After $5.5M FCA Settlement, Institutions Face Bigger Risks for Mishandling Foreign Support

By Theresa Defino

Acting with “deliberate ignorance” and “reckless disregard” are not words that any institution wants to hear associated with its name. But these are at the heart of allegations—now settled—the federal government made against Van Andel Research Institute (VARI), which recently became the first organization to feel the financial sting of a crackdown on inappropriate or nondisclosed foreign involvement in U.S. research. Previously the government has pursued only investigators, and those cases have been rare.

VARI agreed to pay the Department of Justice (DOJ) $5.5 million to resolve allegations that nondisclosures and omissions violated the False Claims Act (FCA). Of the $5.5 million, slightly more than half is restitution and the balance is penalties. Of note: the government specifically called out VARI’s use of a consultant, which it said gave wrong information about what was required to be disclosed.

The independent research institution in Grand Rapids, Michigan, did not admit to wrong-doing, and in its settlement agreement, DOJ argued only that the organization repeatedly failed to disclose recent employment and other support that two now-former researchers had with Chinese entities. Unlike with other FCA settlements, it did not, for example, allege fraud in the conduct of funded research or inappropriate spending of federal funds.

The settlement serves as a reminder—and a warning—to institutions. Not only should they take steps to ensure they are compliant with NIH’s disclosure
requirements, they also may need to consider beefing up training, according to Valerie H. Bonham, a partner with the law firm of Ropes & Gray LLP.

In a statement to RRC, VARI said it cooperated with DOJ’s “civil investigation related to the filing of certain administrative reports and communications” associated with NIH grants. The settlement “is in the best interest of the Institute,” it said, and has “no connection to the quality of the Institute’s science or the validity of our research findings.”

VARI officials added that they “greatly value the support and external scientific review provided by [NIH] as we work to impact human health, and we remain committed to ensuring that our processes meet funding disclosure and NIH requirements.” VARI did not respond to RRC’s request for comments on actions it had taken in light of the settlement nor on what it has learned from this experience that it could share with others.

Several Types of Disclosures Required

Several disclosure requirements come into play for awardees. They must document and disclose to NIH “other support, foreign components, and financial [conflicts of interest],” as the agency pointed out in a July 2019 “reminder.”

Other support, under NIH policy, includes “all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant. This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, financial support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.).”

Regarding foreign support, an awardee that “determines that a portion of the project will be conducted outside” the United States “then will need to determine if the activities are considered significant. If both criteria are met, then there is a foreign component.”

At issue is VARI’s handling of disclosures regarding Huaqiang Eric Xu and Jiyan Ma, who VARI told RRC have resigned, although it did not say when. They did
not respond to RRC’s request for comment. Xu and Ma’s research interests were different, and their cases do not appear to be related other than they both received support from China.

Among other affiliations at Van Andel, Xu was with its Center for Cancer and Cell Biology and Center for Structural Biology and Drug Discovery. He joined Van Andel in 2002.

**DOJ: Work Performed Outside the United States**

Ma studied Parkinson’s disease, prion disease, protein aggregation in neurodegenerative diseases, prions, and pathogenesis of neurodegenerative diseases, according to his website, which was still up as of RRC’s deadline. Ma had been with Van Andel since 2012.

DOJ contended the issues relate to grant applications and progress reports from Jan. 1, 2012, and continued until Aug. 1, 2019, related to one NIH grant each for Xu and Ma. DOJ said VARI “did not include or omitted foreign funding that Drs. Xu and Ma received in direct support of their research endeavors” and “did not include or omitted significant scientific elements or segments of the Xu and Ma grants that were performed outside the United States.”

Further, DOJ alleged VARI made false statements to NIH on or about Dec. 21, 2018.

Regarding Xu specifically, DOJ said between Jan. 1, 2012, and Dec. 31, 2018, he received “grants and other research support from a variety of Chinese sources” that were in direct support of his “research endeavors,” and thus should have been disclosed as “other support” to NIH.

The award DOJ cited is R01GM127710; according to NIH’s database of awards, this was for “structural and functional studies of rhodopsin and G-protein coupled with receptor kinases.” Xu’s NIH funding from 2018 to 2019 was a total of $731,500. His previous NIH awards, dating back to 2005, total more than $7 million, according to the database.

**VARI Formed Center With Shanghai Institute**
This support at issue was not disclosed to NIH even though VARI “was aware” of Xu’s “Chinese affiliations,” DOJ said, adding that VARI “did not take steps to further investigate Dr. Xu’s foreign funding sources, nor confirm the veracity of Dr. Xu’s statements.”

As proof of VARI’s knowledge, DOJ said the institute received a letter in August 2010 stating that Xu had “been awarded” by China’s Thousand Talents Program, and a month later, VARI itself entered into a “strategic collaboration” with the Shanghai Institute of Materia Medica to form the VARI–SIMP Center for Drug Discovery, with Xu as the principal investigator and director.

According to DOJ, “it was known that Dr. Xu would apply for grants in China for work to be done at SIMM.”

Although DOJ is faulting VARI for not disclosing these relationships to NIH, DOJ said Xu had made some disclosures internally, but perhaps not after 2017.

