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Drug Maker Told Studies Would Aid It, Papers Say

By GARDINER HARRISMARCH 19, 2009

An influential Harvard child psychiatrist told the drug giant Johnson & Johnson that planned studies of its medicines in children would yield results benefiting the company, according to court documents dating over several years that the psychiatrist wants sealed.

The psychiatrist, Dr. Joseph Biederman, outlined plans to test Johnson & Johnson's drugs in presentations to company executives. One slide referred to a proposed trial in preschool children of risperidone, an antipsychotic drug made by the drug company. The trial, the slide stated, "will support the safety and effectiveness of risperidone in this age group."

Dr. Biederman was the lead author of a trial published last year concluding that treatment with risperidone improved symptoms of attention deficit and hyperactivity disorder in bipolar children.

Dr. Biederman — who was director of the Johnson & Johnson Center for Pediatric Psychopathology Research at Massachusetts General Hospital, in Boston — is in the middle of two controversies: one involves the use of antipsychotic drugs in children, and the other relates to conflicts of interest in medicine.

He is the world's most prominent advocate of diagnosing bipolar disorder in even the youngest children and of using antipsychotic medicines to treat the disease, but much of his work has been underwritten by drug makers for whom he privately consults. An inquiry by Senator Charles E. Grassley, Republican of Iowa, revealed last year that Dr. Biederman earned at least $1.6 million in consulting fees from drug makers from 2000 to 2007 but failed to report all but about $200,000 of this income to university officials.

Harvard and the National Institutes of Health are investigating whether Dr. Biederman violated federal and university research rules. He has suspended his work with the drug industry during the investigations.

Dr. Biederman has become a key witness in a series of lawsuits filed by state attorneys general claiming that makers of antipsychotic drugs defrauded state Medicaid programs by improperly marketing their medicines. His work helped fuel a rapid rise in the use of these medicines in children.

In November, the lawyers for the states released e-mail messages and internal documents from Johnson & Johnson that showed the company had intended to use its connection with Dr. Biederman to increase sales. The documents became public in a motion filed by plaintiffs' lawyers to compel him to be interviewed.

Dr. Biederman has not responded to messages seeking comment. An article in The Boston Globe in December quoted a letter to the newspaper in which he wrote that while Johnson &

Johnson had sought commercial applications to his work, “any implication that J.&J.’s interests interfered with the center’s work is wrong.”

A spokeswoman for Massachusetts General Hospital said Thursday that she could not comment on pending litigation.

Photo

Dr. Joseph Biederman

Judge Jamie D. Happas of New Jersey Superior Court, who is overseeing the multistate litigation, ruled last year that Dr. Biederman should be deposed. As part of that process, Dr. Biederman provided lawyers with documents relating to his interactions with Johnson & Johnson; the documents included presentations he made over several years summarizing the work of the center, financed by the company.

Peter Spivack, a lawyer representing Dr. Biederman, filed a motion seeking to keep these documents under seal. The New York Times received copies of the documents.

In a letter filed with the court on Thursday, Mr. Spivack said articles in The Times about Dr. Biederman had “publicly embarrassed Dr. Biederman and, in part, led to an agreement to forestall contact with pharmaceutical companies.”

One set of slides in the documents referred to “Key Projects for 2004” and listed a planned trial to compare Risperdal, also known as risperidone, with competitors in managing pediatric bipolar disorder. The trial “will clarify the competitive advantages of risperidone vs. other neuroleptics,” the slide stated. All of the slides were prepared by Dr. Biederman, according to his sworn statement.

In 2005, Dr. Biederman was the lead author of a study comparing Risperdal and Zyprexa, made by Eli Lilly. The study concluded that Risperdal improved subjects’ depressive symptoms but that Zyprexa did not.

A slide listing “Key Projects for 2005” mentioned a planned study in adolescents of Concerta, a stimulant manufactured by Johnson & Johnson. The study will “extend to adolescents positive findings with Concerta in A.D.H.D. N.O.S. in adults,” the slide said, referring to unusual cases of attention deficit hyperactivity disorder.

In 2006, Dr. Biederman was co-author of a study showing that children given Concerta for a prolonged period did not have reduced growth, allaying a significant concern about the medicine.

Josephine Johnston, a research scholar at the Hastings Center, a bioethics research institute, said the documents "raise questions about how well-designed Dr. Biederman's trials were in that he promised a result to his funders."

"It's another shadow over his work," Ms. Johnston said.

In a contentious Feb. 26 deposition between Dr. Biederman and lawyers for the states, he was asked what rank he held at Harvard. "Full professor," he answered.

"What's after that?" asked a lawyer, Fletch Trammell.

"God," Dr. Biederman responded.

"Did you say God?" Mr. Trammell asked.

"Yeah," Dr. Biederman said.