ATTORNEY GENERAL OF THE STATE OF NEW YORK
BUREAU OF CONSUMER FRAUDS AND PROTECTION
HEALTH CARE BUREAU

x

In the Matter of :

GLAXOSMITHKLINE, plc,
d/b/a GlaxoSmithKline,

and

SMITHKLINE BEECHAM CORPORATION,
d/b/a GlaxoSmithKline.

x

ASSURANCE OF DISCONTINUANCE
PURSUANT TO EXECUTIVE LAW
SECTION 63, SUBDIVISION 15

WHEREAS, pursuant to the provisions of Executive Law § 63(12) and General Business Law Article 22-A, Eliot Spitzer, the Attorney General of the State of New York ("Attorney General"), caused an inquiry to be made into the business practices of GLAXOSMITHKLINE, plc, d/b/a/ GlaxoSmithKline, and SMITHKLINE BEECHAM CORPORATION, d/b/a/ GlaxoSmithKline (collectively "GSK"), concerning GSK's alleged failure to disclose material information from Clinical Studies that evaluated the safety and efficacy of GSK's antidepressant medication Paxil® in treating Major Depressive Disorder ("MDD") in children and adolescents ("pediatric population"); and

WHEREAS, on June 2, 2004, the People of the State of New York brought an action against GSK in the New York Supreme Court, New York County, Index No. 04401707, alleging that GSK violated N.Y. Executive law § 63(12) by, among other things, failing to disclose certain material Clinical Study information concerning Paxil® in treating MDD in the pediatric population; and

WHEREAS, the parties have agreed to settle said action by entering into a Stipulation and Consent to an Order and Judgment and by moving the Court to enter said Order and Judgment, which provides, among other things, that GSK will provide public access to the Clinical Study Reports of Paxil® as a treatment for MDD in the pediatric population; and

WHEREAS, GSK announced on June 18, 2004, its intention to launch a Clinical Trials Register ("CTR") that would provide information about Clinical Studies involving GSK Drugs; and

WHEREAS, GSK has since developed a protocol and template for its Clinical Trials Register; and

WHEREAS, the Office of the Attorney General has reviewed that protocol and template and finds that it provides useful information to the medical community; and

WHEREAS, GSK is undertaking to Post on the Internet Summaries of Clinical Study Reports,

IT IS HEREBY AGREED by GSK, its assigns, successors, agents, contractors, employees and subsidiaries, without admitting that it has violated any law of the State of New York, that:

DEFINITIONS

1. The Definitions set out in Appendix A, which is attached to and incorporated in this Assurance, shall be used for the purposes of this Assurance, including all Appendices. Any terms that are not defined in Appendix A shall be interpreted to have the same meaning as they have in ICH's *Guidelines for Industry: Structure and Content of Clinical Study Reports* (July 1996), which is annexed as Appendix D.

GSK's CLINICAL TRIAL REGISTER

2. GSK shall Post on the Internet a Summary of every Clinical Study Report for GSK-Sponsored Clinical Studies involving a GSK Drug. Such summaries shall conform to ICH E3 principles and to the template attached hereto as Appendix B and shall relate to:

(a) GSK-Sponsored Clinical Studies completed after December 27, 2000; and

(b) any other GSK-Sponsored Clinical Studies material to a physician's medical judgment, for those prescription drugs that GSK actively promotes.

For studies initiated after the date of this Assurance, GSK will also make reasonable effort to encourage the publication of, or in the alternative, secure the right to publish on the CTR, studies in which GSK had significant participation but did not sponsor.

3. The Summaries of Clinical Study Reports that GSK Posts shall accurately reflect the methodology used to conduct the Clinical Study and the Data obtained during the Clinical Study.

4. 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 Assurance Date: Summaries of Clinical Study Reports with a Study Completion Date that occurred between December 27, 2000, and the Assurance 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 Assurance Date: (i) With respect to products approved and marketed for any indication prior to the Assurance 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 Assurance Date, Summaries of Clinical Study Reports will be Posted no later than ten months after first marketing.

(c) The parties recognize that, in some instances, 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, that GSK may be required to withhold certain Summaries of Clinical Study Reports to comply with confidentiality provisions in agreements with other parties. In regard to confidentiality agreements, in all future Clinical Studies GSK will use reasonable efforts to exclude previsions limiting the publication of Summaries of Clinical Study Reports. For all past Clinical Studies with such confidentiality

agreements, GSK will make reasonable efforts to secure the right to publish the Summaries of Clinical Study Reports on the CTR.

5. GSK shall clearly and conspicuously state the location of the Posted information (URL and, where relevant, a link) on the Home Page of the GSK Web Site.

ADDITIONAL GSK OBLIGATIONS

6. Within two weeks of the Assurance Date, GSK shall arrange and pay for the publication of the advertisement annexed hereto as Appendix C to run in the next available print and electronic editions (for at least one month on the electronic editions) of each of the following journals: *Journal of the American Medical Association, New England Journal of Medicine, Pediatrics, Annals of Internal Medicine, Journal of the American Academy of Child and Adolescent Psychiatry, Journal of the American Psychiatric Association, Journal of the American Board of Family Practice.* GSK shall arrange for and pay for the advertisement to be placed between the front cover and the first article in the journal. Letters to the editor do not constitute articles for the purpose of this paragraph. Each advertisement must be at least one-half page in size.

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

MONITORING

8. On a random basis, the Office of the Attorney General may request documents, such as Clinical Study Reports, raw Data from such Reports, and annual reports to the FDA, to

confirm that the terms of this Assurance are being complied with and, subject to a reasonable confidentiality agreement, GSK shall cooperate in responding to these requests.

9. For ten years, GSK's Chief Legal Officer will certify to the Office of the Attorney General annually, in a mutually agreeable format, that it has met the terms of this Assurance.

10. Nothing contained in this Assurance shall in any way limit the Attorney's General right to obtain, by subpoena or any other means permitted by law, documents, testimony or other information to determine whether GSK has fully complied with this Assurance.

FUTURE RIGHTS AND OBLIGATIONS

11. Nothing contained in this Assurance herein shall be construed to deprive any individual of any private right of action under the law.

12. This Assurance shall not be admissible in any other case for any purpose.

13. Acceptance of this Assurance by the Attorney General shall not be deemed or construed as an approval by the Attorney General of any of GSK's actions, and GSK shall not make any representation to the contrary.

Acceptance of this Assurance by GSK shall not be deemed or construed to be an admission of liability by GSK or a waiver of any defense which GSK has or may have in any dispute with the Office of the Attorney General or any other person or entity.

15. GSK may apply to the Office of the Attorney General for modification of the obligations imposed by this Assurance in light of changed circumstances, (including, without limitation, the subsequent imposition of different or inconsistent federal or international regulatory requirements).

16. In appropriate circumstances, GSK will, in its sole discretion, make Clinical Study Reports and related Data available to bona fide researchers who are preparing scholarly work for publication in Peer Reviewed Journals.

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:
BUREAU OF CONSUMER
FRAUDS AND PROTECTION

Thomas G. Conway
Assistant Attorney General in Charge

HEALTH CARE BUREAU

Joseph R. Baker, III
Assistant Attorney in Charge

Rose E. Firestein
Assistant Attorney General

Shirley Stark
Assistant Attorney General

Dated: New York, New York
August 26, 2004

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

KING & SPALDING, LLP

By:

J. Sedwick Sollers III, Esq.

Dwight J. Davis, Esq.