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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^[1] 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.^[2]

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).^[3] 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.

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