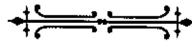
In The

United States Court of Appeals for the Third Circuit



10-4364

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

Plaintiff-Appellant,

v.

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

Defendants-Appellees.

On Appeal from the United States District Court
for the District of New Jersey
Civil Action No. 03-4837 (DMC)

BRIEF FOR DEFENDANTS-APPELLEES

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RESPONSE STATEMENT OF FACTS

Plaintiff-Appellant Dr. Helene Z. Hill ("Dr. Hill"), a Professor of Radiology employed by Defendant University of Medicine and Dentistry of New Jersey ("UMDNJ"), brought this *qui tam* action under the False Claims Act ("FCA"), 31 U.S.C. 3729 to -33, on behalf of herself and the United States Government pursuant to 31 U.S.C. 3730(b)(1), against Defendants-Appellees, UMDNJ, Dr. Roger W. Howell and Dr. Anupam Bishayee. [189a, Amended Complaint].

Prior to filing her Complaint in this matter, in or about April 2001, Dr. Hill approached certain individuals at UMDNJ with allegations of scientific research misconduct directed at Defendant Dr. Bishayee. [*Id.*, ¶ 26]. Dr. Hill asserted that Dr. Bishayee had fabricated experiment data that Dr. Roger Howell subsequently included in a grant application that Dr. Howell, as Principal Investigator, had submitted to the United States Department of Health and Human Services, National Institutes of Health ("NIH") back on October 29, 1999 (the "NIH Grant" or "Grant"). [*Id.*, ¶¶ 19–26].

Upon Defendants' receipt of Plaintiff's allegations and in accordance with UMDNJ's Misconduct in Science Policy, appropriate steps were immediately taken to identify and sequester all materials and data relevant to Dr. Hill's allegations. [1890a, UMDNJ Misconduct in Science Policy; 818a, Report of Initial Inquiry into Allegations of Potential Misconduct in Science Against Anupam

Bishayee, Ph.D., dated June 21, 2001]. UMDNJ's Newark Campus Committee on Research Integrity (the "Committee") was then convened on or about April 11, 2001, to perform a preliminary assessment of Dr. Hill's allegations. [819a]. After reviewing Dr. Hill's allegations, the Committee voted unanimously to immediately commence an initial inquiry in accordance with UMDNJ's Misconduct in Science Policy. The official start date of the inquiry was April 11, 2001. [*Id.*].

After interviewing Drs. Hill, Lenarczyk, Bishayee and Howell and reviewing 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 and the curricula vitae of Drs. Bishayee, Howell and Hill, the Committee issued a fifteen (15) page report on June 22, 2001 (the "First Report"). [817a]. In the First Report, the Committee unanimously concluded "that there was insufficient credible and definitive evidence of misconduct in science to warrant further investigation" of Dr. Hill's allegations. [829a]. On July 2, 2001, UMDNJ's Senior Vice President for Academic Affairs, Robert A. Saporito, D.D.S., in accordance with UMDNJ's Misconduct in Science Policy, reviewed and accepted the initial findings of the Committee. [1056a, Ltr. from Dr. Saporito, dated July 2, 2001]. On that date, Dr.

Saporito forwarded correspondence to Drs. Hill, Bishayee and Howell informing them of his decision that there was insufficient credible evidence of misconduct in science on the part of Dr. Bishayee to warrant further investigation of Plaintiff's allegations. [*Id.*; 1902a, Ltr. from Dr. Saporito, dated July 2, 2001; 1903a (same)].

After UMDNJ closed its investigation, Dr. Hill, apparently unsatisfied with the Committee's review and conclusions relating to her allegations, contacted the United States Department of Health and Human Services, Office of Public Health and Science, Office of Research Integrity ("ORI") and forwarded her allegations to ORI's Division of Investigative Oversight. [1059a, Ltr. from Dr. Hill, dated Aug. 23, 2001]. In accordance with federal regulations, ORI oversees and directs the integrity of Public Health Service ("PHS") research activities. *See* http://ori.hhs.gov/ The PHS is composed of a number of federal offices and agencies, including, among others, the National Institutes of Health ("NIH"), which awarded and funded the Grant in question. Upon receiving Dr. Hill's allegations, ORI contacted UMDNJ and was provided with the First Report, as well as all of the materials and data reviewed by the Committee. [1059a, Ltr. from Dr. Hill, dated Aug. 23, 2001; 1904a, Ltr. from Dr. Fields, dated Sept. 4, 2001]. After reviewing the First Report and all of the materials provided by UMDNJ, and after conducting certain analysis of its own, ORI issued a twenty one (21) page report on September 5, 2002 (the "ORI Report"), concurring with the Committee's

conclusion that there was insufficient evidence to warrant further investigation of Dr. Hill's allegations. [1061a, Cover Letter of Chris B. Pascal, J.D., Director, ORI, dated Sept. 5, 2002, attaching copy of ORI Report].

ORI forwarded copies of its report to Dr. Ruth Kirschstein, ARILO, and Dr. Ronald Geller, AERIO, at NIH. [*Id.*]. Not only did NIH not revoke the Grant, but after the initial Grant concluded in 2005, NIH actually renewed the Grant in 2006 to continue through 2010. [1907a, Renewal Grant Application].

