

DAVID N. KELLEY
United States Attorney for
the Southern District of New York
By: SHEILA M. GOWAN (SG: 8201)
KATHY S. MARKS (KM: 0339)
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, New York 10007
Tel. No.: (212) 637-2697

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA,	:	03 Civ. 6761 (DC)
	:	
Plaintiff,	:	
	:	
- against -	:	COMPLAINT-IN-
	:	INTERVENTION OF THE
	:	<u>UNITED STATES OF AMERICA</u>
WEILL MEDICAL COLLEGE OF	:	
CORNELL UNIVERSITY,	:	
	:	
Defendant.	:	

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The United States of America, by and through its attorney, David N. Kelley, United States Attorney for the Southern District of New York, having filed a notice of intervention pursuant to 31 U.S.C. § 3730(b)(4), alleges for its Complaint as follows:

1. This is a civil action brought by relator Kyriakie Sarafoglou, M.D., on her own behalf and on behalf of the United States of America ("United States") against defendant Weill Medical College of Cornell University ("Weill Medical College"), under the qui tam provisions of the False Claims Act, 31 U.S.C. §§ 3729 et seq. (the "False Claims Act"), to recover damages sustained by, and penalties owed to, the United States as a

result of Weill Medical College's having knowingly presented or caused to be presented to the United States false or fraudulent claims for payment in connection with (i) Grant No. 5M01RR006020 received by Weill Medical College from the United States Department of Health and Human Services, National Institutes of Health ("NIH"), National Center for Research Resources ("NCRR"), Division of Clinical Research, General Clinical Research Centers Program; and (ii) the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. § 1396, for physician services performed at Weill Medical College's Children's Clinical Research Center ("CCRC").

2. The United States brings additional claims against Weill Medical College under the False Claims Act and under the common law for fraud, unjust enrichment and payment under mistake of fact.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the claims brought under the False Claims Act pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331, 1345, over the remaining claims pursuant to 28 U.S.C. § 1345, and over all claims pursuant to the Court's general equitable jurisdiction.

4. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b), 1391(c), because defendant Weill Medical College is located within this District, does

business within this District, and because the acts complained of herein took place in this District.

PARTIES

5. Plaintiff is the United States, on behalf of its agency the United States Department of Health and Human Services ("HHS")/Public Service Agency.

6. Relator Kyriakie Sarafoglou, M.D., was employed by Weill Medical College and its affiliate, The New York Presbyterian Hospital ("NYPH"), beginning in or about August 2001. Dr. Sarafoglou was an assistant professor of pediatric medicine at Weill Medical College, an assistant attending physician in the Division of Pediatric Endocrinology and Metabolism at NYPH, and the Research Subject Advocate for the CCRC.

7. Defendant Weill Medical College, through its physician faculty, engages, inter alia, in clinical practice and medical research, including pediatric research.

8. During the period December 1995 through November 2003, pursuant to NIH Grant No. 5M01RR006020, Weill Medical College operated a CCRC, which was located on the premises of NYPH, and where Weill Medical College physicians and investigators performed medical research and treated patients.

FACTS

I. Background

9. The United States, through NIH, makes grants for the purpose of funding scientific research projects. 42 U.S.C. §§ 241(a)(3), 284(b)(2)(B).

10. The Division of Clinical Research of the NCRR, through the distribution of federal funds by NIH, supports access to the resources and technologies that biomedical investigators require to conduct research that improves human health. The diverse research centers and resources supported by NCRR include General Clinical Research Centers ("GCRC") grants (M01s), which facilitate patient-oriented research in a cost-effective approach.

11. Medical institutions, like Weill Medical College, are eligible for GCRC program support. The primary purpose of a GCRC is to provide the clinical research infrastructure to investigators who receive their primary research funding from the other components of the NIH.

12. The research investigations carried out in a GCRC can include studies of normal and abnormal human physiology and studies of the cause, prevention, progression, control, and cure of diseases that afflict individuals of all ages and ethnic backgrounds.

13. The essential feature common to all GCRCs is the

broad range of patient-oriented scientific inquiry. And, as set forth in NCRR's Guidelines for the General Clinical Research Centers Program (MO1) (the "NCRR Guidelines"), "[b]ecause of the nature of the GCRCs, no single group of investigators or categorical research area may dominate the utilization of the GCRC or use more than one third of the GCRC resources, except for AIDS studies, ..." (hereinafter referred to as the "33 Percent Guideline"). See NCRR Guidelines.

14. The purpose of the 33 Percent Guideline is to facilitate government support of research in a broad array of scientific disciplines within pediatrics, in the case of a CCRC, and not to permit one researcher or discipline to garner all the federal resources and, in effect, dominate the research at the expense of the government.

15. A GCRC MO1 grant is awarded pursuant to the government's authority as provided in 42 U.S.C. § 241, 42 C.F.R. Part 52, and 45 C.F.R. Part 74 or 45 C.F.R. Part 92, as applicable, the NIH Grants Policy Statement and the NCRR Guidelines. See also 42 C.F.R. § 52.8.

16. The NIH requires that each grant application, grant continuation application, and annual progress report submitted by an institution must be signed by the Principal Investigator, who is "responsible for the scientific and technical direction of the project." 42 C.F.R. § 52.2(b). In

addition, the NIH requires that each grant application, grant continuation application, and annual progress report must be signed and certified as true by an official on behalf of the applicant institution. 42 C.F.R. § 52.6(b)(2).

17. The applicant institution, as the recipient or grantee, is the "responsible legal entity." 42 C.F.R. § 52.2. Weill Medical College was the responsible legal entity on the Grant No. 5M01RR006020, project title Children's Clinical Research Center ("CCRC") or General Clinical Research Center ("GCRC").

18. Each grantee institution is responsible and accountable for all funds, property and assets acquired under the grant and is responsible for ensuring that they are used solely for authorized purposes. 42 C.F.R. §§ 52.6, 52.8; 45 C.F.R. § 74.21(b)(3).

19. Each grantee institution has a legal duty to exercise adequate oversight in connection with the federal grants awarded to it by NIH. See 42 C.F.R. §§ 52.2, 52.6(a), 52.8; 45 C.F.R. §§ 74.21, 74.51-74.53.

20. Each grantee institution must establish an institutional GCRC advisory committee (the "GAC"), also known as the scientific advisory committee (the "SAC"), which, inter alia, sets "the general policies for the CCRC, delineates common needs of the CCRC investigators and evaluates projects for CCRC use."

