

UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF NEW JERSEY

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

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

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MCELROY, DEUTSCH, MULVANEY, &  
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Dr. Roger W. Howell and Dr. Anupam Bishayee

**PRELIMINARY STATEMENT**

In this action, Plaintiff-Relator Dr. Helene Z. Hill (“Dr. Hill”) is simply attempting to create false claims under the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the “FCA”) by manufacturing scientific misconduct. Despite undisputable evidence in the record that Defendants, University of Medicine & Dentistry of New Jersey (“UMDNJ”), Dr. Roger W. Howell (“Dr. Howell”) and Dr. Anupam Bishayee (“Dr. Bishayee”) (collectively “Defendants”), have not engaged in scientific fraud in connection with a 1999 grant application R01 CA83838 (“NIH Grant”) submitted to the National Institute of Health (“NIH”), Dr. Hill attempts to piece together a claim for relief from only personal, self-serving anecdotal evidence. Realizing that there is no merit behind her claims, Dr. Hill’s latest ploy involves attempting to discredit Defendants’ integrity by referencing extraneous events and documents with no relation whatsoever to the issues before the Court. More particularly, Dr. Hill tries to distract the Court by referring to the Deferred Prosecution Agreement that UMDNJ entered into and the related appointment of a Federal Monitor in 2005. These smoke screen tactics lack any substantive value and merely highlight the hollowness of Dr. Hill’s claims.

Indeed, despite the voluminous submissions from Dr. Hill to the Court, none of the material facts at issue have been disputed. Instead, the record shows that despite a decade-long pursuit of scientific fraud claims against Defendants and despite the extensive review and investigation of Dr. Hill’s claims by UMDNJ’s Committee on Research Integrity (the “Committee”), the Office of Research Integrity (“ORI”), and the United States Attorney’s Office, there has not been a single suggestion that Dr. Hill’s claims have merit. Not only have these scientific and governmental entities not agreed with Dr. Hill’s claims of fraud, but the NIH – the very same entity that issued the grant monies at issue – also had access to Dr. Hill’s claims

and actually renewed the NIH Grant at the center of this matter.

Separate and apart from the fact that scientific disputes do not fall within the purview of the FCA, Dr. Hill's Amended Complaint suffers from an additional fundamental deficiency – that is – she is unable to conclusively prove that the data, statements, and records at issue in this case are objectively false and/or fraudulent. Not surprisingly, this is the same fatal defect that resulted in the Committee and ORI refusing to further pursue her allegations that Dr. Bishayee had committed misconduct in science. Dr. Hill's claims of retaliation share similar fatal defects as she has failed to provide any evidence whatsoever that she has suffered any cognizable retaliatory adverse employment action or any damages as a result of her alleged engagement in protected whistleblower activity. For the reasons set forth herein and in Defendants' moving papers, Defendants submit that they are entitled to summary dismissal of Plaintiff's claims.

**POINT ONE**

**PLAINTIFF'S CLAIMS ARE RIPE FOR SUMMARY JUDGMENT  
PURSUANT TO FED. R. CIV. P. 56**

As more fully set forth in Defendants' moving brief, in evaluating a motion for summary judgment, if the moving party has made a properly supported motion for summary judgment, the burden shifts to the nonmoving party to "set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e); *Anderson v. Liberty Lobby, Inc.*, 477 U.S.242, 247-48 (1986). Factual disputes do not necessarily result in a denial of the motion. Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. *Id.* at 248.

As the plaintiff in this matter, Dr. Hill, and only Dr. Hill, bears the burden of demonstrating the existence of facts sufficient to prove the essential elements of her FCA claims. Dr. Hill has not done so. Instead, Dr. Hill attempts to obfuscate the material facts from the Court

with immaterial trivial facts detailing her discontent over the review of her claims. While Dr. Hill claims she has set forth additional facts to corroborate her allegations beyond those already examined by the ORI, UMDNJ and the United States Attorney, that evidence amounts to nothing more than complaints that these scientific entities should have done a better job in reviewing and investigating Dr. Hill's claims – not fraud. Indeed, when viewing Dr. Hill's manifesto-like Written Disclosure that she submits in support of her opposition to this motion, it is apparent that Dr. Hill's claims and assertions amount to nothing more than a decade-old personal vendetta against Defendants. At best, Dr. Hill's entire case against Defendants is a scientific disagreement about the data reported by Defendants in connection with one small part of the NIH Grant, which is not actionable under the FCA.

Dr. Hill's claims of retaliation similarly fail as a matter of law. Dr. Hill has failed to provide any evidence whatsoever that she has suffered any cognizable retaliatory adverse employment action or suffered any damages as a result of her alleged engagement in protected whistleblower activity. In fact, Dr. Hill continues to maintain the same employment position at UMDNJ to this very day, with the same salary and benefits. Therefore, Defendants respectfully request that their motion for summary dismissal of Plaintiff's claims and an award of attorneys' fees and costs be granted.

## **POINT TWO**

### **THE FCA IS INAPPLICABLE TO DR. HILL'S CLAIMS BECAUSE HER CLAIMS DO NOT AMOUNT TO A CASE OF SCIENTIFIC FRAUD**

Dr. Hill would have this Court believe that Defendants' position is that no cases involving scientific research are actionable under the FCA. Defendants' argument, however, is not so simplistic. Indeed, Defendants have not disputed that the FCA may apply in cases involving actual scientific fraud. Defendants do, however, dispute that Dr. Hill's case actually

involves scientific fraud or a false claim. Dr. Hill has presented allegations that can only be viewed as a scientific dispute over methodology and interpretation of data which do not give rise to FCA liability and certainly have no place before this Court. Dr. Hill attempts to blur the distinction between fraud, lying, and deceit on the one hand and scientific errors and differences of opinion over scientific methodology on the other. Dr. Hill's denial of these distinctions and her inability to come to grips with the reality that the record before the Court, which she contends "amply and convincingly shows that the data was fabricated and a fraud on the Government committed," simply does not exist, is fatal to her FCA claims.

The transparencies of Dr. Hill's claims are even more pronounced when considering the support proffered by Dr. Hill in support of her position that all cases involving alleged falsification of scientific data are actionable under the FCA. Dr. Hill refers the Court to the ORI website containing the 2005 investigation of Dr. Eric T. Poehlman (the "Poehlman Case"). The Poehlman Case is the only case cited by Dr. Hill as an example of a claim involving scientific research that was actionable under the FCA. While Dr. Hill attempts to draw a comparison between Dr. Poehlman's and Dr. Bishayee's conduct to demonstrate that he similarly engaged in scientific fraud, the circumstances are clearly distinguishable. First, unlike Dr. Poehlman who confessed to the Government that he had falsified and fabricated research and data included in his numerous federal grant applications and publications, (*see <http://ori.dhhs.gov/misconduct/cases/poehlman.shtml>*), Dr. Bishayee has consistently denied falsifying any research or data included in the preliminary studies section of his NIH grant application. When asked by the UMDNJ Committee during its investigation whether he falsified or fabricated any experimental data included in the NIH grant application, Dr. Bishayee affirmatively responded, "No, I did not." (*See Leonard Cert. I, Ex. I, Appendix J*). Further, while

Dr. Poehlman destroyed evidence, presented falsified documents and influenced other witnesses to provide false documents to the investigating authorities during the ORI investigation, Dr. Hill has not raised any similar allegations against Defendants and there is no evidence in the record which suggests that Defendants engaged in any such egregious conduct. In sum, unlike Dr. Poehlman, there is no evidence in the record to support Dr. Hill's claim that Defendants falsified or fabricated research or data to fraudulently obtain federal research funds from NIH. The reason for this is simple -- Dr. Hill's claim is not a case of fraud, but rather simply amounts to a scientific dispute or difference of opinion over interpretation of data, protocols or methodology.

As has been aptly noted by courts confronted with similar types of scientific disagreements, "the legal process is not suited to resolving scientific disputes or identifying scientific misconduct." *United States of America ex. rel. Milam v. The Regents of the University of California*, 912 F.Supp. 868, 886 (D.Md. 1995); *United States ex rel. Anderson v. Northern Telecom, Inc.*, 52 F.3d 810, 815-16 (9th Cir. 1995)(FCA applies to lies, not to statements that are "scientifically untrue"); *United States ex rel. Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992)(the FCA is "concerned with ferreting out 'wrongdoing,' not scientific errors").