On or about November 11, 2002, Dr. Hill initiated a second complaint with the Committee. [1960a, Initial Contact Sheet, dated Nov. 11, 2002]. Dr. Hill's second complaint of scientific research misconduct against Dr. Bishayee was not based on any new evidence, but rather was based only on statistical data that Dr. Hill alleged provided further proof of the falsity of Dr. Bishayee's research data. [*Id.*]. Nonetheless, appropriate steps were immediately taken in accordance with UMDNJ's Misconduct in Science Policy to identify and sequester all materials and data relevant to Dr. Hill's allegations. [1278a, Report of Initial Inquiry into Allegations of Potential Misconduct in Science Against Anupam Bishayee, Ph.D., dated March 10, 2003 ("Second Report")]. The Committee was convened again on or about November 25, 2002, to perform a preliminary assessment of Dr. Hill's second allegations. [1281a]. After reviewing Dr. Hill's allegations, the Committee voted unanimously to commence an initial inquiry in accordance with UMDNJ's

Misconduct in Science Policy. [1282a]. The official start date of the inquiry was November 25, 2002. [*Id.*].

On December 12, 2002, the Committee had a telephone conversation with Dr. Alan Price, Director of ORI, and Dr. John Dahlberg, also with ORI, to clarify the meaning of certain points raised in the ORI Report, specifically with respect to ORI's reference to the independent statistical analysis of the data in question. The key points from this conversation were: (1) Dr. Dahlberg advised the Committee that it is ORI policy that statistical analysis, in the absence of other valid empirical evidence, is not sufficient justification to proceed with an investigation of misconduct in science; (2) in this case, there was no independent evidence of scientific misconduct because there was no evidence generated by someone not a party to the complaint (i.e., someone other than Dr. Hill); and (3) independent control data necessary to evaluate Dr. Bishayee's results were not possible to achieve under the particular circumstances of this case. [1359a, Second Report, Appendix I].

On January 14, 2003, the Committee met again and heard testimony from Dr. Bishayee. Dr. Bishayee was specifically asked whether he falsified experimental data to which he responded, "No, I did not." [1360a, Second Report, Appendix J]. After interviewing Drs. Hill and Bishayee, reviewing the materials and data submitted by Dr. Hill and contacting ORI, the Committee issued a second

report on March 10, 2003 (the "Second Report"). [1278a]. In the Second Report, the Committee unanimously concluded that there was again insufficient credible and definitive evidence of misconduct in science to warrant further investigation of Dr. Hill's allegations against Dr. Bishayee. [*Id.*, 1284a]. On March 21, 2003, UMDNJ's Senior Vice President for Academic Affairs, Robert A. Saporito, D.D.S., in accordance with UMDNJ's Misconduct in Science Policy, reviewed and accepted the findings of the Committee. [1277a, Ltr. from Dr. Saporito, dated March 21, 2003]. On that date, Dr. Saporito forwarded correspondence to Drs. Hill and Bishayee informing them of his decision that there was insufficient credible evidence of misconduct in science on the part of Dr. Bishayee to warrant further investigation. [*Id.*].

After UMDNJ closed its second investigation, Dr. Hill filed the Complaint on October 14, 2003, under seal. [1966a, Original Complaint]. On April 9, 2007, after subpoenaing Defendants and reviewing a substantial production of documents relating to the incidents alleged in Dr. Hill's Complaint for a period of over three-and-a-half years, the United States Attorney's Office filed a Notice of Election to Decline Intervention. [1981a]. On April 16, 2007, the Court entered an Order unsealing this matter. [1984a]. On April 1, 2009, Plaintiff filed an Amended Complaint. [189a]. On April 7, 2009, Defendants filed an Answer to Plaintiff's Amended Complaint and Counterclaim pursuant to 31 U.S.C. § 3730(d)(4),

denying all of Dr. Hill's allegations and seeking attorneys' fees and costs. [205a].

On March 25, 2010, Plaintiff and Defendants filed cross-motions for summary judgment pursuant to Federal Rule of Civil Procedure 56. Both motions were decided by the District Court by way of written opinion dated October 18, 2010. [4a, District Ct. Opinion]. In a seventeen-page decision, the District Court granted Defendants' motion for summary judgment, denied Plaintiff's motion for summary judgment, and dismissed Plaintiff's complaint with prejudice. With regard to Defendant Howell, the Court found as a matter of law that Dr. Howell did not possess the "requisite knowledge or intent to submit false or fraudulent data to NIH" sufficient to give rise to a cognizable FCA violation. [12a]. As to Defendant Bishayee, the District Court held that "there is no evidence that the data submitted to NIH had any material effect on their decision to grant" and, thus found that Plaintiff's allegations could not satisfy the FCA's materiality requirement and also failed as a matter of law. [18a]. As to Plaintiff's claim of workplace retaliation, the Court concluded that she did not suffer "a materially adverse employment action or discrimination of any kind" and therefore her retaliation claim similarly failed as a matter of law. [20a]. This appeal followed.

COUNTERSTATEMENT OF THE ISSUES

As a threshold matter, Defendants submit that Plaintiff's brief is deficient because it fails to comport with the explicit requirements of F.R.A.P. 28(a)(5) and

L.A.R. 28.1(a)(1). Specifically, Plaintiff's brief is conspicuously devoid of the requisite designation by reference to the specific place in the appendix or place in the proceedings at which each issue on appeal was raised, objected to, and ruled upon. L.A.R. 28.1(a)(1). These requirements are particularly important here, as Plaintiff's statement of issues does not align with the issues raised in her brief.

Plaintiff does not address the District Court's decision as to Dr. Bishayee and the "materiality" element of a FCA claim. Further, as discussed, *infra*, Plaintiff's brief also does not address her claims of retaliation. Defendants submit that Plaintiff's failure to raise these issues in her statement of issues and examine them in the substantive portion of the brief constitute a waiver of these issues on appeal. *See Leslie v. Attorney General of the United States*, 611 F.3d 171, 175 n.2 (3d Cir. 2010); *Hill v. City of Scranton*, 411 F.3d 118, 121 n.2 (3d Cir. 2005).

