U.S. DISTRICT COURT
EASTERN DISTRICT OF LA
2005 AUG 25 PM 3:00
LORETTA G. WHYTE
CLERK

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

FELONY

INDICTMENT FOR HEALTH CARE FRAUD

UNITED STATES OF AMERICA	*	CRIMINAL DOCKET NO.	05-266
VERSUS	*	SECTION:	SECT. S MAG. 1
MARIA CARMEN PALAZZO, M.D., Ph.D, MMM	*	VIOLATIONS:	*18 USC §1347* *21 USC §331(e)* *21 USC §333(a)(2)* *18 USC §2*
	*		

* * *

The Grand Jury charges that:

COUNT ONE

I. AT ALL TIMES MATERIAL HEREIN:

A. The defendant, **MARIA CARMEN PALAZZO, M.D., Ph.D., MMM (hereinafter MARIA CARMEN 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 and, as such, was a Medicare "provider" authorized to submit bills for reimbursement for certain medical services to eligible Medicare beneficiaries. **MARIA CARMEN PALAZZO** also earned a Ph.D in the philosophy of anatomy and a Masters Degree in Medical Management.

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B. Touro Infirmary 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.

Medicare

C. Medicare was a federally funded health insurance program which paid for certain inpatient medical and home health services ("Part A"), outpatient medical services ("Part B") and for durable medical equipment 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.

D. Mutual of Omaha, known as the fiscal intermediary, received, adjudicated, settled and paid Medicare Part A reimbursements for Touro Infirmary pursuant to a contract with CMS. Touro Infirmary submitted cost reports to Mutual of Omaha yearly to determine the proper reimbursement of costs from Medicare. Arkansas Blue Cross and Blue Shield (Arkansas BCBS), known as the carrier, 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.

E. On June 1, 1982, **MARIA CARMEN PALAZZO** entered into a provider agreement with Medicare and was assigned Medicare provider number 51603. The defendant used the number to bill the Medicare program for services provided

to qualified Medicare beneficiaries.

F. **MARIA CARMEN PALAZZO** submitted medical claims to Medicare for reimbursement, subject to the agreement and Medicare criteria, rules, regulations and internal procedures.

G. **MARIA CARMEN PALAZZO** submitted Medicare Part B bills to Arkansas BCBS 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 (CPT) code, the name of the facility where the services were rendered, the physician and the supplier of the service.

Medicaid

H. 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. The federal involvement in Medicaid was largely limited to providing matching funding and ensuring that the states complied with minimum standards in the administration of the program.

I. Pursuant to her voluntary application, on July 1, 1990, **MARIA CARMEN PALAZZO** was assigned provider number 0090165 with the State of Louisiana's Medicaid program. By signing the provider enrollment form, **MARIA CARMEN 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. Additionally, **MARIA CARMEN PALAZZO** 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 (CPT)

J. The American Medical Association (AMA) assigned five-digit numerical codes to medical procedures performed by health care providers. The codes were known as Current Procedural Terminology (CPT) codes. The CPT codes, published annually by the AMA, 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 Evaluation and Management (E&M) services provided by health care professionals. Codes were based upon the complexity of the service, the severity of the illness or injury and the average amount of time generally required to perform the service, and the fees paid are commensurate with the amount of work required.

K. 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. For example, there were two sub-categories of office visits (new patients and established patients) and there were two categories of hospital visits (initial and subsequent). The sub-categories were

further divided into levels that describe the nature of physician work by type of service, place of service and the patient status, including the complexity of the service and the time typically required to provide the service.

L. 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 patient's status. Based upon the complexity, severity and time related to the service, CPT E&M codes 99231, 99232, and 99233 stated that a physician would typically require 15, 25 and 35 minutes, respectively to perform the necessary medical services.

M. 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.

Physician Assistants

N. A Physician Assistant (PA) was a non-physician practitioner permitted by the licensing state to provide medical services under the supervision of a medical doctor/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. The physician supervisor did not have to be physically present when a service was being furnished to a patient and could be contacted by telephone, if necessary.

O. 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 only to the PA's Medicare employer. From August 2000, until about May 13, 2002, **MARIA CARMEN PALAZZO** employed a PA.

P. When PAs provided services, Form CMS 1500 had to contain the PA's Provider Identification Number (PIN) in Item Box 33. Item 33 had to contain the employer's name, address and where payment was to be directed.

