Health Care Competition Law in the Shadow of State Action: Minimizing MACs

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Abstract

How should we go about reconciling competition and consumer protection in health care, given the long shadow cast by the state action doctrine? We consider that issue, using a case study drawn from an obscure corner of the pharmaceutical reimbursement market to motivate and inform our analysis. We show how the balance between competition and consumer protection has been distorted by the political economy of health care regulation – compounded by the extension of the state action doctrine far past its defensible borders. If anything, considerations of political economy argue for much greater skepticism about the utility of regulation – and of the state action doctrine -- in the health care space.

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In 2015, Hyman was retained by PCMA, the trade association for PBMs, to prepare a white paper on the competitive consequences of attempts by various states to regulate MACs. That initial white paper - along with a subsequent version - provide the basis of our analysis in Part IV. Hyman was also retained by PCMA’s outside counsel in 2015 to serve as an expert in litigation involving challenges to attempts by Iowa and Arkansas to regulate MACs.

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Attempting to protect competition by focusing solely on private restraints is like trying to stop the flow of water at a fork in a stream by blocking only one of the channels. Unless you block both channels, you are not likely to even slow, much less stop, the flow. Eventually, all the water will flow toward the unblocked channel. The same is true of antitrust enforcement. If you create a system in which private price fixing results in a jail sentence, but accomplishing the same objective through government regulation is always legal, you have not completely addressed the competitive problem. You have simply dictated the form that it will take.¹

I. INTRODUCTION

George Bernard Shaw famously observed that “all professions are conspiracies against the laity.”² In health care, the bill of particulars is long and distinguished, and includes overt price-fixing; attacks on salaried practice and pre-paid health care; and the systematic marginalization and exclusion of competitors.³ Indeed, Professors Havighurst and King accurately note that the entire history of medical care in the United States is a story in which “outbreaks of . . . competition were ruthlessly suppressed. . . .”⁴ Of course, these campaigns were waged in the name of “medical science, quality of care, and professional prerogative,” rather than the naked

² George Bernard Shaw, The Doctors Dilemma (1909). The play was first staged in 1906.
self-interest of the medical profession. But, regardless of the external branding, the effect was the same: the medical profession was able to set the terms of trade, and exclude or substantially limit the authorized scope of practice for new entrants. Emboldened by these successes, other health care providers used similar tactics to protect their turf and set the terms of trade.

In health care, private individuals and entities were the first movers, but those involved quickly recognized the value of enlisting the government in their conspiracies against the laity. Compared to privately-imposed restraints on trade, governmental restraints “are more effective and efficient, and include a built-in cartel enforcement mechanism.” And, as we detail below, governmentally imposed restraints are much harder to attack than private restraints.

The consequences of these dynamics were quite predictable. Over time, the health care marketplace became enmeshed in a complex web of interlocking public and private restraints of trade. Not coincidentally, health care spending, and the rate of spending growth spiraled upward.

For these and other reasons, health care became a target-rich environment for antitrust enforcers beginning in the early 1970s. Indeed, several generations of enforcement personnel at the Federal Trade Commission cut their teeth on merger reviews and cases involving every conceivable participant in the health care sector, including hospitals, doctors, pharmaceutical companies, and pharmacy benefit managers (“PBMs.”) As we noted in a recent article:
Since the 1970s, the FTC has devoted considerable effort to health care, beginning with a major case challenging restrictions on advertising in the medical profession, and then going on from there to bring cases involving every aspect of the health care delivery system. In health care, the FTC has batted through its entire rotation of policy tools, including numerous cases, rulemaking, advisory opinions, hearings, and competition advocacy. More than any other program, the health care program has paid the rent for the FTC’s charter as a competition authority.\(^\text{10}\)

The Department of Justice Antitrust Division and state Attorneys General have also been active in this space, albeit on a less continuous basis than the FTC.

