UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA EX REL. DR. HELENE Z. HILL,	:	CASE NO. 03-4837 (DMC)
PLAINTIFF,	:	
v.	:	
UNIVERSITY OF MEDICINE & DENTISTRY OF NEW JERSEY, DR. ROGER W. HOWELL and DR. ANUPAM BISHAYEE,	:	
DEFENDANTS.	:	

PLAINTIFF'S BRIEF IN SUPPORT OF MOTION
FOR SUMMARY JUDGMENT

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TABLE OF CONTENTS

INDEX TO BRIEF

TABLE OF CASES

TABLE OF STATUTES, RULES, REGULATIONS AND OTHER AUTHORITIES

OPENING STATEMENT

This is an action to recover damages and civil penalties on behalf of the United States of America arising from false claims and statements made and presented by the defendants and/or their agents or employees in violation of the Federal Civil False Claims Act, 21 U.S.C. §3729 et seq. as amended (the "Act"). The violations of the Act involve the Defendants' application for a grant, and the receipt of federal grant monies (Grant No. R01CA83838) based upon the knowing submission of the grant application, periodic progress reports; and, of a competitive renewal grant application to the United States Department of Health and Human Services, National Institute of Health ("NIH"). The applications aforesaid, the progress reports, as well as the findings of certain experiments that had been or were subsequently undertaken, were supported with data, statements and records that were false or fraudulent.

Through the acts described in the Amended Complaint and the Statement of Undisputed Material Facts, defendants and their agents and employees knowingly presented and caused to be presented to the United States Government false and fraudulent claims, records and statements in order to secure funding of NIH grant R01 CA83838.

Through the acts described in the Amended Complaint and otherwise, defendants and their agents and employees knowingly

made, used and/or caused to be made or used false records and statements in order to get such false and fraudulent claims funded by approval by the United States Government of NIH grant RO1 CA83838. The United States, its fiscal intermediaries, and the NIH, unaware of the falsity of the records, statements, and claims made or submitted by defendants and their agents, servants and employees paid and continue to pay defendants grant monies that would not be paid if the truth were known.

Plaintiff United States, its fiscal intermediaries, and the NIH, unaware of the falsity of the records, statements, and claims made or submitted by defendants - or their failure to disclose material facts which would have reduced or precluded government obligations - have not recovered grant monies that would otherwise have been recovered.

Moreover, through the acts described above and otherwise, the defendants and their agents and employees have harassed or otherwise discriminated against plaintiff/relator, Dr. H.Z. Hill, in the terms and conditions of her employment all committed by defendants for the reason that she committed lawful acts; namely, reporting false claims and fraud against the United States internally to defendants, in furtherance of an action under 31 U.S.C. §3730 by the Attorney General, all as described in the foregoing paragraphs. In these respects, defendants

breached 31 U.S.C. §3730(h) and plaintiff/relator is entitled to all relief allowed by law.

By reason of the defendants' false records, statements, claims and omissions, Plaintiff/Relator, Dr. H.Z. Hill, moves for summary judgment and shall demonstrate that the United States and NIH have been damaged, inter alia, in the amount of $2,358,539. Moreover, and as respects to the retaliation claims, defendants breached 31 U.S.C. §3730(h) and plaintiff/relator should be deemed entitled to all relief allowed by law.

POINT I

THE STANDARDS GOVERNING THIS MOTION

Summary judgment is appropriate if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; Ebbert v Daimler Chrysler Corp., 319 F. 3d 103, 108 (3rd Cir. 2003). In evaluating a summary judgment motion, a court must "draw all reasonable inferences in favor of the nonmoving party" Armour v County of Beaver, PA, 271 F 3d 417, 420 (3rd Cir. 2001)(quoting Reeves v Sanderson Plumbing Products, Inc., 530 U.S. 133, 150 (2000).

The initial burden of showing the absence of material facts rests on the moving party, regardless of which party would have the burden of persuasion at trial. Celotex Corp. Catrett, 477 U.S. 317, 323 (1986); Huang v BP Amoco Corp, 271 F.3d 560, 564 (3rd Cir. 2001); Jalil v Avdel, 873 F. 2d 701, 706 (3rd Cir. 1988). If the nonmoving party would have the burden of persuasion at trial, "the party moving for summary judgment may meet its burden by showing that the evidentiary materials of the record, if reduced to admissible evidence would be insufficient to carry the movant's burden at trial. Jalil, 873 F.2d at 706 (citing Chipollini v Spencer Gifts, Inc., 814 F. 2d 893, 896 (3rd Cir. 1987). Once the moving party has made a properly supported motion for summary judgment, the burden shifts to the non-moving party to "set forth specific facts showing that there is a genuine

issue for trial". Fed R. Civ P 56 (e); Anderson v Liberty, 477 U.S. 242, 250 (1986).

POINT II

THE EVIDENCE IN THIS CASE ESTABLISHES THAT DEFENDANTS VIOLATED 31 USC § 3729 (a) (1) and (2).

A. THE STATUTORY FRAMEWORK

A cause of action under the False Claims Act (hereinafter "FCA")[1], 31 USC § 3729 (a) arises when a person:

> (1) 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;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; ***

The Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21, 123 State. 1616 was signed into law on May 20, 2009. In pertinent part, 31 USC § 3729(a) now provides a cause of action against:

> (1) In general. - Subject to paragraph (2), any person who -
>
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

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[1]A private party may assert a claim under the FCA in the name of the United States government, but the complaint must be filed in camera and under seal and served on the government so that the government has the opportunity to intervene. 31 USC § 3730 (b)(2). The private party may elect to pursue the case even if the government declines to intervene, 31 USC §3730(c) (3). Here, the United States notified the court that it would not intervene. 31 USC §(b)(4)(B).

