Common Drug Review
Patient Group Input Submissions

ombitasvir/paritaprevir/ritonavir (Technivie) for genotype 4 chronic hepatitis C

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.
Canadian Liver Foundation — permission granted to post.
Canadian Treatment Action Council — permission granted to post.
HepCBC Hepatitis C Education and Prevention Society – permission granted to post.
Pacific Hepatitis C Network – permission granted to post.

CADTH received patient group input for this review on or before September 28, 2015.

Disclaimer: The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations.

While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

Canadian Liver Foundation

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		Ombitasvir/paritaprevir/ritonavir for chronic hepatitis C genotype 4
Name of the patient group		Canadian Liver Foundation
Name of the primary contact for this submission:		[redacted]
Position or title with patient group		[redacted]
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	Website	www.liver.ca
Permission is granted to post this submission		Yes

1.1 Submitting Organization

When it was founded in 1969, the Canadian Liver Foundation (CLF) was the first organization in the world dedicated to supporting education and research into all forms of liver disease. Today, the CLF continues to be the only national organization committed to reducing the incidence and impact of liver disease for Canadians of all ages living with or at risk of liver disease. The CLF is the sole lay organization in Canada directing funds specifically for liver disease research and has invested more than $23 million in the scientific search for causes, preventative measures and potential treatments for liver disease, including viral hepatitis. As the largest community organization dedicated to liver disease, the CLF reaches over 250,000 Canadians through our public and professional education programs, patient support programs and other fundraising and outreach efforts. Over the past 45+ years, the CLF has invested more than $50 million in health education and prevention programs.

1.2 Conflict of Interest Declarations

a) We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:

In the past, the Canadian Liver Foundation has received unrestricted educational grants and/or has worked on joint initiatives with AbbVie Corporation, Astellas Pharma Canada Inc., Boehringer Ingelheim (Canada) Inc., Gilead Sciences Canada Inc., Janssen Inc., Merck Canada Inc., Novartis Pharmaceuticals Canada Inc. and Hoffmann-La Roche Limited.

b) We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:

Dr. Sherman, Chairperson of the Canadian Liver Foundation, has received honoraria from Abbvie Corporation, Boehringer Ingelheim (Canada) Inc., Merck Canada Inc., Janssen Inc., Hoffmann-La Roche Limited, Gilead Sciences Canada Inc., Vertex and Bristol Myers Squibb.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

To gather a broad range of input for numerous hepatitis C-related CADTH submissions, the CLF has invited patients, caregivers and health care professionals from across Canada to fill out online surveys modelled on the CADTH questionnaire. The more than 400 responses to these surveys have been used in compiling the feedback for this submission. Quotes from survey respondents are included in italics in various sections of this submission. Other information was provided by Dr. Eric Yoshida, Chairperson of the CLF's Medical Advisory Committee.

2.2 Impact of Condition on Patients

Please note: *Quotes in italic text are excerpts from survey responses.*

The physical, mental and emotional toll that hepatitis C can take on individuals is similar across all genotypes. The majority of people living with hepatitis C in Canada are adults in the 'baby boomer' age bracket who may have contracted hepatitis C either here or before coming to Canada and lived with hepatitis C for decades without any obvious symptoms. Regardless of whether they have recently been diagnosed or have been aware of their diagnosis for several years, a large number are now developing advanced liver disease and without treatment will progress to liver failure, liver cancer or need liver transplants.

"I have lived with hepatitis C for approximately 40 years. Symptoms such as insomnia, tiredness, itchiness, poor circulation, constipation and fear of accidently infecting someone else makes day to day life difficult. I am also concerned that delaying treatment is causing more liver damage." – hepatitis C patient

Individuals living with hepatitis C are often reluctant to talk about their disease for fear of the judgement of those closest to them. The stigma associated with hepatitis C can lead to misperceptions and fear amongst family, friends and co-workers and often personal relationships deteriorate or disappear completely. Without these support systems in place, individuals can spiral down into anger, depression and isolation.

"…whenever I have told people about my condition it was always met with criticism, fear and rejection. People seem to "know all about it" when, in fact they do not." -- hepatitis C patient

"I found out four years ago I had Hep C. It has not affected my ability to work, but it is always a huge concern for me. I have no idea when I contracted Hep C, it could have been thirty years ago, it could have been 5 years. Hep C has affected my relationship in a huge way. My spouse was diagnosed at the same time I was and he passed away Jan. 15/14 due to liver cancer caused by Hep C. Financially I am not able to afford any type of treatment for Hep C as I have no coverage whatsoever.." – hepatitis C patient

Psychological and emotional stress only adds to the physical strain which comes as individuals progress to more advanced disease. While some may be able to manage the associated conditions triggered by hepatitis C, others find their lives unbearable due to debilitating symptoms which impact their ability to support themselves or even function on a daily basis. These symptoms can include nausea, headaches, sensitivities to light and food, memory loss, mood swings, itchy skin, abdominal pain, severe joint and muscle pain, portal hypertension, sleeplessness, slowed reflexes, psoriasis, peripheral neuropathy, osteopenia, diarrhea and muscle wasting.

"*I have had HEP C for 38.5 years. I have sensitivities to dairy, wheat, tomatoes, and sugar. Food becomes an issue a big issue for me. I also have low platelets, so I tend to get nosebleeds, bruise easily and have to be careful not to cut myself or injure myself in any way. I have lost interest in gardening because I just don't have the energy for that any more. I do not always sleep well at night, I have to be careful that I don't eat wrong foods as they keep me up as well. I have to be careful not to get colds because my immune system is low. I also get itchy because of bile in the blood and although I take a medication for it, the itch will keep me awake at night especially. I get very frustrated with living like this. It would be wonderful to find out what it is to feel normal." – hepatitis C patient*

Not surprisingly, this litany of symptoms which can differ from individual to individual often means patients who once had full or part-time employment or even their own businesses must leave their jobs and rely on government support programs.

"Since late 1980 I was always ill with flu symptoms, tiredness, nausea, sensitive to light and noise, depressed, aches and physical pain.s I had to quit my job and my relationship with my family went from up and down to critical." – hepatitis C patient

2.3 Patients' Experiences With Current Therapy

Please note: *Quotes in italic text are excerpts from survey responses*.

