July 23, 2014

To the Advisory Committee:

I do not know where to start. I am frustrated by the efforts by some to block the accessibility of Solvadi to all patients with Hepatitis C. It is a miracle that our drug community has gotten this far, to have created a drug that has a cure rate of 90%. How can we withhold this from the public? It is disgusting, unethical and incomprehensible to think that we would keep a patient from receiving the benefits of this drug one day longer.

It has only been in the last three years that I have been staying informed about the newest developments for hepatitis C. I am a poster child of a loved one living in total darkness to the extreme dangers of this disease. My mom learned of having hepatitis C in a letter from the Red Cross dated September 12, 1990. She went on to endure two treatments of Interferon that decade, hoping that she would be the 10-25% who would be cured of the disease. She was not. In 2007, she was told her biopsy showed signs of cirrhosis of the liver. She was given no plan of action and no prognosis of how her disease may progress. She experienced strange symptoms in the years after, that no doctor could fully explain. It was not until December of 2010 that my mom received the news that she had terminal liver cancer. She died at the age of 58 on March 9, 2011. I was 28 years old.

Because hepatitis C was a newer disease, my parents were never well educated about it and never kept abreast of the new developments in the disease. We all saw the disease as similar to heart disease or diabetes that would not really catch up to you until you were really old. My mom's death was a product of inept doctors and poor oversight of my mom's condition. My father would further learn, when looking at the 2007 biopsy report himself in January of 2011, that cancer had been detected but no one informed my parents or made a plan of treatment. My mom's story is a completely tragic one. From the day she learned of her disease she was starting on a path of death. I am so thankful that we had as many years with her as we possibly could.

I want this committee to hear from someone affected by this disease. While everyone is focused on numbers, people are dying. Families are losing their loved ones and this will only get worse as more and more baby boomers learn of their disease. Our family felt completely hopeless. We had no support from our doctors. There was no preventative care put in place for my mom. It was total negligence. I believe that this drug empowers the patient and empowers their families. They do not have to be dependent on a doctor to recognize the signs of cirrhosis, to recognize the signs of cancer, or to put together the most effective treatment plan. Families can now go from a loved one having hepatitis C to a loved one being cured.

This was the last day I saw my mom. She died two weeks after this picture was taken.

Please acknowledge how Hepatitis C destroys the body and takes our loved ones away.

I will never have my mom back.

And she will never meet my daughter/son who is due on January 1.

You all have the power to give people a miracle that we have been praying years for. I hope you feel the burden of this responsibility and the magnitude of your actions.

Thank you for taking the time to hear my story,

Jenny Goslin, daughter of Sheila Pauline Monica Parducci Graham (1952-2011)

MEMORANDUM

PhRMA
RESEARCH • PROGRESS • HOPE

July 31, 2014

To: Jeanene Smith, MD, MPH, Administrator and Chief Medical Officer
Office for Oregon Health Policy & Research

From: The Pharmaceutical Research and Manufacturers of America

RE: Oregon Health Plan Treatment of Hepatitis C Medications

Thank you for the opportunity to comment on both the HERC's and its Value Based Benefits Subcommittee's process for addressing the treatment of Hepatitis C in the Oregon Health Plan (OHP). Issues surrounding patient access to vital medications are of significant importance to us and to our many research-based innovative biopharmaceutical members across the globe. Due to significant unmet medical need, coupled with an innovative and research-driven biopharmaceutical development process here in the United States, diseases like Hepatitis C now have cures, not just treatments. In the long run, these new medical advancements, as well as many more under development, will serve to change the face of medical treatments for several chronic and intractable diseases. That is, assuming physicians and patients have the support and ability to access these new breakthroughs. Unfortunately, however, we view the process being undertaken by the HERC related to newly approved Hepatitis C cures as both a barrier to patient access and a step backwards in the fight against Hepatitis C.

