Press Releases

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For Immediate Release
August 26, 2004

SETTLEMENT SETS NEW STANDARD FOR RELEASE OF DRUG INFORMATION

Glaxo to Establish "Clinical Trials Register" with Information on All Company Drugs

Attorney General Spitzer today announced an agreement that resolves charges that a leading pharmaceutical company concealed information about the safety and effectiveness of one of its drugs.

As part of the agreement, GlaxoSmithKline (GSK) will become the first major drug manufacturer to publicly disclose information on clinical studies of its drugs.

"This settlement holds GSK to a new standard of disclosure about studies concerning its drugs, a standard that helps to ensure that doctors and patients have access to all scientifically sound information so doctors can prescribe appropriate medication for their patients," Spitzer said. "By agreeing to release both positive and negative studies about the safety and efficacy of its drugs, GSK has set an example for the entire pharmaceutical industry."

The Attorney General sued GSK in June alleging that the company withheld negative information about Paxil, a drug used to treat depression. Specifically, GSK conducted at least five studies on the use of Paxil in children and adolescents but only released one of these studies, which showed mixed results on efficacy. The lawsuit alleged that the company suppressed the negative results of the other studies, which failed to demonstrate that Paxil is effective and which suggested a possible increased risk of suicidal thinking and acts in certain individuals. The suit further alleged that GSK failed to disclose this information in "Medical Information Letters" that it sent to physicians.

In settlement documents submitted to the U.S. District Court in Manhattan, GSK agreed to continue its online posting of clinical studies of the use of Paxil in children and adolescents. Those studies were made available after the Attorney General filed his lawsuit. In addition, GSK will establish an online "Clinical Trials Register" that will contain summaries of results for all GSK-sponsored clinical studies of drugs conducted after December 27, 2000 (the date Glaxo Wellcome and SmithKlineBeecham merged) and any earlier studies that may be relevant.

The Clinical Trials Register will present summaries of the results of clinical studies in a standardized format and with content that conforms to the requirements of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. Each clinical study summary posted on the register will contain over 20 categories of information including information regarding the effectiveness of the drug tested, the type and severity of adverse side effects the study participants experienced, whether the goals or other components of the study were changed mid-stream, and whether the study was terminated early before full completion and why.

The settlement also sets forth specific time periods during which GSK will upload data into the Clinical Trials Register. GSK expects to post summaries of clinical studies completed prior to the date of the agreement between now and December 31, 2005. Summaries of clinical studies completed after the date of the agreement for drugs already approved and marketed will, in most cases, be posted to the site no later that ten months after the study completion date. For drugs approved and marketed after the agreement date, summaries of the studies will be posted no later than ten months after the drug is first marketed. GSK will advertise the existence and availability of the Clinical Trials Register in major national medical journals.

As part of the settlement, GSK has also agreed to ensure that all Medical Information Letters and other communications it provides to doctors concerning off-label use of Paxil and other drugs will fairly and accurately reflect the safety and efficacy data from clinical studies concerning off-label use.

GSK will pay $2.5 million in disgorgement and costs to the State of New York.

Spitzer thanked GSK officials for working with his office to resolve the matter.

The investigation and settlement discussions were handled by Assistant Attorneys General Rose Firestein and Shirley Stark, under the supervision of Thomas Conway, Chief of the Consumer Frauds and Protection Bureau, and Joseph Baker, Chief of the Health Care Bureau.

Attachments:

- Consent Order
- Assurance of Discontinuance with Appendices
- New York State Psychiatric Association, Inc. Press Release