Patients with genotype 4 have limited treatment options as the recent breakthrough direct-acting antiviral therapies are only reimbursed for genotype 1 patients (genotype 2 and 3 patients can also access sofosbuvir with or without pegylated interferon and/or ribavirin). Gentoype 4 patients, depending upon their insurance coverage and/or the reimbursement criteria in their province, are primarily eligible for treatment with dual therapy which combines pegylated interferon with ribavirin for 24 - 48 weeks.

Dual therapy involves weekly injections of interferon and 6-8 ribavirin pills per day. Interferon has well documented and often brutal side effects. These side effects include anemia, sleep loss, depression, mood swings, joint pain, rashes, hearing loss, skin sores, hair loss, headaches, chills, nausea, severe fatigue and excessive weight loss.

"*I was diagnosed with chronic Hepatitis C in 2010. I did 48 weeks worth of treatment, which did not work. It is my understanding that I should not have been given Interferon given that I have epilepsy. I still have chronic pain in the upper right quadrant of my stomach, I have severe joint pain and fatigue, and my seizures are now uncontrollable. Since treatment I have also developed Fibromyalgia. Ribavirin and Interferon ruined my life. I am unable to work… I have also seen a neuropsychiatrist and she diagnosed me with an interferon induced cognitive disorder, which has impacted my procedural memory. I also have insomnia .I tried to go back to work on a trial basis in 2012 and was unable to work. During treatment my partner of 7 years left me. I have two dependent children who may very well end up with no Mother. – hepatitis C patient*

"To date I have undergone 4 treatments, none of which have been successful…the last treatment in 2013 I was on interferon, ribavirin and Victrelis. This 48-week treatment was particularly gruelling and I was anemic almost immediately. I suffered from lack of energy, broke out in numerous rashes and my blood, platelet and hemoglobin count was much lower than normal. I was taking approximately 20 pills a day and an injection of interferon once a week. Unfortunately, I was not able to sustain my SVR." – hepatitis C patient

Many patients, regardless of genotype, are unable to take interferon-based therapy due to contraindications.

"Current therapeutic options continue to include pegylated interferon which more than half of our patients cannot take due to underlying issues or are non-tolerant of adverse events. There are many psychiatric issues and health issues that prohibit the use of pegylated interferon. Some of these patients have been waiting for almost two decades for advancements in therapy." – health care professional treating hepatitis C patients

2.4 Impact on Caregivers

Please note: *Quotes in italic text are excerpts from survey responses.*

The burden of care for patients with hepatitis C often falls to spouses, parents and adult children. The symptoms of hepatitis C and the side effects of current therapy can leave patients completely dependent and unable to contribute financially, physically, psychologically or emotionally to the household or the relationship. Caregivers report having to endure their loved one's mood swings, dietary problems, lack of energy and concentration while shouldering the responsibility for managing doctor's appointments, drug regimens and all household responsibilities. Due to a patient's inability to work, caregivers often become the sole income earner which adds even more stress. As the patient's symptoms and behaviour become more difficult to manage, families and marriages can break apart due to stress, financial difficulties and social isolation.

"I'm always on alert for symptoms of another variceal bleed. Plans change at the last minute due to nausea, bleeding gums at night cause severe nausea on numerous mornings. Exhaustion curtails a lot of everyday activities, ascites causes him to be short of breath. So many symptoms impact every day of our lives."— caregiver for hepatitis C patient

As already noted, hepatitis C treatment with interferon-based drug therapies is complex and comes with many side effects which often require additional medication. For physicians and nurses, the challenges of caring and achieving a cure for hepatitis C patients are enormous. Patients require a great deal of education and counselling about treatment options and if they decide to undergo treatment it can require additional tests, lab results, forms and appeal letters before patients can actually access the therapies they need.

"If patients are on pegylated interferon, the nursing hours of care can accumulate very quickly as some have low tolerance to adverse events or are very ill during therapy. Some patients have yet to recover from the adverse events even post therapy." – physician caring for hepatitis C patients

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

As mentioned previously, the CLF compiled its submission using numerous survey responses from patients, caregivers and health care professionals from across Canada. To date, there have been no completed Phase III clinical trials of ombitasvir/paritaprevir/ritonavir involving Canadian patients so we were unable to include feedback from patients who had taken this drug combination.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

a) Based on no experience using the drug:

Among survey respondents, 'interferon-free' has consistently ranked among the top three most important factors patients consider when deciding whether or not to pursue treatment. Interferon-related side effects are a major deterrent especially when coupled with a poor cure rate.

Genotype 4 patients can expect a 40 per cent or less success rate on dual therapy with pegylated interferon + ribavirin. 24-48 weeks of debilitating side effects with so little hope for a cure isn't something that most patients are prepared to endure. In contrast, the prospect of taking three pills (ombitasvir/paritaprevir/ritonavir + ribavirin) per day for only 12 weeks with few side effects and almost 100 per cent chance of a cure is a game-changer for these patients.

Section 4 — Additional Information

In the race to develop interferon-free hepatitis C therapies, the focus has been on genotype 1 patients which comprise the largest population of patients in North America. Dramatic breakthroughs in efficacy, tolerability, pill burden and treatment length mean these patients no longer need to endure months of hell before achieving a cure. It is time to make these same breakthroughs available to genotype 4 patients.

The CASL Consensus Guidelines for Hepatitis C note that 100 per cent of treatment experienced and treatment naïve G4 patients treated with ombitasvir/paritaprevir/ritonavir + ribavirin achieved sustained viral response (SVR) in only 12 weeks. The guidelines recommend ombitatsvir/paritaprevir/ritonavir + ribavirin as one of the options for the treatment of G4 patients with the other being sofosbuvir/ledipasvir (Harvoni).

