IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DEMOCRACY FORWARD FOUNDATION, P.O. Box 34553 Washington, D.C. 20043, *Plaintiff,* vs. OFFICE OF MANAGEMENT AND BUDGET, 725 17th Street, N.W. Washington, D.C. 20503 *Defendant*.	Case No.

COMPLAINT FOR INJUNCTIVE RELIEF

Plaintiff Democracy Forward Foundation brings this action against Defendant Office of Management and Budget ("OMB" or "the agency") to compel compliance with the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"). OMB has refused to respond as required or to produce documents in response to Plaintiff's request concerning, among other things, documents that will shed light on the role Joseph Grogan, a former pharmaceutical industry lobbyist, played in the Trump Administration's decision to delay regulations mandated by the Affordable Care Act that provide for the imposition of penalties on drug manufacturers that knowingly overcharge for their medications under the 340B drug discount program---a program designed to facilitate the provision of care to vulnerable patient populations.

In March 2017, Mr. Grogan was appointed by President Trump to serve as Associate Director of Health Programs at OMB where he has been tasked with leading

the White House "Drug Pricing and Innovation Working Group." In that capacity, Mr. Grogan has worked on issues related to his recent lobbying activity for the pharmaceutical industry. For example, according to lobbying disclosures filed as recently as April 2017, Mr. Grogan personally lobbied for the pharmaceutical industry on issues concerning the 340B drug discount program. The same week Mr. Grogan joined OMB, the Trump Administration hastily published a delay of the 340B rule. Ignoring the mandate of Congress, the Administration has continually delayed the rule. During subsequent delays, Mr. Grogan held bi-weekly meetings with pharmaceutical executives at the White House during which the 340B program was discussed.

Executive Order 13770 prohibits the President's appointees from working on matters that are the same as those on which they lobbied for industry without an ethics waiver.[1] Mr. Grogan has no waiver.[2]

Given Mr. Grogan's significant conflict of interest, and the Trump Administration's rollback of penalties for pharmaceutical companies that overcharge for their drugs, Plaintiff submitted a FOIA request, which is attached hereto as Exhibit A. OMB has refused to produce documents in response to that request, depriving Plaintiff and the public of their right to know how and why the Trump Administration has sided with pharmaceutical companies over the millions of Americans struggling to afford life-saving drugs.

[1] Exec. Order No. 13,770, 82 Fed. Reg. 9333 (Jan. 28, 2017).
[2] Sarah Karlin-Smith, *Trump's Drug Price 'Remedy' Expected to be Industry Friendly*, Politico, June 16, 2017, http://www.politico.com/story/2017/06/16/trump-drug-prices-industry-239659

Jurisdiction and Venue

1. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

2. Venue is proper under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

Parties

3. Plaintiff Democracy Forward Foundation is a not-for-profit organization incorporated under the laws of the District of Columbia and based in Washington, D.C. Plaintiff works to promote transparency and accountability in government, in part, by educating the public on government actions and policies.

4. Defendant OMB is a federal agency within the meaning of FOIA, 5 U.S.C. § 552(f)(1), and is headquartered in Washington, D.C. OMB has possession, custody, and control of records to which plaintiff seeks access.

Factual Allegations

The 340B Drug Pricing Program

5. High pharmaceutical costs are a major barrier to the provision of quality healthcare for millions of Americans.

6. To address this barrier to care, section 340B of the Public Health Services Act ("PHSA") requires certain drug manufacturers to sell products to qualified purchasers (safety-net providers and programs identified in the Public Health Services Act)—known as "covered entities"—at a discounted price.[3] Signed into law by President George H.W. Bush, the 340B program is administered by the Health Resources and Services Administration of the Department of Health and Human Services.

