

State Intrusions into Federal Drug Discount Program: *McCulloch v. Maryland*, Round Two

by Cory L. Andrews

In February 1818 the Maryland General Assembly passed a law taxing every bank operating in the State “not chartered by the legislature.” Only one bank fit that description, the Baltimore branch of the Second Bank of the United States, and everybody knew it. The Bank was widely hated, the tax was popular, and Maryland’s lawyers had a respectable argument that a State may tax any property within its borders.

Chief Justice Marshall rejected it. The States, he wrote, have no power “to retard, impede, burden, or in any manner control” the operations of laws Congress enacts, because the power to tax involves the power to destroy. The deeper point of *McCulloch v. Maryland* concerned form and substance. A State cannot accomplish by indirection what the Supremacy Clause forbids it to do directly, and a law drawn so that it falls only on those who serve federal ends is a law aimed at the federal government, whatever the statute books may call it.

Every first-year law student reads the case. Today’s lawyers in the Maryland General Assembly must have skipped class that day.

On Tuesday the en banc Fourth Circuit [heard argument](#) over a 2024 Maryland statute that applies to a single category of business, a drug manufacturer “that has signed a pharmaceutical pricing agreement” with the United States. The law applies to no one else. If you sign the federal agreement, the Maryland law binds you, and the State may assess a civil fine on each package of pills and pursue criminal penalties to boot. A manufacturer that withdraws from the agreement is outside the law’s reach entirely. West Virginia’s version was argued the same morning. Roughly twenty other States have enacted something similar since 2021.

The agreement at issue is how a manufacturer joins a federal program called [340B](#), which for more than thirty years has required drug companies to sell their products at steep discounts to a list of hospitals and clinics Congress designated as safety-net providers. Congress could not simply order one private company to hand its inventory to another at a fraction of cost, so in 1992 it struck a bargain instead. A manufacturer that wants Medicaid and Medicare Part B to pay for its drugs must offer them to those providers at discounts that can run to a penny a pill. The statute does not require that any of the savings reach a patient, and lately the hospitals’ own lawyers have begun to say as much in court, describing 340B as a funding stream for the institutions rather than a benefit for the people they treat. On the text they are correct, and the candor clarifies whose special interests the state laws are built to protect.

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The program is now the second-largest federal drug program after Medicare Part D, with more than \$100 billion in discounted purchases last year. A good deal of that growth comes from a guidance document the Health Resources and Services Administration issued in 2010, which let hospitals route discounted drugs through an unlimited number of outside “contract pharmacies,” many of them national chains. Under the arrangement that emerged, which the industry calls the replenishment model, the pharmacy fills a prescription from its ordinary shelf stock at the ordinary price. Some weeks later a vendor’s algorithm decides the customer might have been a hospital patient. The hospital then orders a replacement unit at the federal discount, and the hospital, the pharmacy, and the vendor split the difference between the discount and what the customer paid. The customer, whose prescription was filled at the ordinary price, is not part of the arithmetic.

Manufacturers watched discounted drugs go to people who had never set foot in the hospital, and watched discounts get stacked on top of Medicaid rebates, a doubling the statute expressly forbids. In response, the manufacturers began attaching conditions to their offers: one contract pharmacy per hospital, and claims data so the discount could be checked against an actual patient. At first, HRSA tried to prohibit the conditions. The Third Circuit and then the D.C. Circuit held it could not, because the statute obliges manufacturers to “offer” the discount and is silent about how or where the drugs are delivered. “When Congress’s words run out,” the Third Circuit said, “covered entities may not pick up the pen.”

The States picked it up instead. Their laws, in the Justice Department’s description this summer, try “to regulate in HHS’s stead.” In substance, they order manufacturers to keep extending the federal discount to hospitals that have refused the conditions designed to keep the discount honest. On their face, the laws speak of a manufacturer’s duty not to “restrict” or “limit” a pharmacy’s “acquisition” of a 340B drug, which has the sound of mere shipping regulation, and the Fifth and Eighth Circuits accepted that characterization when they upheld laws from Louisiana, Mississippi, and Arkansas. But manufacturers already deliver to every pharmacy in Maryland and West Virginia. What the laws decide is whether the hospital is billed the federal discount price or the ordinary one, and Maryland’s own statute says so. It defines a “340B drug” to include one that “would have been purchased but for” a manufacturer’s conditions, meaning a drug nobody bought at the discount because the discount was withheld. A law about a purchase that never happened is a law about price.

