UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, EX REL. DR. HELENE Z. HILL,	**CIVIL ACTION NO. 03-4837 (DMC)**
Plaintiff,	
vs.	
UNIVERSITY OF MEDICINE & DENTISTRY OF NEW JERSEY, DR. ROGER W. HOWELL and DR. ANUPAM BISHAYEE,	**Document Electronically Filed**
Defendants.	

BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 56

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PRELIMINARY STATEMENT

Defendants, University of Medicine & Dentistry of New Jersey ("UMDNJ"), Dr. Roger W. Howell and Dr. Anupam Bishayee (collectively " Defendants"), respectfully submit this brief in support of their motion for summary judgment on all claims against them.

This case involves nothing more than a dispute over scientific data that dates back over a decade and has already been reviewed and investigated by UMDNJ's Committee on Research Integrity (the "Committee"), the Office of Research Integrity ("ORI") – the federal agency specifically responsible for overseeing and directing the integrity of research activities conducted on behalf of the United States Department of Health and Human Services – and the United States Attorney's Office. Despite already having her allegations of scientific misconduct thoroughly reviewed, investigated and rejected *twice* by the Committee and also by ORI, Plaintiff/Relator Dr. Helene Z. Hill ("Dr. Hill") filed the present claims that set forth the very same allegations that were previously rejected by both the Committee and ORI. In addition to the Committee and ORI, the United States Attorney's Office, after being petitioned by Dr. Hill and conducting its own thorough investigation for nearly three and half years, also elected not to pursue further investigation of Dr. Hill's allegations. Notwithstanding Dr. Hill's participation in and knowledge of these investigations and their conclusions, Dr. Hill has continued in her misguided crusade against Defendants under the guise of government harm. Not surprisingly, despite having the benefit of these investigations, Dr. Hill has still failed to produce any credible evidence of misconduct in science on the part of defendants to warrant any further prolongation of Dr. Hill's claims.

Dr. Hill's allegations amount to nothing more than a scientific dispute, at best. The federal courts, however, have consistently held that cases of alleged scientific misconduct are not

within the scope of the False Claims Act ("FCA"). Indeed, Congress has expressly recognized that disputes over scientific misconduct and methodology are best resolved by the institutions within the scientific community and the governmental entities that provide their research funds. These institutions and entities are more than capable of reporting, investigating, and remedying such disputes and in this case these scientific bodies – the Committee and ORI – unequivocally found that Dr. Hill's allegations were not supported by sufficient credible and definitive evidence. It is now apparent based on Dr. Hill's continued pursuit of the allegations in spite of the conclusions of the Committee and ORI that this action was brought primarily for purposes of harassing Defendants.

Dr. Hill's claims of retaliation share similar fatal defects. Dr. Hill has failed to provide any evidence whatsoever that she has suffered any cognizable retaliatory adverse employment action as a result of her alleged engagement in protected whistleblower activity. In fact, Dr. Hill continues to maintain the same position at UMDNJ to this very day, with the same salary and benefits.

Allowing Dr. Hill's *qui tam* suit to proceed would improperly impose liability on Defendants and compromise the pursuit of legitimate scientific research. For the reasons set forth herein, Defendants are entitled to summary dismissal of Plaintiff's Amended Complaint. Defendants also respectfully submit that based on the lack legal merit to Plaintiff's claims, Defendants are entitled to summary judgment on their Counterclaim and should be awarded attorneys' fees and expenses pursuant to 31 U.S.C. § 3730(d)(4).

STATEMENT OF UNDISPUTED MATERIAL FACTS

Defendants incorporate their Statement of Undisputed Material Facts submitted in support of this motion as if fully set forth at length herein.

LEGAL ARGUMENT

POINT I

PLAINTIFFS' CLAIMS ARE RIPE FOR SUMMARY JUDGMENT PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 56

Summary judgment is proper if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." FED.R.CIV.P. 56(c). The initial burden is upon the party seeking summary judgment to demonstrate its entitlement to such relief. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). This showing can be made by exposing "the absence of evidence to support the nonmoving party's case." *Id.* at 325.

Once the moving party has established its burden, the burden shifts to the non-moving party, who must demonstrate that a genuine issue of material fact remains for the fact finder to resolve. *Id.* at 333, n.3. To satisfy this burden, the non-moving party "may not rest upon the mere allegations or denials" of its pleading. FED.R.CIV.P. 56(e). While the Court must view the evidence in the light most favorable to the non-moving party, to withstand the motion the non-moving party must do more than "simply show that there is some metaphysical doubt as to material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87, 106 S.Ct. 1348, 1356, 89 L.Ed.2d 538, 552 (1986). *See also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252, 106 S.Ct. 2505, 2511, 91 L.Ed.2d 202, 212 (1986) (stating that the "mere existence of a scintilla of evidence" in support of the non-movant's position is insufficient to

overcome summary judgment).

On a motion for summary judgment, the court's function is not to weigh the evidence and determine the truth of the matter, but instead "to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249. An issue is genuine only "if the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Id.* at 248. Disputed facts are considered "material" for the purposes of summary judgment only if a dispute over those facts will affect the outcome of the case. *Ibid.* Unless the party opposing the motion provides evidence that could lead a reasonable jury to find in its favor, a motion for summary judgment must be granted.

In the present case, Dr. Hill cannot set forth even a scintilla of evidence to defeat Defendants' motion. Dr. Hill has failed to establish the existence of facts sufficient to prove essential elements of her claims against Defendants. Despite the fact that Dr. Hill has searched through thousands of documents and conducted extensive discovery, she has failed to produce a single shred of evidence to support an inference of fraud by Defendants. Moreover, the issues before the Court were investigated three separate times by scientific bodies with expertise in this field, and the United States declined to intervene in this action after conducting a thorough investigation into Dr. Hill's claims. The Amended Complaint fails to set forth any additional factual basis to corroborate Dr. Hill's allegations beyond those already examined by the Department of Health and Human Services, Office of Public Health and Science, Office of Research Integrity ("ORI"), UMDNJ and the United States Government. The Amended Complaint simply alleges that Dr. Hill and Dr. Marek Lenarczyk, who coincidentally did not join in Dr. Hill's case, both "suspected [Defendant] Bishayee of fabricating data…as a result of their actions, Hill and Lenarczyk concluded that Bishayee had, in fact, fabricated the experiment's

data and engaged in scientific fraud." (Leonard Cert., Ex. N, Amended Complaint at ¶¶ 25-26). Dr. Hill's allegations are merely legal conclusions masquerading as facts and such allegations should not permit Dr. Hill to defeat this summary judgment motion.

Dr. Hill's claims of retaliation similarly fail as a matter of law. Dr. Hill has failed to provide any evidence whatsoever that she has suffered any cognizable retaliatory adverse employment action as a result of her alleged engagement in protected whistleblower activity. In fact, Dr. Hill continues to maintain the same position at UMDNJ to this very day, with the same salary and benefits. Dr. Hill's allegations of what can be deemed at most workplace shunning by the co-employees that she has asserted claims of fraud and fabrication against are the type of actions that the federal courts have explicitly found fail to qualify as materially adverse. As a result, Dr. Hill is similarly unable to survive summary judgment on her claim for retaliation.

In the absence of facts to establish each of the essential elements for which Plaintiff bears the burden of proof at the time of trial, summary judgment is not only warranted, but required pursuant to FED.R.CIV.P. 56 and the Supreme Court's guidelines. Accordingly, for the reasons set forth in more detail below, Defendants submit that summary dismissal of Plaintiff's claims is appropriate in this case.

POINT II

DR. HILL'S COMPLAINT FAILS TO ESTABLISH THE ELEMENTS OF A CLAIM UNDER THE FALSE CLAIMS ACT

As set forth at length below, even when considering all of the allegations in favor of Plaintiff, Plaintiff's Amended Complaint fails to state a cognizable claim under the False Claims Act, 31 U.S.C. § 3729 to - 33 (the "FCA"). Pursuant to the provisions of the FCA,

> any person who knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the

> United States a false or fraudulent claim for payment or approval…is liable to the United States Governmement for a civil penalty of not less than $5,000 and not more than $11,000, plus three times the amount of damages which the Government sustains because of the act of that person.