[3] *See 340B Drug Pricing Program*, HRSA (last updated Oct. 2017), https://www.hrsa.gov/opa/

7. Covered entities in the 340B program include federally qualified health centers, disease specific programs (e.g., programs providing AIDS Drug Assistance, black-lung clinics and hemophilia treatment centers), and publicly owned hospitals that serve a disproportionate share of low-income patients.[4]

8. As a result of providing medications to covered entities at reduced prices, the 340B Program enables these institutions to stretch scarce federal resources as far as possible, reaching underserved patient populations and enabling them to receive more comprehensive care.[5]

9. Ensuring that drug manufacturers comply with the pricing mandates of 340B has been a challenge. In its 2006 report, the Office of Inspector General of the Department of Health and Human Services found that 14 percent of all drug purchases under the 340B program in June of the preceding year exceeded drug ceiling prices, resulting in total overpayments of $3.9 million.[6]

10. There is continued reason to believe that absent greater enforcement, manufacturers will continue to overcharge covered entities. For example, in August 2017, the U.S. Department of Justice and drug manufacturer Mylan announced a $465 million legal settlement of a lawsuit claiming, among other things, that Mylan overcharged 340B hospitals and other healthcare providers for EpiPen epinephrine auto-injectors.[7]

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[4] *See 340B Eligibility & Registration*, HRSA (last updated Sept. 2017), https://www.hrsa.gov/opa/eligibility-and-registration/index.html

[5] *See 340B Drug Pricing Program*, *supra* note 3.

[6] Office of Inspector Gen., U.S. Dept. of Health and Human Services, Semiannual Report to Congress Apr. 1, 2006-Sept. 30, 2006, ii (2006), *available at* https://oig.hhs.gov/publications/docs/semiannual/2006/Semiannual%20Final%20FY%202006.pdf

[7] *See, e.g.*, Press Release, Dept. of Justice, Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates (Aug. 17, 2017), *available at*

11. To ensure that drug manufacturers comply with the 340B program, the Patient Protection and Affordable Care Act ("ACA") amended the PHSA to task the Department of Health and Human Services with, among other things: (1) "Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices"; and (2) Developing a mechanism by which "the imposition of sanctions in the form of civil monetary penalties" would be assessed against manufacturers that knowingly and intentionally charge a covered entity above the ceiling price.[8]

12. The Obama Administration began the rulemaking process for the 340B pricing methodology and civil monetary penalties provision on September 20, 2010 and issued a final rule on January 5, 2017, following extensive deliberation and public comment periods. The rule was set to go into effect on March 6, 2017.[9]

13. As discussed more fully below, the Trump Administration has delayed the effective date of the rule until July 2018.[10] The Administration first announced its intention to delay the rule the same week industry lobbyist, Joseph Grogan, was appointed Associate Director of Health Programs at OMB.[11]

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https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates; Press Release, Office of the N.Y. Att'y Gen., A.G. Schneiderman Announces $465 Million Joint State-Federal Settlement with Mylan, Maker of Epipens (Aug. 17, 2017), *available at* https://ag.ny.gov/press-release/ag-schneiderman-announces-465-million-joint-state-federal-settlement-mylan-maker

[8] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102, 12 Stat. 119 (2010), *as amended by* Health Care and Education Reconciliation Act, Pub. L. No. 111-152, § 2302, 12 Stat. 1029 (2010) (adding section 340B(d)(1)(B)(vi) of the PHSA).

[9] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210 (Jan. 5, 2017).

[10] *Id*. at 45511 (Sept. 29, 2017).

[11] *Id.* at 12508 (Mar. 6, 2017).

President Trump's Appointment of Industry Lobbyist, Joseph Grogan, As Associate Director of Health Programs at OMB, and the Administration's Delay of Enforcement of the 340B Rule

14. During his campaign for President, Donald Trump publicly criticized the pharmaceutical industry for the high price of life-saving medications. Before his inauguration, he stated that drug companies are "get[ting] away with murder" and stated that he believed the federal government should allow Medicare to negotiate drug prices.[12] He also promised to "drain the swamp" of industry lobbyists.

15. Notwithstanding his campaign promises, President Trump has failed to address rising drug prices and, instead, appointed pharmaceutical industry insiders to key positions that have influence over drug access, pricing, and healthcare policy.

16. Indeed, less than two weeks after he was inaugurated, President Trump met with pharmaceutical company executives in a closed-door meeting.[13]

17. Following this meeting, President Trump appointed former pharmaceutical industry lobbyist Joseph Grogan as the Associate Director of Health Programs for OMB where he was charged with leading the "Drug Pricing Innovation Working Group."

