

Pa. firm to pay \$23M for illegal bone cement tests

October 5 2010, By MARYCLAIRE DALE , Associated Press Writer

(AP) -- A medical devices company will admit criminality and pay the maximum \$23 million fine for illegally testing bone cement on about 200 spinal patients, three of whom died in surgery, U.S. prosecutors said Monday.

Norian Corp. trained surgeons to conduct unapproved clinical tests of its bone cement from 2002 to 2004, subverting U.S. [Food and Drug Administration](#) safeguards, prosecutors said. The trials were stopped after the third patient death, they said.

The cement, which is used to fill in bone defects, is approved for use in the arm but not the load-bearing spine, authorities said. The surgeries often involved older patients with compression fractures, they said.

"The aging of the baby boomer generation makes the market for treatment of VCFs (vertebral compression fractures) a large and lucrative one," prosecutors wrote in a March memo in the case.

Norian and its parent company, Synthes Inc., both based in West Chester, a 35-mile drive west of Philadelphia, not only tested the bone product for unapproved uses but also failed to report the deaths to the FDA and lied to agency investigators, prosecutors said Monday. The deaths occurred in California and Texas.

Norian will plead guilty to conspiracy to impede FDA functions, a felony, and 110 misdemeanor counts of interstate shipping of

misbranded Norian XR. Synthes will plead guilty to the same misdemeanor shipping count.

As part of the agreement, Norian will be sold to an outside buyer, the parent company said.

"Synthes remains committed to operating in accordance with the highest legal and ethical standards, and bringing closure to this matter will permit the company to focus on its mission to improve patient care," the company said in a statement.

Four Synthes executives are awaiting sentencing after each pleaded guilty to the misdemeanor shipping charge. [Prosecutors](#) call their crimes intentional and say a Synthes medical consultant warned that the tests amounted to "human experimentation," according to the March government memo.

Defense lawyers argue that their clients pleaded guilty only as responsible corporate officers and deny any intent. No sentencing dates have been set.

The four executives are: Synthes North America President Michael D. Huggins, 51, of West Chester; senior vice president Thomas B. Higgins, 52, of Berwyn; vice president Richard E. Bohner, 55, of Malvern; and director of regulatory and clinical affairs John J. Walsh, 46, of Coatesville.

According to the June 2009 indictment, the company's pilot studies showed the bone cement product could cause blood clots in humans, while pig research suggested such clots could move to the lungs.

The patients who died suffered severe hypotension, or low blood pressure, following injections of Norian, authorities said. None of the

surgeons could rule out the [bone cement](#) as a factor in the deaths, an FDA investigator has said.

U.S. Attorney Zane David Memeger said Monday that device manufacturers have legal obligations not to test their products on humans without FDA oversight.

"This case is especially troubling because in search of greater profits Norian bypassed this process," Memeger said.

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