

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 10-4364

UNITED STATES OF AMERICA, EX REL.
DR. HELENE Z. HILL

v.

UNIVERSITY OF MEDICINE & DENTISTRY OF NEW JERSEY;
DR. ROGER W. HOWELL; DR. ANUPAM BISHAYEE

Dr. Helene Z. Hill,
Appellant

On Appeal from the United States District Court
for the District of New Jersey
D.C. Civil Action No. 2-03-cv-04837
(Honorable Dennis M. Cavanaugh)

Argued September 13, 2011
Before: SLOVITER, SCIRICA and SMITH, *Circuit Judges*.

(Filed: October 20, 2011)

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OPINION OF THE COURT

SCIRICA, *Circuit Judge*.

At issue is whether the District Court erred in granting summary judgment for defendants, the University of Medicine & Dentistry of New Jersey, Howell, and Bishayee, in this *qui tam* action under the False Claims Act. 31 U.S.C. § 3729 et seq. We will affirm the judgment of the District Court.

I

The University of Medicine & Dentistry of New Jersey (UMDNJ) employed both the appellant, Dr. Helene Hill, and the appellees, Dr. Robert Howell and Dr. Anupam Bishayee in its radiology department where they all collaborated on preliminary research to support a grant application to the National Institutes of Health (NIH) to fund further investigation into the “bystander effect.”¹ The crux of Dr. Hill’s complaint is that data used in support of this grant application was fabricated.

To support her allegations, Dr. Hill contends Dr. Bishayee failed to follow the proper scientific protocol in the first experiment conducted in 1999. Apparently, his results contradicted her own. When she expressed her concerns to Dr. Howell, he allegedly dismissed her suspicions and employed the “fabricated” data in the NIH grant

¹ The “bystander effect” is the phenomenon where the positive or negative response in one cell (such as from a drug) are passed to other neighboring cells. *See Bystander Effect*, Medical Subject Headings, National Library of Medicine, National Institutes of Health, , http://www.nlm.nih.gov/cgi/mesh/2002/MB_cgi?term=bystander+effect (last visited Sept. 27, 2011). This research was to focus on the “bystander effect” in “diagnostic and therapeutic nuclear medicine.”

application. Dr. Hill did not pursue her objections with UMDNJ. Again, in 2001, Dr. Hill once more suspected Dr. Bishayee of fabricating data. She and another research assistant monitored Dr. Bishayee's protocol and concluded the data was fabricated. In her view, the experiment was conducted with contaminated cultures and could not be replicated.

At this time, Dr. Hill presented her claims to the Chair of the Committee on Research Integrity at UMDNJ. After reviewing all of the relevant original data, UMDNJ's Committee on Research Integrity voted to conduct an initial inquiry into the allegations of scientific misconduct. After a thorough investigation – including interviewing all relevant individuals, reviewing the data, protocol, and publications – the committee concluded in July 2001 there was “insufficient credible and definitive evidence of misconduct in science to warrant further investigation.”

In August 2001, Dr. Hill pursued her claims with the Office of Research Integrity (ORI), which supervises the integrity of Public Health Service research activities on behalf of the U.S. Secretary of Health and Human Services. After reviewing UMDNJ's inquiry report and Dr. Hill's supplemental statements, and after conducting an independent analysis of the data and requesting and reviewing supplemental information from UMDNJ, ORI issued a report concluding there was “insufficient evidence to warrant further investigation.” A copy of this report was forwarded to NIH.

Dr. Hill filed a second claim with UMDNJ's Committee on Research Integrity in November 2002 alleging Dr. Bishayee falsified data. The Committee again investigated the allegations – interviewing Dr. Bishayee, consulting with ORI via telephone about the

questions raised in its report, and evaluating the statistical evidence presented by Dr. Hill. The Committee issued its report in March 2003 concluding there was no cause to credit the allegations as the proffered statistics alone were insufficient to warrant further investigation.

Dr. Hill sued defendants seeking treble damages for violations of the False Claim Act and damages for retaliation under 31 U.S.C. § 3730(h). The United States declined to intervene. She then filed an amended complaint and defendants filed an answer and counterclaim.

