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Congress of the United States
House of Representatives
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October 5, 2020

The Honorable Dr. Stephen M. Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

The Subcommittee on Economic and Consumer Policy seeks information about the influence exercised by non-experts in the White House over scientific decision-making at the Food and Drug Administration (FDA). We are particularly concerned that the Office of Information and Regulatory Affairs (OIRA), an obscure office within the White House, is exerting influence over what is supposed to be non-partisan, scientific decision-making.

FDA's Scientific Integrity Has Been Undercut by the White House

The public wants a COVID-19 vaccine that it can trust. Assuredly, FDA and its expert staff want that too. Unfortunately, President Trump has pledged to rush a vaccine into the market, and that undermines public trust in FDA's ability to ensure a safe and effective vaccine.

FDA has recently tried to assure the public that science alone will dictate its decision on whether to make a vaccine available. On September 23, 2020, you testified to the Senate that FDA would soon release guidance setting forth rigorous scientific standards for any Emergency Use Authorization (EUA) of a COVID-19 vaccine. The guidance would also commit to public review of any vaccine by an independent advisory committee of experts before it was made available for public use. You asserted that politics would not play a part in FDA's decision to approve or disapprove a COVID-19 vaccine.[1]

Yet, almost as soon as you had spoken, President Trump asserted that any FDA vaccine decision would have to pass through the White House and that he might overrule you. He said

[1] *Trump Claims White House Can Overrule FDA's Attempt to Toughen Guidelines for Coronavirus Vaccine*, CNN (Sept. 24, 2020) (online at www.cnn.com/2020/09/23/politics/trump-fda-coronavirus-vaccine/index.html).

that he would trust what the pharmaceutical companies tell him about whether to deploy a vaccine, rather than relying on FDA.[2]

I am concerned about the effect such statements will have on the public's confidence in COVID-19 vaccines. The State of New York was concerned enough to declare that it will independently review any COVID-19 vaccine for safety and efficacy before recommending it to its residents.[3]

FDA still has the opportunity to increase public confidence by publishing the standards that it will use to evaluate a vaccine EUA. I called on you to do this in a previous letter and requested your response by September 25, 2020.[4] To date, I have received no response. Recent reports may explain why.

Reports indicate that the White House may be preventing you from releasing it. FDA has reportedly drafted the requested guidance, which would set tough standards for reviewing a vaccine. Among other things, FDA's guidance would reportedly permit an EUA application only after waiting two months from the time that all study participants receive the vaccine, to gain insights on safety and efficacy.[5]

However, President Trump said that FDA's guidance "has to be approved by the White House. We may or may not approve it."[6] Subsequently, Phillip Krause, Deputy Director for FDA's Center for Biologics Evaluation and Research has expressed concern that the White House's objections will prevent FDA from releasing the guidance.[7]

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[2] *Trump Attacks FDA Plan for Tougher Standards on Emergency Vaccine Approval as a 'Political Move,'* Washington Post (Sept. 23, 2020) (online at www.washingtonpost.com/health/coronavirus--vaccine-trump-fda/2020/09/23/bed73438-fda4-11ea-8d05-9beaaa91c71f_story.html); *Eager for a Covid Vaccine, Trump Now Trusts Drug Companies He Previously Villified*, STAT (Sept. 30, 2020) (online at www.statnews.com/2020/09/30/covid-vaccine-trump-trusts-drug-companies-vilified/).

[3] *New York Will Review Virus Vaccines, Citing Politization of Process*, New York Times (Sept. 24, 2020) (online at www.nytimes.com/2020/09/24/nyregion/new-york-coronavirus-vaccine.html?smid=em-share).

[4] Letter from Raja Krishnamoorthi, Chairman, Economic and Consumer Policy Subcommittee, Committee on Oversight and Reform, to Dr. Stephen Hahn, Director, Food and Drug Administration (Sept. 22, 2020) online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/2020-09-22.RK%20to%20Hahn-%20FDA%20re%20EUA%20Guidance%201.pdf).

[5] *FDA Considering Authorization Rules That Could Push Coronavirus Vaccine Past Election Day*, CNN (Sept. 22, 2020 (online at www.cnn.com/2020/09/22/health/coronavirus-vaccine-fda-authorization-rules/index.html).

[6] *Trump Attacks FDA Plan for Tougher Standards on Emergency Vaccine Approval as a 'Political Move,'* Washington Post (Sept. 23, 2020) (online at www.washingtonpost.com/health/coronavirus--vaccine-trump-fda/2020/09/23/bed73438-fda4-11ea-8d05-9beaaa91c71f_story.html).

