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U.S. DISTRICT COURT  
EASTERN DISTRICT OF LA  
2007 JUN 14 PM 3:16  
DORETTA G. WHYTE  
CLERK

**FELONY**

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF LOUISIANA

**SUPERSEDING INDICTMENT FOR HEALTH CARE FRAUD**

UNITED STATES OF AMERICA	*	CRIMINAL DOCKET NO.	
VERSUS	*	SECTION:	<b>05 - 266</b>
MARIA CARMEN PALAZZO, M.D., Ph.D, MMM	*	VIOLATIONS:	<i>18 USC §1347</i> <i>21 USC §331(e)</i> <i>21 USC §333(a)(2)</i> <i>18 USC §2</i>
	*		
	*		
	*		

**SECT. S MAG. 1**

The Grand Jury charges that:

**AT ALL TIMES MATERIAL HEREIN:**

- The defendant, **MARIA CARMEN PALAZZO, M.D., Ph.D., MMM (PALAZZO)** was a duly licensed Medical Doctor (M.D.) specializing in psychiatry, with offices located in New Orleans, Louisiana, in the Eastern District of Louisiana. She was a Medicare "provider" authorized to submit bills for reimbursement for certain medical services to eligible Medicare beneficiaries. **PALAZZO** also earned a Ph.D in philosophy and a Masters Degree in Medical Management.
- Touro Infirmary (Touro) was a non-profit corporation with its principal place of business located at 1401 Foucher Street, New Orleans, Louisiana, which operated as a medical facility.

Fee VSA  
 Process \_\_\_\_\_  
 X Dktd \_\_\_\_\_  
 CiRmDep \_\_\_\_\_  
 Doc. No \_\_\_\_\_

**Medicare and Medicaid**

3. Medicare was a federally funded health insurance program which paid for certain inpatient medical and home health services (Part A) and outpatient medical services (Part B) provided to the elderly and to certain disabled persons. Medicare was funded with Social Security taxes and was administered by the United States Department of Health and Human Services (HHS) through the Centers for Medicare and Medicaid Services (CMS), an agency of HHS.
4. Mutual of Omaha received, adjudicated, settled and paid Medicare Part A claims for Touro pursuant to a contract with CMS. Touro submitted yearly cost reports to Mutual of Omaha to determine the proper reimbursement of costs from Medicare. Arkansas Blue Cross and Blue Shield (ABCBS) received, adjudicated and paid Medicare Part B claims submitted to it by Medicare beneficiaries (patients) or Louisiana health care providers pursuant to a contract with CMS.
5. When **PALAZZO** entered into a provider agreement with Medicare she was assigned a Provider Identification Number (PIN) which she used to bill Medicare for services provided to qualified beneficiaries. When **PALAZZO** submitted claims to Medicare for reimbursement, it was subject to the agreement and Medicare criteria, rules, regulations and internal procedures.
6. **PALAZZO** submitted Medicare Part B bills to ABCBS using a HCFA/CMS Form 1500, the recognized standard claim form in the health insurance industry. The completed form contained the date of service, the place of service, the Current Procedural Terminology code, the name of the facility where the services were rendered, the physician and the

supplier of the service.

7. The Medicaid Program was a jointly funded cooperative venture between the federal and state governments, administered by the states, that provided health care benefits for certain groups, primarily the poor and disabled.
8. Pursuant to her voluntary application, **PALAZZO** was assigned a PIN with Louisiana's Medicaid program. By signing the provider enrollment form, **PALAZZO** agreed that she would abide by all the policies and regulations of Louisiana's Medicaid Program and certified that the information contained on the claim forms she submitted was true, accurate and complete, to the best of her knowledge. **PALAZZO** also agreed that concealment of a material fact or the submission of a false or fraudulent claim could result in prosecution under applicable federal and state laws.

#### **Current Procedural Terminology**

9. The American Medical Association (AMA) assigned five-digit numerical codes to medical procedures performed by health care providers known as Current Procedural Terminology (CPT) codes. The CPT codes set forth a "systematic listing and coding of procedures and services performed by physicians." Medicare, Medicaid and insurance companies established a "usual, customary and reasonable fee" for each service rendered, as described by its corresponding CPT code. Annual CPT code books contained several codes for professional services classified as Evaluation and Management (E&M) services.
10. These E&M services are face-to-face visits made by a physician and reported by a specific CPT code. E&M CPT codes were divided into broad categories such as office visits, hospital visits and consultations. Most of the categories were further divided into

two or more sub-categories of E&M services. The subcategories were divided into levels that described the nature of physician work by type and place of service and the patient status, including the complexity of the service and the time typically required to provide the service. Fees paid were commensurate with the amount of work required.