In order to establish a prima facie case under the FCA sufficient to avoid summary judgment, a plaintiff/relator "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 knew the claim was false or fraudulent.'" *United States ex rel. Hefner v. Hackensack Univ. Med. Center*, 495 F.3d 103, 109 (3d Cir. 2007) *(quoting Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 182 (3d Cir. 2001)). Additionally, the United States, as the real party in interest, must suffer damages as a result of the false or fraudulent claim. *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006); *United States ex rel. Taylor-Vick v. Smith*, 513 F.3d 228, 230 (5th Cir. 2008); *Wilkins ex rel. U.S. v. State of Ohio*, 885 F.Supp. 1055 (S.D. Ohio 1995).

Here, Plaintiff/Relator Dr. Hill has failed to establish a prima facie false claim under the FCA sufficient to avoid summary dismissal of her Amended Complaint. At best, Dr. Hill's Complaint presents a scientific dispute over scientific research and methodology utilized by Defendants in connection with certain scientific experiments and data included in an application for federal grant money. Because Dr. Hill bears the burden of proof in establishing the elements of a prima facie FCA cause of action against Defendants, Dr. Hill must identify evidence that establishes the existence of all three essential elements of a FCA claim in order to survive summary judgment. *United States ex rel. Hefner v. Hackensack Univ. Med. Center*, 2005 WL 3542471, at *4 (D.N.J. 2008). (Leonard Cert. Ex. P). Dr. Hill must provide the Court with evidence demonstrating that Defendants acted knowingly, recklessly or with deliberate ignorance

in submitting or causing to be submitted to the government a false or fraudulent claim for payment – in this case the NIH grant application – that caused the government economic loss. *Ibid.* Even affording Dr. Hill a liberal analysis of the facts of this case, she cannot demonstrate that (1) the scientific data underlying the NIH grant application is objectively false; (2) even if the data is deemed false, that any of the Defendants knew the data was false when submitting the NIH grant application; and (3) that the data was material to the government's funding decision and caused it to suffer an economic loss. Dr. Hill's inability to establish the existence of any of these elements, let alone satisfy all three as she is required to do, is fatal to her FCA claims and Defendants are entitled to summary judgment as a matter of law.

A. The Essential Element of a "False" Claim is Absent from the Record

In order to satisfy the second element under the FCA, Dr. Hill must establish that the claim filed was "false" or "fraudulent." [1] *Hefner*, *supra*, 2005 WL 3542471, at *7 (*citing* 3729(a)(1)). Dr. Hill is unable to meet this burden for at least two reasons. First, the "claims, records and statements" underlying the NIH Grant were not objectively false or fraudulent. Second, the law does not impose FCA liability where there is a dispute about scientific judgments, methods or hypotheses. Because the record is completely devoid of any showing that Dr. Hill's dispute with Defendants' data underlying the NIH Grant is anything other than a scientific dispute at best, Dr. Hill's claims fail as a matter of law.

1. The "Data" is Not "False" or "Fraudulent"

This Court has previously held that "a false or fraudulent claim is one aimed at extracting money the government otherwise would not have paid." *Hefner*, *supra*, 2005 WL

[1] To the extent that Dr. Hill has the ability to show that the purpose and effect of the NIH Grant obtained by Defendants caused the United States to pay out money it was not otherwise obligated to pay, Defendants do not dispute that the NIH Grant may constitute a "claim" within the meaning of the FCA sufficient to satisfy the first element of an FCA cause of action.

3542471, at *7 (*quoting United States ex rel. Drescher v. HighMark, Inc.*, 305 F. Supp. 2d 451, 457 (E.D. Pa. 2004)). There must also be proof of an "objective falsehood" – that is, a statement that is capable of being declared false. *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376-77 (4th Cir. 2008). *See also United States ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000)("At a minimum, the FCA requires proof of an objective falsehood.") (*citing Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1477-78 (9th Cir. 1996)); *Boisjoly v. Morton Thiokol, Inc.*, 706 F.Supp 795, 808 (D. Utah 1988) (finding that the FCA requires a statement of fact that can be said to be either true or false). "Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false." *Roby*, *supra*, 100 F. Supp. 2d at 625 (*citing Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412, 1420-21 (9th Cir. 1992)). More succinctly put, the claim must be a lie. *Hindo v. Univ. of Health Sciences/The Chicago Medical Sch.*, 65 F.3d 608, 613, (7th Cir. 1995), *cert. denied*, 116 S. Ct. 915 (1996) (*citing Wang*, *supra*, 975 F.2d at 1420).

In support of her claim that Defendants engaged in scientific misconduct, Dr. Hill makes two claims: (1) that Dr. Bishayee fabricated and/or falsified and/or plagiarized data in an experiment that took place in September/October 1999 and involved survivability and mutagenicity following irradiation of mammalianV79 cells with the mutant gene HPRT; and (2) that Dr. Bishayee had fabricated and/or falsified data in a second experiment done March 26-30, 2001, concerning the "bystander effect" on mammalian cells. (Leonard Cert., Ex. N, Amended Complaint, ¶¶19-21). The crux of Dr. Hill's allegations is that the data reported in the publications and the Defendants' NIH Grant could not be replicated and Defendants failed to inform their supervisors at UMDNJ or NIH and failed to submit a retraction of the data. (*Id.* at ¶¶23-24, 28-29). Dr. Hill also alleges that Dr. Lenarczyk, "observed and reported to Hill that he

also suspected Bishayee of fabricating data." (*Id.* at ¶25). Unfortunately for Dr. Hill, the evidence before the Court does not support these allegations and thus, her Amended Complaint fails to state a claim for FCA liability.

First, as evidenced by the reports of UMDNJ's Committee on Research Integrity (the "Committee") and the ORI, Dr. Hill can not and has not demonstrated that the data at issue is fabricated. Indeed, the Committee unanimously concluded on two separate occasions that there was insufficient credible and definitive evidence of misconduct in science to warrant further investigation of Dr. Hill's allegations. (Defendants' Statement of Facts, ¶¶ 7-8, 22-25). First, on or about April 11, 2001, the Committee began an official investigation into Dr. Hill's allegations. (Defendants' Statement of Facts, ¶6). The Committee interviewed Drs. Hill, Lenarczyk, Bishayee and Howell and reviewed all of the relevant documents and materials, including, but not limited to, all documents and photographs submitted by Dr. Hill in support of her allegations, the grant application in question, all publications on which the grant was based, all publications appearing subsequent to receipt of the grant which reported on data developed under the grants, all abstracts pending presentation, data collected and recorded by Dr. Bishayee, and the curriculum vitaes of Drs. Bishayee, Howell and Hill. The Committee ultimately issued a fifteen (15) page report on June 21, 2001 (the "First Report"). (Defendants' Statement of Facts, ¶¶ 7-9). In the First Report, the Committee unanimously concluded that there was "insufficient credible and definitive evidence of misconduct in science to warrant further investigation." (Leonard Cert., Ex. C, pg. 14).

After UMDNJ closed its first investigation, Dr. Hill, apparently unsatisfied with the Committee's findings, contacted the ORI. ORI was provided with the Committee's First Report, reviewed all of the materials and data reviewed by the Committee, and conducted its own

investigation before formulating a twenty one (21) page report on September 5, 2002 (the "ORI Report"). (Defendants' Statement of Facts, ¶¶ 11-14). It too concluded that there was insufficient evidence to warrant further investigation of Dr. Hill's claims that Dr. Bishayee had fabricated or falsified data. (Defendants' Statement of Facts, ¶14). Notably, ORI forwarded a copy of its report to NIH. (Defendants' Statement of Facts, ¶ 15). Not only did NIH not revoke the grant in question, but after the initial grant concluded in 2005, NIH actually renewed the grant in 2006 to continue through 2010. (Defendants' Statement of Facts, ¶16).