Partial Hospitalization Programs

Q. Partial Hospitalization Programs (PHP)s were structured to provide intensive psychiatric care and closely resembling that of a highly structured, short term, inpatient hospital program. Patients' psychiatric treatment at a PHP was more intense than outpatient day treatment of psychosocial rehabilitation. Programs providing primarily social, recreational, or diversionary activities are not considered a PHP. The treatment goals should be measurable, functional, time-framed, medically necessary and directly related to the reason for admission. A program that only monitored the management of medication for patients whose psychiatric condition was otherwise stable was not the combination, structure and intensity of services which made up active treatment in a PHP. 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.

R. Medicare coverage required that the PHP services be (1) incident to a physician's service; (2) reasonable and necessary for the diagnosis or treatment of the patient's condition; and (3) be reasonably expected to improve the patient's condition.

Medical Directorships

S. On July 5, 2000, and July 27, 2001, **MARIA CARMEN PALAZZO** entered into Professional Services Agreements (PSA) with Touro Infirmary wherein the parties agreed that **MARIA CARMEN PALAZZO** would provide consultation services for the Adult Psychiatric Programs at Touro Infirmary.

T. On June 1, 2002, and June 1, 2003, **MARIA CARMEN PALAZZO** entered into a PSA with Touro Infirmary wherein the parties agreed that **MARIA CARMEN PALAZZO** would provide Medical Director services for the Inpatient Adult Psychiatric and Adult Partial Hospitalization Programs at Touro Infirmary. The last PSA executed by the defendant and Touro Infirmary specifically stated that it was the intent of Touro Infirmary and **MARIA CARMEN PALAZZO** that the time spent on administrative duties for Touro Infirmary was mutually exclusive of her delivery of patient care. Therefore, the PSA prohibited **MARIA CARMEN PALAZZO** from billing a patient or third party payor for patient care services performed by her during the same period of time that she performed administrative duties for Touro Infirmary.

U. Each PSA was for a one-year term and provided compensation to **MARIA CARMEN PALAZZO** of up to $144,000 per year at a rate of $150 per hour.

Each PSA required **MARIA CARMEN PALAZZO** to provide Touro Infirmary with a written monthly statement recording the amount of time and the services she rendered. If **MARIA CARMEN PALAZZO** did not submit the invoice in writing, Touro Infirmary would not pay her. Each PSA required **MARIA CARMEN PALAZZO** to comply with all federal state and local laws, including those associated with Medicare and Medicaid.

II. THE OBJECT OF THE SCHEME:

From August 2000 until March 2005, **MARIA CARMEN 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 for which she was not entitled. The defendant used the false documentation to support daily bills for low level hospital visits to all of her patients in the PHP. **MARIA CARMEN 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 **MARIA CARMEN PALAZZO** submitted the forms 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 the employ of **PALAZZO,** the defendant began to bill code 99231 visits for each of her PHP patients on those days for services she did not provide.

From a date unknown, until on or about December 31, 2003, and on occasion, in 2004, **MARIA CARMEN PALAZZO** fraudulently obtained money from Medicare and Medicaid by billing Medicare and Medicaid 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, but instead conducted a team medical conference with an interdisciplinary treatment team to discuss and monitor her patients' progress. **MARIA CARMEN PALAZZO'S** practice was to summon an interdisciplinary team to hold a team medical conference after all of the patients left the facility for the day. **MARIA CARMEN PALAZZO** billed Medicare and Medicaid for individual patient visits instead of a team medical conference because she knew that team conferences were not reimbursable by Medicare and Medicaid.

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

III. <u>HEALTH CARE FRAUD</u>:

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 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.

It was part of the scheme and artifice to defraud that **MARIA CARMEN PALAZZO** employed a PA to make daily visits to the Touro Infirmary in-patient and PHP units to document evidence of a patient visit when, in fact, **MARIA CARMEN 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 and perform the services for which bills were being submitted, **MARIA CARMEN 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 support **PALAZZO'S** billings, **PALAZZO** instructed the PA that she would have to become more "creative" in the composing of the patient notes in order for them to be paid by Medicare, while still refusing the PA's request to change her schedule so the PA could provide real, beneficial services to the patients.