11. CPT E&M codes 99231, 99232 and 99233 were subsequent hospital care codes which called for reviews of the medical record and the results of diagnostic studies and changes in the status of an already admitted patient. These codes stated that a physician would typically require 15, 25 and 35 minutes, respectively, at the bedside and on the patient's hospital floor or unit to perform the necessary medical services.
12. CPT E&M code 99361 was a team medical conference conducted by a physician, without the presence of the patient, with an interdisciplinary team of health professionals to coordinate activities of patient care. The expected time period for this E&M code was 30 minutes. Medicare provided no reimbursement for this service.

#### Physician Assistants

13. A Physician Assistant (PA) was a non-physician practitioner permitted by the State of Louisiana to provide medical services under the supervision of a physician. Supervision was defined as the overall direction and management of the professional activity of the PA and for assuring that the services provided were medically appropriate for the patient.
14. Medicare reimbursed PA services at eighty-five percent (85%) of the scheduled fee amount for the same service if provided by a physician. Payment was made to the PA's Medicare employer, not directly to the PA. From approximately August 2000, until about May 2002, **PALAZZO** employed a PA. During that time, Medicare assigned the PA a

PIN. When a PA provided a service to a Medicare beneficiary, the supervising physician was required to reflect on the CMS 1500 either a "AN" modifier in Item Box 24d or the PA's PIN in Item Box 33 along with the employer's name, address and where payment was to be directed.

#### **Partial Hospitalization Programs**

15. Partial Hospitalization Programs (PHP)s were structured to provide intensive psychiatric care and closely resembled that of a highly structured, short term, inpatient hospital program. The treatment goals should be measurable, functional, time-framed, medically necessary and directly related to the reason for admission. Continued treatment in order to maintain a stable psychiatric condition or functional level required evidence that less intensive treatment options could not provide the level of support necessary to maintain the patient and to prevent hospitalization. Touro operated a PHP.

#### **Medical Directorships**

16. On July 5, 2000, and July 27, 2001, **PALAZZO** entered into Professional Services Agreements (PSA) with Touro wherein the parties agreed that **PALAZZO** would provide consultation services for the Adult Psychiatric Programs at Touro.
17. On June 1, 2002, and June 1, 2003, **PALAZZO** entered into a PSA with Touro wherein the parties agreed that **PALAZZO** would provide Medical Director services for the Inpatient Adult Psychiatric and Adult PHPs at Touro.
18. Each PSA was for a one-year term and provided compensation to **PALAZZO** of up to \$144,000 per year at a rate of \$150 per hour. Each PSA required **PALAZZO** to provide Touro with a written monthly statement recording the amount of time and detailing the

services she rendered. Each PSA required **PALAZZO** to comply with all federal, state and local laws, including those associated with Medicare and Medicaid.

**THE OBJECT OF THE HEALTH CARE FRAUD SCHEMES:**

19. From a date unknown, until on or about December 31, 2003, **MARIA CARMEN PALAZZO** fraudulently obtained money from Medicare by billing for “comprehensive subsequent hospital visits” to patients which she purportedly made once a week, when in truth and fact, she did not conduct individual face-to-face visits requiring complex medical decision making. **PALAZZO’S** practice was to instead summon PHP employees to her 7<sup>th</sup> floor office to help create patient notes to facilitate a Medicare billing after all of the PHP patients left the facility for the day.
20. From August 2000 until May 2002, **PALAZZO** used a Physician’s Assistant (PA) to create false documentation supporting the appearance of daily medical visits to PHP patients to falsely and fraudulently receive money to which she was not entitled. The defendant used the false documentation to support Medicare bills for low level hospital visits to all of her patients in the PHP for 4 out of 5 weekdays per week. **PALAZZO** routinely signed and submitted false CMS Form 1500s that did not identify that her PA was the provider of the purported service for which she was billing Medicare and Medicaid, but instead falsely listed on the CMS Form 1500s that she had personally performed the services. Because **PALAZZO** had the forms submitted in this manner, Medicare paid for the services as though **PALAZZO** personally performed the service instead of paying 85% of the amount **PALAZZO** was entitled to receive if a PA performed the service. Further, no reimbursable service was provided by the PA to the

PHP patients. After the PA left **PALAZZO'S** employment, the defendant began billing CPT code 99231 services for each of her PHP patients about four days per week, although no billable service was provided.

21. As a result of the fraudulent billings described above, Medicare paid **PALAZZO** approximately \$477, 901 and Medicaid paid **PALAZZO** approximately \$175, 651.