The campaign against anti-competitive practices within the health care sector has had its ups and downs, but it is clear that it has had an impact on the frequency and severity of privately imposed anti-competitive restraints.\(^\text{11}\) The picture for publicly imposed restraints is considerably murkier, because such restraints are effectively insulated from substantive antitrust scrutiny, as long as they qualify as state action – no matter how overtly anti-competitive they are, and no matter how flimsy their supposed justification. And, in health care, there is no shortage of overtly anti-competitive restraints, imposed on the basis of flimsy or non-existent evidence, at the behest of politically connected special interests.

These dynamics complicate the already complex process of reconciling competition and consumer protection in health care – since much of what is styled as consumer protection is, in fact, provider protection. The same dynamics also argue in favor of re-examining the appropriate boundaries of the state action doctrine.

We examine these issues using a case study drawn from an obscure corner of the pharmaceutical reimbursement market -- maximum allowable cost (“MAC”) schedules. Medicaid and PBMs use MACs to reimburse pharmacies for dispensing generic drugs. MACs were pioneered by state Medicaid programs, and then adopted by PBMs. But, in the past few years, MACs have become the focal point of heated controversies between PBMs.

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\(^\text{10}\) Hyman & Kovacic, supra note 7.

\(^\text{11}\) Plus, in yet another example of demand creating supply, there is now a thriving health care antitrust private bar, along with the requisite ABA section, AHLA practice group, and numerous opportunities to obtain CLE credits for attending health care antitrust conferences in glamorous locales.
and pharmacies – triggering legislative action in 38 states (including Puerto Rico). Although the dispute is invariably cast in terms of consumer protection (framed in terms of patients’ ability to access to pharmacy services), our case study makes it clear that the issue is really about protecting the providers of pharmacy services from the disruptive forces of competition.

Part II lays out some of the complexities of reconciling competition and consumer protection in health care. Part III reviews the basics of the state action doctrine. Part IV presents our case study of MACs. Part V sketches out some suggestions on how to improve matters – both for MACs, and for the larger set of issues for which MACs are a stand-in. Part VI concludes.

II. RECONCILING COMPETITION AND CONSUMER PROTECTION IN HEALTH CARE

How should we think about reconciling competition and consumer protection in health care? The preconditions for perfectly competitive markets (including no barriers to entry or exit; fungible goods; and perfect information) are obviously not applicable to health care. And, in health care, we combine high stakes, profound asymmetries of information, and deep moral opposition to acknowledging the existence of resource constraints.

Because of the felt necessities created by these dynamics, health care is a field dominated by regulation. The laundry list of regulations includes strict restrictions on entry (i.e., licensure, accreditation, certificates of need/public necessity, and restrictions on scope of practice); specification of minimum terms of trade (mandated benefits, any willing providers, voiding of liability waivers); and aggressive ex post enforcement (hospital privileges proceedings; state disciplinary action, and medical malpractice litigation). Each and every one of these regulatory initiatives is sold on the basis that they are absolutely necessary consumer protections – and the alternative is an unregulated market, that would operate “as a savage war of all against all, red in tooth and claw, populated solely by charlatans and snake oil vendors.”

Most of the health law professoriate is perfectly fine with this extensive list of anti-competitive restraints. Indeed, if anything, the health law professoriate has devoted most of its time to identifying and cataloging new ways in which health care markets can be further tamed or supplanted entirely with regulations. (In fairness, that attitude and approach is

12 Hyman & Svorny, supra note 7.
inextricably linked to the general political commitments of the law professoriate, and is not unique to professors that focus on health law). But, for the sake of argument, let’s assume that there is a constituency that might be open to arguments in favor of striking an actual balance between competition and consumer protection, rather than simply assuming that anything and everything that emerges from the legislative and regulatory process is a-ok. What would that argument look like?

