

## United States Attorney District of New Jersey

FOR IMMEDIATE RELEASE December 7, 2010 www.justice.gov/usao/nj CONTACT: Rebekah Carmichael Office of Public Affairs (973) 645-2888

## EXACTECH, INC. AGREES TO CORPORATE COMPLIANCE REFORMS AND MONITOR OVERSIGHT TO ADDRESS ALLEGED VIOLATIONS OF FEDERAL ANTI-KICKBACK STATUTE

High-Level Employee Pleads Guilty to Conspiring to Violate the Statute; Company Agrees to Pay \$2.99 Million to Settle Government Claims

NEWARK, N.J. – Exactech, Inc. (Exactech) has executed a Deferred Prosecution Agreement (DPA), consenting to institute and continue corporate compliance procedures and federal monitoring pursuant to a 12-month agreement with the Department of Justice, Acting United States Attorney J. Gilmore Childers announced today.

A related criminal Complaint filed today alleges Exactech used consulting agreements with orthopaedic surgeons as an inducement to use its artificial hip and knee reconstruction products.

Additionally, Douglas Donofrio, the current Director of Sales for Exactech, Inc.'s Northeast Region, pleaded guilty today to conspiring to violate the anti-kickback statute, admitting he entered into illegal financial arrangements with orthopaedic surgeons to influence their use of the company's products. Donofrio, 45, of Chester, N.J., entered his guilty plea to a criminal Information before Chief United States District Judge Garrett E. Brown in Trenton federal court.

Acting U.S. Attorney Childers stated: "This is a reasonable resolution, giving Exactech credit for the positive steps it has taken while requiring continued reform and compliance to avoid more serious consequences. The agreement does not erase the past, but supports a future corporate culture that will not tolerate kickbacks as business as usual. Unlawful consulting relationships compromise the integrity of our healthcare system, and we will continue to hold institutions and individuals accountable who are willing to put profits over patients."

According to documents filed in this case and statements made in court:

Exactech – a publicly traded national manufacturer and distributor of orthopaedic implant devices and supplies based in Gainesville, Fla.. – is charged in the criminal Complaint with conspiring to violate the federal anti-kickback statute. The criminal Complaint alleges that from 2002 through late 2008, Exactech entered into consulting agreements with certain orthopaedic surgeons which were designed and implemented, in part, to induce the surgeons to use, and cause the purchase of, Exactech's hip and knee reconstruction and replacement products. Provided

Exactech meets all of the requirements provided in the DPA, the agreement will expire in 12 months and the Complaint will be dismissed.

As part of the DPA, Exactech agreed to accept the appointment of a federal monitor to, among other things, review its compliance with the terms of the DPA and all new and existing consulting agreements. The monitor was selected by the U.S. Attorney's Office, consistent with United States Department of Justice guidelines, after a review of monitor candidates and in consultation with the company.

In addition to the DPA, Exactech has reached a civil settlement with the Department of Justice and the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG). As part of the settlement, Exactech has agreed to pay \$2.99 million to settle government claims that the company's fraudulent marketing practices caused false claims to be submitted to the federal Medicare program in violation of the civil federal False Claims Act. The company has also entered into five-year Corporate Integrity Agreement (CIA) with HHS-OIG, which requires additional reforms and monitoring under HHS-OIG supervision.

Donofrio, while an employee of Exactech from approximately 2002 through 2008, conspired with others to offer and enter into improper consulting agreements with orthopaedic surgeons. Donofrio admitted he conspired with others to violate the federal anti-kickback statute by offering agreements designed and implemented, in part, to induce the surgeons to use, and cause the purchase of, Exactech's hip and knee replacement and reconstruction products. Donofrio also admitted to fraudulently inflating entries in work reports used to justify payments to surgeons under consulting agreements with Exactech.

The charge to which Donofrio pleaded guilty carries a maximum potential penalty of five years in prison and a maximum fine of \$250,000, or twice the pecuniary gain or loss from the offense. As part of his guilty plea, Donofrio also agreed to make restitution for losses resulting from the scheme – specifically, from a \$50,000 bonus he received from his employer. Sentencing is scheduled for March 14, 2010.

In September 2007, the U.S. Attorney's Office entered into DPAs with Zimmer, Inc., Depuy Orthopaedics, Inc., Biomet, Inc., and Smith & Nephew, Inc.; and a non-prosecution agreement with Stryker Orthopaedics, Inc. to resolve similar allegations of paying kickbacks to orthopaedic surgeons. The five companies were required to submit to monitoring, and the four companies then executing DPAs also entered into CIAs with HHS-OIG. From September 2007 through the expiration of the DPAs in March 2009, the four companies complied with the terms of their respective DPAs, and the criminal Complaints against them were dismissed in accord with the terms of those agreements. The CIAs remain in effect, and are scheduled to expire in September 2012. In September 2010, the U.S. Attorney's Office entered into a DPA with Wright medical technology, Inc. to resolve resolve similar allegations of paying kickbacks to orthopaedic surgeons. Wright was required to submit to monitoring which will expire in September 2011. Wright also entered into a CIA, which is scheduled to expire in September

2015.

Acting U.S. Attorney Childers credited special agents of HHS-OIG, New York Regional Office, under the direction of Special Agent in Charge Thomas F. ODonnell; and special agents of the United States Postal Inspection Service, under the direction of Inspector in Charge David Collins, for their work in the investigation.

The government is represented by Assistant U.S. Attorney Ronald Chillemi of the U.S. Attorney's Office Health Care and Government Fraud Unit and Assistant U.S. Attorney Alex Kriegsman of the Office's Civil Division.

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Defense counsel:

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