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# United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

A. JAY KHOSLA, STAFF DIRECTOR

JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

May 11, 2018

Mr. Vasant Narasimhan  
Chief Executive Officer  
Novartis AG  
Lichtstrasse 35  
4002 Basel  
Switzerland

Dear Mr. Narasimhan:

I write with deep concern regarding recent news reports that Novartis paid more than \$1 million to a shell company controlled by the President's personal attorney, Michael Cohen. Federal health programs are a major market for Novartis, and the payments were made while the company was negotiating novel payment arrangements with the Centers for Medicare & Medicaid Services ("CMS") for a cancer therapy priced at nearly half-a-million dollars. At the same time, Novartis was seeking approval from the Food and Drug Administration ("FDA") for this new cancer therapy, Kymriah, which has been a key source of revenue for the company's line of oncology drugs, its largest business unit.<sup>1</sup>

The U.S. Senate Committee on Finance has jurisdiction over federal health programs under the Social Security Act, including Medicare and Medicaid. Participation in these programs accounts for a substantial portion of Novartis' U.S. sales, which totaled \$16.9 billion in 2017.<sup>2</sup> For example, in 2015, the most recent year for which data were available, Medicare spent \$2 billion on three Novartis cancer drugs – Gleevec, Sandostatin and Afinitor.<sup>3</sup> In the same year, Medicaid programs spent more than \$320 million (prior to any rebates) on Gleevac and the respiratory drug Xolair.<sup>4</sup>

Novartis has publicly acknowledged that it made monthly payments totaling \$1.2 million to Cohen's firm over the course of a 12-month period ending in February 2018.<sup>5</sup> In a public statement, Novartis said these payments were related to its belief that Mr. Cohen "could advise

<sup>1</sup> Novartis AG, *Form 20-F for the fiscal year ending December 31, 2017*, January 24, 2018, <https://www.sec.gov/Archives/edgar/data/1114448/000104746918000380/a2234185z20-f.htm>, page 111.

<sup>2</sup> Novartis AG, 2017 Annual Report, p. 205, <https://www.novartis.com/sites/www.novartis.com/files/novartis-annual-report-2017-en.pdf>.

<sup>3</sup> Centers for Medicare & Medicaid Services, *Medicare Spending Dashboard 2015*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/2015-Medicare-Drug-Spending/medicare-drug-spending-dashboard-2015-data.html>

<sup>4</sup> Centers for Medicare & Medicaid Services, *Medicare Spending Dashboard 2015*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/2015-Medicaid-Drug-Spending/2015-Medicaid-Drug-Spending.html>

<sup>5</sup> Novartis, "Essential Consultants – Novartis Statement," May 9, 2018, <https://www.novartis.com/essential-consultants>.

the company as to how the Trump administration might approach certain US healthcare policy matters, including the Affordable Care Act.”<sup>6</sup> In a publicly reported comment attributed to an unnamed Novartis employee, “it was almost as if we were hiring [Mr. Cohen] as a lobbyist”<sup>7</sup> despite his lack of health-related policy expertise and your company’s admission that Cohen did not perform any work for Novartis.<sup>8</sup>

Mr. Cohen’s firm is not a health care policy consultancy, nor is Mr. Cohen a registered lobbyist. He is the President’s personal attorney, and Essential Consultants reportedly claimed to be a real estate consulting company.<sup>9</sup> Moreover, the amount of money that Novartis paid Mr. Cohen’s firm far exceeded what it paid any of the registered lobbying firms it engaged during the first 15 months of the Trump Administration. Lobbying records maintained by the Secretary of the Senate show that Novartis paid 15 lobbying firms a total of \$2.5 million during that period, and that no firm received more than \$300,000. By comparison, Novartis rate of payment to Mr. Cohen’s firm was equal to \$300,000 every quarter for an entire year.<sup>10</sup>

