Hill Appellate Brief

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Statements

Subject Matter and Appellate Jurisdiction

Appeal is taken from the Final Decision and Order of the United States District Court for the District of New Jersey (Honorable Dennis M. Cavanaugh, U.S.D.J.), dated October 18, 2010, which granted Defendants' Motion for Summary Judgment and denied Plaintiff's Motion for Partial Summary Judgment (1a). The Decision (4a) and Order (3a) were entered on October 19, 2010. The Court has jurisdiction of this appeal pursuant to 28 U.S.C. § 1291.

Issues

(1) Did the District Court erroneously grant Defendants' Cross-Motion for Summary Judgment and deny Plaintiff's Motion for Summary Judgment?

2. Did the District Court commit error in concluding that the Defendants did not knowingly violate the Federal Civil False Claims Act, 21 U.S.C. §3729 et seq. as amended (" FCA") upon the submission of (a) the 1999 revised grant application to NIH ; (b) periodic progress reports; and (c) the 2005 application for a continuation grant?

3. Does the District Court's decision serve to subvert the NIH grant process by allowing, and/or encouraging a Primary Investigator and Grantee institution to withhold information from the Grant Program Director that cast the validity of the data underlying the grant in doubt because it could not be replicated?

Case

This case asserts claims arising under the FCA. The violations involve the Defendants' application for a research grant, and the receipt of federal grant monies, based upon the knowing submissions of: (a) a 1999 revised grant application; (b) annual progress reports; and, (c) a 2005 competitive renewal grant application to the United States Department of Health and Human Services, National Institute of Health ("NIH"). It is alleged that the applications aforesaid, the progress reports, as well as the findings of certain experiments that had been, or were subsequently

undertaken in furtherance of the grant, were supported with data, statements and records that were false or fraudulent.

The Complaint in this matter was filed in Camera and Under Seal on October 14, 2003 (1966a). On April 6, 2007, the United States filed a Notice of Election to Decline Intervention (1981a). On April 16, 2007, the District Court entered an Unsealing Order (1984a). On July 30, 2007, the Defendants filed an Answer and Counterclaim on behalf of the Defendants. On August 20, 2007, Hill filed an Answer to the Counterclaim. By Leave of Court, an Amended Complaint was filed on April 1, 2009 (189a).

The parties filed Cross-Motions for Summary Judgment on May 25, 2010. On October 18, 2010, the District Court granted the Defendants' Cross-Motion for Summary Judgment and denied the Plaintiff's Motion for Summary Judgment.

Facts

The parties' Statements of Undisputed Material Fact (34a) (93a) and, their respective Responses to the Statements (100a) (107a) (170a) establish that, i**n or about the Summer of 1999, Defendant Howell advised Hill that he and his then post-doctoral research assistant, defendant Bishayee, were engaged in preliminary experiments**

that would be used by Howell to prepare a revised grant application for submission to NIH, and for which he was to serve as the Principal Investigator. Howell's initial grant application had been rejected by NIH. (194a)(Hill S.J. Exhibit 46: *Amended Complaint, ¶13)*; (207a) (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶13*).

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. (233a)(Hill S.J. Exhibit 1: *Hill Certified Written Disclosure, ¶ 24, p.13*); *(285a*) (Hill S.J. Exhibit 3: *Hill Certified Written Disclosure Exhibit 4, Grant Application);* (194a)(Hill S.J. Exhibit 46: *Amended Complaint, ¶14);* (207a)(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 thus 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. (233-236a)(Hill S.J. Exhibit 1: *Hill Certified Written Disclosure, ¶¶ 24-26, p.13-16*); (286a) (Hill S.J. Exhibit 3: *Hill Certified Written Disclosure Exhibit 4, Grant Application, page 2)*.

Hill was designated as a Co-Investigator of the revised grant based upon her extensive experience in radiobiology and ability to design and help to implement various assays that would be used in the experimentation. (195a)(Hill S.J. Exhibit 46: *Amended Complaint, ¶16)*; (207a)(Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶16*) (292-294a)(Hill S.J. Exhibit 3: *Hill Certified Written Disclosure Exhibit 4, Grant Application)*. Defendant Bishayee was designated to serve as the Research Specialist responsible for carrying out the day to day experiments described in the project. (195a)(Hill S.J. Exhibit 46: *Amended Complaint, ¶17)*; (207a) (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶17*).

On two occasions preceding the submission of Howell's revised grant application, Hill observed Bishayee engaged

in preliminary experiments to that application. Hill's observations led her to believe that Bishayee was falsifying the data underlying the experiments and, the conclusions that had been reached by Howell from those experiments. (226a)(237a-250a)(Hill S.J. Exhibit 1: *Hill Certified Written Disclosure, ¶7, p.6 and ¶¶ 27-46, p.17-30*); (Hill S.J. Exhibits 4-13: *Hill Certified Written Disclosure Exhibits 5*-14)[1]; (401a)(Hill S.J. Exhibit 110:

[1] These Exhibits are as follows:

Hill S.J Exhibit 4. The September 20, 1999 Experiment (340a)

Hill S.J. Exhibit 5. Dr.Hill's Observations for the Period of October 11-23, 1999 (349a)

Hill S.J. Exhibit 6. September 6, 1999 experiment (351a)

Hill S.J Exhibit 7. Memo to Dr. Raveché from Dr. Hill, dated May 22, 2001 (358a)

Hill S.J. Exhibit 8. Graph Entitled "Cell Count as a Function of Dose on Day 3 (360a)

Hill S.J. Exhibit 9."Terminal Digits and the Examination of Questioned Data" by James E. Mosimann et.al. (361a)

Hill S.J. Exhibit 10."Data Fabrication: Can People Generate Random Digits?" by James E. Mosimann et.al. (371a)

Hill S.J. Exhibit 11. Analysis of Coulter Counter Counts by Dr.Bishayee, Dr. Hill and Dr. Lenarczyk (396a)

Hill S.J. Exhibit 12. Analysis of Scintillation Counts (397a)

Hill S.J Exhibit 13. Comparisons of Means and Standard Deviations - Data of Dr. Lenarczyk and Dr. Bishayee (398a)

The Effect of Tritiated Thymidine and Hypoxia on the Cell Cycle As It Pertains to Experiments Performed in the Howell Laboratory Between 1999 and 2001); (421a)(Hill S.J. Judgment Exhibit 111: *Evidence Supporting Allegations of Fraud at the N.J. Medical School).*

Hill informed Howell of her observations and suspicions regarding Bishayee. Howell dismissed Hill's concerns and refused to intercede in 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. (313a)(Hill S.J. Exhibit 3: *Grant Application, Figure 7, page 29*); (243a-244a)(Hill S.J. Exhibit 1: *Hill Certified Written Disclosure,¶38, pgs. 23-24*); (340a-398a)(Hill S.J. Exhibits 4-13: *Hill Certified Written Disclosure Exhibits 5-14*); (498a-499a) (Hill S.J. Exhibit 53: *Hill Amended Answer to Defendants' Interrogatory No. 13. p. 29-30);* (208a) (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶20*).

Additionally, Howell presented data purporting to show a bystander effect for Tritiated Thymidine (^{3}HdThd) (310a) (Hill S.J. Exhibit 3: *Grant Application p. 26,*

***Figure 2; p.27, Figure 4; p.42, Figure 12*)**. **These and similar data were also presented in two publications (517a)(Hill S.J. Exhibit 14: *Hill Certified Written Disclosure Exhibit 16:*(Bishayee, *et al.* Radiation Research 152: 88 (1999), Figures 3, 6, 7 and Table 1)(520a-522a); and (527a)(Hill S.J. Exhibit 15: *Hill Certified Written Disclosure Exhibit 17 Bishayee, et al. Radiation Research 155: 335 (2001), Figures 1 and 2)*(529a-530a); (208a)(Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶21*).**

In each instance, the data and results presented showed, and thus claimed there to be, an exponential decline in survival after exposure to tritiated thymidine (^{3}HdThd). Id.

In the course of discovery engaged in by both the United States Attorney's Office and Hill, Defendants have admitted that the data in the experiments that had been designated as being 50% labeled or 100% labeled could not be replicated in 22 trials performed during the period of October 2000 to September 2001. (208a) (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶21*); (499a-

500a) (Hill S.J. Exhibit 53, *Hill Amended Answer to Defendants' Interrogatory No. 14. p.30-31*)[2].

Defendants further admit that this data was repeated and presented in Figure C1 in Howell's 2005 grant renewal application to NIH. (537a)(Hill S.J. Exhibit 54: Howell 10/05 Renewal Grant, p. 35 – Bate Stamped UMDNJ-Hill Confidential 0003854)(571a); (196a)(Hill S.J. Exhibit 46: *Amended Complaint, ¶21);* (208a)(Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶21*); (499a-500a)(Hill S.J. Exhibit 53, *Hill Amended Answer to Defendants' Interrogatory No. 14. p.30-31*).

Subsequent to the approval and funding of Howell's grant in May 2000, an additional post doctoral fellow, Dr. Marek Lenarczyk ("Lenarczyk"), was hired by Howell to conduct other research relating to the grant. Between October 2000 and July 2001, Lenarczyk performed approximately 16 of the 22 trials in which the data reported in the publications and the grant applications could not be replicated. (197a)(Hill S.J. Exhibit 46:

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[2] A representative example of a 50% experiment that was performed is seen at (2009a) (Hill S.J. Exhibit 57: *Lenarczyk Experiment January 15, 2001, V79, 50%).* A representative example of a 100% experiment that was performed is seen at (2015a) (Hill S.J. Exhibit 65: *Lenarczyk Experiment December 14,2000, V79, 100%*).

