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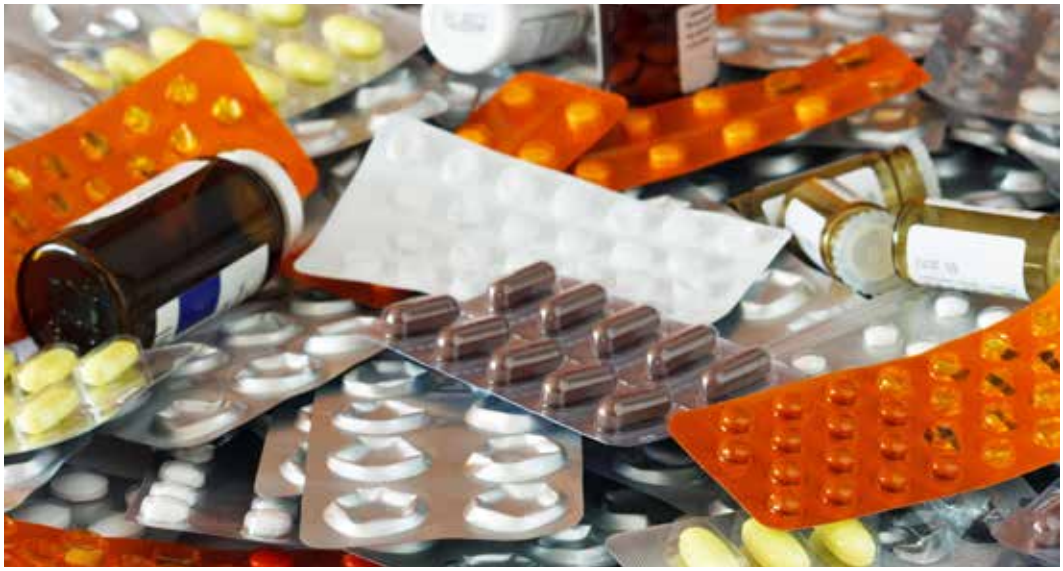

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Recent Developments Regarding Disposal of Pharmaceutical Products

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RECENT ENVIRONMENTAL DEVELOPMENTS MAY IMPACT THE HEALTH CARE INDUSTRY AND SHOULD CONTINUE TO BE MONITORED.

Several environmental developments related to the discarding of pharmaceutical products (including veterinary drugs) are summarized in this alert. Simply put, health care facilities, retailers of pharmaceutical products and even individual consumers may discard drugs that are accidentally spilled or are unused (either by flushing them down a drain or throwing them into the garbage). A discarded drug is considered to be hazardous waste when it meets one of the federal criteria (e.g., if it is flammable, corrosive or reactive; leaches certain toxic chemicals above regulatory limits; or is otherwise hazardous).

Local Pharmaceutical Take-Back Program Upheld by the Courts

Alameda County, California, passed an ordinance requiring pharmaceutical manufacturers to pay "all costs" and be responsible for collecting and disposing of unused medicines in Alameda County (a so-called product stewardship program). The Pharmaceutical Research and Manufacturers of America, the Biotechnology Industry Organization and the Generic Pharmaceutical Association challenged this ordinance as an unconstitutional interference with interstate commerce. On May 26, the U.S. Supreme Court refused to review the decision from the U.S. Court of Appeals for the Ninth Circuit upholding the drug disposal ordinance. *Pharm. Research & Mfrs. of Am. v. Cnty. of Alameda*, No. 14-751 (U.S. May 26, 2015). However, this refusal provides no insight into the ultimate legality of such programs. Environmental groups and like-minded regulators will continue to advocate for such product stewardship programs, and there likely will be more legal challenges. The long-term impact of such programs is almost certainly increased drug prices and the need for all companies in the pharmaceutical supply chain to adapt to these requirements.

