United States Department of Justice

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

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Amerisourcebergen Specialty Group Pleads Guilty to Distributing Misbranded Drugs and is Sentenced to Pay $260 Million to Resolve Criminal Liability

Pharmaceutical Wholesaler Admits to Illegally Distributing Millions of Misbranded Oncology Drug Products and Failing to Register with the Food and Drug Administration

Earlier today, at the federal courthouse in Brooklyn, New York, AmerisourceBergen Specialty Group (ABSG), a wholly-owned subsidiary of AmerisourceBergen Corporation (NYSE: ABC), one of the nation's largest wholesale drug companies and number 11 on the Fortune 500 list, pled guilty to illegally distributing misbranded drugs. ABSG agreed to pay a total of $260 million to resolve criminal liability for its distribution of oncology supportive-care drugs from a facility that was not registered with the Food and Drug Administration (FDA). The guilty plea and sentencing took place before United States District Judge Nina Gershon.

The criminal resolution was announced by Bridget M. Rohde, Acting United States Attorney for the Eastern District of New York; Mark S. McCormack, Special Agent-in-Charge, FDA Office of Criminal Investigations Metro Washington Field Office; Scott J. Lampert, Special Agent-in-Charge, U.S. Department of Health and Human Services, Office of Inspector General (HHS OIG), New York Region; Leigh-Alistair Barzey, Special Agent-in Charge, Defense Criminal Investigative Service (DCIS), Northeast Field Office; and Scott Rezendes, Special Agent-in-Charge, Office of Personnel Management, Office of Inspector General (OPM-OIG).

"Today's guilty plea demonstrates our commitment to investigating and holding accountable any pharmaceutical company that fails to ensure the health and safety of the public. This Office will continue to work actively with the FDA to ensure that those responsible for America's drug supply scrupulously comply with the law and provide safe products that doctors and patients can trust," said Acting United States Attorney Rohde. Ms. Rohde expressed her grateful appreciation to the Department of Justice Consumer Protection Branch, the FDA Office of the Chief Counsel and the Alabama Board of Pharmacy.

"Injectable drugs prescribed for patients – especially vulnerable cancer patients – must be pure, sterile and produced in an FDA-compliant facility that is within the supply chain that FDA oversees," stated Special Agent-in-Charge McCormack. "We will continue to pursue and bring to justice those manufacturers who would violate the public's trust and endanger their health by attempting to avoid FDA's oversight authority."

"Companies that sell oncology drugs from a facility not registered with the FDA threaten the health and safety of cancer patients," stated HHS OIG Special Agent-in-Charge Lampert. "We will continue to work closely with our law enforcement partners to protect patients from such shortcuts."

"The illegal misbranding and distribution of drugs threatens the health and safety of U.S. military members, retirees and their dependents," stated DCIS Special Agent-in-Charge Barzey. "Today's guilty plea is demonstrative of DCIS's ongoing commitment to work jointly with the USAO EDNY, FDA, HHS OIG and OPM-OIG, in order to protect members of the Armed Forces and to ensure the integrity of the Defense Department's TRICARE healthcare system."

"OPM-OIG agents will continue to work with our law enforcement partners to protect Federal employees, annuitants and their families from companies that would put the health of vulnerable cancer patients at risk," stated OPM-OIG Special Agent-in-Charge Rezendes.

As set forth in court records, between 2001 and 2014, two of ABSG's Alabama-based subsidiaries, Medical Initiatives Inc. (MII) and Oncology Supply Company (OSC), prepared millions of syringes that had been pre-filled with oncology supportive care drugs — specifically, Aloxi®, Anzemet®, generic versions of granisetron injection, Kytril®, Neupogen® and Procrit®. Those syringes were shipped to oncology centers, medical practices and physicians for administration to immunocompromised cancer patients undergoing chemotherapy treatment in all 50 states, including to approximately 37 healthcare providers located in the Eastern District of New York.

To prepare pre-filled syringes (PFS), MII removed FDA-approved drug products from their original glass vials and repackaged them into plastic syringes through a process that allowed MII to access and sell excess drug product in the vials, known as "overfill," that MII was able to extract from the vials. As alleged in the Information, however, MII prepared PFS in an unclean, unsterile environment. Accordingly, MII's process for creating PFS resulted in some PFS that contained particles or foreign matter, which MII employees identified and termed "floaters." PFS were also at times not of the quality or purity that MII and OSC represented them to be to their customers.

MII's business model was to combine the contents of multiple vials in a process known as "pooling." However, as set forth in the Information, many of the vials used by MII to prepare PFS were designated by the drug manufacturer as "single use" vials, meaning that the manufacturer could not guarantee the sterility of the drug product if the vials were breached. However, in the pooling process, MII's technicians frequently breached drug vials multiple times, thereby increasing the risk of contamination.

In order to avoid the FDA's regulatory oversight, ABSG did not register MII as a re-packager or manufacturer with the FDA as required by the Federal Food, Drug and Cosmetic Act. Instead, ABSG inaccurately portrayed MII to its customers and to state agencies as a state-regulated pharmacy in the business of dispensing drugs pursuant valid prescriptions and claimed that MII was otherwise in compliance with state pharmacy laws. By holding MII out as a pharmacy, ABSG unlawfully exploited an exemption to the FDA registration requirement that is reserved for legitimate pharmacies, not for manufacturers or re-packagers.

In connection with the guilty plea, ABSG filed a Statement of Facts setting forth those facts which it is admitting.

As part of its guilty plea, ABSG has agreed to pay a $208 million criminal fine, plus $52 million in criminal forfeiture, for a total financial penalty of $260 million. In addition, ABSG has entered into an agreement with the Office and the Department of Justice's Consumer Protection Branch to maintain a compliance and ethics program designed to increase accountability of individuals and corporate board members, to increase

transparency, and to strengthen ABSG's compliance with the FDCA. The compliance and ethics program requires corporate board members to review annually the effectiveness of the company's compliance program and for ABSG to maintain a hotline that will receive and process complaints about any improper practices.

The government's case is being handled by the Office's Business and Securities Fraud Section. Assistant United States Attorneys Alixandra E. Smith and Ameet B. Kabrawala are in charge of the prosecution. Senior Litigation Counsel Patrick Jasperse of the Department of Justice Consumer Protection Branch also provided assistance.

Attachment(s):
Download ABSG Information
Download ABSG Plea Agreement

Topic(s):
Prescription Drugs

Component(s):
USAO - New York, Eastern

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