Moreover, the third issue presented by Plaintiff in her statement of issues is patently deficient and should be disregarded by this Court. For one, what Plaintiff purports to present on appeal—subversion of the NIH grant process—is incomprehensible and seemingly unrelated to the decision of the District Court from which Plaintiff appeals. Further, Plaintiff fails to flesh out this issue in the substantive portion of her brief, and therefore Defendants submit it is also waived. *See Hill*, *supra*, 411 F.3d at 121 n.2 (noting appellants waived their claim that district court improperly dismissed as moot various discovery motions pending at

time that court rendered summary judgment in favor of appellee, since appellants only made passing reference to that claim in "Statement of Issues For Review" in their opening brief).

SUMMARY OF THE ARGUMENT

Defendants-Appellees, University of Medicine & Dentistry of New Jersey ("UMDNJ"), Dr. Roger W. Howell and Dr. Anupam Bishayee (collectively "Defendants"), respectfully submit this brief in opposition to Plaintiff-Appellant's ("Plaintiff" or "Dr. Hill") appeal of the District Court's October 18, 2010 order granting summary judgment in favor of Defendants, denying Plaintiff's motion for summary judgment and dismissing Plaintiff's complaint with prejudice. For the reasons articulated herein, as well as those expressed by Judge Cavanaugh in his written opinion, the decision of the District Court should be affirmed.

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 – the United States Attorney's Office and the District Court. 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 continues in her misguided crusade against Defendants under the guise of government harm. Not surprisingly, the District Court rejected each of Plaintiff's claims, ruled the Complaint lacked merit and dismissed Plaintiff's suit in its entirety. Indeed, the District Court properly discerned Plaintiff's fervor from the substance of her claims, deeming Plaintiff's contentions to be "ultimately unavailing as a matter of law." [5a, District Ct. Opinion]. Distilling the tortuous history of Plaintiff's legal histrionics to their essence, Judge Cavanaugh opined, "Plaintiff's repeated failure to accept the findings of the very oversight committees she sought out has turned this lawsuit into a quest of Quixotic proportions that ultimately must be put to rest." [*Id.*].

Dr. Hill's allegations amount to nothing more than a scientific dispute, at best. The federal courts have consistently held that cases of alleged scientific misconduct are not within the scope of the 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. Moreover, the District Court having reviewed Plaintiff's voluminous factual allegations and submissions as well as the definitive case law on the topic, also concluded that Plaintiff's allegations failed to rise to the level of a cognizable claim under the FCA and mandated dismissal.

Defendants submit that Plaintiff's claims of retaliation have been abandoned on appeal as she fails to address this issue in her moving brief. In the event this Court considers these claims notwithstanding Plaintiff's waiver, they too contain fatal defects. Dr. Hill fails to provide any evidence whatsoever that she suffered any 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.

Plaintiff implores this Court to wholly ignore the legal and factual findings of the District Court. Resurrecting Dr. Hill's *qui tam* suit, however, would only improperly impose further costs and hardship on Defendants and compromise the

pursuit of legitimate scientific research. For the reasons set forth herein, the District Court's decision dismissing Plaintiff's Amended Complaint should be affirmed and Plaintiff's appeal should be denied in its entirety.

LEGAL ARGUMENT

POINT ONE

THIS PANEL REVIEWS THE DISTRICT COURT'S GRANT OF SUMMARY JUDGMENT *DE NOVO*, APPLYING THE SAME STANDARD OF LAW AS THE DISTRICT COURT

The standard of review to be applied by this Court in reviewing the District Court's order granting summary judgment is plenary. *United States ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 495 F.3d 103, 108 (3d Cir. 2007); *Shelton v. Univ. of Med. & Dentistry of N.J.*, 223 F.3d 220, 224 (3d Cir. 2000) ("Our review of the grant of summary judgment is plenary"); *see also Sgro v. Bloomberg L.P.*, 331 Fed.Appx. 932, 937 (3d Cir. 2009) (citing *Lawrence v. City of Philadelphia*, 527 F.3d 299, 310 (3d Cir. 2008) ("[w]e review the District Court's grant of summary judgment de novo, applying the same standard that it used").

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). 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 v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). 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. This matter is devoid of questions of fact. Indeed, the District Court determined each issue as a matter of law. Accordingly, for the reasons set forth herein, the District Court's decision to grant Defendants' motion for summary judgment and to deny Plaintiffs' motion for summary judgment should be affirmed by this Court.

POINT TWO

THE DISTRICT COURT PROPERLY RULED THAT EACH OF PLAINTIFF'S CLAIMS FAILS AS A MATTER OF LAW, THEREFORE ITS DECISION TO GRANT SUMMARY JUDGMENT TO DEFENDANTS, DENY SUMMARY JUDGMENT TO PLAINTIFF AND DISMISS PLAINTIFF'S COMPLAINT WITH PREJUDICE SHOULD BE AFFIRMED

On March 25, 2010, Plaintiff and Defendants filed cross-motions for summary judgment pursuant to Federal Rule of Civil Procedure 56. Both motions were decided by the District Court by way of written opinion dated October 18, 2010. [4a]. In a comprehensive and well-reasoned seventeen-page decision, the

District Court granted Defendants' motion for summary judgment, denied Plaintiff's motion for summary judgment, and dismissed Plaintiff's complaint with prejudice. [20a].

