Drug distributors fined for failing to report suspicious orders of opioids

By Brad Dixon
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Drug distributors have recently been hit with millions of dollars in fines for failing to report “suspicious orders” of prescription painkillers to the Drug Enforcement Agency (DEA). These drug distributors, along with drug manufacturers and retail pharmacies, have contributed to the growing opioid epidemic in the United States.

The opioids that are manufactured by companies such as Purdue Pharma and Insys Therapeutics are distributed to retail pharmacies like CVS and Walgreens by drug distributors, also known as drug wholesalers, who act as middlemen.

The Controlled Substances Act (CSA) requires these drug distributors to identify and report “suspicious orders” of controlled substances to the DEA. Still, drug wholesalers have repeatedly failed to do so, while industry lobbying has curtailed enforcement of the law by the DEA. The recent penalties and fines reflect more the flagrant manner by which the drug distributors have allegedly violated the law, than any renewed effort by regulators to clamp down on the practice.

Earlier this month, McKesson, the nation’s largest drug distributor, paid a record $150 million civil penalty for alleged violations of the CSA. The settlement with the Justice Department requires the company to suspend its sales in Colorado, Ohio, Michigan and Florida for multiple years, although this will be done on a staggered basis that critics say will minimize the order’s impact.

The settlement follows a $13.5 million civil penalty McKesson agreed to in 2008 for failing to develop a system to detect and report suspicious orders of controlled substances. The 2008 settlement required the company to develop a compliance program, but a government investigation found that the company failed to adhere to it.

This past December, drug distributor Cardinal Health agreed to pay $44 million to resolve allegations that it failed to report suspicious orders placed in Maryland, Florida and New York. In Florida, for example, the company’s own investigator warned in 2010 against selling narcotics to the Gulf Coast Medical Pharmacy. The warnings were ignored. While wholesale distributors would normally expect to send 65,000 doses of oxycodone to a pharmacy of this size, Cardinal shipped more than 2 million doses to Gulf Coast in 2011 alone.

Cardinal announced a few weeks ago that it had also reached a $20 million settlement with the state of West Virginia to resolve a lawsuit alleging similar practices in that state between 2007 and 2012. Cardinal flooded West Virginia with 241 million oxycodone and hydrocodone pills during this period, more than any other drug distributor. West Virginia also settled lawsuits with other drug wholesalers, including a $2.5 million settlement with Miami-Luken and a $16 million settlement with AmerisourceBergen.

In nearly all cases, the companies denied any wrongdoing as part of the settlement.

McKesson, Cardinal and AmerisourceBergen are the three largest wholesale drug distributors, accounting for 85 percent of all drug shipments in the United States. The San Francisco-based McKesson, for example, which is currently number five on the *Fortune 500 list*, had $190.8 billion in revenues and $2.3 billion in profits in 2016, according to the company’s annual report.

The fines imposed on the drug wholesalers are minuscule in comparison to their revenues; they are simply another business expense necessary to keep the profits rolling in.

Previously, the DEA had focused its enforcement efforts on doctors, retail pharmacies, and drug manufacturers. In 2005, the DEA began to aggressively crack down on companies distributing prescription opioids by launching its "Distributor Initiative."

According to an October 2016 investigation by the *Washington Post*, starting in 2013 there was political pushback against DEA enforcement, as the pharmaceutical industry ramped up its lobbying of congress. DEA leadership began delaying and blocking enforcement actions, while agency lawyers demanded higher standards of proof to initiate civil cases.

As a result, the number of civil cases filed by the DEA dropped from 131 in 2011 to only 40 by 2014.

In 2014, members of congress, led by Republican representatives Tom Marino of Philadelphia and Marsha Blackburn of Tennessee, proposed legislation that would weaken the DEA's enforcement powers. Between 2014 and 2016, McKesson, Cardinal, AmerisourceBergen and the Healthcare Distribution Alliance, the drug distributor trade group, spent $13 million lobbying congress in favor of the legislation, known as the Patient Access and Effective Drug Enforcement Act.

The Act, which passed and was signed into law by Obama in 2016, requires the DEA to show that there is an "immediate" instead of "imminent" threat to the public before the agency can suspend the licenses of wholesalers, a much more onerous standard to demonstrate. Companies that fail to report suspicious orders can postpone or prevent the DEA from taking action against them by simply submitting a "corrective action plan."

Enforcement by the DEA has been further hampered by the revolving door between pharmaceutical companies and the DEA officials charged with regulating the industry. An investigation by the *Washington Post* this past December found that at least 42 DEA officials had been hired by pharmaceutical companies or their law firms since 2005.

This includes officials from the DEA's Diversion Control Division, which is charged with preventing prescription drugs from reaching the black market and has the power to suspend or revoke the licenses of doctors, pharmacies and pharmaceutical companies. A total of 31 former employees in the diversion division left to work for the pharmaceutical industry or law firms that represent it, including five DEA officials who went to work for McKesson.

"The DEA diversion officials who have gone to the industry since 2005," reports the *Post*, "include two executive assistants who managed day-to-day operations; the deputy director of the division; the deputy chief of operations; two chiefs of policy; a deputy chief of policy; the chief of investigations; and two associate chief counsels in charge of legal affairs and enforcement actions against pharmaceutical companies."

"The high rate of turnover makes you really wonder whether those officials were acting in the interests of the DEA rather than the companies they were regulating," Craig Holman, an expert on revolving-door issues at Public Citizen, told the Post.

"Just by seeing your colleagues going that way, that tells you that you can shape your future employment prospects if you behave accordingly," Holman said.

The irresponsible promotion and distribution of prescription painkillers by unscrupulous pharmaceutical companies, wholesale distributors, and retail pharmacies has exacerbated the opioid epidemic in the United States. According to the Centers for Disease Control and Prevention, the number of opioid overdose deaths in the United States has nearly quadrupled since 1999. Sixty-one percent of the 41,055 drug overdoses in 2014 were due to opioids, an increase of 14 percent compared to the previous year.