

Report on Research Compliance Volume 16, Number 10. October 01, 2019 In Uptick in Prosecutions, Three PIs Face Charges for Over Foreign Support, 'Theft'

By Theresa Defino

As far as the public could tell, August and September weren't very good months for research integrity or, apparently, the appropriate handling of grant funds. The U.S. government recently announced not one but three criminal indictments of principal investigators (PIs) who received NIH and National Science Foundation (NSF) funding.

This rare trio of cases highlights historical concerns over misspent funds, but also cast unwanted attention on the confounding and troubling threat of foreign influences in the research enterprise, which is implicated in one of the cases.

The PIs at issue—two of whom, coincidentally, are from New York state—have pleaded not guilty. Alleged illegal acts by the PIs include testing out equipment made by a company that was also surreptitiously compensating the researcher (including via the purchase of a car) at the same time the firm was also billing the state, creating a shell company to funnel cancer research funds, and secretly pledging to work full time at a Chinese institution while employed at a U.S. one.

At least one expert tells *RRC* the cases reflect heightened attention by law enforcement and Congress, and warns that institutions must respond appropriately when internal concerns arise, as not doing so can lead to costly whistleblower complaints.

"Several factors" have altered the landscape "for federal awardees, and oversight is expanding," said Valerie Bonham, a partner with Ropes & Gray LLP. Among them is the changing rhetoric about the importance of integrity. "Participants who see something wrong have more encouragement from the NIH to raise their concern," she said.

Concerns about foreign influences are continuing to surface in Congress, she added. Most recently, the Senate appropriations committee's HHS fiscal year 2020 bill calls for NIH to "implement a broad education campaign about the requirement to disclose foreign sources of funding and develop enhanced cybersecurity protocols," and to further "evaluate the peer-review system and their internal controls through a lens that takes into account national security threats."

Ignored Employees Have Options

The bill also directs NIH to strengthen its work with the HHS Office of National Security and to dedicate \$5 million toward this effort. These indicate that "the focus on conflicts of interest and problematic foreign affiliations will likely widen," said Bonham.

She noted that "increasingly sophisticated tools to identify and track problems in data collection or reporting, or in grant applications and collaborations, [make improprieties] much harder to hide." At the same time, "employees and colleagues who see something they think is wrong, especially if they feel that their concerns are

not being adequately addressed by leadership, can turn to remedies like the False Claims Act, which can include big payouts if successful," Bonham added.

The HHS Office of Inspector General (OIG) has also recently sought to raise awareness of the need for awardees to self-disclose conflicts of interest, as the University of Kansas did in one of the three new cases that have led to criminal charges against PIs ("HHS OIG Offers Guidance, Form to Encourage Grantee Self-Disclosure of Possible Wrongdoing," *RRC* 16, no. 8).

Details of the three criminal prosecutions follow.

The first of the three was announced on Aug. 16, involving Gerwin Schalk, 48, and was made by U.S. Attorney Grant Jaquith for the Northern District of New York, along with the state's inspector general and an HHS OIG representative. A criminal complaint was filed on Aug. 12; Schalk's initial appearance was the same day as the announcement. He was released "with conditions." The release document was not included in the online file, however. By agreement with Schalk, the government has 60 days from Sept. 9 to file an indictment against him.

The deputy director of the National Center for Adaptive Neurotechnologies, Schalk is also a research scientist employed by the state's Department of Health; he was hired in 1999, according to the indictment. He is listed alternatively as a PI, co-investigator, deputy director, and project leader on four HHS and one U.S. Army award from 2002 to June 30 of this year.

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