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U.S. Department of Justice

United States Attorney

Eastern District of Pennsylvania

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INTERNATIONAL MEDICAL DEVICE MAKER AND FOUR EXECUTIVES CHARGED IN CONNECTION WITH UNLAWFUL CLINICAL TRIALS

PHILADELPHIA – United States Attorney Michael L. Levy and Acting Assistant Attorney General Michael F. Hertz today announced the return of an indictment [1] against Norian Corporation ("Norian"), Synthes, Inc. ("Synthes"), and four top Synthes executives, Michael D. Huggins ("Huggins"), Thomas B. Higgins ("Higgins"), Richard E. Bohner ("Bohner") and John J. Walsh ("Walsh"), charging them for their involvement in conducting clinical trials of a medical device without the authorization of the FDA. Joining in today's announcement were Food and Drug Administration ("FDA") Office of Criminal Investigations Special Agent-in-Charge Kim A. Rice; Department of Health and Human Services ("HHS") Office of Inspector General Office of Investigations Special Agent-in-Charge Patrick Doyle; Defense Criminal Investigative Service ("DCIS") Special Agent-in-Charge Edward Bradley; and Department of Veterans Affairs ("VA") Special Agent-in-Charge Jeffrey G. Hughes, Northeast Field Office, Office of Inspector General.

The indictment charges Norian with a total of 52 felony counts: conspiracy to impair and impede the lawful functions of the FDA and to commit crimes against the United States; 7 counts of making false statements in connection with an FDA inspection; and 44 counts of shipping adulterated and misbranded Norian XR in interstate commerce with intent to defraud. The parent company, Synthes, is charged with 44 misdemeanor counts of shipping adulterated and misbranded Norian XR in interstate commerce, and the four executives, Michael D. Huggins, Thomas B. Higgins, Richard E. Bohner and John J. Walsh, are each charged with one misdemeanor count of shipping adulterated and misbranded Norian XR in interstate commerce. As explained below, these crimes allegedly prevented the FDA from carrying out its role of supervising clinical trials of significant risk devices, and deprived patients of the safeguards provided by FDA oversight of clinical trials.

According to the indictment, Synthes, a Delaware corporation based in West Chester, Pennsylvania, is the United States branch of a large multinational medical device manufacturer

[1] An indictment or information is an accusation. A defendant is presumed innocent unless and until proven guilty.

which specializes in trauma products to treat damaged human bone. Norian, it is alleged, is a wholly owned subsidiary of Synthes, specializing in the manufacture of osteobiologic medical devices, with a principal place of business in West Chester, Pennsylvania.

Defendant Huggins was allegedly employed by Synthes as the President of Synthes North America, a subsidiary of Synthes. It is alleged that in February 2004, Huggins became the President of Synthes Spine, a division of Synthes. Defendant Higgins was allegedly the President of Synthes Spine, a division of Synthes, reporting to Huggins. In February 2004, Higgins allegedly left that position and became Synthes's Senior Vice President of Global Strategy. The indictment alleges that defendant Bohner was employed by Synthes as its Vice President of Operations, reporting to Huggins. Defendant Walsh was allegedly employed by Synthes starting in August 2003 as its Director of Regulatory and Clinical Affairs, Spine Division, and reported first to Bohner and later to Huggins.

The indictment charges that from May 2002 until fall 2004 Norian conspired with others, including Synthes and the four named executives, to conduct unauthorized clinical trials of Synthes's medical devices, Norian XR and Norian SRS,[2] in surgeries to treat vertebral compression fractures of the spine ("VCFs"), a painful condition commonly suffered by elderly individuals. These surgeries were allegedly 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. According to the indictment, before the marketing program began, pilot studies showed the company that the bone cement reacted chemically with human blood in a test tube to cause blood clots. The research also showed, in a pig, that such Norian-caused clots became lodged in the lungs. Notwithstanding this knowledge, the company allegedly proceeded to market the product for VCFs without putting it through FDA-required testing. The company, it is alleged, did not stop marketing the product until after a third patient had died on the operating table. The indictment further alleges that 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 lied to the FDA during an official inspection in May and June 2004.

Levy said, "We have an FDA approval process to be certain that medicines and medical devices that are used in the United States have gone through appropriate testing to determine that the products are safe and effective. The FDA requires its independent review of the tests to ensure that companies do not put their financial interests ahead of the health and safety of the American people. The defendants charged today bypassed the process, with the knowledge that the product that they were marketing posed potentially significant risks. When predictable bad results occurred, they lied to the FDA investigators. They put their profits ahead of responsible business practices and the truth."

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

Hertz said, "This case is another example of the Department of Justice working together as a team to enforce the Food, Drug, and Cosmetic Act against companies and individuals that fail to market their products in compliance with that statute."

"The FDA's Office of Criminal Investigations aggressively pursues and supports the prosecution of those who endanger the public health by circumventing the safeguards the FDA has in place to ensure that clinical trials are adequately supervised and controlled and that the public receives medical devices that have been shown to be safe and effective," said Michael Chappell, acting associate commissioner for regulatory affairs. "We will continue to do all we can to protect the public against companies and their representatives who are not truthful, put patients's health at risk and undermine the regulatory process."

