

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

(1) Plaintiff/Relator, Dr. Helene Z. Hill ("Hill") is a resident of West Orange, New Jersey and a Professor of Radiology employed by the Defendant, University of Medicine and Dentistry of New Jersey ("UMDNJ"). (**Hill S.J. Exhibit 1: Hill Certified Written Disclosure, ¶ 3, p.2).**

(2) Hill began her service as a Professor of Radiology at UMDNJ in September, 1981. (**Hill S.J. Exhibit 46: Amended Complaint, ¶11**); (**Hill S.J. Exhibit 47: Defendants' Answer to Amended Complaint, ¶11**).

(3) Defendant University of Medicine and Dentistry of New Jersey (UMDNJ) is a body corporate and politic established pursuant to the New Jersey Medical and Dental Education Act of 1970, N.J.S.A. 18A:64 G-1 et seq. to present and to operate programs of medical, dental, nursing and health related professions and health sciences education, having its principal place of business in Newark, New Jersey. **(Hill S.J. Exhibit 46: Amended Complaint, ¶5); (Hill S.J. Exhibit 47: Defendants' Answer to Amended Complaint, ¶5).**

(4) Defendant, Dr. Roger W. Howell ("Howell"), is a resident of Millington, New Jersey and a Professor of Radiology employed by the Defendant, UMDNJ. **(Hill S.J. Exhibit 46: Amended Complaint, ¶6); (Hill S.J. Exhibit 47: Defendants' Answer to Amended Complaint, ¶6).**

(5) Defendant, Dr. Anupam Bishayee ("Bishayee"), Bishayee was formerly employed by UMDNJ as a Research and Teaching Specialist, and then as a Research Associate. **(Hill S.J. Exhibit 48:/ UMDNJ Staff Transaction Form dated 10/1/97) (Hill S.J. Exhibit 49:/ UMDNJ Staff Information Adjustment Form dated 8/17/01).**

(6) Hill has spent the majority of her scientific career doing laboratory research, most of it on the subject matter of cancer. Her position, rank and qualifications have afforded Hill both the opportunity, and privilege of obtaining research grants from government and private agencies, that include the United States Public Health Service - National Institutes of Health ("NIH"); the American Cancer Society; and, the New Jersey Cancer Research Commission. **(Hill S.J. Exhibit 1: Hill Certified Written Disclosure, ¶ 3, p.2); (Hill S.J. Exhibit 2: Hill Certified Written Disclosure Exhibit 1, Curriculum Vitae).**

(7) In 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 the United States Department of Health and Human Services, National Institutes of Health, and for which he was to serve as the Principal Investigator. Howell's initial grant application had been rejected by NIH. **(Hill S.J. Exhibit 46: Amended Complaint, ¶13); (Hill S.J. Exhibit 47: Defendants' Answer to Amended Complaint, ¶13).**

(8) Howell's revised grant application set forth a proposal to research the effects of non-uniform distributions of radioactivity and to delineate a biological mechanism known as the bystander effect. The designated outcome of the research was to achieve a better understanding and prediction of the biological response of tumor and normal tissue to non-uniform distributions of radioactivity. (Hill S.J. Exhibit 1: *Hill Certified Written Disclosure*, ¶ 24, p.13); (Hill S.J. Exhibit 3: *Hill Certified Written Disclosure Exhibit 4, Grant Application*); (Hill S.J. Exhibit 46: *Amended Complaint*, ¶14); (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint*, ¶14).

(9) 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. (Hill S.J. Exhibit 1: *Hill Certified Written Disclosure*, ¶¶ 24-26, p.13-16); (Hill S.J. Exhibit 3:

Hill Certified Written Disclosure Exhibit 4, Grant Application, page 2).

(10) Howell and Hill agreed, that in light of their then sharing laboratory space, she would be named 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. (Hill S.J. Exhibit 46: *Amended Complaint*, ¶16); (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint*, ¶16) (Hill S.J. Exhibit 3: *Hill Certified Written Disclosure Exhibit 4, Grant Application*).

(11) Defendant Bishayee was further designated to serve as the Research Specialist responsible for carrying out the day to day experiments described in the project. (Hill S.J. Exhibit 46: *Amended Complaint*, ¶17); (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint*, ¶17).

(12) The revised grant application was submitted to the NIH on or about October 29, 1999. (Hill S.J. Exhibit 46: *Amended Complaint*, ¶18); (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint*, ¶18).

(13) At the time Howell's revised grant application was submitted, NIH had promulgated and made available to NIH grantees, a policy guidance known as the NIH Grants Policy Statement (10/98). **(Hill S.J. Exhibit 50: NIH Grants Policy Statement, Parts I and II (10/98)). The entire NIH Grants Policy Statement can be found on the internet at:**
<http://grants.nih.gov/grants/policy/nihgps/index.htm>.

(14) The NIH Grants Policy Statement sets forth the terms and conditions of all NIH awards issued between October 1, 1998 and February 28, 2001. As such, the Policy Statement was specifically applicable to the grant that Howell submitted on October 29, 1999. **(Hill S.J. Exhibit 50: NIH Grants Policy Statement, Table of Contents - Bate Stamp 001190).**

(15) Part I of the NIH Grants Policy Statement contains a glossary of commonly used terms associated with NIH grants and include, for purposes of this action, the following:

a. "Grant" - defined as "a financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH awarding office anticipates no substantial

programmatic involvement with the recipient during performance of the financially assisted activities".

b. "Grant-Supported Project/Activities - defined as "Those programmatic activities specified or described in a grant application or in a subsequent submissions(s) that are approved by an NIH Institute or Center for funding, regardless of whether Federal funding constitutes all or only a portion of the financial support necessary to carry them out".

c. "Grantee" - defined as "The organization or individual awarded a grant or cooperative agreement by NIH that is responsible and accountable for the use of the funds provided and for the performance of the grant-supported activities. The grantee is the entire legal entity even if a particular component is designated in the award document. The grantee is legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity".