Initially, and most fundamentally, we have serious concerns related to any decision by Oregon not to cover advances in medical science, particularly those that can result in a substantial public health benefit: the cure of a chronic, contagious condition. The public record regarding coverage of Hepatitis C medications reflects little consideration of the medical and quality of life benefits and the corresponding cessation of long-term health interventions that would result from curing hepatitis C.[1] Instead, almost the entire record is comprised of discussions related to the up-front cost of new Hepatitis C medications and the problems associated with administering the OHP in the short-term.

In addition to our concerns related to patients' ability to access new and better medications, we have significant concerns related to the process the HERC and its subcommittees have undertaken to date when reviewing this potential Hepatitis C decision, and we seriously question whether future determinations would be permissible under Oregon's Section 1115 waiver and consistent with the State's obligations under the Medicaid Drug Rebate Program.

For example, significant emphasis has been placed, both in HERC discussions as well as in several media reports on this issue generally, on Oregon's 1115 waiver as the source of the State's authority to limit access. According to HERC's Q&A document on Hepatitis C, HERC indicates that a final decision could

[1] Similarly, the dialogue lumps together different hepatitis treatments by FDA approval date, which is not a clinically appropriate way to develop policies on patient access.

be implemented by October 1, 2014. If HERC made a final determination to place certain Hepatitis C treatments below the line on Oregon's Prioritized List, however, then under the Section 1115 waiver HERC would have to seek approval from the Centers for Medicare and Medicaid Services (CMS) at least 120 days before the planned implementation date so that CMS could "ensure that the Prioritized List is comprehensive enough to provide Medicaid beneficiaries with an appropriate benefit package."[2] The waiver documents further state that any modifications to the Prioritized List may not be implemented until CMS approves the State's amendment request.[3] Yet, to date, we see no evidence that this federal approval process has begun.

Moreover, most of the discussion surrounding the guidance on Hepatitis C seems to be grounded in cost effectiveness considerations and does not appear to encompass much input from the patient and provider community. Notably, Oregon's Section 1115 Waiver Approval references Oregon's commendable "community-focused health systems transformation approach" and requires, consistent with that approach, that the State engage in a "robust public process to ensure community engagement" in developing proposed modifications to the Prioritized List.[4] We hope that HERC and its subcommittees will fulfill their obligation to ensure patients' and providers' voices are heard, seriously considered, and reflected in any final request to CMS for amendment.

We also question how the HERC could satisfy its various state regulatory mandates if it were to restrict patient access to cures by moving certain Hepatitis C medications "below the line." For example, OAR § 410-121-0040[5], states that drugs must generally "be prescribed for conditions funded by the [OHP]," and that generally medications are not covered if prescribed "for a non-covered diagnosis." What is not clear from this provision, however, is how HERC is determining to treat a provider's prescription for an FDA-approved medication, prescribed for a "condition funded by [OHP]" as not a covered service. Further, we question whether this move, which arguably looks like an attempt to single out individual drugs rather than to review a disease state more generally, is consistent with HERC's overall regulatory authority vis-à-vis its division of responsibility with the Oregon P&T Committee. Plainly, the process to date looks quite a lot like an attempt to conduct a "drug class evidence review or medical technology assessment solely of a prescription drug," which would be prohibited under ORS § 414.698(1).

At the federal level, we question how Oregon could deny coverage for an FDA-approved medicine prescribed for a medically accepted indication consistent with its obligations under the Federal Medicaid Drug Rebate Statute[6] The Medicaid rebate statute imposes obligations on manufacturers related to payment of rebates and imposes obligations on Medicaid programs related to the coverage of prescription medications subject to Medicaid rebates. Placing an FDA-approved medicine covered by a Medicaid rebate agreement below the funding line in circumstances where the drug is used for a medically accepted indication (as defined by the rebate statute)[7] does not comport with the coverage requirements set forth in the rebate statute. Prior authorization policies may comport with the Medicaid rebate statute in specified circumstances, but a below the line placement (which would effectively mean complete non-coverage) would not. And, to be sure, the requirements of the rebate statute cannot be waived under Section 1115.[8]

