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# Federal Research Grant Recipients Face False Claims Lawsuit

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Many of the high-profile False Claims Act (FCA) cases against the health care industry have involved allegations that false claims for payment were submitted for items or services provided to Medicare or Medicaid beneficiaries. A recent case, however, highlights the fact that health care providers may face FCA liability based on other types of interaction with the federal government.

In *U.S. ex rel. Jones v. Brigham and Women's Hospital*, __ F.3d ___, 2012 WL 1571232 (1st Cir. May 7, 2012), a whistleblower alleged that the defendants submitted a false application for a research grant to the National Institute on Aging (NIA), a federal agency. Defendants sought the grant to continue their research regarding factors that would predict the onset of Alzheimer's Disease. That research involved the use of MRI scans to track "regions of interest" in the brains of study participants. In the course of their preliminary research conducted before the grant application, the defendants encountered "anatomical anomalies" in the data originally collected, which led them to gather additional data from some (but not all) of the study participants. The whistleblower, who was part of the defendants' research team, raised concerns that the additional data relied upon by defendants to show a causal relationship between certain changes in brain structure and the development of Alzheimer's was flawed because the additional data was not collected through a "blinded" study methodology, but rather, was allegedly "manipulated" and "cherry picked." In response to the whistleblower's concern, the defendants asked an expert to review the data. That expert concluded that the defendants' use of the additional data was appropriate.

Accordingly, the defendants rejected the whistleblower's concerns and proceeded to make a grant application to the NIA. The defendants' grant application represented that the defendants' preliminary research had identified predictive factors for the development of Alzheimer's. The application also represented that a




blinded study methodology had been utilized, thereby rendering the data reliable. The application did not disclose that the defendants' research involved two sets of data, or that the defendants' findings were driven by a revised set of data. The defendants' grant application included certifications, such as: "I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application."

The trial court had dismissed the case on the defendants' motion for summary judgment. However, on appeal, the First Circuit concluded that there were disputed issues of fact that entitled the whistleblower to a trial on his FCA allegations. Thus, the summary judgment for the defendants was vacated and the case was returned to the trial court. The First Circuit rejected the trial court's conclusion that the defendants' research methodology constituted a matter of subjective scientific judgment, rather than an objective falsehood that was necessary to create FCA liability. According to the First Circuit, the whistleblower presented evidence of allegedly false statements that could be objectively false. For example, there was evidence that the defendants allegedly misrepresented in their grant application that they had identified predictive factors for the onset of Alzheimer's based on compliance with a reliable research methodology. The grant application did not disclose that the defendants allegedly deviated from the stated methodology. Moreover, the application concealed that the defendants allegedly "cherry picked" data in order to support its research hypothesis and to promote its grant application. While subjective scientific judgment may be involved in selecting the appropriate research methodology to use, in this case the dispute did not entail which methodology was appropriate, but rather, involved the defendants' alleged failure to use the methodology that the defendants represented had been used to generate their preliminary findings in support of the grant application to the NIA. Thus, there was a triable issue whether the defendants had made "a false record or statement to get a false or fraudulent claim paid or approved by the Government" in violation of the FCA.




The First Circuit also found there was evidence that the allegedly false statements were "material" because if the defendants "selectively manipulated data to produce a statistically significant result, [that] would certainly have had 'a natural tendency to influence'" the NIA's decision to award a research grant to the defendants. Furthermore, the First Circuit concluded there was evidence that the defendants knowingly made the allegedly false statements in the grant application submitted to the NIA. For example, the defendants acknowledged that they did not assess the reliability of the additional data they gathered and relied on in their grant application.

The Jones case demonstrates the importance of verifying all information submitted to a federal agency in any context in which a health care provider is seeking payment from the federal government.