

KATIE PORTER
45TH DISTRICT, CALIFORNIA

FINANCIAL SERVICES COMMITTEE

SUBCOMMITTEE ON
INVESTOR PROTECTION, ENTREPRENEURSHIP,
AND CAPITAL MARKETS

SUBCOMMITTEE ON
CONSUMER PROTECTION AND
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May 13, 2020

Christi Grimm
Principal Deputy Inspector General
HHS Office of the Inspector General
330 Independence Ave SW
Washington, DC 20201

Dear Ms. Grimm,

I write to you today alarmed by the U.S. Office of Special Counsel Whistleblower Complaint submitted by the former Director of the Biomedical Advanced Research and Development Authority (BARDA), Dr. Rick Bright. In his complaint, Dr. Bright documents an environment in which Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response (ASPR), paid more attention to the claims and financial needs of pharmaceutical companies than to scientists. These pharmaceutical companies informed decisions that Dr. Kadlec made about which drugs would receive taxpayer dollars for research, as well as which would be available to Americans in the Strategic National Stockpile and for treatment of COVID-19.¹

I request that you immediately investigate the role that pharmaceutical industry executives, consultants, and other lobbyists have in the federal procurement process and the approval of drugs at ASPR. Especially during the ongoing pandemic, the safety and wellbeing of our families is of the utmost importance. We cannot put big pharmaceutical companies' profits before patients' health.

The "revolving door" of former government officials using their influence as paid lobbyists is a longstanding problem. Dr. Bright's complaint paints a shocking portrait of unfettered lobbyist access and potentially illegal influence over decision making within HHS. In a review of lobbying disclosure reports, my staff found more than 20 senior staff and officials within HHS who had lobbied on behalf of the pharmaceutical industry before serving in the Trump Administration.² This does not include those who had worked for firms that represent pharmaceutical companies but for whom we were unable to verify previous work for those clients. Some of these individuals have already left their posts within the Administration to return to lobbying for the industry.³

¹ Dr. Richard Bright Whistleblower Complaint, OMB No. 3255-0005, Office of the Special Counsel.

² See Open Secrets Revolving Door and Pro Public Trump-Town.

³ See Open Secrets Revolving Door and Pro Public Trump-Town.

BARDA's procurement process should ensure that contracts are awarded according to scientific merit, but Dr. Bright's report provides a series of examples of improper behavior in which pharmaceutical company consultants had direct access to Dr. Kadlec and other senior HHS officials. They used this access to place pressure on BARDA to award contracts not on scientific integrity, but instead on a company being "friends with Jared Kushner," "having Hollywood connections,"⁴ financial necessity,⁵ or simply a pharmaceutical CEO's "unhappiness" with a decision.⁶

These challenges began when Dr. Kadlec was appointed to ASPR. Dr. Bright had recently let a contract with Aeolus Pharmaceuticals expire because Aeolus had been unable to meet necessary requirements. However, shortly after Dr. Kadlec joined, John Clerici, a pharmaceutical industry consultant,⁷ began inquiring as to the status of this issue on behalf of Aeolus.⁸ The Federal Acquisition Regulation (FAR) states that "government business shall be conducted in a manner above reproach and, except as authorized by statute or regulation, with complete impartiality and with preferential treatment for none." Under the Procurement Integrity Act consultants are barred from engaging with BARDA officials after a proposal is submitted and before a contract is awarded.⁹ Dr. Bright's complaint raises significant concerns about whether these laws are being followed under Dr. Kadlec and Secretary Alex Azar's leadership.

HHS officials' actions may also constitute violations of 5 CFR § 2635, which outlines ethics standards for conduct for employees of the Executive Branch. These standards are intended to prevent conflicts of interest, impartiality, and the misuse of position for financial gain. For example, on the advice of Mr. Clerici, Dr. Kadlec directed Dr. Bright to transfer \$40 million to the Strategic National Stockpile to purchase generic Oseltamivir, an influenza antiviral drug. Dr. Bright suggested that ASPR consider a newly approved influenza antiviral instead, as Oseltamivir had recently been shown to be ineffective against some influenza strains.¹⁰ Dr. Bright convened the interagency Flu Risk Management Meeting group, which decided that no additional taxpayer funds should be used for the purchase of Oseltamivir.¹¹ This recommendation was ignored, and Dr. Kadlec and the director of the Strategic National Stockpile, Dr. Greg Burel, moved forward with the purchase of Oseltamivir instead from the pharmaceutical manufacturer Alvogen, a company represented by Mr. Clerici. While not mentioned in Dr. Bright's description of the incident, Eric Hargan, Deputy Secretary of HHS, also has connections to Alvogen, having provided the company legal services in the past.¹²

⁴ Dr. Richard Bright Whistleblower Complaint, p. 33, OMB No. 3255-0005, Office of the Special Counsel.