18. Prior to being appointed by President Trump, Mr. Grogan served as Head of Federal Affairs for the drug manufacturer, Gilead Sciences. While Mr. Grogan led Gilead's lobbying efforts, the company was being investigated by Congress for overcharging patients prescribed their Hepatitis medication Solvaldi. At the time, Rep.

[12] *See, e.g.*, Katie Thomas, *Trump Vows to Ease Rules for Drug Makers, but Again Zeros In on Prices*, The New York Times, Jan. 31, 2017, https://www.nytimes.com/2017/01/31/health/trump-vows-to-ease-rules-for-drug-makers-but-prices-remain-a-focus.html

[13] *See, e.g., id.*

Jeff Miller, the Republican Chairman of the House Committee on Veterans' Affairs, claimed Gilead was "price-goug[ing]" veterans.[14]

19. Mr. Grogan's name appeared in lobbyist disclosures from Gilead Sciences consistently from 2011 into March 2017. During his time as a lobbyist, disclosures show that he lobbied on a wide variety of issues, including but not limited to, the Affordable Care Act implementation, coverage of pharmaceuticals, and cost-sharing. According to lobbying disclosures, Mr. Grogan also personally lobbied Congress and the Department of Health and Human Services regarding implementation and payments associated with the 340B program.

20. On March 6, 2017, the same week President Trump appointed Mr. Grogan to be Director of Health Programs at OMB, the Administration announced its intention to delay enforcement of the 304B rule for 15 days.[15]

21. The Administration has subsequently delayed enforcement of the 340B rule three additional times: on March 20, May 19 and September 29, 2017.[16] Under the most recent rule, the regulation is delayed until July 2018.

22. While the Administration considered these subsequent delays, Mr. Grogan held bi-weekly meetings with pharmaceutical executives in the Eisenhower Executive Office Building, starting on May 4, 2017 and lasting until, at least, the end of June 2017.

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[14] Jeff Miller, *Why is Gilead charging VA $40,000 for drug?* CNN Opinion, Jan. 27, 2016, http://www.cnn.com/2016/01/27/opinions/miller-gilead-drug-price/index.html

[15] 340B Drug Pricing Regulations, *supra* note 11; *See* Jennifer Scholtes and Sarah Ferris, *Major Federal Savings Predicted Under GOP Health Plan*, Politico, Mar. 13, 2017, http://www.politico.com/tipsheets/politico-pulse/2017/03/trump-seeks-conservative-tweaks-to-gop-health-bil-219232

[16] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 14322 (Mar. 20, 2017); *id.* at 22893 (May 19, 2017); 340B Drug Pricing Regulations, *supra* note 10.

23. During these meetings with pharmaceutical executives, Mr. Grogan discussed the 340B program. According to a report by Kaiser Health News:

> "After the working group's first meeting on May 4, Grogan distributed detailed policy recommendations on expediting generic drug approvals, creating a new tax credit "of up to 50 percent" for investments in generic drug manufacturing, distribution and research and development. The documents also propose scaling back the 340B program, which requires drug manufacturers to provide some medicines at a discount to hospitals that treat low-income patients."[17]

Joseph Grogan Does Not Have An Ethics Waiver, Despite the Fact That His Work at OMB Overlaps With Key Areas On Which He Lobbied

24. As Associate Director of Health Programs at OMB, Mr. Grogan has worked on numerous issues that overlap with his prior work as an industry lobbyist, including drug pricing and incentives for drug manufacturers.

25. Executive Order 13770 requires that executive branch appointees, like Mr. Grogan, affirm the following:

> "If I was a registered lobbyist within the 2 years before the date of my appointment . . . I will not for a period of 2 years after the date of my appointment participate in any particular matter on which I lobbied within the 2 years before the date of my appointment or participate in the specific issue area in which that particular matter falls."[18]

[17] Emily Kopp, *Exclusive: White House Task Force Echoes Pharma Proposals*, Kaiser Health News, June 16, 2017, https://khn.org/news/exclusive-white-house-task-force-echoes-pharma-proposals/
[18] Exec. Order, *supra* note 1 at 9333.