d. "Misconduct in Science" - defined as "Fabrication, falsification, plagiarism, or other practices that seriously deviate from those commonly accepted within the scientific community for proposing, conducting, or reporting research. The

term does not include honest error or honest differences in interpretations or judgments of data".

e. "Notice of Grant Award" - defined as "The legally binding document that notifies the grantee and others that an award has been made, contains or references all terms and conditions of the award, and documents the obligation of Federal funds. The award notice may be in letter format and may be issued electronically".

f. "Organization" - defined as "A generic term used to refer to an educational institution or other entity, including an individual that receives and/or applies for an NIH grant or cooperative agreement";

g. "Principal Investigator/Program Director/Project Director" - defined as "An individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee for the proper conduct of the project or activity"; and

h. "Terms and conditions of award" - defined as "All legal requirements imposed on a grant by NIH, whether based on statute, regulation, policy, or other document referenced in the grant award, or specified by the grant award document

itself. The Notice of Grant Award may include both standard and special conditions that red considered necessary to attain the grant's objectives, facilitate post award administration of the grant, conserve grant funds, or otherwise protect the Federal Government's interests." (**Hill S.J. Exhibit 50: NIH Grants Policy Statement, Part I: NIH Grants - General Information-Glossary - Definitions - Bate Stamp 001200-001203**).

(16) The NIH is an organizational component of U.S. Department of Health and Human Services, the mission of which is to improve human health by increasing scientific knowledge related to disease and health. NIH operates under the general policy guidance of the Department in carrying out its mission, which is accomplished through the conduct and support of biomedical and behavioral research, research training, research infrastructure and communications. These efforts take place intramurally (primarily at NIH) and extramurally (through grants, cooperative agreements, and contracts awarded to institutions of higher education, governmental organizations, non-profit research organizations, for-profit organizations and individuals. (**Hill S.J. Exhibit 50: NIH Grants Policy Statement (10/98), Part I: NIH Grants - The National Institutes of Health as a Grant-Making Organization - Bate Stamp 001204**).

(17) The relationship between NIH and its grantees involves those engaged in the scientific or technical aspects of the work as well as those responsible for a variety of support functions. NIH, as a Federal grantor agency, is responsible to Congress and the US taxpayer for carrying out its mission in a manner that not only facilitates research but does so cost-effectively and in compliance with applicable rules and regulations. NIH seeks to ensure integrity and accountability in its grant award and administration processes by relying on a system of checks and balances and separation of responsibilities within its own staff and by establishing a similar set of expectations for grantee operations. Although the roles and responsibilities are ones with which NIH grantees should already be familiar, they assume increasing importance as NIH shifts to a greater reliance on systems compliance and provides greater decision making authority to grantees. **(Hill S.J. Exhibit 50: NIH Grants Policy Statement, Part I: Roles and Responsibilities - Bate Stamp 001204).**

(18) The signature of an authorized institutional official on the application indicates the organization's intent to comply with the laws, regulations and policies to which a grant is subject. That official also attests to the fact that

the information contained in the application is true and complete, and in conformance with Federal requirements and the organization's own policies and requirements. (**Hill S.J. Exhibit 50: NIH Grants Policy Statement, Part I: Legal Implications of an Application - Bate Stamp 001209**).

(19) UMDNJ Chair of Radiology, Associate Dean for Graduate Medical Education and Professor of Radiology, Dr. Stephen R. Baker acknowledged the fact that, for accounting and oversight, he (or a designee of his department) must sign off on all grants associated with the Department of Radiology (**Hill S.J. Exhibit 51: Baker Deposition 13/18-15/6**).

(20) Dr. Baker further acknowledged that a principal investigator: (a) certifies that the grant application is true and complete and accurate to the best of his or her knowledge, (b) submits the grant 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. (**Hill S.J. Exhibit 51: Baker Deposition 15/17-17/1**).

(21) On May 31, 2000, Dr. Baker received Notice of the Howell's Grant Award from NIH. Among the terms and conditions noted therein were the NIH Grants Policy Statement aforesaid (Hill S.J Exhibit 52: *Notice of Grant Award*).

(22) On two occasions preceding the submission of Howell's revised grant application (in September/October 1999), 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. **(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; (Hill**

¹These Exhibits are as follows:

Hill S.J Exhibit 4. The September 20, 1999 Experiment

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

Hill S.J. Exhibit 6. September 6, 1999 experiment

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

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

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

S.J. Exhibit 110 and 111: *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*).

(23) Hill informed Howell of her observations and suspicions regarding Bishayee. Notwithstanding this fact, Howell dismissed Hill's concerns and refused to intercede to Hill's request to investigate Bishayee's actions. Instead, Howell determined to use the results of Bishayee's experiments as part of the preliminary data supporting his revised grant application to NIH. The questioned results were presented by Howell in Figure 7, page 29 of his revised grant application. (Hill S.J. Exhibit 3: *Grant Application, Figure 7, page 29*); (Hill S.J. Exhibit 1: *Hill Certified Written Disclosure, ¶38, pgs. 23-24*); (Hill S.J. Exhibits 4-13: *Hill Certified Written Disclosure Exhibits 5-14*) (Hill S.J. Exhibit 53: *Hill Amended Answer to Defendants' Interrogatory No. 13. p. 29-30*) (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶20*).

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

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

Hill S.J. Exhibit 12. Analysis of Scintillation Counts

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

(24) Howell further presented in his grant application data purporting to show a bystander effect for Tritiated Thymidine ($^3\text{HdThd}$) (Hill S.J. Exhibit 3: *Grant Application* p. 26, Figure 2; p.27, Figure 4; p.42, Figure 12). These and similar data were presented in two publications (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); and (Hill S.J. Exhibit 15: *Hill Certified Written Disclosure* Exhibit 17 Bishayee, et al. *Radiation Research* 155: 335 (2001), Figures 1 and 2); (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint*, ¶21).

(25) 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 ($^3\text{HdThd}$). Id.

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

Exhibit 53, *Hill Amended Answer to Defendants' Interrogatory No. 14. p.30-31*).

