



THE PERILS OF STATE-SANCTIONED PRIVATE REGULATION: A CASE STUDY FROM THE HEALTHCARE MARKETPLACE

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States are increasingly discovering the difficulty of regulating complex markets. No sector embodies this struggle more than health care. Despite wide support for the common goals of increased coverage and controlled costs, many healthcare market regulations prove unwieldy, bringing a host of unintended consequences.

Some States attempt to avoid these complications by delegating regulatory authority to professional boards staffed by practitioners in the regulated industry. States cite the specialization in the industry and generalized federalism grounds to justify transferring power to private bureaucracies. But transfers of regulatory power to self-interested market participants inevitably result, as Adam Smith described it, in a “conspiracy against the public.”¹ In contrast to voluntary industry self-regulatory bodies, such as the Better Business Bureau, private boards wielding government-sanctioned regulatory power tend to punish market rivals and enrich themselves at the public’s expense.

The Mississippi Board of Pharmacy’s regulation of pharmacy benefit managers (“PBMs”) provides an excellent case study of the consequences of what amounts to complete regulatory capture. This LEGAL BACKGROUNDER discusses how Mississippi’s regime harms consumers by assigning the power to regulate PBMs to PBMs’ market rivals. The paper first describes the tension between PBMs and the current Mississippi Board of Pharmacy. It then turns to a case the United States Supreme Court will review this fall, *North Carolina Board of Dental Examiners v. Federal Trade Commission*, which may expose this dubious regulatory model to antitrust liability.² The Court’s decision in *North Carolina Dental* could put an end to this misguided practice of assigning market participants the legal power to oversee their rivals and, as a result, revitalize market competition in a host of areas.

Competition between PBMs and Pharmacies. The goal of PBMs is to lower drug prices for their clients. PBMs necessarily reduce pharmacies’ profits to deliver these savings. They manage the prescription drug benefits for health plan sponsors, such as employers and HMOs. PBMs incorporate several cost-saving practices that reduce prescription drug spending.³ For example, PBMs establish networks of local pharmacies where members can obtain medication at discounted prices, negotiate discounts and rebates from drug manufacturers in exchange for making their drugs a “preferred” medication, provide access to mail order

¹ ADAM SMITH, THE WEALTH OF NATIONS, Book I, Chap. X.

² Opinion of the Commission, *North Carolina Board of Dental Examiners*, Docket No. 9343 (Feb. 8, 2011), available at <http://www.ftc.gov/os/adjpro/d9343/110208commopinion.pdf>.

³ See FED. TRADE COMM’N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 36, (2005), available at <http://www.ftc.gov/reports/harmbenefit05/050906pharmbenefit.rpt.pdf>; U.S. GEN. ACCOUNTING OFFICE, EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES 10-11 (2003) [hereinafter GAO REPORT], available at <http://www.gao.gov/cgi-bin/getrpt?GAO-03-196>.

pharmacies that can dispense drugs at lower costs, evaluate prescribing patterns to ensure that consumers obtain appropriate drugs for the lowest price, and efficiently process claims for their health-plan sponsor clients. Federal regulators have found that as a result of their cost-saving practices, PBMs have been able to significantly reduce both the price of prescription drugs to covered individuals and the overall plan costs of prescription drug coverage. The Federal Trade Commission (FTC) concluded that consumers with PBM-administered prescription drug coverage pay between 15 and 50 percent less for drugs than do non-insured consumers buying the exact same drugs.⁴

However, PBMs are pharmacies' direct market rivals in two areas. First, pharmacies and PBMs negotiate over prescription drug prices. PBMs assemble networks of retail pharmacies where the individuals covered by the prescription drug plan can fill prescriptions. The drug plans offer covered individuals significant incentives to fill prescriptions at the network pharmacies; plans generally will not cover prescriptions filled at out-of-network pharmacies, and consumers often pay lower co-pays at preferred network pharmacies. Pharmacies compete intensely for the significant revenues generated from inclusion in a PBM's network. PBMs use this market competition to negotiate substantial discounts with pharmacies, resulting in lower consumer prices. These price negotiations pit PBMs directly against pharmacies.

Second, retail pharmacies compete with PBM-owned mail-order pharmacies. PBMs' mail-order pharmacies can offer substantial discounts relative to traditional retail pharmacies. They dispense longer prescriptions, requiring fewer claims and less processing time, and fill prescriptions with preferred formulary drugs and equivalent generics when medically appropriate. To encourage these savings, PBMs offer incentives for members to fill prescriptions through mail-order pharmacies.