At the same time as the payments to Mr. Cohen’s firm were being made, the company’s in-house lobbyists were meeting with the White House, FDA, CMS and other Trump Administration agencies regarding a range of issues that could dramatically affect its business.<sup>11</sup> I also note that during this time, the company was seeking, and ultimately received, FDA approval for Kymriah, a breakthrough leukemia treatment with a \$475,000 list price.<sup>12</sup> Novartis also was negotiating with CMS regarding how federal health programs would pay for the drug.<sup>13</sup> In the company’s words, in its negotiations with CMS it was seeking to “[improve] efficiencies in current regulatory requirements in order to deliver value-based care and ensure access.”<sup>14</sup> CMS, for its part, stated that it was seeking to “identify and alleviate regulatory barriers in Medicare and Medicaid as may be necessary to test payment and service delivery models.”<sup>15</sup>

The Senate Finance Committee has a duty to ensure that pharmaceutical companies providing services to federal health programs are conducting business in a legal and transparent manner.

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<sup>6</sup> *Id.*

<sup>7</sup> Ed Silverman, “Trump’s lawyer pitched himself as a fixer to Novartis and got paid \$1.2 million,” *STAT News*, May 9, 2018, <https://www.statnews.com/pharmalot/2018/05/09/trumps-lawyer-cohen-fixer-novartis/>.

<sup>8</sup> Dan Mangan, “Novartis paid Trump lawyer Michael Cohen \$1.2 million for advice on Obamacare – work he was unable to do,” *CNBC*, May 9, 2018; <https://www.cnbc.com/2018/05/09/novartis-paid-trumps-lawyer-michael-cohen-more-than-1-million-for-work-he-was-unable-to-do-company-says.html>.

<sup>9</sup> Sarah Fitzpatrick, et al., “Daniels’ lawyer: Cohen got \$500K from Russian oligarch Viktor Vekselberg,” *NBC News*, May 9, 2018, <https://www.nbcnews.com/news/us-news/daniels-lawyer-cohen-got-500k-russian-oligarch-viktor-vekselberg-n872481>.

<sup>10</sup> *Supra* at note 5.

<sup>11</sup> Novartis, Lobbying Report for the fourth quarter of 2017, January 18, 2018, <https://soprweb.senate.gov/index.cfm?event=getFilingDetails&filingID=FD6D844A-8A09-4715-BA8A-99FA537B4E81&filingTypeID=78>.

<sup>12</sup> Max Nisen, “Read the Fine Print on the \$475,000 Price of a Cancer Breakthrough,” *Bloomberg*, Aug. 31, 2017, <https://www.bloomberg.com/news/articles/2017-08-31/novartis-kymriah-cancer-drug-475-000-but-read-the-fine-print>.

<sup>13</sup> John Wilkerson, “CMS May Test Drug-Pay Schemes Similar To Kymriah’s Outcomes-Based Arrangement,” *Inside Health Policy*, August 30, 2017, <https://insidehealthpolicy.com/inside-cms/cms-may-test-drug-pay-schemes-similar-kymriahs-outcomes-based-arrangement>.

<sup>14</sup> Novartis, Press Release, “Novartis receives first ever FDA approval for a CAR-T cell therapy, Kymriah(TM) (CTL019), for children and young adults with B-cell ALL that is refractory or has relapsed at least twice,” Aug. 30, 2017, <https://www.novartis.com/news/media-releases/novartis-receives-first-ever-fda-approval-car-t-cell-therapy-kymriah-tm-ctl019>.