The argument would begin by noting that markets have developed plenty of strategies for signaling and evaluating quality in health care.\(^{13}\) It would also observe that competition is itself a powerful tool for protecting consumers; legislators are poorly informed under the best of circumstances (and health policy is never made under the best of circumstances); and that legislators and regulators don’t have anywhere near the right incentives to arrive at optimal policy solutions.\(^{14}\) That said, the most entertaining argument for skepticism about the merits and distributional consequences of legislative/regulatory intervention was cuttingly stated by P.J. O’Rourke:

> When government does, occasionally, work, it works in an elitist fashion. That is, government is most easily manipulated by people who have money and power already. This is why government benefits usually go to people who don't need benefits from government. Government may make some environmental improvements, but these will be improvements for rich bird-watchers. And no one in government will remember that when poor people go bird-watching they do it at Kentucky Fried Chicken.\(^{15}\)

Stated differently, in the health care space, governmental action “generally favors the concentrated interests of incumbent providers and hurts, rather than helps, consumers.”\(^{16}\) Given the unsavory alliance of Bootleggers and Baptists that are seemingly required to trigger regulatory action in the health care space, any protection of consumers is likely to be incidental/accidental at best.\(^{17}\) Accordingly, absent proof to the contrary, we should not pretend

\(^{13}\) Id.

\(^{14}\) Id.

\(^{15}\) P.J. O’Rourke, All the Trouble in the World: The Lighter Side of Famine, Pestilence, Destruction and Death 199 (1994).


or assume that health care legislation or regulation actually does much of anything to protect consumers – or was ever intended to do so.\footnote{Hyman, \textit{Getting the Haves}, supra note 16, at 279 (“to date, provider capture of state and federal legislators and regulators is the rule, and the results have not been pretty. Indeed, the status quo . . . is the direct result of regulatory and legislative oversight, with its known susceptibility to symbolic blackmail, “motherhood and apple pie” initiatives, and other forms of government failure.”).}

With that unpleasant framing clearly established, we now turn to the state action doctrine, which significantly limits the ability of antitrust enforcers to attack publicly-imposed restraints on competition.

\section{III. The State Action Doctrine}

Federalism requires that we decide whether, when, and how states can deviate from the dictates of federal law. In antitrust, the Supreme Court has developed and applied the state action doctrine, which gives states broad discretion to override the commands of federal law.\footnote{The doctrine originated in Parker v. Brown, 317 U.S. 341 (1943), which rejected a claim that a state-approved scheme to prorate raisin production in California violated the Sherman Act’s ban on monopolization and conspiracies to monopolize.} States may enact legislation that contradicts the federal antitrust laws and immunizes private actors from antitrust challenge, so long as the state satisfies two conditions.\footnote{California Retail Liquor Dealers Ass’n v. Mideal Aluminum, Inc., 445 U.S. 99 (1980).} The state must \textit{clearly articulate} its purpose to suppress rivalry.\footnote{FTC v. Phoebe Putney Health System, Inc., 133 S.Ct. 1003 (2013).} And the state must \textit{actively supervise} implementation of the anticompetitive regime.\footnote{North Carolina State Board of Dental Examiners v. FTC, 135 S.Ct. 1101 (2015).}

These requirements have tripped up some of the more clumsy attempts to use the power of the state to restrict competition.\footnote{In re South Carolina State Board of Dentistry, \url{https://www.ftc.gov/enforcement/cases-proceedings/0210128/south-carolina-state-board-dentistry-matter}.} But, for those who are able to follow (fairly simple) directions, the path to a government-enforced cartel is well marked – and health care providers have taken full advantage of the invitation to clothe their anti-competitive behavior in the protective garb of state action doctrine. Worse still, courts have shown themselves quite willing to accept even far-fetched invocations of the state action doctrine – although there has been a welcome trend toward a more social regulation evolves when it is demanded by both of two distinctly different groups. ‘Baptists point to the moral high ground and give vital and vocal endorsement of laudable public benefits promised by a desired regulation . . . . ‘Bootleggers’ who expect to profit from the very regulatory restrictions desired by Baptists, grease the political machinery with some of the expected proceeds.”)}
restrictive application of the doctrine in recent years.\textsuperscript{24}

We now turn to our case study, drawn from the depths of the pharmaceutical market.