(27) Defendants further admit that these and similar data were also repeated and presented in Figure C1 in Howell's 2005 grant renewal application to NIH. (Hill S.J. Exhibit 54: Howell 10/05 Renewal Grant, p. 35 - Bate Stamped UMDNJ-Hill Confidential 0003854); (Hill S.J. Exhibit 46: *Amended Complaint, ¶21*); (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶21*); (Hill S.J. Exhibit 53, *Hill Amended Answer to Defendants' Interrogatory No. 14. p.30-31*).

(28) 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. (Hill S.J. Exhibit 46: *Amended Complaint, ¶22*); (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶22*).

(30) Lenarczyk performed the following experiments:

50% Labeled Experiments

(a) Lenarczyk Experiment December 26, 2000, V79, 50% - (Hill S.J. Exhibit 56) (Hill S.J. Exhibit 55: Lenarczyk Deposition 219/14 -222/18).

(b) Lenarczyk Experiment January 15, 2001, V79, 50% - (Hill S.J. Exhibit 57) (Hill S.J. Exhibit 55: Lenarczyk Deposition 224/7-228/1).

(c) Lenarczyk Experiment February 5, 2001, V79, 50% - (Hill S.J. Exhibit 58) (Hill S.J. Exhibit 55: Lenarczyk Deposition 228/6-230/14).

(d) Lenarczyk Experiment June 14, 2001, V79, 50% - (Hill S.J. Exhibit 59) (Hill S.J. Exhibit 55: Lenarczyk Deposition 230/19-232/7).

(e) Lenarczyk/Bishayee Experiment July 5, 2001, V79, 50% - (Hill S.J. Exhibit 60) (Hill S.J. Exhibit 55: Lenarczyk Deposition 232/17-233/15).

(f) Lenarczyk Experiment November 20, 2000, AL-N, 50% - (Hill S.J. Exhibit 61) (Hill S.J. Exhibit 55: Lenarczyk Deposition 233/19-234/14).

(g) Lenarczyk Experiment November 28, 2000, AL-N, 50% - (Hill S.J. Exhibit 62) (Hill S.J. Exhibit 55: Lenarczyk Deposition 234/19-235/8).

(h) Lenarczyk Experiment February 15, 2001, AL-N, 50% - (Hill S.J. Exhibit 63) (Hill S.J. Exhibit 55: Lenarczyk Deposition 235/18-236/6).

100% Labeled Experiments

(a) Lenarczyk Experiment October 2, 2000, V79, 100% - (Hill S.J. Exhibit 64) (Hill S.J. Exhibit 55: Lenarczyk Deposition 156:19-165/1).

(b) Lenarczyk Experiment December 14, 2000, V79, 100% - (Hill S.J. Exhibit 65) (Hill S.J. Exhibit 55: Lenarczyk Deposition 170/18-175/3).

(c) Lenarczyk Experiment May 3, 2001, V79, 100% - (Hill S.J. Exhibit 66) (Hill S.J. Exhibit 55: Lenarczyk Deposition 176/4-177/13).

(d) Lenarczyk Experiment May 21, 2001, V79, 100% - (Hill S.J. Exhibit 67) (Hill S.J. Exhibit 55: Lenarczyk Deposition 179/4-180/1).

(e) Lenarczyk Experiment June 21, 2001, V79, 100% - (Hill S.J. Exhibit 68) (Hill S.J. Exhibit 55: Lenarczyk Deposition 183/1-187/13).

(f) Lenarczyk Experiment November 10, 2000, AL-N, 100% - (Hill S.J. Exhibit 69) (Hill S.J. Exhibit 55: 188/1-193/5).

(g) Lenarczyk Experiment November 28, 2000, AL-N, 100% - (Hill S.J. Exhibit 70) (Hill S.J. Exhibit 55: Lenarczyk Deposition 192/9-194/22).

(h) Lenarczyk Experiment February 19, 2001, AL-N 100% - (Hill S.J. Exhibit 71) (Hill S.J. Exhibit 55: Lenarczyk Deposition 195/2-197/16)

(31) Notwithstanding the fact that the data could not be replicated, Howell and Bishayee each failed to promptly inform their supervisors at UMDNJ of these facts (including but not limited to Dr. Baker, the Chairman of the Radiology Department); and, notwithstanding that each of them had an obligation to do so pursuant to UMDNJ Policies and Guidelines. **(Hill S.J. Exhibit 51: Baker Deposition 9/2-10/8; 12/21-14/8; 15/7-17/1; 21/11-22/24; 25/14-26/15; 28/21-31/20; 32/6-21).**

(32) In this regard the UMDNJ Policies and Guidelines state:

(A) "The Principal Investigator is responsible for:
(a) the timely completion *** of the Transmittal and Approval

Form for Grants and Contracts and the application in conformity with Federal and grantee requirements, and (b) control and administration of the proposal") (**Hill S.J. Exhibit 72: Baker Deposition Exhibit 2; UMDNJ Policy on Funding: Grants and Contracts Proposals: Section III.B.1.a and b.**);

(B) "The Principal Investigator is responsible for: (a) the complete, accurate and timely management of both the programmatic and fiscal aspects of the grant and contract; ***, and, (h) notifying the Grants and Contracts of any changes that affect billing, receivables, and awards". (**Hill S.J. Exhibit 73: Baker Deposition Exhibit 3; UMDNJ Policy on Grants and Contracts Administration: Section IV.B.1.a and IV.B.1.h**);

(C) "Accepted research practices in the clinical, biomedical and social sciences are based on the concept of science as the creation, dissemination and application of new reproducible knowledge ...", *** "Investigations of allegations of research misconduct focus particularly upon research data, and mandate a new co-responsibility, shared by the researcher and the University to ensure the accuracy, completeness and retention of research data." (**Hill S.J. Exhibit 74: Baker Deposition Exhibit 4; UMDNJ's Guidelines for Conduct of Research, Section I**).