<sup>15</sup> CMS, Press Release, “CMS: Innovative treatments call for innovative payment models and arrangements,” Aug. 30, 2017, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-08-30-2.html>

Given the Committee's interests in these matters, I request that you provide the following documents and answer the following questions no later than June 5, 2018:

1. Please provide any contract and any statement of work between Novartis<sup>16</sup> and Mr. Cohen, Essential Consultants, LLC, and/or any other entities owned, managed, or controlled by Mr. Cohen or through which Mr. Cohen provided services.
2. For every payment made between Novartis and Mr. Cohen, Essential Consultants LLC, or any other entity Mr. Cohen provided services through or owned, controlled or was otherwise the beneficial owner of, please provide the following information in table form:
  - the date of the payment;
  - the amount;
  - the name and location of the originator and the account through which the payment originated;
  - the name and location of the financial institution (or other entity) from which the payment transaction originated;
  - the name and location of any beneficiary of the payment and the account to which the payment was made; the name and location of the financial institution (or other entity) to which the payment was made; and
  - the names and locations of any other financial institutions, individuals, or entities that were involved in any transactions related to the payment.
3. Please provide copies of any other lobbying contracts between Novartis and any U.S.-based lobbyists, as well as any other agreements entered into by Novartis seeking advice or consultation as to how the Trump administration might approach certain U.S. health care policy matters.
4. Please explain the internal approval process for the contract with Mr. Cohen, Essential Consultants, LLC, and/or related entities. In so doing, please provide a list of all Novartis personnel who approved the business relationship between Novartis and Mr. Cohen's firm(s). Please also provide a copy of any Novartis guidance document outlining the approval process for lobbying, consulting, or any similar contract, including but not limited to any document that describes different approval thresholds based on the size of the contract, and any documents memorializing the completion of this approval process.
5. Why did Novartis decide to engage Mr. Cohen and/or his firm(s)? What deliverables was the company seeking to gain?
6. Please provide all communications between Novartis and Mr. Cohen, Essential Consultants, LLC, and/or any other entities owned, managed, or controlled by Mr. Cohen or through which Mr. Cohen provided services. These communications should include but not be limited to emails; letters; text messages, instant message or internet transcripts; memos; documents; spreadsheets; data; recordings of video conference or in-person conversations; notes related to any phone, video conference or in-person conversations.

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<sup>16</sup> References to "Novartis" should be understood to include Novartis International AG, Novartis Corporation, or any other entities owned, managed, or controlled by Novartis AG or its agents.

7. Please provide all internal communications regarding, making reference to, or including information received from, Mr. Cohen, Essential Consultants, LLC, and/or any other entities owned, managed, or controlled by Mr. Cohen or through which Mr. Cohen provided services. These communications should include but not be limited to emails; letters; text messages, instant message or internet transcripts; memos; documents; spreadsheets; data; recordings of video conference or in-person conversations; notes related to any phone, video conference or in-person conversations.
8. Please provide all external communications between Novartis and any lobbyists, contractors, consultants, trade groups or other entities regarding making reference to, or including information received from, Mr. Cohen, Essential Consultants, LLC, and/or any other entities owned, managed, or controlled by Mr. Cohen or through which Mr. Cohen provided services. These communications should include but not be limited to emails; letters; text messages, instant message or internet transcripts; memos; documents; spreadsheets; data; recordings of video conference or in-person conversations; notes related to any phone, video conference or in-person conversations.
9. Please provide all external communications between Novartis and the White House, Office of Management and Budget, Department of Health and Human Services, CMS or other federal department, agencies or offices regarding, making reference to, or including information received from, Mr. Cohen, Essential Consultants, LLC, and/or any other entities owned, managed, or controlled by Mr. Cohen or through which Mr. Cohen provided services. These communications should include but not be limited to emails; letters; text messages, instant message or internet transcripts; memos; documents; spreadsheets; data; recordings of video conference or in-person conversations; notes related to any phone, video conference or in-person conversations.
10. Please provide copies of any documents supplied by Novartis to the Department of Justice or any law enforcement agency related to this matter.

If you have any questions or concerns in meeting this request, you may contact my investigative staff on the Senate Finance Committee at 202-224-4515. Thank you for your prompt attention to this important matter.

Sincerely,



Ron Wyden  
Ranking Member

cc: Mr. Thomas Kendris, President, Novartis Corporation