**THE SCHEME TO DEFRAUD:**

22. Beginning in or about August 2000, and continuing until March 2005, in the Eastern District of Louisiana and elsewhere, the defendant **MARIA CARMEN PALAZZO**, did knowingly and willfully execute and attempt to execute a scheme and artifice to defraud health care benefit programs, to-wit: Medicare and Medicaid, and to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money owned by, and under the custody and control of, Medicare and Medicaid in connection with the delivery of, and payment for, health care benefits and services.
23. It was part of the scheme and artifice to defraud that **PALAZZO** employed a PA to make daily visits to the Touro in-patient and PHP units to document evidence of a patient visit when, in fact, **PALAZZO** well knew that such visits were neither reasonable or necessary, and even if they were, the visits could not be accomplished in the limited time **PALAZZO** allotted the PA. Despite the PA's request that she have an adequate opportunity to provide patient care, **PALAZZO** refused to modify the PA's schedule so that the PA could provide proper patient care. When the PA began to copy previously created notes from the patient charts to keep up with the demands of **PALAZZO**, **PALAZZO** instructed the PA that, in order to support the Medicare bills, she would have

to become more “creative” in the composing of the patient notes, while still refusing the PA’s request to change her schedule so the PA could provide real, beneficial services to the patients.

24. It was further part of the scheme and artifice to defraud that the PA was ordered to place herself in the presence of each PHP patient every weekday even if it meant merely shaking their hands or greeting them by name, in order that an invoice could be generated for each encounter. The sole purpose of each such encounter was the generation of a bill and had nothing to do with the rendering of medical services. **PALAZZO** expected the PA to create a patient progress note based upon these fleeting encounters merely to support the bill. **PALAZZO** also instructed the PA to sit in the PHP group therapy sessions to observe the patients and create progress notes which would be used to support a separate billing for CPT E&M code 99231 to Medicare and Medicaid when Palazzo well knew that the same group therapy sessions were billed to Medicare Part A by Touro. Also, the CPT E&M code that **PALAZZO** used to bill for the PA service was an individual face-fo-face visit, and not a group therapy code. In this manner, **PALAZZO** caused Medicare to be billed twice for the same service based upon the submission of the falsified bill.
25. It was further part of the scheme and artifice to defraud that even though a PA was purportedly performing medical services to be billed to Medicare and Medicaid, and there was a requirement on the CMS/HCFA 1500 that the PA be identified as the provider of the service, **PALAZZO** deliberately and falsely identified herself as the service provider to ensure that she receive 100% of the fee schedule reimbursement, rather than 85% as



would have been paid had Medicare known that the provider was a PA.

26. It was further part of the scheme and artifice to defraud that after the PA was no longer employed by **PALAZZO**, continued to falsely bill Medicare and Medicaid for CPT code 99231 visits for each of her PHP patients well knowing that she did not see the individual patients and had not performed a reimbursable service.
27. It was further part of the scheme and artifice to defraud that **PALAZZO** falsely billed CPT codes 99233 and 99232, individual face-to-face services, on days that she performed team medical conferences well knowing that she did not see the individual patients and that the team medical conferences were not reimbursable by Medicare.
28. It was further part of the scheme and artifice to defraud that **PALAZZO** exercised control over the lives of certain psychiatric patients by having them in group homes over which she had ownership, control or influence. The defendant also maintained frequent orders for home health services even though she was allegedly seeing the patients on a daily basis. When the defendant became affiliated with Touro, she eventually moved her patients to "Touro at Home," Touro's home health agency, which was required to hire two nurses who had been with the defendant's patients for years.
29. It was further part of the scheme and artifice to defraud that **PALAZZO** intentionally kept long-term patients enrolled in the PHP for periods of time far exceeding what was medically necessary under Medicare guidelines, without any significant changes in the patients' plans of care, treatment goals and regime and rarely, if ever, discharged them from the program in order that she could continue to falsely charge Medicare and Medicaid for daily patient visits.

30. It was further part of the scheme and artifice to defraud that in March of 2005, when she lost control of the Touro PHP and was no longer a Medical Director at Touro or the PHP, **PALAZZO** unilaterally discharged, with no follow-up plan, all but one or two of her patients from the PHP despite years of certifying their ongoing need for PHP care.

**WAYS AND MEANS:**

31. From September 2000, through May 2002, approximately once a week, usually on a Monday or a Tuesday, **PALAZZO** falsely submitted CMS/HCFA 1500s to Medicare for CPT code 99233 individual face-to-face visits that she had not performed.
32. From June 2002, through October 2003, approximately once a week, usually on a Monday, **PALAZZO** falsely submitted CMS/HCFA 1500s to Medicare for CPT code 99232 individual face-to-face visits that she had not performed.
33. From August 2000, through about May 2002, **PALAZZO** falsely submitted CMS/HCFA 1500s to Medicare and Medicaid for CPT code 99231 services and identified herself as the provider of the services when the defendant well knew that the visits could not have occurred and no reimbursable services were rendered and that a PA merely created supporting documentation for each billing.
34. After May 2002, and continuing through October 2004, **PALAZZO** falsely submitted CMS/HCFA 1500s to Medicare and Medicaid for CPT code 99231 services when the defendant well knew that the visits did not occur and no reimbursable services were rendered.

