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Thanks!

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**Overview of the Increased Cost, Low Benefit and Impacts of EPA's Proposed Management Standards for Hazardous Waste Pharmaceuticals**

EPA's proposed "Management Standards for Hazardous Waste Pharmaceuticals" rule which was published in the September 25, 2015 *Federal Register* is not cost-effective, is burdensome and provides little or no environmental benefit. This proposal requires expired or soon to expire medicines returned in an already highly regulated, closed "reverse distribution" system to be further regulated without properly balancing costs, risks and benefits.

**Returned medicines are already tightly regulated under the Drug Supply Chain Security Act.**

The drug distribution system is highly regulated at both the federal and state levels of government. The Drug Supply Chain Security Act (DSCSA) was enacted on November 27, 2013. With the passage of the DSCSA, the distribution of prescription pharmaceuticals in the U.S. pharmaceutical supply chain is becoming even more secure. The DSCSA has complex requirements regarding the treatment of prescription drug "returns." It imposes different requirements, including data transmission requirements, upon trading partners making and receiving returns, depending, for example, upon whether the product is "saleable" or "nonsalable," the original purchasing circumstances, and where the return is being sent. Prior to November 2013, the Prescription Drug Marketing Act (PDMA) established a closed, tightly controlled system of distribution of prescription drugs in the U.S. The intersection of these potentially competing requirements merits careful consideration.

Distributors of medicines are also strictly regulated by the Drug Enforcement Administration (DEA) pursuant to the Controlled Substances Act (CSA), if they distribute List I chemicals and controlled substances. The DEA, along with state-controlled substance authorities, add an additional and important level of inspection and regulation of our member facilities, ensuring that products with abuse potential are kept in a highly secure environment with strong recordkeeping requirements.

It is critically important that EPA's Proposed Rule not interfere in these important processes by imposing deadlines upon, among other things, product storage and disposal that may not be workable in product recall situations. The intersection of these potentially competing requirements merits careful consideration. Industry wants to be assured that they have the flexibility under the Proposed Rule to meet their FDA and other regulatory obligations.

**Potential Disruption of Delivery of Healthcare to Patients**

The Proposed Rule fails to appreciate how critically important the handling of pharmaceutical returns is to the financial health of the supply chain and the well-being of patients. Any change to current practice could jeopardize the ability of wholesale distributors and/or dispensers to obtain credit from the manufacturer.

The healthcare supply chain has evolved such that healthcare facilities can focus upon treating patients with the best, most appropriate medicines available, but are spared the burdens of holding expensive pharmaceuticals they do not have room to store. Wholesaler distributors hold inventory for their customers and swiftly make it available based upon the healthcare professionals' assessment of patient needs. An entire system of patient care and healthcare services has evolved based upon this "just in time" delivery model that assumes ease of returns for credit.

Initial purchasing decisions can be impacted by changes in returns requirements. For example, a wholesale distributor may be willing to take the financial "risk" of stocking full supplies of a new, potentially beneficial drug product under the assumption that they will obtain credit if the market for the product is not as great as anticipated and an oversupply results. However, the inability to obtain credit for unsold product, or the anticipation of a large increase in operational expenses if they take on

the required role themselves, may change a wholesale distributor's purchasing decisions. Wholesale distributors may forego the volume of purchases they might undertake today. Product shortages could result because the financial risk of oversupply is too great to do otherwise.

**"Intent to Discard" Policy Decision is Flawed**

EPA's current policy is that a wholesale distributor or healthcare facility may send a product to a reverse distributor without deeming this action to be indicative of "intent to discard," and thus not subject to RCRA regulation. This decision matches the practice of the pharmaceutical industry of issuing millions of dollars of credit annually for product returns, which is evidence that returned materials are valuable, and not "waste" that needs additional regulation. The pharmaceutical industry strongly recommends that EPA continue this current policy. EPA relied on faulty assumptions and very limited and dated information to justify changing this policy and subjecting reverse distribution to additional regulation. There was insufficient analysis of the profound impact of these new requirements on pharmaceutical distributors.

Business practices and regulatory oversight of the entire supply chain have changed dramatically with the passage of the Drug Supply Chain Security Act (DSCSA) and the Drug Enforcement Agency's (DEA's) Final Rule for disposal of controlled substances. The rule was developed based on old comments and does not consider current prevailing views or recent regulatory and statutory changes. There is no evidence of any environmental risk from the current reverse distribution system for medicines.

***Potential Environmental Benefits Not Justified by the Estimated Costs and Regulatory Burden***

The proposed Hazardous Waste Pharmaceuticals regulation will impose significant expense with very little benefit. EPA's estimates the cost of the proposed rule, at $37 million annually for the full compliance baseline. The only environmental benefits quantified by EPA for this rule are based on a $4.28 million savings associated with reducing the volume of water used to flush toilets at health care facilities and hospitals. The Regulatory Impact Assessment for this proposed rule shows that environmental benefits for the rule associated with "Reverse Distributors" (parties that take back medicines for a financial credit) will be $0.0 dollars.

The proposed rule states that 'any noncompliance" with 40 CFR 266 Subpart P means that a reverse distributor becomes a RCRA treatment, storage, or disposal facility (TSDF) subject to full RCRA regulation. Because of this aggressive requirement, most, if not all, reverse distributors will be filing to become full-fledged treatment, storage, and disposal facilities (TSDFs), at a cost of millions of dollars of capital and significant annual operating expenses. Minor cases of noncompliance (missing one inspection of stored containers, for example) with no environmental or health impact should not automatically make a facility an unpermitted RCRA facility.