⁵ Dr. Richard Bright Whistleblower Complaint, p. 38, as cited.

⁶ Dr. Richard Bright Whistleblower Complaint, p. 34, as cited.

⁷ John Clerici is Counsel at Blank Rome LLP. According to his staff profile at Blank Rome, Clerici "has played a significant role in the creation and growth of the public health preparedness sector for nearly two decades, helping large pharmaceutical and emerging biotechnology companies access non-dilutive capital to fund the development of biotechnology for emerging disease and engineered threats. He has assisted more than three dozen companies in obtaining over four billion dollars in funding for the research, development, and procurement of public health countermeasures to the federal government..." <https://www.blankrome.com/people/john-m-clerici>.

⁸ Dr. Richard Bright Whistleblower Complaint, p. 36, as cited.

⁹ Consultants may only engage in the BARDA application process by assisting companies in drafting and submitting proposals. Once a proposal is submitted and before the contract is awarded, consultants are disallowed from engaging in the process. 41 U.S.C. §§ 2101-07 and Federal Acquisition Regulation Part 3.104, 48 C.F.R. § 3.104-3.

¹⁰ Dr. Richard Bright Whistleblower Complaint, p. 33, as cited.

¹¹ Dr. Richard Bright Whistleblower Complaint, p. 36, as cited.

¹² Alvogen, Inc. Pro Publica, Retrieved at: <https://projects.propublica.org/trump-town/organizations/alvogen-inc>

In one of the most egregious incidents documented in the complaint, ASPR discounted the opinions of scientific experts to award a contract to Partner Therapeutics, yet another one of Mr. Clerici's clients.¹³ Dr. Kadlec implored Dr. Bright to award a contract to Partner Therapeutics because, "the company was having financial difficulties" and "BARDA should consider strategies to support the company."¹⁴ Dr. Bright, working to preserve the integrity of BARDA, initiated a procurement integrity investigation about the Partner Therapeutics proposal. He soon learned that a former senior BARDA employee had also been hired as a consultant for Partner Therapeutics.¹⁵ It was at this time that Dr. Bright reached out to your office to call for an Inspector General investigation to "help break up the 'cottage industry' of marketing consultants and political influence into these contracts."¹⁶

Dr. Bright's complaint also raises serious concerns about a program known as "ASPR Next." The initiative was created in August 2019, with the intent of investing in "revolutionary advancements in health security products, technologies and innovations, specifically to invigorate operations, response, recovery and medical countermeasure development, deployment and distribution activities."¹⁷ Nearly a year after the project's launch, public information about its work remains minimal, and Dr. Bright's complaint alleges that ASPR Next became no more than a means of circumventing long-established laws and norms for BARDA approval processes.

In February 2020, Dr. Bright was informed that Mr. Clerici and Dr. George Painter, the Director of Emory Institute for Drug Development and President and Chief Executive Officer, Drug Innovation Ventures at Emory were now pursuing approval of a so-called miracle drug for the treatment of COVID-19. Dr. Painter and Mr. Clerici had previously sought funding for EIDD-2801 as a cure-all for a number of viral infections and had been denied because of a lack of appropriate clinical data. Instead of submitting a funding request to the Medical Countermeasures Task Force, as procedure required, Dr. Painter and Mr. Clerici contacted the lead of ASPR Next and the ASPR Strategic Innovation and Emerging Technology Manager Joe Hamel.¹⁸ It was then that Dr. Bright learned that some companies attempting to circumvent the Medical Countermeasures Task Force's "rigorous scientific and contractual review process"¹⁹ were instead asking for funding from ASPR Next. These projects were then escalated to BARDA for funding requests. This is a gross misuse of taxpayer dollars on projects that may or not be scientifically valid, having not undergone the rigorous testing necessary to test for safety and efficacy.

It appears as if multiple clients of the same pharmaceutical company consultant were awarded contracts, regardless of scientific evidence that these were the best choices for the contracts. I ask that you conduct a full review of whether awards during Dr. Kadlec's tenure as ASPR meet the standards established in the FAR, and examine as part of that review:

¹³ Dr. Richard Bright Whistleblower Complaint, p 38, as cited.