Amended Complaint, ¶22); **(208a) (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶22*).**

Despite the fact that the data could not be replicated in any of Lenarczyk's experiments aforesaid, Howell failed to inform the Chairman of the Radiology Department, Dr. Stephen Baker, of Hill's concerns about the data's validity until April 6, 2001 (623a-627a) (Hill S.J. Exhibit 51: *Baker Deposition 38/2-42/10*). But at that point in time, Howell elected to tell Baker that he was first going to request Lenarczyk to repeat some of Bishayee's experiments as a check on the validity of the data that had been submitted in the grant application. Howell did not inform Baker that Lenarczyk had by that point in time actually attempted eleven (11) such experiments without success in replicating the data that Bishayee had generated. (645a)(Hill S.J. Exhibit 75: *Baker Deposition Exhibit 8*). (627a-630a)(Hill S.J. Exhibit 51: *Baker Deposition 42/12-24; 43/13-45/20*).

Howell subsequently failed to inform Baker of yet an additional 11 experiments that Lenarczyk performed <u>after</u> Howell's April 6, 2001 memo to Baker, and in which the data presented in Howell's grant application and in the two publications identified in Paragraph 21 of the Amended Complaint were determined to be at variance.(632a-

636a)(Hill S.J. Exhibit 51: *Baker Deposition 47/1-24; 49/15-51/21; 52/10-53/22*). Howell claimed that he had no obligation to report his inability to replicate Bishayee's experiment results to his Grantor, the NIH (649a-650a)(665a)(Hill S.J. Exhibit 76: *Howell Deposition I 93/1-94/6; 139/7-25*). Consequently, Howell and Bishayee each failed to submit retractions of the data purporting to show exponential survival and a bystander effect that had been set forth in the publications aforesaid and the grant applications. (197a)(Hill S.J. Exhibit 46: *Amended Complaint, ¶24);* (208a) (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶24*).

In or about March 2001, Lenarczyk observed and had reported to Hill that he too was suspicious of the data that Bishayee was reporting to Howell, upon Lenarczyk observing Bishayee setting up an experiment with contaminated cultures (707a-713a)(Hill S.J. Exhibit 55: *Lenarczyk Deposition 41/9-13;47/6-48/1;61/3-63/25;66/9-14;125/17-25*).

On April 10, 2001, Hill reported her personal observations and findings to Howell and to Baker. (198a)(Hill S.J. Exhibit 46: *Amended Complaint, ¶26);* (209a)(Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶26*); (265a-266a)(Hill S.J. Exhibit 1, *Hill*

***Certified Written Disclosure, ¶¶ 58-60, pgs.45-46*); (502a-506a)(Hill S.J. Exhibit 53, Hill Amended Answer to Defendants' Interrogatory Nos. 17,18 and 20, pgs. 33-35,37).**

Upon Hill reporting what she believed to be scientific misconduct (and specifically between April 2001 and September 2001) Howell, Lenarczyk and in some instances Bishayee, undertook to perform yet an additional six (6)experimental trials seeking to replicate the data Bishayee had previously generated and which had supported the grant application. In each and every one of the six (6) experiments, the data reported in the publications and grant application could still not be replicated. Id.; (196a) (198a)(Hill S.J. Exhibit 46: *Amended Complaint, ¶¶ 21 and 27); (208a-209a)(Hill S.J. Exhibit 47: Defendants' Answer to Amended Complaint, ¶¶21 and 27*).

Once again, Howell and Bishayee each failed to inform their supervisors at UMDNJ, or the Grantor, NIH, of these facts. (788a-789a)(Hill S.J. Exhibit 96, U.S. Dept. of Health and Human Services, PHS, Non-Competing Continuation Progress Report, PHS 2590, Section 2.2.6.B (Bate Stamp Page 001160).

Hill's April 10. 2001 Complaint of Scientific Misconduct was referred to UMDNJ's Campus Committee on Research Integrity. (266a-270a)(Hill S.J. Exhibit 1, *Hill Certified Written Disclosure, ¶¶ 61-67, pgs. 46-50);* (Hill S.J. Exhibits 25-27: *Hill Certified Written Disclosure Exhibits 27-28*)[3]; (817a) (Hill S.J. Exhibit 29).

On or about June 21, 2001 the Committee concluded that there was no cause to warrant further proceedings. (270a) (Hill S.J. Exhibit 1, *Hill Certified Written Disclosure, ¶67, pg 50);* (Hill S.J. Exhibits 27-28: *Hill Certified Written Disclosure Exhibits 30-31*)[4]; (817a)(Hill S.J. Exhibit 29: *Report of Initial Inquiry into Allegations of Potential Misconduct in Science Against Anupam Bishayee);* (831a)(Hill S.J. Exhibit 30: *Minutes of Initial Inquiry Meetings and Attachments 1-20 Referred to Therein);*

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[3] These Exhibits are as follows:

Hill S.J. Exhibit 25. Letter from Dr. Raveche to Dr. Hill dated April 12, 2001(814a).

Hill S.J. Exhibit 26. Letter from Dr. Raveche to Dr. Hill dated April 16, 2001 (815a).

[4] These Exhibits are as follows:

Hill S.J Exhibit 27. Letter from Dr. Raveche to Dr. Hill dated June 22, 2001 (816a).

Hill S.J. Exhibit 28. Letter from Dr. Saporito, Senior Vice-President for Academic Affairs to Dr. Hill dated July 2, 2001 (1056a).

(945a)(Hill S.J. Exhibit 31: *Attachments 21-22 Referred to in Minutes of Initial Inquiry Meeting Minutes).*

Hill was not then given a copy of the Committee's Report. It was first provided by Defendants on November 21, 2007 during discovery; specifically, over six (6) years' after it had been issued. (1057a) (Hill S.J. Exhibit 32: *Letter from Scott Flynn, Esq. dated November 17, 2007*).

In August 2001 (and upon being advised only of the Committee's conclusion), Hill undertook to report the evidence she then had available to her, to the Office of Research Integrity of the United States Public Health Service ("ORI"). (276a) (Hill S.J. Exhibit 1, *Hill Certified Written Disclosure, ¶78, pg 56);* (Hill S.J. Exhibits 33-34: *Hill Certified Written Disclosure Exhibits 36-37*)[5].

On September 5, 2002, UMDNJ was informed by ORI/DIO ("Division of Investigative Oversight") that, based on its review of the Report of the Initial Inquiry, it concurred with the conclusion there was insufficient

[5] These Exhibits are as follows:

Hill S.J. Exhibit 33. Letter from Dr. Hill to Dr. Fields dated August 23, 2001 (1059a).

Hill S.J. Exhibit 34. Letter from Dr. Alan Price to Dr. Hill dated August 27, 2001 (1060a).

evidence that had then been presented to warrant further investigation. However, ORI/DIO reported and delineated a number of administrative concerns it had about the handling of the case at UMDNJ. (1061a)(Hill S.J. Exhibit 37: *Letter from Chris Pascal(J.D.), Director/ORI to Dr. Karen Putterman, V.P. for Academic Affairs, UMDNJ, dated September 5, 2002);* (1063a) (Hill S.J. Exhibit 38: *ORI Oversight Report, dated September 5, 2002);*(1087a)*(*Hill S.J. Exhibit 39: *Attachments to ORI Report);* (279a-280a) (Hill S.J. Exhibit 1, *Hill Certified Written Disclosure, ¶84, pg 59-60*); (2026a) (Hill S.J. Exhibit 40: *Written Disclosure Exhibit 38*).

Among the concerns noted by ORI/DIO were:

(a) That the Inquiry Committee had failed to conclude that the major evidence presented in the investigation was the recorded observations of two witnesses (Dr. Hill and Dr. Lenarczyk); their respective lack of motive to fabricate evidence; and which evidence, Dr. Bishayee did not dispute) (1075a) (Hill S.J. Exhibit 38: *ORI Oversight Report, dated September 5, 2002, page 11, f.n.13).*

(b) In failing to discern a reason for Dr. Bishayee to falsify, fabricate or plagiarize data for his

1999 and 2001 experiments, the Inquiry Committee discounted the testimony that the bystander experiment could not be repeated by Drs. Lenarczyk and Dr. Howell; and, if that were true, the doubt about the bystander effect would have been a substantial motive for Dr. Bishayee to falsify data showing such an effect. (1076a) (Hill S.J. Exhibit 38: *ORI Oversight Report, dated September 5, 2002, page 12, f.n.18).*

(c) It was noted that Dr. Hill was never given a copy of the Inquiry Committee Report, but just a letter setting forth its conclusion. This fact denied Dr. Hill the opportunity to comment on, or appeal any factual inaccuracies contained in the report despite ORI finding that Public Health Service regulations mandated that this occur. (1077a) (Hill S.J. Exhibit 38: *ORI Oversight Report, dated September 5, 2002, page 13).*

(d) The Inquiry Committee failed to discuss and never inquired with Dr. Lenarczyk regarding the fact that he was carrying out experiments that could not confirm the bystander effect. (1080a) (Hill S.J. Exhibit 38: *ORI Oversight Report, dated September 5, 2002, page 16).* ORI only learned about this from Dr. Hill during the time period that it reviewed the Inquiry Committee's report. (1081a) (Hill S.J. Exhibit 38: *ORI Oversight Report, dated*