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 day 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. The PA was expected by **MARIA CARMEN PALAZZO** to create a patient progress note based upon these fleeting encounters merely to support the bill. **MARIA CARMEN PALAZZO** also instructed her PA to sit in group therapy sessions occurring at the PHP 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 by Touro Infirmary. Accordingly, the CPT E&M code that **MARIA CARMEN PALAZZO** used to bill for the PA service was an individual face-fo-face visit, and not a group therapy code. In this manner, **MARIA CARMEN PALAZZO** caused Medicare to be billed twice for the same service based upon the submission of the falsified bill.

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, **MARIA CARMEN 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.

It was further part of the scheme and artifice to defraud that the defendant 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 or Medicaid.

It was further part of the scheme and artifice to defraud that after the PA was no longer employed by **MARIA CARMEN PALAZZO,** the defendant 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.

It was further part of the scheme and artifice to defraud that the defendant exercised control over the lives of certain psychiatric patients by having them in group homes over which she had ownership, control or influence. **MARIA CARMEN PALAZZO** insisted that many of

her long term patients enroll in the group homes she either owned or was affiliated and, on occasion, **MARIA CARMEN PALAZZO** refused to discharge a patient from in-patient hospitalization unless or until the patient agreed to go to a group home of **PALAZZO'S** choosing.

It was further part of the scheme and artifice to defraud that the defendant exercised control over the lives of these patients by maintaining a constant order for home health services and directing her patients to agencies with which she was affiliated or had long term relationships with the staff. Often when the defendant changed affiliations with medical facilities, she moved her patients to the home health agency most closely associated with that facility, often having the new agency hire nurses that had been with the defendant at all times material herein.

It was further part of the scheme and artifice to defraud that if the patients failed to show up for the PHP, **MARIA CARMEN PALAZZO** instructed an employee, or a home health nurse, to contact the patient and intimidate them back into the PHP, which was a voluntary program. Once back in the PHP, the defendant continued falsely billing Medicare and Medicaid for daily face-to-face visits with that patient, even though she never rendered the treatments.

It was further part of the scheme and artifice to defraud that the defendant 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, discharging them from the program in order that she could continue to falsely charge Medicare for daily patient visits. Often, if a patient was discharged from the PHP it was only to be cycled into the in-patient unit at Touro by **MARIA CARMEN PALAZZO** whereupon that same patient would reenter the PHP upon discharge

from the in-patient unit.

It was further part of the scheme and artifice to defraud that the defendant, in March of 2005, upon losing control of the Touro PHP and her Medical Directorship at Touro Infirmary, and other factors which affected her relationship with Touro Infirmary, 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.

IV. EXECUTIONS:

A. From September 5, 2000, through November 6, 2001, **MARIA CARMEN PALAZZO** falsely submitted CMS/HCFA 1500s to Medicare and Medicaid for approximately 1,376 CPT code 99233 individual face-to-face visits that she had not performed and were, instead, non-reimbursable PHP team medical conferences held on Tuesdays;

B. From November 12, 2001, through May 27, 2002, **MARIA CARMEN PALAZZO** falsely submitted CMS/HCFA 1500s to Medicare and Medicaid for approximately 787 CPT code 99233 individual face-to-face visits that she had not performed and were, instead, non-reimbursable PHP team medical conferences held on Mondays;

C. From June 10, 2002, through October 20, 2003, **MARIA CARMEN PALAZZO** falsely submitted CMS/HCFA 1500s to Medicare and Medicaid for approximately 2,278 CPT code 99232 individual face-to-face visits that she had not performed and were, instead, non-reimbursable PHP team medical conferences held on Mondays;

D. From August 21, 2000, through January 4, 2002, **MARIA CARMEN PALAZZO** falsely submitted CMS/HCFA 1500s to Medicare and Medicaid for approximately 3,319 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; and

E. From September 12, 2000, through October 1, 2004, **MARIA CARMEN PALAZZO** falsely submitted CMS/HCFA 1500s to Medicare and Medicaid for approximately 16,326 CPT code 99231 services when the defendant well knew that the visits did not occur and no reimbursable services were rendered.

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

COUNT 2

HEALTH CARE FRAUD - MEDICAL DIRECTORSHIPS

I. AT ALL TIMES MATERIAL HEREIN:

The allegations in Count 1, Sections I.A-U, are incorporated by reference as though fully set forth herein.