> (B) knowingly makes, uses or causes to be made or used, a false record or statement material[2] to a false or fraudulent claim.[3]

A "claim" includes any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded. 29 USC § 3729 (c). In other words, a claim is any request or demand for money

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[2]31 USC § 3729(b) (4), defines materiality to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. In United States ex rel Longhi v Lithium Power Technologies, Inc., WL 1959259, at *9 (5th Cir. July 9, 2009), the "natural tendency" test was held to require only:

> "that the false or fraudulent statements either (1) make the government prone to a particular impression, thereby producing some sort of effect, or (2) have the ability to effect the Government's actions, even if this is a result of indirect or intangible actions on the part of the Defendants. All that is required under the test for materiality, therefore, is that the false or fraudulent statements have the potential to influence the Government's decisions."

[3]While the FERA amendments generally took effect on the date of enactment (May 20, 2009) and were deemed to apply to conduct on or after the date of enactment, subparagraph (B) of section 3729(a)(1) was deemed to take effect as if enacted on June 7, 2008 and to apply to all claims under the FCA that were pending on or after that date.

from the Government, made directly or through an intermediary, including a contractor, grantee, or other recipient of federal funds. It encompasses any action with the purpose and effect of causing the United States to pay money not lawfully owned, or depriving the United States of money lawfully due. United States v Richard Dattner Architects, 972 F. Supp. 738, 746-747 (S.D. N.Y. 1997). This broad application of what constitutes a "claim" supports the congressional intent to prevent fraud by attaching liability to the activity presenting the risk of wrongful payment, as opposed to waiting until the government has wrongfully paid money. Id., 55 F.3d at 709-710. United States v Rivera, 55 F. 3d 703, 709 (1st Cir. 1995) ("By attaching liability to the claim or demand for payment, the statute encourages contractors to turn square corners when they deal with the government"). The FCA seeks to redress fraudulent activity which attempts to or actually causes economic loss to the United States government. Hutchins v Wilentz, Goldman & Spitzer, 253 F.3d 176 (3rd Cir. 2001). Actions which have the purpose and effect of causing the government to pay out money are clearly "claims" within the purpose of the FCA. United States v Lawson, 522 F.Supp. 746, 750, (D.NJ 1981); United States v Neifert-White Co., 390 US 228, 233, 88 S.Ct. 959 (1968). The purpose of the FCA was to provide for restitution to the government of money taken from it by fraud. United States ex rel. Marcus v Hess, 317 US

537. 63 S.Ct. 379 (1943). While recovery under the FCA is not dependent upon the government's sustaining monetary damages, the Act is still intended to cover instances of fraud "that might result in financial loss to the Government". Varljen v Cleveland Gear Co., Inc., 250 F.3d 426, 429 (6th Cir. 2001).

Under the broad definition of a "claim" there are a number of different theories of FCA liability that have developed. In this action, Hill alleges three (3) of these theories.

A direct false claim (also referred to as "facial" or "factual claims") arises where a government payee makes a fraudulent submission intended to cause the government to issue payment. As noted above, payment is not a prerequisite to liability. 31 USC § 3729 (a) (1) (A). United States v Neifert-White Co., supra at 230; United States v Rivera, supra. FCA liability is not limited to direct false claims. Liability has also been found to attach to "legally false" claims that a government payee falsely certifies to be in compliance with a condition - usually a statute, regulation, or contract term - and that is a prerequisite to government payment. United States ex rel. Karvelas v Melrose-Wakefield Hospital, 360 F.3d 220, 232, n15 (1st Cir. 2004); United States ex rel. Hendow v University of Phoenix, 461 F. 3d 1166, 1171 (9th Cir 2006). Under the false certification theory, it is not mere regulatory violations that

give rise to FCA liability, but false certification of compliance which creates liability when certification is a prerequisite to obtaining a government benefit. Id. at 1266-1267.

Under an express false certification theory, FCA liability attaches when a claim expressly contains a false statement of compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment. United States ex rel. Hendow, supra. Additionally, the implied false certification theory allows submission of the claim for payment itself to act as the false statement of compliance, where the claim is submitted in violation to a prerequisite to payment. Thus, when evaluating a relator's allegation of implied certification, courts focus on the underlying contracts, statutes, or regulations themselves, rather than on the claimant's actual statements. U.S. ex rel Quinn v Omnicare Inc., 382 F.3d 432, 441-442 (3rd Cir. 2004); U.S. ex rel Conner v Salina Regional Health Care, Inc., 543 F.3d 1211, 1218 (10th Cir. 2008).

Based on the above, it becomes clear that in order to prove a claim under Section 3729 (a)(2), the relator must only show that "(1) the defendant made a record or statement in order to get the government to pay money; (2) the record or statement was false or fraudulent; and (3) the defendant knew it was false or fraudulent. United States ex rel Franklin v Parke Davis, 2003 U.S. Dist. LEXIS 15754, at *2-*6 (D. Mass. Aug. 22, 2003)

(holding that Section 3729 (a) (1) does not require a relator to prove a false statement, just that a false claim was presented, whereas Section 3729 (a) (2) requires a relator to prove that an affirmative false statement led to a false claim).

