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Shire PLC Subsidiaries to Pay $350 Million to Settle False Claims Act Allegations

The Justice Department announced today that Shire Pharmaceuticals LLC and other subsidiaries of Shire plc (Shire) will pay $350 million to settle federal and state False Claims Act allegations that Shire and the company it acquired in 2011, Advanced BioHealing (ABH), employed kickbacks and other unlawful methods to induce clinics and physicians to use or overuse its product "Dermagraft," a bioengineered human skin substitute approved by the FDA for the treatment of diabetic foot ulcers. Shire plc is a multinational pharmaceutical firm headquartered in Ireland, with its United States operational headquarters in Lexington, Massachusetts. Shire sold the assets associated with Dermagraft in early 2014.

"This settlement represents the largest False Claims Act recovery by the United States in a kickback case involving a medical device," said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division. "Kickbacks by suppliers of healthcare goods and services cast a pall over the integrity of our health care system. Patients deserve the unfettered, independent judgment of their health care professionals."

The settlement resolves allegations that Dermagraft salespersons unlawfully induced clinics and physicians with lavish dinners, drinks, entertainment and travel; medical equipment and supplies; unwarranted payments for purported speaking engagements and bogus case studies; and cash, credits and rebates, to induce the use of Dermagraft. The Anti-Kickback Statute prohibits, among other things, the payment of remuneration to induce the use of medical devices covered by Medicare, Medicaid and other federally-funded health care programs, including the Department of Veterans Affairs (VA). Claims filed in violation of the Anti-Kickback Statute are considered false or fraudulent under the False Claims Act. In addition, the Anti-Bribery statute and the Federal Acquisition Regulations prohibit bribes to government officials or employees, including VA physicians, to obtain a contract or favorable treatment under a supply contract. The United States alleged that as a result of their violation of these provisions, ABH and Shire submitted or caused to be submitted to federally-funded health care programs hundreds of millions of dollars of false claims for Dermagraft.

"Flagrant and systemic kickback activity of the type at issue in this case is designed to impair and undermine a physician's independent medical judgment, and will not be tolerated," said U.S. Attorney A. Lee Bentley III for the Middle District of Florida (MDFL). "This lawsuit and today's historic settlement demonstrate our office's vigilant and on-going efforts to safeguard federal health care program beneficiaries from the effects of such illegal and deplorable conduct." In addition to this landmark civil settlement, Mr. Bentley's office continues to work diligently to bring to justice those individuals responsible for these illegal actions. Already, the MDFL has obtained the criminal convictions of three high-level executives who supervised the implementation of the illegal kickback scheme, as well as a number of healthcare providers who received kickbacks.

The U.S. Attorney's Office for the District of Columbia also played an active role in this investigation, seeking redress in the civil agreement announced today for the losses sustained by the VA. "Giving kickbacks and gratuities to healthcare providers corrupts medical treatment by interjecting personal financial incentives into decisions that should focus on what is best for a particular patient," said U.S. Attorney Channing D. Phillips for the District of Columbia. "These types of unlawful incentives are particularly troubling when they seek to corrupt the medical treatment provided to our nation's veterans. We will aggressively pursue any company that engages in such reprehensible and unlawful conduct, which seeks to put a company's financial gains ahead of providing the best medical treatment for those who bravely served in our Armed Forces."

The U.S. Attorneys' Office for the Eastern District of Pennsylvania and the Middle District of Tennessee also contributed to the investigation and resolution of these matters. "Fraud against the health care program that exists for the benefit of our veterans, some of our most cherished citizens, as well as fraud against the Medicare program, is reprehensible and unacceptable," said the Acting U.S. Attorney Louis D. Lappen for the Eastern District of Pennsylvania. "This resolution again demonstrates the capacity of the Department of Justice and our law enforcement partners across the country to work together to address unlawful conduct nationwide that affects veterans and other beneficiaries of federally funded health care programs."

