UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

UNITED STATES OF AMERICA	*	CRIMINAL DOCKET
VERSUS	*	NO: 05-266
MARIA CARMEN PALAZZO, M.D., Ph.D, MMM	*	SECTION : "S"
*	*	*

FACTUAL BASIS

If this matter were to proceed to trial, the government would prove the following facts through competent evidence:

The government would request that judicial notice be taken of the evidence presented, and the verdict rendered, before this Honorable Court in the trial held as to Counts 1 through 40 (hereinafter referred to as the "health care fraud trial").

Kurt Henjes, Associate General Counsel for GlaxoSmitkKline (GSK) would testify that GSK was a pharmaceutical company engaged in developing, testing and marketing pharmaceutical products, including Paroxetine, also known as Paxil. A GSK official and Food and Drug Administration (FDA) Investigator Barbara Wright would introduce the GSK Final Protocol for Studies 704 and 716, designed to evaluate the efficacy and safety of Paxil in children and adolescents with Obsessive-Compulsive Disorder (OCD).

FDA Investigator Wright would introduce into evidence FDA Forms 1572 October 25,

2000, November 23, 2000, and March 1, 2001, as to Study 704, and dated January 31, 2001, February 5, 2001, March 1, 2002, and May 7, 2001, as to Study 716. Investigator Wright would show that on those Form 1572s, the defendant agreed to conduct Studies 704 and 716 in accordance with the protocol and to only make changes in the protocol after notifying the sponsor or, if necessary, for the safety of a study subject. The defendant also agreed to personally conduct or supervise the investigation and to maintain adequate and accurate records in accordance with 21 CFR §312.62, and to comply with all other obligations of clinical investigators found in 21 CFR §312. At the bottom of each Form 1572 was a warning that statements on the form had to be truthful and if found not to be, could result in a prosecution for false statements to a government agency.

David Jones from Research Solutions, LLC would introduce the Addendum to Investigator Agreement Project Work Order signed by the defendant on February 9, 2001. On the form, the defendant acknowledged her responsibilities as an investigator to complete case report forms, perform all study procedures per the protocol, attend and assist in monitoring visits and to adhere to all FDA regulations concerning clinical trials. Susan Ramming of GSK and David Jones would also provide testimony, including the introduction of the Protocols 704 and 716 Payment Chart, which indicates that the defendant would be paid $5,410 and $5,020 for each patient enrolled in Studies 704 and 716, respectively.

Numerous investigators would testify, in accordance with the testimony at the health care fraud trial, that a search warrant was executed at the offices of Dr. Maria Carmen Palazzo on November 3, 2004. Found during that warrant and FDA audits previously conducted, were source documents relative to Study Protocols 704 and 716.

David Jones of Research Solutions would testify that his company was involved in the Protocols to process the regulatory paperwork and that they did not have any direct involvement in conducting the studies or provide any oversight. All payments for Palazzo's involvement in the Protocols were made to Research Solutions who, in turn, paid Dr. Palazzo. Kurt Henjes would testify that for Protocol Studies 704 and 716, GSK paid Research Solutions, L.L.C., who Mr. Henjes believed was the defendant's company, $91,824 as detailed:

- Letter dated November 10, 2000, and invoice transmitting check in the amount of $5,577.60 (Study 704)
- Check dated December 27, 2000, in the amount of $9,316.80 (Study 704)
- Check dated January 15, 2001, in the amount of $9,024.00 (Study 704)
- Check dated January 26, 2001, in the amount of $8,884.80 (Study 704)
- Check dated February 16, 2001, in the amount of $8,217.60 (Study 704)
- Check dated March 2, 2001, in the amount of $7,094.40 (Study 704)
- Check dated March 19, 2001, in the amount of $12,067.20 (Study 704)
- Check dated April 20, 2001, in the amount of $7,512.00 (Study 704)
- Check dated March 20, 2001, in the amount of $2,505.60 (Study 716)
- Check dated April 20, 2001, in the amount of $3,988.80 (Study 716)
- Check dated May 14, 2001, in the amount of $2,016.00 (Study 716)
- Voucher entry dated May 16, 2001, in the amount of $2,433.60 (Study 716)
- Check dated May 30, 2001, in the amount of $2,208.00 (Study 716)
- Check dated August 5, 2001, in the amount of $2,481.60 (Study 716)
- Check dated June 22, 2001, in the amount of $3,297.60 (Study 716)
- Check dated July 9, 2001, in the amount of $2,606.40 (Study 716)
- Check dated July 20, 2001, in the amount of $2,592.00 (Study 716)

FDA Investigators Barbara Wright and Dana Daigle would testify that between July 23, 2001, and August 28, 2001, they conducted an investigation on behalf of the FDA. A Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) letter was issued to the defendant on December 3, 2003, a copy of which is attached at Exhibit A.

Kurt Henjes would testify that a "For Cause Audit" was conducted by GlaxoSmithKline from July 10 through 12, 2001 with reference to Protocol 704 after a previously conducted

routine audit revealed significant problems with the defendant's performance of the drug trial. The results of the audit are attached as Exhibit B.

Barbara Wright, Dana Daigle and several representatives from GlaxoSmithKline who participated in the audit would be able to testify that they witnessed routine failure to follow protocol procedure, enrollment of patients who did not meet protocol criteria, failure to remove a patient from the study whose interest was not served by remaining in the study, failure to notify the sponsor of significant adverse events, and inconsistencies in CGI assessments. These witnesses would testify that the basis for each of Counts 41 through 55 were discovered during the audits and that Exhibits A and B detail the individual study documents which are referred to in Counts 41 through 55. These witnesses would testify as to each specific inaccuracy and/or inadequacy identified in each individual count as it relates to the identified study participant and would introduce the underlying medical and study documentation which establishes any inaccuracy.

GlaxoSmithKline officials would testify that based upon the findings of the audit, the defendant's participation in the clinical studies was discontinued and it was recommended that all data generated by the defendant as to Study 704 be removed from analyses on the basis of the unreliability of the data.

JIM LETTEN
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_____
MARIA CARMEN PALAZZO
Defendant
Date: _____

_____
WILLIAM P. GIBBENS
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