As more fully set forth in Defendants' moving brief, in this case, we have analogous allegations to those in *Milam* and the many other cases that have refused to find FCA violations in scientific disputes. The crux of Dr. Hill's allegations is that the data reported in support of Defendants' NIH Grant could not be replicated and Defendants failed to inform their supervisors at UMDNJ or NIH and failed to submit a retraction of the data. Contrary to Dr. Hill's conclusory allegations, she is unable to provide demonstrative evidence to prove that Dr. Bishayee fabricated the data in question. Rather, Dr. Hill relies exclusively on inferences of falsity that she contends arise because of Defendants' inability to replicate Dr. Bishayee's data

after certain limited testing and certain statistical anomalies that Dr. Hill suggests exist in the data. Dr. Hill's subjective analysis and disagreement with Dr. Bishayee's findings are precisely the type of scientific scrutiny that the courts have consistently found to be outside the purview of the FCA.

As set forth more fully in Defendants' opening brief, Congress has expressly recognized that disputes over scientific misconduct and methodology are best resolved by the institutions within the scientific community and related government agencies, which already have extensive institutional and regulatory mechanisms in place to guard against scientific misconduct and remedy harm when such misconduct is found. *See* 42 U.S.C. 289b(a)(1), 42 C.F.R. §50.102. These institutions and entities are more than capable of reporting, investigating and remedying such disputes – which they did in this case and concluded that Dr. Hill's allegations were without merit. The FCA is simply inapplicable to these disputes. *Milam*, 912 F.Supp. at 886 (“Disagreements over science methodology do not give rise to [FCA] liability.”). Allowing Dr. Hill's dressed-up personal and scientific disputes to proceed as a fraud case under the FCA undermines the scientific research process all together.

### **POINT THREE**

#### **DR. HILL FAILS TO ESTABLISH EACH OF THE ESSENTIAL ELEMENTS OF A FCA VIOLATION**

As set forth in greater detail in Defendants' opening brief, not only is Plaintiff unable to distinguish this case from other non-actionable scientific disputes, but even when considering all of the evidence in her favor, there is no cognizable claim under the FCA. In order to establish a prima facie case under the FCA sufficient to avoid summary judgment, a plaintiff /relator “must prove: ‘(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim

was false or fraudulent.” *United States ex rel. Hefner v. Hackensack Univ. Med. Center*, 495 F.3d 103, 109 (3d Cir. 2007) (quoting *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 182 (3d Cir. 2001)).

Because Dr. Hill bears the burden of proof in establishing the elements of a prima facie FCA cause of action against Defendants, she must identify evidence that establishes the existence of all three essential elements of a FCA claim in order to survive summary judgment. *United States ex rel. Hefner v. Hackensack Univ. Med. Center*, 2005 WL 3542471, at \*4 (D.N.J. 2008) (See Leonard Cert. I, Ex. P). Dr. Hill must provide the Court with evidence demonstrating that Defendants acted knowingly, recklessly or with deliberate ignorance in submitting or causing to be submitted to the Government a false or fraudulent claim for payment – in this case the NIH grant application – that caused the Government economic loss. *Ibid.* Even affording Dr. Hill a liberal analysis of the facts of this case, she cannot demonstrate that (1) the scientific data underlying the NIH grant application is objectively false; (2) even if the data is deemed false, that any of the Defendants knew the data was false when submitting the NIH grant application; and (3) that the data was material to the Government’s funding decision and caused it to suffer an economic loss.

First, as evidenced by the reports of the Committee and the ORI, Dr. Hill can not and has not demonstrated that the data at issue is fabricated. Both of the Committee Reports and the ORI Report are admissible on this issue. Fed. R. Evid. 801(d)(2)(A); *Milam, supra*, 912 F.Supp. at 886 (where the court held that the ORI report was admissible because it was highly probative to the ultimate issue of whether data was manipulated). The Committee unanimously concluded on two separate occasions that there was insufficient credible and definitive evidence of misconduct in science to warrant further investigation of Dr. Hill’s allegations. Further, ORI also concluded



there was insufficient evidence to warrant further investigation of Dr. Hill's claims that Dr. Bishayee had fabricated or falsified data. Finally, the United States Attorney's Office conducted its own investigation over the course of three years after subpoenaing Defendants and reviewing a large production of documents relating to the incidents alleged in Dr. Hill's Amended Complaint. Notably, in 2006, after Dr. Hill extensively reviewed the "new"<sup>1</sup> evidence produced by UMDNJ in response to the subpoenas and prioritized the documents, Dr. Hill made a presentation to the United States Attorney's Office at which time she had an opportunity to present the "new" evidence that she believed showed there had been fraud. (Certification of John P. Leonard, Esq. submitted in Further Support of Defendants' Motion to Summary Judgment ("Leonard Cert. III"), Ex. A, Hill Dep., 52:9-54:3; 55:7-56:11; 57:9-61:25; Hill S.J. Exhibit 111). Notwithstanding the presentation of the allegedly "new" evidence, it is undisputed that the United States Attorney's Office declined to intervene in this matter.

Any argument by Dr. Hill that ORI reached its conclusion without reviewing all of the relevant information and documents and that if ORI had been provided with the "new" evidence received by the US Attorneys' Office from UMDNJ it would have reached a different conclusion, is unfounded. If ORI had determined that there was information, research records or evidence which it had not received but believed was pertinent to its review of Dr. Hill's allegations of scientific misconduct, it was fully within ORI's authority and right to demand it from Defendants. (See <http://ori.dhhs.gov/policies/documents/SamplePolicyandProcedures-5-07.pdf>, 42 C.F.R. §§ 93.300(g), 93.403(b) and (d) (providing that ORI can request from an institution any "information, documentation, research records, evidence or clarification" its finds necessary to carry out its review of an allegation of research misconduct)). Nothing in the

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<sup>1</sup> The reference to "new" evidence is the laundry list of evidence Dr. Hill alleges was not properly considered by or available for review by the Committee and ORI in pages 7 through 12 of her opposition brief.

record, however, indicates that this was the case and, therefore, Dr. Hill's suggestion that ORI made its determination that there was inconclusive and insufficient evidence to warrant a finding of scientific misconduct without reviewing all of the necessary information and documentation is without merit. As the decision of the United States Attorney's Office and the reports of the Committee and the ORI reveal, Dr. Hill can not and has not demonstrated that the data, statements and records at issue are fabricated.

Second, aside from inundating the Court with her many self-written missives and Power-Point presentations setting forth her speculative beliefs of fabrication, the only new evidence offered by Dr. Hill in support of her fraud claims are the questionable and self-serving reports of her experts -- Dr. Michael Robbins and Dr. Joel Pitt. This "new" evidence offered by Dr. Hill is deficient because the testimony of Defendants' expert, Dr. Feinendegen, an undisputed pioneer in the field of thymidine research, conclusively demonstrates that Defendants' results were not objectively false and explains why Plaintiff's theories of fraud, as parroted through Dr. Robbins, are misplaced. Beyond that, Dr. Feinendegen also provides testimony to explain possible reasons why other scientists were unable to replicate Dr. Bishayee's results and testimony to show that the failure to replicate results is a normal part of the scientific progress. The differing opinions of the experts presented in this matter only further buttress Defendants' position that this case is nothing more than a scientific dispute.

Similarly, Dr. Hill is unable to show that Defendants submitted the grant "knowing" that it contained data that was false or fraudulent. *Hefner, supra*, 2005 WL 3542471, at \*9 (See Leonard Cert. I, Ex. P) (without evidence of actual knowledge that the defendants knowingly submitted false claims, the relator was unable to satisfy the scienter requirement of the FCA). Dr. Hill's claim that Dr. Howell had knowledge of any alleged scientific misconduct is based

solely on her own self-serving testimony that she told Dr. Howell about her “suspicions” relating to the results from Dr. Bishayee’s experiments prior to Dr. Howell’s submission of the NIH Grant on or about October 29, 1999, and that Dr. Howell did not investigate her suspicions. (Hill S.J. Exhibit, 46: Am. Comp. ¶¶ 19-21). However, at that point in time, Dr. Hill did not file a formal complaint. The mere fact that Dr. Hill informally expressed to Dr. Howell “suspicion” about Dr. Bishayee’s actions does not establish that Dr. Howell had knowledge about the allegedly false or fraudulent data, statements and records or failed to make an inquiry which would have alerted him that a false claim was being submitted. *See* 42.C.F.R. 50.103(d)(4). When, however, in April 2001, Dr. Hill made a formal complaint about Dr. Bishayee’s experiments and Defendants did have knowledge of potential scientific misconduct, Defendants acted appropriately by immediately commencing an investigation by the Committee and taking appropriate steps thereafter.