**COUNTS ONE THROUGH FOURTEEN - HEALTH CARE FRAUD (Face to Face)**

35. Paragraphs 1 - 34 of this Indictment are realleged and incorporated by reference.

36. On or about the dates set forth in the chart below, in the Eastern District of Louisiana and elsewhere, the defendant, **MARIA CARMEN PALAZZO**, knowingly and willfully executed a scheme and artifice to defraud a health care benefit program, to-wit: Medicare, and to obtain, by means of materially false and fraudulent pretenses, representations and promises, money owned by and under the custody and control of Medicare in connection with the delivery of and payment for health care benefits and services.
37. In the instances below, each being a separate and additional Count of this Indictment, **PALAZZO** falsely billed, and caused to be billed, Medicare for individual face-to-face E&M services she did not perform:

Count	Date	Patient	Claim Number	CPT Number
1	10/3/00	DaEv	531200312133950	99233
2	10/31/00	PhCa	531200314138370	99233
3	11/7/00	DaEv	531200332151990	99233
4	4/10/01	DaEv	531201113102680	99233
5	4/17/01	VaLa	531201117119400	99233
6	11/26/01	UpVa	531201337180080	99233
7	12/3/01	VaLa	531201346117440	99233
8	1/7/02	UpVa	531202025154350	99233
9	1/28/02	RuMa	531202037133530	99233
10	2/4/02	MaDo	531202045143260	99233
11	2/18/02	AaHe	531202065151380	99233
12	3/11/02	MaDo	531202079126490	99233
13	8/5/02	DaEv	531202228134280	99232
14	4/21/03	MaDo	531203120101850	99232

All in violation of Title 18, United States Code, Sections 1347 and 2.

**COUNTS 15 THROUGH 27 - HEALTH CARE FRAUD (PA)**

38. Paragraphs 1-34 of this Indictment are realleged and incorporated by reference.
39. On or about the dates set forth in the chart below, in the Eastern District of Louisiana and elsewhere, the defendant, **MARIA CARMEN PALAZZO**, knowingly and willfully executed a scheme and artifice to defraud health care benefit programs, to-wit: Medicare and Medicaid, and to obtain, by means of materially false and fraudulent pretenses, representations and promises, money owned by and under the custody and control of Medicare and Medicaid in connection with the delivery of and payment for health care benefits and services.
40. In the instances below, each being a separate and additional Count of this Indictment, **PALAZZO** submitted false bills to Medicare and Medicaid as though she was the provider of the service when she knew that a physician's assistant performed the service:

<b>Count</b>	<b>Date</b>	<b>Patient</b>	<b>Claim Number</b>
15	10/11/00	AlFa	531200312133980
16	10/17/00	VaLa	531201036190730
17	11/8/00	AmRa	531200333135130
18	11/9/00	LoSi	531200333135150
19	12/8/00	AmRa	531200357139480
20	2/5/01	PhCa	531201045104580
21	4/27/01	FaWo	531201127201690
22	4/30/01	LoSi	531201129166730
23	5/23/01	FaWo	531201152123910

24	5/24/01	UpVa	531201152123660
25	6/4/01	VaLa	531201173135880
26	6/5/01	DaEv	531201173135950
27	6/27/01	RaCo	531201186119230

All in violation of Title 18, United States Code, Sections 1347 and 2.

**COUNTS 28 THROUGH 40 - HEALTH CARE FRAUD (Medical Director Invoices)**

41. Paragraphs 1 - 34 of this Indictment are realleged and incorporated by reference.

**THE OBJECT OF THE SCHEME:**

42. As a Consultant and Medical Director for Touro from August 1, 2000, until December 31, 2004, **PALAZZO** fraudulently obtained money from Touro by falsely submitting invoices to Touro for time she claimed she spent in her administrative capacity. The false invoices detailed hours she purportedly spent on behalf of Touro on, among other things, inpatient and PHP staffing, meetings with Touro employees, meetings with nursing home representatives and interactions with pharmaceutical companies. In truth and fact, any time the defendant identified as PHP staffing was time spent using Touro's PHP staff to provide her with enough information for her to create a billing for a face-to-face visit with each patient in the PHP that week. **PALAZZO** knew that the time directly related to individual patient care was not reimbursable under her contractual agreements with Touro.

43. Touro paid **PALAZZO** \$150 per hour on the invoices she submitted. Touro listed the payments on annual cost reports submitted to Medicare as operational costs. Based upon those representations, Medicare partially reimbursed Touro for the money it paid to the

defendant. **PALAZZO** knew that she was causing Touro to submit false cost reports to Medicare because she knew that Medicare would not reimburse Touro for her to provide individual patient care.