Not to be deterred, on or about November 11, 2002, Dr. Hill initiated a second complaint with the Committee. Dr. Hill stated that she was "not satisfied with the outcome of her previous complaint regarding the alleged scientific misconduct of Dr. Anupam Bishayee." (Defendants' Stmt. of Facts, ¶¶ 17-26; Leonard Cert., Ex. H, pg. 1). Dr. Hill now alleged that the Defendants' inability to replicate Dr. Bishayee's initial results following certain limited testing, coupled with certain alleged statistical anomalies in the data generated by Dr. Bishayee bolstered her claims of fabrications/falsification. (Leonard Cert., Ex. H). Again, the Committee took the appropriate steps to identify and sequester all materials and data relevant to Dr. Hill's allegations, including all of Dr. Bishayee's research data. (Defendants' Statement of Facts, ¶ 19). After interviewing Drs. Hill and Bishayee, reviewing the materials and data submitted by Dr. Hill, reviewing Dr. Lenarczyk's lab notebooks, and contacting ORI to receive clarification of certain conclusions set forth in the ORI Report, the Committee issued a second report on March 10, 2003 (the "Second Report"). (Leonard Cert., Ex. I). Notably, during Dr. Bishayee's interview he was pointedly asked whether he falsified experimental data, to which he responded, "No, I did not." (*Id.*, Appendix J). In the Second Report, the Committee again unanimously concluded that there was

"insufficient credible evidence of misconduct in science to warrant further investigation" of Dr. Hill's allegations. (*Id.* at pg. 5).

Based on the undisputed record before the Court, Dr. Hill has not set forth even a scintilla of evidence to show that Defendants' data supporting the NIH Grant was objectively false. After careful analysis of all the relevant materials and testimony provided by Dr. Hill, two review bodies composed of scientists and Health Service employees determined that she had failed to present sufficient evidence upon which those bodies could conclude that Dr. Bishayee had falsified or fabricated the data in question. Notwithstanding these prior determinations, Dr. Hill now asks this Court to review the very same evidence and declare to the contrary that the data generated by Dr. Bishayee was in fact false. Quite simply, Dr. Hill is unable to provide any evidence upon which this Court could reach such a contrary position. At best, Dr. Hill has set forth a difference in interpretation of the data in question or a scientific dispute. This, however, is not sufficient to support a reasonable inference that the representation was false within the meaning of the False Claims Act.

2. **Scientific Disputes Are Not Actionable Under the FCA**

Dr. Hill's Amended Complaint fails for the additional reason that her claims fall well short of alleging a valid FCA claim and rather simply allege a scientific dispute. Such allegations are not sufficient to give rise to a valid claim under the FCA. As has been aptly noted by courts confronted with similar types of scientific disagreements, "the legal process is not suited to resolving scientific disputes or identifying scientific misconduct." *United States of America ex. rel. Milam v. The Regents of the University of California*, 912 F.Supp. 868, 886 (D.Md. 1995). *See also United States ex rel. Anderson v. Northern Telecom, Inc.*, 52 F.3d 810, 815-16 (9th Cir. 1995) ("The statutory phrase 'known to be false' does not mean scientifically

untrue; it means 'a lie.'") (citations omitted); *Hindo*, *supra*, 65 F.3d at 613-14 ("[T]here is no false claim or fraud here. At most, the University was perhaps negligent in not ascertaining whether funding had been approved for the radiology residencies before it invoiced the [V.A.] Medical Center for its costs, but negligence is not actionable."); *Wang*, *supra*, 975 F.2d at 1421 ("the common failings of ... scientists are not culpable under the Act"); *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1047-48 (N.D. Ill. 1998) (dispute over exercise of "scientific judgment" held "insufficient to support an FCA action"), *aff'd*, 183 F.3d 730, 733 (7th Cir. 1999); *Boisjoly*, *supra*, 706 F.Supp. at 810 ("[The certification] reflects an engineering judgment .... It is clearly not a statement of fact that can be said to be either true or false, and thus cannot form the basis of a FCA claim."). Simply put, "[d]isagreements over science methodology do not give rise to False Claims Act liability." *Milam*, 912 F.Supp. at 886.

In an almost identical case to the facts presented here, the District Court for the District of Maryland granted summary judgment dismissing all of a relator's claims after concluding that similar scientific disputes did not rise to the level of fraud claims under the FCA. *Milam*, *supra*, 912 F.Supp. 868. The relator in *Milam* was a researcher in defendant Marton's laboratory for four years. *Id.* at 875. The experiment at issue was designed to discover why the effectiveness of a brain tumor drug was increased when administered with other drugs and treatments. During one of the first experiments to test this hypothesis, defendant Tofilon's results led to more than double effectiveness. Relator Milam was subsequently asked to replicate Tofilon's first experiment, but failed to do so. Eventually, Milam claimed that defendants Tofilon, Marton and Deen (Tofilon's co-researchers) "juggled the data and made comparisons where none could, or should have been made." *Id.* at 877. The essence of Milam's claims was that Tofilon's "results varied widely but that he, Deen and Marton selected the two most favorable experiments to

publish." *Ibid.* Specifically, Milam alleged that Tofilon failed to follow appropriate scientific methods and therefore, the experiments produced "non-data," but the defendants continued to report the data to NIH. *Id.* at 878.

Just as in this case, the relator in *Milam* made a formal accusation of scientific misconduct to the University. In response, the University promptly conducted a formal investigation into the validity of the research. *Id.* at 878-79. The University investigator, Wolff, reviewed the data and interviewed witnesses, and concluded that no fraud was involved in Tofilon's research. *Ibid.* Specifically, Wolff could not completely replicate the original experiment with the original slides used by Tofilon because they were of "extremely low quality 'which could have led to the unconscious recording of data that could not be repeated.'" *Ibid.* Thus, Wolff concluded that additional investigation was not needed because of insufficient evidence of scientific misconduct. *Ibid.*

At the close of the University's investigation, the ORI reviewed the inquiries and investigations conducted by the University. *Id.* at 879. The ORI investigated two issues: (1) whether Tofilon, Deen, and Marton "falsified results in publications" and (2) whether Tofilon, Deen, and Marton "failed to properly cite the retractions and retracted publications appropriately in their grant applications." *Ibid.* After its investigation, the ORI found that the quality of Tofilon's slides had so deteriorated that his original experiment could not be duplicated to discover whether the data was falsified. *Ibid.* The ORI found that despite the fact that Tofilon failed to meet standards of good laboratory practice, it could not find "sufficient evidence to warrant further investigation," just as the ORI found in this matter. *Ibid.* In granting summary dismissal of the relator's claims, the court held that the ORI report was "relevant and highly probative in that it is a detailed report, written by a scientific oversight agency, on the precise

issue before this Court." *Id.* at 880.

In dismissing all of the relator's claims under the FCA, the court held that "[a]t most, the Court is presented with a legitimate scientific dispute, not a fraud case. Disagreements over science methodology do not give rise to False Claims Act liability." *Id.* at 886 (*citing Northern Telecom*, *supra*, 52 F.3d at 815-16; *Wang*, *supra*, 975 F.2d at 1421). The court further instructed that "the legal process is not suited to resolving scientific disputes or identifying scientific misconduct." *Ibid.* In support of its holding, and instructive to this Court's evaluation of the allegations raised by Dr. Hill, the court in *Milam* cited a law review article examining the difficulty in evaluating scientific disputes in the courtroom:

> The discord between the scientific and legal approaches to misconduct is well illustrated by the efforts of federal agencies to settle upon a proper definition of "misconduct."...The division between misconduct and legitimate science may be difficult to distinguish, and not even a *mens res* requirement such as "deliberate falsification" is sufficient to adequately distinguish the two. For example, consider the problem of selective reporting of data. The scientific report is by no means a stenographic or historical description of the research completed, nor is it meant to be. The scientist chooses carefully and deliberately what aspects of his research deserve to be reported. In doing so, he exercises the creativity that lies at the heart of science...The essence of scientific genius is the ability to choose what ought to be left out.

Ibid. (*quoting* Dan L. Burk, *Research Misconduct: Deviance, Due Process, and the Disestablishment of Science*, 3 Geo. Mason Indep. L. Rev. 305, 333-34 (1995)).

Following and prior to *Milam*, there have been numerous decisions similarly holding that the legal process is not suited to resolving scientific disputes or identifying scientific misconduct. In *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034 (N.D. Ill. 1998), a former laboratory employee brought a *qui tam* action alleging that the laboratory made false claims to the federal government in connection with its sales of plasma derivatives to federally funded hospitals and

that she was discharged in retaliation for her investigation of those false claims. The relator in *Luckey* contended that the laboratory impermissibly deviated from the standard of care in testing plasma samples. *Id.* at 1047. In concluding that the relator did not present a viable FCA claim, the court referred to *Milam* for the proposition that "the mere deviation from scientific norms is insufficient to support an FCA action." *Id.* at 1048.

