



May 18, 2018

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Via email: secretary@hhs.gov

Re: Investigation into the failure disclose NIH funding in inventions patented by the University of Pittsburgh for flutemetamol F 18),

Dear Secretary Azar:

We are writing to ask the Department of Health and Human Services (HHS) to investigate and if applicable, to remedy a failure to disclose National Institutes of Health (NIH) funding in four inventions patented by the University of Pittsburgh. The four inventions are identified in the FDA Orange Book as patents for Vizamyl (INN flutemetamol F 18), used to evaluate possible cases of Alzheimer's disease or other causes of cognitive decline. Access to the tests is currently restricted, including restrictions on reimbursements by Medicare.

Knowledge Ecology International (KEI) asks that HHS take title to the four patents. The legal basis for the proposed remedy is set out in the attached memorandum, *Bayh-Dole Obligations to Disclose Federal Funding in Patented Inventions*.¹ One of the possible remedies for non-disclosures, as set out in 35 U.S.C. § 202(c)(1) and 37 C.F.R. § 401.14, is for the federal government to take possession of the patent title.

We believe this is an egregious case of non-disclosure. The same three inventors are listed for each of the four patents. Collectively they were the principal investigators in NIH grants involving more than \$66 million.

- According to the NIH RePORTER database, from 1988 to 2018, William Klunk was the principal investigator for grants obtained from the NIH consisting of 52 projects, 35 sub-projects and a total funding amount of \$47,209,483.

¹ Bayh-Dole Obligations to Disclose Federal Funding in Patented Inventions. KEI Briefing Note: 2018:1. Andrew Goldman. Revised March 16, 2018.

- From 1986 to 2018, Chester A. Mathis, Jr. received NIH grants consisting of 31 projects and 12 subprojects with a total funding amount of \$14,936,292.
- From 2003 to 2013, Yanming Wang was listed as the principal investigator for 19 NIH projects involving \$4,116,038 of funding.

This actually understates the amount of federal funding involved, since the inventors have also received NIH research contracts and funding from the Department of Energy for this research.

The inventors have made references to NIH and DOE funding of their work in papers describing the inventions, but did not report the grants on the patents, and the patents do not appear in the NIH RePORTER database.

The patents were subsequently licensed to GE Healthcare. We believe the public interest would be served if the patents were licensed on a non-exclusive basis, permitting more competition in the use of the inventions, resulting in greater innovation and lower prices. Lower prices for flutemetamol F 18 may expand access to the test, which, as Medicare describes, “may be clinically useful in the work up and management of patients with cognitive impairment who are being evaluated for possible Alzheimer’s disease or other causes of cognitive decline.”²

Finally, we note that this one of several letters we have sent to the HHS and/or the NIH, regarding failure of NIH grant recipients to disclose federal funding. We are still waiting to hear the conclusions of investigations regarding Cold Spring Harbor patents on nusinersen (trade name Spinraza), the Pharmasset/Gilead patent on sofosbuvir, the Dana Farber Cancer Institute patents on midostaurin (Trade name Rydapt), multiple institutions’ (including an NIH-funded project at a foreign university) patents on Exondys 51, and the University of Pennsylvania patents on Lomitapide (trade name Juxtapid). We are making these inquiries as a public service, to ensure the public has the opportunity to benefit from the safeguards and public interest provisions in the Bayh-Dole Act, including the obligation by patent holders to make the inventions available to the public on reasonable terms, the ability of the NIH to ensure broad use of inventions for research purposes, and the requirements in the Bayh-Dole Act for domestic manufacturing of products, among other requirements.

Sincerely,



James Love, Director, KEI
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² <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Amyloid-PET.html>

Attachments

1. Vizamyl (INN flutemetamol F 18): Failures to disclose NIH funding for four patents in the FDA Orange Book invented by William Klunk, Chester Mathis, Jr., and Yanming Wang, and assigned to the University of Pittsburgh. Knowledge Ecology International, May 18, 2018.
2. KEI-Briefing-Note-2018-1

Cc:

Dr. Francis Collins, Director, the National Institutes of Health: Francis.Collins@nih.hhs.gov

The Honorable Daniel R. Levinson, Inspector General, Office of Inspector General (OIG), HHS, Dan.Levinson@oig.hhs.gov

Ann M. Hammersla, J.D., Director, Division of Extramural Inventions and Technology Resources
Office of Policy for Extramural Research Administration, hammerslaa@od.nih.gov

Rep. Tom Cole, Oklahoma, Chairman, Labor, Health and Human Services, Education, and Related Agencies, Committee on Appropriations, House of Representatives.

Rep. Rosa DeLauro, Connecticut, Ranking Member, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, Committee on Appropriations, House of Representatives.

Roy Blunt, Chair, Labor, Health and Human Services, Education and Related Agencies, Committee on Appropriations, U.S. Senate

Patty Murray, Ranking Member, Labor, Health and Human Services, Education and Related Agencies, Committee on Appropriations, U.S. Senate