The FCA subjects an individual or company to liability for "knowingly" submitting or causing the submission of a false claim. 31 USC § 3729 (a).

A person acts "knowingly" when he "(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required." 31 USC §3729 (b).

Hence there is no requirement to prove that the defendant actually intended to submit false claims under the FCA. United States v Oakwood Downriver Medical Center, 687 F. Supp. 302, 309 (E.D. Mich. 1988). To the contrary, liability may be established by simply proving deliberate ignorance or reckless disregard for the truth of the claims. Plywood Property Associates v National Flood Insurance Program, 928 F. Supp. 500, 509 (D.NJ 1996); Hagood v Sonoma County Water Agency, 929 F.2d 1416, 1421 (9th Cir. 1991). Mere negligence and "innocent mistakes, however, are not sufficient to establish liability under the FCA. United States ex rel. Plumbers and Steamfitters

Local Union No. 38 v C.W. Roen Construction Co., 183 F3d 1088, 1092 (9th Cir. 1999). The relator need not prove damages. United States ex rel. Virgin Island Housing Authority v Coastal General Construction Services Corp., 299 F. Supp. 2d. 483, 487-488 (D.V.I. 2004).

A relator need not show that the false record resulted in actual payment or approval of a claim by the Government. Id. A relator must only show that the defendant cause a false record or statement to be made or used in the submission of a claim, regardless of the defendant's role in the claim process. United States v President and Fellows of Harvard College, 323 F. Supp. 2d 151, 194 (D. Mass 2004).

The terms "false" and "fraudulent" are not defined in the FCA. The terms, however, do have independent meanings:

> "A common definition of fraud" is an intentional misrepresentation, concealment, or non disclosure for the purpose of inducing another in reliance upon it to part with some valuable thing or belonging to him or to surrender a legal right." "False" can mean "not true," "deceitful," or "tending to mislead." The juxtaposition of the word "false" with the word "fraudulent", plus the meanings of the words comprising the phrase "false claim", suggest an improper claim is aimed at extracting money the government otherwise would not have paid."

Mikes v Strauss, 274 F.3d 687, 695 (2nd Cir. 2001). See also U.S. ex rel. Quinn v Omnicare, Inc., supra.

B. THE NIH GRANTS PROCESS

A grant is a form of federal assistance provided pursuant to Congress' spending power. 31 USC § 6501(4)(A)-(B). Unlike a contract where the government pays for goods or services, a grant is monetary assistance to a non-federal entity authorized by statute to meet the needs that Congress deems to be in the public interest. Id. The grants in this case are discretionary ones that are awarded on a competitive basis. To obtain these funds, Howell submitted a form of application known as a "competing new application".

(http://grants.nih.gov/grants/policy/nihgps/index.htm) (Part I, Application and Review Processes/Types of Applications, Page 7).

Such applications must meet legislative and regulatory requirements, and published selection criteria established for the particular program. After conducting a formal review process that includes peer review of the competing applications, NIH determines which applications best address the program requirements and are most worthy of funding. Id. Part I at pages 11-15.

When the NIH awards a grant, it issues a Notice of Grant Award. The Notice sets out the terms, the project period, the total project amount, the amount authorized for each year, the annual budget and the budget period. Id. Part II/Terms and Conditions of NIH Grant Awards - Parts 1-7.

A grant may be approved for a multi-year period, known as the project period. Under this method of funding, the project is programmatically approved for support in its entirety, but is funded in annual increments known as budget periods. Funds for each subsequent budget period are paid on a non-competitive basis provided funds are available, the grantee has achieved satisfactory progress and the grant continues to be in the best interests of the government. Id. Part II/Terms and Conditions of NIH Grant Awards - Part 3.

To obtain funding for a subsequent budget period under a multi-year grant, a grantee must submit an annual progress report know as a "non-competing continuation application. (Part I, Application and Review Processes/Types of Applications, Page 8). The progress report must be submitted two months before the beginning date of the next budget period, and requires among other things, a description of the progress made over the past year.

http://grants.nih.gov/grants/funding/2590/phs2590.pdf.

Once the project period has ended, the grant is either renewed or closed. 45 CFR §§ 74.71-74-73. To renew grants, grantees submit a "competing continuation application". Renewal applications compete in the same manner as the initial grant application. Id. (Part I, Application and Review Processes/Types

of Applications, Page 8). See also, United State ex.rel Bauchwitz v Holloman, 671 F. Supp 2d 674, 680-682 (E.D. Pa. 2009).

C. HOWELL'S APPLICATION

1. HOWELL SUBMITTED BOTH CLAIMS AND STATEMENTS IN ORDER TO GET NIH TO APPROVE HIS RESEARCH GRANT.

Howell's revised grant application set forth a proposal to research the effects of non-uniform distributions of radioactivity and to delineate a biological mechanism known as the bystander effect. The designated outcome of the research was to achieve a better understanding and prediction of the biological response of tumor and normal tissue to non-uniform distributions of radioactivity (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶14)*.