[7] *Top FDA Vaccine Official Says Vaccine Guidance May Never Be Released*, Politico (Sept. 28, 2020) (online at www.politico.com/news/2020/09/28/fda-vaccine-guidance-may-not-be-released-422648).

Expanded OIRA Power, Diminished OIRA Transparency

President Trump's insistence on White House approval of a vaccine safety guidance was referencing, at least in part, OIRA, an office in the White House that reviews, revises, and ultimately approves or denies nearly all federal agency action. While OIRA has existed since the Reagan Administration, its reach significantly expanded in 2019 when President Trump issued Executive Order 13891, requiring all regulations and even non-binding guidance documents to be funneled through OIRA for review.[8] During the coronavirus crisis, OIRA's review of public health guidance has reportedly expanded even more, now covering almost every document related to COVID-19.[9]

In the spring, the White House Coronavirus Task Force began reviewing COVID-19 guidance. OIRA was also reviewing COVID-19 guidance, as well as sending it to other officials for comment. Many of the reviewers lack public health or scientific experience.[10] For example, White House Chief of Staff Mark Meadows, a former Congressman and real estate developer, recently weighed in on FDA's vaccine guidance, indicating he saw no need for it.[11]

White House review of COVID-19 guidance from FDA's sister agency, the Centers for Disease Control and Prevention (CDC), is likely instructive of the review FDA guidance faces. Reports indicate that CDC guidance must now pass through a phalanx of political appointees at HHS, the White House Coronavirus Task Force, OMB and OIRA, the Department of Homeland Security, the Labor Department, the State Department, and the Department of Education.[12]

The Administration's claims that requiring guidance to be "fully reviewed, studied, and vetted by Administration officials" results in "a process the White House stands by that saved lives."[13] The Subcommittee disagrees.

We are concerned the process lacks clear structure, gives undue weight to the opinions of non-expert political appointees, weakens guidance, and delays its publication.

Until recently, OIRA operated with some modicum of transparency. It published on its website, as required by law, a "publicly available log" of all rules and guidances under review so that the public knew the issues on which it was working.[14] Troublingly, the FDA guidance documents that have been blocked by OIRA in recent months, including the vaccine guidance,

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[8] Exec. Order No. 13891, 84 Fed. Reg. 55235 (Oct. 9, 2019).

[9] *CDC's Messages to Public Were Slowed by Extensive Reviews*, Bloomberg (Sept. 18, 2020) (online at www.bloomberg.com/news/articles/2020-09-18/cdc-s-messages-to-public-were-slowed-by-extensive-reviews).

[10] *Id.*

[11] *Top FDA Vaccine Official Says Vaccine Guidance May Never Be Released*, Politico (Sept. 28, 2020) (online at www.politico.com/news/2020/09/28/fda-vaccine-guidance-may-not-be-released-422648).

[12] *CDC's Messages to Public Were Slowed by Extensive Reviews*, Bloomberg (Sept. 18, 2020) (online at www.bloomberg.com/news/articles/2020-09-18/cdc-s-messages-to-public-were-slowed-by-extensive-reviews).

[13] *Id.*

[14] *Id.*

do not appear on OIRA's website.[15] OIRA has also stopped publishing on its website the list of closed-door meetings it takes with lobbyists on the guidances under review.

To assist the Subcommittee in its review of this matter, provide the following documents and information by October 19, 2020:

1. All FDA actions, including emergency use authorizations and guidance documents, submitted for review to the White House, or any office thereof, related to COVID-19 vaccines, therapeutics, tests, and other regulated products, and all documents and communications related thereto, including all interagency comments including from the White House;

2. All documents and communications from January 1, 2020 to present referring or relating to changes in which agency actions are to be submitted to OIRA;

3. All first drafts of FDA actions and guidance documents sent to OIRA from March 1, 2020 to present, and any documents showing tracked changes of FDA's original guidance documents; and

4. Any document referring or relating to OIRA's decision not to disclose the status of FDA's actions and guidance documents as they undergo OIRA review.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,

Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

Enclosure

cc: The Honorable Michael Cloud, Ranking Member

[15] Office of Information and Regulatory Affairs, Regulatory Actions Currently Under Review by Agency (online at www.reginfo.gov/public/jsp/EO/eoDashboard.myjsp) (accessed Sept. 25, 2020).

Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term “including” shall be construed broadly to mean “including, but not limited to.”

5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.

7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term “individual” means all natural persons and all persons or entities acting on their behalf.