September 5, 2002, page 17, f.n. 23); **(250a-252a) (Hill S.J. Exhibit 1: *Hill Certified Written Disclosure, ¶¶ 47-49), pg 30-32*); (1228a) (Hill S.J. Exhibit 42: *Written Disclosure Exhibit 15*); (1230a-1231a) (Hill S.J. Exhibit 41: *Hill Certified Supplement to Written Disclosure, ¶3, pgs 2-3).* The report notes:**

> **"According to Dr. Hill, Dr. Lenarczyk was carrying out experiments involving the induction of mutants by radiation, but he could not confirm the bystander effect on cell viability (telephone call from Dr. Hill to DIO, August 9, 2001). From the summary of the interview of Dr. Lenarczyk (Attachment 3f), it appears that this concern was not discussed with the Committee, so the Committee may not have known about this question. No details were given in the report regarding Dr. Lenarczyk's experimental system or results, …" (1080a-1081a)(Id. [6]at 16, 17 at f.n.23).**

(e) The Inquiry Committee was criticized for dismissing Dr. Hill's testimony and judgment given she had recognized expertise in mutagenesis, whereas Dr. Howell's expertise in this area (in the judgment of ORI/DIO)was minimal. Thus, in doing so, the Committee may have accepted

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[6] The First Committee also had failed to question Howell about whether anyone had been able to replicate the results of Bishayee (817a) (Hill S.J. Exhibit 29: *Report of the Initial Inquiry into Allegations of Potential Misconduct in Science Against Anupam Bishayee.*) **(831a)** (Hill S.J. Exhibit 30: *Minutes of Initial Inquiry Meetings*).

Coulter count data that appeared by comparison to have been too precise to represent accurately reported data. (1081a) (Hill S.J. Exhibit 38: *ORI Oversight Report, dated September 5, 2002, page 17).*

(f) ORI/DIO employed an accepted method of statistical analysis on the only two (2)experiments then available, seeking to determine the relative frequency with which each of the digits 0-9 appear as the least significant digit in Dr. Bishayee's data. It observed an unusual "reuse" of two numbers, and a high frequency of other numbers in the right-most terminal place of three digit coulter counts. However, given the absence of proper controls for its analysis, it could not, on the data the Inquiry Committee then had before it, resolve whether the Coulter counts were actually fabricated, and found the issue to be unresolved. (1081a) **(Hill S.J. Exhibit 38: *ORI Oversight Report, dated September 5, 2002, page 17).***

(g) Dr. Bishayee's claims regarding the second experiment (March 2001) were found not to be credible. (1083a-1084a) (Hill S.J. Exhibit 38: *ORI Oversight Report, dated September 5, 2002, page 19-20).*

(h) DIO questioned whether the Committee had sufficient competence to conduct adequately the inquiry.

(0177a)(Hill S.J. Exhibit 38: *ORI Oversight Report, dated September 5, 2002, page 13).*

While UMDNJ was given a copy of the ORI/DIO Report dated September 5, 2002, Hill was not. It was first provided to Hill by Defendants in discovery in this case on November 21, 2007. (1057a) (Hill S.J. Exhibit 32: *Letter from Scott Flynn, Esq., dated November 17, 2007*).

As noted, the Campus Committee limited its investigation to the September/October 1999 and March 2001 experiments which Hill had personally observed Bishayee engaged in and had reported pursuant to the Committee procedures. (817a)(Hill S.J. Exhibit 29: *Report of Initial Inquiry into Allegations of Potential Misconduct in Science Against Anupam Bishayee*). During the course of that proceeding, none of the experimental trials that had by that point in time been conducted by Lenarczyk, Howell and/or Bishayee; and, which trials had failed to repeat the exponential declines in the 100% experiments and the bystander effects in the 50% experiments as reported in the grant application and the 2 papers were then known to Hill or made available to the Committee by Howell.(650-651a) (664a-665a)(Hill S.J. Exhibit 76: *Howell Deposition Vol I*

***94/25-95/19; 138/21-139/6*)**. By the point at which UMDNJ advised Hill of the Committee's conclusion in July 2001, 18 of the 22 experiments had been performed that failed to replicate Bishayee's data or results. (48a-49a)(58a) (Hill Statement of Undisputed Material Facts Nos. 28, 30, 44).

The Campus Committee report is silent as to those experiments; and, the absence of such reference is consistent with Howell's belief he did not have an obligation to report the survival results to the Committee (817a) (Hill S.J. Exhibit 29: *Report of Initial Inquiry into Allegations of Potential Misconduct in Science Against Anupam Bishayee*); (649a-650a)(Hill S.J. Exhibit 76: *Howell Deposition Vol I. 93/1-94/6*).

Because of that, the ORI Oversight Report similarly limited its analysis to a review of the September/October 1999 and March 2001 experiments which Hill had personally observed Bishayee engaged in and had reported (1065a)(Hill S.J. Exhibit 38: *ORI Oversight Report, dated September 5, 2002).*

Based on the evidence before it at the time, the ORI/DIO recommended that:

> **"While DIO would normally recommend in such a case that further investigation by a committee with expertise in cell biology, cell culture, or**

> **related research on mammalian cells be carried out, given the weaknesses in the UMDNJ inquiry in this case, DIO does not find sufficient new evidence that would warrant such a recommendation. While it remains unresolved whether the bystander effect was ever reproducible in Dr. Howell's laboratory, as reported in two publications, in the absence of additional evidence of their falsification, these questions would not be a PHS issue of scientific misconduct. Thus DIO recommends that ORI decline to pursue this case further."**
>
> **(1084a-1085a)(Hill S.J. Exhibit 38: *ORI Oversight Report, dated September 5, 2002 at pgs. 20-21)*.**

After the report of the UMDNJ Campus Committee on Research Integrity issued, and during the course of the year in which the ORI/DOI was then reviewing it, Hill was advised by Dr. Kay Fields, an Investigator/Scientist employed by the United States Department of Health, Office of Public Health and Science, Office of Research Integrity, of an additional method of analysis that could be applied to determine the falsity of the data allegedly derived from the experiment that Bishayee had performed in September, 1999. Hill was advised to present any new allegations or evidence directly to UMDNJ, as it was deemed by ORI to be the institution responsible for investigating. (279a-280a)(Hill S.J Exhibit 1, Hill Certified Written Disclosure, ¶¶ 84-87, pgs.59-60) (Hill S.J. Exhibits 88-91:

Hill Certified Written Disclosure Exhibits 39-42)[7]**; (508a-509a) (Hill S.J. Exhibit 53: *Hill Amended Answer to Defendants' Interrogatory No. 22. pgs 39-40*).**

The method of analysis that Dr. Fields/ORI had directed Hill to is based on a paper published by James E. Mosimann (a former senior biostatistician of the Office of Research Integrity), John E. Dahlberg, Nancy M. Davidian and John W. Kreuger entitled "Terminal Digits and the Examination of Questioned Data", Accountability in Research, 9: 75-92, 2002 (361a) (Hill S.J. Exhibit 9) as well as an earlier paper that he authored along with Claire V. Wiseman and Ruth E. Edelman entitled, "Data Fabrication: Can People Generate Random Digits?", Accountability in Research, Vol. 4, pp. 31-35 (371a) (Hill S.J. Exhibit 10). The premise of these papers is that, when people make up numbers, they do not pick them randomly - and that numbers that are generated by electronic instruments should be uniformly distributed or random if they are located in non-significant positions. In the "Terminal Digits…" paper (361a), Mosimann presented four

[7] These Exhibits are as follows:

Hill S.J. Exhibit 88. Letter from Dr. Hill to Dr.Fields dated November 3, 2001 (1256a).

Hill S.J. Exhibit 89. Email from Dr.Hill to Dr. Field dated December 12, 2001 (1257a).

Hill S.J. Exhibit 90. Letter from Dr. Hill to Dr.Price dated August 22, 2002 (1258a)

Hill S.J. Exhibit 91. Letter from Dr. Price to Hill dated September 5, 2002 (1262a).

(4) cases. In two (2) of the cases, numbers are reported that are discrepant as regards their expected uniform nature. In all four cases, when the originators of the numbers were confronted with the analysis, they admitted that the numbers had been fabricated. (245a-250a) **(Hill S.J. Exhibit 1: *Hill Certified Written Disclosure, ¶¶ 40-46, pgs.25-30;* (361a-398a) (Hill S.J. Exhibits 9-13: *Hill Certified Written Disclosure Exhibits 10-14*).**

In November, 2002, Hill initiated a second complaint against Bishayee alleging falsification and/or fabrication of data for the NIH grant. (280a)(Hill S.J. Exhibit 1: *Hill Certified Written Disclosure, ¶87, pg 60*) (Hill S.J. Exhibits 92-93: *Hill Certified Written Disclosure Exhibits 43-44*)[8]; (508a-509a) (Hill S.J. Exhibit 53: *Hill Amended Answer to Defendants' Interrogatory No. 22. pgs 39-40*).

On March 10, 2003, the UMDNJ Campus Committee on Research Integrity again concluded there was no cause to credit the allegations. It did so notwithstanding the fact that Lenarczyk had by then provided his lab notebook to the Committee which contained the 16 trials that he had conducted between October 2000

[8] These Exhibits are as follows:

Hill S.J. Exhibit 92. Letter to Dr. Hill from Dr. Forrester dated November 25, 2002 (1263a).

