

CASE STUDY | DR. P. TREY SUNDERLAND III

## **\$508,050 From Pfizer, but No 'Outside Positions to Note'**

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**BETHESDA, Md. — While reviewing financial disclosure reports from scientists at the National Institutes of Health, ethics officer Olga Boikess noticed that Dr. P. Trey Sunderland III had not declared any jobs with industry.**

**In an e-mail sent in March 2000, Boikess told Sunderland: "You did not list any outside positions."**

**Sunderland, a leading NIH psychiatric researcher, replied: "I do not have any outside positions to note."**

**In fact, Sunderland had been paid \$77,000 in consulting and speaking fees the previous year by Pfizer Inc., now the world's biggest drug company, according to company documents. Between 1998 and 2003, Pfizer paid him \$508,050. He did not seek approval to work for Pfizer, and he did not report any of the income to the NIH, as required by agency rules.**

**Pfizer's payments to Sunderland and his failure to follow the NIH's reporting requirements were described at a congressional subcommittee hearing in June.**

**Subsequent interviews and government and company documents examined by the Los Angeles Times — including the e-mail exchange with the ethics officer — show that Sunderland's paid efforts for Pfizer often overlapped with his NIH role.**

**Sunderland took the fees from Pfizer at the same time that he led an NIH study of Alzheimer's patients in which the company collaborated.**

**He also endorsed use of Aricept, Pfizer's drug for Alzheimer's, during a televised presentation at the NIH in 2003. Sunderland did not tell the audience about his affiliation with the company.**

**Sunderland, 53, is one of the nation's leading researchers on Alzheimer's, the**

malady that causes dementia in approximately 10% of people over age 65.

He joined the NIH in 1982 after earning an undergraduate degree at Harvard University and a medical degree at George Washington University. As chief of the geriatric psychiatry branch at the agency's National Institute of Mental Health, he has focused on finding ways to detect the disease before a patient develops pronounced symptoms.

Pfizer, along with a corporate partner, Eisai Inc. of Japan, stands to gain billions of dollars in sales from early stage treatment of Alzheimer's. The companies jointly market Aricept, which is approved for treating the symptoms of mild to moderate Alzheimer's. The once-a-day pill generated worldwide sales of \$1.6 billion last year, making it the top-selling Alzheimer's drug.

Sunderland also consulted for Eisai from 1999 to 2003, according to information newly provided to the NIH by Sunderland's attorney. Sunderland's income from Eisai was not reflected in documents that the NIH turned over to Congress this year.

Government and company documents show that Sunderland teamed up with Pfizer in both his government and his private roles beginning in 1998. He worked for the company as a paid consultant — and at the same time led his NIH laboratory in an official research collaboration with Pfizer.

While the NIH allows many forms of moonlighting, the agency forbids its scientists from accepting income from a company that is collaborating with their government laboratory.

The policy seeks to protect the independence of the labs and is consistent with federal law, which prohibits employees from being paid by an outside party for performing government work.

The results of the NIH-Pfizer collaboration, announced in April 2003, underscored the promise of early detection of Alzheimer's. An NIH news release quoted Sunderland, who said such diagnoses "could point to new possibilities for preventive" drugs.

The news release did not mention that Sunderland was a paid consultant to Pfizer.

Investigators at the NIH director's office are assessing whether to refer Sunderland's conduct to the inspector general at the Department of Health and Human Services, documents show.

Sunderland declined to answer questions submitted to him for this article.

Sunderland's attorney, Robert F. Muse, said in recent letters to the NIH that his client had not intentionally ignored any rules.

**"Dr. Sunderland deeply regrets that he did not pay more attention to the forms that are now the subject of this review," Muse wrote. "But this lack of attention to outside activity reporting does not justify an inference that he was hiding his outside activities or that a conflict of interest existed."**

**Sunderland began his research of Alzheimer's in the early 1980s by studying elderly patients who were recruited to the NIH Clinical Center, the world's largest facility for experimental medical treatment.**

**Several times a year, the patients returned to have their spinal columns tapped for samples of fluid. Sunderland and his staff would examine the samples for biological "markers" that might provide clues for selecting new treatments. By the late 1990s, Sunderland had collected samples from about 600 spinal taps.**

**In spring 1998, Pfizer joined the NIH in a formal research collaboration. The "material transfer agreement" called for Sunderland's staff to provide samples of the spinal fluid to Pfizer. The company in turn would share its analyses of the materials with the NIH.**

**Sunderland already was on Pfizer's payroll as a consultant, according to company and government records.**

**Within months, the company assigned Sunderland research that even more directly overlapped his government responsibilities. He was "to assist Pfizer in its program to study known markers of Alzheimer's disease," the records show.**

**Sunderland has repeatedly encouraged the use of Aricept and other drugs in its chemical class. At a number of points, he did not acknowledge his role with Pfizer, records show.**