---

[2] June 27, 2014 CMS Waiver Approval at 9, 17.
[3] *Id* at 9.
[4] *Id*.
[5] We note that, consistent with the Medicaid Drug Rebate Statute discussion below, it is unclear how the State could actually carry out enforcement of OAR § 410-121-0040 in general without violating 42 U.S.C. § 1396r-8, since placing any drug subject to a Medicaid Rebate Agreement in a non-covered capacity could trigger a violation of the Rebate Statute. For purposes of this discussion, however, we treat OAR § 410-121-0040 as if was enforceable and note that placing Hepatitis C drugs below the funding line would conflict with that Rule.
[6] 42 U.S.C. § 1396r-8 (Social Security Act § 1927).
[7] The rebate statute defines this term as FDA-approved indications plus additional uses supported by specified drug compendia.
[8] 42 U.S.C. § 1315(a)(1) (listing sections in the Medicaid statute that "the Secretary may waive" in § 1115 demonstrations and not including in that list the rebate statute: 42 U.S.C. § 1396r-8); *see also PhRMA v. Thompson*, 251 F.3d 219, 222 (D.C. Cir.

We have significant concerns that a move to place Hepatitis C drugs subject to a Medicaid rebate agreement below the funding line would put the State in violation of the Medicaid Drug Rebate Statute.

We note also that the Medicaid "expansion population" described in the Affordable Care Act (ACA) must receive benefits under Oregon's Medicaid Alternative Benefit Plan,[9] which must comply with Essential Health Benefit (EHB) requirements. Importantly, federal EHB regulations ban benefit designs that "discriminate[] based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life or other health conditions."[10] Further, under federal law Alternative Benefit Plans can only be based on certain benchmark plans not relevant here (the Federal Employee Health Benefits Program BlueCross/Blue Shield PPO option, State employee plans, and the State's largest commercial HMO) and "Secretary-approved coverage,"[11] meaning "[a]ny other health benefits coverage that the Secretary [of health and Human Services] determines, upon application by a State, provides appropriate coverage for the population proposed to be provided such coverage."[12]

If Oregon were to modify the Prioritized List to delete coverage for newer hepatitis C medications below the line and constrict its Medicaid Alternative Benefit Plan to incorporate the modified version of the Prioritized List, then we believe the State could be in violation of the EHB non-discrimination requirement, and also would need to seek and obtain CMS' approval for this scaled-down coverage package.

Beyond the legal problems stemming from a HERC determination not to cover certain Hepatitis C treatments, we are concerned most fundamentally with State determinations to deny patients access to cures. In the long run, these decisions are unlikely to save any costs, are likely to reduce the quality of patient care, would forego opportunities for public health gains, and unquestionably provide a significant disincentive for future innovation. All of which is bad for Oregon. Therefore we urge Oregon to take a serious look at the long-term benefits -- both to patients and the healthcare system -- that can be achieved when patients have meaningful access to innovative treatments that could reduce the need for expensive and chronic medical interventions later in life.

CC: Darren Coffman, Director, Oregon Health Evidence Review Commission
Ariel Smits, MD, MPH, Medical Director, Oregon Health Evidence Review Commission
Thomas Burns, Director, Pharmacy Programs, Oregon Health Authority
Roger Citron, Administrative Support, Oregon Pharmacy & Therapeutics Committee

---

2001)("Although the Act authorizes the Secretary to waive certain Medicaid requirements for such [§1115] demonstration projects, it does not authorize him to waive any requirements of section 1396r-8's rebate provision…").

[9] CMS Waiver Approval, at 19.

[10] 42 C.F.R. § 440.347(e)(emphasis added).

[11] 42 U.S.C. § 1396u-7(b).

[12] 42 U.S.C. § 1396u-7(b)(1)(D) (emphasis added). *See also* 42 C.F.R. § 440.330(d)(1) ("States wishing to elect Secretary-approved coverage should submit [to CMS] a full description of the proposed coverage (including a benefit-by-benefit comparison of the proposed plan to one or more of the three other benchmark plans specified above or to the State's standard full Medicaid coverage package), and of the population to which coverage will be offered").