Howell's proposal raised significant issues in diagnostic and therapeutic nuclear medicine. His proposed studies would be of significance to patients, since the risk of radiation insult can be drastically underestimated and potentially lead to increased risk of inducing cancer. In contrast, some patients can be over- or under- treated in radionuclide therapy of cancer. Both scenarios can present adverse consequences in the final outcome for the patient. **It is, therefore, critical that patients not be misled about the results of the research (Hill S.J. Exhibit 1: Hill Certified Written Disclosure, ¶¶ 24-26).**

On two occasions preceding the submission of the revised grant application, Hill observed Bishayee engaged in preliminary experiments. Hill's observations led her to believe that Bishayee was falsifying the data underlying the experiments and the conclusions reached by Howell from those experiments (Hill S.J. Exhibit 1: Hill Certified Written Disclosure, ¶¶ 27-46). Indeed, a statistical analysis by Hill of the Coulter counts recorded in Bishayee's 1999 experiments lent additional support to her observations that those numbers had been fabricated. Id.

Hill informed Howell of both her observations and suspicions relating to Bishayee. Notwithstanding this fact, Howell dismissed Hill's concerns and further refused to intercede to Hill's request to investigate Bishayee's actions. Instead, Howell determined to use the results of Bishayee's experiments as part of the preliminary data supporting his revised grant application to NIH. The questioned results were presented by Howell in Figure 7, page 29 of his revised grant application (Hill S.J. Exhibit 1: Hill Certified Written Disclosure, ¶ 38).

In his NIH grant application Howell further presented data purporting to show a bystander effect for Tritiated Thymidine (^{3}HdThd) (Grant application page 26, Figure 2; page 27, Figure 4; and page 42, Figure 12). The data and results presented purported to show an exponential decline in survival after exposure to tritiated thymidine (^{3}HdThd). (Id).

These and similar data were presented in two publications (Bishayee, *et al.* Radiation Research 152: 88 (1999), Figures 3, 6, 7 and Table 1; and, Bishayee, *et al.* Radiation Research 155: 335 (2001), Figures 1 and 2. As will be shown, infra, these data were false and/or fraudulent and intended to cause the NIH to approve and to fund the grant. (Hill S.J. Exhibit 1: Hill Certified Written Disclosure, ¶ 47).

The experiments in question follow one of two similar protocols. In the so called 100% experiments, all the cells in a series of tubes are exposed overnight to ^{3}HdThd in graded doses. The cells are washed and transferred to narrow 400 uL-capacity tubes (Helena tubes), centrifuged to form 'clusters', incubated for 3 days to allow the incorporated ^{3}H to decay and then plated for colonies.(Hill S.J. Exhibit 4 and 6). The results of these experiments are reported in Howell's successful grant application (Hill S.J. Exhibit 3) and in two papers published in Radiation Research (Hill S.J. Exhibits 15 and 16). They show an exponential decline in survival down about 3 logs.

In the so-called 50% experiments, half of the initial tubes in the experiment are incubated overnight without radioactivity (these will be the "bystanders") and are subsequently mixed with radioactive cells before the 3 day cold incubation to allow for ^{3}H to decay. Bishayee's experiments are interpreted to show a bystander effect in that the survival of

the bystander cells is exponential down to 2 logs.(Hill S.J. Exhibit 110 and 111, page 2).

Hill contends that the results of the 100% experiments were impossible for three reasons. First, ^{3}HdThd blocks cell cycle progression so that cells that are not in DNA synthesis (S) phase during the overnight exposure cannot enter S phase and cannot be killed by the radioactive decay of ^{3}H. (Hill S.J. Exhibit 111 at pgs 1, 3-7). Indeed, there are two conditions under which all the cells in the cultures could have entered S phase and been killed; but neither one of those conditions was present in the experiments in question.[4]

The second reason for the impossibility of the exponential decline is that no deoxycytidine (dCyd) was present in the medium at the time of the exposure of the cells to ^{3}HdThd. dCyd abrogates the effect of ^{3}HdThd at blocking the cell cycle[5]. In its absence there can be no exponential decline in survival.

The third reason for the impossibility of the exponential decline is that no attempt was made in the Howell lab protocols to synchronize the cells before the addition of ^{3}HdThd. Had the cells been synchronized, they might possibly have all

[4]See also the expert report of Radiation Biologist, Dr. Michael E. Robbins, Hill S.J. Exhibit 108 at pg. 3).

[5]Id. at page 4.

been in S phase at the time that ^{3}HdThd was added (Hill S.J. 111 at pgs 4-7)[6].

Based on the above, Hill submits that it was biochemically and radio-biologically impossible for the outcomes of Bishayee's 100% experiments to occur, while the outcomes of the 100% experiments performed by Lenarczyk and Howell (all of which failed to replicate Bishayee's results) are entirely consistent with expectation given the conditions under which the experiments were performed. In Lenarczyk's and Howell's experiments, the cells were not synchronized and no dCyd was added to the medium. Under these conditions, 70% or fewer cells were killed by ^{3}HdThd (in contrast to killing of about 99.99% of the cells in Bishayee's experiments under the same conditions). (Hill S.J. Exhibit 110 at 2)[7].

In the 50% experiments, Bishayee's results are also completely at odds with the those of Lenarczyk and Howell based on the results predicted by their 100% survivals. Additionally, neither Lenarczyk nor Howell could demonstrate <u>any</u> bystander effect; meaning, there was no killing of the bystanders in their experiments and most probably due to the result of a condition

[6]<u>Id.</u> at page 4.
[7]See Robbins Report (Hill S.J. 108 at pgs. 2, 5).

known as hypoxia in the Helena tubes. (Hill S.J. Exhibit 110 at pgs.2, 8-11)[8]

In submitting the claim to NIH Howell, as the principal investigator of the Grant: (a) certified that the grant application was true and complete and accurate to the best of his knowledge, (b) that he submitted the grant with knowledge that any false, fictitious or fraudulent statements or claims may be subject to either criminal, civil or administrative penalties;(c) that he accepted responsibility for the scientific conduct of the project; and (d) that he had agreed to periodically provide progress reports regarding the grant. (Hill S.J. Exhibit 50: *NIH Grants Policy Statement (10/98)*, Part I: Legal Implications of an Application) (Hill S.J. Exhibit 51: *Baker Deposition 15/17-17/1*).