The District Court granted the defendants' motion for summary judgment holding that plaintiff failed to establish defendants satisfied the scienter and materiality elements under the False Claims Act and failed to establish that she suffered any adverse employment action.² *United States ex rel. Hill v. Univ. of Med.*, 2010 WL 4116966 at *4, 7-8 (D.N.J. Oct. 18, 2010). Plaintiff appealed.³

II

To establish a prima facie case under the False Claims Act (FCA) a plaintiff must prove: (1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant

² The District Court had jurisdiction over Hill's *qui tam* and retaliation claims under 28 U.S.C. § 1331 and 31 U.S.C. § 3732. On appeal, Hill only raises the *qui tam* claim. We have jurisdiction over the District Court's final order under 28 U.S.C. § 1291.

³ We exercise plenary review over a grant of summary judgment. *United States ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 495 F.3d 103, 108 (3d Cir. 2007). Because there are no genuine issues of material fact in dispute, summary judgment is appropriate. *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 436 (3d Cir. 2004).

knew the claim was false or fraudulent. *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 182 (3d Cir. 2001).

Plaintiff claims the data used in the 1999 grant application, subsequent progress reports, and 2005 renewal application was fabricated citing Dr. Bishayee's failure to follow the protocol, her statistical analysis of the data, and expert witness testimony criticizing the experiment. The District Court found that plaintiff failed to produce evidence the data was false. The relevant scientific bodies – here the Office of Research Integrity and UMDNJ's Committee on Research Integrity – found insufficient evidence of scientific misconduct. Because “[e]xpressions of opinion, scientific judgments or statements as to conclusions which reasonable minds may differ cannot be false,” *United States ex rel. Jones v. Brigham and Women's Hosp.*, 750 F. Supp. 2d 358, 366 (D. Mass. 2010), FCA liability will not attach. After three independent reviews, the District Court found no evidence of scientific misconduct. We agree.

Plaintiff's claim also fails because she cannot establish defendants had the requisite scienter. The FCA imposes liability only on individuals who “knowingly” present a false claim to the government. A person acts “knowingly” when he or she “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b).

Plaintiff argues defendants must have known the data was false based on her allegations and the inability of others to replicate the data. The District Court found these facts were insufficient to establish scienter as defendants could not have “knowingly”

submitted false information at the time of the 1999 grant application as even plaintiff concedes “she was not ‘absolutely certain’ she was correct since she was unfamiliar with and had difficulty using the particular microscope.” And the District Court found the defendants could not have known the data was false at the time of the grant renewal because the data survived scrutiny by UMDNJ twice and ORI once. Finally, plaintiff argues that defendants’ failure to disclose an inability to replicate the data demonstrates knowledge of the data’s falsity. But the District Court found the failure to replicate the data does not demonstrate knowledge of a false claim or an intent to deceive the federal government. While the data “might be proof of a ‘mistake’ or even of ‘negligence’ in performing the work,” *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992), it does not prove that defendants knowingly submitted false information. We agree with the District Court that plaintiff has failed to establish scienter.

Because plaintiff presented evidence only demonstrating a scientific disagreement over the reliability of the data, and not evidence as to defendants’ knowledge of the falsity, liability does not attach.⁴

⁴ Although the parties and the District Court discuss the materiality of the data to the claim, we need not address the issue. At the time of this dispute, we had not recognized an implicit materiality element. *See United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 415 (3d Cir. 1999) (“Given that the False Claims Act prohibits merely making a knowingly false claim and does not require a specific intent to defraud, perhaps *Neder* argues against a materiality requirement.”). Congress has since amended the FCA in the Fraud Enforcement and Recovery Act of 2009, Public Law 111-21, and explicitly imposed a materiality element on claims. Because we find this claim fails for other reasons, we need not address whether the judicially-created materiality element is applicable or whether the retroactive mandate applies to “claims” in the sense of demands made via litigation or “claims” as defined by the FCA. *See Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1327 (11th Cir. 2009).

III

For the foregoing reasons, we will affirm the judgment of the District Court.