

IMPOUNDED

2003-01985
SAM (1)

RECEIVED - CLERK
U.S. DISTRICT COURT

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHP-7299

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

CASE NO.

03-4837
(Dmc)

PLAINTIFF,

v.

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

COMPLAINT

DEFENDANTS.

FILED IN CAMERA
AND UNDER SEAL

ORIGINAL FILED
10-14-03
WILLIAM T. WALSH, CLERK

I. INTRODUCTION

(1) This is an action to recover damages and civil penalties on behalf of the United States of America arising from false statements and claims made and presented by the defendants and/or their agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 21 U.S.C. § 3729 et. seq. as amended (the "Act"). The violations of the Act involve the Defendants' application for, and subsequent receipt of, federal grant monies (Grant No. R01CA83838) based upon the knowing submission of a grant application to the United States

Department of Health and Human Services, National Institute of Health. That application, as well the findings of certain experiments that were subsequently undertaken, were supported with data, statements and records that were false or fraudulent.

(2) The Act provides that any person who knowingly submits or causes to be submitted a false or fraudulent claim to the Government for payment or approval; or makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; or who conspires to defraud the Government by getting a false or fraudulent claim allowed or paid, is liable for a civil penalty of up to \$10,000.00 for each claim submitted or paid, plus three times the amount of the damages sustained by the Government. The Act allows any person having information regarding a false or fraudulent claim against the Government to bring an action for herself (the "Relator") and for the Government and to share in any recovery. The Complaint is filed under seal for 60 days (without service on the Defendants during that period) to enable the Government: (a) to conduct its own investigation without the Defendants' knowledge, and (b) to determine whether to join the action.

(3) Based on those provisions, Plaintiff/Relator seeks to recover damages and civil penalties arising from defendants' presentation of false records, claims, and statements to the United States Government and its agents in connection with defendants' submission and receipt of Grant No. R01CA83838 to and/or from the United States Department of Health and Human Services, National Institutes of Health. Plaintiff/Relator also seeks to recover damages arising from Defendants' unlawful acts upon which the grant monies were paid from federal funds.

II. PARTIES

(4) Plaintiff and 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"). Dr. Hill brings this action for violations of 31 U.S.C. § 3729 et. seq., on behalf of herself and the United States Government pursuant to 31 U.S.C. § 3730 (b) (1). Dr. Hill has personal knowledge of the false records, statements and/or claims presented to the Government by and for the Defendants named herein and/or Defendants' fraudulent practices.

(5) 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.

(6) Defendant, Dr. Roger W. Howell ("Howell"), is a resident of Millington, New Jersey and a Professor of Radiology employed by the Defendant, UMDNJ.

(7) Defendant, Dr. Anupam Bishayee ("Bishayee"), is a citizen of India, but presently resides in, West Orange, New Jersey. Bishayee, formerly employed by Defendants Howell and UMDNJ as a Research and Teaching Specialist, is presently employed by UMDNJ in its Office of Radiation Safety Services.

III. JURISDICTION AND VENUE

(8) This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. § 3729 and § 3730.

(9) This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. § 3732(a), which provides that "[a]ny action under section 3730 may be brought in any judicial district in which the defendant, or in the case of multiple

defendants, any one defendant can be found, resides, transacts business or in which any act proscribed by section 3729 occurred."

(10) Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because Defendants can be found in, reside in, and/or transacted business in this judicial district and because some of the violation of 31 U.S.C. § 3729 described herein occurred in this judicial district.

IV. GENERAL ALLEGATIONS

(11) Hill began her service as a Professor of Radiology at UMDNJ in September, 1981.

(12) 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.

(13) 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.

(14) 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.

(15) 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.

(16) 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.

(17) Defendant Bishayee was further designated to serve as the Research Specialist responsible for carrying out the day to day experiments described in the project.

(18) The revised grant application was submitted to the NIH on or about October 29, 1999.