The draft CADTH Therapeutic Review Report on Drugs for Chronic Hepatitis C recommends sofosbuvir + pegylated interferon + ribavirin for 12 weeks for treatment naïve G4 patients with no cirrhosis. Ombitasvir/paritaprevir/ritonavir however does not require interferon which means that many patients who have previously been ineligible for treatment due to co-morbidities or adverse reactions to interferon could now be treated. This could make a significant change to the number of G4 patients who could now undergo treatment, including patients with chronic anemia (e.g. thalassemia), autoimmune diseases, renal transplant patients and those with psychiatric conditions for whom treatment with interferon was contraindicated.

Genotype 4 is the most common genotype amongst immigrants in Canada from Egypt and the Middle East. Individuals who are Canadian-born or are immigrants and have other hepatitis C genotypes (1,2,3)

are able to access new and more effective treatment options. Genotype 4 patients too deserve to be able to take advantage of the significant progress that has been made in the treatment of hepatitis C.

Canada's liver specialists agree that ombitasvir/paritaprevir/ritonavir ranks as one of the top two most effective treatment options for these patients. Currently, the only treatment option reimbursed for these patients however is interferon-based which places their health and well-being at risk unnecessarily. Interferon-free therapy must be accessible to all hepatitis C patients regardless of geographic location, financial status, treatment status or disease severity. The CLF believes that to effectively treat hepatitis C, the medical community must have access to the most effective treatments for each genotype in order to best meet the needs of their patients. Physicians are the most equipped to decide what treatment option holds the greatest odds of a cure for their patients so there should be no restrictions on access except those dictated by patients' medical conditions.

For the sake of all hepatitis C genotype 4 patients, we call upon CDEC to recommend reimbursement for ombitasvir/paritaprevir/ritonavir for the treatment of hepatitis C genotype 4 without restriction.

Canadian Treatment Action Council (CTAC)

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		OMBITASVIR/PARITAPREVIR/RITONAVIR (AKA: 2D; Abbvie Corporation) Indication: Chronic hepatitis C Infection
Name of the patient group		CTAC
Name of the primary contact for this submission:		[redacted]
Position or title with patient group		[redacted]
Email		[redacted]
Telephone number(s)		[redacted]
Name of author (if different)		[redacted]
Patient group's contact information:	Email	[redacted]
	Telephone	416.410.6538
	Address	555 Richmond St. W, Suite 612. Toronto, ON
	Website	www.ctac.ca
Permission is granted to post this submission		Yes

1.1 Submitting Organization

The Canadian Treatment Action Council (CTAC) is Canada's national non-governmental organization addressing access to treatment, care and support for people living with HIV and hepatitis C. CTAC's organizational goals are to meaningfully engage community members, service providers, policymakers and other relevant stakeholders to identify, develop, and implement policy and program solutions. CTAC understands that treatment access should be considered in its holistic form, encompassing the range of treatment, care and support needs required to reach the most successful treatment experience possible for people living with HIV and/or viral hepatitis co-infection.

Full CTAC membership is reserved for: a) individual people living with HIV (including HCV co-infection); b) organizations, groups or projects with a substantial HIV mandate (including HCV co-infection). Associate CTAC membership is open to any individual, organization, group or project that supports CTAC's mandate and objectives.

1.2 Conflict of Interest Declarations

CTAC received unrestricted organizational and/or educational grants from the following organizations in the 2014-2015 fiscal year: Abbott/Abbvie, Gilead Sciences, Janssen, and ViiV Healthcare.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

On Monday September 21st, 2015, CTAC delivered a national consultation webinar that provided an overview of the Common Drug Review (CDR) patient input process as well as key finding from the 2D (PARITAPREVIR/RITONAVIR/OMBITASVIR) Clinical Trials (PEARL I, with supplemental data from the designs of the AGATE I and AGATE II studies). This consultation was presented by Adam Cook, Policy Researcher at CTAC. CTAC members, organizational partners, and interested stakeholders were invited to participate.

8 people attending the webinar. A link to both the consultation webinar video and online feedback survey were provided to webinar attendees. This link was made available to through CTAC's social media outlets (ctac.ca, YouTube, Facebook, and Twitter) as well as a direct link in the webinar itself. The survey was live and online from September 21st 2015 to September 28th 2015. CTAC has compiled data from the feedback survey, all respondents of which had viewed the webinar.

Four respondents completed the survey in full. 3 identified as female and 1 identifed as male. 2 declared residency in Ontario and 1 each were from Manitoba and British Columbia, respectively. 2 identified as HCV-negative; 1 identified as HCV+; and one identified as having achieved SVR on Harvoni after being a null responder to two separate courses of HCV treatment (PEGASYS and boceprevir). 1 Respondent identified as being a caregiver serving those living with HCV. No respondent had treatment experience with 2D, Holkira Pak, or any of its respective components. Respondents were aware that 2D contains the same components as Holkira Pak, except Dasabuvir, and they were aware that 2D is for the treatment of HCV genotype 4. There were respondents with treatment experience of sofosbuvir, pegylated interferon, ribavirin, boceprevir, and ledipasvir, but there was no treatment experience of Sovaldi.

Due to this submission's similarity to Holkira Pak, some data from CTAC's previous patient input submission regarding Holkira Pak has been used to complement this report.

2.2 Impact of Condition on Patients

Hepatitis C is a serious and life-threatening virus that can impair liver functions, lead to cirrhosis, and is considered the leading cause of hepatocelluar carcinoma. Most recent data from Health Canada suggests that as many as 300,000 Canadians are presently infected with HCV, with as many as 70% of those unaware of their infection and Health Canada data further suggests there are as many as 8,000 new cases annually.