IV. PHARMACEUTICAL MARKETS AND MACs

Pharmaceuticals come in two varieties: branded and generic. Branded drugs capture most of the media attention, and are responsible for a heavily disproportionate share of drug spending -- but generic prescriptions account for more than 85\% of filled prescriptions.\textsuperscript{25} Generic drugs are significantly cheaper than branded drugs -- but in recent years, generic drug prices have trended upward -- sometimes sharply.\textsuperscript{26} Like any other product, generic drug pricing is affected by both supply-side and demand-side factors.\textsuperscript{27}

How much should pharmacies be paid for dispensing pharmaceuticals – and on what basis? That problem has vexed insurers, PBMs, state Medicaid programs, and health policy experts for decades. In most markets, list prices provide a reasonable starting point (if not the actual benchmark) for gauging the amount that must be paid to acquire a product. But, as we detail below, matters in pharmaceutical markets are considerably more complex -- in part because of the product life cycle of generic drugs, and in part because of competition within the pharmaceutical supply chain. As such, using list prices virtually ensures that pharmacies will be overpaid -- sometimes substantially so -- for dispensing drugs. Considerable evidence indicates that payers have been overpaying for prescription drugs (both branded and generic) for decades. We focus in this article on generic drugs. We begin with a brief description of the life-cycle of generic drugs, and of the nature of competition within the pharmaceutical supply chain.

A. Pricing and the Life Cycle of Generic Drugs

A generic pharmaceutical’s life cycle typically starts with a 180-day period of marketing exclusivity, which is granted to the first generic


\textsuperscript{25} Aria A. Razmaria, \textit{Generic Drugs}, 315 JAMA 2746 (2016).


\textsuperscript{27} Of late, there has been a significant run-up in the cost of some generic drugs. \textit{See} Jonathan D. Alpern, William M. Stauffer, and Aaron S. Kesselheim, \textit{High-Cost Generic Drugs — Implications for Patients and Policymakers}, 371 New Engl. J. Med. 1859 (2014) (“Numerous factors may cause price increases for non-patent-protected drugs, including drug shortages, supply disruptions, and consolidations within the generic-drug industry.”)
approved by the Food and Drug Administration (FDA). During this 180-day period, the first-approved generic competes only with the brand name version of the product and any “authorized generics” that the brand manufacturer either makes itself or allows on the market through licensing agreements.

If only one generic is available during the 180-day period, pharmacies can typically acquire the drug for about 20% less than the brand price. If “authorized generics” are also available, the competition is greater -- so the pharmacy’s acquisition cost may be 30% less than the brand price. Drug wholesalers also seek to negotiate discounts – which can be as high as 40-50% when an authorized generic is available. In a competitive market, these discounts will be passed on to pharmacies. However, the list price does not typically reflect the impact of these discounts, or it significantly lags the impact of these discounts.

Once the 180-day exclusivity period ends, the market is open to any generic approved by the FDA, and dramatic savings can result if many generics enter the market, as will happen for highly prescribed medications. Again, the list price typically does not reflect the impact of these price drops, or it significantly lags the impacts of these price declines.

After 1-2 years, the market for a particular generic drug typically matures. Some manufacturers may exit due to low margins or an eroding market for the drug, or as newer medications in the same class also become available in generic form. Mergers can also reduce the number of manufacturers producing a particular drug. As the number of drug manufacturers declines, prices may increase. Prices may also increase in the event of shortages, whether due to manufacturing problems or interruptions in the supply of an active ingredient. Other generic drug manufacturers cannot respond to price increases by entering the market, unless they have FDA approval – and it can be time-consuming to obtain that approval. Once again, the list price generally does not reflect the

28. To secure this marketing exclusivity, the generic drug company must also file what is known as a “paragraph IV certification.” This document indicates that the generic drug company believes any applicable patents are either invalid or will not be infringed.
30. Id at 129-130.
31. Id. at 130.
32. For example, after the 180-day exclusivity period ended for the first generic version of the Lexapro (a popular anti-depressant), eleven additional generics were approved by the FDA. The additional competition drove the price per 10 mg pill down from $2.63 to $0.16 within a month -- a 94% decrease. Id. at 130-131.
33. Id. at 131.
impact of this pricing volatility, or it significantly lags the impact of these price changes.