In October 2005, Howell undertook to apply to the NIH for a competing continuation (i.e. renewal) grant (Hill S.J. Exhibit 54). In undertaking to do so, Howell re-submitted the very same data that he had submitted in his initial revised application, which by then he well knew could not be replicated. Howell then re-certified that data as he had when submitting the initial revised grant application.

In each instance, the Notice of Grant contained a statement re-advising UMDNJ that its acceptance of the award included acceptance of the Terms and Conditions outlined,

[8] Id. at pgs 6-7).

including those terms and conditions identified in the NIH Grants Policy Statement (Hill S.J Exhibits 52 and 101).

Throughout this time, and periodically/annually thereafter, Howell was required to submit progress reports concerning the grant to the NIH. (Hill S.J. Exhibits 97-100). In doing so, Howell undertook to provide reassurances and to re-certify: (a) that the grant application is true and complete and accurate to the best of his knowledge, (b) is submitted with knowledge that any false, fictitious or fraudulent statements or claims may be subject to either criminal, civil or administrative penalties; (c) that he accepted responsibility for the scientific conduct of the project; and (d) that he agreed to periodically provide progress reports regarding the grant) (Hill S.J. Exhibit 96, Section 2.2.1.[9]).

2. THE RECORDS, CLAIMS AND STATEMENTS WERE FALSE AND/OR FRAUDULENT.

The evidence for fraud in the grant applications, progress reports and the two papers is simply overwhelming. As set forth above, it is based upon: (1) the accounts of two eye-

[9]Whether or not these progress reports, or the certifications contained therein, may constitute claims within the meaning of the FCA is not a settled question. Compare United States el. rel. Feldman v Van Gorp, 674 F. Supp. 2d 475 (S.D. NY 2009) (denying summary judgment because the a genuine issue of material fact existed as to whether defendants made false statements in their grant application and progress reports) and United States ex rel. Bauchwitz v Holloman, 671 F.Supp. 2d 674 (E.D. Pa. 2009) (progress reports are not false claims.)

witnesses (Hill and Lenarczyk); (2) the inability of both Howell and Lenarczyk (indeed, anyone for that matter) to ever replicate Bishayee's 100% experiments; (3) the inability of both Howell and Lenarczyk (or anyone for that matter) to ever replicate Bishayee's 50% experiments; (4) the statistical analysis of an expert statistician, Dr. Pitt, that determined there is only a probability of 100 billion to 1 that Bishayee's Coulter counts were not fabricated; (5) as determined by Dr. Pitt, there was a distinctive pattern in Dr. Bishayee's measurements that would lead any reasonable observer to conclude that Dr. Bishayee repeatedly invented one value in each triad of the Coulter counter measurements he had allegedly taken to force his data to conform to the experimental results he wished to report; (6) in determining the relative frequency with which the two least significant digits in Dr. Bishayee's measurements are equal, Dr. Pitt found the probability that the relative frequency of such incidents diverge from the expected frequency as much as they did in Dr. Bishayee's case is less than 0.0000001 (one in ten million); (7) the biochemical and radiobiological principles and analysis by an expert Radiation Biologist, Dr. Michael Robbins, demonstrating Tritiated Thymidine (^{3}H-TdR) blockage of the cell cycle progression; (8) that there was no deoxycytidine (dCyd) in the medium during exposure to ^{3}H-TdR, which fact would have abrogated the effect of ^{3}H-TdR blocking cell cycle progression;

(9) that there was no attempt at synchronization of the cells before adding ^{3}H-TdR which would have allowed all the cells to be in S phase during the ^{3}H-TdR exposure; and (10) the strong likelihood that hypoxia prevailed in the Helena tubes during all of the experiments but most importantly in the 50% experiments. (Hill S.J Exhibits 1, 56-71, 78-83, 104 and 108).

3. THE DEFENDANTS KNEW IT WAS FALSE OR FRAUDULENT.

All of the above demonstrate that Bishayee well knew the data was false or fraudulent. It is further clear that Howell also knew, should have known, or acted with reckless disregard of the falsity of the data before submitting and maintaining the grant in this case.

Hill had informed Howell of her observations and suspicions relating to Bishayee. Notwithstanding this fact, Howell dismissed Hill's concerns and refused to intercede to Hill's request to investigate Bishayee's actions. Instead, Howell determined to use the results of Bishayee's experiments as part of the preliminary data supporting his revised grant application to NIH. (Hill S.J. Exhibit 1 and 3, *Hill Certified Written Disclosure, ¶38, pgs. 23-24 and Exhibit 4 annexed thereto*) (Hill S.J.Exhibit 53, Hill *Amended Answer to Defendants' Interrogatory No. 13. p.29-30*) (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶20*).

It is further clear that Howell well knew the data were false or fraudulent since neither Howell, Lenarczyk, or anyone else could replicate the data presented in the grant applications or publications. The attempts at doing so were not done just once or twice. To the contrary, it was attempted by Howell and Lenarczyk without success on twenty-two (22) occasions between October 2000 and July 2001. Sixteen (16) of those attempts occurred even before Hill initiated her complaint of scientific misconduct to the UMDNJ Campus Committee!

