

Cornell University scientists face charges of fraud

Researchers at Cornell University in New York are under investigation for allegedly enrolling inappropriate participants in research studies and filing false information on protocols with the US National Institutes of Health (NIH) to maintain government funding for a university research center.

A former researcher at the now-closed pediatric center accused the center's director of using the clinic to treat her adult patients and alleged that clinic staff double-billed the NIH and Medicaid for some patients, among other charges.

In response, the US Department of Justice and the NIH both launched investigations into research activities at the university's Children's Clinical Research Center. After a two-year inquiry, Cornell's Weill Medical College in July agreed to pay the federal government \$4.4 million to settle the charges levied by the US Attorney, the Justice Department's litigation arm, in New York City. As part of the settlement, Weill also agreed to cooperate in any subsequent investigations involving research center staff. Cornell did not admit to liability or wrongdoing in the settlement and, in its statement, noted that the case didn't involve "the quality or integrity of the research" and that none of the researchers was the subject of sanctions.

Kyriakie Sarafoglou, then a researcher at the center, first notified the NIH about problems at the center in 2003. Sarafoglou, now an assistant professor at the University of Minnesota, also

common to be presented to the United States **false or fraudulent claims** for payment in connection with (1) Grant No. 5M01RR006020 received by Weill Medical College from the United States Department of Health and Human Services (HHS) and the National Center for Human Genome Research (NCHGR), National Center for Human Genome Research, Division of Clinical Research, Genomics and Biotechnology, the Medicaid Program, Title XIX of the Social Security Act, U.S.C. § 1396, for physician services performed at the College's Children's Clinical Research Center ("CCRC").

2. The United States brings additional claims against Weill Medical College under the False Claims Act and under the common law for fraud, unjust enrichment and payment under mistake of fact.

fraud

payment under
mistake of fact

Cornell University has settled a lawsuit charging its researchers with false claims for payment.

filed a complaint with the Justice Department. The law allows whistleblowers like Sarafoglou to bring claims on behalf of the government and to share in any financial settlements.

In her complaint, Sarafoglou named Weill dean Antonio Gotto, and three administrators and seven physicians at the research center, including former director Maria New, a prominent pediatric endocrinologist. New has since left Cornell and works at the Mount Sinai School of Medicine in New York. Both Cornell and New say her departure was voluntary and New maintains that it was unrelated to the case.

After investigating Sarafoglou's complaint, the US Attorney in July added fraud and other charges, alleging that the center's staff made false statements in grant renewals and annual progress reports and included minimally

active or defunct protocols in grant renewal applications. Doctors at the center performed procedures on staff, never enrolled them in protocols and then charged the NIH for the services, according to the charges.

The complaint also says Weill allowed New to "dominate" use of NIH funds for her patients and protocols in violation of NIH guidelines. The NIH, which sponsors about 80 such research sites, limits individual researchers to using no more than 33% of a center's resources.

But when the US Attorney reviewed Weill's database on actual use, it found, for instance, that in 2003 the program director used 80% of inpatient resources and 67% of outpatient resources. "The case is being reviewed by the appropriate authorities and appropriate action will be taken," says NIH spokesperson Don Ralbovsky.

New declined to comment on the case details, citing the possibility of additional legal action. However, she noted that it is not unusual for a single researcher to exceed the guidelines barring them from using more than 33% of a center's resources. But NIH staff say the guidelines are taken "very seriously" and researchers may only exceed them with permission from the agency.

New remains in good standing at the NIH, retaining several grants. In 2003, she was one of eight scientists to be funded through a new Rare Diseases Clinical Research Network. "I have no explanation for this," says Sarafoglou. "It is perplexing."

Tinker Ready, Boston

New York's AIDS 'superstrain' could be two mediocre strains

Months after New York City public health officials announced the discovery of a so-called 'AIDS superbug,' scientists are exploring whether the unusual case is the result of a dual infection, in which a person contracts viral strains from two different people.

Detected in a homosexual man who used methamphetamine, the superbug rapidly progressed to full-blown AIDS and showed resistance to three antiretroviral drugs, features the officials said signaled an "extremely rare" and potentially treacherous strain. Scientists and activists have since criticized the announcement, saying it caused undue alarm before the case was fully understood.

Researchers at New York's Aaron Diamond AIDS Research Center (ADARC) in March reported that the individual had multiple sexual partners in a short period, combined with a dramatic spike in viral load in just two months (*Lancet* 365, 1031–1038; 2005).

But those factors could be the result of a dual infection, says Geoffrey Gottlieb, an

infectious disease expert at the University of Washington in Seattle. In a letter to *The Lancet* in June, Gottlieb suggested that the case warranted further investigation to rule out the possibility of dual infection (*Lancet* 365, 1923–1924; 2005). Two other letters in that issue also raised questions about the case.

Dual infections occur in less than 10% of new HIV cases and can result either from 'coinfections,' in which individuals contract separate viral strains before developing immune responses, or 'superinfections,' in which an HIV-positive person gets reinfected years after the first exposure. In both cases, infected individuals rapidly advance to AIDS.

In their response to the letters, ADARC researchers agreed with Gottlieb's suggestion (*Lancet* 365, 1924; 2005). "We cannot rule out the possibility of dual infection," wrote Martin Markowitz, ADARC's clinical director.

There are no commercial tests available to detect dual infections, and the cost of testing could set a research lab back by up to

\$5,000. Depending on the number of samples available, it could take researchers up to two months to complete the tests. If the New York scientists began testing the superbug after the *Lancet* letters, they might not yet know the results, but "if the researchers delved into [testing] right from February," Gottlieb says, "they'd know the results by now."

The health department and Markowitz remain tight-lipped, declining repeated requests for test details or when results might be expected. For now, Markowitz says, "the epidemiology of this case is being carefully addressed."

If the case turns out not to be the result of a dangerous new strain, it will weaken the accompanying public health warnings about safe sex and drug use, says Richard Jefferys, basic science and vaccine project director of the non-profit Treatment Action Group. "If there are issues around dual infection," he says, "I hope that they quickly reveal the work that they've done and explain exactly what is going on."

Paroma Basu, Madison