According to the settlement, from 2013 to 2017, Xu reported his affiliation with VARI–SIMP Center for Drug Discovery and “associated remuneration in excess of $10,000 on internal” VARI disclosure forms.

**Did Consultant Steer VARI Astray?**

From June 2018 to March 2019, VARI “failed to disclose certain of the Xu Chinese grants,” including as part of a Dec. 21, 2018, research project report.

DOJ alleged VARI learned about the Chinese grants in June 2018 when reviewing a news release in advance of a paper Xu was publishing, as the awards were apparently included as “funding attributions.” VARI deleted the references in the release, instead of “inquiring further as to the scope or the sources of Dr. Xu’s foreign funding, and rather than determining whether any of the grants listed in the press release required disclosure to NIH,” according to the settlement.

It was just two months later when significant concerns about foreign influences in research came to light in the form of a congressional hearing and a letter[4] from NIH Director Francis Collins to all awardees asking that they ensure compliance with reporting foreign support. On Nov. 30, 2018, NIH sent
VARI a letter “relating specific concerns about potential noncompliance involving Dr. Xu.”

But in a Dec. 21, 2018, response, DOJ said, VARI told NIH that “disclosure was not required because, among other things, ‘there was no undisclosed overlap of any resources, commitment, or scientific endeavor’ between the Xu Chinese Grants and the Xu NIH Grants.”

According to DOJ, VARI relied on “advice from an outside consulting firm” in making that determination.

Yet, DOJ believed that VARI “does not know whether that statement was, or is, accurate, and acted with deliberate or reckless disregard for the truth in making that representation to NIH.”

On the same day as it sent the letter saying disclosure wasn’t required, DOJ contends that VARI falsely stated in progress documents that there had been no changes to report.

**Thousand Talents Program Cited**

The scenario involving Ma is much less detailed in the settlement. It is not clear how Ma came to NIH’s attention, and it is not known whether the agency ever sent VARI a letter requesting it look into his arrangements.

The settlement states only that at some time between Jan. 1, 2017, and Dec. 31, 2018, Ma “received a grant from a Chinese source”; no dollar value is included, nor is there any mention of the Thousand Talents Program. DOJ alleges the grant, however, was “in direct support of Dr. Ma’s research endeavors and constituted ‘Other Support’ that VARI was required to disclose.” Thousand Talents is a Chinese-government-backed recruitment effort.

DOJ also charged that VARI, like with Xu, acted with “deliberate ignorance or reckless disregard” by submitting false just-in-time documents and research reports that did not reveal the Chinese funds as either “other” or “foreign” as required, in connection with the one award.

The award DOJ cited for Ma is 1R01NS110784-01, the study of “immunological approaches to prion disease,” for $563,981 from the National Institute of Neurological Disorders and Stroke. Funding was for fiscal year 2019.
However, Ma previously received at least $4.5 million from NIH for research into synthetically generated mammalian proteins, dating back to 2008 when he was at Ohio State University. The award was transferred to Van Andel in 2013.

VARI, DOJ maintained, “did not take adequate steps to investigate whether Dr. Ma was performing significant elements or segments of NIH-funded research outside of the United States” and did not “take steps to further investigate Dr. Ma’s foreign funding sources...despite being aware of one of Dr. Ma’s Chinese affiliations.” DOJ did not say what that affiliation was or how it knew the VARI was aware of it.

In announcing the settlement, Andrew Birge, U.S. attorney for the Western District of Michigan, said FCA penalties are “harsh by design. I sincerely hope the word gets out on the importance of full disclosure with the government.”

Lamont Pugh III, special agent in charge of HHS’s Office of Inspector General’s Chicago region, said OIG “will continue to investigate allegations of failures to properly report information to ensure the integrity of Departmental programs.”

**Bonham: Time for ‘Self-Examination’**

The time is over to plead ignorance of these problems, said Bonham, who offered three key takeaways from VARI’s ordeal.

“First, institutions should be reviewing their existing policies to make sure they are consistent with NIH’s current thinking regarding ‘other support,’ financial conflicts of interest, and ‘foreign components.’ U.S.-based universities and medical centers need to consider proactive education and training activities for their faculty about the changing landscape of ex-U.S. collaborations and about the ‘foreign influence’ issue more generally,” Bonham said.

“Second, institutions should communicate effectively their concurrent commitments to legal compliance, nondiscrimination, and scientific collaboration,” she added. “Third, institutions should consider self-examination of possible risk areas. This could include existing foreign collaborations, or processes for orienting and vetting visiting scholars and new post docs, for example.”
In its news release, DOJ also gave a nudge to institutions about reporting what they find.

Institutions “concerned about a prior statement on a grant application should know that it is Department of Justice policy that entities or individuals that make proactive, timely, and voluntary self-disclosures to the Department about misconduct will receive credit during the resolution of a False Claims Act case,” the release states.

Said Bonham: “At this point in time, with all of the education and outreach efforts of the NIH and the many media reports about these issues, it is difficult for an institution to suggest that its leadership remains unfamiliar with the risks, applicable laws and policy requirements.”