**SCHEME TO DEFRAUD:**

44. Beginning on or about August 1, 2000, and continuing until present, in the Eastern District of Louisiana and elsewhere, the defendant **MARIA CARMEN PALAZZO**, did knowingly and willfully execute a scheme and artifice to defraud a health care benefit program, to-wit: Medicare, and to obtain, by means of false and fraudulent pretenses, representations, and promises, money owned by and under the custody and control of Medicare in connection with the delivery of and payment for health care benefits and services.
45. It was part of the scheme and artifice to defraud that **PALAZZO** created and submitted to Touro false monthly invoices listing administrative duties she purportedly performed on behalf of Touro knowing that the payments of the invoices would be listed by Touro on its annual cost reports to Medicare and that Medicare would ultimately partially reimburse Touro for the fraudulent invoices.
46. It was further part of the scheme and artifice to defraud that each month **PALAZZO** intentionally and falsely created and inflated her invoices to Touro for services she either did not render or had other staff members perform. **PALAZZO** falsely claimed meetings with Touro personnel knowing such meetings never took place or falsely inflated the time spent in the meetings.
47. It was further part of the scheme and artifice to defraud that the defendant caused Touro

to include on its 2000, 2001, 2002, 2003 and 2004 cost reports those expenses charged by **PALAZZO** due to her fraudulent invoices. Medicare reimbursed Touro a total of approximately \$101,325 based upon the fraudulent invoices.

**WAYS AND MEANS:**

- 48. Every Tuesday between August 2000, and October 2001, and every Monday between November 2001, and December 2004, **PALAZZO** listed between one and five hours for "PHP staffing," knowing that she had not rendered these services.
- 49. Every Monday between August 2001, and October 2004, **PALAZZO** listed between 2 and 3.5 hours for "in-patient staffing," knowing that she had not rendered these services.

**HEALTH CARE FRAUD:**

- 50. On or about the dates set forth in the chart below, in the Eastern District of Louisiana and elsewhere, **MARIA CARMEN PALAZZO**, knowingly and willfully executed and attempted to execute a scheme and artifice to defraud Medicare, a health care benefit program, and to obtain, by means of materially false and fraudulent pretenses, representations and promises, money under the custody and control of the Medicare program, in connection with the delivery of and payment for health care benefits and services.
- 51. In the instances below, each being a separate and additional Count of this Superseding Indictment, **PALAZZO** submitted false invoices to Touro which were used to support its claims for reimbursement of costs to Medicare:

Count	Date of Submission of Invoice
28	1/31/01

<b>Count</b>	<b>Date of Submission of Invoice</b>
29	2/28/01
30	3/31/01
31	4/30/01
32	7/31/01
33	11/30/01
34	12/31/01
35	5/31/02
36	7/31/02
37	8/31/02
38	9/30/02
39	9/30/03
40	10/31/03

All in violation of Title 18, United States Code, Sections 1347 and 2.

**FOOD AND DRUG ADMINISTRATION**

**AT ALL TIMES MATERIAL HEREIN:**

52. SmithKline Beecham, Corp., d/b/a GlaxoSmithKline (SKB) was a pharmaceutical company engaged in developing, testing, and marketing pharmaceutical products including Paroxetine, also known as "Paxil," developed by SKB for the treatment of Obsessive Compulsive Disorder (OCD).
53. Under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations, SKB (drug sponsor) had to apply to the United States Food and Drug Administration (FDA), an agency of the United States, for approval to market Paxil. As a



drug sponsor, SKB was required to demonstrate, through clinical investigations, the safety and effectiveness of Paxil before the FDA would approve Paxil for human use or consumption. Clinical investigations were experiments or studies in which Paxil was administered to a human group. The FDA examined the results, design and conduct of the clinical studies in deciding whether Paxil should be approved for marketing,

54. Before beginning the Paxil clinical study, the FDA required SKB to provide the FDA a detailed investigation plan known as the “study protocol.” The study protocol contained information about how the clinical study would be conducted, where studies would be done and by whom, how the drug's safety would be evaluated, and what findings would require the study to be changed or halted.
55. SKB hired physicians, known as clinical investigators, to carry out the actual clinical studies of the drug on human subjects (study subjects). Each participating physician signed FDA Form 1572 committing to conduct the study in accordance with the study protocol, to personally conduct or supervise the investigation, and to comply with FDA regulations. The FDA required that truthful and correct information be provided in order to evaluate the safety and performance of Paxil before it approved the drug's use by certain groups of individuals.
56. On October 31, 2000, SKB hired **PALAZZO**, a licensed psychiatrist practicing medicine in New Orleans, to participate as a Clinical Investigator in a study involving Paxil, SKB Project 29060, Protocol 704 (SKB 704), to evaluate the efficacy and safety of Paxil in children and adolescents with Obsessive-Compulsive Disorder (OCD). **PALAZZO** agreed to conduct the study in strict compliance with the criteria set forth in the study

protocol. Additionally, **PALAZZO** agreed to personally review all Case Report Forms (CRFs) which contained information regarding each study subject. In return, SKB agreed to pay **PALAZZO** \$5,410.00 for each subject who completed the study.

