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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

JOSHUA SHEINKMAN, STAFF DIRECTOR
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July 11, 2014

Dr. John C. Martin,
Chairman and Chief Executive Officer
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

Dear Dr. Martin:

The Committee on Finance has jurisdiction of matters related to “health programs under the Social Security Act and health programs financed by a specific tax or trust fund,” as provided by Rule XXV of the Standing Rules of the Senate. These federal health care programs include Medicare and Medicaid, which together provide health care to over 100 million Americans and represent nearly \$900 billion in annual federal spending.

The Federal government is the health care industry’s largest customer, and Congress has a responsibility to conduct oversight and ensure that taxpayer dollars are used wisely in a transparent market. Gilead received federal regulatory approval last year for Sovaldi, a drug developed to treat and cure the Hepatitis C virus (HCV). The drug has been hailed as a breakthrough treatment, and its commercial release is a welcome advance in medical research for the 3.2 million Americans infected with HCV and their families.¹

Although Sovaldi has the potential to help people with HCV, at \$1,000 per pill, its pricing has raised serious questions about the extent to which the market for this drug is operating efficiently and rationally. While a standard course of treatment for Sovaldi has been widely reported to cost \$84,000 in the United States, Gilead will offer the drug in other countries for a fraction of the price. In Egypt, for example, Sovaldi could be offered for as low as \$900 per course of treatment – a 99 percent discount of the price in the U.S.²

The total cost of a course of this therapy also remains in question. The U.S. Food and Drug Administration dosage approval shows the price could be higher than the \$84,000 for a standard treatment. Some patients with HCV genotypes 1 and 3 will require 24 weeks of treatment.³ The longer treatment regimen roughly doubles the cost-per-patient-per-treatment to

¹ Centers for Disease Control and Prevention, *Hepatitis C FAQs for the Public*, <http://www.cdc.gov/Hepatitis/C/cFAQ.htm#statistics>, accessed July 10, 2014.

² Maggie Fick and Ben Hirschler, Gilead offers Egypt new hepatitis C drug at 99 percent discount, *Reuters*, March 21, 2014, <http://www.reuters.com/article/2014/03/21/us-hepatitis-egypt-gilead-sciences-idUSBREA2K1VF20140321>, accessed July 10, 2014.

³ U.S. Food & Drug Administration, *Label for Sovaldi (NDA no. 204671)*, December 6, 2013, http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204671s000lbl.pdf, accessed July 10, 2014.

\$168,000 for Sovaldi, not including the additional cost of peg-interferon alfa and ribavirin used in combination treatments.⁴ HCV patients with liver cancer could require 48 weeks of treatment.⁵

The large patient population combined with the high price of each individual treatment creates a question as to whether payors of health care, including Medicare and Medicaid, can carry such a load. Health care experts recently estimated that Sovaldi alone could increase Medicare's spending on prescription drugs by \$2 billion between 2014 and 2015 if just 25,000 patients enrolled in the program's prescription drug benefit, known as Part D, receive prescriptions.⁶ That represents "roughly 10 percent of Part D enrollees with the hepatitis C virus and about one-fourth of enrollees who have been diagnosed." If 75,000 Part D enrollees took the drug during the same period, program costs would increase by \$6.5 billion and premiums for all Part D enrollees could jump 8 percent, "a bigger increase than in any year since 2008."⁷

Sovaldi's cost also could dramatically increase the government's spending in other programs, including health care for prisoners with HCV. According to a recent survey, over 1.8 million people with hepatitis C are currently incarcerated.⁸ This represents up to 32.8 percent of the total cases of HCV in the U.S.⁹ The Federal Bureau of Prisons within the Department of Justice has already approved Sovaldi for use in treating prison populations, and it is reported that it receives a 44 percent discount.¹⁰ Even with this discount, American taxpayers could end up paying billions of dollars buying Sovaldi to treat inmates infected with HCV.