To alleviate these competitive pressures, pharmacists sought stricter regulation of their market rivals. Pharmacists allege PBMs implicate several possible conflicts of interest that could harm patients. For example, some claim that PBMs could profit by passing on to plans only a small portion of the savings PBMs negotiate with drug manufacturers and retail pharmacies. Similarly, pharmacists worry that PBM ownership of some mail-order pharmacies could lead to self-dealing transactions between PBMs and their own pharmacies.

Federal investigations have concluded that these concerns were unfounded. The FTC and Government Accountability Office (GAO) each found that PBMs pass significant portions of payments they receive from drug manufacturers back to benefits plans.⁵ Federal regulators uncovered no evidence of PBM self-dealing. The FTC found that PBM mail-order pharmacies substituted generics for brand-names at similar or greater rates to retail pharmacies and mail-order pharmacies not owned by PBMs.⁶ Both the GAO and the FTC ultimately found that PBM-owned mail-order pharmacies provided consumers with significantly lower drug prices than traditional retail pharmacies.⁷

Subsequent to these federal findings, pharmacists intensified their efforts at the State level. In 2011, the Mississippi legislature shifted regulatory authority over PBMs from the Mississippi Insurance Commissioner to the Mississippi Board of Pharmacy, which consisted entirely of private pharmacists. PBMs must now obtain a license from this Board to operate in Mississippi and must submit sensitive business and financial information to it.⁸ The Board may financially examine PBMs, and may disclose business information it obtains to any health plan sponsor, pharmacist, or pharmacy.

⁴ FED. TRADE COMM'N, *supra* note 3, at 36.

⁵ FED. TRADE COMM'N, *supra* note 3, at 57-60; GAO REPORT, *supra* note 3, at 11-12.

⁶ FED. TRADE COMM'N, *supra* note 3, at 65-70.

⁷ *See id.* at 27-36; GAO REPORT, *supra* note 3, at 10.

⁸ MISS. CODE ANN. §§ 73-21-83; 73-21-157 (West 2013).

Mississippi's Regime Harms Consumers. This one-sided regulatory regime harms competition in Mississippi—and therefore harms consumers. The Board's power to compel and share financial disclosures discourages PBMs' ability to negotiate price terms with drug manufacturers and pharmacies. Drug manufacturers and pharmacies are less likely to offer a PBM favorable terms when doing so will disclose information to other market participants, enabling them to seek similar deals. Likewise, according to antitrust authorities, when pharmacies know what each pharmacy charges each PBM, pharmacies are less likely to compete with each other on price.⁹

Mississippi's pharmacists quickly took advantage of their new found regulatory authority. The Board sought to impose fiduciary duties on PBMs that would have required extensive disclosures and mandated that PBMs account for their profits. Generally, such fiduciary duty mandates are required only when parties cannot easily resolve potential conflicts of interest via contract. The Board's proposal for heightened fiduciary obligation would simply increase PBMs' legal and administrative costs, reducing plan sponsors' benefits. The Board rescinded its proposal last year after a trade organization representing PBMs threatened a federal lawsuit.

Even so, Mississippi pharmacists now have both the incentive and the means to reduce PBMs' ability to compete. As noted above, disclosure requirements give pharmacists access to competitors' private business data. The Board could restrict access to mail-order pharmacies, a major component of PBMs' economies of scale and of consumers' convenience and cost savings. The Board could also require PBMs to give pharmacies the same reimbursement rates and patient copayments they offer to in-network pharmacies, or require sensitive information disclosures to pharmacies in the discount negotiation process.

Such regulatory actions would ultimately harm consumers. They would bear any unnecessary costs imposed on PBMs by pharmacists. Similarly, reduced access to mail-order pharmacies would restrict consumers' access to a substitute for retail pharmacies, increasing prescription drug prices while decreasing access to vital medication. Any additional regulation that benefits pharmacies' bargaining power at PBMs' expense likely harms plan sponsors and consumers: higher payments to pharmacies translate into higher costs for consumers. The FTC advised Mississippi of these harms, noting that pharmacies' and PBMs' adversarial relationship "may create tensions and conflicts of interest for the pharmacy board."¹⁰

U.S. Supreme Court to Weigh in on Deputized Private Regulators. Mississippi's counterproductive approach to State regulation clearly conflicts with federal regulators' sound judgment; an upcoming Supreme Court case may decide that the Mississippi Board of Pharmacy also violates federal antitrust law. In *North Carolina Board of Dental Examiners v. Federal Trade Commission*, the Court will consider whether entirely private actors like the Board are immune from federal antitrust laws regulating concerted action.¹¹ North Carolina's Board of Dental Examiners, which consists primarily of licensed dentists, effectively barred cheaper non-dentists from performing a kind of teeth whitening. Federal antitrust laws forbid market participants from cooperating with one another to drive out unwanted competitors. States' active regulation and supervision can confer limited antitrust immunity on private actors, but the Court must decide whether a Board constituted like North Carolina's qualifies for immunity.¹²

⁹ U.S. DEPARTMENT OF JUSTICE AND FEDERAL TRADE COMMISSION, HORIZONTAL MERGER GUIDELINES § 7 (2010), available at <http://ftc.gov/os/2010/08/100819hmg.pdf>.