57. On or about February 9, 2001, SKB entered into a contract with **PALAZZO**, for the defendant to participate as a Clinical Investigator in an extension study to SKB 704, the Smith Kline Beecham Project 29060, Protocol 716 (SKB 716), to assess the long term safety of Paxil in children and adolescents with major depressive disorder or OCD. **PALAZZO** agreed to conduct the study in strict compliance with the criteria set forth in the study protocol. Additionally, **PALAZZO** agreed to personally review all CRFs which contained information regarding each study subject. In return, SKB agreed to pay **PALAZZO** \$5,020.00 for each study subject who completed the study.
58. From on or about November 20, 2000, through about July 11, 2001, **PALAZZO**, enrolled 17 study subjects in SKB 704 and 9 study subjects in SKB 716.
59. On October 25, 2000, November 23, 2000, and again on March 1, 2001, **PALAZZO** signed FDA Form 1572 in connection with SKB 704.
60. On January 31, 2001, February 5, 2001, March 1, 2001, and again on May 7, 2001, **PALAZZO**, signed FDA Form 1572 in connection with SKB 716.
61. FDA regulations imposed the following specific responsibilities on **PALAZZO** as a clinical investigator on the Paxil study. The defendant was required to:
  - a. prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories included the case report forms and supporting data including, for example, signed and dated consent forms and medical records.

- b. obtain an informed consent from the individual prior to his or her participation in the study.
  - c. promptly report all changes in the clinical investigation research activity to the Institutional Review Board, which is responsible for the initial and continuing review and approval of clinical studies.
  - d. determine if a study subject had, among other exclusion criteria, recent treatments with psychotherapeutic drugs, any history of psychosis, or an identifiable mental disorder which was the main focus of treatment other than OCD.
  - e. *enroll only those volunteering to participate in the Paxil study that met certain criteria, which were set forth in Protocols 704 and 716.*
  - f. administer the Paxil study and visit regularly with the study subjects so that the required data to be submitted to the FDA could be collected and evaluated.
  - g. provide to SKB upon completion of the Paxil study, information about each study subject, including the subject's medical history, laboratory results, and reaction to the Paxil, so that SKB could, in turn, provide the information to the FDA for use in its evaluation of whether Paxil should be approved for human use.
  - h. assess the patients' current conditions and evaluate their dosages during clinic visits.
  - i. prepare a CRF for each study subject which included information as to the dates the study subject came to the clinic, was examined, the dates the study subject took his/her first and last doses of the study medication, whether the study subject reported any adverse effects, and whether the study subject completed the study.
62. Review of clinical investigator conduct and required records and reports was part of the basis for the FDA's evaluation of the drug's safety and effectiveness and the agency's determination as to whether the drug could be approved for marketing. Required records and reports included "source documents" related to patient visits, psychiatric assessments, progress notes, and informed consent documents.
63. Under Title 21, United States Code, Section 331(e), it was unlawful for any person, with

intent to defraud and mislead, to fail to establish or maintain any record, or make any report, required under Title 21, United States Code, Section 355(I), including those records required under 21 C.F.R. §§ 312.62(b) and 312.66.

64. **PALAZZO** reported in the CRFs that all study subjects for the Paxil Study were qualified to participate in the study.

**COUNTS 41 THROUGH 55**

65. Paragraphs 1-21 are incorporated by reference as though fully set forth herein.

66. On the below-listed dates, in the Eastern District of Louisiana, the defendant, **MARIA CARMEN PALAZZO**, with intent to defraud and mislead, failed to prepare and maintain records required under 21 U.S.C. § 355(I), and 21 C.F.R. § 312.62(b), to-wit, adequate and accurate case histories on each individual administered the investigational drug or employed as a control in the investigation, each such failure and causing thereof, as set forth below, being a separate count in this indictment:

Count	Date	Study Subject Number	Inadequate/ Inaccurate Record	Inadequacy/Inaccuracy
41	10/23/00	28133	Kiddie-Sads-Present and Lifetime Version assessment ("K-SADS-PL evaluation")	<ul style="list-style-type: none"> <li>• The defendant's psychiatric evaluation of the subject contained a history of depressive disorder, suicidal ideation, and lying</li> <li>• No mention of depressive disorder, suicidal ideation, or lying appeared in the K-SADS-PL assessment.</li> </ul>