(D) "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. Investigators are obligated to record and preserve data in a form that allows future scrutiny and evaluation. The retention of accurately recorded, well organized and complete original research data and results (including unique reagents and research related biological materials) also provides the most effective response to questions that may arise about the propriety of the conduct of the research. Inability to produce well-kept original research data may place the integrity of the research itself into question." (Hill S.J. **Exhibit 74: Baker Deposition Exhibit 4; UMDNJ's Guidelines for Conduct of Research, Section III**).

(E) "... Each publication should contain the information needed for the replication of the research by scientific peers, and for the assessment of the results and conclusions by knowledgeable readers"; (Hill S.J. **Exhibit 74: Baker Deposition Exhibit 4; UMDNJ's Guidelines for Conduct of Research, Section III**).

(F) "Retractions or corrections of published research should be made promptly when necessary". (Hill S.J. Exhibit 74: *Baker Deposition Exhibit 4; UMDNJ's Guidelines for Conduct of Research, Section V*).

(G) "The faculties and administration of UMDNJ have an important responsibility to maintain high ethical standards in scientific research that is conducted on University premises by University personnel. These standards, based upon well-established principles of scientific research, include validity, accuracy and honesty in proposing and performing research, in collecting, analyzing and reporting research results, and in reviewing the research of others. *** University personnel who commit research misconduct breach their obligations to the University". (Hill S.J. Exhibit 1: *Hill Certified Written Disclosure, ¶61, p.47*); (Hill S.J. Exhibit 16: *Hill Certified Written Disclosure Exhibit 29: UMDNJ's Policy on Misconduct in Science, Section V.A.*

(H) "At any time during the course of the inquiry, investigation or otherwise, the Office of Research Integrity (in the case of research conducted under a PHS grant)... shall be immediately notified by the Senior Vice President for Academic Affairs as soon as it appears that there is substantial evidence

that: (1) there is an immediate health hazard to patients ...; (2) there is an immediate need to protect federal or other funds or equipment; *** "In addition, at any time during the course of the inquiry, investigation or otherwise, the ORI ... shall be apprised of any facts that may affect current or potential federal or other funding for the respondent, or that the ORI ... needs to know to ensure appropriate use of federal ... funds and otherwise protect the public interest". (**Hill S.J. Exhibit 1: Hill Certified Written Disclosure, ¶61, p.47**); (**Hill S.J. Exhibit 16: Hill Certified Written Disclosure Exhibit 29: UMDNJ's Policy on Misconduct in Science, Section V.H**).

(33) Notwithstanding 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 at UMDNJ of Hill's concerns about the data's validity until April 6, 2001 (**Hill S.J. Exhibit 51: Baker Deposition 38/2-42/10**) (**Hill S.J. Exhibit 75: Baker Deposition Exhibit 8**).

(34) In his memo Howell told Baker that he was then first going to request his post-doctoral fellow, Lenarczyk, to repeat some of Bishayee's experiments as a check on the validity of the data that was submitted in the grant application. However, 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. (Hill S.J. Exhibit 51: *Baker Deposition 42/12-24; 43/13-45/20*) (Hill S.J. Exhibit 75: *Baker Deposition Exhibit 8*).

(35) Nor did Howell inform Baker that the data presented in his grant application or in the two publications identified in Paragraph 21 of the Amended Complaint were at variance with all of the 11 experiments which had been previously been performed by Lenarczyk. (Hill S.J. Exhibit 51: *Baker Deposition 45/21-46/22*).

(36) Notwithstanding the fact that the data could not be replicated, Howell subsequently failed to inform Baker of an additional 11 experiments that Lenarczyk performed after 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 at variance. (Hill S.J. Exhibit 51: *Baker Deposition 47/1-24; 49/15-51/21; 52/10-53/22*).

(37) Howell admits that he failed to share these experiments with Baker or, that Lenarczyk had in fact, performed

11 of these experiments prior to his April 6, 2001 memo (**Hill S.J. Exhibit 77: Howell Deposition II 9/10-15/8**)².

(38) Howell asserts that he had no obligation to report his inability to replicate Bishayee's experiment results to his Grantor, the NIH (**Hill S.J. Exhibit 76: Howell Deposition I 93/1-94/6; 139/7-25**).

(39) Howell further denies having had a duty and obligation to affirmatively report his inability to replicate Bishayee's experiment results when Hill thereafter reported what she believed to constitute Scientific Misconduct to the UMDNJ Campus Committee on Scientific Misconduct. (**Hill S.J. Exhibit 76: Howell Deposition Vol. I 95/13-19**) (See infra at No. 43).

(40) Notwithstanding the fact that the data could not be replicated, 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. (**Hill S.J. Exhibit 46: Amended Complaint, ¶24**); (**Hill S.J. Exhibit 47: Defendants' Answer to Amended Complaint, ¶24**).

²The Exhibit identified as Howell-34 in the Howll deposition is identical to Exhibit Baker-8 identified in the Baker deposition. In these moving papers the exhibit appears as Hill. S.J. Exhibit 75.

(41) In or about March 2001, Lenarczyk observed and reported to Hill that he too was suspicious of the data that Bishayee was reporting when Lenarczyk observed Bishayee setting up an experiment with contaminated cultures and not connected to the data Bishayee was showing (**Hill S.J. Exhibit 55: Lenarczyk Deposition 41/9-13; 47/6-48/1; 61/3-63/25; 66/9-14; 125/17-25**) .

(42) In light of their personal observations, Hill and Lenarczyk documented the management of the experiment by Bishayee. (**Hill S.J. Exhibit 1: Hill Certified Written Disclosure, ¶¶ 53-57, pgs. 35-45**) ; (**Hill S.J. Exhibits 17-24: Hill Certified Written Disclosure Exhibits 19-26**)³; (**Hill**

³These Exhibits are as follows:

Hill S.J. Exhibit 17. Log of Observations for Period March 23, 2001 - April 7, 2001.