Given the impact Sovaldi's cost will have on Medicare, Medicaid and other federal spending, we need a better understanding of how your company arrived at the price for this drug. In order for a marketplace to function properly, it must be competitive, fair, and transparent. It is unclear how Gilead set the price for Sovaldi. That price appears to be higher than expected given the costs of development, and production and the steep discounts offered in other countries. An efficient market needs informed consumers to keep costs down. Consequently, we have directed our staff to investigate issues related to Sovaldi and Gilead's pricing of the drug. As part of this investigation, we are seeking information and documents related to the merger of Gilead Sciences, Inc. and Pharmasset, Inc., the original developer of Sovaldi, that was announced November 21, 2011, and the subsequent pricing of Sovaldi.

The following document requests, questions and statements use "Gilead" to refer to Gilead Sciences, Inc., its board of directors, any subsidiaries and contracted third parties; "Pharmasset" is used to refer to Pharmasset, Inc., its board of directors, any subsidiaries and contracted third parties; "Morgan Stanley" refers to Morgan Stanley & Co., LLC, and all its subsidiaries.

⁴ Leof, A., et al., (2014). *Sofosbuvir for the treatment of hepatitis C and evaluation of the 2014 American Association for the Study of Liver Diseases treatment guidelines*. Portland, OR: Center for Evidence-Based Policy, Oregon Health & Science University, p. 7-8, http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/upload/Sofosbuvir_for_HepatitisC_FINAL_5_19_2014.pdf, accessed July 10, 2014.

⁵ *Supra* at note 3.

⁶ Tricia Neuman, et al., The Cost Of A Cure: Medicare's Role In Treating Hepatitis C, *Health Affairs*, June 5, 2014, <http://healthaffairs.org/blog/2014/06/05/the-cost-of-a-cure-medicares-role-in-treating-hepatitis-c/>, accessed July 10, 2014.

⁷ *Ibid.*

⁸ Varan, A.K., et al. "Hepatitis C Seroprevalence among Prison Inmates Since 2001: Still High But Declining." *Public Health Reports*, 129, no. 2 (March/April, 2014): 187-195. (<http://www.ncbi.nlm.nih.gov/pubmed/24587554>), accessed July 10, 2014.

⁹ *Ibid.*

¹⁰ Peter Loftus, New Hepatitis Drugs Vex Prisons, *Wall Street Journal*, April 24, 2014, <http://online.wsj.com/news/articles/SB10001424052702304311204579510054146055222>, accessed July 10, 2014.

“Barclays” refers to Barclays Bank PLC, and all its subsidiaries, including but not limited to Barclays Capital. “Bank of America Merrill Lynch” refers to Bank of America Corporation, and all its subsidiaries, including, but not limited to Merrill Lynch. Any reference to “Sovaldi”, “PSI-7977” or “GS-7977” refers to sofosbuvir, a drug used in the treatment of hepatitis C virus, and any other names or codenames used to refer to said drug, its predecessor, and related formulas, compounds, research or development projects. “Supporting documents” refers to, but is not limited to, emails, faxes, notes, minutes, memoranda, reports, forecasts, transcripts, charts, spreadsheets and government forms.

Please answer the following questions and provide the following documents:

1. Please provide copies of all presentations, financial analyses, and supporting documents given to Pharmasset and/or to Gilead from 2010 to present from Morgan Stanley in its role as Pharmasset’s financial advisor.¹¹
2. Please provide a copy of the fairness opinion prepared by Morgan Stanley in conjunction with Gilead’s final offering price,¹² and all supporting documents related to or referencing the fairness opinion, including but not limited to assumptions about the pricing and market for PSI-7977.
3. Please provide copies of the three prospective commercialization forecasts prepared by Pharmasset’s management “in and prior to September 2011”¹³ and all supporting documents.
4. Please provide copies of Pharmasset’s revised forecasts (prepared before the American Association for the Study of Liver Diseases conference in November 2011)¹⁴ and all supporting documents, including but not limited to assumptions about the pricing and market for PSI-7977.
5. Please provide copies of all communications between Pharmasset’s board and its senior management regarding PSI-7977 and all supporting documents, including assumptions about the pricing and market for the drug.
6. In its final annual financial filing with the Securities and Exchange Commission (SEC), Pharmasset reported that its research and development costs totaled \$176.7 million for the fiscal years ending 2009, 2010 and 2011, the period during which PSI-7977 was being developed.¹⁵ Of that total, Pharmasset attributed \$62.4 million directly to the development of PSI-7977.