B. Pricing and Supply Chain Competition

Wholesalers routinely offer discounts to pharmacies. The most common discount is for prompt payment – but wholesalers may also provide discounts to pharmacies that purchase a minimum quantity of generic drugs. Alternatively, wholesalers can provide discounts on brand name drugs as long as the pharmacy purchases a minimum volume of generic drugs. Drug wholesalers offer these incentives because they earn a disproportionate share of their profits from generics; in 2014, generics generated 16% of their revenue but 75% of their profits.34

To enhance their negotiating leverage, independent pharmacies often join together in buying groups (“PSAOs”) to concentrate their purchases with one or more preferred vendors. In exchange for the PSAO selecting a wholesaler as its preferred vendor, the wholesaler may agree to provide discounts on the group’s consolidated purchases. Some of these discounts may be paid as a quarterly rebate based on the aggregate volume of generics purchased by the group.35 None of these discounts and rebates are typically reflected in the list prices for generics – and they also may not be reflected in the invoice associated with the drug purchase.

C. The Origins of MAC

When Medicaid was launched, it sought to pay providers their actual and justifiable costs – and not one penny more. MACs emerged in the Medicaid program as a tool to do just that – i.e., to set pharmaceutical spending at the minimum amount necessary to obtain the drug in question. State and federal regulations govern the amount that Medicaid can reimburse for prescription drugs. Before MACs were developed, reimbursement generally involved paying the lesser of the estimated acquisition cost (EAC) plus a reasonable dispensing fee, or the providers’ usual and customary charges to the general public. The EAC was typically determined based on published list prices – including the Average Wholesale Price (“AWP”).

At one time, the AWP reflected pharmacy’s acquisition costs, but, it quickly became apparent that there was considerable divergence between the AWP and pharmacists’ true acquisition cost, particularly when generic drugs became more prevalent. Once this became clear, it was necessary to modify Medicaid’s reimbursement formula, to ensure the amounts paid

34 Id. at 113.
35 Id. at 112.
reflected pharmacists’ actual costs (i.e., the acquisition cost plus the costs associated with dispensing the pharmaceutical).

In 1987, the federal government responded by requiring states to implement an aggregate payment limit for specific drugs. The payment limit (known as a “FUL,” for “Federal Upper Limit”) was determined mechanically. Pursuant to this payment limit, the dispensing pharmacy was paid a flat amount for acquiring the dispensed drug, irrespective of its actual acquisition cost. However, some state Medicaid program directors believed they were still overpaying for many drugs. Those states responded by adopting MAC programs, which were similar to FULs, but applied to a far broader array of drugs, and set lower reimbursement levels. Medicaid MACs are calculated based on aggregate figures that reflect pharmacies’ average acquisition cost for a given pharmaceutical product. As of January 12, 2012, all states used FULs and approximately 45 states used MACs in their Medicaid programs.

D. Private-Sector Use of MACs

PBMs use contracts to create pharmacy networks. Approximately 95% of the nation’s retail pharmacies are included in one or more PBM pharmacy networks. A pharmacy that joins a network agrees to accept the terms in their contract (often called a participating pharmacy agreement (“PPA”). The PPA specifies how pharmacies will be reimbursed, details the nature of any MACs that may apply, and spells out the process for resolving disputes. Pharmacies are free to decline to contract with an insurer/PBM for whatever reason they choose – including inadequate reimbursement, uncertainty about the level of reimbursement, or the “hassle factor” of dealing with a particular insurer/PBM.