"The best interest of the patient is, and must be, the primary factor in a physician's decision regarding patient care," said U.S. Attorney David Rivera for the Middle District of Tennessee. "As such, federal law protects patients from medical providers who enrich themselves through bribes and kickbacks by making illegal the payment of remuneration to induce the use of medical devises covered by federally-funded health care programs. Such kickback schemes that interfere with physician-patient relationships and drive up the cost of healthcare for everyone, will be vigorously pursued and aggressively prosecuted."

"U.S. Department of Veterans Affairs healthcare providers are obligated to render care free of any improper financial influences" said Special Agent in Charge Michael E. Seitler of the U.S. Department of Veterans Affairs, Office of Inspector General (VA OIG), Northwest Field Office. "This is particularly important at VA, since we care for many of this nation's heroes who have sacrificed their own welfare for our freedom. In this case, ABH saw a dramatic rise in its sales to the VA during the period of time it provided illegal inducements to multiple VA clinicians across the country. These corrupt practices served to erode the public trust in our healthcare system. The VA OIG is committed to investigating, and bringing to justice, those who engage in these illegal practices."

In addition to the kickback allegations, the settlement also resolved allegations that Shire and its predecessor ABH unlawfully marketed Dermagraft for uses not approved by the FDA, made false statements to inflate the price of Dermagraft, and caused improper coding, verification, or certification of Dermagraft claims and related services.

The allegations resolved by the settlement were brought in six lawsuits filed under the qui tam, or whistleblower, provisions of the False Claims Act, which permit private parties to sue on behalf of the government for false claims and to receive a share of any recovery. The whistleblower shares to be awarded in this case have not yet been determined.

The six qui tam cases, all of which were either filed or transferred to the U.S. District Court for the Middle District of Florida, are captioned: United States ex rel. Vinca v. Advanced BioHealing, Inc., Case No. 8:11-cv-176-T-30MAP; United States ex rel. Harvey v. Advanced BioHealing, Inc., Case No. 8:16-cv-303-T-30TBM; United States ex rel. Medolla v. Advanced BioHealing, Inc., Case No. 8:12-cv-575-T-30TBM; United States, et al., ex rel. Petty v. Shire Regenerative Medicine, Inc., Case No. 8:14-cv-969-T-30TBM; United States ex rel. Webb v. Advanced BioHealing, Inc., Case No. 8:14-cv-1055-T-30EAJ; and United States, et al., ex rel. Montecalvo v. Shire Regenerative Medicine, Inc., Case No. 8:16-cv-268-T-30TBM.

These matters were investigated by the Civil Division's Commercial Litigation Branch; the U.S. Attorneys' Offices for the Middle District of Florida, District of Columbia, Middle District of Tennessee and Eastern District of Pennsylvania; the FBI; the U.S. Department of Health and Human Services (HHS) Office of Inspector General; the VA OIG and the Department of Defense Criminal Investigative Service.

Shire, which cooperated in the government's investigation, has been operating under a Corporate Integrity Agreement entered into with HHS that was implemented in late 2014, after the alleged unlawful conduct resolved by today's settlement occurred, in connection with the settlement of separate False Claims Act allegations.

"Patients must be able to trust that decisions made by their doctors are based on unbiased professional judgment and not personal gain," said Chief Counsel Gregory E. Demske to the HHS Inspector General. "The Office of the Inspector

General will continue to monitor Shire's compliance with federal healthcare programs through its oversight of Shire's Corporate Integrity Agreement."

This settlement illustrates the government's emphasis on combating health care fraud and marks another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by the Attorney General and the Secretary of Health and Human Services. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in this effort is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than $31.4 billion through False Claims Act cases, with nearly $19.6 billion of that amount recovered in cases involving fraud against federal health care programs.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

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Health Care Fraud

Component(s):
Civil Division
USAO - District of Columbia
USAO - Florida, Middle
USAO - Pennsylvania, Eastern
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