In *United States ex rel. Gray v. Lockheed Martin Corp.*, 2010 WL 672016 (E.D. La. Feb. 19, 2010) ("Leonard Cert., Ex. Q), the relator, Gray, who worked in the research and development group of the operations lab at Lockheed Martin, filed a complaint alleging that Lockheed Martin violated the FCA by knowingly presenting or causing to be presented false claims to NASA. Specifically, the relator alleged that Lockheed Martin withheld "critical information from NASA relevant to the true capabilities of the optical technologies" he claimed to develop. The employee believed that everyone at Lockheed Martin was wrong about his technology. The court concluded that "this does not amount to fraud – it was, as NASA employees explained, a 'difference of opinion.'" *Id.* at *7. Quoting *Milam* to support its decision to grant summary judgment dismissing the relator's claims, the court emphasized that "[t]he legal process is not suited to resolving scientific disputes or identifying scientific misconduct." *Ibid.* (*quoting Milam*, *supra*, 912 F.Supp. at 886).

In this case, we have analogous allegations to those in *Milam* and the many other cases that have refused to find FCA violations in scientific disputes. Contrary to Dr. Hill's conclusory allegations, she is unable to provide any demonstrative evidence to prove that Dr. Bishayee fabricated the data in question. Rather, Dr. Hill relies exclusively on inferences of falsity that she contends arise because of Defendants' inability to replicate Dr. Bishayee's data after certain limited testing and certain statistical anomalies that Dr. Hill suggests exist in the data. Dr. Hill's

subjective analysis and disagreement with Dr. Bishayee's findings are precisely the type of scientific scrutiny that the courts have consistently found to be outside the purview of the FCA.

In evaluating these types of scientific disputes, it is important to consider that evaluations of scientific misconduct are best left to the scientific community and related government agencies, which already have extensive institutional and regulatory mechanisms in place to guard against scientific misconduct and remedy harm when such misconduct is found. "Congress [has] ... specifically provided for investigations by entities receiving research grants, 42 U.S.C. 289b(a)(1), and required them to report to the Secretary of the Department of Health and Human Services ("HHS") any investigation of alleged scientific fraud which appears substantial." *McCutchen v. United States Dep't. of Health & Human Svcs.*, 30 F.3d 183, 189 (D.C. Cir. 1994). Under the HHS regulatory scheme, ORI "oversees the implementation of all PHS [Public Health Service] policies and procedures related to scientific misconduct; monitors the individual investigations into alleged or suspected scientific misconduct conducted by the institutions that receive PHS funds for biomedical or behavioral research projects or programs; and conducts investigations as necessary." 42 C.F.R. §50.102. In this case, ORI thoroughly reviewed the allegations of fraud and fabrication levied against Defendants and concluded that there was insufficient evidence for further investigation of Dr. Hill's allegations. (Defendants Statement of Facts, ¶¶ 11-14). The United States Attorney's Office also declined pursuit of Dr. Hill's claims. (Defendants Statement of Facts,¶ 29). While Dr. Hill continues to challenge the propriety of Dr. Bishayee's data notwithstanding these prior investigations, she has failed to provide any new evidence indicating that Defendants actually lied about the data to the government. Absent evidence of "knowing fraud," Dr. Hill's claims cannot survive summary judgment. *Milam*, *supra*, 912 F. Supp. at 889 (*quoting Northern Telecom*, *supra*, 52 F.3d at 815).

B. Not Only Were There No "False" Claims, There Was No "Knowing" Submission of a False Claim

To the extent that Dr. Hill can establish that the NIH Grant was based on data that was "false" or "fraudulent," Dr. Hill must still show that Defendants submitted the grant "knowing" that it contained data that was false or fraudulent. *Hefner*, *supra*, 2005 WL 3542471 at *9. The FCA defines "knowing" and "knowingly" as a person who either has "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information;" or "acts in reckless disregard of the truth or falsity of the information in the claim submitted to the government." 13 U.S.C. 3279(b). While the statutory definition states that "no proof of specific intent to defraud is required," Congress has made explicitly clear "its intention that the act not punish honest mistakes or incorrect claims submitted through mere negligence." *Hefner*, *supra*, 495 F.3d at 109 (*quoting U.S. ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1073 (9th Cir. 1998)). Stated simply, "[t]he requisite intent is the knowing presentation of what is known to be false." *Hindo*, *supra*, 65 F.3d at 613 (*quoting U.S. ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1420 (9th Cir. 1991)). "The phrase 'known to be false' in that sentence does not mean 'scientifically untrue;' it means 'a lie.'" *Wang*, *supra*, 975 F.2d at 1421. The FCA is concerned with ferreting out "wrongdoing," not scientific errors. *Ibid.* (*citing United States ex rel. Dick v. Long Island Lighting Co.*, 912 F.2d 13, 18 (2d Cir. 1990)).

To satisfy the scienter requirement of the FCA, a relator must provide evidence of "knowing fraud." *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996). At issue in *Hagood* was whether the Sonoma County Water Agency fraudulently induced the United States to underbill it. In reviewing the relator's claim under the FCA, the court commented that "the requisite intent is the knowing presentation of what is known to be false, as opposed to innocent mistake or mere negligence." *Id.* (citations omitted).

Similarly, in *Wang*, *supra*, 975 F.2d 1412, the Ninth Circuit affirmed the district court's holding that a corporation did not knowingly submit false claims to the government based on alleged engineering inadequacies. Essentially, the false claim in *Wang* hinged on the relator's criticism of a co-worker's engineering calculations. The Ninth Circuit reasoned that, while a co-workers "miscalculation" and "lack of engineering insight," "might be proof of a 'mistake' or even of 'negligence' in performing the work," "[p]roof of one's mistakes or inabilities is not evidence that one is a cheat." *Wang,* 975 F.2d at 1421. In finding the scienter element unsatisfied, the court noted that "[w]ithout more, the common failings of engineers and other scientists are not culpable under the Act." *Ibid.*; *see also Boisjoly*, *supra*, 706 F.Supp. at 810 ("[The certification] reflects an engineering judgment .... It is clearly not a statement of fact that can be said to be either true or false, and thus cannot form the basis of a FCA claim.").

In *Luckey*, *supra*, the court concluded that even assuming that a submitted claim or certification is later determined to be false, a defendant in a FCA suit would not have "knowingly" submitted a claim "if it was submitted as the product of the defendant's good faith professional opinion or judgment." *Luckey*, *supra*, 2 F. Supp. 2d at 1049. Accordingly, the court concluded that while the relator had produced evidence from which a trier of fact could infer that defendants were using outdated procedures in screening its plasma samples, the relator's failure to demonstrate that defendants' tardiness in implementing the protein test advocated by relator was part of a scheme to defraud the government was fatal to her FCA claim. Indeed, the court stated "[t]he FCA prevents this Court from converting what at best can be called [defendants'] negligence into a lie." *Ibid.* Thus, the court concluded that there was no evidence that would allow a reasonable jury to conclude that defendants were committing fraud as required by the FCA and accordingly granted defendants' motion for summary judgment. *Id.* at 1049-50.

In *Hefner*, *supra*, 495 F.3d 103, the defendant was a medical center that received funding under a federal grant that provided funding for the treatment of AIDS patients. One of the grant's conditions was that it not be used to replace any existing sources of financial support. The defendant interpreted this condition to mean that it could use the grant for services that Medicare would have paid as long as they did not actually bill Medicare and in some instances, used the grant and also billed Medicare for the services. That interpretation turned out to be incorrect. In *Hefner*, the evidence showed the defendant hospital knew that it could not request federal grant funding for services that were also billed to Medicare, but that due to a "breakdown" in the hospital's billing system, such double-billing had occurred. 45 F.3d at 106-07. As soon as the hospital was notified of this problem, however, the hospital took corrective measures and ultimately returned the improper payments to Medicare. *Id.* at 107. In affirming this Court's grant of summary judgment dismissing the relator's FCA claims, the Third Circuit found that, even though the claims submitted were in fact false, the relator had presented no evidence that the hospital knew it was double-billing or that it had any reason to believe there were problems with its billing system. *Id.* at 109-10. Without evidence of actual knowledge that the defendants knowingly submitted false claims, the relator was unable to satisfy the scienter requirement of the FCA. *Ibid.*

"For a *qui tam* action to survive summary judgment, the relator must produce sufficient evidence to support an inference of knowing fraud." *Northern Telecom*, *supra*, 52 F.3d at 815 (*citing Wang*, *supra*, 975 F.2d at 1420). In the cases where a defendant was found to have the requisite intent to substantiate a FCA claim, there has always been substantial evidence, not merely inferences or conclusory allegations, that the defendant was actually knowingly submitting false information to the government. As has already been concluded by the

Committee and ORI, no such evidence exists in this case.

