Scientific Misconduct: Present Problems and Future Trends

Barbara Mishkin, Hogan & Hartson, LLP, Washington, DC, USA

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ABSTRACT: Substantial progress in handling scientific misconduct cases has been made since the first cases were investigated by the NIH Office of Scientific Integrity in 1989. The successor Office of Research Integrity (ORI) has simultaneously reduced the backlog of cases and increased the professionalism with which they are handled. However, a spate of lawsuits against universities, particularly those brought under the federal False Claims Act, threatens to undermine the ORI by encouraging use of the courts as an alternate route for resolving claims of research misconduct. Next steps should include establishing a government-wide definition of scientific misconduct, providing immunity from lawsuits for institutions that follow proper procedures in investigating charges of scientific misconduct, and participating in the development of international guidelines for maintaining scientific integrity.

INTRODUCTION

It has been a tumultuous decade. After a rocky start, ORI seems to have settled down to a more prudent approach in handling scientific misconduct allegations. ORI still needs to speed up its review process to comply with the regulatory time frames for completing inquiries and investigations; but it is clearly making more careful decisions about which allegations to pursue. Its staff now has appropriate training, and its use of negotiated settlements has helped to reduce the backlog of cases. This reduces the provocation to make a case public. The areas in which further change may be anticipated include:

• The definition of scientific misconduct;
• The frequency of False Claims Act suits brought by the federal government;
• The popularity of qui tam suits; and
• Development of International Guidelines.
ACHIEVING A GOVERNMENT-WIDE DEFINITION

The real need, now, is to achieve a government-wide definition of scientific misconduct, because many research projects are funded by more than one agency. Similarly, if it becomes necessary to investigate a large body of a scientist’s research, conducted over an extended period of time, support from multiple agencies likely will be involved. It is clearly infeasible to apply more than one definition of scientific misconduct in a single investigation. Since other articles in this issue address this more fully,\textsuperscript{1,2} there is no need to retrace their steps. To summarize the current situation: the White House-OSTP task force is leaning toward a simple definition of falsification, fabrication, and plagiarism (without the controversial fourth category of serious deviations from accepted practices) despite opposition from the National Science Foundation.\textsuperscript{3} One may expect that the task force will persevere, recalling that it took ten years to reach accord on a government-wide set of regulations (the “common rule”) for protecting human subjects\textsuperscript{4} and it is safe to predict that a uniform, government-wide definition ultimately will be achieved.

FALSE CLAIMS ACT CASES BROUGHT BY THE UNITED STATES GOVERNMENT

Filing false claims for payment or making false statements to the U.S. government may result in a range of penalties from civil fines to incarceration.\textsuperscript{4} In addition, any grant funds awarded because of false claims may be recouped, and the institution filing the false claims may be fined treble damages.\textsuperscript{5} An unusual provision of the False Claims Act, the \textit{qui tam} provision, permits private individuals to sue on behalf of the government (as well as for themselves) if they believe a false claim has been submitted.\textsuperscript{6} If they prove their case, they may be awarded up to 30\% of the damages collected,\textsuperscript{7} which in turn is treble the amount of damages proved.\textsuperscript{8} Although the \textit{qui tam} provisions were enacted during the Civil War to deal with individuals selling defective supplies to the Union Army,\textsuperscript{9} (p.656,1\textsuperscript{FN89}) it has recently been used by student and faculty “whistleblowers” against former research collaborators. (See section on \textit{Qui Tam} suits, pp. 286-288.)

At the same time, the U.S. government has invoked the False Claims Act successfully in a number of cases involving alleged fraud in federal health care programs, such as Medicare, and in biomedical research supported by federal grants and contracts. In recent years, the federal government increased the number of False Claims Act prosecutions in the area of medicine and health by huge amounts.\textsuperscript{10} A Department of Justice attorney recently reported that:

\begin{footnote}
\textsuperscript{[a]} The effort to establish a common rule began in 1981, in response to a recommendation from the President’s Commission for the Study of Ethical Problems in Medicine and Research. The common rule was finally adopted by 16 federal departments and agencies in January 1991, \textit{Federal Register} \textbf{56}: 28002-28032.
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