

1) Conf. of eligibility : YES

2) Patient Group Name & name of representative completing this questionnaire:

HepCBC Hepatitis C Education and Prevention Society.
Representative completing questionnaire: REDACTED.

3) Organization's Address

#20-1139 Yates St. Victoria, BC

4) Postal code

V8V-3N2

5) Conflict of Interest Y/N=YES

6) Describe conflict of interest

HepCBC Hepatitis C Education & Prevention Society has received funding for hepatitis C-oriented projects such as publishing educational materials, organizing educational forums, attending and presenting at educational conferences, advertising in newspapers (events and hepatitis C patient awareness), and holding awareness activities from the following pharmaceutical companies over the last three years: Merck Pharmaceuticals, Hoffman-LaRoche, Vertex Pharmaceuticals, Gilead Sciences, Janssen Pharmaceuticals, Bristol Myers Squibb, Boehringer-Ingelheim, and AbbVie. In addition, the author of this report has attended several educational conferences and meetings for which registration and travel expenses were funded by the pharmaceutical companies listed above.

One of the patients submitting (Pt 1) also received compassionate care from Gilead's Sovaldi Momentum and Janssen's Compassionate Care programs.

Several patients submitting have participated in various Gilead, Janssen, Merck, Boehringer-Ingelheim, and Bristol-Myers Squibb clinical trials in which they received free medications.

7) Read PharmaCare info sheet? YES

8) Describe how the condition or disease for which this drug is used affects the day-to-day life of patients in your group.

HepCBC: Chronic hepatitis C can affect the patient in such a variety of ways. In many cases there are no obvious symptoms for many decades, while the virus is “silently” destroying the liver; or the symptoms may be mistaken for some other disease such as fibromyalgia or chronic fatigue. Those with undiagnosed hepatitis C are unaware of lifestyle changes that could slow the progression of the disease, are unaware that treatment could stop its progression entirely, or that they are in danger of passing a serious disease to others. For others, the symptoms come on strong and obvious, so their doctor is more likely to pursue testing and aggressive treatment.

Besides the physical symptoms, there are many hidden ways chronic hepatitis C affects our daily lives. Depression kills relationships along with joy, and brain fog stifles concentration and clarity, slowly progressing along the spectrum to encephalopathy. Many experience fear of future disability and

inability to support self and family, and fear of losing relationships, housing, or job due to commonly-held stereotypes and stigma against those with hepatitis C. Listen to patient voices below:

Pt2: My hepatitis C has triggered a variety of extrahepatic manifestations, such as fibromyalgia, depression, and various dermatological issues. I also get periods of brain fog when I have viral flares.

Pt4: HIV co-infection. For all these years I was focused on the HIV; at the time I was given a two year life expectancy, so my main concern became the HIV. I never realized the devastation of the HCV until the last few years.

Pt5: I live daily with the very likely possibility that this disease may progress quickly at any time. This is psychologically taxing.

Pt7: My symptoms include chronic fatigue, prolonged sleeping durations, interrupted sleep patterns, impaired cognitive functions, itchy skin, painful and severe cramping of feet, hands and legs, and numerous emergency visits to the hospital for complications with other related body functions due to severe liver disease. These have included getting bands to prevent bleeding inside my esophagus, getting drained for ascites, going into a hepatic coma for several weeks, and going through several months in which I was in danger of dying from kidney or liver failure. They said I was too sick for a transplant, but somehow I have survived.

Pt9: Symptoms of my HCV genotype 3 include brain fog, fatigue, impaired vision impairment and dizziness. These symptoms can last for a day or for hours, come without warning; they cripple my ability to work. From this comes further issues of embarrassment and anxiety having to tell my employer that I can't do my job as expected and the fear of revealing my secret of HCV. This is further compounded when I tell my family I can't work or enjoy the pleasures of life I'm used to, They don't see bandages or crutches and ponder what my illness is really is doing to me.

Pt11: I am a health care worker and no longer can manage the heavy work and stress (due to persistent painful abdominal upsets, mental anxiety, and depression regarding having this serious disease).