A hearty and unique virus, HCV is transmitted through blood-to-blood contact. While approximately 20% of people infected will pass the virus naturally, approximately 80% will not and the presence of the virus will develop into a chronic HCV infection. Asymptomatic for much of its cycle, HCV infection slowly causes significant liver damage, contributing to fibrosis, cirrhosis, and even liver cancer. Past strategies for treatment suggested a wait-and-see approach to determine if the virus was passed naturally, or to confirm that liver damage progression (fibrosis) was fast and severe enough to demand treatment (metavir score > F2). New evidence, however, suggests that more than 60% of all HCV sufferers will sustain fibrosis and incur liver damage necessitating quick and effective treatment. Left untreated for long periods of time, chronic HCV can lead to decompensated liver cirrhosis or hepatocellular carcinoma, the leading causes of liver transplantation in Canada. Consider the impact of this strategy to special populations in Canada, as one caregiver respondent noted, "As an example, an individual I am

working with had taken great strides to achieve stability in her life with the hopes of getting on hepatitis C treatment. She is in supportive housing, and had stopped her substance use. After visiting the hepatitis C clinic and being told she was not eligible because her liver was too healthy, she questioned why she had put all that effort into maintaining sobriety and began her substance use again, putting her housing at risk. She had all the pieces lined up, and would have been in a good spot to initiate treatment, however this news has sent her on a path that may indeed lead to liver damage, but also a more chaotic situation that would not be conducive to an easy treatment for her."

HCV's often-asymptomatic nature is considered an important variable in its prevalence and spread. Many people live unknowingly with this infection and quietly suffer significant damage. As one HCV sufferer responding to CTAC survey reported, "*I was unaware that I had hepatitis C until 2009, some 30 years after contracting it. It is my understanding that there are ongoing symptoms… but all would have been considered a normal part of my adult life as I was a teenager when I was infected.*" Most people seek diagnosis and treatment when experiencing symptoms of fibrosis, cirrhosis, or severe liver damage, but these symptoms are the result of the infection already being possibly decades old. The respondent continued, "*I was diagnosed with F3 liver damage, so it is reasonable to say that hepatitis C treatment saved my life.*" HCV sufferers do sometimes report impact of their infection or liver damage early, however. Many respondents echoed the remarks of one 52 year-old female from British Columbia, who said her symptoms included "Chronic fatigue, some short-term memory concerns." Both of these symptoms significantly impacted the sufferer's ability to maintain employment or social activities.

Also of interest to CTAC, a significant number of people living with HIV infection are co-infected with HCV. Approximately 13,000 Canadians are co-infected with HIV and HCV. Extrapolating from existing Health Canada data, we can postulate that approximately 20% of all people living HIV would be infected with HCV, and approximately 5% of all people living with HCV would be infected with HIV. Not only do people living with co-infection suffer under increased stigma and differing treatment needs, both viruses exacerbate the progression of the other, and many of their respective medications impact one another. For example, patients using HIV protease inhibitor tipranavir-ritonavir must be careful of possible drug interactions with sofosbuvir-based HCV treatments.

While the Public Health Agency of Canada has suggested that a significant proportion of those infected by HCV are receiving treatment, IMS MIDAS market data publicly reports HCV treatment sales, which suggest that approximately only 10,000 of the suspected 250,000+ are currently being treated. While HCV treatments become more effective and more tolerable, the relative lack of sufferers being treated is a conspicuous and jarring discrepancy.

2.3 Patients' Experiences With Current Therapy

Three respondents to the survey had treatment experience or caregiver/service-provision experience with previous standards of care (pegylated interferon with ribavirin; boceprevir; and Harvoni) and these respondents continued to report concerns regarding side effects associated with ribavirin. Ribavirin still has a place in contemporary therapies, depending on treatment history and genotype, and its inclusion in many therapies today (including 2D) was an issue. 1 Respondent reported that they would not be using any future therapy including ribavirin because "my specialist told me there is no way I could ever use a treatment method that includes Ribavirin...my system just can't handle it." While another reported that ribavirin had been traditionally underestimated in its impact to patients, calling its side effects "…more severe. Ribavirin can do nasty things to you."

Respondents identify the most persistent treatment side effects of any HCV treatment as being, "fatigue Insomnia; Constant (daily) headaches; Weight loss; Suppressed appetite; Hair loss; Some cognitive difficulties such as word recall; Depression; Irritability & easy to anger; Short term memory loss; Joint pain." Fortunately, the treatment landscape continues its robust and dynamic course and patient groups are extremely optimistic about the safety and efficacy of new Direct-Acting Antivirals (DAAs) while being very concerned about the public availability and accessibility of the same.

Concerns about the continued use of Ribavirin and the persistence of side effects in contemporary treatments were a regularly reported concern of all patients, as one support worker commented, "For those who do get the treatment, dealing with the side-effects can be extremely difficult, in particular, the depression. The injections associated with the interferon can also be a triggering factor for many people as well as a source of anxiety, given that many individuals being treated for hepatitis C have a history of injection drug use." This was echoed by many caregivers, who regularly noted the social impacts of HCV treatment, including "heavy pill burden, multiple side effects, dealing with needle phobia, or triggers with regard to past lifestyle."

In the post-webinar discussion, attendees made note that the prevalence of genotype 4 in Canada was relatively low compared to the prevalence of genotype 1, and were encouraged that 2D was a medication that might be addressing a genotypic gap in treatment options for Canadians or New Canadians from endemic countries.

2.4 Impact on Caregivers

One respondent identified as a caregiver providing services to people living with HCV. They identified the following as recurrent symptoms of both HCV and its contemporary treatments: fatigue, nausea, depression, anorexia/weight loss, possible treatment failure, and anxiety associated with side effects and the prospect of treatment failure. Respondents noted that were pleased with the safety profile of 2D, but were still very concerned with the continued inclusion of ribavirin in contemporary therapies.

Attendees to the webinar engaged in a thoughtful discussion following the webinar, where access and eligibility requirements became recurring topics. Access to treatment in Canada can be complex considering the 19 separate federal public plans available to over 11 million Canadians who depend on them. This places great pressure on caregivers and service providers to help navigate patients through a complex, dynamic, and often opaque treatment landscape as well as call upon them to begin a quick and coherent uptake of changing treatment requisites and eligibility criteria. One caretaker listed some of their more significant challenges as "being able to provide them with the most up-dated information on treatment regimes, however, then not being able to provide them with the ability to access these newer agents. -keeping them engaged while they wait -helping them understand their degree of disease & inability to predict disease progression/changes." Almost all respondents to the December 10th survey noted that inconsistent access to the same medication across provinces was a very serious obstacle in need of immediate reform. It was reiterated that this discrepancy in access to federally approved medicines across all Canadian provinces was an uncomfortable and counter-intuitive challenge to their understanding of the Canadian health care system.

