

# Supreme Court Upholds State Regulation of Pork: What Does it Mean for the Pharmaceutical Industry?

In a recent Supreme Court decision, the high court upheld a California ballot initiative that bans the sales of certain type of pork in the state. While the challenge of the law is specifically focused on the state pork law, it has significant legal implications for industries beyond the meat industry. The Pharmaceutical Research and Manufacturers of America (PhRMA), representing many biopharmaceutical and biotechnology companies, filed an amicus brief opposing the law due to its potential application to the state regulation of prescription drug prices. In this post, we take a look at the legal challenge and how the ruling on the application of the dormant Commerce Clause impacts the ability of states to regulate interstate sale of goods including prescription drugs.

## The Pork Law and the Dormant Commerce Clause

The case that was considered by the Supreme Court is a legal challenge to California's Proposition 12, a ballot initiative passed in 2018. As codified at Cal. Health & Safety Code §25990(b)(2), the law forbids the in-state sale of whole pork meat that comes from pigs (or their immediate offspring) that are "confined in a cruel manner," including preventing the pig from lying down, standing up, fully extending its limbs, or turning around freely. Intended to promote animal welfare and consumer health, this law increases production costs for both

California and out-of-state producers of pork. Because California imports 99% of the pork it consumes from other states, the cost of compliance with the law would burden mostly out-of-state producers.

Pork industry groups – the National Pork Producers Council and the American Farm Bureau Federation – filed a lawsuit in December 2019 to challenge the law, alleging that Proposition 12 violates the Constitution’s dormant Commerce Clause. Inferred from the Commerce Clause in Article I of the Constitution, the dormant Commerce Clause has been interpreted in case precedents to bar states from discriminating against interstate commerce. While the plaintiffs do not claim the law purposely discriminates against out-of-state companies, they assert that it violates the extraterritoriality doctrine because it has the practical effect of controlling commerce outside the state. Specifically, they claim that Proposition 12 interferes with interstate commerce because imposing these standards on a national industry would force out-of-state producers to invest in expensive alternations to change their operations in order to comply with California pork standards and sell their products to California buyers. Citing the 1970 Supreme Court decision in *Pike v. Bruce Church*, plaintiffs claim the law is unconstitutional because it imposes a burden on interstate commerce that is “clearly excessive in relation to the putative local benefits” and therefore is impermissible.

In April 2020, the district court dismissed the case for failure to state a claim as a matter of law. The Ninth Circuit [affirmed the dismissal](#) in July 2021, ruling that the law regulates in-state and out-of-state conduct in the same way and therefore does not violate the Constitution. The case was granted certiorari for Supreme Court review in March 2022.

## **PhRMA Files Amicus Brief on Behalf of Pharmaceutical Companies**

Another industry that is inherently national in scope, like the pork industry, is the pharmaceutical industry. With rising prescription drug prices, state legislatures across the country have been active in introducing legislation to regulate the practices of pharmaceutical manufacturers, which are interstate in nature. Previously, former Source Managing Editor Anna Zaret and law professor Darien Shanske discussed in a [white paper](#) published by the National Academy for State Health Policy how the dormant Commerce Clause could potentially impact the regulation of pharmaceutical costs.

Given the potential impact the adjudication in this case could have on state regulation of interstate commerce that includes prescription drugs, the Pharmaceutical Research and Manufacturers of America (PhRMA) [filed an amicus brief](#) before the Supreme Court. Representing national pharmaceutical company interests, PhRMA argued against extraterritorial state legislation that would in effect regulate commercial activities nationwide.

Importantly, the brief makes a careful distinction between price control or price affirmation laws and the regulation of other interstate commercial activities as in Proposition 12. Due to the potential impact on the production and sale of prescription drugs, PhRMA opposes and argues against both types of interstate commerce regulation, but based on different legal theories, to ensure that the outcome of one case does not impact the others.

### **State Regulation with Direct and Legal Effects**

PhRMA has filed its own lawsuits challenging two state laws that regulate the nationwide list prices of pharmaceutical products. Enacted in California (Cal. Health & Safety Code § 127677(a), (b)) and Oregon (Or. Rev. Stat. § 646A.683(2), (3)), the

statutes require drug manufacturers to provide advance notice before increasing a prescription drug's wholesale acquisition cost (WAC) beyond certain percentage thresholds. Because a drug's list price must be uniform under federal law, PhRMA argues that these state laws would create conflicts in different states such that the extraterritorial consequences are automatic and unavoidable. In its amicus brief, PhRMA emphasizes that these types of direct and inevitable legal effects on out-of-state commerce exceed "the inherent limits of the enacting State's authority" and are categorically invalid "regardless of whether the statute's extraterritorial reach was intended by the legislature." While the [California challenge](#) was dismissed by the 9th Circuit in September 2022 for lack of evidence, the [Oregon lawsuit](#) is still pending.

