March 4, 2015

US Senator Ron Wyden
221 Dirksen Senate Office Building
Washington DC 20510

Honorable Senator,

As your constituent, I write you with appreciation for affording me the opportunity to speak with your staff about Hepatitis C (HCV) and access to testing, treatment, and care. On February 25, 2016, I was joined by Ann Pickar (Access to Medicines Coalition), Jacki Gethner (Women of a Certain Age and Hep C survivor), John Motter (Cascade AIDS Project and Hep C survivor), and Lorren Saandt (Caring Ambassadors) for a meeting with your staff to discuss HCV in Oregon and to offer input on opportunities for addressing and resolving our state's high disproportionate impact. I am sending you information in follow up to our discussion which I hope may be useful in answering questions posed in your recent request for public comments.

Along with Senator Grassley, your statements about HCV have helped raise awareness about our need for urgent HCV action. A recent Oregon Health Authority (OHA) report highlighted the immediacy of this issue illustrating HCV as impacting Oregonians at a rate 50 percent higher than the national average. Over 47,000 Oregonians are infected, aware of their status. It is estimated as many as double this number are currently infected and unaware. Annually, an average of 34, liver transplants (estimated at more than $600,000 in total costs) take place at Oregon Health & Sciences University with 54% of these transplants attributed to chronic HCV. Annually, an average of 441 Oregonians die from liver failure attributed to HCV infection, a rate six times higher than HIV/AIDS-related deaths and 81% higher than HCV mortality rates nationwide.

In your recent request for public comment, you mentioned the role of "value" in the pricing debate and how value should be represented through price. Before sharing my thoughts on value and price, I'd like to share the role of value per Quality Adjusted Life Year (QALY) for HCV testing according to CDC guidelines. I feel this is important as this disease is transmittable and, according to many published studies evaluating HIV, a person knowing their HIV status equates to a significant decrease in the likelihood of secondary transmission. QALY value for HCV testing at between US $4,200 to $50,000 is comparable with cost effectiveness of colorectal cancer screenings, mammograms, and AC1 diabetes testing. I compare these three to HCV screening as OHA has deemed these three to be priorities in our state, providing incentives to our Coordinated Care Organizations for providers to screen Medicaid patients. I feel it would be of significant value to identify similar incentives, to employ additional resources, for increasing HCV screenings in Oregon given the number of new cases which we can avert. With HIV, $500,000 in lifetime medical treatment costs is averted for every new infection prevented. Applied to Oregon's rate of HCV (currently at 5,000 new infections annually), our state could save as much as $100,000,000 (calculated at 25% reduction in secondary transmissions, 1,250 new cases averted, with $80,000 in HCV treatment cost per person) simply by providing incentives and employing additional resources to better support HCV screenings.

Thank you your statements and your thorough report on Gilead's Sovaldi and Harvoni pricing, two HCV treatments which have recently become available and which are demonstrating sustained viral response rates of at least 90%. Value, applied to treating a HCV infected persons, equates to 15 years of life years gained for patients. At a willingness-to-pay threshold of $100 000 per QALY, sofosbuvir-based therapies were cost-effective in 83% of treatment-naive and 81% of treatment-experienced patients. Given the price of the new HCV treatments, Oregon has decided not to treat HCV positive Medicaid patients until patients' livers have deteriorated to late stage disease progression. While resources and pricing warrant scrutiny and concern, this situation is equivalent to a patient being diagnosed with breast cancer at stage 2 with the patient being instructed they would need to return

when the cancer progresses to late stage: the reasoning being our healthcare system can't afford to treat early. With cancer, I feel this would justifiably call into question ethics in medical practice: I feel the same should be stated for Oregon's current approach to delaying treatment for people living with HCV.

Another question you've asked for public comment on pertains to price transparency. I appreciate Senator Grassley's and your demands of Gilead to produce information centered on this issue. Reasonable measures to improve transparency, I feel, may be illustrated in legislation which has been proposed in many states similar to California's Pharmaceutical Cost Transparency Act of 2015. This legislation would have required manufacturers to produce an annual report on medications which cost "$10,000 or more annually or per course of treatment." The report would have to include the following costs paid by the manufacturer and, separately, the costs paid by "any predecessor in the development of the drug":

- Total costs for the production of the drug, including the total R&D costs
- Total costs of clinical trials and other regulatory costs
- Total costs for materials, manufacturing, and administration attributable to the drug
- Total costs paid by any entity other than the manufacturer or predecessor for research and development, including any amount from federal, state, or other governmental programs, or any form of subsidies, grants, or other support.
- Any other costs to acquire the drug, including costs for the purchase of patents, licensing, or acquisition of any corporate entity owning any rights to the drug while in development.
- The total marketing and advertising costs for the promotion of the drug directly to consumers, including, but not limited to, costs associated with direct to consumer coupons and amount redeemed, total marketing and advertising costs for promotion of the drug directly or indirectly to prescribers, and any other advertising for the drug

I feel these measures would not detract from manufacturers receiving incentives for investing in new drug development. These measures would ensure manufacturers incentives are held accountable for revenue manufacturers receive from public programs such as Medicaid, Medicare, and the Veterans Administration.

Lastly, I would like to address the question of tools which exist, or should exist, to address the impact of high cost drugs. Given Oregon's high disproportionate HCV rate, I feel employing the carve out, (a tool currently used for HIV and mental health medications) is a viable option. An additional option could be Oregon creating a combination of carve outs and carve-ins joining 28 states which have adopted carve-in models. The carve out, as applied to HIV, has generated significant cost savings (not solely for our state's budgets) for the number of new HIV cases which have been averted as a result of minimizing barriers for HIV positive Oregonians to access treatment. The likelihood of secondary HIV transmission is reduced near zero when an HIV positive person has access and adheres to medications to suppress the virus. The same could be stated for cost savings which would likely result were the carve out applied to HCV medications. With Oregon's current approach of delaying treating people living with HCV, our state is passing costs on to Medicare as Oregon's HCV positive population ages. When a person living with HCV enters into Medicare, our federal government will absorb additional costs considering increased liver deterioration will likely results in significant, additional health complications. Our federal government and our state have the choice of investing in cost savings measures such as employing the carve out for HCV medications now, or waiting and incurring additional, unnecessary Medicare costs later.

I want to thank you again for your admirable advocacy on this issue in our nation's capitol. I deeply appreciate your staff for affording me, and the others who joined our meeting, the opportunity to share our thoughts about the urgency of HCV in Oregon.

I hope this input is useful for increasing access to HCV screening and treatment for the thousands of Oregonians who are currently waiting.

Best Always,

Benjamin Gerritz
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