The Honorable Dennis M. Cavanaugh, U.S.D.J. opened his opinion with a recitation of the factual and procedural evolution of the matter, noting that the "origin of this case stems from Plaintiff's belief, based on her observations that she first made in October 1999, that Defendants had submitted fraudulent or falsified data to the National Institute of Health ("NIH") as part of a grant application to conduct experiments on the so-called 'bystander effect,' and subsequently in annual progress reports and in a competitive grant application that was submitted in 2005." [4a–5a]. The District Court noted that Plaintiff has, over the years, reported her suspicions to numerous persons, "oversight committees and governmental agencies including UMDNJ's Committee on Research Integrity ("the Committee"), the Office of Research Integrity ("ORI"), the investigatory arm of NIH, the U.S. Attorney's office and the Defendants themselves." [5a]. Importantly, however, neither the Committee, the ORI, nor the U.S. Attorney's office deemed Plaintiff's contentions meritorious. Indeed, each investigatory body, after a thorough investigation, concluded that Plaintiff's allegations did not merit further investigation, let alone result in a finding of scientific misconduct. Further indicative of the feebleness of Plaintiff's assertions, the U.S. Attorney's

office declined to pursue the matter after subpoenaing substantial documents from Defendants and reviewing the matter for over three-and-a-half years. The District Court noted that notwithstanding the breadth of evidence undermining the validity of her claims, Plaintiff "steadfastly maintained her contention that data was falsified" and accumulated extensive research and documentation in support thereof. [5a]. The District Court, however, properly distinguished between Plaintiff's zeal and the substance of her allegations, ruling Plaintiff's claims to be "unavailing as a matter of law." [5a]. Judge Cavanaugh precisely captured the tortured history of Plaintiff's misguided crusade when he stated, "Plaintiff's repeated failure to accept the findings of the very oversight committees she sought out has turned this lawsuit into a quest of Quixotic proportions that ultimately must be put to rest." [5a].

After a review of the applicable standards, the District Court transitioned into its legal analysis. The District Court distilled each issue presented to its essential and determinative core. As to Defendant Howell, the Court honed in on the element of knowledge, concluding as a matter of law that Howell did not possess the "requisite knowledge or intent to submit false or fraudulent data to NIH" sufficient to manufacture a cognizable FCA violation. [12a]. As to Defendant Bishayee, the District Court focused on the element of materiality, determining that "there is no evidence that the data submitted to NIH had any

material effect on their decision to grant." [18a]. As to Plaintiff's claim of retaliation, the Court concluded that she did not suffer "a materially adverse employment action or discrimination of any kind" and therefore her claim failed as a matter of law. [20a].

A. Plaintiff's Defective Claims Against Defendant Howell

The District Court first addressed Plaintiff's allegation that Dr. Howell, as the principal investigator for the NIH Grant in question, "knowingly supplied false or fraudulent information to NIH" when he submitted the Grant. As set forth in greater detail in Point Three, B, *infra*, the Court aptly noted that a cognizable FCA action requires scienter. [8a]. That is, a person who "knowingly" presents a false claim for payment in violation of the FCA, must have actual knowledge of the falsity of the information, act in deliberate ignorance of the truth or falsity of the information, or act in reckless disregard of the truth or falsity of the information. [8a]. The Court identified the four elements on which Plaintiff based her contention that Dr. Howell knowingly submitted false data: (1) the accounts of two eyewitnesses (Hill and Lenarczyk); (2) the inability of both Howell and Lenarczyk (or anyone for that matter) to replicate Bishayee's 100% experiments; (3) the inability of both Howell and Lenarczyk (or anyone for that matter) to replicate Bishayee's 50% experiments; and (4) the statistical analysis of an expert statistician, Dr. Pitt, who concluded there is "a probability of 100 billion to 1 that

Bishayee's Coulter counts were not fabricated." [8a–9a]. In determining whether Defendant Howell possessed the requisite knowledge of the falsity of the data such that his conduct violated the FCA, the Court considered each of the elements submitted by Plaintiff.

As to the first element, the accounts of two eyewitnesses, the Court corrected Plaintiff's version of the facts, noting that "as of October 1999, Plaintiff *alone* noticed Dr. Bishayee conducting research that she found suspicious." [9a]. The District Court observed that, in fact, it was not until April of 2001 that Plaintiff believed she had sufficient information to approach the Committee about the suspected misconduct, and when she informed Dr. Howell of her suspicions, "*he did not believe the results were fudged.*" [9a]. Accordingly, Judge Cavanaugh concluded that Plaintiff's own statements belied her assertions and held that Plaintiff's statements actually established that "Defendant Howell did not have knowledge as required by the FCA that data was fraudulent or fabricated, nor did he act recklessly." [9a]. Further refuting Plaintiff's argument, the Court observed that Dr. Lenarczyk, the other eye witness "upon whom Plaintiff relies to corroborate her allegations" had not yet been hired and therefore did not observe Dr. Bishayee's suspect conduct. [10a].

The Court similarly rejected the second and third elements of Plaintiff's allegations, concluding that the "inability to replicate data in the 50% and 100%

experiments" was not indicative of scientific misconduct. [10a]. The Court relied upon *United States ex rel. Milam v. Regents of Univ. of California*, 912 F.Supp. 868, 889 (D.Md., 1995), for the proposition that awareness of variant results is "'not sufficient as a matter of law to render [scientific] submissions to be false statements.'" [10a]. Critically, the District Court determined that "the fact that results could not be replicated is proof only that the results could not be replicated." [10a]. In so finding, the District Court gave weight to the ORI's conclusion that "'in the absence of additional evidence of their falsification, this question [whether the results of the bystander effect experiments could be replicated]'" is not an "'issue of scientific misconduct.'" [11a (quoting ORI Report 2001-28, page 000278)].

As to the fourth element submitted by Plaintiff, the statistical analysis of Dr. Pitt, the Court noted that said analysis was done after the ORI investigation and therefore "could not have contributed to Defendant Howell's knowledge as of October, 1999." [11a]. Moreover, Plaintiff's reports and additional investigation into the veracity of the data were not known to Howell at the time he applied for the NIH Grant. [11a]. Accordingly, the District Court found "it is impossible to conclude that Dr. Howell had the requisite knowledge or intent to submit false or fraudulent data to NIH in October, 1999." [12a].

