UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK by ELIOT SPITZER, Attorney General of the State of New York	:	
Plaintiff,	:	Civil Action No. 04-CV-5304 MGC
	:	Judge Cedarbaum
-against-	:	
GLAXOSMITHKLINE, PLC d/b/a GlaxoSmithKline,	:	
SMITHKLINE BEECHAM CORPORATION d/b/a GlaxoSmithKline,	:	
Defendant.	:	

Consent Order & Judgment

On motion of Eliot Spitzer, Attorney General for the State of New York, attorney for the Plaintiffs (Rose E. Firestein, Assistant Attorney General, Bureau of Consumer Frauds & Protection, of counsel), and upon the consent of the Defendants GlaxoSmithKline PLC ("GSK") and SmithKline Beecham Corporation ("SKB") (collectively "GSK"), it is hereby ORDERED:

1. By consenting to the entry of this Consent Order & Judgment, neither GSK nor SKB admits any of the acts alleged in the complaint filed by the Attorney General in the Supreme Court for the County of New York on or about June 2, 2004 (the "Complaint"). GSK does not waive any of its

defenses, including but not limited to, lack of personal jurisdiction, or federal preemption. The State of New York does not admit that the Complaint raises a federal question, that the Court has subject matter jurisdiction or that any of its claims are preempted.

2. As used herein, the following words are defined as follows:

"Clinical Study" means a research investigation on human subjects to answer specific questions about a GSK drug. The term Clinical Study is not limited to a research study that is randomized, controlled, or blinded.

"Clinical Study Report" of a Clinical Study means a description of the protocol, all the Data, and the clinically relevant conclusions drawn from the Data, including the answers to the questions posed in the protocol.

"Data" means all the results and outcome measurements obtained from a Clinical Study. This includes a description and the results of any planned statistical analysis of the Data, as well as a listing of the most common Minor Adverse Events and a more detailed listing of Serious Adverse Events.

"GSK Drug" is a prescription pharmaceutical product that is currently sold for human consumption in the United States by GSK, for which GSK has

both the clinical development responsibility and the legal right to use or disclose such product's Data.

"GSK-Sponsored Clinical Studies" means Clinical Studies of a GSK Drug where GSK is ultimately responsible for regulatory approvals, site selection, protocol development, initiation, monitoring, safety reporting, and Data analysis of the studies, even if some or all of these activities are transferred to another party (*e.g.*, Clinical Research Organization). "GSK-Sponsored Clinical Studies" excludes studies initiated by a third party for which GSK provides some support, for example by way of a grant or supply of medication, but with sponsor responsibilities for study initiation and management agreed in writing to reside with the third party.

"GSK Web Site" refers only to GSK's main corporate Internet site, currently www.gsk.com.

"Off-Label Use" means the use of a GSK Drug to treat a condition, disease or population not listed as an indication on the U.S. Prescribing Information (labeling) for the GSK Drug.

"Post" information means to provide access to the information on an Internet site that provides no-cost and unrestricted access to both the site

and the information GSK has provided through the site. GSK does not fulfill a requirement to Post information under this Consent Order & Judgment if it does so on an Internet site, other than the GSK Web Site, that contains any advertising by any pharmaceutical company or for any pharmaceutical product.

"Study Completion Date" is the date on which the last observation is made either of the last patient who remains enrolled in the Clinical Study or following a decision to terminate the Clinical Study early, whichever happens first.

"Summary of Clinical Study Report" refers to the brief presentations of Clinical Study Reports that are required by ¶ 8 of this Consent Order & Judgment.

3. The Complaint alleges in substance that GSK failed to disclose the results of certain clinical studies of Paxil® (paroxetine HCl) in adolescent and pediatric patients, and that GSK was under a duty under New York law to disclose those results. The U.S. Food & Drug Administration ("FDA") has not approved Paxil® for any adolescent or pediatric indication as of the date of this Consent Order & Judgment. GSK asserts that the Clinical Studies in question related to an unapproved indication for Paxil®, and therefore GSK was under significant restraints imposed by federal law in communicating with physicians about those studies.

4. Soon after the filing of the Complaint, GSK posted on its corporate website reports of GSK-Sponsored Clinical Studies conducted with Paxil® in adolescent and pediatric patients. In addition, GSK has committed to establish and maintain a Clinical Trial Register ("CTR"), in a format generally conforming to the ICHE-3 principles, which will provide public on-line access to Summaries of Clinical Study Reports for all GSK-Sponsored Clinical Studies from December 27, 2000, forward, and any earlier GSK-Sponsored Clinical Studies prior to that date that are likely to be material to a physician's medical judgment of the GSK Drug.