Hill S.J. Exhibit 18. List of Photographs

Hill S.J. Exhibit 19. Seventeen (17) photographs identified in Exhibit 20

Hill S.J. Exhibit 20. Radioactive Materials Inventory and Disposition Record

Hill S.J. Exhibit 21. Pages from Dr. Howell's Notebook

Hill S.J. Exhibit 22. List of Radioactivity Counts of the Aliquots taken from the Helena Tubes in the 10.5° incubator on Saturday, March 31, 2001

Hill S.J. Exhibit 23. Schema for Dr. Howell's protocol

S.J.Exhibit 53: *Hill Amended Answer to Defendants' Interrogatory No. 16. pgs. 32-33*).

(43) As a result of these actions, Hill concluded that Bishayee had, in fact, fabricated the experiment's data and engaged in scientific fraud. Thereafter on April 10, 2001, Hill reported the findings to Howell and to the Radiology Department Chair, Dr. Stephen Baker ("Baker"). **(Hill S.J. Exhibit 46: *Amended Complaint, ¶26*); (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶26*); (Hill S.J. Exhibit 1, *Hill Certified Written Disclosure, ¶¶ 58-60, pgs.45-46*); (Hill S.J. Exhibit 53, *Hill Amended Answer to Defendants' Interrogatory Nos. 17,18 and 20, pgs. 33-35,37*).**

(44) After Hill initiated her complaint and, specifically between April 2001 and September 2001, Howell, Lenarczyk and in some instances Bishayee, undertook to perform yet and additional six (6)experimental trials seeking to replicate the data Bishayee had previously generated and which had supported the grant application. These experiments were as follows:

Hill S.J. Exhibit 24. Map

- (a) Howell Experiment #1, 4/12/01, V79, 50% - (Hill S.J. Exhibit 78) (Hill S.J. Exhibit 76: *Howell Deposition Vol I 126/16-132/10*).
- (b) Howell Experiment #2, 4/19/01, V79, 50% - (Hill S.J. Exhibit 79) (Hill S.J. Exhibit 76: *Howell Deposition Vol I 132/12-136/2*).
- (c) Howell Experiment #3, 5/3/01, V79, 50% - (Hill S.J. Exhibit 80) (Hill S.J. Exhibit 76: *Howell Deposition Vol I 136/4-137/9*).
- (d) Howell Experiment #4, 6/28/01, V79, 50% - (Hill S.J. Exhibit 81) (Hill S.J. Exhibit 76: *Howell Deposition Vol I 137/10-138/20*).
- (e) Howell Experiment # 5, 7/16/01, V79, 100% - (Hill S.J. Exhibit 82) (Hill S.J. Exhibit 76: *Howell Deposition Vol I 83/10-15*).
- (f) Howell Experiment #6, 9/27/01, V79, 100% - (Hill S.J. Exhibit 83) Hill S.J. Exhibit 76: *Howell Deposition Vol I 83/10-15*).

(45) In each and every one of the six (6) experiments, the data reported in the publications and grant application could not be replicated. Id.; (Hill S.J. Exhibit 46: **Amended Complaint, ¶¶ 21 and 27**); (Hill S.J. Exhibit 47: **Defendants' Answer to Amended Complaint, ¶¶21 and 27**).

(46) Notwithstanding the fact that the data could not be replicated, Howell and Bishayee each failed to promptly inform their supervisors at UMDNJ, or NIH, of these facts, notwithstanding that each of them had an obligation to do so. (Hill S.J. Exhibit 51: **Baker Deposition 9/2-10/8; 12/21-14/8**;

15/7-17/1; 21/11-22/24; 25/14-26/15; 28/21-31/20; 32/6-21) (See also Nos. 31 and 32, supra).

(47) Notwithstanding the fact that the data could still not be replicated, 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. (Hill S.J. Exhibit 46: *Amended Complaint*, ¶29); (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint*, ¶29).

(48) Hill's April 10, 2001 complaint was referred to UMDNJ's Campus Committee on Research Integrity. (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*)⁴; (Hill S.J. Exhibit 29).

(49) On or about June 21, 2001 the Committee concluded that there was no cause to warrant further proceedings. (Hill S.J. Exhibit 1, *Hill Certified Written Disclosure*, ¶67, pg 50),

⁴These Exhibits are as follows:

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

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

(Hill S.J. Exhibits 27-28: *Hill Certified Written Disclosure Exhibits 30-31*)⁵; (Hill S.J. Exhibit 29: *Report of Initial Inquiry into Allegations of Potential Misconduct in Science Against Anupam Bishayee*); (Hill S.J. Exhibit 30: *Minutes of Initial Inquiry Meetings and Attachments 1-20 Referred to Therein*); (Hill S.J. Exhibit 31: *Attachments 21-22 Referred to in Minutes of Initial Inquiry Meeting Minutes*).

(50) UMDNJ's Senior Vice-President for Academic Affairs, Dr. Robert Saporito, advised Hill of the Committee's conclusion by letter dated July 2, 2001 (**Hill S.J. Exhibit 28, No. 49, f.n.5 supra**).

(51) Hill was not then given a copy of the Committee's Report of Initial Inquiry into Allegations of Potential Misconduct in Science Against Anupam Bishayee Ph.D. It was first provided by Defendants during discovery in this case; specifically, over six (6) years' later on November 21, 2007

⁵These Exhibits are as follows:

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

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

(Hill S.J. Exhibit 32: *Letter from Scott Flynn, Esq. dated November 17, 2007*).

(52) At the time the Committee report issued in July 2001, UMDNJ did not notify the Department of Health and Human Services, Office of Public Health and Science, Office of Research Integrity of the investigation and decision of the Campus Committee on Research Integrity. (Hill S.J. Exhibit 29: *Report of Initial Inquiry into Allegations of Potential Misconduct in Science Against Anupam Bishayee*).

(53) In August 2001 (after being notified of the Campus 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. (Hill S.J. Exhibit 1, *Hill Certified Written Disclosure*, ¶78, pg 50); (Hill S.J. Exhibits 33-34: *Hill Certified Written Disclosure Exhibits 36-37*)⁶.