In reaching his legal conclusions, Judge Cavanaugh sought guidance from an opinion rendered by this Court in 2007 wherein it affirmed his prior dismissal of a *qui tam* claim under analogous circumstances. [11a]. The District Court observed that under *Hefner*, *supra*, 495 F.3d at 109, three elements are required to establish a prima facie case under the FCA: (1) the defendant presented or caused to be presented a claim for payment; (2) the claim was false or fraudulent; and (3) the Defendant knew the claim was false or fraudulent. [12a]. Applying this standard to the instant matter, Judge Cavanaugh concluded that Plaintiff could not establish a prima facie FCA violation because as "the knowledge requirement is clearly lacking, this Court need look no further at the underlying claim of scientific fraud as to Defendant Howell." [12a].

The District Court also rejected Plaintiff's contentions that each of Dr. Howell's progress report submissions and reapplications for funding constituted "distinct, cognizable submissions of fraudulent data actionable under the FCA." [13a]. The Court determined that prior to 1999, Howell had no reason to doubt the validity of the data. As to Howell's knowledge after 1999, the Court relied upon *Milam*, *supra*, in finding that the ORI report "is relevant and highly probative in that it is a detailed report, written by a scientific oversight agency, on the precise issue before [the] Court." [13a] (citing *Milam*, *supra*, 912 F.Supp. at 880). Accordingly, the District Court held as a matter of law that "Defendant Howell

was entitled to rely on the ORI report to the extent that 'there is insufficient evidence to warrant further investigation,' and thus to conclude that the data he was submitting was not the product of fraud." [13a]. The District Court continued, "[b]ecause it was reasonable for [Dr. Howell] to believe that the data he submitted had been scrupulously examined and found not to have sufficient credible evidence of fraud, there was no recurring bad faith conduct in continuing to use the same data in future submissions to NIH." [13a]. Thus, Judge Cavanaugh ruled that "Defendant Howell can not reasonably be charged with knowledge that Dr. Bishayee had fabricated any data; any suspicions that either he or Plaintiff might have had ought to have been put to rest after these investigations." [13a]. Commenting on the unreasonableness of Plaintiff's Quixotic crusade, the District Court concluded, "[t]he fact that Plaintiff steadfastly disregards the conclusions of three separate investigations by two autonomous institutions is not evidence that Defendant Howell should have done the same." [13a]. For the reasons set forth above and in Point Three, B, *infra*, Defendants submit that the District Court's legal conclusions are sound and should not be disturbed on appeal.

B. The District Court Properly Dismissed Plaintiff's Claims Against Defendant Bishayee

As to Plaintiff's allegations of scientific misconduct against Dr. Bishayee, the District Court held as a matter of law that Plaintiff failed to establish another of

the threshold requirements imposed on a FCA claim – materiality. In order to clarify any previous misunderstandings of the requirements of the FCA, the Court explicitly held that the FCA "imposes a materiality requirement" and concluded that "there is no evidence that the data submitted to NIH had any material effect on their decision to grant." [14a–18a].

In highlighting Plaintiff's inability to satisfy the materiality requirement, the Court aptly noted that the ORI Report actually "addresses the issue of materiality and concludes that the data which Plaintiff believes to have been fabricated was not integral to the decision by NIH to approve the grant application." [16a]. Moreover, the Court interpreted the ORI Report to suggest that "Plaintiff's real objection is to Defendant Bishayee's methodology rather than his results, something which is explicitly outside the scope of research misconduct as defined by the ORI and the Committee." [17a]. More importantly, the Court observed that the ORI report "indicates that the data in the grant application, even if questionably produced, did not adversely affect the review of the grant conducted prior to its approval by NIH. As such, it could not have been material." [17a]. Accordingly, the Court concluded as a matter of law that because said data was not reported as results in Defendants' Grant application, it "is unreasonable that data not reported as results, whether the result of good, bad or indifference science, could have been material to the grant approval by NIH in 1999." [17a].

Buttressing its dismissal of the claims against Dr. Bishayee, the Court took judicial notice of a line of cases that disallows "'FCA claims where the Government knew, or was in possession at the time of the claim, of the facts that make the claim false.'" [18a] (citing *Boisjoly v. Morton Thiokol, Inc.*, 706 F.Supp. 795, 809 (D. Utah 1988); *United States v. Fox Lake State Bank*, 366 F.2d 962, 965 (7th Cir. 1966); *Woodbury v. United States*, 232 F.Supp. 49, 54–55 (D. Or. 1964), *modified*, 359 F.2d 370 (9th Cir. 1966); *United States v. Schmidt*, 204 F.Supp. 540 (D. Wis. 1962)). The District Court determined that once the ORI became involved in 2001, the "NIH was reasonably on notice of Plaintiff's allegations" and therefore pursuant to *Boisjoly, supra*, Plaintiff's FCA claim could not survive summary judgment. [18a]. The District Court's legal rulings are unquestionably supported by the relevant case law and do not warrant reversal.

C. Plaintiff's Deficient Claim of Workplace Retaliation

Turning to Plaintiff's claim of workplace retaliation, the District Court set forth the elements of a prima facie case for retaliation under the FCA sufficient to survive summary judgment. [18a]. A plaintiff must show that "she was engaged in 'protected conduct,' that as a result she was subject to adverse employment action, and that there is a causal nexus between Plaintiff's actions and Defendant's alleged discrimination or retaliatory behavior." [18a (citing *Woodson v. Scott Paper Co.*, 109 F.3d 913, 920 (3d Cir. 1997)].

Having examined the evidence presented by Plaintiff, the District Court concluded that there was no evidence of materially adverse employment action or discrimination against Plaintiff. [20a]. Accordingly, the District Court did not "reach the issue of whether Dr. Hill engaged in 'protected conduct' because the evidence of materially adverse employment action or discrimination of any kind sufficient to defeat a motion for summary judgment [was] lacking." [20a]. Thus, the District Court ruled as a matter of law that Plaintiff's claim of retaliation lacked merit. [20a].

