



July 11, 2018

David J. Apol  
Acting Director  
U.S. Office of Government Ethics  
1201 New York Avenue, N.W., Suite 500  
Washington, DC 20005

*Re: Request for Investigation into Whether Joseph Grogan's Participation in Development of Government Funding Arrangements for New Cancer Treatment Violated Ethics Rules*

Dear Mr. Apol:

We write to request that the Office of Government Ethics (“OGE”) exercise its oversight responsibilities for executive branch ethics programs by investigating, or referring to the appropriate entity for investigation, whether Mr. Joseph Grogan, Associate Director of Health Programs for the Office of Management and Budget (“OMB”) committed ethics violations by his involvement with the development of government-funding arrangements for a new oncology treatment despite his former employer’s significant financial interest in such government action. Mr. Grogan joined OMB on March 6, 2017, as the Associate Director of Health Programs. Prior to accepting that position, from November 2011 to March 2017, Mr. Grogan worked as a registered lobbyist and head of federal affairs for Gilead Sciences, Inc. (“Gilead”)—a bio-pharmaceutical company.<sup>1</sup> During his tenure at Gilead, Mr. Grogan lobbied on a variety of issues, including reimbursement for oncology drugs.<sup>2</sup>

OGE regulations, which apply to OMB employees (5 C.F.R. § 1300.1), make clear that “[p]ublic service is a public trust.” 5 C.F.R. § 2635.101. To ensure the integrity of the federal government, every federal employee must adhere to basic principles of ethical conduct, (*id.* § 2635.101(b)), including “act[ing] impartially and not giv[ing] preferential treatment to any private organization or individual.” *Id.* § 2635.101(b)(8). More specifically, federal ethics regulations require that “[w]here an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of . . . a person with whom he has a covered relationship . . . , and where the employee determines that the circumstances would cause a reasonable person with knowledge of relevant facts to question his

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<sup>1</sup> Joseph Grogan, Executive Branch Personnel Public Financial Disclosure Report (May 4 2017), <https://www.documentcloud.org/documents/4388049-Joseph-J-Grogan-Financial-Disclosure.html>

<sup>2</sup> Gilead Sciences, Inc. Lobbying Report, Fourth Quarter 2016 (Jan. 19, 2017), <https://soprweb.senate.gov/index.cfm?event=getFilingDetails&filingID=07B9E04E-73A1-4C30-BEB8-C16EF134A0A3&filingTypeID=78>.

impartiality in the matter, the employee should not participate in the matter,” absent appropriate disclosure and authorization. *Id.* § 2635.502.

**The CAR-T development project.** Upon joining OMB, Mr. Grogan began working with the Department of Health and Human Services (“HHS”) and Novartis about creating a demonstration project for a new model of government reimbursement for the CAR-T treatment under Medicaid and Medicare.<sup>3</sup> On August 28, 2017, Mr. Grogan’s former employer Gilead publicly announced that it intended to acquire another biopharmaceutical company, Kite Pharma, Inc. (“Kite”) for nearly \$11.9 billion.<sup>4</sup> Kite and Novartis were locked in a public race to obtain FDA approval for CAR-T therapies,<sup>5</sup> receiving their respective approvals in October 2017 and August 2017.<sup>6</sup>

**Mr. Grogan’s August 28 recusal.** After Gilead’s public announcement of its intended acquisition of Kite, on August 28, 2017, Mr. Grogan emailed an OMB ethics official, attaching the article announcing the Gilead-Kite merger and noting that he had been “working on a project in [the CAR-T] therapeutic area which is almost near completion.” Ex. A. Mr. Grogan asked to “touch base” with the ethics official about the issue to make sure he did not “wade into something.” *Id.* The following day, on August 29, the ethics official responded with an email confirming the details of a conversation with Mr. Grogan about the CAR-T issue:

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.

*Id.* The ethics official also confirmed based on her conversation with Mr. Grogan that he had a “covered relationship” with Gilead as his former employer. As a result, Mr. Grogan was to “stay off specific party matters involving Gilead for two years from leaving employment there, pursuant to the Trump Ethics Pledge (two year) and the OGE impartiality regulation (one year).” *Id.*

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<sup>3</sup> See Ex. A; see also 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>.

<sup>4</sup> Press Release, Gilead Sciences, *Gilead Sciences to Acquire Kite Pharma for \$11.9 Billion* (Aug. 28 2017), <http://www.gilead.com/news/press-releases/2017/8/gilead-sciences-to-acquire-kite-pharma-for-119-billion>.

<sup>5</sup> Ned Pagliarulo, *CAR-T Race Heats Up As Kite, Novartis Complete Filings to FDA*, BioPharma Drive (April 2 2017), <https://www.biopharmadive.com/news/car-t-race-heats-up-as-kite-novartis-complete-filings-to-fda/439525>.