New Federal Pharmaceutical Waste Disposal Framework on the Horizon

Over the last few years, the Environmental Protection Agency (EPA) and some states have brought waste disposal enforcement actions against health care facilities. EPA announced in 2008 its intent to regulate health care hazardous wastes via a scaled-back, simpler regulatory approach known as the "universal waste rule" to minimize the previous piecemeal approach. Based on public comments, EPA decided not to finalize the 2008 proposed rule. EPA now plans to issue a notice of proposed rulemaking (NPRM) for management standards for hazardous waste pharmaceuticals in July 2015. *See* Management of Hazardous Waste Pharmaceuticals, 2015 Proposal to Address the Management of Hazardous Waste Pharmaceuticals, *available at* http://www.epa.gov/waste/hazard/generation/pharmaceuticals.htm.

EPA's intent is to develop "health-care facility-specific regulations" with requirements "adapted to the unique issues that hospitals, pharmacies and other health-related facilities face." EPA now recognizes that health care workers are often not familiar with the complex federal hazardous waste regulations and tend to follow long-established health care practices, which may or may not comply with current federal requirements. Additionally, unlike the manufacturing facilities for which the existing regulations were intended, health care facilities may have thousands of different pharmaceutical products, few of which are on the regulatory lists of hazardous wastes or which have not been tested to determine if they meet the "characteristics" that render them

regulated. Traditional health care waste disposal practices (e.g., the location of disposal receptacles, the degree of security associated with the receptacles and the length of storage prior to off-site disposal) were designed to facilitate health care, not waste disposal. Pharmaceutical products range in toxicity from acute hazards — including controlled substances, which are separately regulated by the Drug Enforcement Administration — to low hazards. EPA believes that the scheme in its NPRM will include "notification and tracking" requirements more suited to health care facilities and the "management of unused and/or expired pharmaceuticals, which is known as reverse distribution."

However, even though EPA believes that the rules will make it easier for health care and associated facilities to comply, this does not mean that health care providers will agree. In particular, EPA's intent to include a reverse distribution system to manage unused and/or expired pharmaceuticals should be carefully scrutinized by companies throughout the health care supply chain. Unlike Alameda County, which enacted an ordinance that authorized a reverse distribution system, the existing federal hazardous waste statute does not provide explicit legal authority to require manufacturers to pay for all costs of a product stewardship program. More generally, it remains to be seen whether EPA's proposed new scheme will be flexible enough to address the conditions throughout the diverse health care industry.

EPA will seek public comments on its NPRM. It is advisable that impacted health care companies and industry trade associations (particularly companies with unique circumstances) provide comments. Obviously, EPA cannot address a problem that it does not know exists.

Alleged Impact of Pharmaceuticals Discharged from Sewage Treatment Plants

In April 2015, the Food and Drug Administration (FDA) concluded that there is "research indicating that drugs with endocrine-related activity and, more specifically, drugs with . . . [estrogenic, androgenic, or thyroid hormone pathway activity, i.e., E, A, or T] activity, have the potential to cause developmental or reproductive effects in the aquatic environment at concentrations of 1 ppb" [part per billion or microgram per liter] at locations downstream of sewage treatment plants. *See* FDA, Environmental Assessment: Question and Answers Regarding Drugs with Estrogenic, Androgenic, or Thyroid Activity Guidance for Industry at 2 (draft, April 2015), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444658.pdf. This claim was also made by EPA, the United States Geological Survey and other researchers. As a result, FDA is seeking public comment on its proposal to require drug sponsors to consult

with FDA "early in product development concerning the information FDA may need to determine whether an [environmental assessment] will be required." *Id.*

Pharmaceutical manufacturers are likely to file comments on FDA's finding of potential effects and the increased need for environmental assessments. However, other companies within the health care pharmaceutical supply chain should be aware that the FDA finding may be used (or misused) by local sewage treatment authorities on a case-by-case basis or by EPA through a national pretreatment rule to require health care facilities to minimize discharges of pharmaceuticals into sewage treatment systems (e.g., EPA proposed in 2014 that dental offices install dental amalgam separators to minimize the discharge of mercury from sewage treatment plants into streams, rivers and lakes).

In summary, there are several recent environmental developments that may impact the health care industry and associated companies and that bear continued monitoring.