Based upon these definitive rulings that Plaintiff could not establish prima facie claims for any of her allegations, Judge Cavanaugh denied Plaintiff's motion for summary judgment, granted Defendants' motion for summary judgment, and dismissed Plaintiff's complaint with prejudice. [20a]. Defendants submit that each of the District Court's legal rulings is supported by the established case law and precedents relied on by the Court. Plaintiff has failed to cite any legal basis for overturning the sound rulings of the District Court and the dismissal of Plaintiff's claims should be affirmed.

POINT THREE

THE DECISION OF THE DISTRICT COURT SHOULD BE AFFIRMED BECAUSE PLAINTIFF'S COMPLAINT FAILS TO ESTABLISH THE ELEMENTS OF A CLAIM UNDER THE FALSE CLAIMS ACT AND THEREFORE WAS PROPERLY DISMISSED AS A MATTER OF LAW

A plenary review of the relevant facts and case law necessarily leads to the same conclusions reached by the District Court. The District Court's grant of summary judgment to Defendants and denial of summary judgment to Plaintiff should be affirmed because Plaintiff's Amended Complaint fails to establish the elements of a claim under the False Claims Act. Contrary to Plaintiff's assertions in her moving brief, Defendants did not submit false or fraudulent data to NIH, nor were the statements made therein false or fraudulent. 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").

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.'" *Hefner*, *supra*, 495 F.3d at 109 (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); *United States ex rel. Wilkins v. State of Ohio*, 885 F.Supp. 1055 (S.D. Ohio 1995).

The District Court properly found that Plaintiff failed to establish a prima facie false claim under the FCA sufficient to avoid summary dismissal of her Amended Complaint. Indeed, the District Court noted that, 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. [10a–11a]. 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 Defendant Howell 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 therefore the District Court's decision to grant Defendants summary judgment as a matter of law should be affirmed.

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] *United States ex rel. Hefner v. Hackensack Univ. Med. Center*, 2005 WL 3542471, at *7 (D.N.J. 2008) (citing 31 U.S.C. 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, as set forth in subsection D below, 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. Defendants' Data is Not "False" or "Fraudulent"

"[A] false or fraudulent claim is one aimed at extracting money the government otherwise would not have paid." *Hefner*, *supra*, 2005 WL 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*

[1] Defendants did not dispute below that Defendants' NIH Grant may constitute a "claim for payment" within the meaning of the FCA sufficient to satisfy the first element of an FCA cause of action.

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, supra*, 706 F.Supp. at 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 *United States ex rel. Wang 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 Med. 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, Plaintiff 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. [189a, Amended Complaint, ¶¶19-21]. The crux of Dr. Hill's allegations is that the data reported in the publications and 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.*, ¶¶23–24, 28–29]. 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. Accordingly, the District Court's decision granting summary judgment to Defendants and denying summary judgment to Plaintiff must be affirmed.

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. [829a, First Report; 1278a, Second Report]. First, on or about April 11, 2001, the Committee began an official investigation into Dr. Hill's allegations. [819a, First Report]. 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 curricula vitae of Drs. Bishayee, Howell and Hill. [817a–830a, First Report]. The Committee ultimately issued its First Report, in which the Committee unanimously concluded that there was "insufficient credible and definitive evidence of misconduct in science to warrant further investigation." [829a].

After UMDNJ closed its first investigation, Dr. Hill contacted the ORI. [1059a, Hill Ltr. To Dr. Kay Fields, dated Aug. 23, 2001]. 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 and disseminating the ORI Report. [1061a, ORI Ltr. To UMDNJ, dated Sept. 5, 2002]. 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. [*Id.*]. Notably, ORI forwarded a copy of its report to NIH. [1062a, ORI Report]. 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. [1907a, Grant Renewal App., dated November 1, 2004].

Not to be deterred, on or about November 11, 2002, Dr. Hill initiated a second complaint with the Committee. [1960a, Initial Contact Sheet, dated Nov. 11, 2002]. Dr. Hill stated that she was "not satisfied with the outcome of her previous complaint regarding the alleged scientific misconduct of Dr. Anupam

Bishayee." [*Id.*]. Dr. Hill now alleged that Defendants' inability to replicate Dr. Bishayee's initial results following limited testing, coupled with certain alleged statistical anomalies in the data generated by Dr. Bishayee bolstered her claims of fabrications/falsification. [*Id.*]. 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. [1278a, Second Report]. 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 its Second Report on March 10, 2003. [*Id.*]. Notably, during Dr. Bishayee's interview he was pointedly asked whether he falsified experimental data, to which he responded, "No, I did not." [1360a, Second Report, 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. [1284a, Second Report].

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 – some of it dating back over a decade to 1999 – and to overturn the sound decision of the District Court in contradiction to the weight of the evidence and governing principles of law. The fact that Plaintiff "steadfastly disregards the conclusions of three separate investigations by two autonomous institutions is not evidence" that this Court should do the same. [13a, District Ct. Opinion]. 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.

B. The District Court's Decision Should be Affirmed Because It Properly Concluded as a Matter of Law that Not Only Were There No "False" Claims, There Was No "Knowing" Submission of a False Claim

The District Court's decision should be affirmed because it properly honed in on the determinative issue with regard to Dr. Howell's submission of the Grant – even if Plaintiff could establish that the data submitted was "false" or "fraudulent," she could not establish as a matter of law that Defendants submitted the Grant "knowing" at the time that it contained data that was false or fraudulent. Indeed,

the District Court conclusively ruled that Defendants did not submit the Grant "knowing" that it contained data that was false or fraudulent. [12a, District Ct. Opinion (citing *Hefner*, *supra*, 495 F.3d at 109). 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." 31 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*, *supra*, 81 F.3d at 1478. 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-worker's "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, supra*, 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 v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034 (N.D Ill. 1998), *aff'd,* 183 F.3d 730 (7th Cir. 1999) the court held 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." *Id.* 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. 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. 495 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 the District Court's grant of summary judgment dismissing the relator's FCA claims, this Court 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." *United States ex rel. Anderson v. Northern Telecom, Inc.,* 52 F.3d 810, 815 (9th Cir. 1995) (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 knowingly submitting false information to the government. As has already been concluded by the Committee, the ORI, and the District Court, no such evidence exists in this case.