10940 SW Barnes Road #129
Portland, OR 97225
phone: 503-297-7207
fax: 503-297-0127

July 30, 2014
Members of the Oregon Pharmacy & Therapeutics Committee
Drug Use Research
& Management Division of Medical Assistance Programs
500 Summer Street NE, E35
Salem, OR 97301-1079

To the Members of the Oregon Pharmacy & Therapeutics Committee:

I am writing to you today on behalf of the 100 of Oregonians who are living with Hemophilia and other bleeding disorders and are co-infected with hepatitis C (HCV).

We at the Hemophilia Foundation of Oregon are very familiar with the high cost of critical life sustaining medications. With average costs in excess of $250,000 per patient, per year, our patients rank among the most expensive to treat chronic conditions. Hemophilia is primarily an inherited genetic life long disorder, requiring regular treatment for life. Prior to 1992, many people with bleeding disorders were exposed to hepatitis C (HCV) through the blood supply, before it was screened for HCV. Clotting factor concentrates, the primary treatment for patients were derived from human blood.

It is estimated that of patients born before 1992 approximately 80% are infected with HCV[I]. Approximately 25% of this population has advanced liver disease, and liver disease is the leading cause of death among patients with bleeding disorders.

While previous generation medications have been available to treat HCV, they have been difficult to tolerate, ineffective and in some cases, contraindicated for our patients and have well documented adverse side effects. Many patients have consciously postponed treatment, gambling that new effective treatments will be available.

The addition of Solvadi (sofosbuvir) and newer medications in development offer not only hope for our patients, but also the possibility of a cure. While it remains to be demonstrated how these medications would work in people with bleeding disorders, the potential benefit is incredible.

For these reasons, we are concerned that the proposed guidelines for the use of Solvadi do not consider the needs of all the people who could benefit from this medication. Perfect adherence to prior medications, treatment by a "relevant specialist" and not recognizing the bleeding disorder community in the development these guidelines are barriers to access and care. Liver transplant is generally, not a viable option for our community; our best hope is access to medication.

Thank you for the opportunity to share our comments. If you have any questions, you can reach me at. marita@hemophiliaoregon.org or 503-297-7207

Regards,

Marita Postma
Executive Director

Cascade AIDS Project CAP

July 30, 2014

Members of the Oregon Pharmacy & Therapeutics Committee
Drug Use Research
& Management Division of Medical Assistance Programs
500 Summer Street NE, E35
Salem, OR 97301-1079

To the Members of the Oregon Pharmacy & Therapeutics Committee:

I am writing to you to share our concerns about the proposed guidelines for the use of the medication Solvadi in the treatment of hepatitis C (HCV). While we understand the necessity to use public health care dollars prudently and for the greatest impact in our communities, we are concerned that the proposed guidelines are too limited in scope to accurately address the needs of the estimated 2,600 Oregonians who are co-infected with both HIV and HCV.

Co-infected individuals face a greater mortality rate, as much as 50% compared to people with HIV alone[i]. They are also at an increased risk of complications directly related to their HCV infection[ii] including; HIV disease progression, cardiovascular disease, kidney damage, neurological impairment, diabetes and peripheral neuropathy.

Like HIV, HCV disproportionately impacts communities of people of color, and carries a stigma associated with shame and socially unacceptable behaviors. This stigma presents a barrier to our efforts to educate, test and treat people who are at risk for co-infection. Because HCV is a communicable blood borne pathogen, like HIV, there are public health implications to prevention and treatment. The adoption by the US Preventative Services Task Force (USPTF) of a recommendation to screen populations at risk has added HCV testing as a free preventative measure under the Affordable Care Act. More people than ever can now get tested and linked to care. But what good is a test if there is no cure? Earlier medications for HCV were plagued with side effects so great that patients were unable to complete the course of treatment. They were also ineffective, at best the rate of sustained virological response was no higher than 65%. Earlier treatments were less effective for African Americans, due to genetic response to pegylated interferon, Solvadi cure rates are consistent in black and non-black clinical trail participants.

We have made great strides in treatment and prevention of HIV in recent decades, largely eliminating the many once fatal comorbidities and conditions that patients once succumbed to, and extending the average lifespans, with care and treatment, to that of the uninfected populations. These advances have come at a great price, in human suffering, and financial investment, to arrest a pandemic and public health crisis unprecedented in our lifetimes.