In addition, "[r]esearch studies performed on the CCRC must have GAC approval prior to initiation, except when temporary approval has been given by the Program Director and the IRB for urgent studies created by an unexpected opportunity to study unusual research patients." The GAC must also designate for each protocol, the category, i.e., A (Research Patient), B (Research Service Patient) or D (Industry-Initiated Patient), of inpatient research days and outpatient visits. "The GAC should also review periodically CCRC operations to ensure that CCRC resources are used for the most scientifically justified and relevant projects." See NCRR Guidelines.

21. In addition to the NIH provisions, HHS regulations provide that HHS grant funds shall be expended solely in accord with the approved grant application and budget, the terms and conditions of the award, and the applicable cost principles set forth in 45 C.F.R. Part 74. See also 42 C.F.R. Part 52, 42 C.F.R. § 52.6(a).

22. Grant funds may be expended only for the allowable costs of the activities for which the grant was awarded. 42 U.S.C. § 284; 42 C.F.R. § 52.6; 45 C.F.R. §§ 74.27, 74.73.

23. In or about January 23, 1997, Weill Medical College submitted a competitive renewal application for Grant No. 5M01RR006020 seeking an award on a discrete budget basis to continue to operate its CCRC for an additional five-year period.

Weill Medical College submitted a second renewal application in connection therewith on January 12, 1998. The NIH provisionally approved Weill Medical College's application with a Notice of Grant Award on or about January 27, 1998, and finally approved it on or about March 24, 1999. Thereafter, on an annual basis, Weill Medical College submitted to NIH non-competitive renewal applications for each of the five grant years awarded, as well as annual progress reports.

24. As with its competitive renewal application, in each annual non-competitive renewal application, Weill Medical College was required to submit a proposed budget that included, inter alia, identification of the investigators and the research projects, including, inter alia, the projected number of A (Research Patient) and B (Research Service Patient) in-patient and out-patient days that Weill Medical College proposed to use on the CCRC during the renewal year.

25. The applicable NIH Guidelines required Weill Medical College, when listing the projects or research protocols in its application schedules, to "[e]xclude completed or inactive projects. All projects should be included, even if they are awaiting approval by the [SAC] or the [Institutional Review Board or ("IRB")] at the time of submission of the application. Indicate in a footnote those projects not yet approved at the time the application is submitted." See NIH Guidelines.

26. In addition to the competitive renewal filed by Weill Medical College for Year 9 (for the period December 1, 1998 through November 30, 1999), during the period relevant hereto, Weill Medical College filed non-competitive grant renewals for Year 10 (December 1, 1999 through November 30, 2000), Year 11 (December 1, 2000 through November 30, 2001), Year 12 (December 1, 2001 through November 30, 2002), and Year 13 (December 1, 2002 through November 30, 2003).

27. Weill Medical College, as an entity that bills the Medicaid program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 et seq., is subject to all federal laws, regulations, and policies that pertain to the Medicaid program.

28. Weill Medical College fraudulently concealed from the United States its wrongdoing in connection with the allegations made herein.

II. Weill Medical College Consistently and Knowingly Exceeded the 33 Percent Guideline and Made False Statements to NIH

A. Weill Medical College's Internal Data Shows It Violated the 33 Percent Guideline

29. As the recipient of millions of dollars in federal grants, Weill Medical College was responsible for adhering to the 33 Percent Guideline in its administration of the CCRC. However, Weill Medical College consistently and purposefully failed to abide by the 33 Percent Guideline almost across the board each year in both it's a in-patient and out-patient, and B in-patient

and out-patient use of the CCRC, and falsely projected use of the CCRC by its investigators in the research protocols as identified in its applications for renewal of the grant.

30. Moreover, top officials at Weill Medical College, including the Principal Investigator of the grant, who was the official responsible for the scientific and technical direction of the CCRC, knew that the CCRC Program Director dominated the use of the CCRC with her protocols and patient admissions, that a second physician-investigator consistently used CCRC resources in excess of the 33 Percent Guideline with admissions under a hematology/oncology protocol (the "Hematology/Oncology Investigator"), and that, over all, research relating to pediatric-endocrinology accounted for more than 33 percent of the use of the CCRC, and that often, research relating to hematology/oncology accounted for more than 33 percent of the use of the CCRC.

31. In particular, the database -- or CAMP system -- used by Weill Medical College to track the actual, as opposed to the projected, use of the CCRC shows the following: For Grant Year 7, the Program Director, who is a pediatric endocrinologist, had 221 out of 554 A in-patient days for 39.89% of CCRC use; 82 out of 180 A out-patient days for 45.56% of CCRC use; 108 out of 193 B in-patient days for 55.96% of CCRC use; and 15 out of 22 B out-patient days for 68.18% of CCRC use.

32. For Grant Year 8, the Program Director had 236 out of 659 A in-patient days for 35.81% of CCRC use; 61 out of 92 A out-patient days for 66.30% of CCRC use; 190 out of 357 B in-patient days for 53.22% of CCRC use; and 13 out of 26 B out-patient days for 50% of use.

33. For Grant Year 8S1, the Hematology/Oncology Investigator had 199 out of 434 A in-patient days for 45.85% of CCRC use; the Program Director had 106 out of 187 B in-patient days for 56.68% of use; the Program Director had 73 out of 101 A out-patient days for 72.28% of use; and the Hematology/Oncology Investigator had 88 out of 248 B out-patient days for 35.48% of CCRC use.

34. For Grant Year 9, the Hematology/Oncology Investigator had 267 out of 741 A in-patient days for 36.03% of CCRC use; and the Program Director had 196 out of 233 A out-patient days for 84.12% of CCRC use.

35. For Grant Year 10, the Hematology/Oncology Investigator had 401 out of 950 A in-patient days for 42.21% of CCRC use; the Program Director had 335 out of 950 A in-patient days for 35.26% of CCRC use; the Program Director had 190 out of 211 A out-patient days for 90.05% of CCRC use; and the Program Director had 93 out of 242 B in-patient days for 38.43% of CCRC use.

36. For Grant Year 11, the Program Director had 134

out of 229 A out-patient days for 58.52% of CCRC use; and 162 out of 224 B in-patient days for 72.32% of CCRC use.

37. For Grant Year 12, the Program Director had 169 out of 342 A in-patient days for 49.42% of CCRC use; 173 out of 307 A out-patient days for 56.35% of CCRC use; 46 out of 83 B in-patient days for 55.42% of CCRC use; and 302 out of 508 B out-patient days for 59.45% of CCRC use.

38. For Grant Year 13, the Program Director had 105 out of 132 A out-patient days for 79.55% of CCRC use; and 235 out of 352 B out-patient days for 66.76% of CCRC use.

39. Moreover, Weill Medical College's internal documents show that, on a divisional basis, for Grant Year 6, with respect to A in-patients, endocrinology research protocols accounted for 58.8% of the CCRC's use; for Grant Year 7, endocrinology research protocols accounted for 49.3% of the CCRC's use; and for Grant Year 8, endocrinology research protocols accounted for 43.3% of the CCRC's use.