¹¹ Pharmasset Schedule 14D-9, December 6, 2011, p. 8.

¹² Ibid., p. 12-13.

¹³ Ibid., p. 29-30.

¹⁴ Ibid., p.31-32. Referred to as the “Updated Forecast”, management assumed PSI-7977 would be launched in the United States no earlier than the third quarter of 2014; that a course of treatment using PSI-7977 would be priced at \$36,000 in the United States, and that European Union pricing would be 60% to 70% of the U.S. price.

¹⁵ Pharmasset, Inc., 10-K for the fiscal year ended September 30, 2011, November, 14, 2011, p. 60.

- a. Please provide an itemized accounting of Pharmasset's total research and development costs prior to the completion of the merger with Gilead on January 17, 2012.
 - b. Please provide an itemized accounting of Pharmasset's research and development costs directly attributable to the development of PSI-7977 prior to the completion of the merger with Gilead on January 17, 2012.
7. Gilead retained Barclays and Bank of America Merrill Lynch as its financial advisors for the acquisition of Pharmasset.¹⁶
 - a. Please provide copies of all communication between Barclays and Gilead relating to the valuation and acquisition of Pharmasset, including assumptions, projections, analyses, recommendations, and any related supporting documents about the pricing and market for PSI-7977.
 - b. Please provide copies of all communication between Bank of America Merrill Lynch and Gilead, relating to the valuation and acquisition of Pharmasset, including assumptions, projections, analyses, recommendations, and any related supporting documents about the pricing and market for PSI-7977.
8. Please provide all analyses, recommendations, and supporting documents related to the proposed valuation and acquisition of Pharmasset, including assumptions and projections about the price and market for PSI-7977. Please include all documents related to the following:
 - a. The September 2, 2011 meeting between Pharmasset and Gilead to discuss acquisition;
 - b. The October 7, 2011 proposal from Gilead to purchase Pharmasset for \$125 per share;
 - c. The November 17, 2011 proposal from Gilead to purchase Pharmasset for \$135 per share;
 - d. The November 20, 2011 proposal from Gilead to purchase Pharmasset for \$137 per share.
9. Please provide copies of all communications between Gilead and Pharmasset concerning the proposed valuation and acquisition of Pharmasset, including assumptions and projections about the price and market for PSI-7977. Please include all supporting documents related to the following:
 - a. The September 2, 2011 meeting between Pharmasset and Gilead to discuss acquisition;
 - b. The October 7, 2011 proposal from Gilead to purchase Pharmasset for \$125 per share;
 - c. The November 17, 2011 proposal from Gilead to purchase Pharmasset for \$135 per share;
 - d. The November 20, 2011 proposal from Gilead to purchase Pharmasset for \$137 per share.

¹⁶ Gilead Sciences, Inc., and Pharmasset, Inc., *Gilead Sciences to Acquire Pharmasset, Inc., for \$11 Billion*, November 21, 2011, <http://gilead.com/news/press-releases/2011/11/gilead-sciences-to-acquire-pharmasset-inc-for-11-billion>, accessed July 10, 2014.

