Scientific Misconduct: Risks to Biotechnology

Violations Are Increasingly Prosecuted Under the Federal False Claims Act

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Though scientific research has always been a heavily regulated area, an increasing alphabet soup of government agencies are becoming involved in regulating research misconduct.

Consider that researchers, sponsors, and institutions who receive federal funds have to deal with ORI, which facilitates the RCR, which is located in the OPHS, which is within the OS, which is part of HHS. For those of you without a scorecard, that's the Office of Research Integrity (ORI), which facilitates the responsible conduct of research (RCR), which is located organizationally in the Office of Public Health and Science (PHS), which is within the Office of the Secretary of Health and Human Services (OS), which is part of the U.S. Department of Health and Human Services (HHS).

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Now consider that other arms of the federal government, including the Department of Justice (DOJ) and the Office of Inspector General (OIG) of HHS, are also becoming involved.

And that's not all. PHS is composed of many federal agencies including the NIH, CDC, FDA, and ATSDR. In addition, there are many agencies, administrations, and services interested in the integrity of federally funded research, all of whose oversight is directed, more or less, through the activities, monitoring, and advice of the Office of Research Integrity.

ORI Oversight

ORI oversees the integrity of PHS-funded research, with the exception of regulatory research integrity activities of the FDA. In Fiscal Year 2004, PHS provided more than $30 billion to fund both government and non-government research.

The responsibilities of ORI include the development of policies and procedures that define misconduct; reviewing research reports of misconduct, as well as investigations undertaken by the Office of Inspector General (OIG); recommending administrative actions to the Assistant Secretary of Health; implementing programs designed to promote research integrity; and providing assistance to institutions in conducting investigations of misconduct.

Regulations which became effective in June("Public Health Service Policies on Research Misconduct") require that entities which receive PHS funds develop and implement policies and procedures to investigate allegations of research misconduct and report to ORI the results of its investigations. These new regulations define research misconduct as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or reporting research results.

When ORI receives a report that an institution is investigating an allegation of misconduct, it reviews the report, including all documentation (including grant applications, publications, and transcripts of interviews) to determine the appropriateness and sufficiency of the investigation. ORI also may conduct its own investigation or assessment of allegations.

Once ORI's review and/or investigation is complete, it may negotiate a Voluntary Exclusion Agreement with the researcher without the researcher necessarily admitting any misconduct; it may determine that the allegation was not substantiated; or it may, if a voluntary agreement is not reached, recommend a finding of research misconduct and the imposition of administrative actions to the Assistant Secretary for Health for a final determination.

Those researchers or entities that are subject to administrative action have the right to appeal such determinations. If ORI determines that there has been criminal or civil fraud, it may also refer the matter to the OIG or the Department of Justice for further investigation and enforcement.

Clearly research funding sources have always been interested in watching over research they have funded. Biotech companies are always interested in making sure funding dollars are put to

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good use, and that the research is conducted ethically and honestly. Conducting research properly is not only a regulatory concern, but a business one as well. The risks, however, are changing. While the risks to biotech, researchers, institutions, or sponsors have always included things like loss of federal funding and reputational damage, the risks today can be pecuniary as well—to potentially devastating effect.

False Claims Act Cases

Specifically, there have been a significant number of recent prosecutions of scientific misconduct alleging violations of the Federal False Claims Act (or the "Act"). The False Claims Act prohibits a person from "knowingly" presenting, or causing to be presented, a "false claim" to the federal government to obtain funds from a government program.

The Act defines "knowingly" as including actual knowledge as well as deliberate ignorance or reckless disregard of the truth or falsity of the information submitted. Civil penalties can amount to $10,000 per claim, plus three times the damages incurred by the government. The Act also defines a "claim" very broadly, so that not only can persons or entities be found liable who directly claim funds from the government, but also subcontractors who receive federal funds via third parties.

Although agencies of the federal government may of course prosecute cases under the False Claims Act directly, the Act also allows whistleblowers (called "qui tam relators" under the Act) to bring suit on their own, or together with the federal government. The qui tam relator is eligible for a significant percentage of any award collected through such a suit, whether brought individually or with the government.

Of the recent scientific misconduct cases brought under the False Claims Act, several are worth noting. In March of this year, a settlement was reached in the case of *U.S. v. Poehlman*, which involved Eric Poehlman, an academic researcher conducting federally funded research while employed at the University of Vermont (UVM). A qui tam action was brought by an individual who was a student and then laboratory technician for UVM who worked with the researcher during the time period in question. The government alleged that, among other things, Poehlman falsified and fabricated certain information from his federally funded research and used this falsified data in grant applications to obtain further federal funding for additional research.

The government contended that reviewers of the grant applications relied on this falsified data to determine that a grant should be awarded. Since Poehlman served as the principal investigator and signed the grant applications, certifying the truth of the information submitted, the government found that he violated the False Claims Act.

On April 14, 2005, the government announced that the University of Alabama at Birmingham and two related entities were to pay the U.S. $3.39 million to settle allegations that they violated the False Claims Act in connection with claims submitted as part of the University's health science research activities.

This case was brought in two parallel qui tam suits. The government and the qui tam relators alleged that the University had submitted false claims for payment to federal healthcare programs, including Medicare, and to NIH and other federal agencies that sponsored research grants or that had awarded contracts to the University.

There are several measures a biotech company can take in order to safeguard against potential liability for scientific misconduct. First, ensure that the company has adequate policies and procedures in place to instruct staff involved whether directly or indirectly in clinical research regarding how government funds are to be allocated, and how services and costs are to be documented. Second, companies must make sure that they have an established process in place for promptly identifying, investigating, and reporting allegations of research misconduct.

Last, to the extent that biotech companies contract with institutions to perform sponsored research studies, or otherwise provide grant support for third-party clinical trials, include provisions in such contracts that require the contracted entity to comply with all applicable laws regarding scientific misconduct, and consider including tailored indemnification provisions as necessary. GEN

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