**In 1998, he wrote two medical journal articles praising Aricept, which Pfizer and Eisai had just begun marketing to doctors in the U.S.**

**In one article, Sunderland wrote that Pfizer's drug "appears to be less toxic and better tolerated" than a competing medication. Using either Aricept or tacrine, he wrote, "provides modest significant symptomatic improvement in patients with mild to moderate Alzheimer's disease."**

**Neither article disclosed to its physician readers that Sunderland was a paid consultant to Pfizer. Sunderland's attorney has told the NIH that his client often acknowledged his affiliation with Pfizer when addressing physicians.**

**On April 15, 1999, Sunderland and one of Pfizer's chief researchers spoke together at an NIH conference, where an array of researchers, industry executives and federal regulators came to discuss new ways to develop drugs.**

**Sunderland's counterpart from Pfizer underscored the special value to the company of gaining access to the extensive spinal samples drawn at the NIH.**

**"I want to emphasize," said B. Michael Silber, Pfizer's director of genetics research, "that the beauty of what we're able to do as a partnership has really evolved because of Dr. Sunderland's ability to attract the kinds of patients to be followed in [long-term] studies ... and who are granting us the permission to be able to take samples from them."**

**Silber called the then-ongoing project with the NIH "a very exciting collaboration" that, if successful, would help Pfizer to decide which drugs to push toward "expedited review and approval."**

**Sunderland did not tell the crowd that he was a paid consultant to Pfizer.**

**From 2001 to February of this year, Pfizer also paid consulting fees totaling about \$64,500 to one of Sunderland's NIH staff, biostatistician Karen T. Putnam. Her attorney, David Schertler, said that based on a conversation with Sunderland, Putnam chose not to seek approval from the NIH to consult for Pfizer.**

**During recent questioning by NIH investigators, Sunderland said that he did not recall advising Putnam, according to a summary of the interview.**

**Sunderland was often on the road for Pfizer. From 1999 to June of this year, he appeared as a speaker for Pfizer at more than 80 domestic and international gatherings of doctors, documents show.**

**In July 2003, Sunderland also was coauthor of a report that urged the government and insurers to pay for more prescriptions for seniors with mood disorders, including Alzheimer's. Three coauthors of the report, published in Archives of General Psychiatry, listed their financial ties to Pfizer. Sunderland did not.**

**Pfizer and nine other drug companies helped pay for preparation of the report.**

**On Sept. 16, 2003, Sunderland delivered a public lecture at the NIH, "Alzheimer's Disease: Advances and Hope," during which he summarized his long-term work with the spinal fluids. The session was broadcast several times by C-SPAN.**

**A member of the audience asked Sunderland if he would object to a patient taking Aricept in combination with vitamin E "as an attempt at preventing or delaying possible onset of Alzheimer's."**

**Sunderland replied: "The quick answer is no. I have no problem with it." In fact, he said, "we're advocating" use of multiple medications simultaneously.**

**Again, Sunderland did not tell the audience about his paid role with Pfizer.**

**Sunderland also did not note that his comment on using Aricept for prevention exceeded the purpose for which the Food and Drug Administration approved the drug: treating symptoms of mild to moderate Alzheimer's.**

**Aricept and other drugs in its chemical class increase levels in the brain of a chemical that nerves use to communicate with one another. The drugs have not been proven to prevent or slow or halt the advance of Alzheimer's. On the other hand, doctors are permitted to prescribe drugs for any medical purpose they deem appropriate.**

**Dr. Russell Katz, who supervises the FDA's reviews of drugs for Alzheimer's, said in an agency newsletter last year that the compounds in Aricept's chemical class had "an effect on symptoms." But Katz added that the FDA had "no evidence that they have any effect on the underlying progression of the disease. During treatment, as far as we know, the nerve cells are still dying."**

**And there are side effects: At least 10% of patients who took Aricept in clinical trials suffered nausea or diarrhea — about double the rates of those given a placebo pill, according to Pfizer's data.**

**Muse, Sunderland's attorney, told the NIH in a letter this month that his client had not encouraged use of any Pfizer product "in an unbalanced way." Muse also has presented materials to NIH investigators showing times when his client acknowledged his ties to Pfizer and other drug companies at formal presentations to physicians.**

**"Several NIH administrators," Muse said in a letter to the agency on Aug. 31, also had known about Sunderland's role with Pfizer.**

**"Trey Sunderland has brought honor and distinction to the National Institutes of Health," Muse wrote. "His reputation with colleagues throughout the profession has been sterling. His leading role in the effort to tackle Alzheimer's disease is well recognized both nationally and internationally. His groundbreaking scientific work — and his effective communication of that work in a language that nonscientists can understand — represent the best that the NIH has to offer."**