When? → (19) On two occasions preceding the submission of the revised grant application, Hill observed Bishayee engaged in preliminary experiments. Hill's observations led her to believe that Bishayee was falsifying the data underlying the experiments and the conclusions reached by Howell from those experiments.

When? → (20) Hill informed Howell of her observations and suspicions relating to Bishayee. Notwithstanding this fact, Howell dismissed Hill's concerns and further refused to intercede to Hill's request to investigate Bishayee's actions. Instead, Howell determined to use the results of Bishayee's

Why? →
What reasons were given?

experiments as part of the preliminary data supporting his revised grant application to NIH.

(21) Howell further presented in his grant application data purporting to show a bystander effect for $^3\text{HdThd}$ (Grant application page 26, Figure 2, circles). These and similar data were presented in 2 publications (Bishayee, et al. Radiation Research 152: 88 (1999), Figures 3 circles and 6 inverted triangles; Bishayee, et al. Radiation Research 155: 335 (2001) Figure 2A). These data could not be replicated in more than 8 trials performed in April - June, 2001.

(22) Subsequent to the approval and funding of Howell's grant in July 2000, an additional post doctoral fellow, Dr. Marek Lenarczyk ("Lenarczyk"), was hired by Howell to conduct other research relating to the grant.

(23) In or about March, 2001, Lenarczyk observed and reported to Hill that he also suspected Bishayee of fabricating data when Lenarczyk observed Bishayee setting up an experiment with contaminated cultures. In light of this fact, Hill and Lenarczyk documented the management of the experiment by Bishayee.

(24) As a result of their actions, Hill and Lenarczyk concluded that Bishayee had, in fact, fabricated the

experiment's data and engaged in scientific fraud. On or about April 10, 2001, Hill reported the findings to Howell and to the Radiology Department Chair, Dr. Stephen Baker ("Baker").

(25) The matter was thereafter referred to UMDNJ's Campus Committee on Research Integrity. In July, 2001 the Committee concluded that there was no cause to warrant further proceedings.

(26) After the Committee's report, Howell proceeded to terminate the employment of both Bishayee and Lenarczyk. Additionally, Howell engaged in retaliatory acts against Hill, including his determination to lock her out of the laboratory which contained the supplies and instrumentation necessary for Hill to do research. Howell and others then engaged in other actions that led to the creation of a hostile work environment for Hill which continues to this day.

by whom? → (27) Thereafter, Hill was advised 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 October, 1999 and which data was used to support Howell's revised grant to NIH. Consequently in or about November, 2002, Hill initiated a second complaint against

Bishayee alleging falsification and/or fabrication of data for NIH grant R01CA83838.

reasons
why

(28) Upon its review of the complaint, UMDNJ's Campus Committee on Research Integrity again concluded there was no cause to credit the allegations.

when
are
they
required
to?

(29) As a result of the successive findings of no cause by UMDNJ's Campus Committee on Research Integrity, UMDNJ has never disclosed the details of its findings to the NIH as its policies obligate 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.

are
they
responsible?

who
should
do this?

COUNT ONE

SUBSTANTIVE VIOLATIONS OF THE FALSE CLAIMS ACT

(30) Relator realleges and incorporates by reference the allegations made in Paragraphs 1-29 of this Complaint.

(31). This is a claim for treble damages under the False Claims Act, 31 U.S.C. § 3729-32, as amended.

(32) Through the acts described above, defendants and their agents and employees knowingly presented and caused to be presented to the United States Government false and fraudulent

claims, records and statements in order to secure funding of NIH grant R01 CA83838.

(33) Through the acts described above and otherwise, defendants and their agents and employees knowingly made, used and/or caused to be made or used false records and statements in order to get such false and fraudulent claims funded by approval by the United States Government of NIH grant R01 CA83838.

(34) The United States, its fiscal intermediaries, and the NIH, unaware of the falsity of the records, statements, and claims made or submitted by defendants and their agents, servants and employees paid and continue to pay defendants grant monies that would not be paid if the truth were known.