Hill S.J. Exhibit 93. UMDNJ Policy on Misconduct in Science (1264a).

and July 2001. (200a)**(Hill S.J. Exhibit 46: *Amended Complaint, ¶34)*; (210a) (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶34*); (280a-283a) (Hill S.J. Exhibit 1, *Hill Certified Written Disclosure, ¶¶ 88-92, pgs.60-63*); (1277a) (Hill S.J. Exhibit 94: Written Discloure Exhibit 45 – Letter to Hill from Robert Saporito, Sr. V.P. for Academic Affairs dated March 21, 2003); (1278a) (Hill S.J Exhibit 95: *Report of Initial Inquiry Into Allegation of Potential Misconduct in Science Against Anupam Bishayee Ph.D.)***

The Report of the Committee concluded that:

(a) Statistics, alone, regarding the "randomness" or "uniformity" of the data in question were not sufficient to warrant further investigation; and,

(b) The lack of appropriate independent control data with which to compare the experimental results generated by Dr. Bishayee rendered the questions raised by Dr. Hill's allegation scientifically unanswerable. (1284a)(Hill S.J Exhibit 95: *Report of Initial Inquiry Into Allegation of Potential Misconduct in Science Against Anupam Bishayee Ph.D., page 5*).

During this Inquiry, Howell was neither interviewed by the Committee, nor did he independently advise the Committee of the 6 additional trials he had

conducted between April 2001 and September 2001; and, in which he had failed to replicate the data reported in the publications and grant application. (200a) (Hill S.J. Exhibit 46: *Amended Complaint, ¶35)*; (211a) (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶35*).

In focusing on the statistical analysis that Hill had performed on the two (2) Bishayee experiments performed in 1999 and 2001, the Second Committee failed to attribute any weight to the fact that it had actually requested and been provided Lenarczyk's lab notebook that contained the 16 trials Lenarczyk had conducted between October 2000 and July 2001; and, in which he was unable to replicate the Bishayee data. (76a) (Hill Statement of Undisputed Facts No. 73[9]). Notwithstanding, it unexplainably failed to comment **at all** on the significance of these experiments, or to question Lenarczyk about the notebook and the experiments that it contained (1681a-1682a)(Hill S.J. Exhibit 116, Lenarczyk Deposition 216/10-217/17). It thus re-committed the very error which ORI noted the first committee had made: to wit "The Committee evidently

[9] Indeed the Committtee report incorrectly suggested that 8 of these experiments were experiments that Hill and Lenarczyk had conducted rather than Lenarczyk, Howell and with supervision, Bishayee. (1281a) (Hill S.J Exhibit 95: *Report of Initial Inquiry Into Allegation of Potential Misconduct in Science Against Anupam Bishayee Ph.D.at pg. 2).*

discounted testimony that the bystander experiment could not be repeated by Drs. Lenarczyk and Howell. If this were true, the doubt about the bystander effect would have been a substantial motive for Dr. Bishayee to falsify data showing such an effect". (1076a) (Hill S.J. Exhibit 38, *ORI Oversight Report, at page 12, n.18).*

Once again, neither Howell nor Bishayee undertook to submit retractions of the data purporting to show an exponential survival and a bystander effect that had been set forth in the publications aforesaid and the grant application. (200a)(Hill S.J. Exhibit 46: *Amended Complaint, ¶36);* (211a)(Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶36*).

As a result of the successive findings of no cause by the UMDNJ Campus Committee on Research Integrity, UMDNJ did not disclose Howell's and Bishayee's actions to the NIH, as its policies obligated it to do in the event it internally found substantial evidence of falsification and/or fabrication of data submitted in support of a grant application. Nor did UMDNJ undertake to withdraw the scientific literature that was generated from this data. (200a)(Hill S.J. Exhibit 46: *Amended Complaint, ¶37);* (211a)(Hill S.J. Exhibit 47: *Defendants' Answer to Amended*

***Complaint, ¶37*); (1270a-1271a)(Hill S.J. Exhibit 93: *Hill Disclosure Exhibit 44, pgs. 7-8, ¶ 5.E.10.b.*).**

Upon notice of the grant award in May 2000, and annually thereafter, Howell was then required to submit progress reports concerning the grant to the NIH. In none of the reports did he disclose the fact that the data aforesaid could not be replicated. Nor did he undertake to issue a retraction concerning the alleged validity of the data. (201a)(Hill S.J. Exhibit 46: *Amended Complaint, ¶38);* 211a) (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶38*); (783a-784a)(788a -789a)(Hill S.J. Exhibit 96: *U.S. Dept. of Health and Human Services, Public Health Service, Non-Competing Continuation Progress Report (PHS 2590); Section 2.2.1, Item 13 and Assurances and Certifications, and Section 2.2.6 B & C. Progress Report Summary- Studies and Results/Significance.* http://grants.nih.gov/grants/funding/2590/phs2590.pdf.; **(1368a-1393a)(Hill S.J. Exhibits 97-100: Howell Progress Reports (4) for 7/1/00-6/30/01; 7/1/01-6/30/02; 7/1/02-6/30/03; and 7/1/03-6/30/04). These grant regulations require the Principal Investigator to provide re-assurances and to re-certify:** (a) that the grant application is true and complete and accurate to the best of his or her 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) accepts responsibility for the scientific conduct of the project; and (d) has agreed to periodically provide progress reports regarding the grant). They further require the Institutional Grantee (UMDNJ) to certify: **"that the statements herein are true, complete and accurate to the best of my knowledge, and [that it] accept[s] the obligation to comply with Public Health Services terms and conditions if a grant is awarded as result of this application. I am aware that any false, fictitious, or fraudulent statements or claims my subject me to criminal, civil or administrative penalties". They further require that negative results and technical problems be identified (789a).**

Subsequent to the filing of the Complaint in this matter, Defendants responded to a Subpoena Duces Tecum issued by the United States of America, Department of Health and Human Services, Office of the Inspector General and served personally upon Howell (1399a)(Hill S.J. Exhibit 103: *Subpoena Duces Tecum* dated November 2004). Among the documents that were subpoenaed and produced were:

(4) "Any and all notebooks dealing with the "bystander effect" and related research, including but not

limited to notebooks dated January 1996 through March 2002 and notebooks of Dr. Bishayee, Dr. Lenarczyk, Dr. Helene Hill and Dr. Howell;

(7) "Computer files relating to the "bystander effect": the hard disks of computers should be imaged and copies made of zip disks, CDs and other portable storage media including back up materials";

(10) "Any records of scientists and/or technicians carrying out experiments on the "bystander effect" subsequent to Dr. Anupam Bishayee's departure";

(15) "Dr. Howell's laptop computer and any other computer that may contain information relevant to the "bystander effect" and relevant experiments" (1402a).

The experiments and data provided in response to the Subpoena Duces Tecum contained the independent control data (to wit, Coulter counts) with which a statistician could compare the experimental results generated by Dr. Bishayee. (1679a)(Hill S.J. Exhibit 115 – ORI Technical Assistance Publication: Handling Misconduct – Statistical Forensics: Check Righmost Digits for Uniform Distribution); (1403a) (Hill S.J.Exhibit 104: *Expert Report of Dr. Joel Pitt)*). A statistician could thus employ the additional method of analysis that ORI informed Hill could be applied

to determine the falsity of the data allegedly derived from the experiment that Bishayee had performed in September, 1999 and which data was used to support Howell's revised grant to NIH. Id.

Hill's expert statistician, Dr. Joel Pitt, employed the "Mossiman" technique that ORI had directed Hill to in order to analyze the Coulter counter data. Utilizing the control data obtained from Howell/UMDNJ as well as other University research sites employing Coulter counters[10], Pitt undertook to determine the relative frequency with which each of the digits 0-9 appear as the least significant digit in Dr. Bishayee's data. (1403a) (Hill S.J. Exhibit 104: *Report of Dr. Joel Pitt entitled "Statistical Evidence in Department of Radiology, New Jersey Medical School" and Curriculum Vitae, pages 1-7 and Appendix to Report: Sources of Data Used for Statistical Analysis and Generating Charts).*

Based on that analysis, Dr. Pitt determined the probability that non-fabricated data could result in such frequencies is considerably less than 0.000000000001 (one in one hundred billion).

Dr. Pitt thereafter employed two additional statistical techniques:

a). He found and determined that 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 Coulter counter measurements he had allegedly taken to force his data to conform to the experimental results he wished to report. Dr. Pitt found that this pattern is completely at variance with the pattern in the

[10] Coulter Counter data was also obtained from Case Western Reserve University, Cleveland, Ohio and the University of Texas, Southwestern Medical Center, Dallas Texas. (1424a) (Hill S.J. Exhibit 105: *Certification of Dr. Nicholas P. Ziats/Case Western Reserve University)*1436a) (Hill S.J. Exhibit 106: *Certification of Dr. Woodring Wright/University of Texas, Southwestern Medical Center, Dallas, Texas*).

control data and computer simulation data. (1403a-1404a) (1409a-1413a) (Hill S.J. Exhibit 104: *Report of Dr. Joel Pitt entitled "Statistical Evidence in Department of Radiology, New Jersey Medical School" and Curriculum Vitae, pages 1-2, 7-11).*

b). 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) (1403a-1404a) (1413a-1414a)(Hill S.J. Exhibit 104: *Report of Dr. Joel Pitt entitled "Statistical Evidence in Department of Radiology, New Jersey Medical School" and Curriculum Vitae, pages 1-2, 11-12).*

Simply put, Dr. Pitt concluded that Dr. Bishayee had committed fraud. (1403a-1404a) (1414a-1415a) (Hill S.J. Exhibit 104: *Report of Dr. Joel Pitt entitled "Statistical Evidence in Department of Radiology, New Jersey Medical School" and Curriculum Vitae, pages 1-2, 12-13;)* (1441a) (Hill S.J. Exhibit 107: *Deposition of Pitt at 113*). The Defendants did not offer, or seek to qualify any statistical expert to refute Dr. Pitt's analysis, opinions or conclusions.