Count	Date	Study Subject Number	Inadequate/ Inaccurate Record	Inadequacy/Inaccuracy
42	11/20/00	28133	CRF	<ul style="list-style-type: none"> <li>• <b>PALAZZO'S</b> psychiatric evaluations of the subject contained diagnoses of major depression and impulse control disorder that were not documented in the subject's CRF.</li> <li>• The CRF included the defendant's diagnosis of OCD, when the defendant well knew that the subject did not demonstrate symptoms of OCD and that the diagnosis was inconsistent with the subject's psychiatric history included in the subject's referral materials.</li> <li>• <b>PALAZZO</b> prepared multiple psychiatric evaluations on the subject - some dated the same date - that contained different diagnoses and treatment plans. None of these evaluations noted any specific obsessions or compulsions.</li> <li>• The CRF reported an OCD onset date and age of onset that were inconsistent with the onset date and age described in the Paxil Study screening visit psychiatric intake interview and that were inconsistent with the subject's psychiatric history.</li> <li>• The defendant's diagnosis was inconsistent with the psychiatric evaluations of other practitioners following the termination of the Paxil Study</li> </ul>
43	11/24/00	28135	CRF	<ul style="list-style-type: none"> <li>• <b>PALAZZO'S</b> psychiatric evaluations of the subject contained diagnoses of Depressive Disorder and Oppositional/Defiant Disorder that were not documented in the subject's CRF.</li> <li>• The CRF included the defendant's diagnosis of OCD, when the defendant well knew that subject did not demonstrate symptoms of OCD and that the diagnosis was inconsistent with the psychiatric history included in the subject's referral materials.</li> <li>• The CRF reported an OCD onset date and age of onset that was inconsistent with the subject's actual age.</li> </ul>

Count	Date	Study Subject Number	Inadequate/ Inaccurate Record	Inadequacy/Inaccuracy
44	12/6/00	28136	K-SADS-PL evaluation	<ul style="list-style-type: none"> <li>The subject's K-SADS-PL assessment documented a history of sub-threshold hallucinations and delusions.</li> <li><b>PALAZZO'S</b> psychiatric evaluation of the subject indicated no history of hallucinations or delusions.</li> </ul>
45	12/7/00	28174	CRF	<ul style="list-style-type: none"> <li><b>PALAZZO'S</b> psychiatric evaluations of the subject contained a diagnosis of OCD when the defendant well knew that the subject did not demonstrate symptoms of OCD and that the diagnosis was inconsistent with the psychiatric history included in the subject's referral materials.</li> <li>The CRF represented that the subject was diagnosed with OCD and reported an OCD onset date and age of onset that were inconsistent with the subject's psychiatric history.</li> <li>Material elements of the subject's psychiatric history, such as hyperactivity, attention deficit disorder, and disruptive behavior disorder, were omitted from the CRF.</li> <li>The defendant's diagnosis was inconsistent with the psychiatric evaluations of other practitioners following the termination of the Paxil Study</li> </ul>
46	12/8/00	28138	CRF	<ul style="list-style-type: none"> <li><b>PALAZZO'S</b> psychiatric evaluations of the subject contained a diagnosis of Impulse Control Disorder</li> <li>A diagnosis of Impulse Control Disorder was not documented in the subject's CRF.</li> </ul>
47	12/8/00	28139	CRF	<ul style="list-style-type: none"> <li><b>PALAZZO'S</b> psychiatric evaluations of the subject contained a diagnosis of generalized anxiety disorder, major depression, and mixed personality disorder.</li> <li>These diagnoses were not documented in the subject's CRF.</li> </ul>