II. THE OBJECT OF THE SCHEME:

As a Consultant and Medical Director for Touro Infirmary from August 1, 2000, until December 31, 2004, the defendant, **MARIA CARMEN PALAZZO** fraudulently obtained money from Touro Infirmary by falsely submitting invoices to Touro Infirmary for time purportedly spent in her administrative capacity. The false invoices detailed hours she purportedly spent on behalf of Touro Infirmary on, among other things, inpatient staffing, PHP

staffing, meetings with Touro employees, meetings with nursing home representatives and interactions with pharmaceutical companies. In truth and fact, the defendant spent the time at patient treatment team meetings where the care of her individual patients was discussed. **MARIA CARMEN PALAZZO** knew that the time directly related to patient care was not reimbursable under her contractual agreements with Touro Infirmary.

Touro Infirmary paid **MARIA CARMEN PALAZZO** $150 per hour on the invoices she submitted. Because the payments of the defendant's invoices was an operational cost of the hospital, Touro Infirmary listed these payments on the annual cost reports it submitted to Medicare. Medicare partially reimbursed Touro Infirmary for the money it paid to the defendant based upon the representations in the cost reports. **MARIA CARMEN PALAZZO** knew that she was causing Touro Infirmary to submit false cost reports to Medicare for reimbursement of her administrative expenses because the defendant knew that Medicare would not reimburse Touro for her to provide individual patient care.

Additionally, **MARIA CARMEN PALAZZO** obtained money from Touro Infirmary by false and fraudulent pretenses by deliberately inflating the time for which she invoiced Touro for administrative duties on behalf of Touro Infirmary in order to claim the maximum reimbursement from Touro Infirmary under her contracts.

III. HEALTH CARE FRAUD:

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 and attempt to 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.

It was part of the scheme and artifice to defraud that **MARIA CARMEN PALAZZO** created and submitted to Touro Infirmary false monthly invoices listing administrative duties she purportedly performed on behalf of Touro Infirmary knowing that the payments of said invoices by Touro Infirmary would be listed by Touro Infirmary on its annual cost reports to Medicare and that Medicare would ultimately partially reimburse Touro Infirmary for the fraudulent invoices.

It was further part of the scheme and artifice to defraud that each month **MARIA CARMEN PALAZZO** intentionally and falsely created and inflated her invoices to Touro Infirmary for services she either did not render or had other staff members perform. **MARIA CARMEN PALAZZO** falsely claimed meetings with Touro personnel knowing such meetings never took place or exaggerated the time spent in the meetings. **MARIA CARMEN PALAZZO** falsely charged Touro Infirmary for occasions when she was socializing with personal friends or when she was performing personal business.

It was further part of the scheme and artifice to defraud that the defendant caused Touro Infirmary to include on its 2000, 2001, 2002, 2003 and 2004 cost reports those expenses charged by **MARIA CARMEN PALAZZO** due to her fraudulent invoices. The 2000 cost report of Touro Infirmary was submitted to Medicare on December 4, 2002; the 2001 cost report was submitted to Medicare on April 9, 2003; the 2002 cost report was submitted to Medicare on June 13, 2003; the 2003 cost report was submitted to Medicare on May 26, 2004; and the 2004 cost report was submitted to Medicare on June 10, 2005. Medicare reimbursed Touro Infirmary a total of approximately $101,325 based upon the fraudulent invoices.

IV. EXECUTIONS:

MARIA CARMEN PALAZZO created and submitted the following fraudulent invoices reflecting that:

A. Every Tuesday between August 1, 2000, and October 30, 2001, the defendant listed between one and five hours for "PHP staffing," knowing that she had not rendered these services;

B. Every Monday between November 5, 2001, and December 31, 2004, the defendant listed between 1.5 and 3.75 hours for "PHP staffing," knowing that she had not rendered these services;

C. Every Monday between August 6, 2001, and October 25, 2004, the defendant listed between 2 and 5 hours for "in-patient staffing," knowing that she had not rendered these services;

D. The defendant had conducted PHP staffing and the in-patient staffing when in truth she had conducted team medical conferences (treatment teams), without the presence of the patient, with an interdisciplinary team of health professionals to coordinate activities of patient care.