Finally, not only is the data at issue incapable of being declared objectively false, it also fails to meet the materiality standard of an FCA claim as a matter of law. *United States ex rel. Berge v. Board of Trustees of the Univ. of Alabama*, 104 F.3d 1453, 1460 (4th Cir. 1997)(FCA covers only those false statements that are material to the Government’s decision to pay or approve a claim and concluding that “the materiality of false statements under the False Claims Act is a legal question” and in the context of the FCA the “determination of materiality, although partaking of the character of a mixed question of fact and law, is one for the court”). The record does not demonstrate the data at issue was material to the Government’s funding decision. Rather, the record belies any such suggestion. Indeed, it is undisputed that the Government reviewed the ORI report related to Dr. Hill’s allegations and notwithstanding that fact, it actually extended the funding of the NIH Grant to Defendants.

Despite having already had at least three bites at the apple, Dr. Hill has been unable to proffer evidence to support her claims. Dr. Hill's inability to establish the existence of any of the elements of an FCA claim, let alone satisfy all three as she is required to do, is fatal to her claims and Defendants are entitled to summary judgment as a matter of law.

**POINT FOUR**

**DR. HILL HAS NOT BEEN SUBJECTED TO ANY ADVERSE  
EMPLOYMENT ACTION OR SUFFERED ANY RETALIATION DAMAGES**

As set forth in more detail in Defendants' Motion for Summary Judgment and Defendants' Opposition to Plaintiff's Motion for Summary Judgment, Dr. Hill has failed to establish that she has been subjected to any material adverse employment action by UMDNJ in order to satisfy the "discrimination" element of her FCA claim.

The Supreme Court has made clear that federal law "protects an individual not from all retaliation, but from retaliation that produces an injury or harm." *Burlington Northern & Santa Fe Railway Co. v. White*, 548 U.S. 53, 67 (2006). Engaging in protected activity "cannot immunize that employee from those petty slights or minor annoyances that often take place at work and that all employees experience." *Ibid*. Further, "personality conflicts at work that generate antipathy and snubbing by supervisors and co-workers are not actionable." *Id.* at 68.

It is undisputed here that since the time of Dr. Hill's arguably protected activity, UMDNJ has not terminated, demoted or transferred her. The only support that Dr. Hill provides for her vague allegations of a hostile work environment is that she was "shunned" by her co-workers and felt left out of the group. (Leonard Cert. I, Ex. T, Hill Dep., 85:2-85:6, 97:4-97:7). The law is clear, however, that allegations of mere shunning and passive treatment by co-workers and supervisors resulting in "humiliation" do not rise to the level of material adverse employment action for purposes of Title VII.

Even more fatal to Plaintiff's retaliation claim is her total inability to set forth any position on damages. Even in her opposition papers, Plaintiff still does not present this Court with any alleged damages that she claims to have suffered in this matter. 31 U.S.C. § 3730(h) provides that any employee who is subjected to adverse employment action shall be entitled to all relief necessary to make the employee whole, including "reinstatement with the same seniority status that employee . . . would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination." 31 U.S.C. 3730(h)(2).

Once again, Dr. Hill was not terminated, demoted or suspended by UMDNJ, and, therefore, reinstatement, back pay and interest on back pay are not applicable here. Additionally, when asked if she has experienced any damages from Defendants' alleged retaliatory conduct, Dr. Hill testified that she has not had to seek any attention from a healthcare professional or take any medications for anxiety or depression as a result of the alleged adverse employment action. (Leonard Cert. I, Ex. T, Hill Dep., 93:14-93:17, 93:18-94:4). Also, when asked if she had suffered any monetary damages as a result of the alleged retaliatory acts, Dr. Hill could only provide the speculative and vague response: "I have not been as productive as I would have been if I had stayed working with the division. I've gone off on my own. I've found a new field and I've done okay. But, you know, I might have done better, but who knows. So I can't really say that I have, but I can't really say that I haven't." (*Id.*, 94:5-94:14). Further, Dr. Hill added that going into the new field of studying DNA damage in mitochondria probably would not have changed her rate of pay or benefits. (*Id.*, 94:20-94:25). Dr. Hill has, therefore, failed to provide this Court with any evidence demonstrating that she has suffered damages as a result of Defendants' alleged adverse employment action which entitle her to recovery.

**CONCLUSION**

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

Respectfully submitted,

/s/ John P. Leonard

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DATED: June 28, 2010

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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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

**Plaintiff,**

vs.

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

**Defendants.**

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: **CIVIL ACTION NO. 03-4837 (DMC)**  
:  
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: **CERTIFICATION OF**  
: **JOHN P. LEONARD, ESQ.**  
:

: **Document Electronically Filed**  
:

I, John P. Leonard, Esq. of full age, hereby certify as follows:

1. I am an attorney-at-law of the State of New Jersey and a member of the law firm of McElroy, Deutsch, Mulvaney & Carpenter, LLP, attorneys for Defendants' University of Medicine & Dentistry of New Jersey ("UMDNJ"), Dr. Roger W. Howell and Dr. Anupam Bishayee (collectively "Defendants"). I am the attorney responsible for handling this matter, and I am fully familiar with the facts set forth herein. I submit this Certification in further support of Defendants' Motion for Summary Judgment pursuant to Federal Rule of Civil Procedure 56.

2. Attached hereto as **Exhibit A** is a true and accurate copy of excerpts from the deposition of Dr. Helene Z. Hill taken on January 23, 2009.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the statements made by me are willfully false, I am subject to punishment.

By: s/John P. Leonard  
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DATED: June 28, 2010



EXHIBIT A

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
Civil Action No. 03-4837(DMC)

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

Plaintiffs, :

-vs- :

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

Defendants. :

COPY

DEPOSITION OF:

DR. HELENE Z. HILL

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B E F O R E:

SHARON B. STOPPIELLO, a Certified Court

Reporter and Notary Public of the State of New  
Jersey, at the offices of BUCCERI & PINCUS, ESQS.,  
1200 Route 46, Clifton, New Jersey, on Friday,  
January 23, 2009, commencing at 10:05 a.m., pursuant  
to Notice.

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Page 4

1 HELENE Z. HILL, 3 Silver Spring Road,  
 2 West Orange, New Jersey 07052, is sworn.  
 3 DIRECT EXAMINATION BY MR. LEONARD:  
 4 Q Good morning, Dr. Hill. My name is  
 5 John Leonard. I'm a member of the law firm of  
 6 McElroy, Deutsch, Mulvaney & Carpenter. I represent  
 7 certain individuals and entities, specifically  
 8 University of Medicine & Dentistry of New Jersey,  
 9 Dr. Roger Howell and Dr. Anupam Bishayce in an  
 10 action filed by you pending in the United States  
 11 District Court. It's a qui tam action.  
 12 We're here today to take your deposition. I  
 13 know that you've had your deposition taken before,  
 14 But let me give you some rules as to how we're going  
 15 to proceed, so that this process can be as effective  
 16 and efficient for both of us as possible.  
 17 I will be asking you a series of questions.  
 18 The court reporter sitting to my right will be  
 19 taking down, as she is now, everything that we say  
 20 verbatim. Consequently, I ask that when you respond  
 21 to my question, you do so verbally. You may well  
 22 nod your head and I'll know exactly what you mean,  
 23 but she just won't be able to record it.  
 24 If you are confused by any of my questions  
 25 or you don't understand any of my questions, please

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1 INDEX  
 2 WITNESS DIRECT CROSS REDIRECT RECROSS  
 3 DR. HELENE Z. HILL  
 4 BY MR. LEONARD 4  
 5  
 6  
 7 EXHIBITS  
 8 NO. DESCRIPTION I.D.  
 9 Hill-1 Graph drawn by Dr. Hill of 100%  
 Experiment 62  
 10  
 11 Hill-2 Document entitled "Scientific  
 Misconduct" written by Dr. Hill,  
 Bates stamped 000345-350 87  
 12  
 13 Hill-3 Paper written by Dr. Hill entitled  
 "The impossibility of an exponential  
 14 decline in survival of Chinese hamster  
 cells in the presence of tritiated  
 thymidine," Bates stamped 000362-382 104  
 15  
 16 Hill-4 Written Disclosure of Dr. Hill dated  
 10/10/03, Bates stamped 000001-67 129  
 17 Hill-5 Supplement to Written Disclosure of  
 Dr. Hill dated 4/6/04, Bates stamped  
 000335-361 129  
 18  
 19  
 20  
 21 REQUESTED INFORMATION:  
 22 None  
 23  
 24  
 25

