FDA launches criminal investigation into unauthorized herpes vaccine research

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The Food and Drug Administration has launched a criminal investigation into research by a Southern Illinois University professor who injected people with his unauthorized herpes vaccine, Kaiser Health News has learned.

SIU professor William Halford, who died in June, injected participants with his experimental herpes vaccine in St. Kitts and Nevis in 2016 and in Illinois hotel rooms in 2013 without safety oversight that is routinely performed by the FDA or an institutional review board.

According to four people with knowledge about the inquiry, the FDA’s Office of Criminal Investigations is looking into whether anyone from SIU or Halford’s former company, Rational Vaccines, violated FDA regulations by helping Halford conduct unauthorized research. The probe is also looking at anyone else outside the company or university who might have been complicit, according to the sources who asked not to be identified because of the sensitivity of the matter.

The FDA rarely prosecutes research violations, usually choosing to administratively sanction or ban researchers or companies from future clinical trials, legal experts said. Even so, the agency is empowered to pursue as a crime the unauthorized development of vaccines and drugs — and sometimes goes after such cases to send a message.

In this case, human-subject violations would be deemed
especially serious given Halford was not a medical doctor and had injected people with his experimental vaccine without any routine oversight, experts said.

“Since the research appears to be an effort to totally evade FDA oversight and is egregious, it makes sense the FDA would investigate it as a criminal matter,” said Patricia Zettler, a former FDA lawyer who was told of the criminal investigation by KHN. “There is a deterrent effect for others who might consider this a very brazen way to get out of human subject and FDA requirements.”

The FDA declined to comment. Rational Vaccines did not respond to requests for comment. An SIU spokeswoman said, without elaboration, “The government is investigating and we are cooperating.”

Any resulting criminal prosecution from the investigation could have political ramifications.

Rational Vaccines was co-founded with Hollywood filmmaker Agustín Fernández III and the company received millions of dollars in private investment from investors after the Caribbean trial, including from billionaire Peter Thiel.

Thiel, who for months has refused to respond to questions from KHN, contributed to President Donald Trump’s campaign and is a high-profile critic of the FDA. Thiel is part of a larger libertarian movement to roll back FDA regulations to speed up medical innovation.

The sources familiar with the inquiry said the FDA’s Office of Criminal Investigations, which has dozens of offices across the country, began to aggressively pursue the case weeks ago.

The investigators have interviewed witnesses across the country, asking them to identify Halford’s associates, and have described his actions as possible violations of human-subject guidelines and of FDA regulations, the sources told
The investigators also have expressed interest in whether Halford’s former associates at the university or other researchers and medical professionals outside the university might have helped or known about his conduct, the sources said. They also have raised questions about the company’s knowledge of the violations.

Rational Vaccines helped oversee the Caribbean trial, but the 2013 hotel injections took place before the company was formed.

Under a Supreme Court ruling, a corporate official may be prosecuted for a criminal misdemeanor offense under the Federal Food, Drug and Cosmetic Act even without proof that the official acted with intent or actual knowledge of the offense.

Initially, university officials and Rational Vaccines publicly defended Halford’s research. Rational Vaccines has said it considered the 2016 trial a success — though it is unclear what data it used to support that claim.

After KHN’s investigation revealed that Halford injected people in the United States, not just in the Caribbean, Rational Vaccines took down its website, although it had vowed to continue research.

SIU, a state university with a medical school in Springfield, Ill., initially said it bore no responsibility for the experiments because Halford conducted the research independently and overseas.

After Kaiser Health News raised questions about Halford’s practices, the Department of Health and Human Services asked the university to determine whether his activities violated the institution’s pledge to HHS to follow human-subject safety protocols for all research. SIU’s medical school receives
about $9 million a year in federal research dollars.

SIU has since acknowledged that Halford’s conduct violated university rules and U.S. laws. University officials have denied knowing about his misconduct, an assertion that FDA investigators are still probing, the sources said.

Halford’s actions already raised unusual legal questions because the FDA would not ordinarily have jurisdiction over clinical trials when they occur overseas and the researchers have not sought FDA approval.

It’s also unclear where Halford manufactured the vaccine.

If it was manufactured in the United States, the FDA likely has jurisdiction, said Zettler, a law professor at Georgia State University.

The OCI often goes after such cases of contaminated food, counterfeit or off-label pharmaceuticals. The office was created in the wake of a 1988 scandal in which pharmaceutical executives bribed FDA officials in exchange for speeding up generic drug approvals.

While rare, the OCI occasionally pursues research abuses as a crime. A GlaxoSmithKline researcher, for instance, pleaded guilty in 2010 to charges related to her fabrication of data in a study of children taking the antidepressant Paxil. GlaxoSmithKline later agreed to plead guilty and to pay $3 billion to resolve its criminal and civil liability in the case.

This story also ran on Daily Beast. This story can be republished for free (details).

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