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September 19, 2024

The Honorable Christi A. Grimm
Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Suite 5250
330 Independence Avenue, SW
Washington, DC 20201

Via e-mail: Christi.Grimm@oig.hhs.gov

RE: Request for an Office of Inspector General investigation of conflict of interest allegations against Jeff Shuren, M.D., J.D., the former director of the Food and Drug Administration's Center for Devices and Radiological Health

Dear Inspector General Grimm:

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, respectfully requests that your office immediately launch a formal investigation to scrutinize conflict of interest allegations against Jeff Shuren, M.D., J.D., the former director of the Food and Drug Administration (FDA)'s Center for Devices and Radiological Health (CDRH).

The allegations are detailed in an August 20, 2024, article in *The New York Times* (Hereafter, the Times).[1] According to the article, while Dr. Shuren was the senior FDA official in charge of regulating medical devices, his wife, Allison W. Shuren, was a partner at Arnold & Porter and, from 2015, co-chair of the law firm's Life Sciences & Healthcare Regulatory practice.[2] Despite ethics rules barring Dr. Shuren from working on matters involving clients of Arnold & Porter, Dr. Shuren did not always fully recuse himself. The conduct described by the Times, if confirmed, represents a serious violation of ethics agreements signed by Dr. Shuren and undermines public trust in the integrity of the FDA's regulation of medical devices during the time that Dr. Shuren was the CDRH director. Dr. Shuren became the acting director of CDRH beginning in September 2009 and

[1] Jewett C. He regulated medical devices. His wife represented their makers. *New York Times*. August 20, 2024. https://www.nytimes.com/2024/08/20/health/fda-medical-devices-ethics.html. Accessed September 17, 2024.

[2] Allison W. Shuren. https://www.arnoldporter.com/en/people/s/shuren-allison-w. Accessed August 28, 2024.

was appointed the permanent director in January 2010.[3] In July 2024 Dr. Shuren announced that he was transferring to the FDA's Office of Commissioner and would retire from the FDA later in 2024.[4]

Among the allegations about Dr. Shuren in the Times article are the following:

--"Dr. Shuren signed ethics agreements obtained by the Times that were meant to wall him off from matters involving Arnold & Porter's business. But it's not clear how rigorously the ethics agreements were actually enforced."

--"[Ms. Shuren's] partner at the helm of the firm's life sciences team began representing Theranos, the discredited blood testing company, in 2015, demanding the F.D.A. halt an inspection at its sites in California. While Dr. Shuren said he was recused from the matter, court records suggested he remained involved."

--"In another case, Ms. Shuren's firm was working on a $63 billion acquisition of the company Allergan in 2019 when Dr. Shuren initially declined to urge a recall of the company's breast implants tied to a rare cancer."

--"The couple's work overlapped again in 2022 when Dr. Shuren announced a proposal to strengthen warnings given to patients preparing for LASIK vision correction surgery. Two of Ms. Shuren's clients opposed the plan; the recommendations have yet to be put in place."

In response to questions from the Times, it appears that the FDA has already confirmed some of the allegations:

"...Shannon P. Hatch, an F.D.A spokeswoman, said the agency has found that 'it appears there were certain instances from about 10 years ago for which Dr. Shuren should have either recused himself or sought ethics authorization to participate to avoid any potential appearance of bias.' Ms. Hatch confirmed that the lapses occurred in the Theranos case as well as another one identified by the Times involving Alcon, an eye care drug and device company that was a client of Ms. Shuren's. In 2014, Alcon went before an agency committee convened to

[3] FDA Organization. Jeff Shuren M.D., J.D. https://www.fda.gov/about-fda/fda-organization/jeff-shuren. Accessed September 17, 2024.

[4] Jewett C. He regulated medical devices. His wife represented their makers. *New York Times*. August 20, 2024. https://www.nytimes.com/2024/08/20/health/fda-medical-devices-ethics.html. Accessed September 17 2024

advise on whether to approve a lens implanted in the eye. According to a meeting transcript, Dr. Shuren signed off on the appointment of eight new voting members and a new chairman for the hearing, which recommended approval."

The FDA, especially given what is already known about its actions from the Times article, has institutional interests that would preclude a thorough and unbiased internal investigation. Through its access to FDA records and documents and its ability to interview FDA staff who were involved in these matters, the HHS Office of Inspector General can conduct a thorough investigation, including an examination of any other problematic activities of Dr. Shuren that the Times was unaware of.

An independent investigation by the HHS Inspector General is necessary to ensure public confidence in the integrity of the investigation.

Public Citizen hopes that you share our concerns regarding these troubling matters, and we look forward to an appropriate, favorable response to our request. Please contact me at rsteinbrook@citizen.org if you have any questions or need additional information.

Sincerely,
Robert Steinbrook
Robert Steinbrook, M.D.
Director
Public Citizen's Health Research Group