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August 7, 2008

The Honorable Mark Falk, U.S.M.J.
United States District Court
United States Courthouse and Post Office Building
1 Federal Square, Room 457
Newark, NJ 07101

Re: United States, ex Rel Hill v. UMDNJ, Howell and Bishayee
Case No. 03-cv-4837 (DMC/MF)
MDMC File No. U0063-1009

Dear Judge Falk:

We represent Defendants, University of Medicine and Dentistry of New Jersey, Dr. Roger W. Howell and Dr. Anupam Bishayee, in connection with the above-referenced matter. Please accept this letter brief in lieu of a more formal submission as Defendants' position with regard to the Motion to Quash the Deposition Subpoena issued to Dr. Thomas Hei.

On its face, Dr. Hill's identification of certain Columbia University scientists in her Answers to Defendants' Interrogatories, including Dr. Eric Hall, Dr. Thomas Hei, Dr. Hongning Zhou and Dr. Rudranath Persaud, and her current efforts to depose certain of those scientists suffers from two primary and overriding defects. Either Dr. Hill is improperly attempting to force these scientists to provide unretained expert testimony in violation of Fed. R. Civ. P. 45 (c)(3)(B)(ii) or she is merely seeking to elicit only factual information from these individuals that is wholly irrelevant to the claims alleged in this matter and thus not properly discoverable.

Plaintiff's own opposition brief acknowledges this quandary and attempts to persuade the Court that she is not improperly seeking expert testimony from the named Columbia scientists. On the last page of Plaintiff's opposition brief she frames the testimony that she anticipates eliciting from Dr. Hei as follows: "In sum, Dr. Hei is not being asked to give opinions based on his specialized skills and knowledge. He is only being asked what actual experiments were performed in his laboratory and what the outcomes were." While this limitation would avert a violation of Fed. R. Civ. P. 45 (c)(3)(B)(ii), it directly results in fulfillment of the second deficiency highlighted above –

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the improper deposition of a non-interested third party with absolutely no first hand knowledge of the facts in dispute in this matter.

In short, Plaintiff's claims in this matter are that scientists at UMDNJ falsified and/or fabricated experimental data that was submitted to the United States government to improperly obtain federal grant funds. Defendants' Answer and Counterclaim in response to Plaintiff's allegations rely primarily on the substantial and thorough prior investigations that have been conducted of Plaintiff's claims and that have consistently vindicated Defendants. More specifically, in April 2001 Plaintiff Dr. Hill approached certain individuals at UMDNJ with allegations of scientific research misconduct directed at Defendant Dr. Bishayee. She alleged that Dr. Bishayee fabricated and/or falsified data in one or more experiments that were conducted under a grant from the National Cancer Institute, National Institutes of Health (the "grant"), on which Dr. Howell was the principle investigator and Dr. Hill a co-investigator. 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. 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. Upon 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.

After interviewing Dr. Hill, Dr. Marek Lenarczyk, a post doctoral fellow employed by Dr. Howell, and Defendants Drs. 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-page report on June 22, 2001 (the "First Report"). In the First Report, the Committee unanimously concluded that there was insufficient credible and definitive evidence of misconduct in science to warrant further investigation of Dr. Hill's allegations. 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.

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. ORI oversees and directs the integrity of Public Health Service ("PHS") research activities. The PHS is composed of a number of federal offices and

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agencies, including, among others, the National Institutes of Health (“NIH”), which awarded and funded the grant in question.

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. 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-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. ORI forwarded a copy of its report to NIH. 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.

Apparently still unsatisfied, Dr. Hill initiated a second complaint with UMDNJ’s Newark Campus Committee on Research Integrity on or about November 11, 2002. 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. As with the review of Dr. Hill’s initial complaints, 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. UMDNJ’s Newark Campus Committee on Research Integrity was convened again on or about November 25, 2002, to perform a preliminary assessment of Dr. Hill’s second allegations.

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

After UMDNJ closed its second investigation, Dr. Hill, filed her Complaint on October 14, 2003. In accordance with the Federal False Claims Act, the Complaint remained under seal while the federal government conducted another thorough investigation of Plaintiff’s claims. In or about November 2004, the United States Attorney’s Office issued a subpoena to UMDNJ demanding a large production of documents relating to the incidents alleged in the Complaint. UMDNJ, with the assistance of outside counsel, complied with the subpoena and additional document requests issued by the government. After reviewing all of the materials forwarded by UMDNJ and directing FBI agents to conduct in person interviews of relevant individuals,

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the United States Attorney's Office filed a Notice of Election to Decline Intervention on or about April 9, 2007.

It goes without saying that no one at Columbia University, and certainly not the scientists named in Plaintiff's Answers to Interrogatories and recent subpoenas, has any relevant first hand knowledge of the facts and circumstances of these prior investigations or the facts at the heart of both those investigations and Plaintiff's Complaint. Unless Plaintiff is in fact attempting to elicit expert testimony from these scientists, which they have already told her they are refusing to voluntarily provide her with, then any testimony they may provide will be absolutely irrelevant to this case and only result in Defendants and Columbia University bearing unnecessary litigation costs. Accordingly, Defendants respectfully request that the Court grant Columbia's motion to quash.

Should Your Honor have any questions or require any additional information, we shall make ourselves available at the Court's convenience.

Respectfully submitted,

McELROY, DEUTSCH, MULVANEY & CARPENTER, LLP

/s/ John P. Leonard
John P. Leonard

cc: Sheldon H. Pincus, Esq.
Paul J. Fishman, Esq.
Susan Steele, Assistant U.S. Attorney