The discovery engaged in by the U.S. Attorney and Hill further resulted in its review and analysis by an expert Radiation Biologist retained by Hill, Dr. Michael E. Robbins. (1443a) (Hill S.J. Exhibit 108: *Expert Report of Dr. Robbins entitled "Evidence of Fraud in the Department of Radiology, at the New Jersey Medical School");* (1467a) (Hill S.J. Exhibit 109: *Curriculum Vitae for Dr. Robbins); (1523a)(*Certification of Dr. Robbins*).*

Dr. Robbins concluded that the Bishayee data is fraudulent based: (a) biochemical and radiobiological principals that are well-documented in the scientific literature; and (b) his knowledge and experience of the cell cycle. As more particularly set forth in his report (1444a), Dr. Robbins concluded that Bishayee could not have achieved the exponential declines in the data he presented because:

(a) Tritiated Thymidine (^{3}H-TdR) (which had been used by Bishayee and Howell in these experiments) blocks the cell cycle at the beginning of the DNA synthesis phase of the cell cycle, causing DNA synthesis to stop. Specifically, ^{3}H-TdR blocks cell cycle progression so that cells that are not in DNA synthesis (S) phase during their overnight exposure cannot enter S phase and cannot be killed by the radioactive decay of ^{3}H.

(b) The experiment protocols did not call for the addition of deoxycytidine (dCyd) to the medium at the time of the exposure of the cells to ^{3}H-TdR. Deoxycytidine would have abrogated the effect of the ^{3}H-TdR at blocking the cell cycle; and, in its absence there can be no exponential decline in survival.

(c) Neither Bishayee nor Howell made any attempts in their experiment protocols to synchronize the cells before the addition of ^{3}H-TdR. Had the cells been synchronized, they might possibly have all been in S phase at the time the ^{3}H-TdR was added.

(d) The presence of hypoxia in the Helena tubes used in the experiments also supports the conclusion of fraud.

(1443a) (Hill S.J. Exhibit 108: *Expert Report of Dr. Robbins entitled "Evidence of Fraud in the Department of Radiology, at the New Jersey Medical School").*

At the request and direction of the U.S. Attorney's Office in 2004 or 2005, Howell had also prepared

a document entitled "Summary of Experiments". In this document, Howell attempted to propose a number of factors that might explain the differences in the data generated by Bishayee and the data generated in experiments performed by Lenarczyk and Howell. (1542a) (Hill S.J. Exhibit 102: *Howell Deposition Exhibit 29*); (1804a-1805a)(Hill S.J. Exhibit 123: Howell Deposition Vol. I *140/7-25*, 146/1-12); (667a) (Hill S.J. Exhibit 76: *Howell Deposition Vol I; 145/17 –25*).

Howell never shared this document with Drs. Baker (his Department Chair), Putterman (the Vice President for Academic Affairs) or Raveche (who had headed the Initial Campus Committee on Scientific Misconduct) (666a-667a)(Hill S.J. Exhibit 76: *Howell Deposition Vol.I 144/25-145/12*).

When deposed, the 'factors' that Howell identified in his summary proved to be simple conjectures and suppositions, as Howell admitted he never undertook any analysis or investigation to determine whether any of the factors had, in fact, served to cause his inability to replicate the data set forth in the grant applications and publications.

Thus:

(a) He had not observed any changes in the pH of the media, nor did he undertake any analysis or investigation to determine whether in fact there had been such changes in the pH of the media (668a-671a)(Hill S.J. Exhibit 76: *Howell Deposition Vol I. 150/18-153/17*).

(b) He did not engage in any experimentation to determine whether the source of microfuge tubes that the clusters were maintained in was, in fact, a variable that contributed to his inability to replicate the data (672-674a)(Hill S.J. Exhibit 76: *Howell Deposition Vol. I 159/9-161/14*).

(c) He did not undertake any analysis or investigation to determine whether in fact levels of trace elements in UMDNJ de-ionized water from which the cell culture media is prepared in fact was a variable that contributed to his inability to replicate the data (674a-680a)(Hill S.J. Exhibit 76: *Howell Deposition Vol. I 161/15-167/6*).

(d) He did no investigation or analysis of the wetting agents on the filter apparatus used to sterilize cell culture media, and had no data to support that it had occurred (680a)(Hill S.J. Exhibit 76: *Howell Deposition Vol. I 167/7-25*).

(e) He did not do any experiments to determine that the methods used to clean bottles used to prepare and store media was in fact a variable that contributed to his inability to replicate the data (681-683a)(Hill S.J. Exhibit 76: *Howell Deposition Vol. I 168/2-170/25*).

(f) He did no investigation or analysis of the sodium bicarbonate to determine whether in fact it was a variable that contributed to his inability to replicate the data (684a-686a)(Hill S.J. Exhibit 76: *Howell Deposition Vol. I 171/1-173/3)*.

(g) He never did any experiments or tests to determine, and lacked data to establish whether the incubator was in fact a variable that contributed to his inability to replicate the data (686a-686a)(Hill S.J. Exhibit 76; *Howell Deposition Vol. I 173/8-175/2*).

(h) He had no data or facts to support his hypothesis that the fetal calf serum used was in fact a variable that contributed to his inability to replicate the data. Nor did he do any experimentation to determine it to be a fact (688a-694a) (Hill S.J. Exhibit 76: *Howell Deposition Vol. I 175/4-181/17*).

i. He undertook no experimentation to determine whether the flasks that the cells were grown in

was in fact a variable that contributed to his inability to replicate the data (694a-696a)(Hill S.J. Exhibit 76: *Howell Deposition Vol. I.181/18 – 183/15*).

j. He did no analysis or experimentation with regard to determining whether different V79 cells that were used during his attempted repeat experiments contributed to the fact he could not replicate the data 696a-704a)(Hill S.J. Exhibit 76: *Howell Deposition Vol. I 183/16-191/2*).

Based on all of the above, Hill contends it should have been concluded that Defendants engaged in knowing violations of the FCA.

Related Cases and Proceedings

None

Standard of Review

The Court exercises plenary review of the District Court's grant of summary judgment of Defendant's claims and the denial of Plaintiff's claims. Hutchins v Wilentz Goldman and Spitzer, 253 F.3d 176 (3rd Cir. 2001). In so doing, the Court applies the same standard of review as applied by the District Court. FDIC v Bathgate, 27 F.3d 850, 860 (3rd Cir.1994). Specifically, the Court determines whether "the pleadings, the

discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law". Fed.R.Civ.P 56(c)(2).

Argument

Summary of Argument

The District Court Opinion erroneously limited its focus and determination to the evidence that was known to Hill at the time Howell submitted his revised 1999 grant application to NIH. The opinion failed to give appropriate weight to any of the information and evidence that was obtained through subpoena issued by the U.S. Attorney and/or in further discovery engaged in by Hill. That evidence demonstrated that: (1) at the time of the 1999 grant application (2) at time annual progress reports were submitted to NIH; and/or (3) at the time Howell submitted the 2005 continuation grant, Defendants knowingly had relied, and continued to rely, on false or fraudulent data. Thus the District Court erroneously applied the standards applicable to the claim because the Defendants had actual knowledge of the information; acted in deliberate ignorance of the truth or falsity of that information; and/or in reckless disregard of the truth or falsity of the information. Summary Judgment should therefore have been granted to Plaintiff and denied to Defendants.

Argument

THE DEFENDANTS SUBMITTED CLAIMS AND STATEMENTS TO NIH THAT WERE FALSE AND FRAUDULENT

A. The Statutory Framework

A cause of action under the FCA, 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;
>
> (B) knowingly makes , uses or causes to be made or used, a false record or statement material[11] to a false or fraudulent claim.[12]

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[11] 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."

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 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

[12] 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.

FCA. United States v Lawson, 522 F.Supp. 746, 750, (D.NJ 1981); United States v Neifert-White, 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). 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 Onmicare, Inc. 382 F.3d 432 (3rd Cir. 2004).

THE NIH GRANTS PROCESS

The Court's attention is respectfully directed to United States ex rel. Bauchwitz v Holloman, 671 F.Supp. 2d 674, 680-682 (E.D. Pa. 2009) in which the district court set forth and explained the process of seeking NIH grants and continuation grants, and in submitting annual progress reports. (See also (1551a) Hill S.J. Exhibit 50: *NIH Grants Policy Statement (10/98)*; and, (770a) Hill S.J. Exhibit 96:*U.S. Dept. of*

Health and Human Services, PHS, Non-Competing Continuation Progress Report, PHS 2590).