26. EO 13770 provides that the restrictions set forth above may be waived but only if the President or his designee explicitly grants a waiver.[19]

27. According to news reports, Mr. Grogan has not been granted an ethics waiver, meaning that under Executive Order 13770 he is required to recuse himself from issues on which he previously lobbied.[20]

28. Given Mr. Grogan's significant conflict of interest, and the Trump Administration's rollback of penalties for pharmaceutical companies that overcharge for their drugs, Democracy Forward Foundation filed a FOIA request with the Office of Management and Budget to discover the role pharmaceutical lobbyists played in shaping Administration policies.

29. The request, which was transmitted on June 22, 2017, sought production of the following records within 20 days:

- Any and all records that constitute any ethics waiver received by Mr. Grogan.
- Any and all records that refer or relate to Mr. Grogan receiving an ethics waiver.
- Any and all records that refer or relate to guidance provided by any OMB official to Mr. Grogan regarding his ethical obligations or potential conflicts of interest created by Mr. Grogan's former employment at Gilead Sciences.
- Any and all records provided to or generated by the Drug Pricing and Innovation Working Group.
- Any and all records identifying the members of the Drug Pricing and Innovation Working Group.

[19] *Id.* at 9335.
[20] Karlin-Smith, *supra* note 2.

30. That same day, OMB acknowledged receipt of the request and assigned the request an OMB FOIA number of 2017-280, attached hereto as Exhibit B.

31. Other than sending this form acknowledgement, OMB has not communicated with Plaintiff regarding its FOIA request.

32. Pursuant to 5 U.S.C. §§ 552(a)(6)(A)(i), OMB was required to determine whether to comply with the FOIA request within twenty (20) working days of receipt of the request and to notify plaintiff immediately of its determination, the reasons therefor, and the right to appeal any adverse determination.

33. OMB's determination regarding plaintiff's FOIA request was due nearly two months ago.

34. As of the date of this complaint, OMB has failed to: (1) determine whether to comply with the FOIA request, (2) notify plaintiff of any such determination of the reasons therefor, (3) advise plaintiff of the right to appeal any adverse determination, or (4) produce the requested records or otherwise demonstrate that the requested records are exempt from production.

35. Because OMB has failed to comply with the time limit set forth in 5 U.S.C. §§ 552(a)(6)(A) and 552(a)(6)(B)(i), plaintiff is deemed to have exhausted any and all administrative remedies pursuant to 5 U.S.C. § 552(a)(6)(C).

Claim for Relief
Count One (Violation of FOIA, 5 U.S.C. § 552)

36. Plaintiff incorporates by reference the foregoing paragraphs as if fully set forth herein.

37. By failing to respond to plaintiff's request within the statutorily mandated time period, OMB has violated its duties under 5 U.S.C.§ 552, including but not limited to the

duties to conduct a reasonable search for responsive records, to take reasonable steps to release all nonexempt information, and to not withhold responsive records.

WHEREFORE, plaintiff prays that this Court:

1. order defendant to conduct a search for any and all responsive records to plaintiff's FOIA request using search methods reasonably likely to lead to discovery of all responsive records;

2. order defendant to produce, by a date certain, any and all non-exempt responsive records and a *Vaughn* index of any responsive records withheld under a claim of exemption;

3. enjoin defendant from continuing to withhold any and all non-exempt responsive records;

4. order defendant to grant plaintiff's request for a fee waiver;

5. award plaintiff its costs, attorneys' fees, and other disbursements for this action; and

6. grant any other relief this Court deems appropriate.

Dated: October 13, 2017

Respectfully submitted,

/s/ *Skye L. Perryman*

Javier M. Guzman
(D.C. Bar No. 462679)
Skye L. Perryman
(D.C. Bar No. 984573)
Democracy Forward Foundation
P.O. Box 34553
Washington, D.C. 20043
(202) 448-9090
jguzman@democracyforward.org
sperryman@democracyforward.org