

# Old Law Puts a New Wrinkle in Fraud Probes

*An 1863 statute intended to stop contractor fraud could upset the government's plans for dealing with scientific misconduct*

WHEN THE PUBLIC HEALTH SERVICE last year laid out procedures for investigating allegations of scientific misconduct, most research organizations were pleased. The government had accepted their primary demand: scientists, not lawyers or accountants, should be the first to decide whether a researcher had behaved improperly. But two cases filed under provisions of a recently amended 19th-century law could make an end run around PHS's bureaucratic procedures, sending some misconduct cases directly into the courts.

The cases have been filed under the False Claims Act of 1863, amended in 1986, which gives significant financial incentives to whistleblowers to bring charges against institutions they believe have made fraudulent use of federal funds. Once a whistleblower's complaint is filed, the Justice Department must decide whether to enter the case. Last week, government officials said that the cases involve federally supported institutions that were already being investigated for misconduct by the PHS's Office of Scientific Integrity at the National Institutes of Health. The names of the institutions will remain secret until the Justice Department decides how to proceed with the cases.

Research institutions are worried that the False Claims Act could transform petty laboratory disagreements into federal court cases, forcing juries to decide issues of scientific conduct. That's exactly what most researchers have been anxious to avoid, and why they have fought so hard for something like the PHS procedures to keep scientific misconduct investigations in the hands of scientists. "If this becomes the way to go," says Carol Scheman of the Association of American Universities, "all of the groundwork painstakingly covered to deal with these issues will be out the window."

The False Claims Act allows individuals to bring a legal action, formally known as a qui tam motion, in the name of the federal government. If the Justice Department declines to pursue the case, whistleblowers can do so on their own. The rewards are substantial: up to 30% of any money recovered. And since the False Claims Act calls for treble damages, sizable sums of money can be involved.

In the past 3 years, most False Claims Act cases have been brought against defense contractors and to a lesser extent medical care providers accused of abusing federal Medicaid funds. Lisa Hovelson, a lawyer who helped draft the False Claims Act amendments when she worked on the Senate judiciary committee, says the amendments were passed at a time when press accounts of defense fraud were rampant. The financial rewards were intended to overcome the liabilities of accusing a large contractor of fraud, says Hovelson.

Although defense fraud was uppermost in the minds of legislators, they were aware the amendments had other implications. "The False Claims Act is very broad, and it involves basically every program that uses federal money," says Hovelson.

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But if the legislators realized the act might someday be applied to scientific misconduct cases, officials at the PHS did not. "It really came as a shock to us to realize that we had to deal with this," says Lyle Bivens, acting director of the PHS Office of Scientific Integrity Review. Bivens says his office has decided to put two ongoing investigations on hold after qui tam actions were filed, to give the Justice Department time to complete its preliminary investigation. He declined to reveal which institutions were involved since the qui tam motions were filed under seal, but he added that the secret nature was part of the reason PHS suspended its investigations.

"We were concerned that we might be conducting an investigation—going out and interviewing scientists and people involved in the case—knowing that this action had been filed and unable to tell them," says

Bivens. "When they find out later that this had been filed, it would look like we were being very duplicitous in the process."

But AAU's Scheman feels that this approach is particularly misguided. She argues that in establishing procedures for dealing with scientific misconduct, Congress and PHS took steps with one primary goal in mind: to preserve the reliability of research. Believing that the best guarantor of this is the PHS, she insists that the PHS ought to demand that its investigation take precedence over any Justice Department inquiry. The point of establishing a mechanism for dealing with scientific misconduct was to separate it from other fraud issues facing the government. "Issues of scientific substance, which these are, have to be adjudicated by scientists—not by judges, not by juries, and not by lawyers," says Scheman.

Sheila Jasanoff of the Cornell University program on science, technology and society and a member of the American Association for the Advancement of Science/American Bar Association National Conference of Lawyers and Scientists agrees that current laws are not ideally suited to dealing with scientific misconduct cases.

"Criminal law—like incentives, like bounties and penalties and treble damages, make most sense where the distinction between right and wrong conduct is relatively clear," she says. "The line between clearly unacceptable and clearly acceptable conduct is broader than cases of ordinary statutory violation." Although Jasanoff agrees that whistleblowers' best interests may not be served if scientists are permitted to judge their peers, Jasanoff does not feel the magnitude of the problem justifies the potential for damage to the scientific establishment if it is prone to routine litigation.

Since the law was amended in 1986 there have been 206 cases filed, of which the Justice Department has entered 31, declined to enter 81, and 94 are still pending. Defense cases, where contracts are often worth tens or hundreds of millions of dollars, are expected to remain the chief target of qui tam motions. But Herbert L. Fenster of McKenna, Conner & Cuneo says that non-profit institutions may be more vulnerable than industry because they don't police their contracts as closely, and they are less able to afford a negative judgment.

Still, there will be less financial incentive to file a motion in cases of misconduct involving NIH grants, which typically involve hundreds of thousands of dollars. But federal officials are concerned. "You wouldn't want to stimulate this and generate widespread frivolous filings of these kinds of actions," says PHS's Bivens. "But it is a route that's available." ■ JOSEPH PALCA