



The Dormant Commerce Clause: What Impact Does It Have on the Regulation of Pharmaceutical Costs?

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When states attempt to regulate pharmaceutical drug costs, the pharmaceutical industry usually responds with several legal arguments. One set of arguments is based on the Dormant Commerce Clause (DCC).

The Commerce Clause of the Constitution gives Congress the authority to regulate commerce between states. The judge-made constitutional rules (case law) governing how far states can go with law and policy that may affect interstate commerce is defined by the DCC. This paper summarizes this legal doctrine, analyzes what type of state legislation is most likely to fail a legal challenge under this doctrine, and shows that a well-constructed state regulation of pharmaceuticals should survive a DCC challenge.

We believe that the key to avoiding DCC problems is for states to impose regulations that resemble those that have long been imposed on other products and services, including hospital billing, electricity, and consumer interest rates (usury), and food preparation, and consumer disclosures.

Legal problems for a state regulating pharmaceuticals might arise under the DCC as a result of two features of a state law:

- First, a state law can run into trouble if it imposes large costs on interstate commerce that are out of proportion to the expected benefit to the public.
- Second, challenges may arise if a state links its regulation to actions occurring in other states. For example, a state law that required pharmaceuticals within the state be priced no higher than the prices charged in other states would face a strong DCC challenge.

I. What is the DCC and how does it limit state pharmaceutical legislation?

The federal Constitution grants Congress the power to regulate interstate commerce under the Commerce Clause, which is an affirmative grant of power. A long-standing judicial interpretation of the Commerce Clause prohibits states from discriminating against the commerce of another state. This prohibition is known as the dormant or negative Commerce Clause. The classic example of an activity barred by DCC is a state imposing a tax on goods imported from another state, but not taxing similar goods produced in-state in order to protect an in-state industry. When a state “facially” discriminates against businesses from other states in this way, it almost always fails.

However, if states adopt legislation aimed at more transparent or lower pharmaceutical costs, they are not doing so to protect a local industry and thus are outside the core concern of the DCC. These laws do not involve facial discrimination against an out-of-state business because they apply in the same way to pharmaceuticals manufactured inside and outside the enacting state.

What DCC arguments does the pharmaceutical industry make?

The first argument sometimes made by the industry is rooted in a subsidiary DCC test that courts use to assess whether state or local law violates the DCC. This test does not focus on whether the law discriminates against out-of-state commerce, but on whether “the burden imposed on [interstate] commerce [by the law] is clearly excessive in relation to the putative local benefits [provided by the law].” This balancing test is known as “Pike balancing” after a key case in which it was applied. An example of a state law that failed this test was a state law requiring interstate trucks to use a particular – and unusual - kind of mudguard. On the one hand, there were (at most) minor benefits associated with using a particular kind of mudguard. On the other hand, there were vast costs imposed on interstate trucking firms if they were actually required to use only one special kind of mudguard within a state while other states required different kinds of mudguards. The Supreme Court struck down the law because the burden on interstate commerce of complying with different mudguard rules clearly outweighed the minimal local benefits.

The second argument likely to be made by the pharmaceutical industry is based on a DCC doctrine that prohibits extraterritorial state regulation. Under the extraterritoriality doctrine, states are forbidden from directly regulating commerce that occurs outside of the regulating state. On the one hand, this prohibition is just common sense. Of course, one state cannot impose its regulations upon another state’s citizens. Courts have primarily used this doctrine to strike down state laws that tie regulation of a multi-state enterprise to the regulations of another state. For example, in one key case, Connecticut required beer importers to affirm that their prices were no higher than what the importers charged in two neighboring states.

Some attempts to regulate the cost of pharmaceuticals have similarly tied the acceptable prices to the average of the prices paid in other jurisdictions. This is a sensible and easily administrable way to get one’s citizens a good deal, and has analogues to how many nations control their drug costs. Nevertheless, because of precedents like the one involving beer prices, one federal district court struck down a Washington, DC law in part because it aimed to regulate drug prices in roughly this same way -- by limiting the price of drugs sold in DC based on international prices.

II. Most legislative efforts to reduce pharmaceutical costs can avoid DCC problems

Unlike the Washington, DC law, most types of state legislation targeting pharmaceutical costs are unlikely to be successfully challenged under the DCC. This paper examines four types of legislation: 1) price transparency; 2) pharmacy benefit manager (“PBM”) regulations; 3) drug importation; and 4) rate setting.

Price transparency laws, addressed in NASHP’s [model legislation](#), require pharmaceutical companies to provide information about how drugs are priced in order to help policymakers and consumers understand costs and how they can be lowered.

- States have sought to reform the business practices of PBMs through several types of legislation, including laws that require PBMs to obtain state licenses, define PBM fiduciary duties, and require PBMs to disclose certain information.
- States that wish to purchase drugs from Canada are considering drug importation legislation. NASHP’s [Wholesale Importation Model Legislation](#) is an example that would allow importation by creating a state-administered wholesale drug importation program.

- Finally, rate-setting regulation allows a state commission to set prescription drug payment rates for certain expensive prescription drugs that create excess costs in the state. NASHP has also outlined this type of regulation in its [Rate-Setting Model Legislation](#).