40. Other Weill Medical College internal documents that tracked admissions for the period 1999 through 2002 show that endocrinology and hematology/oncology protocols consistently accounted for use in excess of that permitted by the 33 Percent Guideline both on an in-patient and an out-patient basis. In particular, with respect to in-patient use, for Grant Year 9, hematology/oncology protocols accounted for 36% of the A in-

patient CCRC use, and endocrinology accounted for 46% of B in-patient CCRC use. For Grant Year 10, endocrinology protocols accounted for 35% of A in-patient CCRC use, and hematology/oncology protocols accounted for an additional 43% of A in-patient CCRC use, and endocrinology protocols accounted for 42% of B in-patient CCRC use. For Grant Year 11, endocrinology protocols accounted for 37% of A in-patient CCRC use, and endocrinology protocols accounted for 75% of B in-patient use. For Grant Year 12, endocrinology protocols accounted for 52% of A in-patient CCRC use, and endocrinology protocols accounted for 62% of B in-patient CCRC use.

41. With respect to out-patient use, Weill Medical documents show that: For Grant Year 9, endocrinology protocols accounted for 49% of A out-patient and 49% of B out-patient CCRC use, while hematology/oncology protocols accounted for 43% of B out-patient use. For Grant Year 10, endocrinology protocols accounted for 64% of A out-patient and 35% of B out-patient CCRC use, while hematology/oncology protocols accounted for 61% of B out-patient CCRC use. For Grant Year 11, endocrinology protocols accounted for 60% of A out-patient and 39% of B out-patient CCRC use, while hematology/oncology protocols accounted for 43% of B out-patient CCRC use. For Grant Year 12, endocrinology accounted for 56% of A out-patient and 76% of B out-patient CCRC use.

B. NIH's Warning to Weill Medical College About the 33 Percent Guideline

42. On March 15, 2000, NIH explicitly advised top officials at Weill Medical College, including the Principal Investigator and the Program Director, that, at least with respect to the projections in the budget submitted in connection with Weill Medical College's non-competitive renewal for Year 10, Weill Medical College's application showed that the Program Director had requested use of 44% of the CCRC resources in violation of the 33 Percent Guideline. NIH told Weill Medical College that "[i]n accordance with GCRC Guidelines, request is made to reduce [the Program Director's] utilization to no greater than 33% of the total A days to be used on [CCRC]."

43. Weill Medical College's internal documents show that it purposefully delayed responding to NIH's direction until after the next SAC meeting on April 18, 2000, at which time the SAC would consider the approval of four new research protocols that had been presented by addendum.

i. Weill Medical College's False Statements Concerning the Need for Additional A In-Patient Days

44. Meanwhile, on April 10, 2000, Weill Medical College sought from NIH an increase in the number of A in-patient days that had been awarded under the grant. In connection with this request, Weill Medical College falsely represented to NIH that "there [were] currently four new protocols pending in the

[SAC] that will require the availability of A bed days."

45. One of these protocols – Protocol Number 0698-259 – involved the use of a video tape and was entitled "Video Instructions (on burn care): Its Impact on Patient Comprehension and Compliance." The protocol does not require the use of A in-patient days, but instead relates to the viewing of a videotape about burn care for children, and the subsequent taking of a written examination by parents to test the knowledge that they have gained from the videotape. This protocol was never used at Weill Medical College.

46. Another protocol – Protocol Number 0400-172 – was entitled "An Evaluation of the Safety and Pharmacokinetics of Single, Escalating Oral Doses of FTC in HIV-1 Infected or Exposed Pediatric Patients Aged Less Than 18 Years Old". It involved a projected total of 8 in-patient days. While it was approved by the SAC on May 26, 2000, effective April 18, 2000, for use on the CCRC, there never were any admissions under it. In any event, this was to be a D study (Industry-Initiated) – not an A study (Research Patient) – so it was completely irrelevant for purposes of an award of A days.

47. Another protocol – Protocol Number 0999-873 – was entitled "The T Cell Abnormality in Immune Mediated (Type 1) Diabetes." This was also approved by the SAC for use on the CCRC effective April 18, 2000. However, this protocol, which

essentially involved a blood test, did not utilize any A in-patient days in Year 10. Indeed, there was only one A in-patient day ever used under this protocol and that was in Year 11.

48. The fourth protocol - Protocol Number 1099-909 - was entitled "A Vaccine For Immune Mediated Diabetes." There were no A in-patient visits under this protocol ever; let alone in Year 10. Indeed, it is unlikely that any in-patient visits in Year 10 were truly anticipated. See Paragraphs 66, 88 and 90, infra.

**ii. Weill Medical College's False Statements
"Clarifying" the Program Director's Use of
the CCRC**

49. Meanwhile, in an April 10, 2000 letter to NIH, Weill Medical College stated that it wanted to "clarify" the issue NIH had raised on March 15, 2000 concerning the Program Director's use of A inpatient days. Weill Medical College told NIH that the number of the Program Director's days reported in Schedule 1 was based on "SAC application of estimates of maximum number of possible patients rather than actual numbers," and that "endocrine protocols for which [the Program Director] is not the [principal investigator] centering on behavioral or psychological evaluation were erroneously attributed [to her]" in the original schedule submitted with the non-competitive renewal.

50. While Weill Medical College's April 10, 2000 letter does not identify these "endocrine protocols," they could

only be Protocol Number 1196-570 entitled "Psychologic Development After Early-Prenatal Dexamethasone Exposure," and Protocol Number 1296-623 entitled "Psychobiology of Congenital Adrenal Hyperplasia."

51. Previously, in Weill Medical College's annual progress report for Year 9, submitted to NIH and signed by the Program Director on April 17, 2000, Weill Medical College identified the Program Director as the principal investigator for Protocol Number 1196-570, and that the Program Director had two large grants in her name "Directly Supporting This Study" which listed her as principal investigator.

52. Furthermore, in Weill Medical College's annual progress report for Year 10, signed by the Program Director on June 18, 2001, Weill Medical College continued to identify the Program Director as the principal investigator for Protocol Number 1196-570, and that she had one large grant in her name "Directly Supporting This Study" which listed her as principal investigator.

53. Moreover, all IRB approvals subsequent to Year 10 for the renewal of Protocol Number 1196-570, and Weill Medical College's filings with NIH identify the Program Director as the principal investigator for this protocol. This was consistent with an internal census activity report prepared by Weill Medical College from the CAMP system which showed that, in the prior Year

9, the Program Director used 75 in-patient days under this protocol Number as the principal investigator.