Here, the ORI and UMDNJ (twice) have determined that there is insufficient evidence to conclude that the data presented by Dr. Bishayee was fabricated. Simply put, both the ORI and UMDNJ concluded that the data necessary to make such a determination is not available and thus it is not possible to objectively determine whether Dr. Bishayee fabricated the data. Moreover, Dr. Hill has failed to uncover or present any evidence to show that Defendants knowingly submitted data that they knew to be false to the NIH.

There is simply no direct evidence and no evidence from which a jury could reasonably draw an inference that Defendants knowingly presented a false or fraudulent claim to the NIH. The evidence put forth by Dr. Hill has already been deemed inconclusive and insufficient to warrant a finding of scientific misconduct against Defendants. Furthermore, UMDNJ cannot be held liable for submission of false claims unless one of its employees knowingly submitted a false claim. *See Milam*, *supra*, 912 F. Supp. at 889. Therefore, it is not possible for a fact finder to find that any of Defendants "knowingly" submitted false data to NIH and Dr. Hill's claims should be dismissed as a matter of law.

C. **The "Data" Was Not Material to the NIH's Decision to Fund the Grant**

Finally, not only is the data at issue incapable of being declared objectively false, it also fails to meet the materiality standard of an FCA claim as a matter of law. The record does not demonstrate the data at issue was material to the government's funding decision. Rather, the record belies any such suggestion. Indeed, it is undisputed that the Government reviewed the ORI report related to Dr. Hill's allegations and notwithstanding that fact, it actually extended the funding of the NIH Grant to Defendants.

Several federal courts have determined that the FCA covers only those false statements

that are material to the government's decision to pay or approve a claim. *United States ex rel. Berge v. Board of Trustees of the Univ. of Alabama*, 104 F.3d 1453, 1459 (4th Cir. 1997); *United States v. Data Translation, Inc.*, 984 F.2d 1256, 1267 (1st Cir. 1992); *Gray*, *supra*, 2010 WL 672016. In order to satisfy the FCA materiality requirement, a false claim must have "a natural tendency to influence, or [be] capable of influencing, the decision of the decision making body to which it is addressed." *Kungys v. United States*, 485 U.S. 759, 770 (988); *Berge, supra*, 104 F.3d at 1460.

In *Berge*, the relator, a doctoral candidate in nutritional sciences at Cornell University brought a *qui tam* action under the FCA against the University of Alabama at Birmingham and certain University officials ("UAB"), alleging that UAB had made false statements to NIH in its annual progress reports under an NIH grant. 104 F.3d at 1456. Specifically, the relator alleged that UAB made false statements to NIH by including an abstract of one of the individual defendant's work which allegedly plagiarized the relator's own work and that UAB knew of the plagiarism. Notably, after the complaint was filed, the government investigated to determine whether it would choose to prosecute the matter on its own behalf. The OIG conducted an investigation but recommended that no action be taken and the government declined to become involved. *Id.* at 1456. Nonetheless, after a ten-day jury trial, a jury returned a verdict in favor of the relator, finding FCA liability against all of the defendants except one. On appeal, however, the Fourth Circuit found that the evidence was insufficient to show that UAB made false statements to the government and that those alleged false statements were material. *Id.* at 1460-62.

In reversing the jury verdict, the Fourth Circuit concluded that "the materiality of false statements is a legal question" and in the context of the FCA the "determination of materiality,

although partaking of the character of a mixed question of fact and law, is one for the court." *Id.* at 1460 (*citing United States ex rel. Butler v. Hughes Helicopter Co.*, 1993 WL 841192 (C.D.Cal. Aug. 25 1993)(holding that the materiality of false statements under the FCA is a legal question for the court)). Indeed, where the case for materiality is so weak that "no reasonable juror could credit it," materiality is a threshold question for the court to resolve. *Ibid.* (*citing U.S. v. Gaudin*, 515 U.S. 506 (1995).

Here, just as in *Berge*, Dr. Hill has provided no evidence that the data supporting the NIH grant is false let alone materially capable of influencing NIH's funding decision. More particularly, Dr. Hill's claims of scientific misconduct have already been considered and dismissed on three separate occasions by two scientific bodies. At each juncture, as set forth above, the review of Dr. Hill's allegations yielded an insufficient finding of falsity or fraud on the part of Defendants. Moreover, not only did NIH not revoke the grant in question, but after the initial grant concluded in 2005, NIH actually renewed the grant in 2006 to continue through 2010. While not dispositive, the decisions by the Committee and ORI coupled with the decision of the US Attorney's office to not pursue this matter undermine Dr. Hill's claims. Furthermore, the NIH's renewal of the Grant in question even after ORI reviewed Dr. Hill's allegations contradicts any suggestion that the allegedly false data improperly influenced the NIH's decision to award and then renew the Grant. Despite having already had at least three bites at the apple, Dr. Hill has been unable to proffer additional evidence to support her claims. Where the case for materiality is so weak that "no reasonable juror could credit it," materiality is a question of law for the court to resolve. Indeed, here, Dr. Hill cannot meet her burdens of establishing either falsity, knowledge or materiality, let alone all three required elements of an FCA claim, and as a consequence, judgment as a matter of law is appropriate.

POINT III

DR. HILL'S RETALIATION CLAIM FAILS AS A MATTER OF LAW BECAUSE NO MATERIALLY ADVERSE EMPLOYMENT ACTION RESULTED FROM ANY PROTECTED ACTIVITY

"The FCA protects 'whistleblowers' who pursue or investigate or otherwise contribute to a *qui tam* action, exposing fraud against the United States government." *McKenzie v. BellSouth Telecom., Inc.*, 219 F.3d 508, 513 (6th Cir. 2000) (citation omitted). In pertinent part, the FCA provides that:

> [a]ny employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole.

31 U.S.C. § 3730(h).

A plaintiff employee asserting a cause of action under § 3730(h) must show that: "(1) [s]he engaged in 'protected conduct' (i.e., acts done in furtherance of an action under § 3730) and (2) that [s]he was discriminated against because of [her] 'protected conduct.'" *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 186 (3d Cir. 2001) (*citing United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 736 (D.C.Cir. 1998)). For an employee to demonstrate that she was discriminated against "because of" conduct in furtherance of a FCA suit, the employee must in turn make two showings: (a) "[her] employer had knowledge that [she] was engaged in 'protected conduct'"; and (b) "that [her] employer's retaliation was motivated, at least in part, by the employee's engaging in 'protected conduct.'" [2] *Hefner*, *supra*, 495 F.3d at

[2] An employee's retaliation cause of action under the FCA is composed of three essential elements: (1) engaging in protected conduct, (2) employer knowledge and (3) employer discrimination. There is variation between jurisdictions

111; *see also Yesudian*, 153 F.3d at 736. At that point, the burden shifts to the employer to prove that the employee would have been terminated even if the employee had not engaged in the protected conduct. *Hefner*, *supra,* 495 F.3d at 110.

In order for Dr. Hill's FCA retaliation claim to survive summary judgment, she must make a showing sufficient to establish that she engaged in protected conduct. *See Hefner*, 495 F.3d at 110. Dr. Hill must also show that she was discriminated against by UMDNJ and that the alleged discrimination constituted an adverse employment action. *See id.* Finally Dr. Hill must show that there is a causal connection between the alleged adverse employment action and alleged protected conduct. *See id.*

(1) UMDNJ Did Not Subject Dr. Hill to any Adverse Employment Action

Assuming arguendo for purposes of this motion that Dr. Hill was in fact engaged in protected conduct in continuing to pursue her allegations even after the Committee, ORI and the US Attorney refused to agree with her conclusions of fabrication/falsification, in order to succeed on a retaliation claim under the FCA, Dr. Hill must also show that UMDNJ discriminated against her. *Hutchins*, *supra*, 253 F.3d at 186. When analyzing evidence of discrimination and retaliation under 31 U.S.C. § 3730(h), jurisdictions often look to the area of federal employment law for support. *See Boze v. Gen. Elec. Co.*, 2009 WL 2485394, at *2 (W.D.Ky. Aug. 11, 2009) (applying Title VII when determining what constitutes an adverse employment action under the FCA) (Leonard Cert., Ex. R). Courts have held that in order for an employee to fulfill the "discrimination" element of a FCA claim, the employee must offer evidence that her employer took action against her sufficient to constitute an adverse employment action. *Id.* An employment decision does not meet the standard of an adverse

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regarding the formation of the retaliation test, with courts applying either a two-prong, three-prong or four-prong test. However, the factors and the application for all of the tests is qualitatively the same in all jurisdictions. *See Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1052 n.11 (N.D Ill. 1998).

employment action "unless the decision 'would be sufficient to constitute an adverse employment action under Title VII.'" *Id.* (*citing Moore v. California Institute of Tech. Jet Propulsion Lab.*, 275 F.3d 838, 848 (9th Cir. 2002)).

