

Press Releases

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ATTORNEY GENERAL MADIGAN: PHARMACEUTICAL DISTRIBUTOR MUST PAY \$625 MILLION OVER ALLEGATIONS OF DISTRIBUTING UNAPPPROVED & ADULTERATED DRUGS

Chicago — Attorney General Lisa Madigan today announced a \$625 million settlement with pharmaceutical distributor AmerisourceBergen Corporation (ABC) to settle allegations that the company sold adulterated drugs across the country.

The settlement with 43 other states and the federal government resolves allegations that ABC and certain of its subsidiaries improperly sold cancer drugs that were not regulated by the Food and Drug Administration (FDA). ABC allegedly adulterated cancer drugs Aloxi®, Anzemet®, Kytril®, Neupogen®, Procrit®, as well as the generic version of Kytril® by "breaking the seal" and supplying the drugs in pre-filled syringes without FDA oversight. Illinois will receive more than \$1 million as part of the settlement.

"ABC sold the public prescription drugs without proper oversight and in violation of the law," Madigan said. "This settlement holds these drug companies accountable for their reckless actions."

The settlement resolves allegations concerning a purported pharmacy under ABSG, Medical Initiatives Inc. (MII), which pooled vials of drugs used during chemotherapy in order to create Pre-filled Syringes (PFS) to sell to practitioners. The investigation revealed MII was not a pharmacy, but a so-called re-packager that was required to apply for a New Drug Application (NDA) to sell the PFS. To prepare the PFS, MII broke the seal of the FDA-approved drug vials and repackaged them into plastic syringes that allowed MII to sell the excess drug product in the vials, known as "overfill." The PFS, which were prepared in an unsterile environment and often contained particles of foreign matter, were then shipped to providers through another branch of ABSG, which was named Oncology Supply Company (OSC). MII did not comply with pharmacy regulations in any state where it was licensed. Additionally, since there was no new NDA, the drugs were unapproved by the FDA and adulterated, therefore not eligible for reimbursement by government healthcare programs.

Under the settlement, ABC will pay nearly \$100 million to Medicaid programs. ABC subsidiary, AmerisourceBergen Specialty Group (ABSG), previously pleaded guilty to illegally distributing misbranded drugs in September 2017. ABSG is the parent entity for companies in the specialty pharmaceutical market, including biotechnology and oncology, in addition to pharmaceutical manufacturers and providers. ABSG agreed to pay \$260 million in criminal fines and forfeitures.

The settlement also resolves double billing for drug vials that occurred when MII used the overfill drug product, and it also addressed unlawful kickbacks provided to physicians to induce them to purchase one of the drugs, Procrit®, in PFS rather than vials.

The investigation that led to the settlement resulted from three actions originally filed in 2010, 2012 and 2014 in the U. S. District Court for the Eastern District of New York under the federal False Claims Act and various state false claims statutes.

Deputy Bureau Chief Heather Tullio D'Orazio with Madigan's Medicaid Fraud Bureau led a National Association of Medicaid Fraud Control Units (NAMFCU) team that participated in the investigation and conducted the settlement negotiations with ABC on behalf of the states. Other members of the team included representatives from the following attorneys general offices: California, Florida, New York and Oregon. Madigan's office works in conjunction with the Illinois State Police Medicaid Fraud Control Bureau to investigate and prosecute civil and criminal cases of Medicaid Fraud.

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