10. Please provide copies of the analysis of the fair value of the In-Process Research and Development (IPR&D) related to GS-7977 cited in Gilead's 10-Q filed with the U.S. Securities and Exchange Commission (SEC) for the quarter ending March 31, 2012,¹⁷ and all supporting documents related to the preparation of this valuation. Identify and describe the key assumptions in the IPR&D valuation.
11. Please provide copies of the analysis of the fair value of IPR&D related to sofosbuvir cited in Gilead's 10-K filed with the SEC for the fiscal year ending December 31, 2012,¹⁸ and all supporting documents related to the preparation of this valuation. Identify and describe the key assumptions in the IPR&D valuation.
12. Please provide an itemized accounting of research and development costs¹⁹ related directly to the development of sofosbuvir that was incurred by Gilead after the completion of the Pharmasset merger on January 17, 2012. This accounting should include separate line items for personnel costs, clinical studies, materials and supplies, licenses and fees, milestone payments under collaboration arrangements, overhead allocations, facilities costs and the value contracts with contract research organizations (CROs) related directly to the development of sofosbuvir.
13. Before Gilead could complete its acquisition of Pharmasset, both companies were required to file pre-merger notifications with the U.S. Federal Trade Commission (FTC).
 - a. Please provide copies of Gilead's filing with the FTC, all documents provided to the FTC pursuant to 16 C.F.R. §803.1 and 16 C.F.R. §803.2, all communications with the FTC related to the filing, and all supporting documents related to the filing.
 - b. Please provide copies of Pharmasset's filing with the FTC, all documents provided to the FTC pursuant to 16 C.F.R. §803.1 and 16 C.F.R. §803.2, all communications with the FTC related to the filing, and all supporting documents related to the filing.
14. Please provide copies of the marketing and pricing plans prepared for, and being used in, the launch of Sovaldi in the U.S. and internationally,²⁰ including all communications and supporting documents related to the preparation of these plans, materials, and prices.
 - a. Looking forward, please describe how the commercial success of Sovaldi, as evidenced by first quarter sales, will affect marketing and pricing plans, including the cost of production, and future prices in the U.S. and internationally. If there will not be any effect, explain why.

¹⁷ Gilead Sciences, Inc. Form 10-Q for the quarterly period ended March 31, 2012, May 4, 2012, p. 16.

¹⁸ Gilead Sciences, Inc., Form 10-K for the fiscal year ended December 31, 2012, February, 27, 2013, p. 105.

¹⁹ Gilead Sciences, Inc., Form 10-K for the fiscal year ended December 31, 2013, February 25, 2014, p. 60.

²⁰ Gilead Sciences, Inc., Form 10-Q for the quarterly period ended March 31, 2014, May 5, 2014, p. 29. Gilead's Selling, General, and Administrative expenses (SG&A) for the quarter ending March 31, 2014, "increased by \$173.8 million or 46%, compared to the same period in 2013, due primarily to a \$113.6 million increase in headcount and other expenses to support the ongoing growth and expansion of our business, which includes ongoing launches of Sovaldi in the United States and internationally as well as the anticipated launch of idelalisib."

15. Sovaldi is currently prescribed in combination with other medications, which increases the total cost per patient per course of treatment.²¹ Gilead has applied for approval to sell single-dose combinations of Sovaldi with other drugs.
 - a. If approval is granted for a single-dose combination drug, how will it affect the future price of Sovaldi?
 - b. Please provide copies of any pricing plans, marketing plans, or price estimates related to these pending combination drugs, and all supporting documents related to the plans and related forecasts.
16. Please provide copies of Gilead's estimates of the U.S. treatment cost-per-patient and U.S. cost-per-cure for each of the FDA's approved genotype-based treatment regimens for Sovaldi, including itemization of the cost of Sovaldi, the cost of combination drugs, and all supporting documents used in developing such estimates.
17. Looking forward, what are Gilead's expected changes in the treatment cost-per-patient and the cost-per-cure of Sovaldi-based treatment over the next five years for each of the FDA approval regimens for the U.S. HCV populations?
18. Oregon Health & Science University researchers reviewed treatment guidelines for Sovaldi jointly issued by several professional societies, concluding there is a "substantial risk of conflict of interest influencing the recommendations from both individual panel members and funding sources."²² The organizations' website shows 18 of the 27 panel members involved in developing the guidance for the American Association for the Study of Liver Disease (AASLD) and the Infectious Diseases Society of America (IDSA) disclosed either a direct financial relationship with Gilead or received institutional funding from the company.²³ Both groups, and a third collaborating partner, the International Antiviral Society-USA (IAS-USA), have all received funding from Gilead.²⁴
 - a. Please provide an itemized accounting of all payments from 2009 to present between Gilead and/or Pharmasset and the following organizations:
 - i. AASLD
 - ii. IDSA
 - iii. IAS-USA
 - b. Please provide an itemized accounting of all payments from 2009 to present between Gilead and/or Pharmasset and the expert panel members that developed the AASLD/IDSA treatment guidelines for HCV.²⁵
 - c. For each organization or individual identified in (a) or (b), provide:
 - i. Date of payment
 - ii. Payment description

²¹ *Supra* at note 3.

