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NEWSLETTER

Court Upholds Alameda County Unused Drug Stewardship Mandate

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As most observers had expected, U.S. District Court Judge Richard Seeborg, sitting in San Francisco, on August 28, granted Alameda County summary judgment against the pharmaceutical industry in its challenge to the county's mandate that drug manufacturers provide a program or programs to collect their unused pharmaceutical products. *Pharmaceutical Research and Manufacturers of America, et al. v. County of Alameda*, No. C 12-6203. Appeal to the U.S. Court of Appeals for the Ninth Circuit is now expected, as well as a further effort to obtain Supreme Court of the United States review if the District Court decision is upheld on appeal.

The case is a test of the "dormant Commerce Clause" of the U.S. Constitution, which prohibits state and local governmental regulation that "unduly" interferes with interstate commerce.

The Alameda County ordinance at issue required producers of prescription drugs to fund or operate take-back programs in the county if any of their drugs were sold there. As the District Court explained, the ordinance was crafted "to place the entire cost of such programs on the producers; retail pharmacies are exempt, and sellers are prohibited from passing the expense directly to Alameda County consumers by adding a fee at the point of sale." The precedent the ordinance set was sufficiently troubling to industry that plaintiffs in the case included both the name-plaintiff "big pharma" trade association (PhRMA) and the Generic Pharmaceutical Association (GPhA), typically bitter enemies.

Few legal observers were surprised by the outcome, since dormant Commerce Clause challenges face substantial hurdles, at least where facial discrimination against foreign companies does not exist. And

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here, there is none. In fact, several of the companies subject to the mandate operate facilities in Alameda County, including manufacturing facilities (albeit not for drugs sold in the county).

Affected companies have launched a handful of other constitutional challenges to mandatory product stewardship programs, but with little success. In 1999, the National Electrical Manufacturers Association (NEMA) filed a challenge to a Vermont statute that required labeling of mercury-containing fluorescent light bulbs. NEMA initially obtained an injunction against the bill on both the dormant Commerce Clause and First Amendment (free speech) grounds, but the U.S. Court of Appeals reversed and vacated it. *National Electric Manufacturers Association v. Sorrell,* 272 F.3d 104 (1st. Cir. 2001). The Court of Appeals there found that "[a]lthough a regulation might violate the Commerce Clause by creating market incentives that encourage out-of-state manufacturers to abandon a state market while encouraging in-state manufacturers to pick up the slack, the instant regulation is evenhanded …." A subsequent suit by the consumer electronics industry against New York City's extraordinarily burdensome e-waste program (which, among other things, required manufacturers to directly retrieve e-waste from any resident in the city) was dismissed after the state adopted a preemptive, and somewhat less burdensome, e-waste program. *Consumer Electronics Association, et al., v. City of New York*, No. 09-6583 (S.D.N.Y. 2009).

In the *Alameda* case, the plaintiffs focused on the dormant Commerce Clause issue. They signaled the potentially sweeping impact of an industry victory—at least at the appeal stages—by arguing, in their Motion for Summary Judgment, that "[i]f this novel ordinance were permissible, then localities could free-ride on interstate commerce by, for example, requiring interstate newspapers to conduct the state's paper recycling program or requiring wine growers to engage in glass recycling wherever their bottles are distributed." The likely *Simpsons*esque reaction of some readers to such outrage—"d'oh!"—signals, at the very least, how important activists are going to view this case as it proceeds up the appellate ladder.

Presumably because of their overall strategy, the plaintiffs did not devote equal attention to a question that is important to many emerging "producer responsibility" programs: Is there really a legitimate health or environmental concern underlying the ordinance? By its terms, the ordinance is intended to address the risk of poisoning from mishandling of prescription drugs and the risk of water contamination arising from unwanted or expired drugs passing in wastewaters. Substantial questions exist about how large those threats are and whether, in the face of the dormant Commerce Clause's requirement, those burdens are balanced against benefits where there is no facial discrimination against foreign entities. The *Alameda* plaintiffs' focus on the rules governing per se dormant Commerce Clause violations serves their appellate interests, but leaves for future cases the question of how big of a burden local governments really must face before burdensome product stewardship rules are constitutionally acceptable.