

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Monday, October 1, 2018

AmerisourceBergen Corporation Agrees to Pay \$625 Million to Resolve Allegations That it Illegally Repackaged Cancer-Supportive Injectable Drugs to Profit From Overfill

The Department of Justice announced today that AmerisourceBergen Corporation and its subsidiaries AmerisourceBergen Specialty Group (ABSG), AmerisourceBergen Drug Corporation (ABDC), Oncology Supply Company (OSC), and Medical Initiatives Inc. (MII) (collectively, "ABC") have agreed to pay \$625 million to resolve allegations arising from its operation of a facility that improperly repackaged oncology-supportive injectable drugs into pre-filled syringes and improperly distributed those syringes to physicians treating vulnerable cancer patients. ABC is one of the nation's largest wholesale drug companies and ranked number 11 on the Fortune 500 list. The drugs involved in ABC's scheme were Procrit®, Aloxi®, Kytril® and its generic form granisetron, Anzemet® and Neupogen®.

Last year, AmerisourceBergen Specialty Group, a wholly-owned subsidiary of AmerisourceBergen Corporation, pled guilty to illegally distributing misbranded drugs and agreed to pay \$260 million to resolve criminal liability for its distribution of these drugs from a facility that was not registered with the Food and Drug Administration (FDA). The settlement announced today resolves ABC's civil liability to the United States under the False Claims Act for causing false claims for the drugs it repackaged to be submitted to federal health care programs.

"The \$885 million combined civil and criminal resolution with ABC underscores our determination to utilize all tools at our disposal to pursue illicit schemes that seek to profit from circumvention of important safeguards designed to protect the nation's drug supply," said Assistant Attorney General Joseph H. Hunt of the Department of Justice's Civil Division. "We will continue to be particularly vigilant where these schemes put the health and safety of vulnerable patients at risk."

"ABC placed corporate profits over patients' needs, endangering the health of vulnerable cancer patients," stated United States Attorney Donoghue. "This settlement, and the substantial penalty ABC has agreed to pay, reflect this Office's firm commitment to protecting those in need of healthcare and holding to account those who put the health and safety of patients at risk." Mr. Donoghue expressed his appreciation to the Department of Veterans Affairs and the National Association of Medicaid Fraud Control Units for their assistance.

The United States contends that ABC sought to profit from the excess drug product or "overfill" contained within the original FDA-approved sterile vials for these cancer supportive injectable drugs by establishing a pre-filled syringe program through a subsidiary that it claimed was a pharmacy. The United States alleged that the "pharmacy" was in reality a repackaging operation that created and shipped millions of pre-filled syringes to oncology practices for administration to cancer-stricken patients. As part of this operation, ABC purchased original vials from their respective manufacturers, broke their sterility, pooled the contents, and repackaged the drugs into pre-filled syringes.

The United States alleged that ABC never submitted any safety, stability, or sterility data to the FDA to show that its operation ensured the safety and efficacy of the repackaged drug products. It further alleged that, at times, these

pre-filled syringes were prepared in non-sterile conditions, contaminated with bacteria and other unknown particles, and lacked the required quality and purity.

In addition, by harvesting the overfill, ABC was able to create more doses than it bought from the original vial manufacturers. The United States alleged that ABC's scheme enabled it to bill multiple health care providers for the same exact same vial of drug, causing some of those providers to bill the Federal Health Care Programs for the same vial more than once. The scheme also allegedly enabled ABC to increase its market share by offering various product discounts, which it leveraged to obtain new customers and to keep existing customers buying its entire portfolio of oncology drugs.

The settlement also resolves allegations that ABC gave kickbacks to physicians to induce them to purchase Procrit through the pre-filled syringe program. The alleged kickbacks were in the form of general pharmacy credits provided to customers, but which were not identifiable as specific to Procrit on the invoice.

Through these actions, the United States contended that ABC caused false claims to be submitted to the Centers for Medicare and Medicaid Services ("CMS"), the Department of Defense's Defense Health Agency, which administers TRICARE, the Office of Personnel Management, which administers the Federal Employees Health Benefit Program, and the United States Department of Veterans Affairs (collectively, the "Federal Healthcare Payors"). Under the terms of today's settlement, ABC will pay \$581,809,006 plus accrued interest to the federal government and \$43,190,994 plus accrued interest to state Medicaid programs.

"Drug companies such as ABC that seek to boost profits at the expense of cancer patients unnecessarily put the health and safety of this vulnerable population at risk," stated HHS-OIG Special Agent-in-Charge Lampert. "Greed must never be a part of medical decision making. HHS-OIG, along with our law enforcement partners, is committed to protecting patient quality of care, and this settlement should serve as a warning to drug companies that are tempted to shortchange patient well-being."

The settlement resolves allegations contained in three separate actions filed against ABC under the qui tam, or whistleblower, provisions of the False Claims Act. Under the act, private parties may sue on behalf of the government for false claims for government funds and to receive a share of any recovery. The relator share of the federal portion of the civil settlement will be \$93,089,441.

The settlement was the result of close cooperation between the U.S. Attorney's Office for the Eastern District of New York, the Civil Division, Commercial Litigation Branch, the Office of Inspector General of the Department of Health and Human Services, the Food and Drug Administration, the Department of Defense, the Office of Personnel Management, the Department of Veterans Affairs, and the state attorneys general and Medicaid Fraud Control Units. The three cases are captioned United States ex rel. Michael Mullen v. AmerisourceBergen Corporation, et al., Civil Action No. CV-10-4856 (E.D.N.Y); United States ex rel. Omni Healthcare Inc. v. AmerisourceBergen, et al., Civil Action No. CV-12- 1178 (E.D.N.Y); United States ex rel. Daniel Sypula and Kelly Hodge v. AmerisourceBergen Drug Corporation, et al., Civil Action No. CV-14-5278 (E.D.N.Y.).

Excepted as otherwise admitted as part of its guilty plea or the statement of facts accompanying the civil settlement agreement, the claims resolved by the civil settlement are allegations only, and there has been no admission of liability.

Topic(s):
False Claims Act

Press Release Number:
18-1277

Component(s):
Civil Division
USAO - New York, Eastern