Researcher received undisclosed payments of $300 000 from Pfizer

Jeanne Lenzer Boston

A federal research scientist working for the US National Institute of Mental Health (NIMH) pleaded guilty last week to a charge that he had not declared a conflict of interest to his employers.

Pearson “Trey” Sunderland III pleaded guilty to a misdemeanor charge that he failed to report about $300 000 (£150 000; €290 000) worth of consulting fees and expense payments from Pfizer. Under the plea agreement, Dr Sunderland will pay back the $300 000 to the federal government, and prosecutors say they plan to recommend that he also serve 400 hours of community service and be placed on probation for two years.

Dr Sunderland’s activities came under scrutiny when Susan Molchan, a former NIMH researcher, blew the whistle on him when she suspected that he had diverted samples of cerebrospinal fluid that she had obtained during a study of 25 subjects.

When Dr Molchan left the NIMH in 1997, the samples came under the control of Dr Sunderland. Dr Molchan became suspicious when in 2004 she tried to obtain some of the samples, but Dr Sunderland was only able to account for 2-3% of the cerebrospinal fluid that should still have been in storage. When Dr Molchan asked for the linked clinical data, Dr Sunderland told her that it had been purged because it was more than 5-7 years old.

Dr Molchan’s charges triggered a Congressional inquiry. A report issued by the House Committee on Energy and Commerce in June concluded that Sunderland had transferred more than 32 000 samples of cerebrospinal fluid and plasma to Pfizer.

According to the report, cerebrospinal fluid samples from 538 subjects, who participated in 14 studies at NIMH, were sent to Pfizer, including subjects from Dr Molchan’s study. The committee found that there were “reasonable grounds” to conclude that Dr Sunderland received compensation from Pfizer “for activities that were derived directly from his official acts in providing Pfizer access to spinal fluid samples… and linked clinical data and that Dr Sunderland used NIH employees and resources to provide such access.”

The samples were considered “extraordinarily valuable” because they were obtained at several points over a period of years. The samples were prized for their ability to aid in the identification of biomarkers in early Alzheimer’s disease.

Dr Sunderland also endorsed cholinesterase inhibitors, including donepezil (Aricept, Pfizer), as a treatment for Alzheimer’s disease in medical journal articles. For example, in the Journal of Clinical Psychiatry he wrote, “Donepezil, recently approved for use in mild to moderate Alzheimer’s disease, appears to be less toxic and better tolerated than tacrine,” again without explaining his financial ties to Pfizer (1998;59(suppl):s31-5).

The report also found that separate from his undeclared consulting fees with Pfizer, he received $311 150 in lecture fees between 1996 and 2004, for talks that were, the committee observed, “arranged by Pfizer’s marketing team charged with promoting Aricept.”

The report raised questions about the nature of informed consent from the human subjects who donated their tissue samples because most subjects, according to the report, were not told about the Pfizer “collaboration.”

The NIH did not respond to inquiries at this time.

The full version of this article is available at bmj.com.


Pfizer stops clinical trials of heart drug

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Pfizer, the world’s largest drug company, suddenly halted phase III clinical trials of torcetrapib on 2 December. Torcetrapib is a new agent that increases concentrations of “good” high density lipoprotein (HDL) cholesterol.

Only two days earlier, Pfizer executives had said that they hoped to ask the US Food and Drug Administration for approval next year.

Pfizer said that “in the interests of patient safety” it was stopping the clinical trials of torcetrapib (called Illuminate) because the independent data safety monitoring board found more deaths and cardiovascular events in patients taking the drug. The trials included 7500 patients who were taking a combination of torcetrapib and atorvastatin (marketed as Lipitor) and 7500 patients who were taking atorvastatin alone. There were 82 deaths in the group taking the combination, compared with 51 in the group taking atorvastatin.

The trial investigators were instructed to tell patients to stop taking the combination, and Pfizer also notified the FDA.


Pfizer began trials of torcetrapib in combination with atorvastatin, which inhibits the production of LDL cholesterol. In October, Joseph Falco, Pfizer’s chief medical officer, said that the combination increased HDL cholesterol by 55-60% and decreased LDL cholesterol by 50-60%.

On 30 November, John LaMattina, president of Pfizer Global Research and Development, said, “We are first in class, and we intend to remain best in class in a category that has the potential to change the face of cardiovascular medicine.”

Then Philip Barter, director of the Heart Research Institute in Australia and chairman of the steering committee overseeing the Illuminate study, told Pfizer that the data safety monitoring board had found higher mortality and morbidity in the torcetrapib-atorvastatin group and recommended ending the study. Dr Barter said, “We were very surprised by the information received from the DSMB [data safety monitoring board], the only body with access to the unblinded safety data. We believed the study was coming along as expected, and this new information was totally unexpected and disappointing; given the potential benefits of the drug.”

The company said it had invested about $800m over 15 years in developing the drug. After the announcement its shares fell about 10%.

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