This development of medical science knowledge is extremely important in the daily work of the caretaker, but only complement the more traditional task of aiding patients' experience of stigma and social isolation, as one noted, "There are many challenges in supporting people with hepatitis C…social issues including stigma due to ignorance of transmission risks as well as assumptions made about individuals' lifestyles. This stigma often comes from doctors and other medical staff as well as support

workers in community organisations, and can be an unexpected barrier to receiving service." Even these obstacles only serve to further exacerbate other existing challenges, such as staffing ("we don't have enough personnel to take care of these people,") or funding ("not being able to get funding for certain treatments is a challenge,").

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

The information in this section was gathered in the same means as described in section 2.1.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

No respondent had any experience at all with 2D. No respondent had any experience at all with 3D. This is a regular issue in providing patient input in Canada. We call upon CADTH to take leadership in connecting treatment-experienced, clinical trial participants with patient input-submitting organizations like CTAC. The Canadian Drug Experts Committee (CDEC) would be better served in their challenging deliberations by having patient input reports representing as many people as possible. In many cases, new drugs have been available in other foreign or private markets, or clinical trials have produced treatment experienced patients in the thousands, but this data is lost to the patient input gathering process and our work is compromised as a result. If CADTH is earnest and courageous about taking seriously its commitment to evidence-based decisions, we challenge them to take leadership in addressing this very serious and impactful gap in the patient input process.

All respondents noted the interesting situation of Canada having a genotype 1 HCV prevalence but 2D being a medication for the treatment of genotype 4, which represents less than 2% of the overall burden in the country. HCV+ or Treatment-Experienced respondents would not have been eligible for this treatment, but all respondents were very pleased that more research has led to treatment options for other genotypes. Specifically, the genotype 4 burden is traditionally highest in the Middle East, Sub-Saharan Africa, and is a particular problem in Egypt, where this genotype accounts for over 90% of all HCV infections. As Canada enjoys immigration and New Canadians with heritage from these areas, respondents were hopeful that 2D would complement treatment options in Canada and likely address a serious gap in our ability to treat those with genotype 4.

Section 4 — Additional Information

CTAC continues to acknowledge and appreciate CADTH and CDEC suggestions as to how to improve patient input submissions. CTAC was extremely pleased to be involved in stakeholder feedback interviews conducted with CADTH's Impact and Evaluations Advisor, Andrew Dzuba, in April of 2015. CTAC would love to hear of any further work or initiatives in response to that feedback. Further, CTAC is excited and motivated to discuss revisions, reform, and refinements to the patient input process that can better represent the patient voice as well as improve the work of not only submitting organizations, but the CDR as a whole.

Hep C BC Hepatitis C Education and Prevention Society

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		ombitasvir/paritaprevir/ritonavir
Name of the patient group		HepCBC Hepatitis C Education and Prevention Society
Name of the primary contact for this submission:		[redacted]
Position or title with patient group		[redacted]
Email		[redacted]
Telephone number(s)		[redacted]
Name of author (if different)		[redacted]
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	Website	www.hepcbc.ca
Permission is granted to post this submission		Yes

1.1 Submitting Organization

Founded in 1996, HepCBC is a registered non-profit society run by and for people infected with, or affected by, hepatitis C. Our mission is to provide education, prevention and support to those living with HCV. We have an office in Victoria and have recently opened another in downtown Vancouver, BC. Most of our staff are volunteers with experience (either past or present) of hepatitis C. We also employ 4 contractors on part-time, short-term contracts. We run activities and groups in many areas of the Lower Mainland and travel throughout the province doing outreach. Our representatives attend provincial, federal and international conferences and participate at health-related events. In addition, we provide support and information globally through our website. Other activities include: publication of a monthly bulletin (the *hepc.bull*), plus peer support, anti-stigma activities and prevention education to the general public, general hepatitis information, particularly to baby-boomer, aboriginal and immigrant communities and those living in rural/remote locations. We support and encourage testing among at-risk groups, including those who no longer fall into this category but may have contracted hepatitis C decades ago either through the blood system (whether in Canada or abroad) or through recreational drug use. We also work alongside other organizations, including local HIV/AIDS organizations to support those co-infected (for example with hepatitis B and/or HIV).

1.2 Conflict of Interest Declarations

a) We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:

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 and on buses (events and hepatitis C

patient awareness), and holding awareness activities from the following pharmaceutical companies over the last four years: Merck Pharmaceuticals, Hoffman-LaRoche, Vertex Pharmaceuticals, Gilead Sciences, Janssen Pharmaceuticals, Bristol Myers Squibb, Boerhinger-Ingelheim, and AbbVie, plus support from Rx&, the pharmaceutical umbrella organization.

b) We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:

2 of us who have completed patient submissions and both of the authors of this report have attended several educational conferences and meetings for which registration and travel expenses were funded by the pharmaceutical companies listed in (a) above.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

The information was generated using data from:
(1) patient surveys advertised through our website and our email list. There were only 5 submissions from people either living with hepatitis C or affected by hepatitis C. All were from British Columbia.
(2) one of us is a volunteer, who has actively staffed HCV+ phone and email support lines over the course of several years and therefore has an in-depth knowledge of patient concerns and experiences; both authors of this report are patient-researchers who have been reading scholarly articles about HCV for many years (20+ in one case).
(3) input from our monthly support meetings has also been included.