²² *Supra* at note 4, p. 21

²³ AASLD/IDSA, Recommendations for Testing, Managing, and Treating Hepatitis C, Disclosure Information, http://hevguidelines.org/disclosure_information, accessed July 10, 2014.

²⁴ See AASLD 2012 Annual Report p. 29, <http://www.aasld.org/aboutus/Documents/2012AnnualReport.pdf>, accessed July 10, 2014; IDSA Industry relations, Grants and Contributions 2010 – 2014, http://www.idsociety.org/IDSA_Industry_Relations, accessed on July 10, 2014; IAS-USA Cases on the Web Grant Support, <https://www.iasusa.org/cow-grant-support>, accessed on July 10, 2014.

²⁵ AASLD/IDSA, Recommendations for Testing, Managing, and Treating Hepatitis C, Disclosure Information, http://hevguidelines.org/disclosure_information, accessed on July 10, 2014.

- iii. Amount of payment
 - iv. Year-end or year-to-date payment total and cumulative total payments for each organization or individual
 - d. Describe any communications between employees of Gilead and the organizations and individuals identified in (a) and (b) regarding the AASLD/IDSA treatment guidelines for HCV. Please provide all supporting documents related to those communications.
19. Gilead's advertising and promotional expenses have increased from \$116.6 million in 2011 to \$216.2 million in 2013.²⁶
- a. How much money does Gilead plan to spend on advertising and promotional expenses in 2014?
 - b. How much money does the company plan to spend on advertising and promotion of Sovaldi in 2014?
 - c. How much money did the company spend on advertising and promotion of Sovaldi prior to January 1, 2014?
20. Gilead has included Sovaldi in its patient assistance program, which includes coupons for reducing the cost of patient co-pays.²⁷ Gilead estimated that 30,000 patients were treated with Sovaldi during the first quarter of 2014.²⁸
- a. How many patients have been treated in the United States with Sovaldi to date?
 - b. How many patients in the United States have been assisted by Gilead's patient assistance program to date?
 - c. What percentage of patients does Gilead expect to be covered under this program?
 - d. What is the average outlay-per-patient in the patient assistance program?
 - e. What percentage of the patient's cost for Sovaldi will the payment assistance program cover for each of the FDA-approved treatment regimens?
 - f. What patients are eligible for this assistance? What patients are ineligible for this assistance?
 - g. There are a number of HCV-infected populations, such as those exposed through intravenous drug use, contaminated blood and those born to someone infected with the virus. Describe the patient populations expected to be covered by the Sovaldi patient assistance program.
 - h. How are the costs of this assistance accounted for within Gilead's financials, e.g. are they deducted as part of the company's Selling, General, and Administrative (SG&A) expenses?
21. Sovaldi is and will be sold in multiple countries, many of which are expected to receive significant discounts compared to the price in the U.S.

²⁶ *Supra* at note 19, p. 96.

²⁷ Gilead, *Support Path for Sovaldi*, <http://www.gilead.com/responsibility/us-patient-access/support%20path%20for%20sovaldi>, accessed on July 10, 2014.

²⁸ *Supra* note at note 20, p. 27.

- a. Please provide a list of all countries where Sovaldi is or will be sold, and the corresponding price or planned price for each country. Describe how the company reached the price for each country.
- b. How are the revenue, costs and any discounts associated with international sales, such as Egypt, accounted for within Gilead's financials, e.g. are they deducted as part of the company's Selling, General, and Administrative (SG&A) expenses?

Thank you in advance for your assistance in this matter. Please begin producing documents and information on a rolling basis no later than 14 days—and complete production no later than 60 days— after the receipt of this letter. Please contact our staff as soon as possible to discuss prioritizing the order in which responsive documents and information should be produced.

Please direct any questions about this letter to David Berick, Chief Investigator, or Elizabeth Jurinka, Chief Health Policy Advisor for Chairman Wyden, and to Jason Foster, Chief Investigative Counsel, or Rodney Whitlock, Health Policy Director for Senator Grassley.

Sincerely,



Ron Wyden
Chairman



Charles E. Grassley
Member