

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

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<b>UNITED STATES OF AMERICA,</b>	:	
<b>EX REL. DR. HELENE Z. HILL,</b>	:	<b>CIVIL ACTION NO. 03-4837 (DMC)</b>
	:	
<b>Plaintiff,</b>	:	
	:	
<b>vs.</b>	:	
	:	
<b>UNIVERSITY OF MEDICINE &amp;</b>	:	
<b>DENTISTRY OF NEW JERSEY, DR.</b>	:	<b><u>Document Electronically Filed</u></b>
<b>ROGER W. HOWELL and DR.</b>	:	
<b>ANUPAM BISHAYEE,</b>	:	
	:	
<b>Defendants.</b>	:	
	:	
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**DEFENDANTS’ LOCAL CIVIL RULE 56.1 STATEMENT  
OF UNDISPUTED MATERIAL FACTS**

Pursuant to Local Civil Rule 56.1, the moving defendants University of Medicine & Dentistry of New Jersey (“UMDNJ”), Dr. Roger W. Howell and Dr. Anupam Bishayee (collectively “ Defendants”), submit the following undisputed material facts in support of their motion for summary judgment on all claims against them:

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).

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).

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).

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”)).

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).

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.).

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.).

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).

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).

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.).

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).

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.

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.).

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).

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

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).

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).

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.).

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")).

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.).

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.).

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).

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).

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.).

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.).

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).

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.).

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).

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).

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

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

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).

Respectfully submitted,

/s/ John P. Leonard

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