Count	Date	Study Subject Number	Inadequate/ Inaccurate Record	Inadequacy/Inaccuracy
48	12/19/00	28171	CRF	<ul style="list-style-type: none"> <li>• <b>PALAZZO'S</b> psychiatric evaluations of the subject contained diagnoses of generalized attention deficit hyperactive disorder ("ADHD") and schizophrenia.</li> <li>• These diagnoses were not documented in the subject's CRF.</li> </ul>
49	12/19/00	28171	K-SADS-PL evaluation	<ul style="list-style-type: none"> <li>• The subject's K-SADS-PL assessment indicated that hallucinations were not present in the subject.</li> <li>• <b>PALAZZO'S</b> psychiatric evaluations stated that the subject hallucinated.</li> </ul>
50	12/19/00	28172	K-SADS-PL evaluation	<ul style="list-style-type: none"> <li>• The subject's K-SADS-PL assessment indicated that hallucinations were not present in the subject.</li> <li>• <b>PALAZZO'S</b> psychiatric evaluations stated that the subject admitted to hallucinations.</li> </ul>
51	12/19/00	28172	CRF	<ul style="list-style-type: none"> <li>• The subject's psychiatric evaluations were not reported accurately in the CRF, in that the K-SADS-PL assessment contained documentation that the subject had ADHD that was not documented in the CRF.</li> </ul>
52	12/21/00	28173	CRF	<ul style="list-style-type: none"> <li>• <b>PALAZZO'S</b> psychiatric evaluation of the subject contained a diagnosis of OCD when the defendant well knew that the subject did not demonstrate symptoms of OCD and that the diagnosis was inconsistent with the psychiatric history included in the subject's referral materials.</li> <li>• The CRF reported an OCD onset date and age of onset that were inconsistent with the subject's psychiatric history.</li> <li>• A material element of the subject's psychiatric history, ADHD, was omitted from the CRF.</li> </ul>
53	5/23/01	28175	Source documents	<ul style="list-style-type: none"> <li>• Study records purported to document that <b>PALAZZO</b> examined the subject, whereas in <i>truth and fact, the defendant did not.</i></li> </ul>
54	5/23/01	28191	Source documents	<ul style="list-style-type: none"> <li>• Study records purported to document that <b>PALAZZO</b> examined the subject, whereas in <i>truth and fact, the defendant did not.</i></li> </ul>

Count	Date	Study Subject Number	Inadequate/ Inaccurate Record	Inadequacy/Inaccuracy
55	5/24/01	28190	Source documents	<ul style="list-style-type: none"> <li>Study records purported to document that <b>PALAZZO</b> examined the subject, whereas in truth and fact, the defendant did not.</li> </ul>

All in violation of Title 21, United States Code, Sections 331(e), 333(a)(2) and Title 18, United States Code, Section 2.

### ASSET FORFEITURE

67. The allegations contained in Counts 1 through 40 are hereby realleged and incorporated by reference for the purpose of alleging forfeiture to the United States of America pursuant to the provisions of Title 18, United States Code, Section 982.

68. As a result of the offenses alleged in Counts 1 through 40, the defendant **MARIA CARMEN PALAZZO** shall forfeit to the United States pursuant to Title 18, United States Code, Section 982(a)(7), any and all property, real and personal, that constitutes or is derived directly or indirectly, from gross proceeds traceable to the commission of the offenses as a result of the violations of Title 18, United States Code, Section 1347, which are Federal Health Care offenses within the meaning of Title 18, United States Code, Section 24, including but not limited to:

\$754,877 in United States Currency and all interest and proceeds traceable thereto, in that such sum in aggregate represents the amount of proceeds obtained as a result of the aforesaid offenses or is traceable to such property.

69. If any of the above-described forfeited property, as a result of any act or omission of the defendant,

1. cannot be located upon the exercise of due diligence;


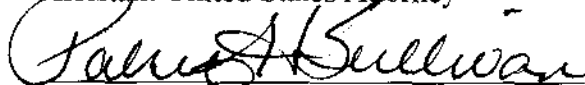


2. has been transferred, sold to, or deposited with, a third person;
3. has been placed beyond the jurisdiction of the Court;
4. has been substantially diminished in value; or
5. has been commingled with other property which cannot be subdivided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p) as incorporated by Title 18, United States Code, Section 982(b) to seek forfeiture of any other property of said defendant up to the value of the above forfeitable property;

All in violation of Title 18, United States Code, Section 982(a).

A TRUE BILL:

  
\_\_\_\_\_  
FOREPERSON  
\_\_\_\_\_  
JIM LETTEN (8514)  
UNITED STATES ATTORNEY  
\_\_\_\_\_  
JAN MASELLI MANN (9020)  
Chief, Criminal Division  
Assistant United States Attorney  
\_\_\_\_\_  
PATRICE HARRIS SULLIVAN (14987)  
Assistant United States Attorney

New Orleans, Louisiana  
June 14, 2007

No. \_\_\_\_\_

**UNITED STATES DISTRICT COURT**

Eastern        District of        Louisiana  
Criminal        Division

THE UNITED STATES OF AMERICA


vs.

MARIA CARMEN PALAZZO, M.D., Ph.D., MMM  
**SUPERSEDING INDICTMENT**

**SUPERSEDING INDICTMENT FOR VIOLATION OF  
THE FEDERAL CONTROL SUBSTANCES ACT.**

VIOLATION: 18 USC §1347  
21 USC §331(e)  
21 USC §333(a)(2)  
18 USC §22

A true bill

  
\_\_\_\_\_  
Foreperson

Filed in open court this \_\_\_\_\_ day  
of \_\_\_\_\_ A.D. 2007.

\_\_\_\_\_  
Clerk

*Patricia Harris Sullivan*  
\_\_\_\_\_  
PATRICE HARRIS SULLIVAN  
Assistant United States Attorney