⁶These Exhibits are as follows:

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

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

(54) On September 4, 2001, the Division of Investigative Oversight (DIO), Office of Research Integrity, notified UMDNJ it had received allegations of possible scientific misconduct for falsification on the part of Bishayee and with regard to the grant that Howell served as Principal Investigator. **(Hill S.J. Exhibit 35: Letter from Dr. Kay Fields to Dr. Karen Putterman, dated September 4, 2001).**

(55) Only then, on September 7, 2001, did UMDNJ provide ORI/DIO with a copy of its report of Initial Inquiry **(Hill S.J. Exhibit 36: Letter from Dr. Karen Putterman to Dr. Kay Fields, dated September 7, 2001)).**

(56) One year later, on September 5, 2002, Hill and UMDNJ were informed by ORI/DIO that, based on its review of the Report of the Initial Inquiry, it concurred with the conclusion there was insufficient 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. **(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); (Hill S.J. Exhibit 38: ORI Oversight Report, dated September 5, 2002); (Hill S.J. Exhibit 39: Attachments to ORI Report); (Hill**

S.J. Exhibit 1, Hill Certified Written Disclosure, ¶84, pg 59-60) (Hill S.J. Exhibit 40: Written Disclosure Exhibit 38).

(57) 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 **(Hill S.J. Exhibit 38: ORI Oversight Report, dated September 5, 2002, page 11, f.n.3).**

(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. **(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 any factual inaccuracies contained in the report despite ORI finding that Public Health Service regulations mandated that this occur. (**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. (**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. (**Hill S.J. Exhibit 38: ORI Oversight Report, dated September 5, 2002, page 17, f.n. 23**); (**Hill S.J. Exhibit 1: Hill Certified Written Disclosure, ¶¶ 47-49**), **pg 30-32**); (**Hill S.J. Exhibit 42: Written Disclosure Exhibit 15**); **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, ..." (Id. at 17, 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 Coulter count data that appears by comparison to have been too precise to represent accurately reported data. **(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 then two (2) available experiments, 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.

(But See Pitt Report, *infra* at no. 101.) (**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. (**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. (**Hill S.J. Exhibit 38: ORI Oversight Report, dated September 5, 2002, page 13).**

(58) 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. (**Hill S.J. Exhibit 32: Letter from Scott Flynn, Esq., dated November 17, 2007).**

(59) The Campus Committee investigation had limited its initial 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. (**Hill S.J. Exhibit 29: Report of Initial Inquiry**

into Allegations of Potential Misconduct in Science Against Anupam Bishayee).

(60) 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. **(Hill S.J. Exhibit 76: Howell Deposition Vol I 94/25-95/19; 138/21-139/6).**

(61) The Campus Committee report is silent in regard 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 **(Hill S.J. Exhibit 29: Report of Initial Inquiry into Allegations of Potential Misconduct in Science Against Anupam Bishayee); (Hill S.J. Exhibit 76: Howell Deposition Vol I. 93/1-94/6).**

(62) 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 pursuant to the Committee procedures. (Hill S.J. Exhibit 38: *ORI Oversight Report*, dated September 5, 2002).

(63) 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."

(Hill S.J. Exhibit 38: *ORI Oversight Report*, dated September 5, 2002 at pgs. 20-21).

(64) After the Committee's report, Bishayee resigned his position as Research Associate and his employment was terminated effective August 17, 2001 (Hill S.J. Exhibit 49). His letter of resignation was drafted and provided to him to sign by Howell. (Hill S.J. Exhibit 84: *Bishayee Deposition 102/14-*

105/22) (Hill S.J Exhibit 53: *Hill Amended Answer to Defendants' Interrogatory No. 20. p.37*).

(65) Bishayee was subsequently re-employed by UMDNJ in its Office of Radiation Safety Services. (Hill S.J. Exhibit 85: *Staff Position/Transaction Form*). Bishayee later resigned from that position and presently resides in Kent, Ohio. (Hill S.J. Exhibit 46: *Amended Complaint, ¶7*); (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint, ¶7*).

(66) Lenarczyk also determined to prematurely end his employment in the Howell laboratory, as he felt uncomfortable working on the research project, particularly since the reported data that was serving to underlie the research could not be replicated despite repeated attempts by himself, Howell and Bishayee to do so. (Hill S.J. Exhibit 55: *Lenarczyk Deposition 61/3-63/25; 71/1-74/22; 78/18-79/16; 136/16-137/6*).

67) Howell thereafter commenced engaging in retaliatory acts against Hill. These acts included:

(a) At a meeting on July 6, 2001, Howell told Plaintiff that he wanted nothing more to do with Plaintiff. This statement was made in spite of the fact that Dr Baker had just appointed him Division Chief of Radiation Research and that he was,

therefore, acting as Plaintiff's supervisor. (Hill S.J. Exhibit 86: *Hill Deposition 78/12- 19*) (Hill S.J. Exhibit 1, *Hill Certified Written Disclosure*, ¶¶72-73, pg 53); (Hill S.J. Exhibit 43: *Written Disclosure Exhibit 32 - Memo from Dr. Baker to Howell dated July 2, 2001*): (Hill S.J Exhibit 53: *Hill Amended Answer to Defendants' Interrogatory No. 21. p.38-39*).

(b) On or before July 29, 2001, Howell changed the locks in the Division in order to prevent Plaintiff from having access to the shared laboratory space and only leaving her with access to one small lab (F468) which she was then to share with Dr Azzam. (Hill S.J. Exhibit 1, *Hill Certified Written Disclosure*, ¶74, pg 54); (Hill S.J Exhibit 53: *Hill Amended Answer to Defendants' Interrogatory No. 21. p.38-39*).

(c) Howell presented Plaintiff with two memos that specifically denied her access to all but that lab. (Hill S.J. Exhibit 1, *Hill Certified Written Disclosure*, ¶84, pg 59-60); (Hill S.J. Exhibit 44-45: *Written Disclosure Exhibits 33-34: Howell Memos dated July 30, 2001 and July 31, 2001*) (Hill S.J Exhibit 53: *Hill Amended Answer to Defendants' Interrogatory No. 21. p.38-39*).

