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NEWSLETTER

California Suit May Decide Who Pays for Pharmaceutical Take-Backs

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Take a look in your medicine cabinet. Chances are you have medications that are expired or you will not use. Do you know what you should do with them?

The U.S. Food and Drug Administration (FDA) suggests that they be flushed down the toilet or thrown away, but environmental advocates argue that just puts drugs in rivers, streams, and landfills. Many local governments operate programs to safely collect unused, unwanted, or expired medications from their citizens at taxpayer expense. But these pharmaceutical "take-back" programs can be expensive and complicated. Now, local governments and stewardship activists are looking to push the costs of these programs onto industry.

Last year, Alameda County, CA, became the first locality to require pharmaceutical manufacturers to establish privately funded programs to collect prescription drugs. The ordinance covers all prescription drug manufacturers—both brand name and generic. However, it exempts over-the-counter drugs, medical devices, vitamins or dietary supplements, and cosmetics or personal care products, such as soap and antiperspirants.

Manufacturers quickly responded with an extraordinary level of intra-industry cooperation. Trade associations for both brand-name and generic pharmaceutical manufacturers and manufacturers of biotechnology products joined together to sue Alameda County to stop the new program. *Pharmaceutical Research and Manufacturers of America et al. v. Alameda County, California et al.*, No. 3:12-cv-06203-RS (N.D. Cal.). The plaintiffs argue that the scheme violates the U.S. Constitution by imposing local government costs on out-of-state companies engaged in interstate commerce. They argue that distribution of their products to Alameda County residents does not grant the government the right to mandate the take-back program.

Alameda County counters that used pharmaceuticals are garbage and that collecting garbage is a "core local function." The county claims it has the right to ensure its garbage is collected appropriately, through whatever means it sees fit. It also argues that the sale of each company's products gives the county the authority to tax the manufacturers and require them to support a collection program. Pharmaceutical companies that wish to not participate, the county argues, may simply choose not to sell within that county.

A hearing was set for June 27, 2013, for arguments on cross motions for summary judgment. While a decision in the trial court may come shortly thereafter, this argument is unlikely to be settled any time soon. Whoever loses will appeal, perhaps ultimately to the Supreme Court of the United States.

While a win by the plaintiffs may throw cold water on other take-back proposals, an Alameda victory would probably irresistibly invite other local and state governments to mandate similar industry-funded programs. Indeed, already King County, WA, recently announced that it is adopting a similar program. It is not hard to then foresee claims for nationwide consistency.

Rolling out collection programs nationwide would face some significant legal and logistical hurdles that are specific to pharmaceutical take-back programs. Current regulation of take-back programs is left almost entirely to the states. This means that any effort to create nationwide or multi-state collection programs will face potentially conflicting regulations in the various states.

Federal regulations also pose serious complications. For instance, the U.S. Drug Enforcement Administration (DEA) currently places severe limitations on the collection and disposal of controlled substances. Under current federal law, controlled substances may not be commingled with non-controlled substances. This effectively prevents the use of a single collection receptacle. Further, accepting controlled substances requires DEA pre-approval of a collection site and the continuous presence of a law enforcement officer. For this reason, collection programs have typically been conducted by or in conjunction with the local police department.

Also, there are additional limitations that stem from product-specific rules. For example, medications containing mercury and nitro-based medications require separate packaging and storage. The collection of needles and other "sharps" also carries its own set of regulatory complexities, including separate packaging and a variety of mandatory disposal practices on both a state and federal level.

Recognizing these difficulties, Congress and federal agencies seek to create more opportunities for private entities to operate take-back programs. In 2010, Congress passed the Secure and Responsible Drug Disposal Act of 2010 (SRDDA). It was intended to allow patients to deliver unused controlled pharmaceuticals to "appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion." The act specifically encourages the development of privately operated collection programs.

To implement the SRDDA, late last year the DEA proposed three options for the disposal of controlled drug products: 1. take-back events, 2. mail-back programs, and 3. collection receptacles. *See* 77 Fed. Reg. 75783 (Dec. 21, 2012). These regulations would resolve some of the current impediments to collection programs by allowing controlled drug substances to be commingled with non-controlled drug products. Privately-operated collection programs could accept both types of unused drug products in one collection receptacle. The proposal would also limit the need for law enforcement involvement, and allow private entities to offer collection receptacles. While far from perfect, it would create a uniform national scheme for controlled substance disposal, and would allow private entities to more easily provide drug disposal services.

While current DEA efforts may resolve these collection issues, environmental and other waste disposal regulations still pose significant burdens. On the plus side, unlike other collection programs for EPA-regulated products—such as batteries—the EPA has stated that it does not view patient-returned drugs to be hazardous waste. However, other environmental requirements still apply. Perhaps most important, simply sending collected pharmaceuticals to the landfill will likely not be an option.

The pharmaceutical industry may wish to follow the lead of other industries, such as the electronics and rechargeable battery industries, to establish a cooperative program to collect on behalf of a group, or all, of the pharmaceutical manufacturers. These programs typically establish a single private entity to collect products on behalf of a group of manufacturers. The manufacturers then pay for the operation of the company on a pro-rata, market share, or other cost-sharing arrangement. Indeed, the Alameda ordinance specifically encourages manufacturers to participate in industry-wide collection programs, and adopts many of the tenets of the electronics and battery programs. For instance, collection programs must accept any and all unwanted drugs, regardless of which company originally manufactured the drug.