2.2 Impact of Condition on Patients

In the last few years HepCBC has done 14 hepatitis C drug submissions for both CADTH and BC PharmaCare, and have answered Questions 2.2, 2.3, and 2.4 as many times. Our respondents are, understandably, feeling rather jaded because they are being asked to answer the same questions so many times. However, we acknowledge that, with so many new DAAs "in the pipeline", requests for input are becoming more frequent. To avoid re-inventing the wheel we suggest you review our more detailed answers in our five most recent hepatitis C drug submissions, made in July, August, October and December of 2014 and in March of 2015 (in which 2 separate submissions were made for 2 drugs from the same company).

http://hepcbc.ca/wp-content/uploads/2015/03/20150310_daclatasvir_DAKLINZA_CADTH_redact.pdf

http://hepcbc.ca/wp-content/uploads/2015/03/20150310_asunaprevir_SUNPREVA_CADTH_redact.pdf

http://hepcbc.ca/wp-content/uploads/2015/01/20141221_ombitasvir_paritaprevir_ritonavir_dasabuvir_CADTH_redact.pdf

http://hepcbc.ca/wp-content/uploads/2014/10/20141008_ledipasvir_sofosbuvir_HARVONI_CADTH_redact.pdf

http://hepcbc.ca/wp-content/uploads/2014/10/20140711_sofosbuvir_SOVALDI_Pharmacare_redact.pdf

2.3 Patients' Experiences With Current Therapy

See Section 2.2 above.

2.4 Impact on Caregivers

See Section 2.2 above. In addition to the many previous "Impact on Caregivers" sections already written, we'd like to review this statement made for Holkira Pak:

(M, 65): "The new therapies are so gentle compared to interferon-containing regimes. I do not see AbbVie's 3D as having any impact on caregivers at all (during the patient's time of treatment)."

This last comment is extremely important in relation to this particular drug combination review: it is fair to suggest that the AbbVie combination currently under review for G4 infection is likely to be perceived by patients and caregivers in a similar way to the perception of Holkira Pak, as it is an identical combination minus dasabuvir.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

The information was gathered in the same way as for previous submissions **(See Section 2.1)**. An online patient survey; personal experiences of volunteers and staff; and input from our monthly support meetings. In addition, although we are aware that CADTH has access to all published data, we have referred to academic literature in support the some of the points we make, particularly in the following section.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

a) Based on no experience using the drug:

HepCBC believes that there is certainly a gap in treatment options for the less common genotypes in Canada. The percentage of sufferers infected with genotype 4 (GT4) globally has been estimated from 8.3%[(1)] to as high as 20%, depending on various researcher assumptions and data collection methods.

The estimated number of sufferers in North America with GT4 approximates 55,000, accounting for only 1.2% of infections in this region[(1)]. These numbers are not small, even if they appear to be in terms of overall percentages of HCV infection in North America.

However, GT4 is the overwhelmingly predominant GT in North Africa and the Middle East; in fact, other GTs are quite rare there. Moreover, increased global mobility means that the less common genotypes that we see in Canada (such as GT4) can and will travel. We already know that European countries are starting to see an increase in numbers of those infected with GT4. Regarding Canada specifically, in addition to economic migration, we are currently witnessing "compassionate migration" in the form of the movement of Syrian refugees to many countries including ours. The infection rate in Syria is estimated to be between 1%-2% of the population[(2)], of which most will be GT4. Therefore, it is fair to suggest that there is the possibility that the countries with significant Syrian refugee intake may well see a rise in numbers of those affected with hepatitis C, GT4. These countries could include Canada as it meets its obligations to the current crisis. While we are in no way suggesting that these groups are likely to transmit the virus to Canadian citizens or Permanent Residents (as Syrians are likely to have been infected via the blood system in Syria rather than to be PWIDs), we are raising the possibility of a potential rise in numbers of GT4 sufferers in Canada over the coming years.

Treatment with peg-interferon and ribavirin, which is currently approved for GT4, yields success rates of between only 43% to 70% for a 48 week course of treatment[(3)]. Some GT4s are now being treated with

sofosbuvir+peg-interferon+ribavirin with a much higher rate of SVR. A drug combo like ombitasvir, paritaprevir and ritonavir (both with or without ribavirin) would be much easier for GT4 patients to tolerate as it does not contain interferon, and has equally high or higher rates of SVR.

We would, however, much prefer ribavirin-free regimens due to their minimal if any side-effects. The shorter treatment time of the new DAAs definitely diminish ribavirin's negative impact somewhat. Adverse events reported for this combo are extremely mild, primarily consisting of known ribavirin-related issues such as fatigue, nausea, rash, insomnia, and asthenia.

We are looking with interest at the Agate 1 trial which showed that success rates for treatment either with or without ribavirin can be almost the same if the treatment period is prolonged (i.e. to 24 weeks). It has even been shown to cure people with compensated cirrhosis, and those who have failed treatment with Harvoni and Sovaldi. This is pretty amazing.

OUR RECOMMENDATION: The approval of the ombitasvir, paritaprevir and ritonavir combo (both with or without ribavirin), with its great SVR rates of between 91%-100% [(4)], would provide better treatment options for GT4s. All drugs in the AbbVie combination under review have already been approved by Health Canada for GT1, except that one ingredient (dasabuvir) is left out of the combo as it does not demonstrate activity against GT4, while the other DAAs do[(3)]. The FDA approved this GT4 triple combination (brand name: Technivie), with and without ribavirin on July 24, 2015 [(5)]. HepCBC believes Health Canada should follow the FDA's lead so that all GT4 patients in North America have the option of an effective all-oral option. Cutting treatment time down to some 25% of what it has been thus far while increasing cure rates to between 91%-100% provides a clear rationale for approval. Finally, Technivie has been demonstrated to be safe and effective with few adverse effects or even side effects[(5)]. Therefore, it seems likely that in the absence of any complicating factors, this would be an excellent all-oral GT4 HCV treatment regime. Taking this new drug combo for such a short period of time will require less clinical management expertise and time, fewer hospital visits, and less time off work.

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

We never were able to interrogate anyone who has had experience with this new drug combo.

Section 4 — Additional Information

HepCBC warmly welcomes this new treatment, the first interferon-free treatment for genotype 4. However we are still very worried that the current high cost of DAAs for HCV will result in higher demands that patients meet stringent treatment criteria, not for any medical reasons but to limit the quantity of treatments paid for by the provincial/territorial drug plans. We know that the sooner treatment is started, the more likely it is to work, and the more likely it is to prevent cancer, heart disease, and other hepatic and non-hepatic manifestations of hepatitis C. Earlier treatment also results in a greater quantity of quality-adjusted years of life added to patients' lives.