54. As for Protocol Number 1296-623, Weill Medical College's annual progress report for Year 10 identified the Program Director as the principal investigator. This did not change until Year 11 and Year 12 when an investigator from Columbia University was identified as the principal investigator.

**iii. Weill Medical College's False Statements
in Its Revised Schedule**

55. On April 24, 2000, after the April 18, 2000 SAC meeting, Weill Medical College wrote to NIH addressing the issue of the Program Director's use of the CCRC for Year 10. Attached to the letter was a revised schedule for the continuing grant application that showed a projected reduction in the Program Director's use for Year 10.

56. A Weill Medical College internal spreadsheet version of the revised schedule quantifies the reduction in use at 32 percent, which - if true - would comply with the 33 Percent Guideline. The revised schedule reduces the Program Director's projected use from 810 days to 575 days - in other words, takes from the Program Director 235 of the days that were previously identified under her protocols in the original schedule.

57. Standing alone the reduction of such a large number of days potentially had an impact on the grant. It could affect (1) the number of A in-patient days that NIH would award

Weill Medical College under the grant; and (2) the in-patient A ancillary reimbursement rate that would be awarded by NIH. As a result, upon information and belief, Weill Medical College undertook to reduce the Program Director's projected use to 32 percent all the while keeping its projected numbers at the same level as reported in the original schedule submitted to NIH in order to preserve the budgetary status quo of its continuing grant application.

58. Upon information and belief, Weill Medical College, knowing that it was under scrutiny by NIH, reviewed the true performance of all the protocols that it had identified on the original schedule, dropped from its revised schedule protocols that were not in actual use on the CCRC and/or did not have SAC approval, as required by NCRG Guidelines (see supra at Paragraph 25), and massaged the projected in-patient use on a protocol by protocol basis to reduce the Program Director's projected use to 32 percent yet maintain the total projected number of A in-patient days upon which the application for the award was based.

59. In particular, comparison of the original schedule submitted to NIH with the revised schedule submitted on April 24, 2000 shows that Weill Medical College continued to identify eleven protocols on the revised schedule that it had previously listed on its original schedule but that it eliminated five of

the protocols previously identified on that same schedule. All but one of the eleven protocols kept by Weill Medical College on its revised schedule had actual activity in Year 9: The one that did not was Protocol Number 0396-287, which last had activity in Y8s1.

60. Review of the actual use of the CCRC on a protocol by protocol basis makes apparent the reason for the elimination of the five protocols on the revised schedule. In particular, the projected activity on the original schedule bore no relation to actual use. For example, Protocol Number 1297-066, for which Weill Medical College had projected use at 60 A in-patient days, in fact, never admitted any patients ever.

61. Protocol Number 0296-232, for which Weill Medical College had projected use at 9 in-patient days, had last admitted a patient for 2 days in March 1998. Moreover, the file for this protocol does not show that it was ever approved for use on the CCRC by the SAC beyond its one-year renewal on February 12, 1998. Accordingly, Weill Medical College had violated NCRR Guidelines when it had identified this unapproved and inactive protocol on the original schedule.

62. Protocol Number 0894-511, for which Weill Medical College had projected use at 60 A in-patient days, had last been used in 1996 and 1997 when 23 in-patient days were used. The file for this protocol does not show that it was ever approved

for use on the CCRC by the SAC beyond its one year renewal on February 12, 1998, either. Accordingly, Weill Medical College had violated NCRR Guidelines when it had identified this unapproved and inactive protocol on the original schedule.

63. Protocol Number 1296-612, for which Weill Medical College had projected use at 200 A in-patient days, only ever used 4 A in-patient days, and those were in September and December of 1997. The file for this protocol does not show that it was ever approved for use on the CCRC by the SAC beyond its one year renewal on February 12, 1998, either. Accordingly, Weill Medical College had violated NCRR Guidelines when it had identified this unapproved and inactive protocol on the original schedule.

64. Finally, Protocol Number 1293-279, for which Cornell had projected use at 20 A in-patient days, had only used 48 A days combined in 1996 and June 1997, and 1 day in June 1998. Like the others, the file for this protocol does not show that it was ever approved for use on the CCRC by the SAC beyond its one year renewal on February 12, 1998. Accordingly, Weill Medical College had violated NCRR Guidelines when it had identified this unapproved and inactive protocol on the original schedule.

65. By eliminating these five protocols from its revised schedule, Weill Medical College lost 349 projected A in-patients days for purposes of its continuing grant application.

Thus, to maintain the level of projected numbers first identified to NIH on its original schedule, Weill Medical College had to restore these 349 days, all the while re-assigning 235 (or 810 minus 575) of the Program Director's days to maintain its total of 1,809 projected days upon which the award was based yet reduce the Program Director's use to 33 percent.

66. Weill Medical College added Protocol Number 1099-909, described in Paragraph 48, supra, and projected 100 A in-patient days for that protocol. In fact, this protocol was never used: the FDA required a Phase I safety trial in adult patients before implementing the Phase II trial on the pediatric population.

67. Weill Medical College added Protocol Number #0999-873, described in Paragraph 47, supra, and projected 100 A in-patient days for that protocol. In fact, not surprisingly because it essentially involved a blood test (see id.), this protocol only ever used 1 A in-patient day and that was in Year 11.

68. Weill Medical College added Protocol Number 0698-278, and projected 30 days of A in-patient use. This protocol actually used 14 days in Year 10, and there were no other admissions under the study.

69. Weill Medical College substituted Protocol Number 1293-279, which had been identified on the original schedule,

with Protocol Number 0595-895, and projected 20 days of A in-patient use. This latter protocol, unlike Protocol Number 1293-279, used at least 1 A in-patient day in Year 9, but it never used any days in Year 10.

70. The additions described in Paragraphs 66 through 69, supra, gave Weill Medical College's revised schedule 250 more projected A in-patient days. Yet Weill Medical College still had to find 99 additional days to restore the 349 days projected in the five eliminated protocols (250 + 99), and it had to reduce the Program Director's projected use by 235 days to get her to 575 days with a 32% usage and reassign these projected days to another investigator under different protocols.

71. Upon information and belief, Weill Medical College accomplished this task in two steps: First, in its revised schedule Weill Medical College falsely re-assigned Protocol Number 1196-570 to a different investigator than the Program Director, who had been identified as the principal investigator in the original schedule, and gave the "new principal investigator" 75 days of A in-patient use. This had the effect of giving the "new principal investigator" 55 of the Program Director's days, plus adding 20 more days to the revised schedule.