An adverse employment action under Title VII is defined as an action that a reasonable employee would have found "materially adverse, which, in this context, means it well might have dissuaded a reasonable worker from making or supporting a charge of discrimination." *Burlington Northern & Santa Fe Railway Co. v. White*, 548 U.S. 53, 68 (2006). This "judicially administrable" objective test, which focuses on the materiality of the challenged action from the perspective of a *reasonable* employee, is meant to screen out groundless retaliation claims based on "trivial conduct" that is only subjectively adverse. *Id.* at 70. It "avoids the uncertainties and unfair discrepancies that can plague a judicial effort to determine a plaintiff's unusual subjective feelings." *Id.* at 68-69.

Changes in the actual terms and conditions of employment, such as a termination, demotion, or reduction in pay are almost always "materially adverse," and therefore usually qualify as an "adverse employment action." *See Boze*, 2009 WL 2485394, at *2; *Crady* v. *Liberty Nat. Bank & Trust Co. of Ind.*, 993 F.2d 132, 136 (C.A.7 1993) ("A materially adverse change might be indicated by a termination of employment, a demotion evidenced by a decrease in wage or salary, a less distinguished title, a material loss of benefits, significantly diminished material responsibilities, or other indices that might be unique to a particular situation"). Where, however, the alleged adverse action was not a concrete change in the terms of employment, courts must confirm that the alleged adverse action was objectively *material*, as opposed to an objectively *minor* slight:

> We speak of *material* adversity because we believe it is important to separate significant from trivial harms. Title

> VII, we have said, does not set forth a general civility code for the American workplace.

Burlington Northern, 548 U.S. at 68. The Supreme Court has made clear that federal law "protects an individual not from all retaliation, but from retaliation that produces an injury or harm. *Id.* at 67. Engaging in protected activity "cannot immunize that employee from those petty slights or minor annoyances that often take place at work and that all employees experience." *Id.* As a result, not "'every low evaluation or other action by an employer that makes an employee unhappy or resentful [is] considered an adverse action,' otherwise 'paranoia in the workplace would replace the prima facie case as the basis for a . . . cause of action' for retaliation." *Boze*, 2009 WL 2485394, at *2 (*citing Primes v. Reno*, 190 F.3d 765, 767 (6th Cir. 1999)).

Further, "personality conflicts at work that generate antipathy and snubbing by supervisors and co-workers are not actionable." *Burlington Northern*, 548 U.S. at 68 (giving the example that a "supervisor's refusal to invite an employee to lunch is normally trivial, a nonactionable petty slight"); *see also MacKenzie v. City and County of Denver*, 414 F.3d 1266, 1279 (10th Cir. 2005) (holding that "silent treatment" is "mere passive treatment [that] does not constitute an adverse employment action"). In *Flannery v. Trans World Airlines, Inc.*, 160 F.3d 425, 426 (8th Cir. 1998), the plaintiff, Jeanette Flannery, was a Reservation Sales Agent in TWA's Frequent Flyer Bonus Department. Flannery alleged that she was discriminated against by a supervisor after she reported sexual remarks he made to her to her supervisor. Flannery claimed she was retaliated against because she was ordered to remove a fan from her desk, her work hours were changed, she was reprimanded for a dress code violation, her parking space was moved further from her work station, and she was admonished for liberally awarding or refunding frequent flyer miles to customers. *Id.* at 427. However, Flannery did not lose any pay,

seniority, or benefits as a result of this reassignment. *Id.* The court held that the "shunning" did not rise to the level of an adverse employment action where the plaintiff did not allege that the ostracism resulted in a reduced salary, benefits, seniority or responsibilities. *Id.* at 428; *see also Manning v. Metropolitan Life Ins. Co.*, 127 F.3d 686, 693 (8th Cir. 1997) (ostracization was not of sufficient intensity to rise to the level of an adverse employment action), *Miller v. Aluminum Co. of America*, 679 F.Supp. 495, 505 (W.D. Pa. 1988) (plaintiff must show more than occasional unkind words, snubs and perceived slights to prove adverse employment action). If conduct such as shunning and ostracism were actionable, "minor and even trivial employment actions that an irritable, chip-on-the-shoulder employee did not like would form the basis of a discrimination suit." *MacKenzie v. City & County of Denver*, 414 F.3d at 1279 (*quoting Smart v. Ball State Univ.*, 89 F.3d 437, 441 (7th Cir. 1996)).

The *Burlington Northern* case provides a good example of the limited types of materially adverse actions, short of firing or demotion, that nevertheless qualify as an injury or harm. The plaintiff in that case, Sheila White, was a female who worked on a railroad track gang. 548 U.S. at 57. Her primary job was to operate a forklift, which was objectively determined to be one of the cleaner, more desirable jobs on the track gang. *Id.* at 55. White was sexually harassed by a supervisor while on the job, and reported the harassment to railroad management. *Id.* at 58. The harasser was then punished by the railroad. *Id.* One of White's other supervisors, upset about White's report and the resulting punishment of his colleague, permanently reassigned White from her usual forklift duty to objectively less desirable, more arduous, and dirtier track labor tasks. *Id.* at 53, 58. The Supreme Court found that this reassignment was material, and thus qualified as an "adverse employment action" upon which the plaintiff could base a retaliation claim. *Id.* at 71, 79. The Supreme Court made it clear, however, that "reassignment of job duties

is not automatically actionable." *Id.* at 71. The transfer in *Burlington Northern* could be considered retaliatory only because the track labor duties to which White was reassigned were by all accounts more arduous and dirtier; that the forklift operator position required more qualifications, which is an indication of prestige; and that the forklift operator position was objectively considered a better job and the male employees resented White for occupying it. *Id.*

Numerous cases since *Burlington Northern* provide good examples of the employer actions that do ***not*** qualify as "materially adverse," and therefore cannot, as a matter of law, support a retaliation claim. For instance, in *Boze*, *supra*, Randall Larkins, an employee at a manufacturing plant operated by General Electric Aviation ("GE"), brought a *qui tam* action against GE alleging that GE knowingly sold defective aircraft parts from one of its facilities to the government in violation of the FCA. 2009 WL 2485394, at *1. Larkins alleged that he engaged in protected activity when he participated, assisted and testified in a grand jury investigation of GE by federal authorities in regard to illegal activities, and that GE retaliated against him in violation of the anti-retaliation provisions of the FCA. *Id.* at 1-2. Larkins alleged that he had suffered numerous adverse employment actions including denial of promotions, fabricated problems with job performance and attendance, lack of protection from threats of violence, intrusive surveillance and punitive job assignments. *Id.* at 3-8. Specifically, Larkins alleged that upon his return from a sick leave, he discovered that GE had attempted to illegally lock him out of the GE facility in retaliation for his grand jury testimony and that he was told he was being suspended pending a review of his time and attendance. *Id.* at 6. Larkins could not, however, recall when this incident occurred, which member of management told him he was suspended and whether, at the time of the incident, he had received prior warnings about his attendance and tardiness. *Id.* Regarding the alleged lock out, the court found that "missing from

the record [was] any evidence that [gave] rise to an inference that GE suspended Larkins because he testified before the grand jury." *Id.* The court dismissed Larkin's claim of retaliation, finding that it failed "simply because many of the alleged employment decisions made by GE [did] not constitute adverse employment action." *Id.* at 9.