In designing and implementing a PPA, the PBM must balance two competing goals: it wants to ensure a broad network of pharmacies at which prescriptions may be filled (since ease of access to covered services is one of the “products” the PBM is selling to payers), but it also has to control the

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36 42 C.F.R. sec. 447.301 et seq.
37 The Patient Protection and Affordable Care Act (“PPACA”) modified the formula for calculating a payment limit. The federal government is still in the process of implementing this change. For an estimate of the impact of these changes, see Office of Inspector General, Analyzing Changes to Medicaid Federal Upper Limit Amounts (Oct. 2012), available at http://oig.hhs.gov/oei/reports/oei-03-11-00650.pdf.
cost of the covered services (since low cost is also one of the “products” the PBM is selling). If a PBM errs in one direction (i.e., through overly generous payments for pharmaceuticals), it will ensure a broad network of pharmacies, but the covered services will be less affordable – meaning the PBM may not get the business for which it is bidding. Conversely, if the PBM errs in the other direction (i.e., through inadequate payment for pharmaceuticals, excessive hassle factor or DIR fees, and the like), pharmacies will decline to contract; will drop out of the PBMs’ network; or will refuse to stock pharmaceuticals for which the MAC payment is insufficient. Employers and employees will not value a pharmacy network that is too limited along any of these dimensions – meaning the PBM may not get the business for which it is bidding.

When properly designed, MACs help PBMs steer a middle-ground between these two extremes. By paying the average acquisition costs incurred by a well-run pharmacy, MACs create the necessary incentive for pharmacies to purchase and dispense the lowest-priced generics that are available in the market. Of course, periodic adjustments are necessary to deal with unanticipated or extraordinary circumstances, but market forces serve to discipline over-reaching by all involved parties (i.e., pharmacies, PBMs, and employers/employee benefit plans).

E. The Effect of MACs: A Dose of Theory

What are the effects of including a MAC in a PPA? MACs have had at least five distinct effects. First, MACs encourage pharmacies to dispense the generic version of applicable pharmaceuticals. Second, MACs heighten competition among generic manufacturers. Third, MACs help ensure that pharmacies are not being overpaid for the services they provide. Fourth, MACs lower spending on pharmaceutical benefits, thereby reducing the cost of prescription drug coverage. Finally, MACs make prescription drug reimbursement more efficient.

1. Incentivizing Pharmacies to Dispense Generics

When pharmacies are only paid the amount specified in the MAC, they have a substantially increased incentive to acquire and dispense generic drugs. This dynamic means that a MAC will increase the share of generic drugs that are dispensed, compared to a pure cost-based reimbursement system. In the absence of a MAC, the pharmacy’s incentives are quite different, since it will be paid based on a list price that often bears little

40 Id. at 5 (“Because pharmacy reimbursement is based on a single MAC price (regardless of whether a generic or brand version of a drug is dispensed), the program creates a financial incentive to substitute lower-cost generic equivalents for their brand-name counterparts.”)
resemblance to the actual acquisition cost. Under those circumstances (i.e., absent a MAC), a pharmacy that dispenses a higher-priced drug (i.e., the brand name version) will actually be paid more – increasing the cost of providing prescription drug benefits, without providing any commensurate benefits.

2. Increasing Competition Among Generic Manufacturers

When pharmacies only receive the amount specified in the MAC, they have an increased incentive to “shop for the best deal,” and find generic drugs at the lowest possible price (since they get to keep the difference between the acquisition price and the MAC). This heightens price competition among generic drug manufacturers and drug wholesalers, who know that offering lower-priced generics will help drive more sales.

Absent a MAC, pharmacies have much less incentive to buy the lowest-cost generic, since their reimbursement is based on the list price (which, as noted above, often bears little relationship to the acquisition cost). Under those circumstances, pharmacies will predictably seek to maximize the difference between the list price and their actual cost, rather than simply buying the lowest-cost generic.

3. Ensuring Pharmacies Are Not Overpaid

Cost-based reimbursement can lead to various forms of gaming that result in excess payments to pharmacies. For example, pharmacies have an incentive to dispense higher-priced drugs, particularly if they are paid a percentage mark-up on their incurred costs. MACs help prevent this behavior, and ensure that the requisite services are obtained at a level consistent with actual costs.