THE CLAIM SUBMITTED AND THE STATEMENTS MADE THEREIN WERE FALSE AND/OR FRAUDULENT

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 tritiated thymidine (^{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.(340a)(351a)(Hill S.J. Exhibit 4 and 6). The results of these experiments are reported in Howell's successful grant application (285a)(Hill S.J. Exhibit 3) and in two papers published in Radiation Research (517a)(527a)(Hill S.J. Exhibits 14 and 15). 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.(401a) (421a)(Hill S.J. Exhibit 110 and 111, page 2).

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. (1575a)(Hill S.J. Exhibit 50: *NIH Grants Policy Statement (10/98*), Part I: Legal Implications of an Application); (611a-613a) (Hill S.J. Exhibit 51: *Baker Deposition 15/17-17/1*).

In submitting the October 2005 competing continuation (i.e. renewal) grant (537a) (Hill S.J. Exhibit 54), Howell undertook to re-submit the very same data which by then he well knew (by virtue of 22 failed attempts), 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, including those terms and conditions identified in the NIH Grants Policy Statement (2027a) (1535a-1537a)(Hill S.J Exhibits 52 and 101).

Throughout this time, and periodically/annually thereafter, Howell was also required to submit progress reports concerning the grant to the NIH. (1368a, 1377a, 1389a and 1393a) (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) **(784a)(Hill S.J. Exhibit 96,Section 2.2.1.)**.

It is clear that these statements, certifications and progress reports may serve to establish false claims within the meaning of the FCA. United States ex rel. Cantekin, v University of Pittsburgh, 92 F. 3d 402, 406 (3rd

Cir. 1999); United States ex rel. Berge, v Board of Trustees of the University of Alabama, 104 F. 3d 1453 (4th Cir. 1997) United States ex rel. Feldman v Van Gorp, 674 F. Supp. 2d 475 (S.D.N.Y. 2009); United States ex rel. Resnick v Weill Medical College of Cornell University, 2010 WL 476707 (S.D.N.Y. 2010). The PHS regulations mandate that progress report describe the studies directed toward specific aims during the current budget year; the positive and negative results obtained; and whether technical problems were encountered (Section 2.2.6) (788a-789a).

With all due respect to the District Court, its Opinion glosses over the fact that the experimental results set forth in the 1999 and 2005 grant applications could not be replicated. In so doing, the court disregarded well established scientific policies and principles; to wit, that research scientists must well know and be guided that, in order for experimental results to be accepted as valid, the results must be capable of being replicated. (1670a)(Hill S.J. Exhibit 74, UMDNJ Guidelines for Conduct of Research, Section III)("The goal of scientific record-keeping is to provide sufficient information so that the research can be repeated by another investigator who is appropriately experienced, and so that questions arising after publication can be answered.")

Even assuming that Howell did not know the results were false at the time he submitted the application in 1999 (a fact not conceded based on the record evidence in this case), he clearly had to have that knowledge once Bishayee's results could not be replicated in the 22 experiments thereafter conducted between October 2000 and September 2001. Those experiments should have raised a red flag to any responsible scientist. The red flags required Howell to show why the data could not be replicated when neither he nor Lenarczyk could confirm Bishayee's results. This information should also have been shared with Howell's Department Chair, Baker, whose office had signed onto the grant as Grantee for UMDNJ and to his Program Director at NIH. Instead, in April 2001, and despite the knowledge he then possessed, Howell undertook to tell Baker that he was **only then** going to commence experiments to determine whether the Bishayee results were valid (645a-646a)(Hill S.J. Exhibit 75: *Letter from Howell to Baker dated April 6, 2001).* Howell thus deliberately misled Baker.

Nor did Howell share this information with either of the UMDNJ Campus Committees and/or to ORI. Instead, Howell consciously elected to withhold that information from these bodies in the face of Hill's complaints. He deliberately chose not to reveal to either

Committee that Bishayee's experimental results could not be confirmed. Howell did not tell them, and the reports of the Committees demonstrate that they did not ask Howell. Rather than recognize this conduct as a knowing act of concealment, the District Court rewarded the Defendants for engaging in a "Don't tell, Don't ask" investigatory procedure. Indeed the District Court should have recognized this scheme when it suggested that, because the Campus Committee's and ORI each concluded as they did, it was more unlikely that Hill, as she persisted (i.e. sought out the withheld facts), could demonstrate that Howell acted knowingly or in deliberated disregard of the truth[13]. Respectfully, the District Court failed to discern that it had taken Hill's perseverance in commencing suit; a U.S. Attorney subpoena duces tecum; and, extensive pre-trial

[13] See United States ex rel Milam v Regents of University of California ("Milam"), 912 F. Supp. 868, 880 (D. Md. 1995) holding 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).

discovery for Defendants to first disclose and to produce not only the 22 experiments but the very control data which the Committee's had available to it all along had they known what to look for and ask for it. It was this very evidence that allowed Hill to show Howell's failure to explain these facts was clearly evident to him back in 1999 and continues to be ignored by Defendants to the present day.

This Court should not be persuaded by the District Court's Opinion suggesting that Howell superficially complied with the Committee by physically producing his lab notebooks (15a). The Opinion, however, favors the Campus Committee report, and omits any recognition that Howell's failure to come forth factually with what had occurred; and, what ORI found to be a lack of Committee expertise and other deficiencies in analyzing the information, effectively allowed Howell to cloak the grant in a fraudulent deception.

Indeed, among the shortcomings and concerns that the September 2002 ORI Report noted with regard to the First Campus Committee, was whether it had sufficient competence to adequately conduct the inquiry. (1067a - 1068a)(1077a)(Hill S.J. Exhibit 38: *ORI Oversight Report, dated September 5, 2002, at pages 3-4 and f.n. 4; page 13).*

ORI found there was no radiation biologist who could have contributed the expertise needed in what it described as the **basic** science and cell biology of the research at issue; and among those serving on the committee, were 4 Deans whose Medline citations had indicated minimal recent bench-science publications.

Moreover, the second Campus Committee had 5 carryovers from the first committee and still lacked any person qualified in basic science let alone in Radiation Biology or cell biology. (1280a)(Hill S.J Exhibit 95: *Report of Initial Inquiry Into Allegation of Potential Misconduct in Science Against Anupam Bishayee Ph.D.at pg. 1).*

The record evidence demonstrated that, even when Lenarczyk undertook to share some of his experiments that showed Bishyee's results could not be replicated with the First Campus Committee, the Committee conspicuously chose not examine or evaluate them.

Because the Second Committee had considered, but deliberately failed to get an expert statistician to assist and to advise it (1355a)(Hill S.J Exhibit 95: *Report of Initial Inquiry Into Allegation of Potential Misconduct in Science Against Anupam Bishayee Ph.D.at Appendix G, Page 3) ("The Committee will begin inquiries about an appropriate*

outside expert to render an opinion about the validity of Dr. Hill's analysis and its relevance for the allegation of falsification of data"), it limited themselves solely to a telephone call about the two experiments that ORI had analyzed from the first committee.

Dr. Pitt's report (1403a), however, demonstrates that a statistical analysis by a competent expert retained by the Second Committee would have demonstrated that Bishayee had fabricated that data. Thus, ORI did not determine that the data necessary to make a determination as to whether Bishayee had fabricated results would never be available. All ORI was saying was that, on the data that had been made available to the first committee (i.e. the 2 experiments), it was inconclusive. Defendants' claim below, that Hill has failed to uncover or present any evidence to show that Defendants knowingly submitted data that they knew to be false to NIH, is specious.

Contrary to what the District Court believed, Howell was obligated to advise his Program Director at NIH about these facts. It is reasonable for this Court to conclude that the Program Director would have then decided to what level of inference these variant results rose to. In lieu thereof, Howell clearly acted in reckless disregard of the truth and the District Court gave him a free pass

despite the fact that Howell's results bear on public health and are used as a guide for nuclear medicine, both therapeutic and diagnostic; and, in chemo- and radiation therapy.

Moreover, at the times that Howell and UMDNJ submitted progress reports and the 2005 competitive renewal, the fact that 22 experiments had failed to confirm the results of Bishayee's 100% and 50% experiments, and that Howell and Lenarczyk had confirmed each others results but not Bishayee's was clearly known. These facts clearly demonstrated the statistical impossibility of the Coulter counts in Bishayee's experiments, which Dr. Pitt, upon being provided adequate controls through discovery, proved that the data submitted with the 1999 application was fraudulent. He did so based on the recognized techniques employed by ORI in such matters (1679a)(Hill S.J. Exhibit 115). The failure of the District Court to properly recognize that Pitt's statistical analysis related to, and cogently analyzed and showed the Bishayee data that was produced before the grant application was submitted in 1999 and on which the grant application was based to be fraudulent.

The withholding of these facts, demonstrate that NIH approval of a continuation grant to Howell in 2005 and/or

received a copy of the ORI 2002 report is of no probative value. The Defendants offered no competent and admissible evidence to show that the NIH Study Section that reviewed Howell's renewal application in 2005 had any knowledge about the allegations. Indeed there is not one word of them mentioned in the application itself (537a) (Hill S.J. Exhibit No. 54), and Howell admitted that he never uttered a word to his Program Director at NIH. (79a-81a)(Hill Statement of Undisputed Material Fact Nos. 88-91). Even more important, he never alerted the scientific community to inability to replicate the results by publishing retractions. Milam, supra at 877 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 with NIH. 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 (1655a)(1662a)(1665a)(Hill S.J. Exhibits 72-74) (1886a-1889a) (Hill SJ Exhibits 113- 114).