(d) Plaintiff collaborated with Dr Édouard Azzam until April 19, 2002. On that day, Dr. Azzam displayed extreme anger at Plaintiff as a result of his having found out that Plaintiff had reported the alleged misconduct to the Office of Research Integrity (ORI) at the USPHS. Azzam told Plaintiff that she was a bad person because Plaintiff would be responsible if Dr Howell's children found out that he had done a bad thing. Further, that Plaintiff would be responsible if Dr Howell's post-doctoral fellows lost their jobs. Azzam shouted several times at Plaintiff that he was an Arab. Plaintiff believed that it was Azzam's desire and attempt to intimidate the Plaintiff. **(Hill S.J Exhibit 53: Hill Amended Answer to Defendants' Interrogatory No. 21. p.38-39) .**

(e) Since that time and to this day, Howell and Azzam have shunned Plaintiff and treated her like an outsider. Plaintiff has not been included in any activities of the Division of Radiation Research. As a result of this treatment, Plaintiff has been made to feel lonely and depressed. Plaintiff has not been able to accomplish as much as she would have liked to and has had to develop new avenues of research resulting in her being less productive than she would have been had she been an active member of the Radiation Research Division Research group. **(Hill**

S.J Exhibit 53: *Hill Amended Answer to Defendants' Interrogatory No. 21. p.38-39*); (Hill S.J. Exhibit 1: *Hill Certified Written Disclosure, ¶¶ 72-83, pgs.53-59*) (Hill S.J. Exhibit 87: *Written Disclosure Exhibit 35: Memo from Hill to Dr. Putterman - Grievance*); (Hill S.J. Exhibit 51: *Baker Deposition 54/7-57/7; 60/10-61/20*).

(69) As a result of these acts, Hill has suffered humiliation; felt less productive than had she stayed working in the division, and required to change fields to studying DNA damage in mitochondria. This has further required her to work off campus at times (Hill S.J. Exhibit 86: *Hill Deposition 84/16-87/2; 94/7- 98/2*).

(70) 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 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 and which data was used to support Howell's revised grant to NIH. 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.

(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; (Hill S.J. Exhibit 53: *Hill Amended Answer to Defendants' Interrogatory No. 22. pgs 39-40*).

(71) 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 (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 (Hill S.J. Exhibit 10). The premise of these papers is that, when

⁷These Exhibits are as follows:

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

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

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

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

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 his paper (Hill S.J. Exhibit 9), Mosimann presented four (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. **(Hill S.J. Exhibit 1: Hill Certified Written Disclosure, ¶¶ 40-46, pgs.25-30) (Hill S.J. Exhibits 9-13: Hill Certified Written Disclosure Exhibits 10-14) .**

(72) In November, 2002, Hill initiated a second complaint against Bishayee alleging falsification and/or fabrication of data for NIH grant 1R01CA83838-A1. **(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; (Hill S.J. Exhibit 53: Hill Amended Answer to Defendants' Interrogatory No. 22. pgs 39-40) .**

⁸These Exhibits are as follows:

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

Hill S.J. Exhibit 93. UMDNJ Policy on Misconduct in Science

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

(74) 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. (**Hill S.J Exhibit 95: Report of Initial Inquiry Into Allegation of Potential Misconduct in Science Against Anupam Bishayee Ph.D., page 5**).

(75) During this Initial Inquiry, Howell was never interviewed by the Committee and further failed to 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. (**Hill S.J. Exhibit 46: Amended Complaint, ¶35**); (**Hill S.J. Exhibit 47: Defendants' Answer to Amended Complaint, ¶35**).

(76) Moreover, neither Howell nor Bishayee ever 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. (**Hill S.J. Exhibit 46: Amended Complaint, ¶36**); (**Hill S.J. Exhibit 47: Defendants' Answer to Amended Complaint, ¶36**).

(77) 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 there is

substantial evidence of falsification and/or fabrication of data submitted in support of a grant application. Nor has UMDNJ undertaken to withdraw the scientific literature that was generated from this data. (Hill S.J. Exhibit 46: *Amended Complaint*, ¶37); (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint*, ¶37); (Hill S.J. Exhibit 93: *Hill Disclosure Exhibit 44*, pgs. 7-8, ¶ 5.E.10.b.).

(78) The Complaint in this matter was filed in Camera and Under Seal on October 14, 2003.

(79) On December 17, 2003, the Court entered an Order Partially Lifting the Seal upon consideration of the United States Ex Parte Application for Partial Lifting of the Seal.

(80) On December 29, 2003 an Order Staying, but not dismissing the action was entered.

(81) On April 6, 2007, the United States filed a Notice of Election to Decline Intervention.

(82) On April 16, 2007, the Court entered an Unsealing Order.

(83) The Defendants thereafter waived service of the Summons and Complaint.

(84) On July 30, 2007, the Defendants filed an Answer and Counterclaim on behalf of the Defendants.

(85) On August 20, 2007, Hill filed an Answer to the Counterclaim.

(86) By Leave of Court, an Amended Complaint was filed on April 1, 2009.

(87) The Defendants filed an Answer to the Amended Complaint of April 7, 2009.

(88) Upon notice of the grant award in May 2000, and annually thereafter, Howell was 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. **(Hill S.J. Exhibit 46: Amended Complaint, ¶38); (Hill S.J. Exhibit 47: Defendants' Answer to Amended Complaint, ¶38); (Hill S.J. Exhibit 96: U.S. Dept. of Health and Human Services, Public Health Service, Non-Competing Continuation Progress Report (PHS 2590).** <http://grants.nih.gov/grants/funding/2590/phs2590.pdf>.

(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) .

(89) Howell did not report his inability to replicate the data even though Section 2.2.1 of PHS 2590 (Hill S.J. Exhibit 96), requires 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). (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) .

(90) Moreover, in submitting the Progress Reports, UMDNJ further certifies that " I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept 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". (Hill S.J.