SUGGESTED SOLUTION 1 (Temporary Triage): We do understand the glaring urgency of treating those who are in most danger of progressing to de-compensation or liver cancer, or needing a liver transplant. We believe that in return for treating these patients, most patients remaining might accept waiting an extra year or two for treatment. After those most critically in danger are treated, treatment should simply be offered to "anyone with active chronic hepatitis C" (regardless of the state of liver damage).

SUGGESTED SOLUTION 2 (Economies of Scale): We urge those negotiating drug prices at all levels of government to offer to increase the number of patients treated in return for a lower price. One way of increasing the number of patients treated is to screen and identify more of them through initiatives such as age-cohort testing, which we recommend. Another way is to lower or abolish medically-unsound treatment criteria. HepCBC strongly opposes the use of such criteria as proof of liver damage such as "high or higher than Fibrosis-score 2".

References:

(1) Messina, J. P., Humphreys, I., Flaxman, A., Brown, A., Cooke, G. S., Pybus, O. G. and Barnes, E. (2015), Global distribution and prevalence of hepatitis C virus genotypes. Hepatology, 61: 77–87. doi: 10.1002/hep.27259

(2) Mohamed A. Daw and Aghnaya A. Dau, "Hepatitis C Virus in Arab World: A State of Concern," The Scientific World Journal, vol. 2012, Article ID 719494, 12 pages, 2012. doi:10.1100/2012/719494

(3) University of Washington (2015) Hepatitis C Online: Treatment of HCV Genotype 4: http://www.hepatitisc.uw.edu/go/treatment-infection/treatment-genotype-4/core-concept/all [accessed on 15/09/2015]

(4) Abbvie (24/07/2015) TECHNIVIE™ (ombitasvir, paritaprevir, and ritonavir tablets) Receives FDA Approval as the First and Only All-Oral, Interferon-Free Treatment for Genotype 4 Chronic Hepatitis C in the U.S. http://abbvie.mediaroom.com/index.php?s=20295&item=122629 [accessed on 15/09/2015]

(5) FDA US Food and Drug Administration (24/07/2015) FDA approves Technivie for treatment of chronic hepatitis C genotype 4: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm455857.htm [accessed on 15/09/2015]

Pacific Hepatitis C Network

Section 1 — General Information

Name of the drug CADTH is reviewing and indication(s) of interest		**ombitasvir/ paritaprevir/ ritonavir**
Name of the patient group		Pacific Hepatitis C Network
Name of the primary contact for this submission:		[redacted]
Position or title with patient group		[redacted]
Email		[redacted]
Telephone number(s)		[redacted]
Name of author (if different)		
Patient groups contact information:	Email	info@pacifichepc.org
	Telephone	604 740 1092
	Address	PO Box 192, Roberts Creek BC, V0N 2W0
	Website	www.pacifichepc.org
Permission is granted to post this submission		Yes

1.1 Submitting Organization

Pacific Hepatitis C Network's mission is to provide a means for sharing information and coordinating mutual support and action that will strengthen the capacity of individuals and organizations throughout British Columbia to prevent new HCV infections and to improve the health and treatment outcomes of people already living with HCV. Our members include people living with chronic hepatitis C, people who are HCV antibody positive, people at-risk for hepatitis C infection, and anyone interested or concerned about hepatitis C (service providers, health care providers, family, friends).

1.2 Conflict of Interest Declarations

a) *We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:*

PHCN has received one-time project grants from AbbVie Corporation, Bristol-Myers Squibb, Gilead Science, Janssen Pharmaceuticals, and Merck Canada for the "Hepatitis C Treatment Information Project" (http://www.pacifichepc.org/hepctip/), an online hep C treatment information resource.

b) *We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:*

The Pacific Hepatitis C Network declares no conflicts of interest in the preparation of this submission.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

Information was gathered through an online survey that was live between August 28 and September 19, 2015. The survey stated that all submissions were anonymous and asked all of the questions that this

patient input submission suggested, including a few general questions about the patient's health and wellbeing. Invitations to complete the survey were sent out by word of mouth, through our mailing lists, and by posting the survey's information on our website and Facebook page. We received 37 completed surveys.

2.2 Impact of Condition on Patients

Hepatitis C (HCV) is a serious and potentially life-threatening liver disease that may lead to liver fibrosis, cirrhosis, cancer, liver failure, and even death. However, in many cases those life-threatening HCV developments are only fought after patients spend years worrying over the future and rearranging their lives around HCV and its symptoms. This makes hep C debilitating, even if it doesn't lead to hospital stays or liver transplants. As some have described it, hep C is a disease that kills slowly by degrees and is able to affect all aspects of life.

Hepatitis C symptoms are numerous and affect patients differently. Symptoms, reported by our members, range from "have not had hep C symptoms" to "having muscle and joint pain" to having symptoms that disrupt their daily life. For example:

> "…my whole life, my physical and mental capabilities, was affected. I could hardly walk a block without having to rest. Abdominal swelling prevented me from sleeping on my right side. My family has had to watch me die by degrees. 'Brain fog' made me feel like I didn't matter. I was very prepared to die. I turned into an agoraphobic; worrying and not wanting to leave the house. My immune system depleted. I didn't want to be around other people who were sick. Always aware of the places I may get sick. I felt a complete loss of hope."

"Brain fog", mentioned above, is a common symptom of hep C. The experience of "brain fog" includes difficulty thinking, remembering, understanding, and focusing. It can be very disabling, impacting negatively on a person's ability to function at home and in the workplace.

People with "brain fog" describe having to take manual jobs requiring less cognitive function, even though this can pose other challenges if that work requires physical labour of any kind, as fatigue is sometimes also a symptom of hepatitis C.

Comments received about how HCV impacts quality of life were: "It all depends on the amount of fatigue I feel, if bad it is a stay at home day and I was at one time a active person", as well as, "work--I am too tired for the physical demands of my work", and "I am extremely exhausted most of the time."

However, the above quote not only touches on "brain fog" and fatigue, but it also expresses the uncertainty, loss of hope, helplessness, and worry, that often surrounds hep C. Hep C doesn't only take physical tolls on patients, but also takes psychological and emotional tolls on patients and their support networks as well. This is due, in part, to the fact that it is a disease that one often has to wait and get sicker before receiving treatment while also being a disease that people die of before being able to find a treatment able to treat them. One member wrote: "To be rid of something that has the potential to destroy one's body would have profound physical and psychological benefits."