Similarly, in *Aryain v. Wal-Mart Stores Texas LP*, 534 F.3d 473 (5th Cir. 2008), the plaintiff, Jenna Aryain, was a cashier in a Wal-Mart oil change department. Aryain reported to the store manager, Gwendolyn Furr, and the assistant manager, Chelly Whiddon, that her immediate male supervisor in the oil change department was sexually harassing her. The managers investigated the complaint, but could not substantiate it, and reported their findings to Aryain. *Id.* at 476-77. Wal-Mart then granted Aryain's father's request that she be transferred to the infants department. After the complaint and transfer, Furr and Whiddon allegedly (1) required Aryain to break down clothing racks and move them to the back of the store on a hot day, (2) denied her breaks when she said her back hurt, (3) watched Aryain on a security camera while she loaded a clothing rack into a bin behind the store, (4) looked at Aryain angrily, laughed at her, and talked about her. Furthermore, Furr allegedly (5) made Aryain wait for long periods of time to speak to her, and (6) left her off of a work schedule. *Id.* at 477-78. Finally, Aryain alleged that (7) Wal-Mart retaliated against her by transferring her to the infants department (even though her father requested the transfer on her behalf). *Id.* at 485. The Fifth Circuit upheld summary judgment in Wal-Mart's favor on all claims because "[a]s a matter of law, these allegations do not rise to the level of material adversity. Instead, the court held that they fall into the category of petty slights, minor annoyances, and simple lack of good manners that employees regularly encounter in the workplace, and which the Supreme Court has recognized are not actionable retaliatory conduct." *Id.*

Further, in *James v. Metropolitan Gov't of Nashville*, 243 Fed. Appx. 74 (6th Cir. 2007), the plaintiff, Maralyn James, a library employee, filed an EEOC charge against the Nashville Government alleging age discrimination, disability discrimination, and retaliation. After filing this charge, James's employer (1) denied her request for a lateral transfer, (2) gave her bad employment evaluations, and (3) imposed new "cataloguing quotas" upon her, which required that she increase her productivity. *Id.* James alleged that these were materially adverse employment actions motivated by her EEOC Complaint. The Sixth Circuit disagreed:

> [N]one of these things James complained about significantly affected her professional advancement. James continued to work and received the same pay despite her Title VII claims. She also continued to receive bad evaluations but those were not markedly worse than earlier ones and the evaluations did not affect her earnings. Her employment conditions were essentially unchanged after she filed with the EEOC. James's allegations are not actionable because they failed to significantly impact her professional advancement and would not have dissuaded a reasonable person from filing a Title VII claim.

[*Id.* at 79.]

Dr. Hill alleges that an adverse employment action was taken against her when her administrative title of division chief was removed. (Leonard Cert., Ex. T, Deposition of Helene Hill, 82:23-83:4). This action, however, was simply a result of the reorganization of the divisions of the UMDNJ's Radiology Department. The Radiology Department was originally composed of four divisions of greatly disparate sizes – the Diagnostic Radiology division had forty members, the Radiation Therapy division had three members, the Radiation Research division had three members, and the Cancer Biology division had one member – Dr. Hill. On or about July 11, 2001, Dr. Baker decided that since the Cancer Biology division was a one-person division (Hill Dep., 83:24-84:6), since Dr. Hill was no longer performing independent research

(Hill Dep., 148:17-25; 37:21-38:4), and since Dr. Hill was already sharing laboratory space with the three members of the Radiation Research division (Hill Dep., 78:5), it made sense to combine those two divisions. Upon the combination of these two divisions, Dr. Baker appointed Dr. Howell as the new Chief of the Division of Radiation Research. (Leonard Cert., Ex. U, Baker Dep., 54:19-54:22). Dr. Baker's decision to reorganize the divisions of the Radiology Department made functional and organizational sense for UMDNJ and constituted a valid and reasonable employment decision fully within his authority. It is undisputed that since the time of Dr. Hill's arguably protected activity, UMDNJ did not terminate her, demote her or transfer her and that she did not experience any reduction in salary or benefits. In fact, Dr. Hill continues to maintain the same position, salary and benefits to this very day.

Dr. Hill also alleged that an adverse employment action was taken against her when Dr. Howell restricted her from accessing the division's larger laboratory (Leonard Cert., Ex. T, 78:5-78:10). On July 31, 2001, Dr. Howell, shortly after being named Chief of the Radiation Research Division, issued a memo identifying the office and laboratory space assigned to each employee. (Leonard Cert, Ex. V, Howell July 31, 2001 Memo). Every member of the Radiation Research division received the memo from Dr. Howell and was informed that they were now only permitted access to their designated office and laboratory space. (*Ibid.*). As a result of this memo, Dr. Hill no longer had access to the division's larger laboratory. (*Ibid.*). Dr. Hill admitted, however, that she was only denied access to the larger laboratory for a mere period of several days or at most a few weeks (Leonard Cert., Ex. T, Hill Dep., 82:6-8).

Finally, Dr. Hill alleges in her Complaint that Dr. Howell and others "engaged in other actions that led to the creation of a hostile work environment." (Leonard Cert., Ex. N, Amended Complaint, ¶ 32). At her deposition, however, Dr. Hill admitted that she was not called any

names (Leonard Cert., Ex. T, Hill Dep., 81:22-82:23), was never threatened (*Id.*, 81:24-82:5), did not have to seek attention from a healthcare professional (*Id.*, 93:14-93:17), and did not have to take any medications for anxiety or depression as a result of the alleged adverse employment action. (*Id.*, 93:18-94:4). The only support that Dr. Hill provides for this vague allegation of a hostile work environment is that she was "shunned" by her co-workers and felt left out of the group. (*Id.*, 85:2-85:6, 97:4-97:7). In particular, Dr. Hill alleges that Dr. Howell informed her that he "wanted nothing more to do with [her]" (*Id.*, 78:12-78:19) and "has not spoken to [her], except in public, since that time." (*Id.*, 78:15-78:16). The law is clear that without evidence of some more tangible change in duties or working conditions that constitute a material employment disadvantage, such as reduced salary, benefits, seniority or responsibilities, Dr. Hill's general allegations of snubbing and ostracism are not sufficient to rise to the level of an adverse employment actions for purposes of Title VII. Dr. Hill cannot show that the alleged discriminatory acts she suffered from UMDNJ constituted actionable adverse employment action and, therefore, her retaliation claim under the FCA must fail as a matter of law.

(2) There is No Causal Connection Between the Alleged Protected Conduct and Alleged Discrimination

Finally, to succeed in her retaliation claim under the FCA, Dr. Hill must establish that she was discriminated against "because of" conduct in furtherance of a False Claims Act suit. *Hutchins*, *supra*, 253 F.3d at 186; *Hefner*, *supra*, 495 F.3d at 111. In order for an employee to establish that there was a causal connection between the employment decisions and the protected conduct, an employee must show that: (a) "his employer had knowledge [she] was engaged in 'protected conduct'"; and (b) "that [her] employer's retaliation was motivated, at least in part, by the employee's engaging in 'protected conduct.'" *Hutchins*, *supra*, 253 F.3d at 186; *Hefner*, 495 F.3d at 111.

(a) UMDNJ Did Not Have Knowledge that Dr. Hill was Engaged in Protected Conduct

Section 3730(h) requires that the protected conduct be "in furtherance of an action under this section." 30 U.S.C. § 3730(b). An employee's conduct, therefore, must put an employer on notice of the "distinct possibility of False Claims Act litigation." *Hutchins*, 253 F.3d at 188. An employer's knowledge is essential because without knowledge that an employee is contemplating bringing a False Claims Act suit, "there would be no basis to conclude that the employer harbored § 3730(b)'s prohibited motivation [,] i.e., retaliation." *Id.* at 188.

An inquiry into whether an employee puts his employer on notice consists of whether the employee "engaged in conduct from which a fact finder could reasonably conclude that the employer could have feared that the employee was contemplating filing a qui-tam action against it or reporting the employer to the government for fraud." *Ibid.* Litigation is a "distinct possibility" only if the evidence reasonably supports such fear; if the evidence does not support this fear, litigation would not have been a distinct possibility. *Ibid.* Not all complaints by employees to their supervisors are sufficient to put employers on notice of the "distinct possibility" of FCA litigation. *Id.*, at 190.

