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Office of The Attorney General
- Anne Milgram, *Attorney General*

Landmark Settlement Reached with Medical Device Maker Synthes

1st of Its Kind Agreement Removes Conflicts-of-Interest from Clinical Trials

Attorney General Also Moves to End Conflicts Throughout the Industry

Settlement Agreement | AG's letter to the FDA

TRENTON -- Attorney General Anne Milgram and Division of Law Director Robert Gilson announced today that the State has entered into a settlement agreement with medical device maker Synthes, Inc. that resolves allegations Synthes failed to disclose financial conflicts-of-interest among doctors who conducted clinical testing on its products.

Under the Assurance of Voluntary Compliance agreement, Synthes must disclose any future payments made by the company to physicians conducting clinical trials on its devices, as well as any investments held by such physicians in the devices they test. A $3 billion global company, Synthes has also agreed to stop paying clinical trial physicians with company stock or stock options.

Based in West Chester, Pa., Synthes is known principally for its work in spinal and trauma products and devices. The state's investigation focused on allegations that most doctors conducting clinical trials for Synthes' ProDisc Total Disc Replacement System, ProDisc-L and ProDisc-C had a financial stake in the outcome.

Milgram said the apparently common industry practice of clinical trial physicians being paid by – or holding considerable stock in -- companies whose products they are testing is wrong, and leaves the clinical trial process lacking in integrity.

"It is outrageous that doctors who are testing and, in many cases, recommending the use of certain high-risk medical devices are being compensated with stock in the very companies that make the devices," said Milgram. "All patients – but especially those considering high-risk devices such as spinal disc replacements -- deserve honest, objective clinical trial information about the products available."

Milgram said the Synthes agreement should serve as a template for the entire industry.

In a letter to the federal Food and Drug Administration (FDA) sent today, the Attorney General said she is hopeful the Synthes terms will become "best practices" for disclosure among medical device makers. Milgram's letter described the problem of undisclosed financial conflicts-of-interest among clinical investigators as "rampant," and called on the FDA to more effectively address the problem by adopting rules that require full public disclosure. Copies of the Attorney General's FDA letter went to Senator Max Baucus, Chairman of the U.S. Senate Committee on Finance, and

to Senator Charles E. Grassley, the ranking member of that committee.

In addition, Milgram said her office issued subpoenas today to five major medical device manufacturing companies seeking information about their business practices.

“Medical device makers have a duty to make certain that clinical trial results are accurate and unbiased,” the Attorney General said. “In creating these financial incentives for doctors, Synthes and the rest of the industry have done the exact opposite. Going forward, if the industry will not address this problem voluntarily, we most certainly will.”

Milgram described the Synthes settlement as the first of its kind because of its disclosure provisions, as well as its ban on compensating clinical researchers with company stock. She said the latter provision runs counter to widespread industry practice – a practice she called unacceptable.

Currently, she said, many clinical investigators stand to profit significantly if the trials in which they are involved are successful. Often, she explained, these financial interests are not disclosed to the public -- including the human subjects participating in the trials and the patients who rely on the devices.

ProDisc was developed by a start-up company known as Spine Solutions Inc. A New York investment firm, Viscogliosi Brothers, helped found Spine Solutions and financed the disc’s development and research. The Viscogliosi Brothers offered the ProDisc clinical investigators substantial investment opportunities in Spine Solutions, as well as consulting contracts that included gifts of company stock and stock options. Synthes, Inc. bought Spine Solutions in 2003 and failed to fully disclose these conflicts of interest to the FDA. FDA approved Synthes’ applications for pre-market approval of ProDisc, even when the financial conflict disclosures were plainly inadequate.

In her letter to the FDA, Milgram took the agency to task for its lax handling of the Synthes application.

For example, she noted, a number of disclosure forms contained in the Synthes submission to FDA were signed and dated, but were otherwise left blank. Other forms indicated that clinical investigators had significant equity interests in the Synthes product they were testing, but offered no details.

Synthes’ failure to adequately disclose “should have been obvious from even a cursory review of its FDA submissions,” Milgram wrote, yet the FDA “did nothing” and ultimately approved Synthes applications for pre-market approval without delay or further inquiry into the apparent conflicts.

In announcing the Synthes settlement today, Milgram said it is vital that, nationwide, the medical device manufacturing industry change the way it approaches clinical testing.

“We cannot allow financial conflictsof-interest to infect the clinical trial process. It is a betrayal of the public trust, and has the potential to jeopardize patient well-being,” she said.

Under terms of the settlement, Synthes, Inc. has agreed to publicly disclose – on its Web site – any financial relationships with doctors conducting its clinical research trials. The company has also committed to disclosing such financial conflicts-of- interest to the research institutions that serve as clinical trial locations, and to the FDA.

“Such disclosure is not required by the FDA, but it should be,” said Milgram.

Under terms of the settlement Synthes, Inc. has agreed to:

Prohibit compensation of clinical investigators tied to the outcome of the clinical trial

Pay clinical investigators “fair market value compensation” for their clinical trial work, as well any other consulting services they provide to the company

Collect information on financial interests from clinical investigators

Create a Financial Interest Information Database that will record all relevant financial interests related to clinical investigators

Disclose all financial interests of all clinical investigators on the company’s Web site

Provide complete disclosure of financial interests to the FDA and conduct reasonable due diligence to insure that the disclosures are complete and accurate

Disclose all financial interests directly to health care facilities serving as clinical trial sites

Provide Financial Interest and Disclosure training to employees.

“We are committed – as evidenced by our investigation of Synthes – to doing everything within our power to ensure fairness and transparency in the clinical trial process. We call on the FDA to become more aggressive in this regard, and we call on medical device makers themselves to publicly disclose information concerning who has a financial stake in the devices being tested,” said Milgram.

“As things stand,” Milgram added, “the public often has no knowledge that a ‘clinically tested and recommended’ medical device was evaluated and endorsed by people with a financial stake in seeing it sell. This is simply wrong and it must stop.”

The Synthes agreement pertains to all ongoing and future clinical trials, except for those conducted outside the U.S. and not intended for use in the marketing of products in this country.

In addition to the other settlement terms, Synthes will pay the state a total of $236,000 as reimbursement for fees and costs related to the investigation.

The Synthes case was handled by Deputy Attorney General Megan Lewis, Chief of the Division of Law’s Affirmative Litigation Section, and Deputy Attorney General Michelle T. Weiner.