4. Lowering Prescription Drug Spending – and the Cost of Prescription Drug Coverage

When we combine the first three effects with the lower price at which generics are dispensed, it becomes clear that MACs help lower prescription drug spending – which in turn reduces the cost of prescription drug coverage. In an analysis of Medicaid MACs, the HHS Office of Inspector General (“OIG”) concluded that MACS had “significant value” in “containing Medicaid drug costs.”\textsuperscript{41} The OIG also noted that if all states adopted the strictest MAC program then in use in 2011, generic drug spending would decline by more than 20% in fourteen states, and total

\textsuperscript{41} Id. at 21 (“Our findings demonstrate the significant value MAC programs have in containing Medicaid drug costs.”)
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Medicaid pharmaceutical spending would have been $966 million lower.\textsuperscript{42}

5. Enhanced Market Efficiency

Each drug manufacturer has its own unique list price for every dosage and variation of each drug that they sell. As discussed previously, these list prices vary widely, and bear little relationship to pharmacies’ actual acquisition cost. A MAC cuts through the forest of individual list prices, and specifies the reimbursement that will be paid, regardless of the list price and the actual acquisition cost. Payers need not inquire into the specifics of individual transactions, and instead simply pay the standardized amount. By eliminating the need to conduct individualized assessments, MACs help lower transaction costs and structure the market more efficiently, thereby improving system performance.

F. Legislative Efforts

In the last three years, thirty-eight states have adopted MAC-related legislation.\textsuperscript{43} We provide a list of these states and the associated statutes in the appendix. \textit{Inter alia}, these statutes require public disclosure of each PBMs’ MACs and the methodology for arriving at the amounts that will be paid; limit the circumstances in which MACs may be used (i.e., by requiring a certain number of A-rated equivalents); require the submission of proprietary information regarding MACs to public authorities; specify particular methods and time-frames for MAC appeals and payment adjustments, including requiring retroactive payments; and in a few instances require PBMs to reimburse the actual acquisition costs that are incurred, even if a cheaper alternative was available in the marketplace.

G. Likely Effects of MAC Legislation

From a competition law perspective, none of these initiatives are likely to improve the performance of the pharmaceutical market, and most seem quite likely to make things worse. First, restrictive state-specific criteria undermine the flexibility of PBMs to develop and implement MACs. Mandatory public disclosure of MACs and the specifics of the underlying methodologies are unlikely to benefit consumers, since both will probably lead to less intensive competition and higher prices.\textsuperscript{44} Requiring specific

\textsuperscript{42} Id. Wyoming’s MAC program resulted in the greatest aggregate savings.
\textsuperscript{43} In addition, federal legislation was proposed, but was not enacted. S. 867, 113\textsuperscript{th} Cong. (2013-2014), at https://www.congress.gov/bill/113th-congress/senate-bill/867.
\textsuperscript{44} In pharmaceutical markets, the intensity of competition is a function of various factors, including the ability of PBMs to obtain a competitive advantage by developing more effective MACs. Forced disclosure of MAC methodologies may undermine PBMs’ incentive to invest in such efforts (since other PBMs will be able to free-ride). In that environment, PBMs will be less likely to innovate – meaning that MACs will be less effective than they could be. Stated differently, compelled disclosure can create a risk to
methods and timeframes for MAC appeals and payment adjustments—including requiring “retroactive” payments—is also likely to have unintended effects. Such provisions seem likely to result in administrative complexity and unpredictability, which will in turn result in increased costs.