Yet knowing that the data could not be replicated, Howell and Bishayee deliberately withheld that information from the Committee; instead responding solely to the information that Hill had personally witnessed and which was available to her at the time.

Howell then continued to rely on that data each time he filed a progress report on the grant and then re-applied for additional funding in 2005.

These acts subjects Howell, Bishayee and UMDNJ to liability for "knowingly" submitting or causing the submission of a false claim; and/or knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government, 31 USC § 3729 (a) and (b); since, a person acts "knowingly" when he "(1) has actual knowledge of the information; (2) acts in deliberate

ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required." 31 USC § 3729 (b).

POINT III

THIS CASE PRESENTS A CLASSIC CASE OF FRAUD IN SCIENTIFIC RESEARCH AND NOT SIMPLY A SCIENTIFIC DISPUTE.

Throughout this case Howell has hid his head in the sand about the fraud, while continuing to wrongfully take NIH grant money that would clearly have been made available to scientists submitting valid, competing applications for research. Despite Howell's acknowledging the inability to replicate Bishayee's results using the experimental protocols that he devised, he has been left to provide supposition and conjecture, not competent evidence, to defend his fraud. (See Statement of Undisputed Material Facts Nos.94-96).

In United States ex rel Milam v Regents of University of California ("Milam"), 912 F. Supp. 868, 874 (D. Md. 1995), the relator claimed that several universities and researchers working on the same brain tumor research project submitted false information in a grant application to the NIH to continue their research. The relator claimed that the researchers falsified data regarding their research in order to receive a NIH grant. The relator further asserted that the defendants skewed their data in a light more favorable to the outcome which they had predicted. It was further claimed that the experiments used in the NIH grant application were not conducted in accordance with the scientific method, a standard of conducting research to ensure reliable

results. Id. at 868, 874, 880-881. More specifically, Milam claimed that the researchers falsified the data submitted in the grant application because she could not replicate the experiments which invalidated the results of the defendants' experiments. Id. at 881.

The court found that other scientists could replicate the experiments and that the relator was unable to replicate the experiments because she had altered the experiments. Under those circumstances, the court held that the relator did not state a FCA claim because there was a scientific dispute over whether the data was from the experiments was false. The court stated that, at most, it was presented with a legitimate scientific dispute and not a fraud case. Id.

The matter sub judice is clearly distinguishable from the Milam case. The most significant way it is distinguishable lies in the fact that the data, alleged to be false in Milam, was able to be replicated by other scientists using the same protocols that the defendants had used. Indeed the case found that Milam's inability at replicating the data occurred because she had altered those protocols. In the matter sub judice, **not one** scientist has been able to replicate Bishayee's data using

the specific protocols that were developed by Howell and which then served to support the grant application.[10]

Milam also serves to demonstrate what both science and the law must reasonably expect of a responsible scientist who becomes faced with legitimate and cogent allegations of fraud and, overwhelming proof of false or fraudulent data. It is thus evident that when attempt(s) at replicating the subject matter data could not be accomplished in the Milam case, it was first reported to the Dean, and then the Dean and that scientist published retractions and the issue was discussed the non-replications with NIH. Milam, supra at 877. The scientist did not just continue to line his pockets with the grant monies and hide his head in the sand. The process of reporting/retracting pending verification and replication is precisely what should have happened pursuant to the UMDNJ Policies and Guidelines; Policies and Guideline for the Conduct of Research; and, Policy on Misconduct in Science (Hill S.J. Exhibits 72-74). The Statement of Undisputed Material Facts demonstrates that this did not occur despite Howell having a clear and unmistakable duty to do so.

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[10]In Paragraph 21 of its Amended Answer defendants admit this fact as "technically correct" but then suggested that the data has been replicated by other researchers. While the defendants may attempt to show other research showing the existence of the bystander effect, they cannot show it was demonstrated using the protocols that Bishayee did and which Howell and Lenarczyk could not replicate after 22 attempts.

Milam, supra at 880, also holds that, while an ORI report is admissible and may be probative under Rule 801(d)(2)(A) of the Federal Rules of Evidence, its findings are not entitled to preclusive effect in an FCA action. Indeed, the decision notes that the level of intent required for ORI to proceed with an administrative action is intentional falsification - clearly a higher level of intent than that required under the FCA. In contrast to Milam, the facts in this case establish that Howell acted knowingly in submitting and re-submitting the grant containing this data. 31 USC § 3729 (a) and (b).

Consequently, this Court should not be led by the defendants to conclude that the ORI report is fatal to Hill's case. Indeed it is not, especially given the fact that it reviewed but a limited amount of data available to Hill at the time she initiated her complaint to UMDNJ. Once, however, the United States compelled Defendants to respond to the Subpoena Duces Tecum, the evidence which had not been disclosed, and which supports these claims, came to light. Based on that evidence, it is submitted the Court should find that the defendants violated 31 USC § 3729 (a) and (b).

POINT IV

RETALIATION

31 USC § 3730 (h) provides that:

> "Any 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, initiating of, testimony for, or assistance in an action filed or to be filed under this section shall be entitled to all relief necessary to loyee whole. Such relief shall include reinstatement with the same seniority status such employee would have had but for the discrimination, 2 times the amount of back pay, interest on back pay, and compensation for any special damages[11] sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees ***"[12]

This whistleblower provision protects employees who assist the government in the investigation and prosecution of violations of the FCA. Hutchins v Wilentz, Goldman & Spitzer, supra at 186. This provision broadly protects employees who assist the government and encourage individuals to expose fraud. Id.

