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July 11, 2018

The Honorable Mick Mulvaney
Director
Office of Management and Budget
725 17th Street NW
Washington, D.C. 20503

Dear Director Mulvaney:

I am writing to request documents regarding the role of Joseph Grogan, a former drug company lobbyist and your Associate Director of Health Programs at the Office of Management and Budget (OMB), in developing an outcomes-based payment model for the drug company Novartis and its chimeric antigen receptor T-cell (CAR-T) cancer treatment, Kymriah.

Documents obtained through a Freedom of Information Act request filed by the non-profit organization Democracy Forward indicate that Mr. Grogan was working on a demonstration project to develop a payment model for Novartis's CAR-T therapy while his former employer, Gilead Sciences, Inc., was seeking to acquire its own CAR-T therapy. Gilead now has a CAR-T therapy approved by the Food and Drug Administration (FDA) and plans to "engage actively with Medicare to ensure we are doing all we can to support access" to the drug.[1]

Mr. Grogan's actions appear to run afoul of the Trump Administration's own ethics rules, and they raise serious concerns about whether President Trump's drug pricing policies are intended to benefit drug companies rather than American consumers.

Mr. Grogan's Background as a Drug Company Lobbyist

Prior to joining your staff, Mr. Grogan led the Federal Affairs Division of Gilead. According to Gilead's lobbying disclosures, Mr. Grogan's work included lobbying OMB, the Department of Health and Human Services (HHS), and other federal agencies on matters such as "coverage and reimbursement of pharmaceuticals," "oncology products," and "access issues."[2]

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[1] *Months After Approval, Breakthrough Cancer Drug Given to Just Five Patients*, Bloomberg (Dec. 14, 2017) (online at www.bloomberg.com/news/articles/2017-12-14/cancer-patients-with-little-time-left-wait-for-gilead-s-new-drug).

[2] Joseph Grogan, Gilead Sciences, Inc., *Quarter Four Lobbying Report* (2016) (online at https://soprweb.senate.gov/index.cfm?event=getFilingDetails&filingID=07B9E04E-73A1-4C30-BEB8-

During the time Mr. Grogan led Gilead's lobbying efforts, the company was taking steps to expand its oncology business, including through the acquisition of its own CAR-T therapy. According to Securities and Exchange Commission (SEC) filings, Gilead began engaging in acquisition discussions as early as 2015 with Kite Pharmaceuticals, a company that was working to develop its own CAR-T therapy, now known as Yescarta.[3] News outlets began reporting on a potential deal in 2016.[4]

Gilead began accelerating its efforts in early 2017, just before Mr. Grogan left the company to join the Trump Administration. In January, Gilead hired Novartis' former Head of Global Oncology Development to lead its oncology division.[5] Shortly thereafter, Gilead CEO John Milligan announced that acquisition was "top of mind" for the company in 2017.[6] According to SEC filings, Gilead and Kite entered into a "mutual confidentiality agreement" in February 2017 concerning a "potential transaction between the companies."[7] Mr. Grogan left Gilead to join the Trump Administration the next month, on March 6, 2017.[8]

Mr. Grogan's Role in the Novartis Demonstration Project

Mr. Grogan's role as your Associate Director of Health Programs at OMB grants him "sweeping authority over drug pricing, entitlement programs and other aspects of federal health policy."[9]

Documents obtained through a Freedom of Information Act request suggest that Mr. Grogan used this authority to collaborate with Novartis on a demonstration project involving a

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[3] *Offer to Purchase Kite Pharma, Inc. by Gilead Sciences, Inc.* (Sept. 5, 2017) (online at www.sec.gov/Archives/edgar/data/882095/000104746917005534/a2233171zex-99_1a1a.htm).

[4] *See After Losing Medivation, Who Is Gilead Going After Next?*, Forbes (Sept. 19, 2016) (online at www.forbes.com/sites/kenkam/2016/09/19/who-is-gilead-about-to-buy/#5767570213f8); *3 Potential Acquisition Targets for Gilead Sciences, Inc.*, Motley Fool (Nov. 16, 2016) (online at www.fool.com/investing/2016/11/16/3-potential-acquisition-targets-for-gilead-science.aspx).

[5] *The Inside Story of How a $12 Billion Deal for a Revolutionary Cancer Treatment Came Together*, Business Insider (Sept. 6, 2017) (online at www.businessinsider.com/how-the-kite-pharma-gilead-sciences-12-billion-came-together-2017-9); *With Kite in the Bag, Gilead Boosts Oncology Chief Riva to the Head Table*, FiercePharma (Oct. 17, 2017) (online at www.fiercepharma.com/pharma/kite-bag-gilead-boosts-oncology-chief-riva-to-head-table).

[6] *Gilead CEO: M&A is Top of Mind for Us This Year*, CNBC (Jan. 10, 2017) (online at www.cnbc.com/video/2017/01/10/gilead-ceo-ma-is-top-of-mind-for-us-this-year.html).