(35) Plaintiff United States, its fiscal intermediaries, and the NIH, unaware of the falsity of the records, statements, and claims made or submitted by defendants - or their failure to disclose material facts which would have reduced or precluded government obligations - have not recovered grant monies that would otherwise have been recovered.

(36) By reason of the defendants' false records, statements, claims and omissions, the United States and NIH have been damaged in the amount of \$1,358,075.

COUNT TWO

FALSE CLAIMS ACT CONSPIRACY

(37) Relator realleges and reincorporates by reference the allegations made in Paragraphs 1-29 of this Complaint.

(38) This is a claim of treble damages under the False Claims Act, 31 U.S.C. § 3729 et.seq., as amended.

(39) Through the acts described above and otherwise, defendants entered into a conspiracy or conspiracies among themselves and with others to defraud the United States and NIH by obtaining and receiving payments for NIH grant R01 CA83838 based on false and fraudulent claims, records and statements. Defendants have also conspired to omit disclosing or to actively conceal facts which, if known, would have reduced or denied government payments or obligations to them or resulted in repayments from them to the government. Defendants have taken substantial steps in furtherance of those conspiracies, inter alia, by preparing a false or fraudulent grant application, by submitting such grant application to the Government for approval or payment, and by directing their agents, consultants, and personnel not to disclose and/or to conceal defendants' fraudulent practices.

proof?

Howell

(40) The United States, its fiscal intermediaries, and NIH, unaware of defendants' conspiracies or the falsity of the records, statements and claims made by defendants and their agents, employees and co-conspirators, and as a result thereof, have paid and continue to pay grant monies that they would not otherwise have paid. Furthermore, because of the false records, statements, claims, and omissions by defendants and their agents, employees and co-conspirators, the United States, its fiscal intermediaries, and NIH have not recovered grant funds from the defendants that would otherwise have been recovered.

(41) By reason of defendants' conspiracies and the acts taken in furtherance thereof, the United States and NIH have been damages in the amount of \$1,358,075.

COUNT THREE

RETALIATION

(42) Relator realleges and reincorporates by reference the allegations made in Paragraphs 1-29 of this Complaint.

(43) This is a claim of treble damages under the False Claims Act, 31 U.S.C. § 3729 et.seq., as amended.

(44) Through the acts described above and otherwise, the defendants and their agents and employees have harassed or otherwise discriminated against plaintiff/relator in the terms

and conditions of her employment all committed by defendants for the reason that she committed lawful acts; namely, reporting false claims and fraud against the United States internally to defendants, in furtherance of an action under 31 U.S.C § 3730 by the Attorney General, all as described in the foregoing paragraphs. In these respects, defendants breached 31 U.S.C. § 3730(h) and plaintiff/relator is entitled to all relief allowed by law.

PRAYER

WHEREFORE, plaintiff/relator prays for judgment against the defendants as follows:

(1) That defendants cease and desist from violating 31 U.S.C. § 3729 et.seq. ;

(2) That the Court enter judgment against defendants in an amount equal to three times the amount of damages the United States has sustained as a result of defendants' actions, as well as a civil penalty against each defendant of \$10,000 for each violation of 31 U.S.C. § 3729;

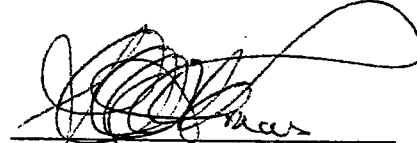
(3) That plaintiff/relator be awarded the maximum amount allowed pursuant to § 3730 (d) of the Federal Civil False Claims Act;

(4) That plaintiff/relator be awarded all costs and expenses of this action, including attorneys' fees;

(5) That the United States and plaintiff/relator receive all such other relief as the Court deems just and proper.

Dated: October 10, 2003

Bucceri & Pincus, Esqs.



By: Sheldon H. Pincus
Counsel for Qui Tam Plaintiff,
Dr. Helene Z. Hill