Pt13: Symptoms such as insomnia, tiredness, itchiness, poor circulation, swelling of belly and constipation, fear of accidentally infecting someone else, make day to day life difficult.

Pt14: I am a HepC 1a stage 3 patient. My life has been severely impacted by HepC. I was placed on long-term disability in 2005, and Canada Disability Pension as I was no longer able to work.

My low energy level, my ability to sleep, and most likely my vitiligo, porphyria, and auto-immune deficiencies could all be HepC related.

Pt15: Completely fatigued, general daily activities have suffered including work. Induces arthritis flare-ups

Pt16: My family and I live with the fear of what's to come.

Pt17: Fatigue , stomach and bowel discomfort , crawling skin , the thought of cancer or liver failure or both.

Pt18: I am tired an hour after I wake up and have no energy to do things. I can only do one task per day. If I shop, I cannot go out in the evening. My legs hurt from carrying extra water. I do not digest food easily and cannot tolerate most meat and dairy. My diet consists of toast , peanut butter and fruit and

veggies. My stomach is always bloated and uncomfortable. I feel depression a great deal of time because quality of life is very poor. I cannot support myself because I cannot retain employment due to this illness. I have to rely on my common law spouse to support me and at times we can barely make rent.

Pt19: After I was diagnosed with chronic hep C, genotype 4, and severe cirrhosis of the liver, it made sense why I've been tired all the time. I can sleep for 16 to 20 hours and after being up for an hour I'm tired again to the point of going back to bed for awhile. I stopped working two years ago now and it is boring and hard. I'm too tired to read or write, even. I suffer dizzy spells and lose my equilibrium at times where I feel like I'm going to fall over. My skin is really itchy especially at night which makes sleep difficult. My left foot and tummy have recently swollen a bit; my G.P. said it's from the liver not clearing things normally.

Pt20: I am a baby boomer infected with hepatitis C, genotype 3, as well as a professional health care provider working full-time in a rural area. I have many clients who are also infected with hepatitis C.

Pt21: I was diagnosed with Hepatitis C ten months ago and I am now learning to live with the knowledge that this disease is slowly destroying my liver. I received blood transfusions 34 years ago and although I have remained fairly healthy I now find myself in the early stages of advanced liver fibrosis. My life is now concentrated on trying to stay healthy both physically and mentally. It is a huge emotional adjustment. Specific symptoms that I deal with are fatigue, joint inflammation and a compromised immune system.

Pt24: I was diagnosed in 1995 with Hepatitis C, however, I was well aware at the point of infection during a root canal operation in 1989 that something had entered my body that was making me chronically ill.

Pt25: I was diagnosed with Hep C last year. I have had Hep C for over 40 years and it has affected my life profoundly, I now realize. I never used drugs; I believe I caught it when I was working in a medical lab in the early 70's. Over the years, my liver has been damaged, resulting in fatigue, mood swings, difficulty sleeping, thyroid problems, and a host of other symptoms.

9) If the patients in your group have tried the drug under review, please tell us about the effects they experienced.

HepCBC: Most people with hepatitis C in British Columbia remain untreated. Baby boomers tend to be the ones most in danger of being hospitalized or dying from hepatitis C, so are more in urgent need of treatment to prevent imminent complications of severe liver disease. However, ironically it is the younger patients who would most benefit from treatment in terms of quality years of life recovered. Also, the earlier in the disease in which treatment is given, the more likely it is to be successful.

Two patients actually have taken sofosbuvir, one through a trial with ribavirin only, and one recently was able to patch together a way of privately arranging for "sim-sof" (simeprevir and sofosbuvir only) treatment. A couple others knew people who had successfully taken sofosbuvir. The consensus was that sofosbuvir is a real game-changer in terms of severity of side-effects, treatment time, and efficacy compared to current and former treatments. Here are their own words:

Pt 1: I just completed a treatment one week ago. I took the interferon-free, ribavirin-free treatment combo of Janssen's simeprevir and Gilead's sofosbuvir for 3 months, 2 pills/day, with practically no side effects. Within a day or two, all fibromyalgia was gone. Side effects included mild insomnia, depression after 4 weeks, sun-sensitivity and itchiness. All very manageable, and the shorter treatment also minimized side-effects. One week post-treatment, 50% of side-effects are gone, and the fibromyalgia is still gone!