[7] Kite Pharmaceuticals Securities and Exchange Commission Filing, Schedule 14D-9 (online at www.sec.gov/Archives/edgar/data/1510580/000119312517276737/d450961dsc14d9.htm).

[8] Email from Joseph Grogan to Yasaman Sutton, Assistant General Counsel and Alternate Designated Agency Ethics Official, Office of Management and Budget (Mar. 5, 2017) (online at https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/OMB-Democracy%20Forward-000006-11_Redacted.pdf).

[9] *Former Drug Industry Lobbyist Helps Steer Trump Drug Plan*, Politico (May 27, 2018) (online at www.politico.com/story/2018/05/27/trump-drug-plan-lobbyist-joe-grogan-609170).

payment model for Kymriah—at the same time that Gilead was working to acquire its own competing CAR-T therapy—without disclosing his apparent conflict of interest.

On August 28, 2017, Gilead announced that it had agreed to purchase Kite Pharmaceuticals, which included the acquisition of "an emerging class of cancer immunotherapies that are expected to generate billions." A press report at the time noted that "Wall Street and Gilead shareholders have long been expecting Gilead to use its cash pile for a big-ticket acquisition."[10]

The same day that Gilead announced the Kite acquisition, Mr. Grogan sent an email to an ethics official at OMB, writing:

> I'd like to touch base with you at some point today about the article above. I have been working on a project in this therapeutic area which is almost near completion and I want to make sure I don't wade into something here.[11]

The following day, the OMB official responded that Mr. Grogan would be recused from future work on the demonstration project because of his potential conflict of interest. Summarizing their discussion, the ethics official wrote:

> You explained that you have been in discussions with Novartis regarding a possible demonstration project that will most likely also now involve Gilead following its acquisition of Kite, an entity which also works in the very specialized arena that the demo will involve. As of Gilead's announcement yesterday of its plans to buy Kite, you are recused from the demo because it involves your former employer, Gilead.[12]

Later that day, Mr. Grogan sent an email to his supervisors to inform them of his recusal. In that email, he acknowledged that he had had "several discussions with Novartis about the possibility of a demonstration project for this novel therapy and had also spoken to HHS."[13] Yet,

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[10] *Gilead to Buy Kite Pharma in $11.9 Billion Deal*, CNBC (Aug. 28, 2017) (online at www.cnbc.com/2017/08/28/gilead-to-buy-kite-pharma-for-about-11-billion-in-cash-dow-jones.html).

[11] Email from Joseph Grogan, Associate Director of Health Programs, Office of Management and Budget, to Yasaman Sutton, Assistant General Counsel and Alternate Designated Agency Ethics Official, Office of Management and Budget (Aug. 28, 2017) (online at https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/OMB-Democracy%20Forward-000017-19%20redacted_Redacted.pdf).

[12] Email from Yasaman Sutton, Assistant General Counsel and Alternate Designated Agency Ethics Official, Office of Management and Budget, to Joseph Grogan, Associate Director of Health Programs, Office of Management and Budget (Aug. 29, 2017) (online at https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/OMB-Democracy%20Forward-000017-19%20redacted_Redacted.pdf).

[13] Email from Joseph Grogan, Associate Director of Health Programs, Office of Management and Budget, to Russell Vought, Deputy Director, Office of Management and Budget, and Emma Doyle, Chief of Staff, Office of Management and Budget (Aug. 29, 2017) (online at https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/OMB-Democracy%20Forward-000017-19%20redacted_Redacted.pdf).

Mr. Grogan never previously disclosed his potential conflict of interest to ethics officials. Mr. Grogan claimed that he had "no knowledge that such a purchase was a possibility," even though Gilead was actively pursuing the acquisition while Mr. Grogan was still at the company, and the possibility of a deal had been publicly reported as early as 2016.

The next day, on August 30, 2017, Novartis announced FDA approval for the use of Kymriah in children and young adults. The announcement included a statement by the Novartis CEO praising the demonstration project that Mr. Grogan had been working on:

> Novartis has been at the forefront of outcomes-based pricing and is very pleased to work with CMS on this first-of-its-kind collaboration with a technology that has the potential to transform cancer care.[14]

Questions About Mr. Grogan's Disclosures

The timing of Mr. Grogan's disclosures raises serious questions about his actions. Mr. Grogan waited to disclose his potential conflict of interest until Gilead publicly announced the Kite purchase, even though Gilead had been actively pursuing the acquisition while Mr. Grogan was still at the company.

In addition, Mr. Grogan's disclosure came one day before Novartis announced its new FDA approval and publicly praised the demonstration project. Mr. Grogan acknowledged in internal communications that the project was "near completion" by the time he alerted ethics officials to his potential conflict.[15] The Centers for Medicare and Medicaid Services (CMS) reportedly decided to cancel the demonstration project earlier this year after lawyers at HHS "expressed discomfort over how much Novartis itself was influencing the arrangement." According to internal emails, HHS lawyers were "'surprised and concerned' with Novartis' interactions with the agency" and cautioned that agency officials had been "'unusually deferential' to the company's recommendations for evaluating the drug."[16]

Mr. Grogan's work on the demonstration project for Kymriah appears to have violated the Trump Administration's ethics pledge. The pledge requires that Trump Administration officials refrain from participating in: "any particular matter involving specific parties that is directly and substantially related to my former employer" or "any particular matter on which I

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[14] *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*, Novartis (Aug. 30, 2017) (online at www.novartis.com/news/media-releases/novartis-receives-first-ever-fda-approval-car-t-cell-therapy-kymriahtm-ctl019).