¹⁴ Dr. Richard Bright Whistleblower Complaint, p 38, as cited.

¹⁵ Dr. Richard Bright Whistleblower Complaint, p 38, as cited.

¹⁶ Dr. Richard Bright Whistleblower Complaint, p 38-39, as cited.

¹⁷ ASPR Next Broad Agency Announcement, General Services Administration, Retrieved at: https://beta.sam.gov/opp/826a435bbae7570b1f9f66ab3fcb54bf/view?keywords=aspr%20next&sort=-relevance&index=opp&is_active=true&page=1

¹⁸ Dr. Richard Bright Whistleblower Complaint, page 59, as cited.

¹⁹ Dr. Richard Bright Whistleblower Complaint, page 59, as cited.

1. Recommendations from bodies involved in the consideration of these contracts;
2. Consultants representing these clients and their involvement in the contract process;
3. Past or future employment of individuals working at HHS from August 2017 through May 2020, specifically at BARDA or the FDA by pharmaceutical companies pursuing contracts;
4. Past or future employment of individuals, including Dr. Michael Callahan, working as contractors for HHS and advising on the procurement process from August 2017 through May 2020;
5. Scientific merit of contracts awarded;
6. Contracts awarded to companies denied by BARDA but then approved by ASPR Next;
7. Preexisting social relationships with contract recipients and consultants; and
8. Political influence over contract selection.

Additionally, I ask that you respond to the following questions by May 22, 2020:

1. In late 2018, Dr. Bright reached out to the Office of the Inspector General to request an investigation into procurement integrity. Was an investigation ever conducted, and if not, will the IG commit to launching such an investigation?
2. What companies have been awarded funding under ASPR Next? Who reviewed the applications for this funding, and if there were recommendations against funding these projects for a lack of scientific evidence, were these projects sent to another department under ASPR?
3. Similar initiatives started by Dr. Kadlec, such as the Division of Research, Innovation and Ventures (DRIVE), were intended to "lower the barriers for entry" for companies and increase access to funding.²⁰ Has HHS OIG conducted a review of new projects, such as DRIVE and ASPR Next, for improper industry or political influence, and if not, will HHS OIG agree to do so?
4. In what capacity did officials at HHS know John Clerici before they were appointed to or hired by the agency, and how many contracts were awarded to clients of Mr. Clerici's? Did Dr. Kadlec or others in his office violate ethics standards for federal employees, which prevent an employee from using their public office for the private gain of a "friend?"²¹ Did Mr. Clerici or Mr. Kadlec engage in practices that violated the Federal Acquisition Regulation, or did they direct others to do so? If you do not currently know this information, will you commit to investigating these issues and answering these questions shortly?
5. Did Dr. Kadlec or any other individuals mentioned in the OSC complaint ever seek ethics advice regarding interactions with John Clerici or any of his clients, recuse themselves from government activities that were the subject of meetings or correspondence with John Clerici or any of his clients, or receive any ethics waiver to allow them to work on issues that were the subject of meetings or correspondence with John Clerici or any of his clients? Did Dr. Kadlec or any other individuals mentioned in the complaint ever pursue assistance from HHS ethics

²⁰ HHS' \$25M health security accelerator launches in 'pro-investment environment,' S&P Global, Retrieved at: <https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/44828880>

²¹ 5 CFR § 2635.702 Use of public office for private gain: "An employee shall not use his public office for his own private gain, for the endorsement of any product, service or enterprise, or for the private gain of friends, relatives, or persons with whom the employee is affiliated in a nongovernmental capacity, including nonprofit organizations of which the employee is an officer or member, and persons with whom the employee has or seeks employment or business relations."

officials to assess their impartiality in procurement decisions? Did any other HHS staff or officials formerly employed by a pharmaceutical company approach the OIG for assistance or to report allegations involving Dr. Kadlec or any other individuals mentioned in the OSC complaint?

We cannot put patients' lives at risk to boost the profits of large pharmaceutical companies. Their lobbying is no substitute for science-based public health. Thank you for your time, and I look forward to hearing from you.

Very truly yours,

A handwritten signature in blue ink that reads "Katie Porter". The signature is fluid and cursive, with the first name "Katie" and the last name "Porter" clearly distinguishable.

KATIE PORTER
Member of Congress