### State Regulation with Indirect and Economic Effects

Turning to the state pork regulation at issue, PhRMA's brief first attempts to establish the application of the extraterritoriality doctrine to the regulation of a wider range of commercial activities beyond price control. PhRMA argues that the prohibition on extraterritorial state legislation should not be limited to price control or price affirmation statutes because interstate commerce is not just the sale of goods, but includes "every negotiation, contract, trade, and dealing" that occurs across state borders. The brief then asserts that even though Proposition 12 on its face only regulates in-state activity, it has indirect effects on farming and production practices nationwide because of the pork producers' fully integrated supply chain that serve the national market. Pork producers would have to restructure their entire operations to comply with California's law, thereby affecting out-of-state practices. When a statute has only indirect effects on interstate commerce, PhRMA points to the legal standard established in *Pike v. Bruce Church*, which examines whether the

state's interest is legitimate and balances the burden on interstate commerce versus the local benefits. PhRMA argues that when a state regulates a commercial activity that inherently requires national uniformity, as in the pork industry and arguably the pharmaceutical industry, altering out-of-state behavior to comply with the law "is not merely inconvenient or costly, it is functionally impossible," suggesting that the burden outweighs the state interests.

### **Supreme Court Decision and Implications for Pharma**

After oral arguments in October 2022, the Supreme Court [issued an opinion](#) in May that upheld the lower court decision, validating the pork regulation. In a 5-4 ruling, Justice Neil Gorsuch wrote for the majority and acknowledged that *Pike* established that a state law is unconstitutional under the dormant Commerce Clause if it imposes a burden on interstate commerce that is "clearly excessive in relation to the putative local benefits," which the plaintiffs have failed to show.

#### **Split Opinion on Application of the Pike Balancing Test**

Notably, while the majority concurred that Proposition 12 did not violate the dormant Commerce Clause under the *Pike* test, their reasoning and application of the test are divided. Within the majority, Justices Gorsuch and Thomas said that plaintiffs did not meet the high bar for showing violation of the dormant Commerce Clause on non-discriminatory grounds. In terms of applying the *Pike* test, they believed that courts are not well positioned to engage in a balancing test in this case because the costs and benefits are difficult to compare, as the court must weigh California's moral interest in animal welfare against the pork producers' interest in avoiding compliance costs. Justices Sotomayor and Kagan disagreed that the court did not

have the capability to conduct a cost-benefit analysis in this case but said that plaintiffs failed the Pike test because they did not prove “substantial burdens.” Finally, Justice Barrett said the groups did prove “substantial burdens,” but could not apply the Pike test because the benefits and costs in this case cannot be properly evaluated by a court. Meanwhile, the dissent written by Chief Justice Roberts and joined by Justices Alito, Kavanaugh and Jackson said the case should be remanded to the Ninth Circuit to consider the Pike question.

Ultimately, all justices agreed that the Commerce Clause is not interpreted to mean that any state law affecting states outside their boundaries are invalid and the plaintiffs didn’t meet the bar for showing that Proposition 12 imposed “substantial burdens” on interstate commerce.

#### *What Does it Mean for the State Regulation of Pharmaceuticals?*

The high court ruling in favor of a state law resulting in indirect economic effects could be seen as a broader endorsement of state regulation of interstate commerce that has the potential to extend to industries beyond the pork industry. At the same, two caveats should be considered with this decision. First, given the difference in application and interpretation of the Pike test in this case, it may not be as straightforward for future stakeholders to clearly evaluate the validity of a state regulation and whether it would run afoul of the dormant Commerce Clause. Second, as PhRMA was eager to distinguish in its amicus brief filed in this case, PhRMA’s pending litigation challenging state price control statutes may rest on different legal theories that could also potentially reach the Supreme Court. As a result, the jury may still be out on the future of state regulation of interstate commerce, including its impact on prescription drugs.

Nonetheless, this decision is a notable divergence from the Fourth Circuit ruling that struck down Maryland's generic drug pricing law on the same grounds of extraterritoriality doctrine under the dormant Commerce Clause. The dissenting opinion and academics have [criticized the decision](#) as misconstruing the pharmaceutical industry. This latest Supreme Court ruling in favor of state regulation of commerce, coupled with [the court's 2020 validation](#) of Arkansas' right to regulate prescription drug prices in [Rutledge v. PCMA](#) (albeit on the grounds of ERISA preemption), could give states more confidence to pass laws regulating the sale of pharmaceutical products.