Pt18: I heard very good things about it and talked to people who were lucky to get the trials. They had tried the old pegatron treatment several times and were unresponsive. Now they are virus free after the new treatment.

Pt21: I am one of the folks that was on the 16 week Gilead Sciences GS-7977 (now Sovaldi)/Ribavirin combo- study arm -July 4 2012-Sept 4 2012. I don't think I had any side effects from the Sovaldi. It is my understanding any side effects that I did experience were from the Ribavirin. I did have anemia, low hemoglobin count,160-115, and considerable exhaustion to contend with but I was still able to complete the 16 week program.

Pt24: I am aware of someone who had a positive experience and viral clearing with this pharmaceutical, Sovaldi. They had tried and failed on interferon and ribavirin, but succeeded with Sovaldi.

10) What drugs or other treatments have the patients in your group used, or are currently using, for the condition or disease for which this drug is used?

Please list all of the drugs and tell us about the experience of the patients in your group with each treatment.

HepCBC: Patients in our group have taken the full spectrum of hepatitis C drugs, starting with the interferon-only treatment, continuing into the current DAAs in interferon-free cocktails. Some never took treatment because their disease does not seem to be progressing rapidly, or their doctors feared the treatment would be too hard on their fragile bodies.

Pt2: Years ago I tried Intron A and had breakthrough. The treatment was very hard. Then I went on a trial with Intron A and Ribavirin. It was really hard, I failed that as well. The third time I went on a trial with Pegasys and Ribavirin and after a year I finally had normalized ALT's. But I failed that. All those interferon treatments were very hard on me, and I swear it took years to clear the interferon from my body. That stuff really makes you crazy. Finally, I was accepted into the Merck Trial of MK-5172 and MK-8742, and after 2 weeks my viral load went down to 80 copies from over 10 million. But it triggered an extended period of atrial fibrillation (pre-existent condition) and they pulled me off the trial

Pt3: I've watched my friends go through the horror show of interferon and the damage it's done to their immune systems. And all of it for what? Most of them couldn't continue and it's not effective in most cases. I've been seeing the revolving door since 1999 and the same backwards thinking still is the same presently as it was back then!

Pt4: To help lessen my pill burden for HIV I had to clear the HCV. I just finished one looong year of triple therapy: Incivek, interferon, and ribavirin, the hardest treatment I have ever done, and this treatment was done by telephone and e-mail from my home in rural B.C.

Pt5: I was a participant in a drug study in which I was treated UNSUCCESSFULLY with the BC standard of care drug regimen of pegylated interferon, telaprevir and ribavirin. After 22 weeks of miserable and profoundly debilitating side effects this treatment was stopped on October 2013. As of today, 8 months post treatment, I am now just coming out from under the side effects experienced from these medications.

Pt6: I and 17 others in my treatment group (HepCBC NOTE:with interferon and ribavirin) were told we would be able to continue working. By the second month, none of us could continue working. Most of us, 80%, were depressed.

Pt8: I was on a Boehringer-Ingelheim trial of faldaprevir, ribavirin, & BI 207127 from April 2013 for 16 weeks—virus was nondetectable after 7 weeks. But it came back 4 weeks later.

Pt9: I did 26 weeks of Pegatron. My experience with Pegatron was disabling both mentally and physically. I was lethargic, had loss of appetite, mood swings, brain fog and vision problems. I was unable to work or drive and normally house-bound. My cognitive ability was severely limited as well as my social interaction with family and friends, I often felt totally alone. It was an absolute horrible experience.

Pt12: I have been on four other chemotherapy treatments and have been a non-responder. I do not remember the name of the first or second one but the third one was Pegasys (interferon and ribavirin) and the fourth one was boceprevir (plus interferon and ribavirin). These treatments all made me very, very ill.