While the District Court Opinion attempts to soft pedal these facts as simply constituting "conflicting data", it is respectfully submitted this Court must now undertake to correct that erroneous characterization. Conflicting data that is the result of fabrication may well rise to the level of research misconduct and does so in this case. The NIH Grants Policy Statement (1568a)(Hill S.J Exhibit 50) defines misconduct as "Fabrication, falsification, plagiarism, or other practices that seriously deviate from those commonly accepted within the scientific community for proposing, conducting, or reporting research". Clearly making up data or results and recording them or reporting them as Bishayee did constitutes fabrication. Manipulating research materials, equipment, or processes, which Bishayee did and Hill and Lenarczyk observed, constitutes falsification. Omitting data or results such the research is not accurately represented in the research record, as Howell did, is similarly falsification. Had the District Court not drawn the line at October 1999, all of these aspects of research misconduct were demonstrated in the evidence presented on Plaintiff's motion for summary judgment.

THE IMPACT OF THE EXPERT REPORTS ON THE SUMMARY JUDGMENT MOTIONS

The expert reports that were submitted in support of Hill's Summary Judgment Motion provided further evidence that Defendants knowingly violated the FCA.

A. Radiation Biologist

Dr. Robbins, an esteemed radiation biologist (1467a), concluded the Bishayee data and results were impossible to generate, and thus fraudulent, because:

(1) Tritiated thymidine (^{3}H-TdR) blocks the movement of cells through the various phases of the cell cycle. Thus cells that are not in the S phase of the cell cycle during the overnight incubation with ^{3}H-TdR cannot enter the S phase, will not incorporate^{3}H-TdR into their DNA, and will not be killed by the subsequent radioactive decay of the $^{3}H^{14}$ (1445a) (Hill S.J. Exhibit 108 at 3); (1523a) (Certification of Robbins);

(2) No deoxycytidine (dCyd) was present in the medium at the time the cells were exposed to ^{3}H-TdR. Thus its absence in the medium failed to prevent the ^{3}H-TdR from blocking cell movement through the cell cycle (1446a) (Hill S.J. Exhibit 108 at 4); and

(3) No attempt was made to synchronize the cells into the same phase of the cell cycle prior to treatment of with ^{3}H-TdR (1446a) (Hill S.J. Exhibit 108 at 4).

Reason 1

[14] While taking issue with Reason No. 1 of the Robbins report the Defendants expert, Dr. Feinendegen concedes that, if Robbins is correct on Reason No. 1, he would agree with Robbins on Reasons 2 and 3 (1684a) (Feinendegen Report) (1748a) ((1728a-1730a) (Hill S.J Exhibit 117: Feinendegen Deposition at 173/10-22; 88/17-90/17).

Based on his review of the Bishayee experiments before him, Robbins opined that Tritiated thymidine (^{3}H-TdR) blocked the movement of cells through the various phases of the cell cycle. Thus cells that were not in the S phase of the cell cycle during the overnight incubation with ^{3}H-TdR could not enter the S phase, did not incorporate^{3}H-TdR into their DNA, and were not killed by the subsequent radioactive decay of the ^{3}H. Data reporting the contrary were thus fraudulent. **(See also Hill S.J. Exhibit 111 at pgs 1, 3-7)(421a-427a).**

Defendants' expert, Dr. Feinendegen, had opined that tritiated thymidine does not always serve to block the cell cycle; and, that the blocking depends on the amount of thymidine molecules that have entered the cellular nucleotide pool (the "thymidine pool")[15] (1685a-1686a). [16] But Dr. Feinendegen never specifically identified the size of the pool for V79 cells, referring instead to what he called "indirect evidence" of what the pool size is (1709a-1713a) (Hill S.J. Exhibit 117: Feinendegen Deposition 40/13-44/6). In contrast, Robbins noted that Feinendegen's sophistry is the scientific equivalent of not specifying the pool size. He noted that there is nothing in the scientific literature that specifies what the pool size in V79 cells is, as opposed to a range (1755a) (Hill S.J. Exhibit 118: Robbins Deposition 70/2-70/23).

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[15] Thymidine is a building block of DNA and the thymidine pool contains the precursors for DNA (1707a) (Hill S.J. Exhibit 117: Feinendegen Deposition at 33).

[16] An understanding of the "pool" is gleaned by considering the analogy of an Olympic size swimming pool to a child's wading pool. If one throws a bucket of dye into the pool it has no noticeable effect on the color of the water. If one throws that same bucket of dye into a children's wading pool, it does affect the color. The size of the pool thus needs to be known to determine the effect that the dye thrown in has on the color of the water (1708a) (Hill S.J. Exhibit 117: Feinendegen Deposition 34/6-25).

Feinendegen further sought to distinguish between high and low specific activity ^{3}H-TdR; stating that high specific activity ^{3}H-TdR permits sufficient numbers of tritium atoms to be incorporated into the DNA without perturbing the cell cycle. He concluded that Bishayee used high specific activity ^{3}H-TdR that permitted 100% labeling of the cells to occur without perturbing the cell cycle. On page 8 of his report (1690a), he calculates that concentration of thymidine to have been 0.12 micromole. In such concentration, Feinendegen indicates there was no reason for deoxycytidine (Robbins Reason 2) or cell synchronization (Robbins Reason 3) to be utilized or performed. (1686a); (1717a-1718a); (1728a-1730a) (Hill S.J. Exhibit 117: Feinendegen Deposition 63/20-64/6 and 88/17-90/17) because the cell cycle was not perturbed.

Robbins easily refuted Feinendegen's hypothesis that the amount of tritiated thymidine that was added in the **Bishayee experiments** was too small to affect the thymidine pool and therefore not interfere with the cell cycle (1755a) (Hill S.J. Exhibit 118: Robbins Deposition 70/2-72/16)[17]. He noted scientific literature which convincingly demonstrated that the effects of adding ^{3}H-TdR in concentrations even on the order of one hundred fold **lower** than the concentrations used by Bishayee perturbed the cell cycle. (1759a-1764a) (Hill S.J. Exhibit 119: J. E. Cleaver, Thymidine Metabolism and Cell Kinetics, North-Holand Publishing Company - Amsterdam, John Wiley & Sons, Inc - New York, 1967, pp 85-90). This concentration of tritiated thymidine is **smaller** than what Feinendegen believed was too low to block the cell cycle in Bishayee's

[17] Robbins commented on the thymidine pool at the invitation of Defendants at his deposition (1752a-1753a)(Hill S.J. Exhibit 118: Robbins Deposition at 57/9-61/17). The scheduling order made no provision for his reply to Dr. Feinendegen's report. It is noted that his report had cited to the literature which dealt with the issue of the thymidine pool and on which he had relied in rendering his opinion. (1755a) (Hill S.J. Exhibit 118: Robbins Deposition 70/2-23)

experiments; and, would, in fact, perturb the cell cycle. Another journal paper, (1765a) Cleaver J.E., Holford, R.M., Investigations into the Incorporation of [3H]thymidine into DNA in L-strain cells and the Formation of a Pool of Phosphorylated Derivatives During Pulse Labelling. Biochim Biophys Acta 103, 654-671, 1965 (Hill S.J. Exhibit 120), demonstrates that a 1/1000th fold (10^{-9} M) thymidine affected the pool ((1776a).[18] This concentration is also **lower** than that used by Bishayee and thus renders Feinendegen's hypothesis impotent.

Robbins further refuted Feinendegen on the issue of high specific activity, pointing out and relying on two additional articles in the scientific literature: (1) Hu, V.W., Black, G.E., Torres-Duarte, A., Abramson, F.P. 3H-thymidine is a defective tool with which to measure rates of DNA synthesis. FASEB J 16, 1456-1457, 2002 (1783a) (Hill S.J. Exhibit 121); and, (2) Keprtova J and Minarova, E. The effect of 3H-thymidine on the proliferation of in vitro cultured mammalian cells. Gen Physiol Biophys 4, 81-92, 1985 (1790a) (Hill S.J. Exhibit 122). Feinendegen admitted his familiarity with the Hu paper and the fact it shows there to be biphasic, rather than exponential killing of cells using high specific activity tritiated thymidine (1783a)(1787a) (Hill S.J. Exhibit 121) (Hill S.J. Exhibit 117: Feinendegen Deposition 103/`2-104/24)[19]. Feinendegen acknowledged the high specific activity to be about the same specific activity as that used by Bishayee. (Id.). Indeed, the concentration was .13 micromole. (See Hill S.J. 121 at the

[18] Feinendegen admitted he has cited this paper in his book, but deliberately omitted any reference to it his report (1713a-1715a) (Hill S.J. Exhibit 117: Feinendegen Deposition 44/12-47/12).

[19] A biphasic decline in survival is one where there is a decline followed by a plateau of survival. When there is an exponential decline, there is no plateau. (1803a) (Hill S.J. Exhibit 123: Howell Deposition 60/ 4-10).

section entitled “Materials and Methods: Cell-labeling Protocols) as compared to .12. micromole for Bishayee (1783a).

The Keprtova paper also showed biphasic, rather than exponential, killing of V79 cells when no deoxycytidine was added to the medium, using high specific activity ^{3}H-TdR that was only one-third (1/3rd) the amount that Bishayee had utilized (1791a – 1793a) (Hill S.J. Exhibit 122); (1739a-1743a) (Hill S.J. Exhibit 117: Feinendegen Deposition 94/6-17; 99/3-103/11).

