

## Report on Research Compliance Volume 18, Number 9. August 26, 2021

### 'Dr. Zheng Did Not Disclose Any of This'

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By Theresa Defino

As requested by NIH in April 2020, Ohio State University dug into the affiliations of Song Guo Zheng, MD, PhD, hired barely a year earlier as chair of OSU's Division of Rheumatology and Immunology in the Department of Internal Medicine.

Penn State University, where Zheng had previously worked, notified NIH that it received an anonymous tip he had secret foreign affiliations and support. In November 2020, Zheng pleaded guilty to making false statements, agreed to repay nearly \$4 million, and is now appealing his 37-month prison term—imposed May 14.<sup>[1]</sup>

According to most measures, Zheng's case moved fairly quickly through the court system; he was arrested May 22, 2020, less than a month after Michael Lauer, NIH deputy director for extramural research, made NIH's investigative request to OSU.

By that fall, OSU was ready to share the results of its investigation, which Morley Stone, OSU senior vice president for research, did in an Oct. 9, 2020, letter back to Lauer. Although marked confidential, RRC obtained the 47-page document, which includes 20 exhibits, from the publicly available case file. Stone's response provides a rare and revealing look into how an institution could conduct such an investigation, the steps taken along the way and the type of findings that might be expected.

Of note: OSU said in other court documents that responding to government inquiries in this case cost nearly \$500,000, and part of Zheng's plea agreement requires him to pay for it, along with restitution to NIH.

OSU officials were "not aware of how much compensation or remuneration Dr. Zheng has received through the various external academic, grant, Talent Program, and commercial entities" they uncovered, but Stone said in his letter that "we understand that these types of relationships typically include personal financial compensation as well as other kinds of research."

Lauer asked OSU to "review compliance with [NIH] policies on Other Support, Foreign components, Financial Conflicts of Interest, and affiliations on two active NIH awards" for which Zheng was the principal investigator (PI), according to Stone's response. OSU additionally investigated his two subawards, from the Medical College of Wisconsin and from the University of Utah.

Stone wrote that OSU "performed an extensive review of Dr. Zheng's research activities on the questioned grants," and that this had revealed a host of "engagements [that] are on-going, however, it appears almost all (as noted) predate his employment at Ohio State."

He also pointed out that "Dr. Zheng did not disclose any of this information to the university before and during his employment at Ohio State."

### **Appointments, Funding, Patents, Papers**

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OSU uncovered the following related to Zheng:

- “Affiliations with at least five foreign entities to include: employment as a Professor at Third Affiliated Hospital, Sun Yat-sen University; Adjunct Professor at Fudan University and Haushan Hospital Affiliated with Fudan University; Director, Fudan University Institute of Rheumatology, Immunology and Allergy; Research Team Instructor at ‘Zheng Songguo Expert Work Station’ Qujing No. 1 Hospital; and Distinguished Professor, Guilin Medical University.
- “Evidence that Dr. Zheng has previous and/or current participation in numerous People’s Republic of China (PRC) foreign government talent recruitment programs, including in the Sun Yat-sen University’s Hundred Talents Program.
- “Evidence of numerous foreign funding awards to Dr. Zheng including: two active NNSFC [National Natural Science Foundation of China] awards (81671611, 81871224) that are on-going; two NNSFC awards (31200678, 30728007) that have ended since Dr. Zheng’s employment at Ohio State; a National Key R&D Award (2017YFA0105800) that appears to be on-going; and a Program for Guangdong Introducing Innovative and Entrepreneurial Teams award (2016ZT06S252) that we cannot confirm is active.
- “Evidence of fifteen Chinese patents that list ‘ZHENG Songguo’ as an applicant or inventor. We cannot conclusively determine that they are all associated with Dr. Song Guo Zheng from Ohio State. However, many of the patents also list co-inventors who are known associates of Ohio State’s Dr. Zheng.
- “Evidence that Dr. Zheng has equity interests or holds/held key positions in a number of PRC-based companies including as Chief Scientist at Guangdong Vitalife Biotechnology Co. Ltd.
- “Through a search of the PRC corporate registry for ‘ZHENG Songguo’ we have identified possible affiliations with five to ten PRC based companies. As with the Chinese patents, there is insufficient evidence or available public information to determine if all of these correspond to Ohio State’s Dr. Song Guo Zheng but there is circumstantial evidence supporting his association based on the research area and geographical locations of the companies. One of the associations (Zhuhai Zhongjing Tairuige Biotechnology Co. Ltd.) appears to have been initiated during Dr. Zheng’s employment at Ohio State.
- “Evidence of at least eleven unapproved Foreign Components, primarily consisting of research collaborations based at Sun Yat-sen University.
- “Evidence of at least sixteen instances of items/resources including foreign funding that should have been reported as Other Support.”

