



*State of New Jersey*  
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May 5, 2009

The Honorable Joshua M. Sharfstein, M.D.  
Acting Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Commissioner Sharfstein:

I write, on behalf of the consumers and citizens of the State of New Jersey, to express my grave concern about the rampant undisclosed financial conflicts of interest of physicians participating in the clinical trials of drugs and medical devices. Clinical investigators are expected to act objectively in testing the safety and effectiveness of the drugs or medical device they are testing. But when the investigators stand to profit from United States Food and Drug Administration ("FDA") approval of the product they are testing, there is a significant possibility that these conflicts will undermine the integrity of the clinical trial process.

In February 2008, the State of New Jersey launched an investigation into the financial conflicts of interests of the surgeon-investigators participating in the clinical trials for Synthes, Inc.'s ProDisc Total Replacement System, ProDisc-L and ProDisc-C ("ProDisc"). The investigation revealed that a majority of the physicians who participated in these clinical trials had significant investments in the products — investments that would have been worthless had the product failed to obtain regulatory approval from the FDA. And, the investigation revealed that Synthes, which acquired ProDisc while the clinical trials were underway, failed to disclose these financial conflicts of interest to the FDA.

Yet, despite the fact that Synthes' failure to adequately disclose these interests should have been obvious from even a cursory review of its FDA submissions, the FDA did nothing to regulate these conflicts. A number of the disclosure forms were signed and dated, but were otherwise left blank. Others indicated that the clinical investigator had a significant equity interest in the product, but did not attach the requisite details. But the FDA approved Synthes' applications for premarket approval without any delay or further inquiry into this issue.



As a result of this investigation, the State has entered into a settlement agreement with Synthes that requires the company, going forward, to fully disclose the financial conflicts of interest of its clinical investigators to the public and to the FDA. Pursuant to this agreement, Synthes will, inter alia, (1) monitor, collect and disclose any and all payments to clinical investigators, including investments held by the investigators in the product they are testing, on the company's website and to the FDA; (2) prohibit compensation of clinical investigators tied to the outcome of the clinical trial, including company stock or stock options; (3) pay clinical investigators "fair market value compensation" for their clinical trial work, as well any other consulting services they provide to the company; and (4) disclose all financial interests directly to health care facilities serving as clinical trial sites. A copy of the agreement is attached.

I am gravely concerned about the conflicts of interest that pervade the medical device industry – particularly with respect to high-risk devices - and their deleterious effects upon consumers. The State of New Jersey calls upon the FDA to (1) heighten its oversight authority in this area and to rigorously enforce the conflict of interest disclosure rules and regulations; and (2) promulgate regulations that require all medical device manufacturers and pharmaceutical companies to adequately disclose the conflicts of interests of clinical investigators to the public. It is our hope that the provisions in our Agreement with Synthes will become part of best practices for the entire medical device industry.

Very truly yours,



Anne Milgram  
Attorney General

Cc:

Honorable Charles E. Grassley  
Ranking Member  
United States Senate Committee on Finance

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