5. GSK shall make all reasonable efforts to Post the Summaries of Clinical Study Reports in accordance with the following time requirements:

a. Studies completed prior to the date of this Order: Summaries of Clinical Study Reports with a Study Completion Date that occurred between December 27, 2000, and the Order Date, or which occurred prior to December 27, 2000, but are likely to be material to a physician's medical judgment, will be posted by December 31, 2005.

b. Studies completed after the date of this Order: (i) With respect to products approved and marketed for any indication prior to the Order Date, Summaries of Clinical Study Reports will be posted no later than ten months after the Study Completion Date, except that the Posting shall occur within eight months of the Study Completion Date if, by that time, either no peer reviewed journal has accepted an original article

concerning the Clinical Study or the peer reviewed journal that has accepted such an original article agrees to publish the article irrespective of whether GSK Posts the Summary of the relevant Clinical Study Report.

(ii) With respect to products approved for an initial indication after the Order Date, Summaries of Clinical Study Reports will be Posted no later than ten months after first marketing.

c. There may be a delay in Posting complete Summaries of Clinical Study Reports because GSK must seek intellectual-property protection or comply with policies of peer reviewed journals to which manuscripts have been submitted for publication; and, further, GSK may be required to withhold certain Summaries of Clinical Study Reports to comply with confidentiality provisions in agreements with other parties.

With regard to agreements with other parties, in conformance with the intent of this Consent Order & Judgment, in all future Clinical Studies GSK will use reasonable efforts to exclude provisions limiting the publication of Summaries of Clinical Study Reports. For all past agreements with such confidentiality provisions, GSK will make reasonable efforts to secure the right to publish the Summary of the Clinical Study Report on the CTR.

6. Within ten days of the entry of this Consent Order & Judgment, SKB shall tender to the Attorney General the total of $2.5 million as disgorgement and costs by check payable to the State of New York and delivered to the

Office of the Attorney General of the State of New York, 120 Broadway, New York, New York 10271, ATTN: Rose E. Firestein, Bureau of Consumer Frauds & Protection. Upon failure to pay this amount within five days of the date payment is due, a money judgment in the amount due, plus interest, shall be entered in favor of the People of the State of New York, and the Attorney General shall have execution thereof.

7. GSK shall ensure that all Medical Information Letters and other communications it provides to physicians concerning Off-Label Use of a GSK Drug shall fairly and accurately reflect the safety and efficacy Data from Clinical Studies concerning such Off-Label Use.

8. For ten years after February 1, 2005, GSK shall operate and maintain the CTR and make it available to the public on-line by clearly and conspicuously providing the location on the Home Page of the GSK Web Site. In addition, for the same period, GSK shall make available to the public on-line Clinical Study Reports of GSK-Sponsored Clinical Studies of Paxil® in adolescent and pediatric patients, to the extent such Clinical Study Reports are not otherwise included in the CTR. GSK may apply to the Court for modification of the obligations imposed by this ¶ 8, pursuant to Federal Rules of Civil Procedure, in light of changed circumstances during the ten year period. In the event GSK applies for modification, it will comply with the notice provisions in ¶¶ 13-14 below.

9. For ten years following the date this Consent Order & Judgment is entered, and within two months of the completion in final form of the letter in question, GSK shall provide to the Office of the Attorney General each Medical Information Letter or other communication, including each revision of such letter or communication, that is sent to a New York Doctor of Medicine or Doctor of Osteopathy by or on behalf of GSK concerning the use of Paxil® to treat Major Depressive Disorder in children or adolescents.

10. This Consent Order & Judgment shall not be admissible in any other case for any purpose.

11. The State of New York and GSK hereby consent to the entry of this Consent Order & Judgment, which shall constitute a full, complete settlement of the action between the parties concerning Paxil® that was initiated by the Complaint.

12. Any notice given pursuant to this Consent Order & Judgment shall be given by certified mail to: Office of the Attorney General, Bureau of Consumer Frauds & Protection, 120 Broadway, 3rd Floor, New York, New York 10271, ATTN: Rose E. Firestein, Assistant Attorney General.

13. Any party to this Consent Order & Judgment may apply to this Court for such other and further relief as may be necessary to effectuate the terms of this Consent Order & Judgment, upon ten days written notice to all other parties, deliverable by certified mail.

14. Nothing contained in this Consent Order & Judgment shall be construed to deprive any individual of any private right of action under the law.

15. This Court shall retain jurisdiction of this Consent Order & Judgment, and in all other respects the Complaint will be dismissed with prejudice.

WHEREFORE, the following signatures are affixed hereto on the specified dates:

AGREED TO by the parties:

Dated: New York, New York
August 26, 2004

ELIOT SPITZER
Attorney General of the
State of New York

By:
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Dated: New York, New York
August 26, 2004

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GlaxoSmithKline
SMITHKLINE BEECHAM CORPORATION,
d/b/a/ GlaxoSmithKline

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SO ORDERED:

Dated: New York, New York
August 26, 2004

Miriam Goldman Cedarbaum, U.S.D.J.