72. Next, upon information and belief, Weill Medical College arbitrarily inflated the number of A in-patient days

projected to be used under other protocols by 260 more days to arrive at the total number of projected days (1,810) identified in its original schedule, and to absorb the "lost" days previously assigned to the Program Director. The arbitrariness of the inflations is borne out by the prior year's projection schedule, which shows that on the original schedule, Weill Medical College, again, for the most part, just carried over the projected numbers from Year 9. Once the inflated numbers were part of the revised Year 10 schedule, these numbers, for the most part, were carried over into the projections for Years 11 and 12 regardless of whether there was any activity under the protocols in Years 10 and 11. See, e.g., Paragraphs 66-69, supra.

73. Finally, when, in the revised schedule submitted to NIH, Weill Medical College adjusted the Program Director's projected use downward to reach the 32%, it did so without regard to the truth or falsity of its asserted new "projections." For example, for Protocol Number 0296-223, the revised schedule projected the Program Director's use at 70 A in-patient days for the year. Yet, the CAMP database shows that, as of April 24, 2000, the day Weill Medical College submitted the revised schedule to NIH, the Program Director had already used 145 A in-patient days under this protocol - more than twice the amount in the "revised projection" submitted to NIH in connection with its continuing grant application.

iv. Weill Medical College's Continued False Statements Made to Obtain More A In-Patient Days

74. On May 3, 2000, Weill Medical College gave NIH an "update" on its need for more A inpatient days. Absent from the update was any mention of the four protocols pending SAC review that had been the basis for the request not even four weeks earlier on April 10, 2000. See supra at Paragraphs 44-48. Instead, Weill Medical College claimed it needed more days for two protocols with "anticipated admissions." A spreadsheet that identified "Scheduled Admissions" for two old protocols was included: An Oral Iron Chelation for Thalassemia (Protocol Number 0294-341); and the Crigler-Najjar Type I Syndrome (Protocol Number 1197-029 or the "Crigler-Najjar protocol").

75. With respect to Protocol Number 0294-341, Weill Medical College already knew this protocol was a high user of CCRC resources since it had been tracked on the internal spreadsheet since 1994-95 and 1995-96 when it was run by a prior principal investigator, and then again in 1996-97.

76. On May 12, 2000, Weill Medical College again wrote to NIH claiming that the shortage of A days "represents a serious difficulty for us and we do not wish to discourage our new investigators." There were no "new investigators," however.

77. The subsequent A activity for Year 10 - after NIH

permitted Weill Medical College to re-budget to add 100 additional A in-patient days shows that no "new investigators" used the CCRC. The only investigators who used it after May 12, 2000, besides those whose protocols had used it prior to that date, were two investigators whose protocols had been initiated some years previously. In particular, one of the investigators had initiated his protocol in August 1994, and, on September 28, 2000, admitted 1 patient - status post bone marrow transplant - for 1 day on the CCRC. As for the other "new investigator", in July and August 2000, he admitted 8 patients under Protocol Number 0698-278 for a grand total of 14 A in-patient days.

78. Nevertheless, on May 15, 2000, Weill Medical College again wrote to NIH claiming it had that very day received a request from an investigator to admit a patient from Egypt on the Crigler-Najjar protocol. This protocol had been previously mentioned in Weill Medical College's May 3, 2000 letter to NIH in which it claimed there were two patients with "scheduled admissions" totaling 300 days from June through November 2000.

79. Weill Medical College did not tell NIH whether this patient is one of the two patients referred to in its May 3rd letter. But it claimed that it needed at least two months for planning, and that it would try to delay the patients' admission until August or September.

80. Nor did Weill Medical College tell NIH that -

notwithstanding that just two months earlier NIH had warned Weill Medical College about the Program Director's over use of the CCRC - it was business as usual on the CCRC. Of the 94 in-patient A admissions between April 10, 2000, when Weill Medical College first sought an award of additional A in-patient days and May 15, 2000, more than 50% of A in-patient days used were by the Program Director. Weill Medical College also did not disclose that the Hematology/Oncology Investigator's use accounted for 36.2% of the other days used.

81. On May 26, 2000, NIH agreed to permit Weill Medical College to reallocate patient days among A, B, C and D day categories in order to increase its award to 700 A days, but with no cost to the grant.

82. Nevertheless, on July 26, 2000, Weill Medical College again wrote NIH: "[w]e wish to impress upon you the urgency of this matter in view of the following: ... one of the foremost experts on the Crigler-Najjar Type 1 Syndrome, has two patients who must be admitted to the [CCRC] before December 1st. Without the additional 100 A inpatient days, we shall have to tell [this investigator] that he may not execute [the Crigler-Najjar protocol]."

83. But, this investigator had already seen two patients in Year 10 under the Crigler-Najjar protocol: One with an admission on August 15, 1999 and a discharge on January 28,

2000, and the other with an admission on October 22, 1999 and a discharge on January 16, 2000, for a total of 105 A in-patient days in Year 10. Moreover, this investigator was never told by Weill Medical College that he could not have access to the CCRC for his patients and he was never denied use of it when he required it for research under this protocol.

84. Moreover, this investigator never had four patients enrolled in this protocol, only three, with the first two patients admitted as discussed in Paragraph 83, supra, and the third patient admitted in Year 11. But even if this investigator had another patient or required an admission in Year 10, on June 20, 2000 more than a month before Weill Medical College wrote its July 26, 2000 letter to NIH claiming that it needed an award of more A in-patient days for this protocol, Weill Medical College already had made its own internal decision to arrange for any patients enrolled in this protocol to be outpatients so that "they would have the freedom of staying at an outside facility during their research participation because of the length of the study."

85. Finally, contrary to Weill Medical College's statement to NIH in its July 26, 2000 letter to the effect that "[w]e have already had to postpone or cancel other prospective admissions due to our lack of available A inpatient days," no users of the CCRC were denied access to the facilities if they

needed it to conduct research on their approved protocols.

86. In fact, from July 26, 2000 through to the end of the Year 10, excepting use by the Hematology/Oncology Investigator, and 3 A in-patient days used by an investigator on a genetics protocol, all the A in-patient days were used for endocrinology protocols – with the most days by far at 85 – used by the Program Director.

87. And, notwithstanding the revised schedule sent to NIH on April 24, 2000 in response to NIH's clear direction concerning the 33 Percent Guideline, the Program Director finished Year 10 with 35.26% of the A in-patient visits, and the Hematology/Oncology Investigator with 42.21% of CCRC use, both in violation of the 33 Percent Guideline.

**v. Weill Medical College's False Statements
In Its Year 10 and 11 Annual Progress Reports
Concerning Protocol Number 1099-909**

88. On or about January 8, 2001, the principal-investigator for Protocol Number 1099-909, advised the Weill Medical College Institutional Review Board (the "IRB") that his protocol had not been initiated because the FDA required a Phase I safety trial in adult patients. See also Paragraph 66, supra.

