PHARMACEUTICAL INDUSTRY

New standard of disclosure set for clinical trials

The New York State Attorney General's office is heralding a "new standard of disclosure" for clinical trial findings after reaching an agreement with GlaxoSmithKline to settle a lawsuit that alleged GSK committed consumer fraud by concealing studies indicating the antidepressant paroxetine could lead to suicidal behaviour in children.

The settlement obliges GSK to maintain an online clinical trials registry for the next decade. The registry will feature summaries of all its sponsored trials (from Dec. 27, 2000, onward) including information about safety and efficacy, type and severity of side effects, midstream methodologic changes and early terminations.

Trial results must be posted within 10 months after a drug is first marketed, and GSK must advertise the registry in journals.

Included as evidence in the lawsuit was a leaked confidential memo (*CMAJ* 2004; 170[5]:783) that indicated GSK had withheld negative information stemming from clinical trials that assessed the efficacy of paroxetine in treating depression in children.

The settlement will help "ensure that doctors and patients have access to all scientifically sound information so doctors can prescribe appropriate medication for their patients," New York State Attorney General Eliot Spitzer stated.

Although the deal has a 10-year duration, GSK spokesperson Mary Anne Rhyne says the company intends to make the registry permanent. Rhyne said GSK decided to settle the lawsuit, including US$2.5 million in costs and disbursements, out of a sense of civic responsibility. "This [registry] is something we're proud of. It's a big commitment of time and energy and resources but we hope that it will be helpful."

The creation of the GSK registry may persuade other drug companies to follow suit, notes Canadian Institutes of Health Research Vice-President (Research) Dr. Mark Bisby. "Whatever you can say about the pharmaceutical industry, they do like to be seen as good citizens."

The registry may also provide further impetus for creating comprehensive, centralized registries that report the findings of all trials undertaken by pharmaceutical firms, as was recently urged by the International Committee of Medical Journal Editors. ICMJE members will no longer publish results of unregistered trials (*CMAJ* 2004;171[6]:606-7).

The American Medical Association has also asked the US government to create a mandatory comprehensive trials registry. — *Wayne Kondro*, Ottawa

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