¹⁰ Letter from Susan S. DeSanti et al., Director Office of Policy Planning, Fed. Trade Comm'n et al. to Mark Formby, Representative, Mississippi House of Representatives 4 (March 22, 2011), available at <http://www.ftc.gov/os/2011/03/110322mississippipbm.pdf>.

¹¹ *North Carolina Board of Dental Examiners v. Federal Trade Commission*, 717 F.3d 359 (4th Cir. 2014), cert. granted 134 S. Ct. 1491 (2014) (No. 13-534).

¹² "State action" antitrust immunity inquires: (1) whether the challenged activity is "clearly articulated and affirmatively expressed as state policy;" and (2) whether the anticompetitive conduct is "actively supervised by the State." *Patrick v. Burget*, 486 U.S. 94, 100 (1988).

If North Carolina's board loses, then the Mississippi Board of Pharmacy won't be far behind. The Court could conclude that States do not insulate self-interested private individuals from liability when regulating with State authority. If so, Mississippi's Board—and other similarly constituted industry regulators—could face massive personal antitrust liability for attempting to subvert market competition through misuse of regulatory authority. Federal antitrust laws provide for treble damages and mandatory attorneys' fees.

These antitrust penalties are merely one dimension of federal law that discourages States from delegating regulatory authority to self-interested private individuals.¹³ The Due Process Clauses of the federal and State Constitutions or federal and State non-delegation doctrines could support additional legal challenges for private regulators. They could also inhibit a State board's ability to regulate in specific circumstances, or even invalidate an entire agency's authority to regulate a profession.

Amicus briefs filed by State attorneys-general in support of the North Carolina Board's *certiorari* petition advance arguments based on federalism principles. Those arguments are misguided. Federalism advocates might view Mississippi's regime as a success for local sovereignty over national preferences. Federalism embraces the concept of subsidiarity: allowing the governmental unit closest to the people to decide a given question.¹⁴ But local policies must give way to national policies when States impose negative externalities through regulatory decisions. Mississippi's system clearly threatens to affect other States' prescription drug consumers. When the Board of Pharmacy forces PBMs to disclose sensitive business information to pharmacies, pharmacies and other entities in the supply chain may use this to their advantage in other States. For example, pharmacies in Alabama could demand similar discounts and pricing arrangements to those that PBMs negotiated in Mississippi. Mississippi's disclosure regime could reduce competition across the industry and increase prices to consumers nationwide.

More fundamentally, the purpose of federalism is not to give two governments dual regulatory control, but instead to allocate functions *between* levels of government. The federal government has consciously taken a balanced approach to PBM regulation.¹⁵ Thus, invoking federalism principles does not justify giving Mississippi's pharmacists a second chance at obtaining regulations that will drive up prices and harm consumers both inside and outside Mississippi.

Conclusion. Mississippi's transfer of regulatory power from neutral public officials to a cadre of self-interested market participants provides States and consumers a cautionary example. The Mississippi Board of Pharmacy, like the North Carolina Board of Dental Examiners—and all similar schemes that involve literal regulatory capture—uses its substantial regulatory discretion to undermine its market rivals at the public's expense. Neither legislators nor consumers should be misled by appeals to technical expertise. Nor do these programs serve federalism ends, as they merely generate costly additional regulations. Worse still, these regulatory arrangements may violate federal competition laws. The Supreme Court will address that issue this fall in *North Carolina Board of Dental Examiners*. The ramifications of an FTC victory in that case will resonate in Mississippi and throughout the nation.

¹³ See generally Sasha Volokh, *The New Private Regulation Skepticism: Nondelegation, Due Process, & Antitrust Challenges*, 37 HARV. J.L. & PUB. POL'Y ___ (2014).

¹⁴ Steven G. Calabresi & Lucy D. Bickford, *Federalism and Subsidiarity: Perspectives from US Constitutional Law*, 5 (2011), Faculty Working Papers, Paper 215, available at <http://scholarlycommons.law.northwestern.edu/facultyworkingpapers/215>.

¹⁵ CONG. BUDGET OFFICE, ISSUES IN DESIGNING A PRESCRIPTION DRUG BENEFIT FOR MEDICARE (2002), available at <http://www.cbo.gov/ftpdocs/39xx/doc3960/10-30-PrescriptionDrug.pdf>.; FED. TRADE COMM'N, *supra* note 3; GAO REPORT, *supra* note 3.