89. Notes by a Weill Medical College IRB reviewer dated January 29, 2001 show that, given the FDA request for the Phase I adult trial, the "study has not begun and it will probably not begin for at least another year," and that the

"protocol is essentially on hold - no patients may be enrolled until the Phase I study is complete."

90. On January 29, 2002, the IRB terminated the protocol because the principal-investigator did not submit it for annual renewal.

91. However, in addition to continuing to include this protocol in its projections in its grant renewal applications, in its annual progress report for Grant Year 10, signed by the Program Director on or about June 18, 2001 -- six months after the principal-investigator told the IRB about the Phase I safety trial in adult patients --, Weill Medical College told NIH "[n]o patient has yet been studied since the FDA ha[s] requested many additional safety studies in mice. These have now been completed and the FDA submission will soon be returned."

92. And, in its annual progress report for Grant Year 11, signed by the Program Director on or about April 5, 2002 -- three months after the IRB terminated Protocol Number 1099-909 --, Weill Medical College falsely told NIH that the protocol was active, and reported 1 A in-patient visit and 1 B out-patient visit under the protocol for that grant year.

vi. Weill Medical College's SAC and Its Principal Investigator Completely Abdicated Their Oversight Responsibility

93. Indeed the CCRC projected use, as reported in revised schedule sent to NIH on April 24, 2000, and as reported

in every continuing grant application that Weill Medical College submitted to NIH, bears no relation to actual use. For the most part, Weill Medical College simply carried forward the projected numbers for each protocol into the projections for the next grant year regardless of whether the protocol was "live," meaning whether the protocols had any activity in the prior year, whether it was anticipated that the protocols would actually be used in the new grant year, and in some cases whether the protocols had even been renewed and approved for use on the CCRC by the SAC.

94. The SAC failed in its oversight function of the CCRC by allowing the Program Director and the Hematology/Oncology Investigator to dominate the resources of the CCRC in violation of the 33 Percent Guideline. See also Paragraphs 17, 19 and 20, supra.

95. The SAC failed in its oversight function of the CCRC by allowing protocols to be identified (with patient use projections) on the schedules submitted to NIH seeking continuing grant application renewals when those protocols were not approved and had not been renewed for use on the CCRC. See also Paragraphs 17, 19, 20, 24 and 25, supra.

96. The Principal Investigator failed in his responsibility for the scientific and technical direction of the CCRC under the Grant No. 5M01RR006020 when he failed to ensure that the physicians who used the CCRC adhered to the 33 Percent

Guideline, and that all of the information in the continuing grant applications, including its schedules, and in the annual progress reports submitted to NIH was complete and accurate. See also Paragraph 16, supra.

97. The fact that the CCRC was being dominated by the Program Director and the Hematology/Oncology Investigator would have been material to NIH's decision to fund the CCRC at Weill Medical College, and NIH would not have made its award if it had known that certain investigators and the pediatric-endocrinology division dominated the use of the CCRC in violation of the 33 Percent Guideline.

III. Weill Medical College's Failure To Account For Its Outpatient Use Awarded Under The Grant

98. Weill Medical College's method for accounting for the outpatient visits charged to Grant No. 5M01RR006020, by its own admission, was "lackadaisical," the accounting work was not performed in a "routine manner," and there were "big holes in the information given to [the Grant Administrator]," who was responsible for inputting the information on the CAMP system, which was then reported to NIH.

99. The original source documents for inputting the out-patient information into the CAMP system were patient routing sheets, and log scheduling data. Even though there are places on the routing sheets for entries concerning the type of protocol, the type of patient research activity, and the name of the

investigator, this information is missing from a large portion of the original source documents. Accordingly, a number of entries for out-patient visits charged to the grant as reported in the CAMP system are completely unsupported by the contemporaneous documents.

**IV. Weill Medical College Charged To The Grant Services
For Two "Private Patients"**

100. Weill Medical College charged Grant No. 5M01RR006020 with costs associated with medical care received by two CCRC Grant Administrators. Neither Grant Administrator was a pediatric patient at the time of treatment, nor did they become enrolled in any protocols approved for use on the CCRC as pediatric patients.

101. The first Grant Administrator was approached informally in her work-space by a physician-investigator concerning a medical condition. It was suggested that the Grant Administrator receive a blood test, and then meet with two investigators to discuss the results. After doing so, the Grant Administrator received a recommendation for treatment, which did not involve the prescription of any drugs. There is no evidence that the Grant Administrator actually participated in any protocols, even though the services provided to her were charged to the grant.

102. Similarly, the second Grant Administrator was approached informally in her work-space by a Weill Medical

College physician concerning her physical condition, and the possibility that she was at risk for a medical condition. This Grant Administrator underwent at least one test, and had a few visits with the physician, who considered her to be a private patient, and who has no recollection or knowledge of whether this Grant Administrator was ever enrolled in a randomized pediatric clinical trial approved for the CCRC under which her test and visits were charged to the grant.

V. Weill Medical College Enrolled Adult Patients In Pediatric Protocols Approved For Use On The CCRC And Charged Services Relating To Their Treatment To The Grant

103. The Program Director improperly used the resources of the CCRC – a pediatric unit – for her adult patients. Weill Medical College's CAMP system shows that, for the period encompassed on the system, the Program Director treated 394 patients on the CCRC who were born prior to 1980 – in other words, who were at least 23 years old.

104. Review of a small random sample of medical records of patients who were treated on the CCRC showed that at least five of eight patients (or 62.5%) in this group of 374 treated by the Program Director first came to the CCRC as adult patients.

105. Top officials at Weill Medical College knew that the Program Director used the CCRC to treat her adult patients, and, upon her replacement, the new Program Director instructed her to cease using the CCRC for these adult patients.

VI. Weill Medical College Charged The Grant For In-Patient Nursing Services That It Never Received

106. In Grant Years 7 through 8S1, NIH paid Weill Medical College for in-patient nursing costs on a per diem unit basis at only four to five full time equivalents ("FTEs").

107. In Grant Year 9, in which Weill Medical College applied for and was awarded a competitive renewal of Grant No. 5M01RR006020 on a discrete unit basis, NIH approved nursing costs 13.5 FTEs, and paid Weill Medical College in accord with its budgeted nursing costs.

108. In Grant Year 10, Weill Medical College applied for and NIH approved nursing costs at 14 FTEs and again paid Weill Medical College in accord with its budgeted nursing costs.

109. Weill Medical College itself did not employ nurses. Instead, it purchased the services of nurses employed by NYPH to work on the CCRC.

110. In both Grant Year 9 and Grant Year 10, Weill Medical College paid NYPH based upon the budgeted nursing costs as set forth in Weill Medical College's grant renewal applications, and not based on the actual costs incurred by Weill Medical College, even though Weill Medical College drew down from the government all of the money allotted for nursing in its continuing grant applications.

