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By Theresa Defino

◆ **Nearly a decade after irregularities were first noticed in clinical trials that ultimately led to a misconduct finding and a guilty plea for embezzlement, the HHS Office for Human Research Protections (OHRP) has closed its books on its investigation related to Alexander Neumeister, M.D.,** formerly a psychiatry and radiology professor at New York University (NYU) Grossman School of Medicine. The lengthy March 21 closeout determination letter from OHRP to Imad Alsayed, NYU vice president of clinical research operations and regulatory affairs, doesn't identify Neumeister but notes that the Office of Research Integrity (ORI) made a "determination" in the case on Jan. 7, 2020. On that date, ORI published an announcement that Neumeister agreed to exclude himself from government-funded programs for two years effective Dec. 13, 2019, for "intentionally, knowingly, and/or recklessly falsifying and/or fabricating data in the clinical records of research supported by six (6) NIMH [National Institute of Mental Health] grants, resulting in the inclusion of falsified and/or fabricated research methods and results in four (4) published papers." Neumeister agreed to the sanction but did not admit to the misconduct.

The letter appears to be the first public acknowledgement that OHRP was aware and deeply involved in issues related to Neumeister, particularly long before he was the subject of a scathing story in *The New York Times* in 2016. OHRP's letter describes a process that started with a not-for-cause evaluation begun in May 2014 but which expanded to a site visit after NIMH "informed" OHRP of concerns related to six NIMH-funded studies and that the principal investigator had been placed on leave "due to significant irregularities in his management of certain research projects." *The New York Times* later revealed that NYU had "quietly shut down eight studies at its prominent psychiatric research center and parted ways with a top researcher after discovering a series of violations in a study of an experimental, mind-altering drug." The letter notes that the investigator had reported "deviations" that had occurred with a study in June and July 2013. During the ensuing years, NYU conducted various audits and investigations of Neumeister and corresponded with OHRP numerous times, most recently in September 2020; it is not clear whether OHRP ever imposed sanctions on NYU for noncompliance. OHRP said that NYU had updated its policies and procedures, "strengthened its general human subjects training requirements," and taken a number of other actions, including expanding its "internal audit capacity by creating a central administrative office known as Human Research Regulatory Affairs." Prior to Neumeister's misconduct finding, he pleaded guilty to "theft of government funds" and "admitted stealing $87,000 from New York University and various grant programs from 2012 to 2014." Neumeister was "required to repay $76,000 after stealing money while he was at Yale from 2004 through 2010, though that was not part of the criminal case resulting in his plea," the Associated Press reported in October 2018. Although he faced jail time, Neumeister was sentenced to play piano at various indigent care centers at least twice weekly for three years in Connecticut. (4/14/22)

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