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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

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January 21, 2016

To the Health Care and Patient Community:

On December 1, 2015, we released the results of an 18-month investigation examining how Gilead Sciences, Inc., developed, priced, marketed and sold the hepatitis C drug Sovaldi, and its follow-on drug, Harvoni.¹

Based on more than 20,000 pages of internal documents, the report provides a comprehensive window into how one major pharmaceutical company priced and sold two blockbuster drugs. Our investigation showed that in considering how to price its drugs, Gilead prioritized revenue and profit maximization over patient access.² Furthermore, the company was determined to keep the drugs' wholesale prices high and payer discounts low "whatever competitors do or whatever the headlines."³ Gilead's pricing and sales strategy led many insurers to strictly limit access for Sovaldi and Harvoni.⁴ As a result, "patients who could benefit from these drugs did not receive them due to the high cost."⁵

We launched this investigation largely out of concern about the challenges that Gilead's pricing decisions posed for public payers and the negative impact that restricted access had on patients within those systems. The price of Sovaldi and Harvoni remains a cause for concern for public payers.⁶ As the report states, "the public and private payer community continue to face a higher cost for the prevailing (new) standard of care, and higher overall costs because the new generation of HCV drugs is better tolerated and will most likely be far more widely prescribed."⁷

The report's conclusion identifies questions for further consideration. This open letter seeks to gather information from the public about how to address policy issues including the financial impact of high prices of breakthrough drugs, ensuring patient access, and improving marketplace transparency. To that end, we respectfully request thoughtful feedback that keeps in mind the balance of investing in innovative therapies of the future, with the broader concern of how the American people and health system will be able to afford them:

¹ Senate Print 114-20, "The Price of Sovaldi and its impact on the U.S. Health Care System.," December 1, 2015, <http://1.usa.gov/1QmTpel>

² *Id.*, at p. 43

³ *Id.*, at p. 58

⁴ For examples of payer rebate strategy, see *id.* at p. 66-67. For discussion of access restrictions put in place by payers, see *id.*, at p. 87 (Medicaid), 93 (Federal Bureau of Prisons), 96 (private payers), and Appendix B (a compilation of access restrictions supplied by the Oregon Health & Sciences University).

⁵ *Id.* at p. 120

⁶ *Id.* at p. 114-115

⁷ *Id.* at p. 120

- 1) What are the effects of a breakthrough, single source innovator drug on the marketplace?
- 2) Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?
- 3) What role does the concept of “value” play in this debate, and how should an innovative therapy’s value be represented in its price?
- 4) What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?
- 5) What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?

More information on these questions can be found in Section 7 of the report, on pages 117 through 123. Please send all responses in PDF format to Report_Feedback@finance.senate.gov by the close of business on March 4, 2016. All submissions will be considered part of the public record.

Thank you for your consideration and input.

Sincerely,



Ron Wyden
U.S. Senator



Charles Grassley
U.S. Senator