111. On August 16, 2000, Weill Medical College notified NYPH that the actual costs for nursing services on the CCRC were

considerably less than the costs that had been budgeted and awarded as per the continuing grant applications because not all of the nursing positions identified to NIH had been filled. However, Weill Medical College told NYPH that it had paid NYPH for the full costs associated with the nursing FTEs awarded by NIH for Grant Years 9 and 10, and "[t]herefore, the NIH CCRC funds paid to Nursing exceed NYPH expenditure for the CCRC."

112. On September 15, 2000, Weill Medical College again notified NYPH that "The National Institutes of Health" paid for nursing services that had not been performed on the CCRC.

113. On September 18, 2000, Weill Medical College notified NYPH that CCRC nurses paid for under the grant "are being pulled from the CCRC to staff the floor." Weill Medical College told NYPH that "[t]he current practice of using our nurses to cover other units without due consultation and consideration could be considered a misuse of federal funds and must cease."

114. On December 28, 2000, Weill Medical College notified NYPH that as of that date four of the nurses whose salaries were being paid 100% by the grant did not work 100% on the CCRC, and that for at least a three month period in Year 10, these four nurses had spent only six out of ninety days working on the CCRC. Weill Medical College further admitted that "[t]he NIH believes that the CCRC nurses are working only on the CCRC

because we are paying 100% of their salary and fringe benefits."

115. Weill Medical College did not return to the government the funds that it had drawn down to pay the salaries of the nurses who were not working on the CCRC, nor did Weill Medical College tell the NIH that it was not receiving the nursing services that it had requested and had been awarded under the grant.

116. Moreover, in its non-competitive renewal application for Grant Year 11, Weill Medical College asked for and was awarded 14.5 FTEs for nursing services, even though Weill Medical College knew that it had not fully utilized the 14 FTEs that it had been awarded by NIH in Grant Years 9 and 10.

117. On July 17, 2001, Weill Medical College, apparently concerned that it would be subject to a government audit, told NYPH that "We have not had the appropriate number of nurse FTEs assigned to the CCRC since the competing renewal started in December 1999." And that, the payroll data showed that Weill Medical College had used grant funds to pay for "four full time nurses who have virtually never worked on the CCRC." (Emphasis supplied).

118. An internal Weill Medical College document shows that, on August 14, 2001, the Principal Investigator was advised that Weill Medical College might be subject to a "repayment requirement" on the CCRC because Weill Medical College had used

government money to pay NYPH for nursing services based on the grant budget rather than based on the actual services that had been provided under the grant.

119. Neither the Principal Investigator, nor any other official at Weill Medical College took any action to return to the government the funds that it had drawn down to pay the salaries of the nurses who were not working on the CCRC, or otherwise disclose to NIH that it had not received the nursing services that Weill Medical College charged to the grant.

120. On September 10, 2001, the Weill Medical College Associate Dean, Responsible Conduct of Research, Institutional Official - the official in charge of compliance for Weill Medical College - was told by the Program Director that "[t]he grant has been charged for nurses who have not worked on the CCRC. Thus, this is a charge for services not rendered." Nevertheless, neither the Associate Dean, nor any other official at Weill Medical College took any action to return to the government the funds that Weill Medical College had drawn down to pay the salaries of the nurses who were not working on the CCRC, or otherwise disclose to NIH that it had not received the nursing services that Weill Medical College charged to the grant.

121. In addition to the fact that Weill Medical College drew down grant funds for nursing costs that the CCRC never received, there were three nurses who were identified by name and

had their salaries included in Weill Medical College's grant renewal applications for Grant Years 12 and 13, even though these three nurses had not worked for NYPH since the end of Grant Year 10.

122. The fact that these nurses were not replaced by other nurses on the CCRC, and yet salary requests for them and/or their replacements continued to be made for them in subsequent grant years would have been material to NIH's funding decision.

123. If NIH had known that Weill Medical College had never replaced these nurses, and ipso facto that the nursing services were not in fact necessary to the CCRC, NIH would not have awarded salaries for these three nursing positions in Grant Years 12 and 13.

124. Weill Medical College fully understood the import of its continued requests for the payment of salary support for nursing positions that were never filled: In an internal memo, which, upon information and belief was prepared after October 2002, Weill Medical College acknowledged that if it was not using the nurse funding that it had requested from the government, "we probably should not be requesting it in the first place." But that if Weill Medical College were to return the nursing salaries to the government, Weill Medical College acknowledged that it would reflect negatively on their grant showing "low census" (meaning actual patient use of the CCRC), and that "too many

nurses have been awarded to us."

VII. Weill Medical College Charged The Grant For The Full Salaries Of Certain Employees Who Did Not Dedicate 100 Percent Of Their Work Activities To The Grant

125. In Grant Year 9 and continuing through Grant Year 13, Weill Medical College requested funding for, and NIH paid, one-hundred percent of the salary costs for the Grant Administrator. However, during those grant years, the Grant Administrator only spent fifty percent of her work effort on CCRC activities, and spent the remaining fifty percent of her work effort on the non-government funded business of the Weill Medical College Pediatric Endocrinology Division, and the non-government funded business of the chairman of that division.

126. In addition, Weill Medical College requested funding for, and NIH paid in Grant Years 7 through 13, one-hundred percent of the salary costs for four laboratory technicians, one laboratory aide, and one out-patient nurse, even though those employees did not dedicate one-hundred percent of their work effort to CCRC activities, and instead spent a portion of their time on the non-government funded business of the Weill Medical College Pediatric Endocrinology Division.

127. In particular, while the four laboratory lab technicians and the laboratory aide performed work on tests conducted on the CCRC for approved protocols, fifty percent of their work effort was spent on performing non-granted related

tests or work for the Pediatric Endocrinology Division. And, while the CCRC out-patient nurse performed work on the CCRC, approximately fifty percent of her time was spent drawing blood and servicing private insurance patients.

128. The Grant Administrators and the Program Director were fully aware of the circumstances surrounding these employees who had multi-departmental tasks, but whose salaries were paid 100 percent by the grant. When one Grant Administrator questioned whether the grant should be charged in full for the salaries of these employees, she was told "it was normal for resources to be used for more than just the CCRC."

VIII. Weill Medical College Billed Medicaid For Certain Physician Services Charged To The Grant

129. Weill Medical College billed the Medicaid program for twenty-three in-patient fee-for-service charges that were incurred in connection with protocols performed on the CCRC, and which charges were also paid for by the grant.

130. Weill Medical College billed the Medicaid program for fourteen out-patient fee-for-service charges that were incurred in connection with protocols performed on the CCRC, and which charges were also paid for by the grant.

