July 8, 2010

Michele M. Leonhart
Acting Administrator
U.S. Drug Enforcement Administration
600 Army Navy Drive
Lincoln Place East - Room 6295
Arlington, VA 22202

Dear Ms. Leonhart:

The member companies of the Healthcare Distributor Management Association (HDMA) are committed to fulfilling their obligations under the Controlled Substances Act (CSA), including the maintenance of effective controls to guard against the diversion of controlled substances. Our members work closely with headquarters and regional DEA offices to ensure that orders for controlled substances are distributed in compliance with the CSA. To that end, the sharing of relevant information by DEA and distributor registrants is essential, especially since wholesale distributors are not provided access to the aggregate Automation of Reports and Consolidated Orders System (ARCOS) data received by DEA.

Since 2008, HDMA members have been able to utilize the association's "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" as a template for meeting their obligations under the CSA. This guideline was commended by DEA Chief Counsel Wendy Goggin in an October 17, 2008 letter to HDMA. Our members have taken steps to better understand their customers and their businesses given DEA's guidance to industry that reliance on DEA registration or state licensing alone is not sufficient to validate customers. However, there are limitations to what information distributors can lawfully obtain from their customers, and sophisticated criminal elements are not likely to be truthful when questioned by their wholesale suppliers.

Further, a distributor does not have the independent ability to determine whether a pharmacy or physician customer is ordering from multiple distributors -- only DEA possesses that information via the ARCOS reporting process. As you can imagine, knowledge that a customer is purchasing suspiciously large aggregate amounts of controlled substances from a variety of distributors would be information very relevant to our members in meeting their obligations under the CSA. Knowledge of that information, or other unusual patterns of ordering, would lead to further diligence and likely cessation of further shipments until adequate explanations could be provided.

Identification and reporting of suspicious orders, to be truly effective, must be a two-way street. We therefore request that DEA:

(1) establish criteria and a system for the agency to inform distributor registrants when, based on DEA analysis of ARCOS or other data, there is reason to believe a customer's ordering may be considered suspicious; and

(2) clarify its position on the agency's authority and willingness to respond to inquiries by registrants about customer ordering patterns based on information available to DEA.
HDMA's distributor members take great pride in the essential role they play to ensure that patients have access to a safe, secure, and reliable source of medications. They are equally committed to eliminating diversion and meeting their obligations under the CSA. Timely information is essential to meeting this dual obligation. This is the reason we ask DEA to be even more forthcoming as it receives information that would be extremely relevant to a distributor's decision whether or not a customer order is suspicious.

Thank you for your consideration of this request and for the Agency's continued willingness to work collaboratively with distributor registrants for the benefit of our shared mission.

Sincerely,

Scott M. Melville
Senior Vice President, Government Affairs, and General Counsel

cc: Mr. Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control
Mr. Mark Caverly, Chief, Liaison and Policy Section, Office of Diversion Control