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ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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September 23, 2020

The Honorable Christopher Wray
Director, Federal Bureau of Investigations
FBI Headquarters
935 Pennsylvania Ave, NW
Washington, DC 20535-0001

Dear Director Wray,

We write to request a briefing from the Federal Bureau of Investigations (FBI) to provide more details on the FBI Bioterrorism Risk Assessment Group's (BRAG) approach to tackling the challenge of foreign influence on the Federal Select Agent Program (FSAP) and related research through the Security Risk Assessment (SRA) Program, established under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act, Pub. Law No. 107-18).¹ We are interested in the challenges faced prior to the pandemic and the adjustments since the May 2020 issuance of the updated SRA protocols during the COVID-19 pandemic.² The Bioterrorism Act prohibits a laboratory from providing an individual with access to dangerous select agents or toxins unless that individual has been approved by the Secretary of either the Departments of Health and Human Services (HHS) or Agriculture (USDA), based on an SRA.

Under the FSAP regulations (42 C.F.R. 73.10(g)), "an individual's access approval **will be denied or revoked** if the individual is within any of the categories described in 18 U.S.C.

¹ Department of Justice, Office of Inspector General, *Inspection of the FBI's Security Risk Assessment Program for Individuals Requesting Access to Biological Agents and Toxins*, I-2005-003, (March 2005) available at <https://oig.justice.gov/reports/FBI/e0503/final.pdf>

² U.S. Department of Health and Human Services, *Update on Processing Security Risk Assessments During the COVID-19 Pandemic Response*, Federal Select Agent Program (May 20, 2020) available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2006294012-hr-2020_sra_during_covid19_pandemic.pdf

175b” (definition of “restricted person”). In addition, under 42 C.F.R. 73.10(h), an individual’s access approval **may be** denied, limited, or revoked if the FBI identifies the individual as being reasonably suspected by any Federal law enforcement or intelligence agency for committing a crime as defined in Title 18 of the U.S. Code (U.S.C., 18 USC 2332b(g)(5)); knowing involvement with an organization that engages in domestic or international terrorism as defined in Title 18 of the U.S.C. (18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or being an agent of a foreign power as defined in Title 50 of the U.S.C. (50 U.S.C. 1801); or it is determined such action is necessary to protect public health and safety.

In the National Institutes of Health (NIH) FY 2021 budget document, NIH observed that the U.S. biomedical enterprise is made possible because the overwhelming majority of researchers participating in NIH grants, whether U.S. or foreign-born, are honest contributors. NIH properly recognized the importance of scientific collaborations, including those involving international institutions, to advance its mission. We strongly agree with NIH on these points.

Plans for ensuring FSAP and biomedical research program integrity and security is of great public interest and needs to be protected from intellectual property theft and undue foreign influence.³ As the largest funder of biomedical research in the world, the NIH research community faces significant exposure to risks related to undue foreign influence on research, with funding awarded to more than 300,000 researchers at more than 2,500 research institutions globally.⁴

According to a report by the Office of Inspector General for the Department of Justice, an SRA is valid for five years and fingerprints are re-run every three years.⁵ Research into information security for compliance with select agent regulations suggests that continuous monitoring of personnel would detect breaches of information that may not be otherwise revealed in a five year review.⁶

We would appreciate the FBI setting up a briefing for Minority Committee staff to provide more details about the SRA process and, to the extent possible, any assessments on the effectiveness of the screening. We would respectfully request a briefing by October 7, 2020, to cover the following questions:

1. What information is gathered specific to foreign influence and financial sponsorship and other grant funding received by the applicant?

³ *About NIH*, National Institutes of Health, available at <https://www.nih.gov/about-nih> (last visited Feb. 5, 2020); *Budget*, NAT’L INST. OF HEALTH, available at <https://www.nih.gov/about-nih/what-we-do/budget> (last visited Feb. 5, 2020).

⁴ *Id.*

⁵ Department of Justice, Office of Inspector General, *Inspection of the FBI’s Security Risk Assessment Program for Individuals Requesting Access to Biological Agents and Toxins*, I-2005-003, (March 2005) available at <https://oig.justice.gov/reports/FBI/e0503/final.pdf>.

⁶ Lewis, et al. Vol 13, No. 3, 2015 Information Security and Select Agent Research available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4486445/pdf/hs.2014.0090.pdf>

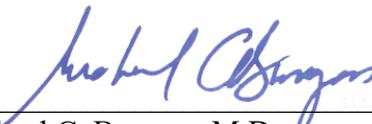
2. Per calendar year, of completed SRAs, please provide how many were granted eligibility for unrestricted access, how many were canceled or withdrawn, and how many were designated as restricted persons?
3. Have an increased number of SRA's been received since the pandemic?
4. When BRAG determines an applicant is a restricted person or when that determination is appealed, how does BRAG coordinate information sharing with other federal agencies?
5. What are BRAG's efforts to address ongoing concerns related to undue foreign influence on biomedical research involving access to federal select agents?

Your assistance is greatly appreciated. Should you have any questions, and to schedule the requested briefing, please contact Alan Slobodin or Diane Cutler of the Minority Committee Staff at (202) 225-3641.

Sincerely,



Greg Walden
Republican Leader
Committee on Energy and Commerce



Michael C. Burgess, M.D.
Republican Leader
Subcommittee on Health



Brett Guthrie
Republican Leader
Subcommittee on Oversight and
Investigations