131. By billing the Medicaid program for services that Weill Medical College had already charged to Grant No. 5M01RR006020, Weill Medical College fraudulently double-billed the government for these services.

132. The Medicaid program would not have paid for these services if it had known that the government had already paid for these services under Grant No. 5M01RR006020.

133. The NIH would not have paid for these services under Grant No. 5M01RR006020 if it had known that the Medicaid program had paid for these services on a fee-for-service basis.

FIRST CLAIM

**Violations of the False Claims Act
(31 U.S.C. § 3729(a)(1))**

134. The United States incorporates by reference paragraphs 1 through 133 above as if fully set forth herein.

135. The United States seeks relief against defendant Weill Medical College under Section 3729(a)(1) of the False Claims Act, 31 U.S.C. § 3729(a)(1).

136. As set forth above, defendant Weill Medical College knowingly, or with reckless disregard for the truth, presented and caused to be presented to an officer, employee or agent of the United States, false or fraudulent claims for payment, in connection with (1) its administration of Grant No. 5M01RR006020, including but not limited to, its application for competitive renewal in Year 9, and its continuing grant applications to NIH, and draw downs of funds; and (2) its requests for reimbursement under the Medicaid program.

137. The United States paid Weill Medical College under Grant No. 5M01RR006020 and under the Medicaid program because of

the fraudulent acts and conduct of defendant Weill Medical College.

138. By reason of these false claims, the United States has sustained damages in a substantial amount to be determined at trial.

SECOND CLAIM

**Violations of the False Claims Act
(31 U.S.C. § 3729(a)(2))**

139. The United States incorporates by reference paragraphs 1 through 133 above as if fully set forth herein.

140. The United States seeks relief against defendant Weill Medical College under Section 3729(a)(2) of the False Claims Act, 31 U.S.C. § 3729(a)(2).

141. As set forth above, defendant Weill Medical College knowingly, or in reckless disregard for the truth, made, used, and caused to be made and used, false records and statements, to get false and fraudulent claims paid or approved by the United States in connection with (1) its administration of Grant No. 5M01RR006020, including but not limited to, its application for competitive renewal in Year 9, and its continuing grant applications to NIH, and draw downs of funds; and (2) its request for reimbursement under the Medicaid program.

142. The United States paid such false or fraudulent claims because of the acts and conduct of defendant Weill Medical College.

143. By reason of these false claims, the United States has sustained damages in a substantial amount to be determined at trial.

THIRD CLAIM

Common Law Fraud

144. The United States incorporates by reference paragraphs 1 through paragraph 133 above as if fully set forth herein.

145. Defendant Weill Medical College made material misrepresentations of fact to the United States with knowledge of, or in reckless disregard of, their truth, through (1) its administration of Grant No. 5M01RR00602, including but not limited to, its application for competitive renewal in Year 9, and its continuing grant applications to NIH, and draw downs under Grant No. 5M01RR00602; and (2) its requests for reimbursement under the Medicaid program.

146. Defendant Weill Medical College intended that the United States would rely upon the accuracy of the false representations referenced above.

147. The United States made substantial payments of money under Grant No. 5M01RR00602 and under the Medicaid program in justifiable reliance upon defendant Weill Medical College's false representations.

148. Defendant Weill Medical College's actions caused

the United States to be damaged in a substantial amount to be determined at trial.

FOURTH CLAIM

Unjust Enrichment

149. The United States incorporates by reference paragraphs 1 through 133 above as if fully set forth herein.

150. By reason of the payments by the United States to defendant Weill Medical College, based on the claims for payment submitted by defendant Weill Medical College under Grant No. 5M01RR00602, and under the Medicaid program, defendant Weill Medical College was unjustly enriched. The circumstances of defendant Weill Medical College's receipt of these payments are such that, in equity and good conscience, defendant Weill Medical College should not retain these payments, the amount of which is to be determined at trial.

FIFTH CLAIM

Payment Made Under Mistake of Fact

151. The United States incorporates by reference paragraphs 1 through 133 above as if fully set forth herein.

152. The United States seeks relief against defendant Weill Medical College to recover monies paid under mistake of fact.

153. The United States paid defendant Weill Medical College under Grant No. 5M01RR00602 under the erroneous belief

that defendant Weill Medical College was entitled to payment of its budgeted funds on the ground that Weill Medical College had complied with the applicable NIH rules, guidelines, regulations, and program instructions. This erroneous belief was material to the United States' decision to make the award of and to fund Grant No. 5M01RR00602. In such circumstances, the government's payment of federal funds to defendant Weill Medical College under Grant No. 5M01RR00602 was by mistake and was not authorized.

154. The United States paid defendant Weill Medical College under the Medicaid program under the erroneous belief that defendant Weill Medical College was entitled to its claims for reimbursement and had not double-billed the government under Grant No. 5M01RR00602 for these same services. This erroneous belief was material to the United States' decision to pay Weill Medical College's claims for reimbursement. In such circumstances, the government's payment of federal funds to defendant Weill Medical College under the Medicaid program was by mistake and was not authorized.

155. Because of these payments by mistake, identified in Paragraphs 153 and 154, supra, defendant Weill Medical College has received money to which it is not entitled.

156. By reason of the foregoing, the United States was damaged in a substantial amount to be determined at trial.

WHEREFORE, plaintiff, the United States, requests that


judgment be entered in its favor and against defendant Weill Medical College as follows:

- (a) On the First and Second Claims for Relief (Violations of the False Claims Act, 31 U.S.C. § 3729(a)(1) and (2)), for treble the United States' damages, in an amount to be determined at trial, plus a \$10,000 penalty for each false claim presented prior to September 29, 1999, and a \$11,000 penalty for each false claim presented after September 29, 1999;
- (b) On the First and Second Claims for Relief, an award of costs pursuant to 31 U.S.C. § 3729(a);
- (c) On the Third Claim for Relief (Common Law Fraud), in an amount to be determined at trial, together with costs and interest;
- (d) On the Fourth Claim for Relief (Unjust Enrichment), in an amount to be determined at trial, together with costs and interest;
- (e) On the Fifth Claim for Relief (Payment Made Under Mistake of Fact), in an amount to be determined at

- (f) trial, together with costs and interest; and
- (g) awarding such further relief as is proper.

Dated: New York, New York
June 15, 2005

DAVID N. KELLEY
United States Attorney for the
Southern District of New York,
Attorney for Plaintiff the
United States of America

By: 
SHEILA M. GOWAN (SG: 8201)
KATHY MARKS (KM: 0339)
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, New York 10007
Tel. No.: (212) 637-2697

TO:
Stephen J. Immelt, Esq.
HOGAN & HARTSON LLP
111 South Calvert Street, Suite 1600
Baltimore, MD 21202

Counsel for Weill Medical College of Cornell University