"It is never acceptable for the health care industry to place the profit motive over people's well being," said Patrick Doyle. "The FDA review process was put in place to protect the nation's citizens. Should these companies and executives ultimately be found guilty, they will have to pay a price for placing at risk the very people for whom they purported to provide relief."

Summary of the Charges

The indictment charges that from the beginning, the intended market for Norian XR was for an unapproved use, i.e., in surgeries to treat VCFs. According to the indictment, the company recognized early on that there were two possible solutions to this problem: (1) the legal solution, which was to disclose to the FDA the intended use of the product and then to try to secure FDA approval of XR for use in surgeries to treat VCFs after obtaining an investigational device exemption ("IDE") to investigate the safety and efficacy of the product, and (2) the illegal solution, which was to promote XR for use in VCFs through a limited so-called "test market," during which the company would evaluate the safety and efficacy of the product in unapproved clinical trials and judge their success according to its own standards. The indictment charges that the company and its co-conspirators consciously and deliberately chose the illegal solution. That is, according to the indictment , the company intentionally bypassed the requirement that it obtain permission from the FDA to conduct clinical trials of the XR device on human beings for an unapproved use – permission that it knew it needed. With the so-called "test market," the company allegedly tried to save time and money by cutting out the FDA's oversight of clinical trials of its device. The indictment charges that the company did this for two principal reasons: to rush XR to the market first, before its competitors, and to generate published studies that it could use later to convince other surgeons to use XR off-label to treat VCFs.

Starting as early as late summer 2002, the company allegedly approached selected spine surgeons and asked them to use a predecessor device, SRS, in VCF procedures as part of an initial Synthes "test market" for SRS. Despite a June 2002 plea from one of Synthes's own surgeon consultants that conducting such a "test market" would "amount to human experimentation whose only defense seems to be that it will be a small study [,]" Norian and its coconspirators allegedly embarked on the SRS "test market." According to the indictment, the company taught the selected

surgeons the recipe for mixing SRS with barium sulfate to make it more radiopaque, a process called "back-table mixing," and trained two groups of surgeons in the use of SRS to treat VCFs. After training the two groups of surgeons as initial "test market" sites, the company allegedly enlisted these "test market site" surgeons to train other surgeons on how to use XR to treat VCFs.

According to the indictment, the company conducted two XR "Test Market Kick-Off" surgeon meetings, and one surgeon forum, from August of 2003 through mid-January 2004, training approximately 52 spine surgeons how to use Norian XR to treat VCFs. It is charged that, after the third person died on the operating table during a surgery in which a Norian cement was used to treat VCFs, the company cancelled the future surgeon forums. The indictment alleges that the company considered, but rejected, the idea of recalling or removing XR from the market, either of which actions would have required them to notify the FDA.

Three months later, according to the indictment , when the FDA conducted an unannounced inspection at the Norian plant in West Chester, focused on whether or not Norian and Synthes had conducted an unauthorized clinical trial of XR, a number of Synthes employees, including individual defendants Huggins, Bohner and Walsh, made materially false and misleading statements to the FDA investigator.

(End Summary of Charges)

"The Department of Defense is outraged by a company that potentially puts our military personnel, their family members, and veterans at undue risk for serious medical complications or even death, just to increase their corporate bottom line," said DCIS Assistant Special Agent in Charge Kenneth Maupin. "Criminal matters that affect the welfare, morale and readiness of our men and women in the military are of the highest priority to the Defense Criminal Investigative Service. Our military put their lives on the line every day for the American people. They deserve to feel safe that they and their families are not put at undue risk when having a medical procedure."

"Corporate profits and individual greed, which caused the company to skirt the rules and compromise patient safety, were at the core of this investigation," said VA Inspector General George Opfer. "This team of investigators worked tirelessly to move this case forward and our citizens were well served by their efforts."

INFORMATION REGARDING THE DEFENDANTS

NAME	ADDRESS	AGE OR YEAR OF BIRTH
Norian Corporation	West Chester PA	
Synthes, Inc.	West Chester PA	
Michael D. Huggins	West Chester PA	51

NAME	ADDRESS	AGE OR YEAR OF BIRTH
Thomas B. Higgins	Berwyn PA	52
Richard E. Bohner	Malvern PA	55
John J. Walsh	Coatesville PA	46

If convicted defendant Norian Corporation faces a maximum possible sentence of a fine of $26,000,000, five years probation, full restitution, forfeiture of $469,800 and special assessments of $20,800. Defendant Synthes faces a maximum possible sentence of a fine of $8,800,000, five years probation, full restitution, forfeiture of $469,800 and a special assessment of $5,500. Each of the individual defendants faces a maximum sentence of one year in prison, a fine of $100,000, full restitution and one year of supervised release.

This case was investigated by the United States Food and Drug Administration ("FDA") Office of Criminal Investigations; the United States Department of Health and Human Services ("HHS") Office of Inspector General ("OIG"); the Department of Defense Criminal Investigative Service ("DCIS"), and the Veterans' Administration OIG. The case is being prosecuted by Assistant United States Attorneys Mary E. Crawley, Gerald B. Sullivan, David J. Caputo, Laura A. Pawloski, Associate Chief Counsel, FDA Office of Chief Counsel, and Joel Schwartz, Trial Attorney, U.S. Department of Justice, Office of Consumer Litigation.

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