A Fourth Circuit panel saw this and held, over a dissent in each case, that the West Virginia and Maryland laws were likely preempted. Those decisions no longer stand. The States petitioned for rehearing, the full court granted it, and under the circuit’s rules the grant vacated the panel opinions, which is why the question was argued again from scratch on Tuesday. The Justice Department came in on the manufacturers’ side at the rehearing stage, with a brief that asks the en banc court to reach the panel’s result but to rest the holding on the ground Marshall first laid down in 1819: a State may not single out those who help the federal government carry out its programs for a burden it imposes on no one else.

The Supreme Court restated that rule in 2022 in *United States v. Washington*, a unanimous decision reversing the Ninth Circuit in a case involving workers at a federal cleanup site in Washington State. A State may not regulate the federal government directly, the Court said, and it may not “discriminate against the Federal Government or those with whom it deals.” If Congress intends to let States single out those who deal with the federal government for distinctive burdens, Congress has to say so. Under *Washington*, a federal statute’s silence on the point cuts against the State. The States’ entire case rests on the observation that the 340B statute never mentions contract pharmacies. That is true, and it does

not matter. The argument also mistakes the kind of law 340B is. The program is not a regulation of general applicability that happens to reach drug companies. It is a voluntary bargain, struck under the Spending Clause, between the United States and the manufacturers that accepted its terms. A State that adds obligations to one side of that bargain is amending a federal agreement it never signed, and no amount of talk about gaps in the statute changes what it is doing.

The question is whether Maryland may impose obligations on a company for no reason other than that the company has signed an agreement with the national government. The States say their laws punish conduct: a manufacturer is fined for refusing to extend the 340B discount to a contract pharmacy, not for joining the program. But the 340B discount exists only because the manufacturer signed the agreement. A company that never signed owes no discount, can refuse every pharmacy in Maryland, and violates nothing. The conduct the State punishes can be committed only by a federal signatory, so the law regulates signatories no matter what it says. *McCulloch* settled in 1819 that a State may not do that to the federal government, and *Washington* extended the rule to the private parties the government relies on to run its programs.

Readers who don't care about pharmaceutical pricing should care about this anyway. The principle is a constitutional one that transcends any administration. If Maryland can attach conditions to the federal drug-discount bargain, then a State can impose a surtax on landlords who accept federal housing vouchers or create special liability for companies that contract with Immigration and Customs Enforcement. You may approve of some of those federal programs and loathe others. The Supremacy Clause does not let fifty legislatures amend any of them one State at a time.

The bargain is not self-sustaining, either. Congress set the price of admission to Medicaid and Part B in 1992 at a level it judged manufacturers would pay, and every State mandate raises that price. When it rises far enough, some companies decline to pay it. Bausch Health left Medicaid and 340B last year, citing "legislative changes," and dozens of its drugs are now unavailable to Medicaid patients nationwide, including in States that never passed a contract-pharmacy law. How much of that risk the programs can absorb is a judgment only Congress can make, and a patchwork of state mandates makes it anyway, without a vote. The Supreme Court anticipated the problem in *Astra USA v. Santa Clara County* in 2011, when it held that 340B must be administered "harmoniously and on a uniform, nationwide basis" and that a "multitude of dispersed and uncoordinated" enforcers would defeat it. The Court was describing lawsuits by hospitals, but twenty-one state enforcement regimes present the same problem.

None of this should be read as a defense of 340B as it stands. The program has drifted a long way from what Congress enacted in 1992, and the political branches know it. A Senate discussion draft circulated in June would be the first real revision of the statute in fifteen years, and HRSA has adopted a rebate model, set to take effect January 1, 2027, that depends on the same claims data the state laws would let hospitals keep to themselves. The Fourth Circuit has been asked a narrower question, and the answer is the same one Maryland first heard in 1819: a state may not burden the federal government by burdening the people the federal government does business with.