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

COUNTS 3-17

FOOD AND DRUG ADMINISTRATION

I. AT ALL TIMES MATERIAL HEREIN:

A. 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").

B. Under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations, SKB (sometimes referred to as "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,

C. 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.

D. SKB hired physicians, known as clinical investigators, to carry out the actual clinical studies of the drug on human subjects (hereinafter referred to as "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.

E. On October 31, 2000, SKB hired **MARIA CARMEN 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 (hereinafter "SKB 704"), to evaluate the efficacy and safety of Paxil in children and adolescents with Obsessive-Compulsive Disorder (OCD). **MARIA CARMEN PALAZZO** agreed to conduct the study in strict compliance with the criteria set forth in the study protocol. Additionally, **MARIA CARMEN PALAZZO** agreed to personally review all Case Report Forms ("CRFs") which contained information regarding each study subject. In return, SKB agreed to pay **MARIA CARMEN PALAZZO** $5,410.00 for each subject who completed the study.

F. On or about February 9, 2001, SKB entered into a contract with **MARIA CARMEN 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 (hereinafter "SKB 716"), to assess the long term safety of Paxil in children and adolescents with major depressive disorder or OCD. **MARIA CARMEN PALAZZO** agreed to conduct the study in strict compliance with the criteria set forth in the study protocol. Additionally, **MARIA CARMEN PALAZZO** agreed to personally review all CRFs which contained information regarding each study subject. In return, SKB agreed to pay **MARIA CARMEN**

PALAZZO $5,020.00 for each study subject who completed the study.

G. Beginning on or about November 20, 2000, and continuing through about July 11, 2001, **MARIA CARMEN PALAZZO**, enrolled 17 study subjects in SKB 704 and 9 study subjects in SKB 716 ("the Paxil Study")

H. On October 25, 2000, November 23, 2000, and again on March 1, 2001, **MARIA CARMEN PALAZZO** signed FDA Form1572 in connection with SKB 704.

I. On January 31, 2001, February 5, 2001, March 1, 2001, and again on May 7, 2001, **MARIA CARMEN PALAZZO**, signed FDA Form 1572 in connection with SKB 716.

J. FDA regulations imposed the following specific responsibilities on **MARIA CARMEN PALAZZO** as a clinical investigator on the Paxil study. The defendant was required to:

1. 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.

2 obtain an informed consent from the individual prior to his or her participation in the study.

3. 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.

4. 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.

5. enroll only those volunteering to participate in the Paxil study that met certain criteria, which were set forth in Protocols 704 and 716.

6. 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.

7. 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.

8. assess the patients' current conditions and evaluate their dosages during clinic visits.

9. 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.

K. 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.

L. 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.

M. **MARIA CARMEN PALAZZO** reported in the CRFs that all study subjects for

the Paxil Study were qualified to participate in the study.

II. Paragraphs I. A-U of Count 1 are incorporated by reference as though fully set forth herein.

III. 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**
3	10/23/00	28133	Kiddie-Sads-Present and Lifetime Version assessment ("K-SADS-PL evaluation")	• The defendant's psychiatric evaluation of the subject contained a history of depressive disorder, suicidal ideation, and lying • No mention of depressive disorder, suicidal ideation, or lying appeared in the K-SADS-PL assessment.

Count	Date	Study Subject Number	Inadequate/ Inaccurate Record	Inadequacy/Inaccuracy
4	11/20/00	28133	CRF	• **MARIA CARMEN PALAZZO'S** psychiatric evaluations of the subject contained diagnoses of major depression and impulse control disorder that were not documented in the subject's CRF. • 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. • **MARIA CARMEN PALAZZO** 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. • 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. • The defendant's diagnosis was inconsistent with the psychiatric evaluations of other practitioners following the termination of the Paxil Study
5	11/24/00	28135	CRF	• **MARIA CARMEN PALAZZO'S** psychiatric evaluations of the subject contained diagnoses of Depressive Disorder and Oppositional/Defiant Disorder that were not documented in the subject's CRF. • 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. • The CRF reported an OCD onset date and age of onset that was inconsistent with the subject's actual age.