Pt13: I have not yet tried treatment due to fear of side-effects, rigidity of pill dose schedule, as well as length of treatment time. Also I have been waiting for new drugs which provide better cure results, and therefore will hopefully only have to do this once.

Pt14: The worst experience was the most recent where Victrelis was combined with a ribavirin/interferon combination. Absolutely no energy, lying in bed for days on end. Depressed for 4 months with 8 more months to go. Headaches, body pain, skin rashes, confusion, anemia.

Pt16: My doctor has suggested I wait until something more effective like sofosbuvir becomes available.

Pt17: First treatment. Ribavirin, peginterferon (Redipen). Viral Load went from 350,000 to 32,000. Treatment was unsuccessful (partial response); stopped at 28 wks.

Second treatment. Ribavirin, peginterferon (Redipen), and boceprevir (Victrelis). Viral Load went from 1.3 Million to 37. Treatment was unsuccessful (partial response); stopped at 28 weeks.

Pt18: I went through the 52 week Pegatron - Interferon/ribavirin treatment in 2009. I had severe anemia and had seven blood transfusions throughout the last part of the treatment. I was responding to treatment, but a month after finishing, it came back.

Pt20: Two years ago I completed 24 weeks of treatment with peginterferon alpha plus ribavirin. I suffered significant side effects from this treatment, including taking many sick days from my job; requiring work accommodation when at work; and needing expensive medications for the treatment of side effects. Without my extended benefits plan I could not have afforded the treatment for the side

effects and would have had to stop the treatment. In the end it turned out that the treatment was not effective and I was a null responder.

Pt23: On Interferon I became very ill. I could not eat, walk, or stand. I was dizzy, breathless, very ill, and very depressed. I was taken off interferon treatment because it was not working.

Pt24: I took Interferon Alpha 2B + Ribavirin and had complete viral clearance. However I had long lasting side effect recovery – in fact I'm still recovering from the side effects after 14 years.

Pt25: I have recently completed the Pegasys treatment for genotype 2 (end of treatment on July 3) and am still waiting for the final results of my blood work. The last 6 months of treatment have been extremely difficult for me, and my family. I was sick and chilled for several days after each injection of interferon, would slowly recover a bit, like climbing out of a pit, and be ready for the next injection. I have suffered from dizziness, breathlessness, extreme fatigue, irritability, difficulty with social interactions, anxiety, itchy skin and scalp, and in general have been uncomfortable all of the time. It is the longest 6 months I have ever experienced, and I pray that my results for RNA load will be good 6 months from now, and that my ordeal will not have been in vain.

Pt27: My treatment was ribavirin, pegylated interferon, and telaprevir. Side effects included severe fatigue, nausea, pain, diarrhea, sleep disturbances, and anxiety.

Pt 29: I was in a Bristol-Myers Squibb clinical trial of daclatasvir and asunaprevir. I had already failed 5 previous treatments, all of which had interferon. This was my first interferon-free treatment. It had no side-effects whatsoever, it was only 6 months instead of a year, and it WORKED! At 18 months post-treatment I remain HCV-free!

11) Please tell us why your organization believes this drug should be included in the BC PharmaCare program.

HepCBC: We are not enthusiastic about the current treatment under consideration, though we do hope it will be approved for reimbursement. We are instead advocating approval of DAAs such as Sovaldi and Galexos on a 'stand-alone' basis, so that doctors will be free to customize treatment according to an individual patient's unique needs. The current approval calls for reimbursing Sovaldi only if used in treatment with interferon and/or ribavirin. In other countries, Sovaldi is recognized to be best paired with other DAAs such as Janssen's simeprevir or Bristol-Myers Squibb's daclatasvir, without requiring the use of the harsh and less efficacious older medications. We currently see only rich British Columbians able to afford the best hepatitis C treatments.

Price of the new DAAs, in this case Sovaldi, looks to be a formidable barrier to treatment, and we hope to be able to applaud BC PharmaCare and Gilead for negotiating a price which enables the system to treat everyone who needs this life-saving medication.

