United States Department of Justice

THE UNITED STATES ATTORNEY'S OFFICE
EASTERN DISTRICT of NEW YORK

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AmerisourceBergen Corp. To Pay $625 Million To Settle Civil Fraud Allegations Resulting From Its Repackaging And Sale Of Adulterated Drugs And Unapproved New Drugs, Double Billing And Providing Kickbacks

Settlement Resolves Federal and State False Claims Act Claims Arising from ABC's Operation of a Sham Pharmacy that Illegally Repackaged Injectable Drugs Under Insanitary Conditions to Profit from Overfill

AmerisourceBergen Corporation (ABC), one of the nation's largest wholesale drug companies, and its subsidiaries AmerisourceBergen Specialty Group (ABSG), AmerisourceBergen Drug Corporation (ABDC), Oncology Supply Company (OSC), and Medical Initiatives, Inc. (MII) (collectively, "ABC" or "the Company"), entered into a settlement with the United States in which it agreed to pay $625 million to resolve civil liability under the False Claims Act, 31 U.S.C. § 3730 *et seq.* The claims against ABC arise from its repackaging and distributing of Pre-Filled Syringes (PFS) that were not approved for sale or use by the U.S. Food and Drug Administration (FDA). The drugs involved in the scheme were Procrit®, Aloxi®, Kytril® and its generic form granisetron, Anzemet® and Neupogen®, all supportive drugs for cancer patients undergoing chemotherapy treatment (the PFS Drugs).

As part of the civil settlement, ABC admitted that between January 2001 and January 2014, MII and OSC operated a program that created, packed and shipped millions of PFS to oncology practices for administration to vulnerable cancer patients (the PFS Program). At MII, an ABC subsidiary located in Alabama, the drug product was removed from the original glass vials and multiple vials of the product were pooled in untested plastic containers. Then the drug, including the overfill[1], was extracted and repackaged into syringes. By harvesting the overfill, ABC was able to create more doses than it bought from the original vial manufacturers and avoid opening some of the vials. ABC retained the unopened vials and sold them to other customers and to its subsidiary ABDC for resale. During the 13 years the PFS Program was in operation, MII manufactured thousands of syringes daily, and eventually over one million syringes per year. These syringes were sold throughout the United States. Approximately 57% of the patients who were injected with the PFS were Federal Health Care Program beneficiaries. The profit from the PFS Program was between $2.3 and $14.4 million annually for a total profit of at least $99.6 million.

ABC's scheme enabled it to bill multiple health care providers for the 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 enabled ABC to increase its market share by offering various product discounts, which it leveraged to obtain new customers and to keep existing customers who purchased its entire portfolio of oncology drugs. ABC excluded the entire PFS Program from its standard regulatory audit and pedigree compliance programs.

This civil settlement brings to $885 million the total penalties that ABC has paid to resolve liability resulting from the PFS Program. Previously, in September 2017, ABSG pleaded guilty to a criminal violation of 21 U.S.C. §§ 33l(a) and 333(a)(l) for the introduction of misbranded drugs into interstate commerce, as such drugs were manufactured and prepared at MII, an establishment not registered with the FDA pursuant to 21 U.S.C. § 360. In connection with that guilty plea, ABSG paid $260 million in criminal fines and forfeiture.

Richard P. Donoghue, U.S. Attorney for the Eastern District of New York; Joseph H. Hunt, Assistant Attorney General for the Civil Division of the Department of Justice; Mark S. McCormack, Special Agent-in-Charge, U.S. Food and Drug Administration, Office of Criminal Investigations (FDA-OCI); Scott J. Lampert, Special Agent-in-Charge, U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG), New York Region; Bret D. Mastronardi, Special Agent-in-Charge, U.S. Office of Personnel Management, Office of the Inspector General (OPM-OIG); and Leigh-Alistair Barzey, Special Agent-in-Charge, Defense Criminal Investigative Service (DCIS), Northeast Field Office, announced the settlement.

“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 also expressed his appreciation to the Department of Veterans Affairs and the National Association of Medicaid Fraud Control Units for their assistance.

“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 Hunt. “We will continue to be particularly vigilant where these schemes put the health and safety of vulnerable patients at risk.”

“U.S. patients rely on the FDA to ensure that injectable chemotherapy drugs are safe and effective. When companies attempt to avoid FDA’s oversight authority, they endanger these vulnerable patients’ health,” stated FDA-OCI Special Agent-in-Charge McCormack. “We will continue to pursue and bring to justice those who violate the public’s trust.”

“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.”

“Ensuring that Federal employees, retirees, and their families are protected from the adulteration of drugs and other harmful practices is of the utmost importance to the OPM-OIG,” stated OPM-OIG Special-Agent-in-Charge Mastronardi. “We will continue to aggressively investigate and prosecute all individuals who pursue profit at the expense of patient safety. I’d like to thank our criminal investigators and their law enforcement partners for their hard work and dedication on this case.”

“Ensuring the integrity of TRICARE, the U.S. Department of Defense's health care plan, is of paramount importance to the Defense Criminal Investigative Service (DCIS),” stated DCIS Special Agent-in-Charge Barzey. “Today’s settlement is the result of a joint agency effort to investigate pharmaceutical companies that manufacture and sell adulterated drugs that could threaten U.S. military members, retirees and their dependents.”