Page 5

1 stop and let me know that. I will rephrase the  
 2 question and hopefully do it in a way that you do  
 3 understand it. If you do understand a question,  
 4 I'll assume that you have understood the question.  
 5 Fair enough?  
 6 A Yes.  
 7 Q You were just placed under oath.  
 8 That oath is the same as if you were testifying at  
 9 trial or in a court of law. Do you understand that?  
 10 A Yes, I do.  
 11 Q The court reporter can only record  
 12 one of us at a time. Therefore, I ask that you  
 13 allow me to finish my question before you give your  
 14 response, and I will let you finish your response  
 15 before I start another question. Okay?  
 16 A Okay.  
 17 Q Your counsel sitting to your right,  
 18 Mr. Pincus, may make an objection in response to one  
 19 of my questions. If he does, I ask that you please  
 20 suspend your answer, let he and I discuss the  
 21 objection, and do not answer unless or until he  
 22 instructs you to.  
 23 A Okay  
 24 Q If you need a break at any time, just  
 25 say so. We're not in a marathon. Anytime you want

Page 50	Page 52
1 just they had other cases they were more interested	1 A No.
2 in?	2 Q You have no idea what you sent them?
3 A Yes.	3 A No, I really don't remember.
4 Q And your basis for that is?	4 Q Do you remember the last time you
5 A What I said, that there were other, more	5 sent them something?
6 important cases that involved a whole lot more	6 A No.
7 money, like \$80,000,000, the cardiology case	7 Q Do you remember the first time you
8 Q What is the status of that case?	8 sent them something?
9 A I have no idea.	9 A Well, I do remember that I sent memos, and I
10 Q How do you know that that case was	10 sent a memo and a letter to the U.S. Attorney, that
11 more important to them than this case?	11 I made a presentation to them, and that I followed
12 A Because \$800,000,00 is a whole lot more than	12 that up with a memo and a letter clarifying and
13 \$1,400,000, and many people involved	13 adding points to what I had said. And that would
14 Q Isn't it true that you're	14 have been, let's see, I think in 2006, when they
15 speculating? You don't, in fact, know that that	15 decided not to take the case.
16 case was more important to them than this case?	16 Q So is it fair to say that once you
17 A That's true.	17 found out they decided not to take the case, you
18 Q And isn't it also true that as far as	18 undertook efforts to convince them to participate in
19 you know, that case could well have been concluded	19 the case?
20 years ago?	20 A Yes.
21 A I do not believe that case has been	21 Q And the presentation you just
22 concluded. The chairman of medicine, as far as I	22 mentioned, can you tell me what that consists of?
23 know, is still not back at the medical school, and I	23 A It was a PowerPoint presentation in which I
24 believe that case is still pending. I think that we	24 presented what at that time was the evidence that I
25 would have been told, as members of the medical	25 had that I believed that there had been a fraud.
Page 51	Page 53
1 school faculty, if the case had been concluded.	1 Q Where did you put on this PowerPoint
2 Q And you have from time to time	2 presentation?
3 supplied additional documentation to the U.S.	3 A Actually, unbelievably, the U.S. Attorney's
4 Attorney, have you not?	4 office didn't have Microsoft Office so that I could
5 THE WITNESS: Have I supplied	5 make a PowerPoint presentation. But I had printed
6 additional documentation to the U.S. Attorney?	6 it out and I had printed copies for the U.S.
7 MR. PINCUS: Do you want me to answer	7 Attorney, herself, and for the FBI agent who was
8 this question? She's making an inquiry of me. I	8 also printed, and for Mr. Pincus and myself. And I
9 can't really answer your question. If you know, you	9 went through it as though I was presenting it as a
10 can answer the question. If you don't know, that's	10 PowerPoint on the screen.
11 the response that you should give.	11 Q To whom did you make this
12 A I'm not really sure.	12 presentation?
13 Q Do you have any recollection of	13 A To the U.S. Attorney and the FBI agent and
14 putting packets of materials together and mailing it	14 Mr. Pincus was there and I was there.
15 to anybody at the U.S. Attorney's office subsequent	15 Q And do you recall the U.S. Attorney's
16 to the filing of the complaint?	16 name?
17 A I'm sure that we did.	17 A Another senior moment. Susan, her first
18 Q Do you have a recollection as to how	18 name is Susan.
19 many times you did?	19 Q Steel?
20 A No.	20 A Steel, thank you.
21 Q Do you have a recollection whether it	21 Q And how about the FBI agent?
22 was more or less than six times?	22 A That was Mary Beth, Mary Beth Gardocki.
23 A No.	23 Q How long did this presentation last?
24 Q Do you have a recollection of what it	24 A Oh, a couple of hours.
25 was that you sent them?	25 Q And the entire time the only people

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1 in the room besides yourself were Susan Steel, Mary  
 2 Beth Gardocki and Mr. Pincus?  
 3 A That's right.  
 4 Q And you basically had printed a hard  
 5 copy of your PowerPoint presentation?  
 6 A Right.  
 7 Q Provided each person a copy?  
 8 A Right.  
 9 Q And walked them through it?  
 10 A Right.  
 11 Q Explaining, I assume, each page and  
 12 each item in detail.  
 13 A Right.  
 14 Q Did anybody ask questions during the  
 15 presentation?  
 16 A I don't recall.  
 17 Q Do you recall when the presentation  
 18 occurred?  
 19 A I have the date in my notes, but I don't  
 20 have it in my head.  
 21 MR. LEONARD: Shelly, to the extent  
 22 that you have that date, could you just provide it  
 23 to me?  
 24 MR. PINCUS: After we get done doing  
 25 follow-up requests in a letter, I'll look back in my

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1 these documents?  
 2 A A lot of time. I went down probably -- I  
 3 could keep a record. I don't know whether I kept a  
 4 written record of the number of times I went to the  
 5 FBI office. Probably five sessions in the FBI  
 6 office. But then more like 10 or 12 sessions in the  
 7 U.S. Attorney's Office, and I would spend maybe two  
 8 or three hours each time.  
 9 Q So collectively, 17 sessions each of  
 10 two or three hours duration?  
 11 A Yes, right, 30 or 40 hours probably.  
 12 Q Were you provided a desk or access to  
 13 documents? What would you do during these session?  
 14 A Well, with the FBI, Mary Beth Gardocki had  
 15 to watch me very carefully. So she was always with  
 16 me. I couldn't even go to the ladies' room by  
 17 myself. When I was in the U.S. Attorneys Office  
 18 they gave me a conference room, and I was able to go  
 19 to the ladies' room by myself.  
 20 Q What exactly were you looking for?  
 21 Did you know what you were looking for when you went  
 22 there?  
 23 A I knew that Howell had not been able to  
 24 repeat the experiments. I also had a zip drive from  
 25 Lenarczyk, and I knew I had seen his experiments.

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1 records, and I'm fairly certain I can provide you  
 2 the date that occurred.  
 3 MR. LEONARD: Okay.  
 4 Q What do you recall Susan Steel saying  
 5 upon the conclusion of the presentation?  
 6 A I don't recall.  
 7 Q Did the presentation include  
 8 information that you believe the U.S. Attorney did  
 9 not have previously?  
 10 A Yes.  
 11 Q What new information do you believe  
 12 you were bringing to present them?  
 13 A That summer I spent a great deal of time in  
 14 the FBI offices and the Office of the U.S. Attorney  
 15 going through the documents that had been  
 16 subpoenaed. And I discovered at that time that the  
 17 results of experiments that had been done, the  
 18 repeat experiments that had been done by Dr. Howell,  
 19 which were entirely at odds with reports that had  
 20 been made, experiments that had been done by Dr.  
 21 Bishayee; that Bishayee's results were  
 22 scientifically impossible, and that there was a very  
 23 good scientific explanation for the results that Dr  
 24 Howell and Dr. Lenarczyk had gotten  
 25 Q How much time did you spend reviewing

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1 There are two types of an experiment,  
 2 there's the 50 percent experiment and there's the  
 3 100 percent experiment. I had only focused on the  
 4 50 percent experiment because that involved this  
 5 so-called "bystander effect."  
 6 Well, why was I doing it? They asked me to  
 7 do it, that's why I was doing it.  
 8 Q Who asked you to do it?  
 9 A The U.S. Attorney and the FBI, they asked me  
 10 to go through the documents. There were 11 books  
 11 that they had subpoenaed. The first time they  
 12 called me in they asked me just to prioritize the  
 13 documents. They hardly told me what was in any of  
 14 them, but I prioritized them as best I could. And  
 15 then there was one box, Box 6, which really seemed  
 16 to contain the copies of most of the notebooks that  
 17 would have been important. And they asked me to go  
 18 through them.  
 19 Q Okay.  
 20 A And so I did.  
 21 Q I think my question, though, was what  
 22 you were looking for when you went there?  
 23 A Well, that's what I'm saying, is that I  
 24 didn't really know what I was looking for. They  
 25 asked me to go through the documents, and at their