The financial cost of this advancement was at the time considered staggering as well. AZT, the first medication approved to treat HIV cost $10,000 when it was released in 1987, making it, at the time, "the most expensive prescription drug in history." according to the New York Times. Adjusted for inflation it would cost more than $20,000 today. This is still a bargain compared to the $600,000 average lifetime cost of care for HIV patients.

208 Southwest Fifth Avenue, Suite 800 Portland, Oregon 97204

t› 503 223 5907
f› 503 223 6437
cascadeaids.org

Estimates vary greatly for the cost of care for lifetime HCV care from $205,760 (adjusted for inflation) according to the journal Hepatology[iii] to $280,000 in 2012 according to the Cornell Center for Advanced Computing[iv] for liver transplant. This amount does not include the cost of anti-rejection medications at $36,000[v] per year for life.

When viewed as a cost benefit analysis the equation is simple; $64,680[vi] to cure a person now or well in excess of $3.6 million over the estimated 18 year average life expectancy[vii] for a transplant patient in the future, assuming organs are available.

This debate is greater than the cost of one medication, it is the ethical debate we must engage in where we consider the cost in pain, human suffering, the quality and the quantity of the lives we have the opportunity to provide for our fellow Oregonians living with HCV.

Thank you for the opportunity to speak on this issue. If you have any questions, please feel free to contact me at 503 278 3810.

Sincerely,

Tyler TerMeer
Executive Director

208 Southwest Fifth Avenue, Suite 800 Portland, Oregon 97204

t) 503 223 5907
f) 503 223 6437
cascadeaids.org

[i] Branch AD et al. *Mortality in HCV-infected patient with a diagnosis of AIDS in the era of combination anti-retroviral therapy.* Clin Infect Dis, online edition, 2012.
[ii] Operskalski, Eva, Kovacs, Andrea *HIV/HCV Co-infection: Pathogenesis, Clinical Complications, Treatment, and New Therapeutic Technologies*
http://link.springer.com/article/10.1007/s11904-010-0071-3/fulltext.html
[iii] Homie Razavi, Antoine C ElKhoury, Elamin Elbasha, Chris Estes, Ken Pasini, Thierry Poynard, & Ritesh Kumar *Chronic Hepatitis C Virus (HCV) Disease Burden and Cost in the United States* Hepatology. Jun 2013; 57(6): 2164–2170.
[v] MATLAB Crunches Hepatitis C Virus Data http://scitechdaily.com/matlab-crunches-hepatitis-c-virus-data/
[vi] California Pacific Medical Center, *Liver Transplant Costs*
http://www.cpmc.org/advanced/liver/patients/topics/finance.html
[vii] The cost of Solvadi after the 23% Medicaid rebate.
[viii] *Long-Term Survival After Liver Transplantation in 4,000 Consecutive Patients at a Single Center,* Jain, A et al, Annals of Surgery Oct 2000; 232(4): 490–500.
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1421181/

208 Southwest Fifth Avenue, Suite 800 Portland, Oregon 97204
t› 503 223 5907
f› 503 223 6437
cascadeaids.org

Caring Ambassadors Program
Lorren Sandt, Executive Director
P.O. Box 1748
Oregon City, OR 97045

**Public Comment**
**Proposed Sovaldi Guidelines**

OSU Drug Use Research and Management Program
Oregon Drug Use Review / Pharmacy & Therapeutics Committee
July 31, 2014

The Caring Ambassadors Program is a national, nonprofit, advocacy organization based in Oregon City, Oregon. We respectfully submit our written comment on the proposed criteria and suggested revision to the current Hepatitis C PDL class on Sofosbuvir for treatment of Chronic Hepatitis C (CHC) Virus.

