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Research Center Tied to Drug Company

By GARDINER HARRIS

When a Congressional investigation revealed in June that he had earned far more money from drug makers than he had reported to his university, Dr. Joseph Biederman, a world-renowned child psychiatrist, said that his "interests are solely in the advancement of medical treatment through rigorous and objective study."

But e-mails and internal documents from Johnson & Johnson made public in a court filing reveal that Dr. Biederman pushed the company to fund a research center at <u>Massachusetts General Hospital</u> whose goal was "to move forward the commercial goals of J&J," the documents state. The documents also show that Johnson & Johnson wrote a draft summary of a study that Dr. Biederman, of <u>Harvard University</u>, was said to author.

Dr. Biederman's work helped to fuel a 40-fold increase from 1994 to 2003 in the diagnosis of pediatric bipolar disorder and a rapid rise in the use of powerful, risky and expensive antipsychotic medicines in children. Although many of his studies are small and often financed by drug makers, Dr. Biederman has had a vast influence on the field largely because of his position at one of the most prestigious medical institutions in the world.

Johnson & Johnson manufactures Risperdal, also known as risperidone, a popular antipsychotic medicine. More than a quarter of Risperdal's use is in children and adolescents.

Last week, a panel of federal drug experts said that medicines like Risperdal are being used far too cavalierly in children and that federal drug regulators must do more to warn doctors of their substantial risks. Other popular antipsychotic medicines, also referred to as neuroleptics, are Zyprexa, made by Eli Lilly; Seroquel, made by AstraZeneca; Geodon, made by Pfizer; and Abilify, made by Bristol-Myers Squibb.

Thousands of parents have sued Johnson & Johnson, AstraZeneca and Eli Lilly, claiming that their children were injured after taking the medicines, whose risks the companies minimized, the parents claim. As part of the suits, plaintiffs' attorneys have demanded millions of documents from the companies. Nearly all of those documents have been provided under judicial seals, but a select few that mentioned Dr. Biederman became public after plaintiffs attorneys sought a judge's order to require Dr. Biederman to be interviewed by plaintiff attorneys under oath.

In a motion filed two weeks ago, attorneys for the families argued that they should be allowed to interview Dr. Biederman under oath because his work has been crucial to the widespread acceptance of pediatric uses of antipsychotic medicines. To support this contention, the lawyers included more than two dozen documents, including e-mails from Johnson & Johnson that mentioned Dr. Biederman. That interview request has yet to be ruled upon.

Exhibit I, page 1 of 3

1 of 3

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The documents offer an unusual glimpse into the delicate relationship that drug makers have with influential doctors. In one November 1999 e-mail, John Bruins, a Johnson & Johnson marketing executive, begs his supervisors to approve a \$3,000 check to Dr. Biederman in payment for a lecture he gave at the University of Connecticut.

"Dr. Biederman is not someone to jerk around," Mr. Bruins wrote. "He is a very proud national figure in child psych and has a very short fuse."

Mr. Bruins wrote that Dr. Biederman was furious after Johnson & Johnson rejected a request that Dr. Biederman had made to receive a \$280,000 research grant. "I have never seen someone so angry," Mr. Bruins wrote. "Since that time, our business became non-existant (sic) within his area of control."

Mr. Bruins concluded that, unless Dr. Biederman received a check soon, "I am truly afraid of the consequences."

A series of documents described the goals behind establishing the Johnson & Johnson Center for the study of pediatric psychopathology, for which Dr. Biederman still serves as chief.

A 2002 annual report for the center stated that its research must satisfy three criteria: improve psychiatric care for children, have high standards and "move forward the commercial goals of J&J," according to court documents.

"We strongly believe that the center's systematic scientific inquiry will enhance the clinical and research foundation of child <u>psychiatry</u> and lead to the safer, more appropriate and more widespread use of medications in children," the report stated. "Without such data, many clinicians question the wisdom of aggressively treating children with medications, especially those like neuroleptics, which expose children to potentially serious adverse events."

A February 2002 e-mail from Georges Gharabawi, a Johnson & Johnson executive, stated that Dr. Biederman approached the company "multiple times to propose the creation" of the center. "The rationale of this center is to generate and disseminate data supporting the use of risperidone in" children and adolescents, the e-mail stated.

Johnson & Johnson gave the center \$700,000 in 2002 alone, documents show.

A June 2002 e-mail from Dr. Gahan Pandina, a Johnson & Johnson executive, to Dr. Biederman included a brief abstract of a study of Risperdal in children suffering disruptive behavior disorder. The study was intended to be presented at the 2002 annual meeting of the American Academy of Child & Adolescent Psychiatry, the e-mail stated.

"We have generated a review abstract, but I must review this longer abstract before passing this along," Dr. Pandina wrote. One problem with the study, Dr. Pandina wrote, is that the children given placebos and those given Risperdal both improved significantly, "so, if you could, please give some thought to how to handle this issue if it occurs."

The draft abstract that Dr. Pandina included in the e-mail, however, stated that only the children given Risperdal improved, while those given placebos did not. Dr. Pandina asked Dr. Biederman to sign a form listing himself as author so the company could present the study to the conference, according to the e-mail.

Exhibit I, page 2 of 3

2 of 3

"I will review this morning," Dr. Biederman responded, according to the documents. "I will be happy to sign the forms if you could kindly send them to me." The documents do not make clear whether Dr. Biederman approved the final summary of the brief abstract in similar form or asked to read the longer report on the study.

Drug makers have long hired professional writers to compose scientific papers and then recruited well-known doctors to list themselves as authors. The practice, known as ghostwriting, has come under intense criticism recently, and medical societies, schools and journals have condemned it.

In June, a Congressional investigation revealed that Dr. Biederman had failed to report to Harvard at least \$1.4 million in outside income from Johnson & Johnson and other makers of antipsychotic medicines.

In one example, Dr. Biederman reported no income from Johnson & Johnson for 2001 in a disclosure report filed with the university. When asked by Senator <u>Charles E. Grassley</u>, a Republican of Iowa, to check again, Dr. Biederman said he received \$3,500. But Johnson & Johnson told Mr. Grassley that it paid Dr. Biederman \$58,169 in 2001.

On Monday, David J. Cameron, a Harvard spokesman, said the university was still reviewing Mr. Grassley's allegations against Dr. Biederman. He added that they had not seen the drug company documents in question and that the university is not directly involved in the child psychiatry center at Massachusetts General Hospital.

Calls to Dr. Biederman were not returned. Johnson & Johnson did not immediately comment or make executives available for comment.

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Exhibit I, page 3 of 3