Feinendegen’s citation to K. Fujikawa-Yamamato and S. Odashima entitled “Synergistic effects of of hydroxyurea and thymidine on the growth inhibition of V79 cells” Cell Structure and Function 14, 399-405 (1989) to claim that the minimum concentration of thymidine in the culture medium required for blocking V79 cells in various phases of the cell cycle is about 500 times higher than the concentration used by Bishayee (Leonard Certification: Exhibit D at 8-9) fails to refute the literature relied on by Robbins because that experiment dealt only with thymidine and not tritiated thymidine (1716a) (Hill S.J. Exhibit 117: Feinendegen Deposition 47/16-48/21). Moreover, Robbins noted that the experiments cited in Feinendegen’s report were based on entirely different experimental designs – to show blockage of the cell cycle by thymidine. In contrast the Bishayee experiments used tritiated thymidine not to look at the cell cycle effect, but to see what consequences radiating cells had on cell survival.(1753a-1754a)(1756a) (Hill S.J. Exhibit 118: Robbins Deposition 61/18-62/25; 78/4-79/5). Feinendegen was thus comparing apples to oranges in his report. This is not surprising given how little information Feinendegen reviewed in order to prepare his report. He admits that in preparing his report, he never read any of the experiment protocols (1719a-1720a) (Hill

S.J. Exhibit 117: Feinendegen Deposition 75/14-76/14)[20]. In contrast, Robbins did review all of the protocols (1751a) (Hill S.J. Exhibit 118: Robbins Deposition 17/7-15).

Based on the above, Robbins analysis of both the Bishayee data and the scientific literature overwhelmingly demonstrated that ^{3}H-TdR did block the movement of cells through the various phases of the cell cycle; and, that the exponential kill rates reported by Bishayee were fraudulent. His opinion thus supports a grant of summary judgment to Plaintiff.

Reason No. 2

Because Feinendegen hitched his star only to Reason No. 1, he refused to acknowledge the relevancy of the literature that supports Robbins conclusion that deoxycytidine needed to be added to the medium used in the Bishayee experiments in order to prevent the cell cycle block effect of ^{3}H-TdR (Hill S.J. Exhibit 108: Robbins report at 2 and 4)(1444a and 1446a). See: (1) (1807a) Bedford et al**,** "Cell Killing by Gamma Rays and Beta Particles from Tritiated Water and Incorporated Tritiated Thymidine", Rad Research 63: 531 (1975) (exponential killing of V79 cells by tritiated thymidine in a medium containing deoxycytidine) (1810a)(1815-1816a) (Hill S.J. Exhibit 124); (2) (1820a) Marin & Bender**,** ´A Comparison of Mammalian Cell-Killing by Incorporated ^{3}H-thymidine and ^{3}H-uridine", Int J Rad Biol 7: 235 (1963) (exponential killing of Chinese hamster cells by tritiated thymidine in a medium containing deoxycytidine) (1821a)(1824a) (Hill S.J. Exhibit 125); (3) (1830a) Chan et al.**,** "The Radiotoxicity of Iodine-125 in Mammalian Cells", Rad Research 67: 332 (1976) (exponential killing of V79 cells in a medium containing deoxycytidine) (1831a)(1833a)

[20] Feinendegen acknowledged he has never been retained as an expert in the United States and has been retired for over 16 years (1705a-1706a) (Hill S.J. Exhibit 117: Feinendegen Deposition 8/22-9/19).

(Hill S.J. Exhibit 126); (4) (1842a) Burki and Okada**,** " Killing of Cultured Mammalian Cells by Radioactive Decay of Tritiated Thymidine at -196ºC", Rad Research 41: 409 (1970)(to overcome biphasic survival curves, deoxycytidine was added to the tritiated thymidine) (1847a-1848a) (Hill S.J. Exhibit 127); (1721a- 1728a) (Hill S.J. Exhibit 117: Feinendegen Deposition 81/18- 88/16).

Feinendegen further refused to acknowledge the relevance of papers showing that survival was biphasic, rather than exponential, when deoxycytidine was absent from the medium. See: (1) (1858a) Drew and Painter**,** "Action of Tritiated Thymidine on the Clonal Growth of Mammalian Cells", Rad Research 11: 535 (1959) (biphasic killing of cells with no added deoxycytidine) (1858a) (1860a) (Hill S.J. Exhibit 128); (2) (1868a) Drew and Painter, " Further Studies on the Clonal Growth of HeLa S3 Cells Treated withy Tritiated Thymidine" Rad Research 16: 303 (1962)(biphasic killing of cells with no deoxycytidine added) (1868a) (1873a)(Hill S.J. Exhibit 129); (3) (1790a) Keprtova & Minarova, " The Effect of 3H-Thymidine on the Proliferation of In Vitro Cultured Mammalian Cells", Gen Physiol Biophys 4: 81 (1985) (biphasic killing of cells with no deoxycytidine) (1792a-1793a) (Hill S.J. Exhibit 122); (4) (1783a) Hu et al**.** '^{3}H-thymidine is a defective tool with which to measure rates of DNA synthesis'. FASEB J publ on-line 7/1/2002 (biphasic killing of cells using high specific activity tritiated thymidine and no added deoxycytidine) (1783a) (1787a)(Hill S.J. Exhibit 121); (5) (1877a) Persaud, et al. , **"**Assessment of Low Linear Energy Transfer of Radiation Induced Bystander Mutagenesis in a Three Dimensional Culture Model" Cancer Research 65:9876 (2005)(biphasic killing of cells with no added deoxycytidine) ((1877a-1878a)(Hill S.J. Exhibit 130); (1731a – 1747a) (Hill S.J. Exhibit 117: Feinendegen Deposition 91/3-107).

Bishayee could not even indicate whether the protocols for his experiments called for the use of deoxycytidine in the medium. Bishayee had no recollection of ever using deoxycytidine, nor did he even know what deoxycytidine is (1881a-1882a) (Hill S.J. Exhibit 131: Bishayee Deposition 71/19-72/13). By that admission, it is reasonable to conclude deoxycytidine was never added to the medium. Feinendegen concludes that deoxycytidine was not added to the medium (1686a). See also (426a)(455a) **(Hill S.J. Exhibit 111).**

Reason No. 3

Robbins report notes that if all the cells were in the same phase of the cell cycle then there was a possibility that they would have been in the S phase of the cell cycle at the time the ^{3}H-TdR was added. No attempt was made by Bishayee to synchronize the cells into the same phase of the cell cycle. (1444a) (1446a) (Hill S.J. Exhibit 108: Robbins Report at 2 and 4).

Bishayee indicated he did not even know what cell synchronization is, let alone having an ability to recall ever making an attempt to doing so. (1883a-1884a) (Hill S.J. Exhibit 131: Bishayee Deposition 72/14-73/24). By that admission, it is reasonable to conclude he never did it. Indeed, Feinendegen concludes that Bishayee correctly chose not to synchronize, but omits to state the facts on which he found that to be conscious choice (1686a).

Feinendegen noted and concedes that if Robbins is correct on Reason No. 1, he would agree with Robbins on Reason 3 (1748a) (1728aa-1730a) (Hill S.J. Exhibit 117: Feinendegen Deposition 173/10-22; 88/17-90/17). See also (424a- 427a) **(Hill S.J. 111 at pgs 4-7).**

Based on the above, 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)(402a) (Hill S.J. Exhibit 110 at 2)[21].

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 known as hypoxia

[21] See Robbins Report (1444a)(1447a) (Hill S.J. 108 at pgs. 2, 5).

in the Helena tubes. (402a) (408a-411a) (Hill S.J. Exhibit 110 at pgs.2, 8-11)[22]

B. The Statistician

The statistical analysis of Dr. Pitt (1403a), 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);

C.

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

[22] Id. at pgs 6-7) (1448a-1449a).

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. (221a)(1403a) (1443a) ((Hill S.J Exhibits 1, 104 and 108). Based on the above, the District Court erroneously granted summary judgment to Defendants when in fact it should have been granted to Plaintiff.

Indeed, 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. 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).

Conclusion

Based on all of the above, this Court is requested to reverse the Order of Summary Judgment below; to grant partial summary judgment to Hill; and, to then remand the matter to the District Court for consideration of the issue of damages.

Combined Certifications

I, Sheldon H. Pincus, certify as follows:

1. Sheldon H. Pincus, whose name appears on this brief, is a member in good standing of the Bar of this Court.

2. This brief complies with the type-volume limitations of Rule 32 (a)(7)(B) of the Federal Rules of Appellate Procedure as it contains 13,235 words, excluding the parts of the brief exempted by Rule 32 (a)(7)(B)(iii).

3. This brief complies with the typeface and type style requirements of Rules 32(a)(5) and (6) of the Federal Rules of Appellate Procedure as it has been prepared using Microsoft Word (Microsoft Office Professional Edition 2003) in proportionally-spaced, Times New Roman font with 14 point type.

4. A virus check of the electronic version of this brief was performed using AVG Internet Security Software, and the document was found to be virus free.

5. The text of the electronic version of this brief is identical to the hard copies filed with the Court on the same day as the electronic filing.

6. A copy of this brief was served upon John P. Leonard, Esq. and Scott S. Flynn, Esq., Counsel for Appellees, as well as Susan Steele, U.S. Attorney by electronic mail simultaneous with its electronic filing and two hard copies were thereafter served by hand delivery at counsel's address of record.

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