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Can an NIH grant application form the basis of a False Claims Act case?

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Rose, Chinitz & Rose's
Alan D. Rose Sr.

Whether allegedly false statements on a National Institutes of Health grant application for federal funding can support a False Claims Act case was up for debate at the U.S. Court of Appeals for the 1st Circuit.

The Sept. 15 oral argument in *U.S. ex rel. Jones v. Brigham & Women's Hospital* concerned a whistleblower's appeal of an October 2010 summary judgment ruling in favor of the defendants by Judge William G. Young of the District of Massachusetts.

Whistleblower Kenneth James Jones, the lead statistician on the NIH-funded project, and co-plaintiff Priscilla Pitt Jones claim the defendants made false statements in an application for a \$12 million, five-year NIH grant for an Alzheimer's disease research project, which ran from 2002 to 2007.

The original qui tam complaint was filed in the U.S. District Court for the District of Columbia in June 2006. It was moved to the Boston federal court in August 2007.

Jones sued Marilyn Albert, the project's principal investigator, and neuro-anatomist Ronald Killiany, a co-investigator who used magnetic resonance imaging (MRI) scans to map regions of the subjects' brains.

Jones also sued Brigham & Women's and Massachusetts General Hospital, which were parties to the NIH grant. Both are teaching hospitals of defendant Harvard Medical School. Harvard University, the medical school's parent organization and another defendant, employed many of the scientists who worked on the grants.

Another named defendant, Marie Kijewski, a principal investigator and program director for a different project who referenced the allegedly fraudulent data in a different NIH application, was dismissed from the case early.

Jones' 1st Circuit brief claims that "Killiany fraudulently manipulated MRI data, after the conduct of reliability studies and inconsistent with the study protocols, in order to establish a false statistical significance for his hypothesis." He argues that the defendants falsely

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reported data results that were generated by Killiany's second set of entorhinal cortex measurements as preliminary data on the grant.

Killiany's MRI study referenced in the grant application claimed that a one-time volumetric measurement of particular brain regions, including the entorhinal cortex, which is a hub for a memory and navigation network, could predict with 93% accuracy which subjects would develop Alzheimer's within three years.

Jones' brief argues that there is substantial evidence that Killiany failed to follow a blinded, reliable methodology. It also claims that Killiany was not blinded when he cherry-picked normal subjects with the smallest entorhinal cortex volume measurements to produce data that exaggerated group differences.

Jones' brief further states that "even after learning of Killiany's misconduct, defendants applied for scarce NIH funds, and included a statement of the falsified MRI data results."

The defendant's 1st Circuit brief argues that "disputes over scientific judgment and methods do not suffice to make out an FCA claim." Their brief also states that Jones has not proven that Killiany's original measurements of the entorhinal cortex were accurate and that the re-measurements were inaccurate.

"A disagreement among scientists as to boundaries of the [entorhinal cortex] drawn on MRI, including which drawings are "more accurate" or "less accurate" does not demonstrate truth or falsity," the defendants' brief states.

The defendants' brief also argues that Jones has no proof that Killiany was not blinded to the status of the subjects whose entorhinal cortex measurements he studied.

Judges Kermit Lipez and Jeffrey Howard sat on the 1st Circuit panel with along with 7th Circuit Judge Kenneth Ripple, who sat by designation.

Lipez told plaintiffs' lawyer, Jeremy Friedman, a solo practitioner in Oakland, Calif., that he thinks he's "going to be able to demonstrate that there was a dispute between experts taking a different view of what was going on here."

In Young's view, "it reflected a disagreement among experts in scientific community about how these [measurements should be done]," Lipez said. "It's not about truth or falsity; it's a dispute about the science."

Friedman countered that "the disagreement among the scientists in the case does not go to this point."

"This isn't a disagreement over which protocol to use," Friedman said. "This is a question of whether or not you're allowed to alter that protocol to reach a desired result and only alter it for some of the subjects but not the others."

Lipez then asked Friedman what makes the defendants' alleged false statements culpable under the False Claims Act: "Are you relying on the general certification language that accompanies the application to NIH?"

Friedman said that certification language is key, and the grant application also requires applicants to state their preliminary data.

Lipez also asked about Jones' claim that the other defendants were required to investigate and report Killiany's alleged scientific misconduct: "Do you or do you not rely on this general certification language [for that claim]?"

Friedman answered that there was an express certification that "specifically refers to the regulation requiring the investigation and disclosure of suspected scientific misconduct."

During his oral argument time, the defendants' lawyer, Alan Rose of Boston-base Rose, Chinitz & Rose, argued that "there is no evidence proving that any statement made in the grant application was false or knowingly false. There's no evidence that Killiany was not

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blinded to the group status of the individuals whose [entorhinal cortex] he was reviewing."

Lipez asked Rose if a scientist's opinion is subject to questions if the opinion is later found to be based on facts the scientist knew were untrue or questionable.

Rose replied that he didn't see any evidence in the record that a jury could conclude is a false statement.

"Our experts' report includes a long description of scientific studies that have replicated Dr. Killiany's point," Rose said. "There's no evidence in the record that [entorhinal cortex] volume is not a predictor of Alzheimer's."

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