Regarding publications, a search “from 2019 to the present” turned up 26 publications Zheng authored in 2019 and 2020. On these he only listed OSU. “However, before Dr. Zheng came to Ohio State, it appears that he frequently listed a joint affiliation,” according to Stone. “We located 23 publications in which Dr. Zheng stated that he was affiliated with both his domestic institution—then, Penn State—and the Third Affiliated Hospital of Sun Yat-sen University.”

## **Review Team Included Attorneys in China**

OSU undertook the review with help from outside the institution—but officials “were not able to interview Dr. Zheng. Therefore we had to rely solely on publically (sic) available information and our own limited internal records to conduct our review,” Stone’s letter said.

Its internal team included representatives from OSU “Offices of Research, Compliance and Integrity, Technology Commercialization, and Legal Affairs, as well as individuals from the university’s College of Medicine,” according to Stone. OSU also hired the Boston-based law firm Ropes & Gray LLP, whose employees in its China offices conducted some of the work.

OSU also reviewed “limited documentation provided by Dr. Zheng” and undertook an “extensive review of publications, grant applications, progress reports, and conflict of interest disclosure[s].”

It also did a “targeted search of e-mails for references to talent recruitment programs and other relevant search terms,” such as Sun Yat-sen University. Stone said officials searched using “key words in English and Mandarin,” provided by Patricia Valdez, NIH’s extramural research integrity officer.

Ropes & Gray staff in China also conducted a “media review, company and patent search in China,” and provided Chinese language translation services.

## **No Disclosures Despite Explicit Questions**

Zheng, Stone wrote, had numerous, regular and mandatory opportunities to report these outside interests—which he should have been aware of, given he had been an NIH awardee “for more than 10 years.”

“He did not provide disclosures required during the process to transfer NIH awards from Penn State to Ohio State, nor did he disclose during progress reporting on these awards while he has been at Ohio State,” Stone said.

These failures were not for lack of knowledge, Stone argued, as Zheng “completed various required training courses as part of his onboarding process, including the national CITI [Collaborative Institutional Training Initiative] online course for the responsible conduct of research with a specific module on conflicts of interest.”

He also noted that “Dr. Zheng took the CITI training in February 2019, on the exact same day he completed his 2018 eCOI [electronic conflict of interest] disclosure. In April 2019, he received email notifications directing him to disclose all foreign affiliations.”

Zheng completed three eCOI disclosure forms prior to his arrest and never included the activities OSU discovered. This came even after instructions were expanded in 2019 to require “disclose foreign positions, affiliations, or entrepreneurial activities,” said Stone.

## **Lab Closure Cost 7 Their Jobs**

Stone also described the timeline of events following receipt of Lauer’s letter.

On May 1, 2020, according to Stone, OSU “physically secured all of Dr. Zheng’s office and research spaces by changing the locks without notifying Dr. Zheng or his lab members that this was occurring.”

Five days later, “Dr. Zheng and his lab members were asked to come to campus and each was notified of the concerns received, and provided notice of the university’s investigation. Dr. Zheng was reassigned off-campus and his laboratory staff were all placed on administrative leave. Immediately prior to meeting with Dr. Zheng, his electronic access to university research services and locations was suspended and Dr. Zheng’s university electronic devices were sequestered and imaged,” Stone wrote. Zheng was later terminated.

Also on May 6, OSU suspended Zheng’s NIH grants, meaning that “no billing, draw down, purchasing or new appointments” could be made. Working with NIH, the awards were transferred to a new PI “to complete the research projects.”

With the closing of Zheng’s lab, five research staff resigned, Stone said, and “the remaining two research staff were terminated through a reduction in force and their employment ended on August 31, 2020.”

Stone concluded his letter to Lauer with a pledge and a request.

“We continue to work on policies and procedures to strengthen and improve our COI process and welcome feedback from NIH on other best practices that we should be considering,” he wrote.

1 Theresa Defino, “First Jail Term for Undisclosed Foreign Support Appealed; NIH’s Lauer Laments ‘Tragic’ OSU Case,” *Report on Research Compliance* 18, no. 9 (September 2021).