We are also very concerned about HCV treatment criteria. Treatment is far more successful the earlier it is initiated, though currently British Columbians whose organ damage has not progressed "sufficiently" are unable to access treatment. They need, at minimum, an ALT score 1.5X upper limit of normal, or Fibrosis level 2 from either a liver biopsy or Fibroscan. ALT is known to be a poor determinant of liver damage at best, and is particularly a poor determinant for women.

We also fear there will be a temptation on the part of PharmaCare to only treat with Sovaldi those who have failed current standard of care. Requiring ill individuals to take a long treatment involving interferon would be a cruel requirement of questionable economic value.

Finally, there is a great disparity in hepatitis C treatment between two groups: urban vs. rural, and those with private insurance vs those solely dependent on PharmaCare. This is an equity issue beyond the reach of this review, but something we hope PharmaCare will investigate and strive to address at some point.

Pt2: Sovaldi works!!! and it works fast. I think that the more interferon-free treatments we have available will mean a cure for everyone who takes them. Not all hepC drugs work for all people with HCV because of IL28B differences, genotypes, other conditions and Q80K polymorphisms. But what needs to be highlighted is that we do not need any treatments that include interferon!

Pt3: I am really sad that you still have to take interferon with this new drug. What is the point? Nothing has really changed. I've waited 14 years so far for a cure without interferon or some version of it and it looks like I will be waiting a lot longer if I can. I'm glad if you think this is great news to me, but I just shake my head and feel sad.

Pt5: This disease comes with a huge cost in terms of quality of life to patients as well as a huge cost to the medical system in the end stages of the disease.

Pt7: 97% cure rate, no side effects, shorter duration of treatment. The number one drawback is the cost, it's very expensive.

Quite often patients with Hepatitis C are unemployed due to the impairment of their physical and mental health caused by Hepatitis C as it is impossible to maintain employment, making the high cost of the drug Sovaldi out of reach.

Pt10: because I have other conditions which require drugs, being cured of HCV would make it easier for specialists to treat them. I think that if Hep C is eradicated with this drug Sovaldi, people like me would be a lot less burden on the health care system.

Pt12: I am now awaiting sofosbuvir (Sovaldi) to become available by PharmaCare in the Province of Manitoba. I know how very important this new drug is and I am offering my support to the patients in BC who also require same to save their lives.

Pt13: If sofosbuvir, along with simeprevir, become available through BC PharmaCare, I will definitely try treatment. Including Sovaldi in the BC PharmaCare program will cure many people of this costly disease, and decrease doctor's visits, lab visits, hospital visits, etc. This drug being available through PharmaCare would make treatment a reality for me.

Pt14: Sovaldi has to be approved now by BC Pharmacare. As well, Galexos should be approved for partial responders who suffer from the severe side-effects associated with riba/interferon.

Medications exist that would allow me to live a normal life. I should be allowed to enter into an affordable treatment. It would appear that Sovaldi and Galexos is the solution. I deserve a HepC free life. Every HepC sufferer does when the cure is available. I believe the time to kill the dragon is now. Thank-you.

Pt15: I believe if I had this drug along with the other treatment that I took I would not have relapsed.

Pt19: I can't afford it, I wish I could, at up to a 96% cure rate I want the cure. Yes please approve sofosbuvir, I think it should be in the PharmaCare program. My life depends upon it actually... If this drug is approved then I can hopefully get cured of hep C and my liver can regenerate itself and I can go back to normal life. If not then I can expect liver failure if I don't get a transplant, which in my understanding is extremely expensive for the medical world and there is no guarantee of success. Or I will suffer liver failure for sure and a slow, expensive hospital stay and death. I prefer the cure; please let it be.

Pt20: The majority of my clients infected with hepatitis C are living in poverty and do not have extended benefit plans. They could not afford (as I was able to) over-the-counter and prescription medications used to treat side effects. In addition, people have heard stories about the side effects and are simply afraid to take peginterferon alpha plus ribavirin. With their struggle for daily survival, the future possible dangers of cirrhosis and liver cancer seem too far away compared to dealing with side effects in the here and now. It's crucial to get more effective treatments for hepatitis C on the market so that competition (in addition to PharmaCare's hard bargaining) can lower the prices of all treatments. It's also important to have simpler treatments that don't require multiple dosing throughout the day, and for those living in poverty - a refrigerator to store medications or frequent trips to a laboratory for testing (I went weekly for several months).