In its investigation, the United States determined that for each of the drugs that were converted into PFS, ABC failed to submit a New Drug Application or a Biologics License Application demonstrating the safety and efficacy of the PFS and did not receive FDA approval to manufacture the PFS. For this reason, the PFS, distributed throughout the United States for 13 years, were unapproved new drugs. In addition, ABC did not register MII with the FDA as a repackager. By avoiding registration, ABC also evaded FDA inspection and important safety and sterility safeguards, including current good manufacturing practices ("cGMP"), required of repackagers to ensure that their drug products are safe and effective. The United States contends that ABC was aware of the requirements to register, submit to inspection and prepare drugs in accordance with cGMP, but chose not to comply. Instead, the government's investigation revealed that ABC falsely represented to physician customers that MII was a pharmacy. Through this claim, ABC sought to avoid FDA regulations because certain pharmacy practices are regulated under applicable state pharmacy laws. However, MII did not comport itself as a pharmacy. For example, MII did not obtain valid prescriptions, check for harmful potential drug interactions, or see or counsel patients. As ABC admitted, on many occasions, MII assigned the name of an individual to a set of PFS, and OSC subsequently shipped PFS that were in a bag labeled with that individual's name, despite the fact that the individual was not in fact a patient who was to be administered a PFS. In some instances, the individual's name assigned to the set of PFS was a staff member at a physician customer (such as a nurse or office manager); in others, the individual was no longer a patient of the physician customer, either because the individual was no longer receiving treatment and/or because the individual was deceased. In addition, MII often filled orders that had been submitted with a single patient name, and/or assigned a single individual's name to an order of PFS, far in excess of plausible and/or safe use of the drug product contained in the syringes. In addition, the United States contends that ABC represented to physicians that its repackaging procedures followed aseptic technique and complied with all applicable laws. The United States determined that the PFS were prepared in an unclean environment, were contaminated with actual filth, and were not of the quality or purity that ABC represented.

The settlement also resolves allegations that ABC gave kickbacks to physicians to induce them to purchase drugs through the PFS program. The alleged kickbacks were in the form of general pharmacy credits provided to the customer, which were not identifiable on an invoice as specific to Procrit®. OSC billed customers for Procrit® at full price and at the end of the week or month added a "general credit" to the customers' account. Credits were not given for other drugs. The pharmacy rebate was not listed on the invoice as related to Procrit®; it was listed as a pharmacy rebate for pharmacy sales.

With the exception of the facts contained in the Statement of Facts attached to the settlement agreement, the settlement is not an admission of wrongdoing by ABC.

The settlement is the culmination of a multi-year parallel civil and criminal investigation by this Office into allegations contained in three *qui tam* actions filed against ABC in the United States District Court for the Eastern District of New York.[2] On August 31, 2017, the United States intervened in those actions, which were unsealed today. The cases are *U.S. ex rel Michael Mullen v. AmerisourceBergen, et al.* No. 1:10-4856; *U.S. ex rel Omni Healthcare Inc. v. AmerisourceBergen, et al.* No. 12-CV-1178; and *U.S. ex rel Daniel Sypula, RPH and Kelly Hodge v. AmerisourceBergen, et al.,* No. 1:14-5278. All of the cases are pending before the Honorable Nina Gershon. The criminal case was resolved through a plea agreement in September 2017. *United States v. AmerisourceBergen Specialty Group, LLC,* CR. No. 17-507 (NG). In connection with the settlement, ABC also entered into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services, Office of Inspector General ("HHS-OIG"). In addition, ABC and 43 States have an agreement in principle to resolve claims under the States' false claims acts.

The civil investigation and settlement with ABC were handled by the Office's Civil Division. Assistant United States Attorneys Deborah B. Zwany and Matthew Silverman are in charge of these cases and were assisted by former Affirmative Civil Enforcement Coordinator Emily Rosenthal. The Office of Criminal Investigation at FDA, the Offices of the Inspector General at the Department of Health and Human Services, the Department

of Defense, the Office of Personnel Management and the Department of Veterans Affairs assisted in the investigation of these cases. Sanjay Bhambhani, Department of Justice, Civil Frauds Section, and Jay Speers and Elizabeth Silverman, New York State Medicaid Fraud Control Unit assisted in the settlement of these cases. The criminal case against ABC was prosecuted by Assistant United States Attorneys Alixandra E. Smith and Ameet B. Kabrawala of the Office's Business and Securities Fraud Section.

[1] The term "overfill" is a frequently used term in the pharmaceutical industry generally meaning the amount of extra drug above and beyond the labeled dose that is contained in an FDA-approved vial of drug. The overfill is not listed on the FDA-approved drug label. The reason manufacturers put overfill in each vial of drug is to ensure that the health care provider administering the drug will be able to extract the full labeled dose from the vial to give to the patient. *See, e.g.*, 75 Fed. Reg. 73170, 73466-67 (Nov 29, 2010). It is also not included in the price of the vial.

[2] *United States ex rel. Daniel Sypula v. AmerisourceBergen Corp.*, was originally filed in the Eastern District of Michigan and transferred to the Eastern District of New York.

Attachment(s):
Download Settlement Agreement and Attachments
Download Corporate Integrity Agreement

Topic(s):
Health Care Fraud

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

Contact:
John Marzulli
Tyler Daniels
United States Attorney's Office
(718) 254-6323

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