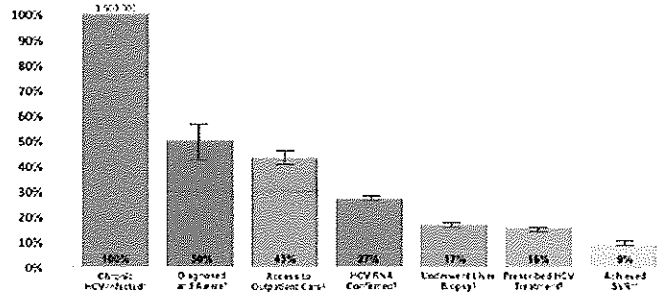
Your proposed guideline to make people develop cirrhosis of the liver (creating another disease besides HCV he person is living with) is horrific. We respectfully ask you to reconsider this to include F2 and F3 patients.

A cirrhotic liver fails to perform the normal functions of the liver, which leads to liver failure. Cirrhotic livers are more prone to become cancerous and liver failure leads to serious complications, even death. HCV is reported to be the leading cause of chronic hepatitis, cirrhosis and liver cancer and a primary indication for liver transplant in the Western World. [Rosen 2011] "The morbidity and mortality associated with chronic HCV are mainly attributable to its progression toward cirrhosis and hepatocellular carcinoma." [Rauch 2010]

A recent cohort analysis of 528 HCV infected patients with cirrhosis found baseline health-related quality of life (HRQOL) was significantly impaired with the most profound impairments in physical activity, energy, vitality, and fatigue. [Younossi, 2014]

**You are exposing Oregonians with cirrhosis to An individual risk of developing HCC at 1-6% per year.** [Sangiovanni Gastroenterology 2004]. You will need to scan all of these patients every 6 months for Liver cancer. You must consider the all downstream fiscal and societal costs when looking at this disease and how to treat it.

Figure 2. Treatment Cascade for People with Chronic HCV Infection, Prevalence Estimates with 95% CI




Hepatitis C not only the most prevalent bloodborne viral disease in the U.S. and the largest infectious disease outbreak in our life time, but also the deadliest.[Edlin, Nature] HCV is potentially curable with antiviral therapy, but only a minority of patients have been diagnosed and, of those, fewer than 20% have been offered treatment due to of the difficult side

effects of interferon containing regimens.

In the US, chronic HCV is the most common cause of liver disease and is responsible for at least 15,000 deaths annually. Unfortunately, the morbidity and mortality associated with HCV infection will continue to increase over the next few decades.[Davis 2010] Despite what is thought to be a very slow progression to cirrhosis, HCV-related mortality due to liver failure and hepatocellular carcinoma has increased substantially since 1995, especially in persons 45 years and older with the greatest increases in males and non-Hispanic blacks.10 It has now become an important cause of premature mortality due to the relatively young ages of those dying from HCV-related causes. [Wise 2010] In addition to liver disease burden, chronic HCV impacts wellbeing. [Younossi, 2013]

Criterion #5 states that medication being prescribed by or in consultation with a hepatologist. Again this further discriminates against those that cannot access a hepatologist nor is it the community standard. Infectious disease specialists, gastroenterologists and NP's have successfully treated for years with therapies that had much more difficult side effects. It is already a long wait list to see a hepatologist, how can a handful of these doctors also handle consulting on all the cases?

Further discrimination is against the African American population since the Sofosbuvir is really their only treatment option and the new standard of care.

Criterion #6 asks, "Has the patient had documented noncompliance to previous treatment?" What does this mean? Therapy in the past was a yearlong not 12 weeks. What are the criteria here? Past poor adherence in the first 12 weeks?

Arkansas has just had it 1st lawsuit because of the restrictions they are proposing. This will happen in Oregon if you continue to discriminate against people accessing the Oregon Health Plan. Please remember your waiver states you cannot do harm to the citizens. Creating a new population of people with cirrhosis is a deadly path for all concerned.

Thank you for your time and consideration.

Lorren Sandt

Executive Director

Caring Ambassadors Program

one in four
chronic health

a voice for patients
kin.org

July 31, 2014

Members of the Oregon Pharmacy & Therapeutics Committee
Drug Use Research
& Management Division of Medical Assistance Programs
500 Summer Street NE, E35
Salem, OR 97301-1079

To the Members of the Oregon Pharmacy & Therapeutics Committee:

My name is BJ Cavnor, and I serve as the Executive Director of One in Four Chronic Health, a collaborative serving people living with chronic health conditions. For the record, our organization has received unrestricted educational grants from pharmaceutical companies, but we have never received any money, gifts or in-kind contributions from Gilead Sciences.