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<p>1 request, I was going through the documents. And</p> <p>2 basically what I thought that I was looking for was</p> <p>3 the actual data that had been generated by Bishayee.</p> <p>4 I already knew from the ORI that the Coulter</p> <p>5 counter, this particle counter that was used to</p> <p>6 count the cells, were -- how shall I say -- out of</p> <p>7 whack. Bishayee Coulter counts were not consistent</p> <p>8 with random distribution, which they should have</p> <p>9 been. So I thought I was looking for more evidence</p> <p>10 of Coulter counts being not consistent with random.</p> <p>11 So I was focusing on the Coulters, but I also looked</p> <p>12 at the data, as well</p> <p>13 And actually, I was coming to the end of</p> <p>14 looking through this Box Number 6, and I came upon</p> <p>15 the repeat experiments that had been done by Howell.</p> <p>16 And I had not looked at the 100 percent experiments</p> <p>17 that Lenarczyk had sent me, because I had not</p> <p>18 suspected that there was anything wrong with</p> <p>19 Bishayee's 100 percent experiments.</p> <p>20 But what I saw, I came upon the stuff from</p> <p>21 Howell's notebook, and there were two experiments</p> <p>22 there that were 100 percent experiments. And I went</p> <p>23 through the first one and I saw that the data went</p> <p>24 down like that and then plateaued. I know you can't</p> <p>25 draw that on your transcript.</p>	<p>1 (indicating). So there was a many-fold difference</p> <p>2 in survival between Bishayee's results and Howell's</p> <p>3 results in this 100 percent experiment.</p> <p>4 Q In these documents that you were</p> <p>5 looking at?</p> <p>6 A In these documents that I was looking at.</p> <p>7 Q Just so we're clear, you had no</p> <p>8 firsthand knowledge of these experiments?</p> <p>9 A No.</p> <p>10 Q You're just looking at copied pages</p> <p>11 contained in a box?</p> <p>12 A Right.</p> <p>13 Q Dr. Hill, can I have that piece of</p> <p>14 paper? We're just going to have it marked as an</p> <p>15 exhibit.</p> <p>16 MR. LEONARD: Would you mark this as</p> <p>17 Hill-1, please?</p> <p>18 THE WITNESS: Well, why don't I</p> <p>19 identify them.</p> <p>20 MR. LEONARD: Sure.</p> <p>21 THE WITNESS: We'll do this</p> <p>22 scientifically correctly. This is Howell and this</p> <p>23 is Bishayee (indicating).</p> <p>24 Q And this is for 100 percent</p> <p>25 experiments?</p>
Page 59	Page 61
<p>1 MR. LEONARD: Why don't you provide</p> <p>2 Dr. Hill a piece of paper and she can draw it and</p> <p>3 we'll mark it as an exhibit.</p> <p>4 A All right. So in the papers and in the</p> <p>5 grant application and so forth, this would be</p> <p>6 <math>^3\text{HdThd}</math>, which is an abbreviation for tritiated</p> <p>7 thymidine. So this is your "X" axis, this is</p> <p>8 tritiated thymidine, it's a dose. This is the</p> <p>9 survival. We call it is S divided by <math>S_0</math></p> <p>10 (indicating).</p> <p>11 Bishayee's results were an exponential</p> <p>12 decline like that. This is 100 percent experiment</p> <p>13 (indicating).</p> <p>14 Q Do you want to use two different</p> <p>15 colors? That will help you out.</p> <p>16 MR. PINCUS: Why don't you leave</p> <p>17 Bishayee's in red, like you did, and now continue in</p> <p>18 black.</p> <p>19 THE WITNESS: I'm going to do Howell</p> <p>20 in black.</p> <p>21 MR. PINCUS: Let the record reflect</p> <p>22 that Bishayee's results were drawn in red.</p> <p>23 A Howell's results went like that. The number</p> <p>24 here is 1.0, this is .5, let's say, this is .1, this</p> <p>25 is .01. Actually, his results go down to .001</p>	<p>1 A 100 percent experiments. I was stunned.</p> <p>2 Q You were stunned when you saw that?</p> <p>3 A I was stunned. And I lay awake at night.</p> <p>4 Because I thought this was a 50 percent experiment.</p> <p>5 And I had go back through and I had to look at the</p> <p>6 beginning, and it wasn't a 50 percent experiment, it</p> <p>7 was a 100 percent experiment. And I had believed</p> <p>8 Bishayee's 100 percent survival, the exponential</p> <p>9 decline. And now I'm looking at Howell's 100</p> <p>10 percent results and it's plateauing at 50 percent</p> <p>11 and I couldn't believe it. And I lay awake at night</p> <p>12 thinking what's going on, what's going on.</p> <p>13 And then I'm a biochemist, I'm a radiation</p> <p>14 biologist, and I know that thymidine blocks the cell</p> <p>15 cycle. And the explanation for Howell's results is</p> <p>16 that the tritiated thymidine was blocking the cell</p> <p>17 cycle. Cells are only going to be killed if they go</p> <p>18 into the phase of DNA synthesis.</p> <p>19 And I realized that the explanation for</p> <p>20 Howell's results were that half the cells in the</p> <p>21 population were not going into DNA synthesis, they</p> <p>22 were being blocked. And they had to have been</p> <p>23 blocked by the tritiated thymidine. So I knew then</p> <p>24 that that was what the explanation was, and that</p> <p>25 Bishayee's results were impossible. And that's what</p>

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1 MR. LEONARD: Thank you for your  
2 time, Dr. Hill.  
3 THE WITNESS: Okay.  
4 (Whereupon the deposition is  
5 adjourned at 2:45 p.m.)  
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1  
2  
3 CERTIFICATION  
4  
5 I, SHARON B. STOPPIELLO, License  
6 Number XIO1163, a Certified Court Reporter  
7 and Notary Public of the State of New  
8 Jersey, certify that the foregoing is a  
9 true and accurate transcript of the  
10 deposition of DR. HELENE Z. HILL, who was  
11 first duly sworn by me at the place and on  
12 the date hereinbefore set forth.  
13 I further certify that I am neither  
14 attorney nor counsel for, nor related to or  
15 employed by, any of the parties to the  
16 action in which this deposition was taken,  
17 and further that I am not a relative or  
18 employee of any attorney or counsel employed  
19 in this case, nor am I financially  
20 interested in the action.  
21  
22 A Notary Public of the State of New Jersey  
23 My commission expires June 28, 2013  
24 I.D. No. 2045915  
25

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

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UNITED STATES OF AMERICA,	:	
EX REL. DR. HELENE Z. HILL,	:	CIVIL ACTION NO. 03-4837 (DMC)
	:	
Plaintiff,	:	
	:	
vs.	:	<u>Document Electronically Filed</u>
	:	
UNIVERSITY OF MEDICINE &	:	
DENTISTRY OF NEW JERSEY, DR.	:	
ROGER W. HOWELL and DR.	:	
ANUPAM BISHAYEE	:	REPLY TO PLAINTIFF'S RESPONSE
	:	TO DEFENDANTS' STATEMENT OF
Defendants.	:	<u>UNDISPUTED MATERIAL FACTS</u>
	:	

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Defendants University of Medicine & Dentistry of New Jersey ("UMDNJ"), Dr. Roger W. Howell and Dr. Anupam Bishayee (collectively "Defendants"), submit the following Reply to Plaintiff's Response to Defendants' Statement of Undisputed Material Facts.

1. Plaintiff/Relator Dr. Helene Z. Hill ("Dr. Hill"), a Professor of Radiology employed by Defendant University of Medicine and Dentistry of New Jersey ("UMDNJ"), brought this *qui tam* action under the False Claims Act ("FCA"), 31 U.S.C. 3729 to -33, on behalf of herself and the United States Government pursuant to 31 U.S.C. 3730(b)(1), against Defendants, UMDNJ, Dr. Roger W. Howell and Dr. Anupam Bishayee. (Certification of John P. Leonard ("Leonard Cert."), Ex. N).

PLAINTIFF'S RESPONSE: ADMITTED.  
DEFENDANTS' REPLY: UNDISPUTED.



2. Prior to filing her Complaint in this matter, in or about April 2001, Dr. Hill approached certain individuals at UMDNJ with allegations of scientific research misconduct directed at Defendant Dr. Bishayee. (Id., ¶ 26).