The similarities between *Hefner* and the instant case are striking. Indeed, in *Hefner*, this Court affirmed Judge Cavanaugh's grant of summary judgment on a

qui tam claim based on defendant's lack of the requisite knowledge. Similarly here, the District Court ruled that Plaintiff failed to establish that Defendant Howell – the principal investigator on the Grant – knew the data submitted to NIH was false and therefore her FCA failed as a matter of law. In point headings one, two and three of her brief on appeal, Plaintiff argues that the District Court opinion erroneously limited its decision to the evidence known to Hill in October 1999, when Defendants applied for the NIH Grant and that Defendants' progress reports and 2005 continuation Grant constituted independent and cognizable acts of fraud. In so arguing, Plaintiff asks this Court to wholly ignore the factual findings and legal conclusions of the District Court, which is well-supported by the evidence and in accordance with the reasoning of *Hefner*. As the District Court noted, Dr. Howell had no reason to suspect the data was false in October 1999 when he applied for the Grant. In fact, it was not until April of 2001 that Plaintiff informed Dr. Howell of her suspicions. [9a, District Ct. Opinion]. Most importantly, the District Court ruled as a matter of law that Defendant Howell was entitled to rely on the ORI report and was not required to personally review and evaluate the multitude of complaints and documents generated by Dr. Hill after 1999. [13a, District Ct. Opinion (citing ORI Report 2001-28, p. 000278)]. Thus, the District Court held that it was reasonable for Dr. Howell to "believe that the data he submitted had been scrupulously examined and found not to have sufficient

credible evidence of fraud," and therefore he "can not reasonably be charged with knowledge that Dr. Bishayee had fabricated any data; any suspicions that either he or Plaintiff might have had ought to have been put to rest after these investigations." [*Id.*]. Undoubtedly, Judge Cavanaugh's ruling that "Defendant Howell did not have knowledge as required by the FCA that data was fraudulent or fabricated, nor did he act recklessly" is supported by the weight of the evidence. [9a, District Ct. Opinion]. This reasoning is sound and in accordance with that set forth by this Court in *Hefner*, and thus Judge Cavanaugh properly held as a matter of law that Defendants lacked the knowledge required to sustain an FCA claim. Indeed, faced with analogous facts and rulings by the District Court, this Court in *Hefner* affirmed Judge Cavanaugh's grant of summary judgment in favor of Defendants. This Court should be guided by its previous ruling and again affirm the District Court.

C. The District Court's Determination that the "Data" Was Not Material to the NIH's Decision to Fund the Grant Should be Affirmed

The data at issue is incapable of being declared objectively false and, as noted by the District Court, it fails to meet the materiality standard of an FCA claim as a matter of law. In Plaintiff's fourth point heading, she argues that Judge Cavanaugh failed to give appropriate weight to the information obtained by U.S. Attorney subpoena or the investigation by Plaintiff herself. Contrary to Plaintiff's

assertions, the District Court did weigh all the evidence before it. Simply because Judge Cavanaugh – similar to every other authority that Plaintiff has presented her grievances to – rejected Plaintiff's contentions does not undermine the validity of his rulings. In fact, the District Court correctly determined that the record does not demonstrate that the data at issue was material to the government's funding decision. As Judge Cavanaugh observed, 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); *United States ex rel. Gray v. Lockheed Martin Corp.*, 2010 WL 672016 (E.D. La. Feb. 19, 2010). 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, 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)). In accordance with this established legal precedent, the District Court properly decided materiality as a matter of law and thus its decision should be affirmed.

Here, just as in *Berge*, Plaintiff failed to provide evidence that the data supporting the NIH Grant is false, let alone materially capable of influencing NIH's funding decision. More particularly, Plaintiff's claims of scientific misconduct have already been considered and dismissed on three separate occasions by two scientific bodies. The District Court weighed this very fact in finding Plaintiff's claims lacked merit. 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, but after the initial Grant concluded in 2005, NIH actually renewed the Grant in 2006 to continue through 2010. Indeed, the NIH's renewal of the Grant 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.

Furthermore, the District Court took judicial notice of the fact that the ORI report put NIH on notice of potential weaknesses of the data and notwithstanding this information, NIH renewed and extended the Grant. [19a, District Ct. Opinion]. The District Court properly applied *Boisjoly*, *supra*, 706 F.Supp. at 809,

in holding that Plaintiff's FCA claims must fail as a matter of law because the Government knew, or was in possession at the time of the claim, of the facts that Plaintiff alleges make the claim false. It is further worth noting that Plaintiff presented no expert testimony regarding the materiality of the data to the NIH's decision to fund and renew the Grant.

For the reasons set forth above, the District Court's conclusion that the data was not material to the NIH's decision to fund the Grant and therefore fatal to Plaintiff's FCA claim must be affirmed by this Court.