Another member wrote about always feeling like their health is unreliable and wondered if they would have taken more chances, in their social life and their career, if they weren't always concerned that their health wasn't up to the challenge.

Lastly, these physical and psychological tolls are often worsened by the social isolation, which comes from suffering fatigue, other hep C symptoms, the worry of passing HCV on, and from the stigma that comes as a result of having hepatitis C, a communicable disease. Someone stated that they are "afraid of passing this on so no intimate contact since being diagnosed. Makes for a very lonely existence." Another recalled sharing her diagnosis with coworkers in confidence and having them spread the news to the entire office. As a result, some of her coworkers quit, stating that they were worried about getting it themselves from her and then passing it on to their families.

This social isolation is extremely damaging, as we know that those who are socially isolated have poorer health outcomes, do not access care as quickly or as often as they could, and can have more hospitalizations due to acute illness.

2.3 Patients' Experiences With Current Therapy

Hepatitis C genotype 4's current standard of care is pegylated interferon with ribavirin, a treatment known for its side effects and for not having a high success rate treating hep C genotype 4.

Patients' experiences with pegylated interferon with ribavirin range from being able to continue work while on treatment to experiencing such severe side effects that they virtually couldn't function and needed help with basic daily living and childcare. However, experiencing few or no side effects wasn't an experience described by many who completed our survey. A quote collected was "My treatment with peginterferon and ribaviron were very hard to sustain for 24 weeks."

Also, when asked about pegylated interferon with ribavirin financial reasons and the fear of missing work because of side effects were felt to be two of the main barriers of hep C treatment.

"Treatments that have little side effects are the way to go. The side effects of earlier treatments were absolutely horrible and deterred people from wanting treatment."

2.4 Impact on Caregivers

The need for hope and the worry and concern over health and well-being that comes with not feeling in control of one's health and future isn't experienced by just those living with HCV, but by their caregivers as well. All caregivers express concern about how hep C is impacting the health of their loved one and, if they hadn't yet had treatment, concern also about what treatment will be like.

One of the most difficult situations for a caregiver is when treatment has failed and their loved one is still ill, or if treatment isn't an option. A caregiver, for example, shared that when her husband was diagnosed, "the doctors just said to get his affairs in order."

When treatment was an option, caregivers talked about the complexity of needing to stay both alert to possible very adverse reactions while not interfering or being ''in the face" of their loved one on treatment.

Furthermore, treatment not only affects the lifestyles of the patients but the lifestyles of their loved ones as well. For example, suffering from treatment side effects decreases what one can do and increases the workloads, such as household chores and income earning, of others. A caregiver, when asked about her experience while her husband was taking treatment, said that it was very hard being the only one working in their household for such an extended period of time.

Some caregivers end up feeling resentful of their partners and then guilty because they were mad at a sick person.

In addition to feeling overwhelmed and resentful, they also reported suffering from depression, lack of sleep, and additional stress while their loved one was seeking treatment.

After treatment some caregivers said that their lives returned to normal, especially after a successful treatment with fewer adverse effects, but not always. Sometimes their loved ones continue to experience fatigue and other post-treatment conditions that continue to impact their lives and their families.

Section 3 — Information about the Drug Being Reviewed

3.1 Information Gathering

Information was gathered through an online survey that was live between August 28 and September 19, 2015. The survey stated that all submissions were anonymous and asked all of the questions that this patient input submission suggested, including a few general questions about the patient's health and wellbeing. Invitations to complete the survey were sent out by word of mouth, through our mailing lists, and by posting the survey's information on our website and Facebook page. We received 37 completed surveys.

3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

a) *Based on no experience using the drug:*

Those with HCV have high expectations for ombitasvir/ paritaprevir/ ritonavir. These expectations include, but are not limited to, the following:

- High cure rates allowing patients to "be able to live normal lives"/to improve their lifestyles/quality of life by being able to feel better, be more productive, and quit worrying so much about their health or spreading hep C to others
- Fewer and less debilitating side effects allowing more patients, such as those who relapsed or couldn't tolerate or complete treatment with pegylated interferon with ribavirin to seek treatment
- Fewer and less debilitating side effects allowing more patients to work as they desire while taking treatment
- A reversal or slowing down of liver fibrosis or cirrhosis so that they won't be at such risk of liver failure or cancer
- Shorter treatment lengths

b) *Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:*

Two people indicated that they had experience with ombitasvir/ paritaprevir/ ritonavir. They said that they experienced side effects (insomnia, headaches, itchy skin) but when asked if the side effects were better or worse than what they thought they would be, their answers were divided. One of them wrote that "it was less harsh than interferon". The other person wrote that they had expected the treatment and side effects to be easier to deal with than they were.

Section 4 — Additional Information

“Shortened time of treatment, less side effects, higher SVR rates, the ability to continue working while being treated”, “an end of worrying over the health of my liver”, “healthier livers”, “being cured faster and will not have to go thru multiple treatments”, and “quick treatments that cure all GTs” are all now expected of hepatitis C treatments.

There is a want to get better, to improve one's health, and to fully participate in all that they dream of being involved in or that they haven't allowed themselves to dream of because of concerns around their hep C. There is hope that new and greatly improved treatments are coming and that the treatments will be available to them.

However, we are concerned that treatments, such as ombitasvir/ paritaprevir/ ritonavir, that treat genotype 4, a less common genotype in Canada, will remain unaffordable and unreachable. We are concerned as well that some patients may have to first undergo and fail treatment with pegylated interferon with ribavirin with a lower cure rate before having access to drugs like ombitasvir/ paritaprevir/ ritonavir.

Lastly, along with individual lives being saved and improved dramatically, early eligibility for and completion of treatments with ombitasvir/ paritaprevir/ ritonavir are likely to result in financial cost savings to healthcare systems and should be considered. Ultimately, we think that the wisest course is a reasonable balance between cost and clinical best practice in treating as many people as quickly as possible.