[15] Email from Joseph Grogan, Associate Director of Health Programs, Office of Management and Budget, to Yasaman Sutton, Assistant General Counsel and Alternate Designated Agency Ethics Official, Office of Management and Budget (Aug. 28, 2017) (at https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/OMB-Democracy%20Forward-000017-19%20redacted_Redacted.pdf).

[16] *CMS Quit Test of Pricey Cancer Treatment Amid Concerns Over Industry Role*, Politico (July 9, 2018) (online at www.politico.com/story/2018/07/09/cms-quit-test-of-pricey-cancer-treatment-amid-concerns-over-industry-role-674086).

lobbied within the 2 years before the date of my appointment" or "the specific issue area in which that particular matter falls."[17] An OMB ethics official informed Mr. Grogan in February 2017—before he joined the Administration—that he would receive a "limited recusal" for his prior lobbying work and that OMB "may or may not seek a waiver" from the Administration's ethics rules. [18] However, it does not appear that Mr. Grogan ever obtained a waiver to work on the Novartis demonstration project.

At the same time Mr. Grogan was working with Novartis on the demonstration project, the company was seeking other avenues to gain access to the Trump Administration. Former Novartis CEO Joe Jiminez was one of several pharmaceutical executives who met with President Trump in January 2017. Shortly before that meeting, Mr. Jiminez expressed an interest in working on "outcomes-based pricing" and "being a leader in that space."[19]

Mr. Jiminez has acknowledged that his company entered into a "consulting" contract with President Trump's former personal lawyer, Michael Cohen, one month later, in February 2017, paying him monthly installments of $100,000 for a total of $1.2 million.[20] The company reported that after meeting with Mr. Cohen in March 2017—the same month that Mr. Grogan joined the Trump Administration—it determined that Mr. Cohen was unqualified to perform any work, yet it paid him the full contract amount.[21]

Request for Documents

For the reasons set forth above, I request that you produce the following documents by July 23, 2018:

(1) all documents and communications relating to the development of an outcomes-based payment model or demonstration project for Kymriah or any other CAR-T therapy, including documents or communications between Mr. Grogan and officials at HHS, including officials at the Center for Medicare and Medicaid Innovation, about its initiation, design, or timeline;

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[17] Exec. Order No. 13770, 82 Fed. Reg. 9333 (Jan. 28, 2017).

[18] *Former Drug Industry Lobbyist Helps Steer Trump Drug Plan*, Politico (May 27, 2018) (online at www.politico.com/story/2018/05/27/trump-drug-plan-lobbyist-joe-grogan-609170); Email from Yasaman Sutton, Assistant General Counsel and Alternate Designated Agency Ethics Official, Office of Management and Budget, to Joseph Grogan (Feb. 24, 2017) (online at https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/OMB-Democracy%20Forward-000006-11_Redacted.pdf).

[19] *Trump to Meet Novartis CEO, Other Pharma Bosses on Tuesday*, Reuters (Jan. 31, 2017) (online at https://uk.reuters.com/article/usa-trump-pharmaceuticals/trump-to-meet-novartis-ceo-other-pharma-bosses-on-tuesday-idINKBN15F1DB).

[20] *Healthcare Giant Novartis Says it Signed a $1.2 Million Contract with Michael Cohen's Consulting Firm, Took One Meeting, and Realized He Couldn't Help Them*, Business Insider (May 9, 2018) (online at www.businessinsider.com/novartis-payments-to-michael-cohen-linked-essential-consulting-2018-5).

[21] *Id.*

(2) all communications between any officials at OMB, including Mr. Grogan, and individuals associated with Novartis Pharmaceuticals, Gilead Sciences, or any other pharmaceutical company, including any calendar entries for meetings, communications about meetings, and documents exchanged at meetings;

(3) all communications between any officials at OMB, including Mr. Grogan, and Michael Cohen, including any calendar entries for meetings, communications about meetings, and documents exchanged at meetings*;*

(4) all communications between Mr. Grogan and any officials at FDA regarding the approval process for Kymriah, Yescarta, or any other CAR-T therapy;

(5) all documents and communications provided by Mr. Grogan to OMB ethics officials prior to starting his position on March 6, 2017, and any documents provided thereafter; and

(6) all communications between Mr. Grogan and OMB ethics officials regarding potential conflicts of interest or discussions of recusals or ethics waivers;

Thank you for your prompt attention to this matter.

Sincerely,

Elijah E. Cummings
Ranking Member

cc: The Honorable Trey Gowdy, Chairman