<sup>6</sup> Arlene Weintraub, *Move over, Novartis: Kite and Gilead Break Into CAR-T Market With Early Axi-Cel Nod*, FiercePharma (Oct. 18 2017), <https://www.fiercepharma.com/regulatory/kite-and-gilead-join-novartis-red-hot-car-t-market-early-axi-cel-approval>.

Also on August 29, Mr. Grogan emailed both OMB’s Deputy Director and Chief of Staff to advise that he was recusing himself from “discussing any potential demonstration project that HHS might engage in involving [CAR-T].” Ex. A. Mr. Grogan, however, did not advise that the CAR-T demonstration project was well underway, even though the potential project was publicly announced the following day.<sup>7</sup> Mr. Grogan went on to state that “I had no knowledge such a purchase was a possibility” and “[i]t is conceivable that Kite/Gilead would want to participate in such a demonstration if indeed it were to become a reality.” Ex. A. He then noted that “recusal was proper” and that the demonstration project could continue “through the normal process of approving demonstrations that HHS designs and seeks to launch.” *Id.*

**Gilead’s intended acquisition.** Gilead had been in discussions with Kite about a possible merger since 2015, and in February 2017—one month prior to Mr. Grogan leaving the company—Gilead and Kite signed a confidentiality agreement to protect their ongoing merger discussions.

The following timeline is illustrative:

- In 2015, Gilead and Kite began having “informal discussions” about Kite’s oncology business.<sup>8</sup>
- In January 2017, Gilead hired Alessandro Riva, who had previously run the oncology department for Novartis, and whom Gilead described as a “critical leader” in helping it to determine how to advance in the oncology drug therapy market.<sup>9</sup>
- In January 2017, top officials from Gilead and Kite met to discuss Gilead’s interest in oncology.<sup>10</sup>
- In February 2017, Gilead and Kite entered into a confidentiality agreement surrounding negotiations over a potential merger.<sup>11</sup>
- In March 2017, Mr. Grogan left Gilead to join OMB, where he worked on the CAR-T demonstration project.
- In May 2017, following Mr. Grogan’s departure, Gilead’s Chief Scientific Officer publicly said the company was “narrowing in on” cell therapy as an approach to cancer drug development.<sup>12</sup>

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<sup>7</sup> Press Release, Novartis, *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-kymriahtm-ctl019>.

<sup>8</sup> Kite Pharma, Inc., *U.S. SEC Schedule 14D-9: Solicitation/Recommendation Statement 15*, <https://www.sec.gov/Archives/edgar/data/1510580/000119312517276737/d450961dsc14d9.htm> (accessed Apr. 11, 2018).

<sup>9</sup> Fast Money, *Gilead CEO: M&A Is Top of Mind for Us This Year*, CNBC (Jan. 10 2017), <https://www.cnbc.com/video/2017/01/10/gilead-ceo-ma-is-top-of-mind-for-us-this-year.html>

<sup>10</sup> Lydia Ramsey, *The Inside Story of How a \$12 Billion Deal for a Revolutionary Cancer Treatment Came Together*, Business Insider (Sept. 6, 2017), <http://www.businessinsider.com/how-the-kite-pharma-gilead-sciences-12-billion-came-together-2017-9>.

<sup>11</sup> *Id.*; Kite Pharma, Inc., *supra* note 8.

<sup>12</sup> Max Nisen, *Gilead Keeps Muddying the M&A Waters*, Bloomberg (May 31, 2017), <https://www.bloomberg.com/gadfly/articles/2017-05-31/gilead-cancer-drug-m-a-muddying-the-waters>.

Gilead's substantial steps toward entering the CAR-T market and, in particular, pursuing an acquisition of Kite, during the period Mr. Grogan worked at Gilead as its chief lobbyist raises serious questions as to whether he was required to recuse himself from the CAR-T demonstration project on a date earlier than August 28, 2017, or, indeed, whether he should have ever worked on the CAR-T project at all. If, in fact, Mr. Grogan knew about Gilead's intended merger with Kite and its plans to enter the CAR-T market prior to August 28, 2017, it appears that he should not have engaged personally in the CAR-T demonstration project, absent appropriate disclosure and authorization.

Accordingly, we respectfully request that you take steps to determine, through appropriate investigation by OGE or through referral to another entity, whether Mr. Grogan has complied with his ethics obligations, specifically 5 C.F.R. § 2635.502(a) and President Trump's ethics pledge.<sup>13</sup> If any violation is found, we further request that appropriate remedial and disciplinary actions be taken.

Sincerely,

Anne Harkavy  
Executive Director  
Democracy Forward Foundation

Karianne Jones  
Counsel  
Democracy Forward Foundation

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<sup>13</sup> That pledge independently prohibits federal appointees from participating for two years in matters that are "directly and substantially related" to the appointee's former employer. Exec. Order No. 13770, 82 Fed. Reg. 9333, 9333 (Jan. 28, 2017).