I would like to speak to you today on the proposed guidelines for the use of Solvadi for hepatitis C (HCV) patients. Not since the introduction of highly active antiretroviral therapy (HAART) in 1996 have we seen such improvement in treating viral infections.

While there had been much said about this drug, most of the conversation has focused on the cost, and not the efficacy. The medical ramifications of this and other new drugs in the pipeline are remarkable; we now possess a treatment that can cure HCV in 95% of patients. We can prevent the leading cause of liver cancer deaths in our country and dramatically improve lives of the 65,000 Oregonians living with HCV if and when they require treatment.

The consideration of cost is necessary, not only because of rising health care expenditures, but also so are able to provide care to as many Oregonians as possible, with a finite amount of money.

I would ask that if we are going to debate the cost of Solvadi we do so on a level playing field. Starting with the actual cost of the drug. I understand that the actual price negotiated cannot be publically disclosed, but can we at least begin by using an amount that incorporates the 23.1% Medicaid Rebate, authorized by Section 1927 of the Social Security Act.

That would reduce the price to $64,680, still a great deal of money, but it is a starting place. We also know that other states have been successful in negotiating lower prices, as have the Veterans Administration and the Federal Bureau of Prisons. That lowers the price to $36,960, compared to the cost of telaparevir to a pegylated interferon and ribavirin treatment at $65,000 to $81,000 for a course of treatment. Using boceprevir in combination treatment ranges from $45,000 to $80,000[1].

Comparing Solvadi to existing treatments based on price illustrates the overall cost of treatment, for a more accurate picture.

On the issue of efficacy, the update prepared in July of this year, *Abbreviated Class Update: Hepatitis C* uses clinical guidelines from the World Health Organization (WHO) and the European Association for the Study of the Liver (EASL), the Institute for Quality and Efficiency in Health Care (IQWIG) in Germany, the UK National Health Service, the National Institute for Health Care and Excellence (NICE) also based in the UK, the Federal Bureau of Prisons and the Veterans Administration.

We are curious why recommendations and clinical guidelines were not included from the Centers for Disease Control and Prevention[2], the American Association for the Study of Liver Diseases, the Infectious Disease Society of America[3], or the National Institutes of Health[4], which has current guidelines on the treatment of HIV/HCV co-infected pregnant women, including relevant information on bioavailability of HIV medications during HCV treatment?

The International AIDS Conference has just ended in Australia, and HCV was appropriately recognized as an emerging global health crisis. The issues of affordability and access were foremost with researchers, activists, and governments. Angry activists confronted pharmaceutical manufacturers over drug pricing, something that I personally haven't seen happen since introduction of new HIV drugs in the early 1990's.

At the conference, International AIDS Society president Francoise Barré-Sinoussi spoke of the potential impact activists, patients, providers and governments can have one the availability and pricing of new drugs, "Let's use the experience gained in HIV to reduce HCV treatment cost and make universal access a dream come true for the 150 million people with hepatitis C".

We could not agree more. We have learned from history by working together with pharmaceutical manufacturers, patients, providers, insurance companies and government will we be able to achieve prevention and treatment goals for people living with HCV.

Thank you for the opportunity to speak to you today. If you should have any questions, I can be reached at 206/601-8453.

Regards,

BJ Cavnor,
Executive Director

References

[1] The Hepatitis C Pipeline, Swan, T. The Body Pro, September 2011 http://www.thebodypro.com/content/65293/the-hepatitis-c-treatment-pipeline.html

[2] Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease http://www.cdc.gov/hepatitis/hcv/Management.htm

[3] Recommendations for Testing, Managing, and Treating Hepatitis C http://hcvguidelines.org/full-report/initial-treatment-hcv-infection-patients-starting-treatment

[4] Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States http://aidsinfo.nih.gov/contentfiles/lvguidelines/perinatalgl.pdf