or meet for coffee.

Vernon telephone buddy, M-F 10-6 Contact Peter, pvanbo@gmail.com Tel. 250-309-1358.

YouthCO HIV and Hep C Society of BC. Call for appts or drop in M-F 10-6. 205-568 Seymour St, Vancouver 604-688-1441, 1-855-YOUTHCO Stewart info@youthco.org, www.youthco.org

VIDC HCV Treatment Support Group 9:30AM-12PM Every Friday 200-1200 Burrard St. Contact info@vidc.ca

Whitehorse, Yukon-Blood Ties Four Directions Contact 867-633-2437 1-877-333-2437 admin@bloodties.ca

OTHER PROVINCES

ONTARIO: Barrie Hepatitis Support

Contact Jeanie for info/ appointment

<u>jeanievilleneuve@hotmail.com</u>

Hamilton Hepatitis C Sup-port Group 1st Thurs. monthly, 6-7 PM, Hamilton Urban Core Community Health Centre, 71 Rebecca St, Hamilton. Contact Maciei Kowalski, Health Promoter 905-522-3233 mkowalski@hucchc.com

Hep C Team, AIDS Committee of North Bay & Area. Education, outreach, treatment, individual & group support, harm reduction, needle exchange. 269 Main St. W. Suite 201, North Bay. Contact 705-497-3560, 1-800-387-3701 or hepccommcoord@gmail.com, www.aidsnorthbay.com

Hepatitis C Network of Windsor & Essex County Last Thurs. monthly, 7 PM, Teen Health Centre-Street Health Program Office, 711 Pelissier St., Suite 4, Windsor. Contact Andrea Monkman 519-967-0490 or

hepcnetwork@gmail.com. http://hepcnetwork.net

Kingston Hep C Info HIV/ AIDS Regional Service. Contact 613-545-3698, 1-800-565-2209 <u>hars@kingston.net</u> <u>www.hars.ca</u>

London Hepatitis Hep C **Support** 186 King St, London. For those infected as well as affected by Hep C. Contact: 519-434-1601. 1-866-920-1601

www.hivaidsconnection.com

Niagara Health System -Hepatitis C Care Clinic (HCCC) Clinics:

New Port Centre-Port Colborne, 4 Adams Street - St Catharines, Niagara Falls Hospital. Education, counseling, individual/group support, treatment, outreach, and harm reduction. Contact 905-378-4647 ext 32554 and HCCC@niagarahealth.on.ca www.niagarahealth.on.ca/ services/hepatitis-c-care

Oshawa Community Health Centre Hepatitis C Team Drop-in, lunch provided each Thurs. 12-1 PM, 79 McMillan St. www.ochc.ca Contact 1-855-808-6242

Owen Sound Info, support. Contact Debby Minielly m n i e ly@publichealthgreybruce.on.ca

1-800-263-3456 Ext. 1257, 519-376-9420 Ext. 1257, www.publichealthgreybruce.on.ca

Peel Region (Brampton, Mississauga, Caledon) 905-799-7700 healthlinepeel@peelregion.ca

St. Catharines Contact Joe 905-682-6194

Toronto CLF 1st Mon. monthly Oct.—June, 7:30 PM, North York Civic Centre, 5100 Yonge Street. Contact Billie 416-491-3353, ext. 4932.

bpotkonjak@liver.ca www.liver.ca

Thunder Bay Hep C support. Contact Sarah Tycholiz 807-345-1516 (or for 807 area only 1-800-488-5840)

Unified Networkers **Drug Users Nationally** undun@sympatico.ca

York Region Hepatitis C Education Group 3rd Wed. monthly, 7:30 PM, York Region Health Services, 4261 Hwy 7 East, B6-9. Unionville. Contact 905-940-1333, 1-800-361-5653 info@hepcyorkregion.org www.hepcyorkregion.org

OUEBEC:

Quebec City Region Contact Renée Daurio 418-836-2307 reneedaurio@hotmail.com

CAPAHC support group meetings 3rd Thurs. monthly 6-8PM, 032-2065, rue Parthenais, Montreal. Contact 514-521-0444 or 1-866-522-0444

ATLANTIC PROVINCES

Hepatitis Outreach Society of NS. Info and support line for the entire province. Call 1-800-521-0572, 902-420-1767 Online Peer Support: <u>info@hepns.</u> www.hepns.ca

PRAIRIE PROVINCES:

Manitoba Hepatitis phone and email support and outreach. Contact Kirk at info@mbhepc.org. Direct line: 1-204-231-1437

Manitoba CLF each Thu 1:30-3. 375 York Avenue, Suite 210, Winnipeg, Contact Bianca 204-831-6231 bpengelly@liver.ca

Medicine Hat, AB Hep C Support Group 1st & 3rd Wed. monthly, 6:30 PM, HIV/ AIDS Network of S.E AB Assoc, 550 Allowance Ave. Contact 403-527-7099 bettyc2@hivnetwork.ca

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To list Canadian groups here, please send your details to <u>info@hepcbc.ca</u> It's free!