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[11]Special damages also include damages for emotional distress. Hammond v Northland Counseling Center, Inc., 218 F .3d 886, 893 (8th Cir. 2000).

[12]The 2009 FERA amendments to the retaliation provisions of the FCA apply only to retaliation claims arising from conduct on or after May 20, 2009. For this reason, the amendments are not discussed nor do they apply to the issues in this case.

A plaintiff asserting a cause of action under this provision must show by a preponderance of the evidence (1) she engaged in "protected conduct" (i.e. acts done in furtherance of an action under § 3730) and (2) that she was discriminated against because of her "protected conduct". United States ex rel. Yesudian v Howard Univ., 153 F.3d 731, 736 (D.C. Cir. 1998). In proving that she was discriminated against "because of" conduct in furtherance of the FCA, a plaintiff must show that (1) her employer had knowledge she was engaged in "protected conduct", and (2) that her employer's retaliation was motivated, at least in part, by the employee's engaging in protected conduct. Id. At that point, the burden shifts to the employer to prove the employer would have taken the action even if he had not engaged in the protected conduct. Mikes v Strauss, 889 F. Supp. 746, 754 (S.D.N.Y. 1995). The plain language of the statute demonstrates that any type of discrimination will be sufficient to support an action for retaliation, provided the other statutory elements are established. Burlington Northern & Santa Fe Railway Co., v White, 548 U.S. 53 (2006)(holding that retaliation against an employee includes actions taken by an employer that are not directly related to the worker's employment or cause the employee harm outside the workplace). Id. at 69

"Protected conduct" requires a nexus with the "in furtherance" prong of the FCA. McKenzie v BellSouth Telecomm.,

Inc. 219 F.3d 508, 515 (6th Cir. 2000). The inquiry involves determining whether the plaintiff's actions sufficiently furthered 'an action filed or to be filed under' the FCA and, thus, equate to 'protected conduct'. Id. at 516. Section 3730 (h) specifies that "protected conduct" includes "investigation for, initiating of, testimony for, or assistance in" a FCA suit. 31 USC § 3730 (h).

Determining what activities constitute "protected conduct" does not require the plaintiff to have developed a winning *qui tam* action. Yesudian, supra at 739. These activities can include internal reporting and investigation of an employer's false or fraudulent claims. Id. at 742. See also Childree v UAP/GA CHEM, Inc. 92 F. 3d 1140 (11th Cir. 1996), cert.denied, 519 U.S. 1148 (1997). The FCA was enacted to encourage parties to report fraudulent activity and was intended to "protect employees while they are collecting information about a possible fraud, before they have put all the pieces of the puzzle together. Yesudian, supra at 740.

To show that an employee was discriminated against "because of" their "protected conduct", a plaintiff must show her employer had knowledge that she was engaged in "protected conduct" and that the employer retaliated against her because of that conduct". Third Circuit law holds that the knowledge prong of § 3730 requires the employee to put his employer on notice of

the "distinct possibility" of FCA litigation. Hutchins v Wilentz, Goldman & Spitzer, supra at 188. This is a fact sensitive issue. Yesudian, supra 153 F.3d at 741-45; But see, United States ex rel. Karvelas v Melrose-Wakefield Hospital, 360 F.3d 220, 236 (1st Cir. 2004) (holding that conduct in furtherance of an action under the FCA is conduct that reasonably could lead to a viable FCA action). Whether an employer is on notice of the 'distinct possibility" of FCA litigation is also a fact specific inquiry. The employer, however, is on notice of the "distinct possibility" of litigation when an employee takes actions revealing the intent to report or assist the government in the investigation of a FCA violation. Id. at 189; Neal v Honeywell Inc., 33 F.3d 860, 865 (7th Cir. 1994) (reporting of false data to supervisor and employer).

The acts of retaliation in this case include:

a. Upon his being appointed the Chief of Radiation Research Division and Hill's supervisor, Howell stated to Hill that he wanted nothing more to do with her.[13]

b. Howell changed the locks in the Division in order to prevent Plaintiff from having access to the shared laboratory space and only leaving her with access to one small lab which she

[13]As to this act, Dean Baker testified: "It's a statement I would not expect from anybody who works for me … So it's not just a statement taking on a supervisory capacity, it's a hostile, non-productive statement".(Hill S.J. Exhibit 51: *Baker Deposition 54/19-56/5*).

was then to share with another professor, Dr. Azzam. (Hill S.J. Exhibit 86: Hill Deposition 78/5-10; 79/9-13).

c. Howell has shunned Hill continually since 2001; including but not limited to inviting her to a single division meeting. (Hill S.J. Exhibit 86: Hill Deposition 78/15-79/2).

d. Howell's actions have resulted in Hill being shunned and denied any form of collegiality by other members of the department, including Dr. Azzam who she was directed to share lab space with.(Hill S.J. Exhibit 86: Hill Deposition 79/9-80/17).

e. Despite having engaged in protective activity by reporting Bishayee, Baker told her that she had made the Department look bad; and thereafter immediately made Howell her immediate supervisor (Hill S.J. Exhibit 86: Hill Deposition 82/21-83/23).

All of this humiliation was suffered simply because Hill had followed the University guidelines in for reporting scientific misconduct that she had observed Bishayee engaged in. (Hill S.J. Exhibit 86: Hill Deposition 84/16-87/2).