All four types of legislation would be evaluated under “Pike Balancing” and all four should succeed if designed not to be too burdensome on interstate commerce. All of the proposed legislation is unlike the laws that have failed the Pike balancing test, such as the law requiring trucks to use unusual mudguards, for (at least) two reasons. First, as a report of the US Senate Special Committee on Aging has demonstrated [here](#), the challenge to the health of citizens posed by spikes in drug costs is very substantial – unlike the special mudguards requirement. Indeed, the Supreme Court regularly emphasizes that courts should be particularly deferential when states are regulating to promote the health of their citizens. Second, and as NASHP has explained [here](#), the market for pharmaceuticals is already monstrously complicated and Balkanized and is quite expensive to navigate. None of the proposed reforms would add an appreciable burden on interstate commerce, much less an excessive burden relative to the administrative obligation the pharmaceutical industry already bears.

As for price transparency, these statutes are only asking the industry to disclose *public* information it has anyway about how drugs are priced. If the laws are crafted with due regard for administrative costs, the pharmaceutical industry cannot reasonably argue that complying with transparency laws substantially burdens interstate commerce.

Similarly, with PBM regulations, the focus of reform proposals is generally to promote greater transparency. For instance, one reform would ban gag clauses that keep price information from consumers. PBMs cannot reasonably argue that there is any excess burden, much less a burden on interstate commerce, in laws that make sure *pharmacists* -- not PBMs -- are allowed to share information they already have with consumers about cheaper alternatives to their prescriptions.

The drug importation law requires a slightly different analysis. As this reform would permit importation of pharmaceuticals from other countries, it does not impact trade between other states at all. That said, there is a *foreign* dormant Commerce Clause doctrine that seeks to protect the role of the federal government in implementing foreign policy, including trade policy. A state could not enter into a trade agreement with a foreign country. However, the drug importation act is designed to comply with the requirements set forth under federal law. Because the federal government has already provided a roadmap detailing how states can import drugs from abroad, it does not undermine the federal power over international relations for states to follow that roadmap, and it does not implicate larger nation-to-nation trade agreements.

Finally, there is the question of how rate-setting regulation fares under *Pike* Balancing. The pharmaceutical industry will argue that dealing with a state regulatory regime – and perhaps many state regulatory regimes – would be extremely burdensome on its participation in interstate commerce. This argument should fail if the state law is well crafted. All commercial payors, Medicare, Medicaid, and other state programs *already* set health care reimbursement rates for both brand name and generic drugs. Thus, it is not plausible to argue that a more organized system of drug reimbursement regulation in one state is a significant new burden on the pharmaceutical industry’s involvement in interstate commerce. Furthermore, unlike the classic cases where a law is struck down under *Pike* balancing, there is no local industry that is in any way relieved from this state burden.

III. Rate-setting regulation and extraterritoriality

The primary argument the pharmaceutical industry is likely to raise -- and the only DCC argument made successfully against state drug cost regulations recently -- is that the changes in law violate the extraterritoriality doctrine. The doctrine has been successfully invoked when state laws have attempted to link permissible prices in one state to prices in another. Price transparency, PBM regulation and drug importation do not involve setting costs at all and so appear unlikely to pose extraterritoriality problems. The main extraterritoriality challenge may be to rate regulation.

However, unlike the laws the Supreme Court has struck down under this doctrine, rate regulation as written into NASHP's model act would not regulate pharmaceutical costs through reference to out-of-state prices. The only drugs the act would impact are those that are priced in such a way so as to trigger review -- specifically through a high cost in absolute terms or through a high increase in costs. The model act specifically excludes consideration of costs charged to other states in its cost analysis. Thus, the actions of other states do not trigger review. Indeed, in Phase Two of its cost analysis, the model act directs the commission to take a closer look at the operation of the manufacturer and to assess whether there are "excess costs" based on assessing a fair rate of return on the manufacturer's investment as apportioned to the state based on sales. Evaluating a fair rate of return on investment is a longstanding -- and long accepted -- tool of utility regulators. Similarly, apportioning activity using a rough formula is a long-established method that states use to tax multistate enterprises.

The pharmaceutical industry will still contend that rate regulation is forbidden extraterritorial regulation because it has downstream effects on out-of-state transactions between pharmaceutical manufacturers and wholesale distributors.

This argument should fail because it proves too much, meaning that under the pharmaceutical industry's interpretation of the law, nearly all state regulations of a multi-state industry would be unconstitutional. In practice, states exert regulatory control that impacts other states all the time, especially in an integrated and increasingly digital economy. Aside from its impracticality, a sweeping extraterritoriality rule also raises federalism concerns because such a rule gives federal judges sweeping powers to strike down state and local laws. Accordingly, the Supreme Court has explained that a forbidden extraterritorial effect must either be express or inevitable. Applying this test, the Supreme Court found that a Maine law similar to the model act did not have an extraterritorial effect. The Maine law required drug manufacturers to reduce prices within Maine or face significant additional procedures if those manufacturers wanted their products to be used within Maine's Medicaid program. Because there was no express tying or inevitable extraterritorial effect, the law was upheld. Similarly, rate regulation does not inevitably impact out-of-state transactions. The only inevitable effect falls on transactions that occur in the enacting state.

IV. Conclusion

The DCC is judge-made law created by past legal decisions, instead of statutes, and predicting its future development cannot be done with certainty. We have explained why, based on existing law, the reforms under consideration should pass muster under the DCC so long as they satisfy two conditions: they do not impose a large new burden on interstate business out of all proportion to the hoped for benefit; and they do not explicitly link in-state costs to out-of-state prices.

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