

Pharmaceutical Take Back: Next Stop, Supreme Court Review of the Dormant Commerce Clause

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The Ninth Circuit's September 30 rejection of the pharmaceutical industry's challenge to Alameda County, California's 2012 used drug take back mandate (*Pharmaceutical Research and Manufacturers of America, et al. v. County of Alameda*, No. 13-16833) was expected by many observers. Industry's theory of the case—that the ordinance violates the “Dormant Commerce Clause” of the U.S. Constitution by discriminating against interstate commerce—was rejected as not adequately supported by existing case law. Many disinterested observers have assumed that the industry's ultimate goal is to give the Supreme Court a new chance to refine its Dormant Commerce Clause jurisprudence. With state and local governments considering and enacting a variety of economic and other regulation that impacts product manufacturing, business operations, and technical operations around the country, the Court may be prepared to revisit the Dormant Commerce Clause.

We will know in the next several weeks. The appellants have three months to seek Supreme Court review, unless they request rehearing by a larger Ninth Circuit panel (what is referred to as “rehearing *en banc*”). But seeking rehearing is entirely optional. An early petition for certiorari to the Supreme Court seems more likely.

The remainder of this article provides some modest background about the challenged ordinance and similar others, a brief discussion of the basis of the Ninth Circuit's ruling, and some observations about what is likely to happen next.

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The Alameda Ordinance

Alameda County's "Safe Drug Disposal Ordinance" requires that any prescription drug producer whose products are sold in Alameda County—whether brand name or generic—collect and safely dispose of unwanted prescription drugs. It reflects both concern with the misuse and abuse of older medicines and pills and concern that excess quantities of those materials are reaching waterways through sewer systems (and inadequate sewage treatment). Companies subject to the requirements can implement plans independently or in combination. In fact, a large coalition of companies organized as the Pharmaceutical Product Steward Working Group (PPSWG) has formed to meet the requirements and submitted a plan to county authorities. To date, however, it has not been approved.

A similar ordinance is in place in Seattle, and many jurisdictions have sponsored individual drug take back days. With the decision of this court, many more localities can be expected to impose more comprehensive requirements.

Pharma's Legal Theory

The industry's legal theory, now rejected at both the trial and appellate court level, is that the Alameda Ordinance violates the U.S. Constitution because it imposes obligations on companies from outside the County. The legal hook for the challenge is the so-called "Dormant Commerce Clause." It is an outgrowth of the Commerce Clause, which dictates that "Congress shall have Power . . . [t]o regulate Commerce . . . among the several States." The Dormant Commerce Clause seeks to interpret the implication of this rule: that states and local governments cannot impose laws that discriminately disrupt interstate commerce. Essentially, that is, lower levels of government cannot adopt protectionist measures that favor local interests at the expense of outsiders.

This is a *bona fide* principle, supported by a considerable body of case law. The difficulty with extending the dormant commerce clause as the pharmaceutical industry has advocated is that case law establishes several criteria for invoking it. And the Ninth Circuit concluded that the Alameda Ordinance, on its face, does not meet them.

For example, to invoke dormant commerce clause protection, a plaintiff must show that the challenged requirements impose barriers against only products produced out-of-state—that is, that it is discriminatory. But the Alameda Ordinance applies equally to pharmaceuticals whether manufactured in Alameda County (as some are) or outside.

Industry's difficulty is demonstrated in last month's decision by the appellate court's observation that the appellants could cite no precedent supporting key elements of their arguments. If the court were to accept it, the Ninth Circuit panel wrote, it would be "break[ing] new ground."

Now What?

Even if the Supreme Court agrees to hear a further appeal of this case, that will not occur before next year. In the meantime, implementation of the Alameda and Seattle ordinances almost certainly will proceed, and similar mandates no doubt will be enacted elsewhere.

Some, if not all, of those probably will be challenged in court. Last month's ruling is only binding in the Ninth Circuit, which includes Seattle. This leaves ten more circuits where the law is unsettled. Moreover, there is a way to distinguish the *PhRMA* decision on its face, at least as to some jurisdictions. One of the reasons the court rejected industry's discrimination argument was that "three of Plaintiffs' members have their corporate headquarters or principal place of business in Alameda and two of Plaintiffs' members have facilities in Alameda that manufacture prescription drugs for commercial distribution." The same probably will not be true in every other jurisdiction that adopts a take back law.

In the meantime, the existing ordinances, and no doubt some new ones, will be implemented. This has been facilitated by the Drug Enforcement Agency's September 9, 2014, revision of its drug control regulations. (79 Fed. Reg. 53520 (Sept. 9, 2014)). But there still will be substantial challenges to be faced, both in assuring security—unlike used newspapers or batteries, few are interested in stealing the collected products—and in logistics. And the very different mindsets of regulatory agencies and the varying segments of the highly-competitive pharmaceutical industry may make smooth program design and implementation difficult.

Beyond pharmaceutical regulation, we also can expect additional litigation over the bounds of the dormant commerce clause, as state and local governments explore regulation often explicitly intended to affect production, operations, supply chains, and technologies, far beyond the enacting jurisdiction's borders.