POINT V

DAMAGES

The FCA was enacted to provide restitution to the Government for losses sustained as a result of fraud. United States ex rel. Marcus v Hess, supra at 551-552. Damages awarded under the FCA are calculated to assure that they afford the Government complete indemnity for the injury done it. United States ex rel. Compton v Midwest Specialties, Inc., 142 F. 3d 296 (6th Cir. 1998). The just method of determining damages necessarily varies with the facts of the particular case. United States v Ben Grunstein & Sons Co., 137 F. Supp. 197, 209 (D.N.J 1956)[14].

False certification cases involve a defendant that claims certain statutory benefits after either explicitly or implicitly falsely declaring that specific criteria or conditions required by a contract or policy have been met. A false certification of compliance with contractual specifications or policy conditions renders a claim for payment "false or fraudulent" within the meaning of the FCA regardless of whether the false certification actually affects the performance of the contract. United States v Aerodex, Inc., 469 F.2d 1003, 1007 (5th Cir. 1972).

[14]This motion seeks a determination that the defendants are liable for damages. It is acknowledged that a limited hearing on the quantum of damages may be necessary.

Under false claims cases involving research grants, it has been held that the damages due are the full amount of government monies that have been paid. United States ex rel. Longhi v Lithium Power Technologies, Inc., 530 F. Supp. 2d 888, 889 (S.D. Tex. 2008). Longhi, the defendants were found liable under the FCA for falsely misrepresenting their experience and ability in procuring several government research grants under the Small Business Innovation Research Program. The defendants argued that there were no recoverable damages because the government had fulfilled the program's purpose - a small business had received research funding. The court disagreed, noting that the program's purpose was to fund eligible deserving small businesses which the defendants were not. After establishing that the grants would not have been awarded had the defendant properly represented its abilities, the court found that the damages were all government monies that had been paid to defendants through the fraudulently procured grants, trebled. Id. Accordingly, the defendants in this case are liable for the full amount of the two grants, $2,358,539, trebled.

The basic measure of damages in false certification cases is the amount of that the defendant's false statements "caused" the Government to pay, i.e. the amount paid that is more than the amount the Government would have paid if the statements were true. The circuits are split regarding measuring damages in

this type of case. The Sixth and Seventh Circuit recognize the "but for" measure of damages. United States v Ekelman & Associates, Inc., 532 F.2d 545, 550 (6th Cir. 1976); United States v. First National Bank of Cicero, 957 F.2d 1362, 1373 (7th Cir. 1992). The Third, Fourth, Fifth and Eighth Circuits have adopted the "actual loss" test, which focuses strictly on the Government's loss as a result of the false statement. United States v Hibbs, 568 F.2ed 347 (3rd Cir. 1977)[15]; United States ex rel. Harrison v Westinghouse Savannah River Co., 352 F 3d 908, 914 (4th Cir. 2008); United States v Miller, 645 F.2d 473 (5th Cir. 1981); United States v Cooperative Grain and Supply Co., 476 F.2d 47, 63-64 (8th Cir. 1973). It is submitted that under this test, the same result should follow.

In addition to damages that flow directly from the submission of a false claim, there are additional damages that are available in an FCA action. They include:

1. Treble damages. See 31 USC §§ 3729(a)(1) to 3729(a)(7).

[15]But see, United States of America ex rel. Cantekin v University of Pittsburgh, 192 F. 3d 402, 417 (3rd Cir. 1999) acknowledging, but electing to not then decide whether Cicero, supra, and the 1986 amendments to the FCA, requires application of the "but for" test so as to impose liability because the subject matter of the false statement was the source of the government's loss) (nevertheless finding that the evidence in an NIH case demonstrated that the grant might not have been approved but for the false statements).

2. Statutory Penalties. See 31 USC §§ 3729(a)(1) to 3729(a)(7). The 1986 amendments set the new range of penalties form $5000 to $10,000, in addition to trebling actual damages. United States ex rel. Atkinson v Pennsylvania Shipbuilding Company, 2000 WL 1207162 at *9 (E.D. Pa 2000) ("The FCA provides for … two separate civil remedies and the recovery of damages is only one of them"). The 1986 amendments to the FCA expressly state that each separate false claim constitutes a claim for which a penalty shall be imposed.

In 1990, The Federal Civil Penalties Inflation Adjustment Act ("FCPIAA") was enacted to adjust federal fines and penalties to the rate of inflation (Pub. L. No. 101-410, 104 Stat. 890 (Jan. 23, 1990. In 1990 the Department of Justice increased the range from $5,500 to $11,000 (28 CFR §85.3(a) (9).

3. Debarment. See United States v Glymph, 96 F. 3d 722 (4th Cir. 1996); United States v Hatfield, 108 F. 3d 67 (4th Cir. 1997)[16]

4. Relator's Fees - 31 USC § 3730 (d) (1).

5. Attorney's Fees and Costs - 31 USC § 3730 (d)(5).

The damages available for acts of retaliation are set forth in 31 USC § 3730 (h), and were discussed above in Point IV).

[16]Whether that is appropriate or not is a determination to be made by the Court and or the United States of America.

Based on the proofs adduced, it is respectfully submitted that all the aforementioned remedies should be considered appropriate in this proceeding.

CONCLUSION

For all of the foregoing reasons, it is respectfully requested that Plaintiff's motion for summary judgment be granted.

Respectfully submitted,
BUCCERI & PINCUS, ESQS.

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