Exhibits 97-100: Howell Annual Progress Reports (4) for the periods 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) .

(91) Thereafter, in October 2005, and still notwithstanding the fact that the data could not be replicated, Howell undertook to apply to the NIH for a renewal grant. In undertaking to do so, Howell re-submitted the same data which he had submitted in his initial revised application. This data he knew could not be replicated and had otherwise failed to report or retract. (Hill S.J. Exhibit 46: *Amended Complaint*, ¶39); (Hill S.J. Exhibit 47: *Defendants' Answer to Amended Complaint*, ¶39) (Hill S.J. Exhibit 54: *Howell 10/05 Renewal Grant*, p. 35 - Bate Stamped UMDNJ-Hill Confidential 0003854) .

(92) On July 12, 2006, UMDNJ received Notice that NIH had approved Howell's renewal grant (Hill S.J. Exhibit 101: *Notice of Grant Award - Bate Stamped UMDNJ 0003888-94*) .

(93) The Notice of Grant contained a statement re-advicing 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 (**Hill S.J. Exhibit 101: Notice of Grant Award - at Bate Stamp 0003888 and 0003890**).

(94) In response to the failure to replicate the data presented in support of the grant and in publications; and, at the request and direction of the U.S. Attorney's Office in 2004 or 2005, Howell prepared a document entitled "Summary of Experiments" that 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. (**Hill S.J. Exhibit 102: Howell Deposition Exhibit 29**) (**Hill S.J. Exhibit 76: Howell Deposition Vol I 140/7-25; 145/17 - 146/12**).

(95) 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) (**Hill S.J. Exhibit 76: Howell Deposition Vol.I 144/25-145/12**).

(96) The 'factors' that Howell identifies in his summary are but conjectures and suppositions on his part, as Howell admits that 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 (**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 (**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 (**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 (**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 (**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 (**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 (**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 **(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 **(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 **(Hill S.J. Exhibit 76: Howell Deposition Vol. I 183/16-191/2)** .

(97) During the course of these proceedings the 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 **(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".

(98) Review of the reports of UMDNJ Campus Committee reports ORI/DIO will determine that, with the exception of the two experiments that Hill had reported, most if not all of these experiments and data had not previously been known or made available to Hill at the time she initiated her complaints to either of the UMDNJ Campus Committees on Research; or, to the ORI/DIO **(Hill S.J. Exhibits 29, 38 and 95)**.

(99) The experiments and data provided in response to the Subpoena Duces Tecum contained independent control data (to wit, Coulter counts) with which a statistician could compare the experimental results generated by Dr. Bishayee. **(Hill S.J. Exhibit 113) (Hill S.J. Exhibit 104)**.

(100) The experiments and data provided in response to the Subpoena Duces Tecum contained independent control data with which a statistician could 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 **(Hill S.J. Exhibit 113) (Hill S.J. Exhibit 104)**.

(101) An expert statistician was retained by Hill in this case. Dr. Joel Pitt, who employed the "Mossiman" technique that ORI had directed Hill to in order to analyze the Coulter counter data. Dr. Pitt, utilizing the control data obtained from Howell/UMDNJ as well as other University research sites employing Coulter counters⁹, 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. **(Hill S.J. Exhibit 104: Report of Dr. Joel Pitt entitled "Statistical Evidence in Department of Radiology, New Jersey Medical School" and**

⁹Coulter Counter data was also obtained from Case Western Reserve University, Cleveland, Ohio and the University of Texas, Southwestern Medical Center, Dallas Texas. **(Hill S.J. Exhibit 105: Certification of Dr. Nicholas P. Ziats/Case Western Reserve University) (Hill S.J. Exhibit 106: Certification of Dr. Woodring Wright/University of Texas, Southwestern Medical Center, Dallas, Texas)**.

Curriculum Vitae, pages 1-7 and Appendix to Report: Sources of Data Used for Statistical Analysis and Generating Charts).

(102) 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)

(103) Dr. Pitt thereafter employed two additional statistical techniques to this data:

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 control data and computer simulation data. **(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) (**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).**

(104) Based on the above statistical analysis, Dr. Pitt concluded that Dr. Bishayee had committed fraud. Moreover, when the statistical results are considered in combination with direct observation of scientific misconduct by Bishayee and the irreproducibility of his results, the conclusion that Bishayee committed fraud is inescapable. (**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).**

(105) The techniques and methodology that Dr. Pitt employed with regard to mathematics and statistics were ones that are scientifically valid and accepted in the mathematics/statistics community; and, based on a reasonable degree of both mathematical and statistical probability (**Hill S.J. Exhibit 107: Deposition of Pitt at 113).**

(106) The Defendants have not offered, or sought to qualify any statistical expert to refute Dr. Pitt's analysis, opinions or conclusions.

(107) The receipt of the documents and experiments produced by Defendants in response to the Subpoena Duces Tecum, has further resulted in review and analysis thereof by an expert Radiation Biologist retained by Hill, Dr. Michael E. Robbins. (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"*) (Hill S.J. Exhibit 109: *Curriculum Vitae for Dr. Robbins*).

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

(a) Tritiated Thymidine (^3H -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, ^3H -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 ^3H .

(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 ^3H -TdR. Deoxycytidine would have abrogated the effect of the ^3H -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 ^3H -TdR. Had the cells been synchronized, they might possibly have all been in S phase at the time the ^3H -TdR was added.

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

(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"*).

(109) Dr. Robbins report is consistent with what Hill had previously concluded based on her review personal observations and her review and analysis of the subpoenaed information.

(a) "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" (Hill S.J. Exhibit 110: *Certification of Dr. H.Z. Hill*) (Hill S.J. Exhibit 111), and,

(b) A Power Point Presentation entitled "Evidence Supporting Allegations of Fraud at the N.J. Medical School" (Hill S.J. Exhibit 110: *Certification of Dr. H.Z. Hill*) (Hill S.J. Exhibit 112).

BUCCERI & PINCUS, ESQS.

By: /Sheldon H. Pincus/

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