D. 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." *Milam*, *supra*, 912 F.Supp. at 886. *See also Northern Telecom*, *supra*, 52 F.3d at 815–16 ("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*, *supra*, 2 F. Supp.2d at 1047–48 (dispute over exercise of "scientific judgment" held "insufficient to support an FCA action"); *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*, *supra*, 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. at 868. The relator in *Milam* was also a researcher in defendant's laboratory. *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 defendant 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 rea* 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*, *supra*, 2 F. Supp.2d 1034, 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 *Gray*, *supra*, 2010 WL 672016, 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 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. [1061a, ORI Report]. The United States Attorney's Office also declined pursuit of Dr. Hill's claims. [1981a, Notice of Election to Decline Intervention]. 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 could not survive summary judgment. *Milam*, *supra*, 912 F. Supp. at 889 (quoting *Northern Telecom*, *supra*, 52 F.3d at 815). Thus, the District Court's decision should be affirmed.

POINT FOUR

THE DISTRICT COURT'S DISMISSAL OF PLAINTIFF'S RETALIATION CLAIM SHOULD BE AFFIRMED BECAUSE THE COURT PROPERLY DETERMINED THAT PLAINTIFF'S CLAIM FAILS AS A MATTER OF LAW BECAUSE SHE DID NOT SUFFER A MATERIALLY ADVERSE EMPLOYMENT ACTION

As a threshold matter, Defendants submit that Plaintiff has abandoned her retaliation claim on appeal as her brief fails to address the issue. It is well-settled that a claim is waived on appeal if Appellant's opening brief is silent on the issue. *Leslie v. Attorney General of the United States*, 611 F.3d 171, 175 n.2 (3d Cir. 2010) (noting an appellant's failure to identify or argue an issue in his opening

brief constitutes waiver of that issue on appeal); *Hill v. City of Scranton*, 411 F.3d 118, 121 n.2 (3d Cir. 2005) (citations omitted) (noting appellants waived their claim that district court improperly dismissed as moot various discovery motions pending at time that court rendered summary judgment in favor of appellee, since appellants only made passing reference to that claim in "Statement of Issues For Review" in their opening brief). However, in order to provide the Court with a comprehensive view of the District Court's ruling below, Defendants address Judge Cavanaugh's dismissal of Plaintiff's retaliation claim. Should this Court consider this issue, the District Court's decision should be affirmed for the reasons set forth below as well as those expressed by Judge Cavanaugh in his written opinion dated October 18, 2010.

"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*, *supra*, 253 F.3d at 186 (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 111; *see also Yesudian*, *supra*, 153 F.3d at 736.

In order for Dr. Hill's FCA retaliation claim to survive summary judgment, she was required to establish that she engaged in protected conduct. Dr. Hill also needed to show that she was discriminated against by UMDNJ and that the alleged

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[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 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*, *supra*, 2 F. Supp. 2d at 1052 n.11.

discrimination constituted an adverse employment action. Finally Dr. Hill had to show that there is a causal connection between the alleged adverse employment action and alleged protected conduct. As held by the District Court, Plaintiff cannot demonstrate that she suffered an adverse employment action and therefore her entire retaliation claim fails as a matter of law.

A. The District Court Properly Ruled as a Matter of Law that UMDNJ Did Not Subject Dr. Hill to any Adverse Employment Action

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). 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 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*, *supra*, 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, *supra*, 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*, *supra*, 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*, *supra*, 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"); *Flannery v. Trans World Airlines, Inc.*, 160 F.3d 425, 428 (8th Cir. 1998) (holding that workplace "shunning" does not rise to the level of an adverse employment action where the plaintiff does not allege that the ostracism resulted in a reduced salary, benefits, seniority or responsibilities); *Manning v. Metropolitan Life Ins. Co.*, 127 F.3d 686, 693 (8th Cir. 1997) (finding 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) (holding that 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*, *supra*, 414 F.3d at 1279 (quoting *Smart v. Ball State Univ.*, 89 F.3d 437, 441 (7th Cir. 1996)).

In the instant case, the District Court properly distilled Plaintiff's allegations of adverse employment action to their essence, concluding that they failed to amount to anything more than being forced to share workspace with a colleague and being shunned by fellow employees. [19a, District Ct. Opinion]. 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, Plaintiff's general allegations of snubbing and ostracism are not sufficient to rise to the level of adverse employment actions for purposes of Title VII. Thus, in alignment with *Boze, supra*, the District Court ruled as a matter of law that Plaintiff's inability to establish that she suffered a materially adverse employment action was a fatal defect to her retaliation claim as a whole. [20a, District Ct. Opinion]. Accordingly, the District Court declined to address the issue of whether Plaintiff engaged in protected conduct and dismissed Plaintiff's claim of retaliation in its entirety. [*Id.*].

As Plaintiff waived this issue on appeal, Defendants submit that they need not inundate the Court with prolonged and superfluous analysis of this issue. Stated simply, the District Court's decision to dismiss Plaintiff's retaliation claim under the FCA as a matter of law must be affirmed.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that Plaintiff/Appellant Dr. Helene Z. Hill's Appeal be denied.

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Dated: April 27, 2011

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CERTIFICATION OF ADMISSION

I hereby certify that I am admitted to practice before the United States Court of Appeals for the Third Circuit.

By: /s John P. Leonard
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CERTIFICATION OF SERVICE

I, John P. Leonard, an attorney admitted to the bar of this Court, hereby certify that on, I have caused Defendants'/Appellees' Brief to be electronically filed and to be sent via overnight mail, to the following persons at the addresses noted below:

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CERTIFICATION OF IDENTICAL COMPLIANCE AND VIRUS CHECK

I, John P. Leonard, an attorney admitted to the bar of this Court, hereby certify that the text of the E-Brief filed on April 27, 2011, and hard copy of the brief filed by overnight mail on April 27, 2011, are identical. A virus check using McAfee VirusScan Enterprise version 8.5i was performed on the E-Brief and no virus was detected.

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Dated: April 27, 2011

CERTIFICATION OF COMPLIANCE WITH RULE 32(a)

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 13,025 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2002 in 14 Point font, Times New Roman style.

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