**PLAINTIFF'S RESPONSE:** ADMITTED. Plaintiff further responds that the actions that she undertook prior to the filing of the Complaint in this matter are more particularly described in Plaintiff's Statement of Undisputed Material Facts ¶¶ 22, 23, 41, 42, 43, 48-49, 53 and 70. See S.J. Exhibits No. 1, 3-13, 17-29, 31, 33-34, 46-47, 53, 55, 72, 88-93, 110 and 111 identified in those enumerated paragraphs.

**DEFENDANTS' REPLY:** UNDISPUTED.

**Plaintiff's additional assertions are not relevant or responsive to the stated fact and do not, in any way, dispute the stated fact.**

3. Dr. Hill asserted that Dr. Bishayee had fabricated experiment data that Dr. Roger Howell subsequently included in a grant application that Dr. Howell, as Principal Investigator, submitted to the United States Department of Health and Human Services, National Institutes of Health ("NIH") on October 29, 1999 (the "NIH Grant"). (Id., ¶¶ 19-26; Leonard Cert., Ex. A, Grant Application).

**PLAINTIFF'S RESPONSE:** ADMITTED.

**DEFENDANTS' REPLY:** UNDISPUTED.

4. In accordance with UMDNJ's Misconduct in Science Policy, appropriate steps were immediately taken to identify and sequester all materials and data relevant to Dr. Hill's allegations. (Leonard Cert., Ex. B, UMDNJ Misconduct in Science Policy; Ex. C, Report of

Initial Inquiry into Allegations of Potential Misconduct in Science Against Anupam Bishayee, Ph.D., dated June 21, 2001 (“First Report”).

**PLAINTIFF’S RESPONSE:** DENIED. See Plaintiff’s Statement of Undisputed Material Facts ¶¶ 56-57, 59, and 60-63. See Hill S.J. Exhibit Nos. 29, 37-40 and 76 identified in those enumerated paragraphs.

**DEFENDANTS’ REPLY:** UNDISPUTED.

**Plaintiff’s Response is improper as Local Rule 56.1(a) requires that for any statement with which Plaintiff disagrees, Plaintiff is to state each material fact in dispute and cite to affidavits or other documents submitted in connection with the motion.**

**Plaintiff’s additional assertions set forth in ¶¶ 56-57 and 59 of Plaintiff’s Statement of Undisputed Material Facts are not relevant or responsive to the stated fact and do not, in any way, dispute the stated fact. To the extent that Plaintiff relies upon the UMDNJ Committee Reports and ORI Oversight Report to dispute Paragraph 4, the Reports speak for themselves.**

**Further, many of the paragraphs from Plaintiff’s Statement of Undisputed Material Facts upon which Plaintiff relies are in dispute. Paragraph 60 is disputed, as it is not known what Hill knew during the course of the Committee investigation and the cited references do not conclusively establish Plaintiff’s assertion. In the testimony cited by Plaintiff, when questioned about certain 100% experiments, Howell testified that he did not recall if he reported them to the Committee. (Hill S.J. Exhibit 76: Howell Deposition Volume I, 94:25-95:19). When questioned about certain 50% experiments, Howell testified that he did not discuss the documents with Raveche, Baker, Putterman or his program director at NIH, but he was never questioned about whether he had reported these**

experiments to the Committee. Hill S.J. Exhibit 76: Howell Deposition Volume I, 138:21-139:6). Defendants further dispute any inference that the cited references establish any such obligation that Defendants were required to report the experiments to Hill or the Committee under the circumstances of this case.

For Paragraph 61, it is not disputed that the Campus Committee report is silent in regard to “those experiments,” however, the remainder of Paragraph 61 improperly sets forth argument as opposed to facts. See Lite, N.J. Federal Practice Rules, Comment 2 to L.Civ.R. 56.1 (Gann) (citing numerous New Jersey District Court decisions admonishing parties for including legal argument and conclusions in statement of facts).

For Paragraph 62, it is disputed that the ORI Oversight Report “limited” its analysis in any way. The ORI Report shows that the ORI reviewed all of the materials reviewed and investigations conducted by the UMDNJ Committee, which established the scope of its investigation based on the allegations presented to it by Plaintiff. (Hill S.J. Exhibit 38: ORI Oversight Report).

Therefore, based on Plaintiff’s inability to cite to specific facts in the records to dispute this fact, it is undisputed for purposes of Defendants’ motion.

5. UMDNJ’s Newark Campus Committee on Research Integrity (the “Committee”) was then convened on or about April 11, 2001, to perform a preliminary assessment of Dr. Hill’s allegations. (See Leonard Cert., Ex. C).

PLAINTIFF’S RESPONSE: ADMITTED.

DEFENDANTS’ REPLY: UNDISPUTED.

6. After reviewing Dr. Hill's allegations, the Committee voted unanimously to immediately commence an initial inquiry in accordance with UMDNJ's Misconduct in Science Policy. The official start date of the inquiry was April 11, 2001. (Id.).

PLAINTIFF'S RESPONSE: ADMITTED.

**DEFENDANTS' REPLY: UNDISPUTED.**

7. After interviewing Drs. Hill, Lenarczyk, Bishayee and Howell and reviewing all of the relevant documents and materials, including, but not limited to, all documents and photographs submitted by Dr. Hill in support of her allegations, the grant application in question, all publications on which the grant was based, all publications appearing subsequent to receipt of the grant which reported on data developed under the grants, all abstracts pending presentation and the curriculum vitas of Drs. Bishayee, Howell and Hill, the Committee issued a fifteen (15) page report on June 22, 2001 (the "First Report"). (Id.).

PLAINTIFF'S RESPONSE: It is ADMITTED that the Committee issued a fifteen (15) page report on June 22, 2001 (the "First Report"). The remaining allegations are DENIED. See Plaintiff's Statement of Undisputed Material Facts ¶¶ 56-57, 59, and 60-63. See Hill S.J. Exhibit Nos. 29, 37-40 and 76 identified in those enumerated paragraphs.

**DEFENDANTS' REPLY: UNDISPUTED.**

**Plaintiff's Response is improper as Local Rule 56.1(a) requires that for any statement with which Plaintiff disagrees, Plaintiff is to state each material fact in dispute and cite to affidavits or other documents submitted in connection with the motion.**

**Defendants incorporate their reply from Paragraph No. 4.**

**Therefore, based on Plaintiff's inability to cite to specific facts in the records to**

**dispute this fact, it is undisputed for purposes of Defendants' motion.**

8. In the First Report, the Committee unanimously voted "that there was insufficient credible and definitive evidence of misconduct in science to warrant further investigation" of Dr. Hill's allegations. (Id., pg. 14).

PLAINTIFF'S RESPONSE: ADMITTED.

DEFENDANTS' REPLY: **UNDISPUTED.**

9. On July 2, 2001, UMDNJ's Senior Vice President for Academic Affairs, Robert A. Saporito, D.D.S., in accordance with UMDNJ's Misconduct in Science Policy, reviewed and accepted the initial findings of the Committee. (Leonard Cert., Ex. D, Letters from Dr. Saporito to Drs. Hill, Howell and Bishayee, dated July 2, 2001, advising that he accepted the Committee's findings).

PLAINTIFF'S RESPONSE: It is ADMITTED that Dr. Saporito accepted the initial findings of the Committee. The remaining allegations are DENIED. See Plaintiff's Statement of Undisputed Material Facts ¶¶ 56-57, 59, and 60-63. See Hill S.J. Exhibit Nos. 29, 37-40 and 76 identified in those enumerated paragraphs.

DEFENDANTS' REPLY: **UNDISPUTED.**

**Plaintiff's Response is improper as Local Rule 56.1(a) requires that for any statement with which Plaintiff disagrees, Plaintiff is to state each material fact in dispute and cite to affidavits or other documents submitted in connection with the motion. Defendants incorporate their reply from Paragraph No. 4 to oppose Plaintiff's purported attempts to cite any alleged factual disputes arising under her Statement of Undisputed**

**Facts.**

**Therefore, based on Plaintiff's inability to cite to specific facts in the records to dispute this fact, it is undisputed for purposes of Defendants' motion.**

10. On that date, Dr. Saporito forwarded correspondence to Drs. Hill, Bishayee and Howell informing them of his decision that there was insufficient credible evidence of misconduct in science on the part of Dr. Bishayee to warrant further investigation. (Id.).

PLAINTIFF'S RESPONSE: ADMITTED.

**DEFENDANTS' REPLY: UNDISPUTED.**

11. After UMDNJ closed its investigation, Dr. Hill, apparently unsatisfied with the Committee's review and conclusions relating to her allegations, contacted the United States Department of Health and Human Services, Office of Public Health and Science, Office of Research Integrity ("ORI") and forwarded her allegations to ORI's Division of Investigative Oversight. (Leonard Cert., Ex. E, Correspondence between ORI and UMDNJ, dated September 4-7, 2001).