Excellent results have been seen for people like me with genotype 3 with just ribavirin added to SOVALDI. Our treatment course is longer, but dropping the interferon reduces other costs associated with its side effects, in addition to the direct drug costs.

...Like 75% of people currently living with hepatitis C, I have early-stage disease which represents a tremendous window of opportunity to intervene before my health starts to rapidly deteriorate and require expensive medical interventions and I am forced to leave employment and go on a costly disability plan.

I am a health care provider, but my extended benefits plan does not cover SOVALDI. There is a serious irony in that statement. How can I continue to care for clients, unless I too can access treatment? What are the costs to the system if I have to exit the workforce early? As my spouse and I age, without treatment I am unlikely to be able to care for him if he needs it and he may end up in care sooner than if he had a healthy spouse.

...Treatment for hepatitis C may also serve a primary prevention role with the suppression of virus reducing transmission to others.

Pt22: This drug appears to have the ability to eradicate the Hepatitis C virus. Although it still needs to be taken with peginterferon alfa and ribavirin, there is a much better chance of a positive outcome. The side effects of the interferon can be debilitating, especially to someone of my gender and age (female, 63 yrs), but the benefits would definitely outweigh the pain. Currently 24-48 weeks of treatment with the available funded drugs has only a 75 % chance of a cure, and failure would mean having to endure subsequent costly rounds of difficult treatment. The most cost effective and caring solution is to make Solvaldi available now and for all people living with this disease. Why postpone treatment when outcomes are better while the liver is still healthy? Even with the high cost of this drug it would mean

less health care expense in the long run if the patient was cured. We need to catch up with other countries and start making this drug available. I hate to think that in Canada today the wealthy have an advantage over those that have no choice but to depend on the health care system.

Pt25: I believe this treatment should be covered by BC PharmaCare, because the existing treatment has side-effects which are very costly. If I had had to work, or look after young children, I would not have been able to complete this standard treatment, and my liver would have continued to sustain further damage. The cost to society for liver disease is huge. Liver transplants are extremely expensive. Lost work, broken relationships, and other medical costs associated with liver disease are very high. Knowing how expensive Solvadi is, I believe it should at least be available for patients who have tried to complete the standard treatment, without achieving a cure. If I have a SVR in 6 months, I will say my standard treatment was well worth the side-effects, but if not, or for those who cannot complete the standard treatment for medical reasons, I fully believe Solvadi should be made available by BC PharmaCare. I am 66 years old, with many productive years left, if a cure is achieved.

Pt27: In Canada, we are still awaiting the kind of hepatitis C treatment now recommended for federal prisoners in the USA! New guidelines, calling for interferon and ribavirin-free use of sofosbuvir (by pairing it with simeprevir) were just released in May 2014 and are available here:

http://www.bop.gov/resources/pdfs/hepatitis_c_current.pdf.

Pt24: We feel that Solvadi should be added to the pharmaceutical ‘toolkit’ available to doctors and patients in BC and that past pharmaceuticals also remain listed on the formulary so that there are valid treatment options available in real time for as many patients as possible.

BC has the highest number per capita in Canada of persons infected with Hepatitis C variants. It is cost effective in the long term PharmaCare budget to treat patients and achieve viral clearance, stopping the progression of the disease that would create further costs in the health system budget.

At this point in time there is not a single “one-fits-all” pharmaceutical for persons infected with any of the hepatitis C genotypes, therefore doctors and patients need a repertoire of evidence-based medicine that can be selected from to customize a treatment program for the individual patient’s best short term and long term health outcomes.

HepCBC: We wish to add our support to the sentiments of Pt 24 above, and encourage BC PharmaCare to approve Sovaldi for use not only with interferon and ribavirin, but also as a stand-alone component of a customized drug “cocktail” for patients.