CARDINAL HEALTH REACHES SETTLEMENT WITH DEA

BACKGROUND
On Tuesday, May 15, 2012, Cardinal Health ("Cardinal") and the Drug Enforcement Agency ("DEA") reported that they had reached a settlement related to Cardinal’s Lakeland, Florida distribution center’s ("Lakeland’s") DEA license. This settlement resolves the ongoing litigation between Cardinal and the DEA due to the DEA’s Immediate Suspension Order (“ISO”) issued to Lakeland on February 2, 2012. On February 29, 2012, a federal judge lifted the temporary restraining order against the DEA. As a result, Lakeland could no longer distribute controlled substances. Although Cardinal appealed the decision to the United States Court of Appeals for the District of Columbia Circuit, it has since chosen to settle with the DEA. A summary of the February 2012 actions against Cardinal is available here.

SETTLEMENT DETAILS
As a result of the settlement, Lakeland will be prohibited from shipping controlled substances for two years. Lakeland will remain open and functioning as usual for non-controlled substances that it supplies to area pharmacies. Additionally, Cardinal signed a Memorandum of Agreement ("MOA"), which pertains to all of Cardinal's distribution facilities. The MOA obligates Cardinal to improve certain anti-diversion procedures. Furthermore, the MOA mandates that Cardinal will conduct site visits of pharmacies that appear to have suspicious orders of controlled substances from any of its facilities. Also, Cardinal will hire extra field inspectors to investigate Florida pharmacies. As a result of the settlement, Cardinal will begin reporting suspicious pharmacy orders for controlled substances directly to DEA Headquarters instead of the DEA Field Offices. Per the MOA, the DEA reserves the right to pursue civil penalties against Cardinal. Lastly, the DEA confirmed that it is planning no further administrative actions at other Cardinal facilities. The obligations contained within the MOA are binding for five years.

BASIS FOR ACTION AGAINST CARDINAL
Cardinal previously entered into a settlement with the DEA in 2008 to resolve claims that Lakeland distributed high amounts of hydrocodone, which is the primary ingredient in Vicodin. It resulted in a $34 million fine, as well as a previous Memorandum of Agreement ("2008 MOA") that contained similar provisions as those in the current MOA. Cardinal admitted that its due diligence efforts as a result of the 2008 MOA were inadequate. This failure to comply with the 2008 MOA served as a partial basis for the February 3, 2012 ISO.

In addition to its actions against Cardinal, the DEA has issued ISOs to two CVS pharmacy stores that were customers of Lakeland. These actions are still pending, and Hall Render will continue to monitor these actions.

THE GOVERNMENT’S PERCEIVED PRESCRIPTION DRUG EPIDEMIC
In actions such as the one taken against Cardinal, the DEA is attempting to combat what it describes as a prescription drug epidemic. Particularly in Florida, but also throughout the United States, prescription drug abuse is rising drastically according to the DEA. For example, one of Cardinal’s primary offenses in Lakeland was the supply of over twelve million dosage units of oxycodone to just four area pharmacies during a three year period. The Centers for Disease Control and Prevention ("CDC") has stated that prescription drug abuse results in more deaths than any other type of drug (accounting for 75% of all overdoses in the U.S.), and prescription drug overdoses now lead to more deaths than car accidents.

An estimated seven million Americans abuse prescription drugs; thus, it is likely that the DEA will continue to increase its prescription drug regulation enforcement. Because it is less tedious to analyze the data of distribution centers and pharmacies than it is to evaluate the prescribing techniques of a particular physician, pharmacies and distribution centers should continue to develop their compliance programs in order to satisfy regulatory obligations.

If you have any questions or would like additional information about this topic, please contact Susan Bizzell at 317.977.1453 or sbizzell@hallrender.com, Nicholas Gonzales at 414.721.0486 or ngonzales@hallrender.com or your regular Hall Render attorney.

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