PLAINTIFF'S RESPONSE: ADMITTED. See Plaintiff's Statement of Undisputed Material Facts ¶ 53. See Hill S.J. Exhibits Nos. 1 and 33-34 identified in that paragraph.

**DEFENDANTS' REPLY: UNDISPUTED.**

12. In accordance with federal regulations, ORI oversees and directs the integrity of Public Health Service ("PHS") research activities. The PHS is composed of a number of federal offices and agencies, including, among others, the National Institutes of Health ("NIH"), which

awarded and funded the grant in question.

PLAINTIFF'S RESPONSE: ADMITTED.

DEFENDANTS' REPLY: UNDISPUTED.

13. Upon receiving Dr. Hill's complaints, ORI contacted UMDNJ and was provided with the First Report, as well as all of the materials and data reviewed by the Committee. (Id.).

PLAINTIFF'S RESPONSE: ADMITTED. See Plaintiff's Statement of Undisputed Material Facts ¶¶ 54-55. See Hill S.J. Exhibits Nos. 35-36 identified in those enumerated paragraphs.

DEFENDANTS' REPLY: UNDISPUTED.

**Plaintiff's additional assertions are not relevant or responsive to the stated fact and do not, in any way, dispute the stated fact.**

14. After reviewing the First Report and all of the materials provided by UMDNJ, and after conducting certain analysis of its own, ORI issued a twenty one (21) page report on September 5, 2002 (the "ORI Report"), concurring with the Committee's conclusion that there was insufficient evidence to warrant further investigation of Dr. Hill's allegations. (Leonard Cert., Ex. F, Cover Letter of Chris B. Pascal, J.D., Director, ORI, dated September 5, 2002, attaching copy of ORI Report).

PLAINTIFF'S RESPONSE: It is ADMITTED that based on the materials that ORI had before it at the time it concurred with there was insufficient evidence to warrant further investigation. In so doing, ORI further raised a number of administrative concerns it had about the handling of the case by the Committee. These concerns are more particularly set forth in

Plaintiff's Statement of Undisputed Material Facts ¶¶ 56-57, 59, and 60-63. See Hill S.J. Exhibits Nos. 29, 37-40 and 76 identified in those enumerated paragraphs.

**DEFENDANTS' REPLY:                   UNDISPUTED.**

**Plaintiff's additional assertions are not relevant or responsive to the stated fact and do not, in any way, dispute the stated fact.**

15. ORI forwarded copies of its report to Dr. Ruth Kirschstein, ARILO, and Dr. Ronald Geller, AERIO, at NIH. (Id.).

PLAINTIFF'S RESPONSE:            ADMITTED. Plaintiff states affirmatively that there is no competent evidence that either of these individuals were members of the NIH Study Section that reviewed Howell's grant applications or that they supplied the ORI report to the NIH Study Section.

**DEFENDANTS' REPLY:                   UNDISPUTED.**

**Plaintiff's additional assertions are not relevant or responsive to the stated fact and do not, in any way, dispute the stated fact.**

16. Not only did NIH not revoke the grant in question, but after the initial grant concluded in 2005, NIH actually renewed the grant in 2006 to continue through 2010. (Leonard Cert., Ex. G, Renewal Grant Application).

PLAINTIFF'S RESPONSE:            ADMITTED that in October 2005, Howell undertook to apply to NIH for a renewal grant; and, that on July 12, 2006, UMDNJ received Notice that NIH had approved Howell's renewal grant. See Plaintiff's Statement of Undisputed Material Facts ¶¶ 91-92. See Hill S.J. Exhibits Nos. 29, 37-40 and 76 identified in those enumerated paragraphs.



Plaintiff further responds that there is no competent evidence to establish that the NIH Study Section that reviewed the renewal grant or whether Howell's Grant Administrator were in any way aware of the allegations of scientific misconduct. Howell admits that he never informed him of that fact or his inability to replicate the data. See Plaintiff's Statement of Undisputed Material Facts ¶¶ 88-91. See Hill S.J. Exhibits Nos. 46-47, 96-100 identified in those enumerated paragraphs.

**DEFENDANTS' REPLY:                   UNDISPUTED.**

**Plaintiff's additional assertions are not relevant or responsive to the stated fact and do not, in any way, dispute the stated fact.**

17. On or about November 11, 2002, Dr. Hill initiated a second complaint with the Committee. (Leonard Cert., Ex. H, UMDNJ Committee on Research Integrity Initial Contact Sheet, dated November 13, 2002).

PLAINTIFF'S RESPONSE:            ADMITTED. Plaintiff further responds: See Plaintiff's Statement of Undisputed Material Facts ¶¶ 70-72. See Hill S.J. Exhibits Nos. 1, 9-13, 53 and 88-91, identified in those enumerated paragraphs.

**DEFENDANTS' REPLY:                   UNDISPUTED.**

**Plaintiff's additional assertions are not relevant or responsive to the stated fact and do not, in any way, dispute the stated fact.**

18. Dr. Hill's second complaint of scientific research misconduct against Dr. Bishayee was not based on any new evidence, but rather was based only on statistical data that Dr. Hill alleged provided further proof of the falsity of Dr. Bishayee's research data. (Id.).

PLAINTIFF'S RESPONSE: DENIED. In addition to the statistical data provided by Hill, Lenarczyk had provided his lab notebook to the Committee which contained the 16 experiment trials he had conducted between October 2000 and July 2001; and which experiments had failed to replicate the data generated by Bishayee and, which had been reported by Bishayee and Howell in the grant applications and publications. See Plaintiff's Statement of Undisputed Material Facts ¶¶ 73, 28, 30. See Hill S.J. Exhibits Nos. 46-47, 56-71 and 95 identified in those enumerated paragraphs.

Additionally, the committee had graphs that compared the bystander results of experiments performed by Lenarczyk and Howell to those of Bishayee and which demonstrated that Bishayee's data could not be replicated. See Hill S.J. Exhibit No. 95, Appendix F.

**DEFENDANTS' REPLY: Defendants do not dispute that the Committee was provided with and reviewed the materials referenced in Plaintiff's Response before reaching its conclusion that there was again insufficient credible and definitive evidence of misconduct in science to warrant further investigation of Dr. Hill's allegations.**

19. Nonetheless, appropriate steps were immediately taken in accordance with UMDNJ's Misconduct in Science Policy to identify and sequester all materials and data relevant to Dr. Hill's allegations. (Leonard Cert., Ex. I, Report of Initial Inquiry into Allegations of Potential Misconduct in Science Against Anupam Bishayee, Ph.D., dated March 10, 2003 ("Second Report")).

PLAINTIFF'S RESPONSE: DENIED. See Plaintiff's Statement of Undisputed Material Facts ¶¶ 75-77. See Hill S.J. Exhibit Nos. 46-47 and 93 identified in those enumerated paragraphs.

**DEFENDANTS' REPLY:           UNDISPUTED.**

Plaintiff's Response is improper as Local Rule 56.1(a) requires that for any statement with which Plaintiff disagrees, Plaintiff is to state each material fact in dispute and cite to affidavits or other documents submitted in connection with the motion.

Further, Plaintiff cites to paragraphs from her Statement of Undisputed Material Facts which are in dispute. Paragraph 75 is disputed. Not only was Howell never interviewed by the Committee, Howell was not advised of the purpose of the Committee's second review at that time. Accordingly, while it is not disputed that Howell did not otherwise advise the Committee of all trials conducted between April 2001 and September 2001, Defendants dispute any inference that he had an obligation to do so under the circumstances of this case. (Hill S.J. Exhibit 46: Amended Complaint, ¶35); (Hill S.J. Exhibit 47: Defendants' Answer to Amended Complaint, ¶35).

Paragraph 77 is disputed. UMDNJ acted in accordance with its Misconduct in Science Policy in handling Hill's complaints against Bishayee. The Report of Initial Inquiry made a finding of no cause, "i.e., insufficient credible evidence of misconduct in science to warrant further investigation." (Hill S.J. Exhibit 95: Report of Initial Inquiry, page 5). Pursuant to UMDNJ's Misconduct in Science Policy, if the recommendation of the Initial Inquiry Committee is accepted by the Senior Vice President for Academic Affairs, the case is closed. (Hill S.J. Exhibit 93, Misconduct in Science Policy, page 7). By letter dated March 21, 2003, Saporito, the Senior Vice President for Academic Affairs, advised Hill that he accepted the Committee's findings and closed the case. (Hill S.J. Exhibit 94: Letter from Saporito to Hill). As Plaintiff accurately cites from the Policy, in the absence of "substantial evidence of falsification and/or fabrication of data," the University was not

obligated to report its findings to NIH. NIH, however, was provided a copy of the ORI Report. (Hill S.J. Exhibit 37: Cover Letter of Chris B. Pascal, J.D., Director, ORI, dated September 5, 2002, attaching copy of ORI Report).

