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FORMER EXECUTIVES OF INTERNATIONAL MEDICAL DEVICE MAKER SENTENCED TO PRISON IN UNLAWFUL CLINICAL TRIALS CASE

PHILADELPHIA – Thomas Higgins, 55, of Berwyn, PA, Michael Huggins, 54, of West Chester, PA, and John Walsh, 48, of Coatesville, PA, all former executives with Synthes, Inc., and its subsidiary Norian Corporation, were each sentenced to prison today for charges related to illegal clinical trials of a medical device without the authorization of the Food and Drug Administration. Higgins and Huggins were each sentenced to nine months in prison; Walsh was sentenced to five months. The sentences were announced by United States Attorney Zane David Memeger, Acting Deputy Assistant Attorney General for the Consumer Protection Branch Maame Ewusi-Mensah Frimpong, Special Agent in Charge Antoinette V. Henry of FDA's Office of Criminal Investigations, Metro Washington Field Office, and Special Agent in Charge for the United States Department of Health and Human Services, Office of the Inspector General Nick DiGiulio.

A fourth former Synthes executive, Richard Bohner, 56, of Malvern, PA, will be sentenced at a later date. All four previously pleaded guilty to one misdemeanor count of shipping adulterated and misbranded Norian XR in interstate commerce. It is one of a few cases in which company executives have been sentenced to a term of imprisonment for a misdemeanor violation of the Food, Drug and Cosmetic Act. Huggins was immediately remanded; Higgins was given two weeks to report to prison; Walsh must report on November 28, 2011.

The individual defendants, by virtue of their respective positions, were "responsible corporate officers" at various time during the events described in the indictment. From May 2002 until fall 2004 Norian conspired with others, including Synthes and the former executives, to conduct unauthorized clinical trials of Synthes's medical devices, Norian XR and Norian SRS,[1] commonly called "bone cement", in surgeries to treat vertebral compression fractures of the spine ("VCFs"), a painful condition commonly suffered by elderly individuals. These surgeries were performed despite a warning on the FDA-cleared label for Norian XR against this use, and in the face of serious medical concerns about the safety of the devices when used in the spine. Before the marketing program began, pilot studies showed the company that the bone

[1]Norian SRS and Norian XR were bone cements that were used in treating fractures.

cement reacted chemically with human blood in a test tube to cause blood clots. The research also showed, in a pig, that such cement-caused clots became lodged in the lungs. Notwithstanding this knowledge, the company proceeded to market the product for VCFs without putting it through FDA-required testing. The company did not stop marketing the product until after a third patient had died on the operating table. After the death of the third patient in January 2004, Norian and Synthes did not recall Norian XR from the market – which would have required them to disclose details of the three deaths to the FDA – but, instead, compounded their crimes by carrying out a coverup in which they made false statements to the FDA during an official inspection in May and June 2004.

In addition to the prison term, U.S. District Court Judge Legrome D. Davis ordered each of the defendants to pay a fine in the amount of $100,000.

Norian, itself, was charged with and pleaded guilty to one felony count of conspiracy to impair and impede the lawful functions of the FDA and to commit crimes against the United States, and 110 misdemeanor counts of shipping adulterated and misbranded Norian XR in interstate commerce. The parent company, Synthes, was charged with one misdemeanor count of shipping adulterated and misbranded Norian XR in interstate commerce. Synthes, a corporation based in West Chester, Pennsylvania, is the United States branch of a large multinational medical device manufacturer that specializes in trauma products to treat damaged human bone. Norian was a wholly owned subsidiary of Synthes, specializing in the manufacture of osteobiologic medical devices, with a principal place of business in West Chester, Pennsylvania. Upon conviction, Norian's parent Synthes entered a Divestiture Agreement with the Department of Health and Human Services Office of Inspector General under which it agreed to sell all Norian assets within a limited period of time.

"When corporate executives authorize clinical trials of a medical device without the FDA's permission and without regard for known safety risks, including death, those executives must be held accountable," said Memeger. "In this case, the defendants conducted illegal human experiments beyond the scrutiny of the FDA. They subjected frail and elderly patients - among the most vulnerable members of our society - to serious safety risks. Today's sentences should clearly put health care industry executives on notice that when they violate the law and harm individuals for the sake of corporate profits, they will go to prison."

"The Department of Justice is committed to holding individual corporate officers accountable for their criminal conduct," said Acting Deputy Assistant Attorney General for the Consumer Protection Branch Maame Ewusi-Mensah Frimpong. "As the Court found, these senior managers knew about and participated in unlawful human experimentation that disregarded the safety of all members of society. Because of the Court's sentences today, they will answer for their actions."

"The public's trust in the medical device industry is compromised when pharmaceutical executives put aside their integrity for profits" said Special Agent in Charge Antoinette V. Henry of FDA's Office of Criminal Investigations, Metro Washington Field Office. "The conviction of these pharmaceutical executives exemplifies the successful efforts by FDA's Office of Criminal

Investigations and its law enforcement partners to hold these individuals accountable and not allow them to escape liability by hiding behind a corporate shield."

"Holding executives accountable for corporate wrong doing continues to be a priority for our office," said Special Agent in Charge for the United States Department of Health and Human Services, Office of the Inspector General Nick DiGiulio. "We are hopeful that the sentences handed down today will encourage executives in the health care industry to play by the rules and to consider patient safety over profits."

This case was investigated by the United States Food and Drug Administration Office of Criminal Investigations; the United States Department of Health and Human Services Office of Inspector General; the Defense Criminal Investigative Service, Department of Defense; and the Veterans' Administration Office of Inspector General. The case was prosecuted by Assistant United States Attorneys Mary E. Crawley and Gerald B. Sullivan and Laura A. Pawloski, Associate Chief Counsel, FDA Office of Chief Counsel, with assistance from the Consumer Protection Branch of the Department of Justice.

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