Count	Date	Study Subject Number	Inadequate/ Inaccurate Record	Inadequacy/Inaccuracy
6	12/6/00	28136	K-SADS-PL evaluation	• The subject's K-SADS-PL assessment documented a history of sub-threshold hallucinations and delusions. • **MARIA CARMEN PALAZZO'S** psychiatric evaluation of the subject indicated no history of hallucinations or delusions.
7	12/7/00	28174	CRF	• **MARIA CARMEN PALAZZO'S** 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. • 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. • Material elements of the subject's psychiatric history, such as hyperactivity, attention deficit disorder, and disruptive behavior disorder, were omitted from the CRF. • The defendant's diagnosis was inconsistent with the psychiatric evaluations of other practitioners following the termination of the Paxil Study
8	12/8/00	28138	CRF	• **MARIA CARMEN PALAZZO'S** psychiatric evaluations of the subject contained a diagnosis of Impulse Control Disorder • A diagnosis of Impulse Control Disorder was not documented in the subject's CRF.
9	12/8/00	28139	CRF	• **MARIA CARMEN PALAZZO'S** psychiatric evaluations of the subject contained a diagnosis of generalized anxiety disorder, major depression, and mixed personality disorder. • These diagnoses were not documented in the subject's CRF.

Count	Date	Study Subject Number	Inadequate/ Inaccurate Record	Inadequacy/Inaccuracy
10	12/19/00	28171	CRF	• **MARIA CARMEN PALAZZO'S** psychiatric evaluations of the subject contained diagnoses of generalized attention deficit hyperactive disorder ("ADHD") and schizophrenia. • These diagnoses were not documented in the subject's CRF.
11	12/19/00	28171	K-SADS-PL evaluation	• The subject's K-SADS-PL assessment indicated that hallucinations were not present in the subject. • **MARIA CARMEN PALAZZO'S** psychiatric evaluations stated that the subject hallucinated.
12	12/19/00	28172	K-SADS-PL evaluation	• The subject's K-SADS-PL assessment indicated that hallucinations were not present in the subject. • **MARIA CARMEN PALAZZO'S** psychiatric evaluations stated that the subject admitted to hallucinations.
13	12/19/00	28172	CRF	• 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.
14	12/21/00	28173	CRF	• **MARIA CARMEN PALAZZO'S** 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. • The CRF reported an OCD onset date and age of onset that were inconsistent with the subject's psychiatric history. • A material element of the subject's psychiatric history, ADHD, was omitted from the CRF.
15	5/23/01	28175	Source documents	• Study records purported to document that **MARIA CARMEN PALAZZO** examined the subject, whereas in truth and fact, the defendant did not.

Count	Date	Study Subject Number	Inadequate/ Inaccurate Record	Inadequacy/Inaccuracy
16	5/23/01	28191	Source documents	• Study records purported to document that **MARIA CARMEN PALAZZO** examined the subject, whereas in truth and fact, the defendant did not.
17	5/24/01	28190	Source documents	• Study records purported to document that **MARIA CARMEN PALAZZO** examined the subject, whereas in truth and fact, the defendant did not.

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

I. The allegations contained in Counts 1 and 2 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.

II. As a result of the offenses alleged in Counts 1 and 2, 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, Section1347, 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 aforestated offenses or is traceable to such property.

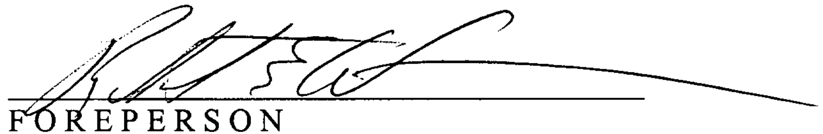
III. If any of the above-described forfeited property, as a result of any act or omission of the defendant,

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;

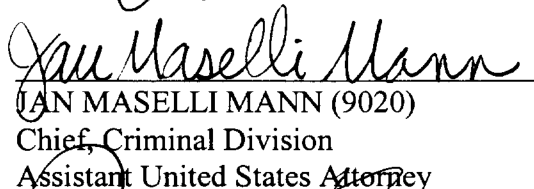
it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p) as incorporated by Title 18, United States Code, Section 982(b) to seek forfeiture of any other property of said defendant up to the value of the above forfeitable property;

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

A TRUE BILL:

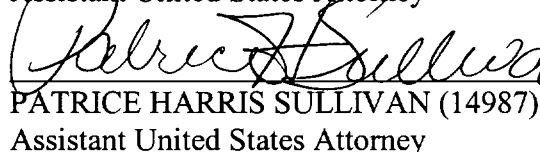


FOREPERSON



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
August 25, 2005