Therefore, based on Plaintiff's inability to cite to specific facts in the records to dispute this fact, it is undisputed for purposes of Defendants' motion.

20. UMDNJ's Newark Campus Committee on Research Integrity (the "Committee") was convened again on or about November 25, 2002, to perform a preliminary assessment of Dr. Hill's second allegations. (Id.).

PLAINTIFF'S RESPONSE: ADMITTED.

DEFENDANTS' REPLY: UNDISPUTED.

21. After reviewing Dr. Hill's allegations, the Committee voted unanimously to commence an initial inquiry in accordance with UMDNJ's Misconduct in Science Policy. The official start date of the inquiry was November 25, 2002. (Id.).

PLAINTIFF'S RESPONSE: ADMITTED.

DEFENDANTS' REPLY: UNDISPUTED.

22. On December 12, 2002, the Committee had a telephone conversation with Dr. Alan Price, Director of ORI, and Dr. John Dahlberg, also with ORI, to clarify the meaning of the ORI's Report, specifically with respect to the independent statistical analysis of the data. The key points from this conversation were: (1) Dr. Dahlberg advised the Committee that statistical analysis, in the absence of other valid empirical evidence, is not sufficient justification to

proceed with an investigation of misconduct in science; (2) in the case at question, there was no independent evidence of scientific misconduct because there was no evidence generated by someone not a party to the complaint; and (3) independent control data, necessary to evaluate Dr. Bishayee's results were not possible to achieve under the particular circumstances of this case. (Id., Appendix I).

PLAINTIFF'S RESPONSE: It is ADMITTED that Appendix I of the Second Committee Report contains a description of what is claimed to have been a telephone conversation that took place between Dr. Price, Dr. Dahlberg and Dr. Forrester. It is DENIED that the Committee did not have before it other valid empirical evidence on which to conclude that the data had been fabricated.

In addition to the statistical data provided by Hill, Lenarczyk had provided his lab notebook to the Committee which contained 16 experiment trials he had conducted between October 2000 and July 2001; and which experiments failed to replicate the data generated by Bishayee and reported by Bishayee and Howell in the grant applications and publications. See Plaintiff's Statement of Undisputed Material Facts ¶¶ 73, 28, 30. See Hill S.J. Exhibit Nos. 46-47, 56-71 and 95 identified in those enumerated paragraphs.

Additionally, the committee had graphs that compared the bystander results of experiments performed by Lenarczyk and Howell to those of Bishayee and which demonstrated that Bishayee's data could not be replicated. See Hill S.J. Exhibit 95, Appendix F.

Moreover, there was no discussion reported concerning the fact that proper, independent control data was available beyond that contained in the two Bishayee experiments reviewed. It was available through obtaining and analyzing the lab notebooks maintained before and after the two experiments conducted by Bishayee; Howell, and other post-doctoral fellows who worked in

the lab. (See Hill S.J. Exhibit Nos. 1, ¶ 89). This data was subsequently obtained pursuant to the U.S. Attorney's Subpoena Duces Tecum (Hill S.J. Exhibit 103), and analyzed by Dr. Pitt thereafter (Hill S.J. Exhibit 104).

**DEFENDANTS' REPLY:           UNDISPUTED.**

**Plaintiff's Response does not attempt to dispute the facts cited in this Paragraph. While Plaintiff's additional assertions are not relevant or responsive to the stated fact and do not, in any way, dispute the stated fact, Defendants do not dispute that the Committee was provided with and reviewed the materials referenced in Plaintiff's Response before reaching its conclusion that there was again insufficient credible and definitive evidence of misconduct in science to warrant further investigation of Dr. Hill's allegations.**

23. On January 14, 2003, the Committee met again and heard testimony from Dr. Bishayee. Dr. Bishayee was asked whether he falsified experimental data to which he responded, "No, I did not." (Id., Appendix J).

**PLAINTIFF'S RESPONSE:           It is ADMITTED that such statement is alleged to have been made in the Committee minutes.**

**DEFENDANTS' REPLY:           UNDISPUTED.**

24. After interviewing Drs. Hill and Bishayee, reviewing the materials and data submitted by Dr. Hill, and contacting ORI to receive clarification of the meaning of certain conclusions set forth in the ORI Report, the Committee issued a second report on March 10, 2003 (the "Second Report"). (Id.).

PLAINTIFF'S RESPONSE: It is ADMITTED that the Committee issued a second report on March 10, 2003. It is DENIED that all of the materials and data it had before it was reviewed and considered. See No. 22, above.

DEFENDANTS' REPLY: **UNDISPUTED.**

**Plaintiff's Response is improper as Local Rule 56.1(a) requires that for any statement with which Plaintiff disagrees, Plaintiff is to state each material fact in dispute and cite to affidavits or other documents submitted in connection with the motion.**

**Therefore, based on Plaintiff's inability to cite to specific facts in the records to dispute this fact, it is undisputed for purposes of Defendants' motion.**

25. In the Second Report, the Committee unanimously concluded that there was again insufficient credible and definitive evidence of misconduct in science to warrant further investigation of Dr. Hill's allegations. (Id.).

PLAINTIFF'S RESPONSE: ADMITTED.

DEFENDANTS' REPLY: **UNDISPUTED.**

26. On March 21, 2003, UMDNJ's Senior Vice President for Academic Affairs, Robert A. Saporito, D.D.S., in accordance with UMDNJ's Misconduct in Science Policy, reviewed and accepted the initial findings of the Committee. (Leonard Cert., Ex. J, Correspondence from Saporito to Dr. Hill, dated March 21, 2003).

PLAINTIFF'S RESPONSE: ADMITTED.

DEFENDANTS' REPLY: **UNDISPUTED.**

27. On that date, Dr. Saporito forwarded correspondence to Drs. Hill and Bishayee informing them of his decision that there was insufficient credible evidence of misconduct in science on the part of Dr. Bishayee to warrant further investigation. (Id.).

PLAINTIFF'S RESPONSE: ADMITTED.

**DEFENDANTS' REPLY: UNDISPUTED.**

28. After UMDNJ closed its second investigation, Dr. Hill, filed the Complaint on October 14, 2003, under seal. (Leonard Cert., Ex. K, Plaintiff's Initial Complaint, filed under seal on October 14, 2003).

PLAINTIFF'S RESPONSE: ADMITTED.

**DEFENDANTS' REPLY: UNDISPUTED.**

29. On April 9, 2007, after subpoenaing Defendants and reviewing a large production of documents relating to the incidents alleged in Dr. Hill's Complaint, the United States Attorney's Office filed a Notice of Election to Decline Intervention. (Leonard Cert., Ex. L, U.S. Attorney General's Notice of Election to Decline Intervention, dated April 9, 2007).

PLAINTIFF'S RESPONSE: ADMITTED that the United States Attorney's Office filed a Notice of Election to Decline Intervention on April 9, 2007 and that a large production of documents had been subpoenaed from the Defendants. There is, however, no competent evidence on which to admit or deny which of those documents had been reviewed and considered by the United States Attorneys Office in its Notice of Election.

**DEFENDANTS' REPLY: UNDISPUTED.**

**Plaintiff's additional assertions are not relevant or responsive to the stated fact and**



**do not, in any way, dispute the stated fact.**

30. On April 16, 2007, the Court entered an Order unsealing this matter. (Leonard Cert., Ex. M, Court Order, dated April 16, 2007).

PLAINTIFF'S RESPONSE: ADMITTED.

**DEFENDANTS' REPLY: UNDISPUTED.**

31. On April 1, 2009, Plaintiff filed an Amended Complaint. (Leonard Cert., Ex. N).

PLAINTIFF'S RESPONSE: ADMITTED.

**DEFENDANTS' REPLY: UNDISPUTED.**

32. On April 7, 2009, Defendants filed an Answer to Plaintiff's Amended Complaint and Counterclaim pursuant to 31 U.S.C. § 3730(d)(4), denying all of Dr. Hill's allegations and seeking attorneys' fees and costs. (Leonard Cert., Ex. O).

PLAINTIFF'S RESPONSE: ADMITTED.

**DEFENDANTS' REPLY: UNDISPUTED.**

Respectfully submitted,

/s/ John P. Leonard

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DATED: June 28, 2010