In *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 948 (5th Cir. 1994), the Court of Appeals for the Fifth Circuit found an employee did not engage in "protected conduct" nor did he put his employer on notice of potential False Claims Act litigation when he reported to his supervisors that the company was billing the government for various helicopter projects without properly substantiating the charges. The court noted the plaintiff "never used the terms 'illegal,' 'unlawful' or '*qui tam* action' in characterizing his concerns about [the] charges." *Id.* at 951; *see also Mann v. Olsten Certified Healthcare Corp.*, 49 F. Supp. 2d 1307, 1307 (M.D.Ala. 1999). Additionally, an inference that an employer was on notice of an employee's protected conduct is

weakened where the matter that is subject to investigation is found not to have been fraudulent. *See U.S. ex. rel. Quinn v. Omnicare, Inc.*, 2003 WL 24296532, at *11 (D.N.J. March 28, 2003) ("[T]he fact that the policy subject to investigation was not fraudulent . . . also makes it harder to infer that Defendants were on notice of protected conduct") (Leonard Cert., Ex. S).

Dr. Hill has not established that UMDNJ was on notice that she was engaging in allegedly protected conduct "in furtherance of" an action under 30 U.S.C. § 3730(b). Dr. Hill provides in her Amended Complaint that she first brought her allegations of scientific research misconduct forward during a conversation she had with Dr. Howell in which she informed him of her observations and suspicions regarding data from Dr. Bishayee's experiments. (Leonard Cert., Ex. N, Amended Complaint, ¶ 20). Additionally, Dr. Hill testified that, "[w]hen I blew the whistle, I was following the instructions of the university" and that she had been told that "if we observed misconduct we were supposed to report it to our supervisor. I was following the rules of the university when I did what I did." (Hill Dep. 85:9-85:10, 85:18-85:25). It is clear that Dr. Hill came forward with her allegations because she felt "an obligation and a duty" to do so under the UMDNJ guidelines (Hill Dep. 152:11-152:12). At no point, however, does Dr. Hill provide this Court with any support which shows that she came forward with her allegations with the "distinct intention" of bringing FCA litigation against UMDNJ or that she performed any actions which notified UMDNJ about her plans to do so. Additionally, no where does Dr. Hill allege that she used the terms 'illegal,' 'unlawful' or '*qui tam* action' when she characterized her concerns about the data results from Dr. Bishayee's experiments. Further, since the grant application in question was found not to be false or fraudulent by the Committee in two separate investigations and by ORI after it conducted its own independent investigation, and since the NIH decided not only not to revoke the grant application but to renew it through 2010, it is that much more

difficult to infer that UMDNJ was on notice that Dr. Hill was engaging in protected conduct.

(b) UMDNJ Did Not Retaliate Against Dr. Hill "Because of" Her Engagement in "Protected Conduct"

To establish a causal connection between alleged adverse employment action and alleged protected conduct where there is an absence of direct evidence of retaliatory intent, an employee "must produce sufficient evidence from which an inference could be drawn that the adverse action would not have been taken in the absence of the protected conduct." *Boze*, *supra*, 2009 WL 2485394, at *5 (*quoting Weigel v. Baptist Hosp. of E. Tenn.*, 302 F.3d 367, 381 (6th Cir. 2002). A plaintiff can generally make a showing of the motivation element through "evidence that defendant treated the plaintiff differently from similarly situated employees or that the adverse action was taken shortly after the plaintiff's exercise of protected rights." *Nguyen v. City of Cleveland*, 229 F.3d 559, 563 (6th Cir. 2000).

Dr. Hill alleges that UMDNJ removed her division title "because of" her decision to come forward with her allegations of scientific research misconduct. As previously discussed above, UMDNJ made an employment decision to reorganize the Radiology Department. Dr. Baker, as Chairman of Radiology at UMDNJ, determined that reorganizing the four divisions of disparate size into three larger, more uniform divisions made functional and organizational sense for the Department. The employment decision was reasonable and justifiable and fully within Dr. Baker's authority as Chairman. The fact that Dr. Hill no longer had her division title after the reorganization was simply an unintentional result of the two departments being merged. Further, loss of her division title was of minor significance because it did not change her academic title of full professor or in any way modify her salary or her current rights, responsibilities or activities within the Department.

Dr. Hill also alleges that UMDNJ no longer permitted her to access the larger laboratory

"because of" her decision to come forward with her allegations of scientific research misconduct. However, Dr. Hill was not the only employee affected by this employment decision. Each member of the newly formed Radiation Research division received the July 30, 2001, memorandum from Dr. Howell and was informed about the changes made to their office and laboratory space. Dr. Hill has failed to provide this Court with any evidence showing that as a result of this employment decision, she was treated differently than the other employees in her division. Moreover, Dr. Hill has failed to provide any evidence which supports a conclusion that the timing of the reorganization was suspect or inferred retaliation. In actuality, the timing of Dr. Howell's decision to re-assign office and laboratory space was extremely reasonable. The Radiology Department had recently been reorganized; a new Radiation Research division had been formed; and Dr. Howell had recently accepted his new position as chief of the Radiation Research division.

Dr. Hill's conclusory allegations fail to state a claim for retaliation. Nowhere in her Amended Complaint does Dr. Hill allege a factual predicate concrete enough to support her conclusory statement that she was retaliated against because she engaged in conduct protected under the FCA. Although Dr. Hill makes strong accusations, she has not come forward with any direct or even circumstantial evidence to support a conclusion that the alleged employment decisions did, in fact, constitute retaliation for her engagement in protected conduct. Dr. Hill has failed to show that there was a causal connection between the employment decisions and the protected conduct.

In sum, Dr. Hill had failed to show that she engaged in protected conduct, that she suffered an actionable adverse employment action, or that there exists any causal connection between her claimed protected conduct and the allegedly adverse employment actions that she claims to have

encountered. Therefore, her statutory retaliation claim under 30 U.S.C. ¶ 3730(h) fails as a matter of law and summary judgment in favor of UMDNJ is warranted.

POINT IV

UMDNJ IS ENTITLED TO RECOVER ATTORNEYS' FEES AND EXPENSES FROM DR. HILL AS A RESULT OF THIS FRIVOLOUS LITGATION

31 U.S.C. § 3730(d)(4) governs the award of costs in FCA cases and provides that a defendant in a *qui tam* action may be entitled to an award of its reasonable attorneys' fees and expenses if it prevails in the action and the court finds "that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment." The legislative history of the FCA's fee shifting provision indicates Congress's strong desire to discourage bad faith actions under the FCA:

> The Committee added this language in order to create a strong disincentive and send a clear message to those who might consider using the private enforcement provision of this Act for illegitimate purposes. The Committee encourages courts to strictly apply this provision in frivolous or harassment suits as well as any applicable sanctions available under the Federal Rules of Civil Procedure.

S.Rep. No. 99-345, at 29, U.S. Code Cong. & Admin. News 1986, at p. 5294. Additionally, "a district court may in its discretion award attorney's fees to a prevailing defendant . . . upon a finding that the plaintiff's action was frivolous, unreasonable, or without foundation, even though not brought in subjective bad faith." *Christiansburg Garment Co. v. EEOC,* 434 U.S. 412, 421 (1978).

A review of the series of events which preceded the institution of this action shows that Dr. Hill frivolously brought this complaint. As described in more detail above, on three separate occasions, Dr. Hill's allegations of scientific research misconduct were thoroughly investigated

by highly experienced and respected scientific bodies composed of individuals with extensive scientific backgrounds and impressive resumes. In each instance, each committee and agency put together a substantive and detailed report summarizing the investigation that had been conducted and the results that were reached. In each instance, each committee and agency independently concluded that there was insufficient definitive evidence to warrant further investigation of the alleged misconduct. Based on these events, Dr. Hill, or Dr. Hill's counsel, had more than sufficient reason to know, prior to filing this action, that her claims were manifestly insufficient and futile and not likely to succeed. And yet, despite the overwhelming evidence demonstrating that there was insufficient definitive evidence to warrant further investigation into Dr. Hill's allegations, Dr. Hill filed this FCA claim against UMDNJ, Dr. Howell and Dr. Bishayee. In sum, Dr. Hill's claims have no underlying justification in fact and lack legal merit and, as a result, UMDNJ, Dr. Howell and Dr. Bishayee are entitled to an award of attorneys' fees and expenses under Section 3730(d)(4).

CONCLUSION

Based on the foregoing, Defendants respectfully submit that the Court should grant their Motion for Summary Judgment and dismiss Plaintiff's Amended Complaint pursuant to Federal Rule of Civil Procedure 56 with prejudice.

Respectfully submitted,

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