The provisions which require PBMs to pay at least actual acquisition costs are particularly pernicious. The inflationary consequences of cost-based reimbursement are well known, and help explain why such reimbursement schemes have fallen into disfavor in health care. The same dynamic has played out in the context of government procurement. The Federal Trade Commission (“FTC”) has studied these issues, and issued three detailed advocacy letters in 2004, 2006, and 2011 on the impact of mandated disclosure of PBM contract terms. See Letter from FTC staff to Rep. Mark Formby (March 22, 2011), available at http://www.ftc.gov/policy/policy-actions/advocacy-filings/2011/03/ftc-staff-letter-honorable-mark-formby-mississippi; Letter from FTC staff to Rep. Terry G. Kilgore (October 2, 2006), available at http://www.ftc.gov/be/V060018.pdf; Letter from FTC staff to Rep. Greg Aghazarian (Sept. 7, 2004), available at http://www.ftc.gov/staff-letter-honorable-mark-formby-mississippi. The FTC and Department of Justice also issued a lengthy joint report on health care and competition policy in 2004 that discussed these issues, and a report in 2005 that provided extensive information on PBM operations. See Improving Health Care, supra note 3; Federal Trade Commission, Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies (Aug. 2005), available at http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf. To be sure, the FTC was studying a different set of issues, but the risks to competition of compelled transparency are analogous. One of us (Hyman) was a co-author of the 2004 advocacy letter, and both of us worked on the FTC-DOJ report.

Prior to 1983, Medicare relied on cost-based reimbursement for inpatient hospitalization. Medicare payments were accordingly based on whatever costs the hospital incurred—and each hospital had virtually complete freedom to determine its own cost structure. The result was entirely predictable: Medicare costs for inpatient treatment skyrocketed, as hospitals determined that there were no effective constraints on the amounts they could bill, as long as they had legitimately incurred the associated costs.

After the consequences of cost-based reimbursement became clear, a bipartisan consensus in favor of a different payment system emerged. In 1983, Medicare switched to a prospective payment system ("PPS"), which paid a standardized amount, irrespective of the actual costs incurred by the hospital. A small number of hospitals were excluded from the PPS. However, payment for the overwhelming majority of hospitals switched virtually overnight from cost-based reimbursement to the PPS.

Hospitals suddenly had an incentive to pay attention to the costs they incurred for treating each patient, instead of simply passing those costs on. Although there have been issues with the implementation of PPS, there has been no serious discussion of a return to cost-based reimbursement for hospitals.

For many years, the federal government used cost-based procurement for defense contracts. Unfortunately, this approach created little incentive for defense contractors to perform in the most efficient way possible, since they knew their costs would be reimbursed, however much they were. Cost-based reimbursement also meant that the government assumed most of the risks of performance, because it had agreed to pay the
problems with cost-based contracts were well known to defense contractors and to Congress.\textsuperscript{47} Federal procurement regulations now specify that cost-based reimbursement contracts may only be used when the contracting officer certifies that a fixed-price type contract can’t be used.\textsuperscript{48}

To sum up, restrictions on the use of MACs that push pharmaceutical purchasing toward cost-based reimbursement will lead to increases in pharmaceutical spending and increases in the cost of prescription drug coverage. The magnitude of these increases are obviously subject to considerable uncertainty,\textsuperscript{49} but the directional effect seems clear.

contractor its full allowable incurred costs until the job was accomplished, or the contract was terminated. Unsurprisingly, cost-based contracts sometimes resulted in sizeable cost over-runs (relative to the originally estimated and budgeted cost) for defense procurement.\textsuperscript{47} A book by then-Representative Henry Waxman concisely summarizes the prevailing wisdom on the perils of cost-based reimbursement:

One Halliburton official told us that the company’s mantra was “Don’t worry about price. It’s a cost-plus.” One needn’t be a math wiz to understand how quickly this system inflates costs and even gives contractors an incentive to run up enormous bills.

\textit{HENRY WAXMAN, THE WAXMAN REPORT: HOW CONGRESS REALLY WORKS (2009).}

More specifically, the contracting officer must certify that the circumstances do not allow the agency to define its requirements sufficiently to allow for a fixed-price type contract; or the uncertainties involved in contract performance do not permit costs to be estimated with sufficient accuracy to use any type of fixed-price contract. And, when a cost-based contract is used, the contracting officer is required to employ appropriate surveillance measures, to provide assurance that efficient methods and effective cost controls are in place. FAR 16.301-3(a).

\textsuperscript{48} We have located two attempts to “score” the impact of state-level regulation of MACs. One study, done by Visante, estimated that spending on the affected pharmaceuticals would increase by 31-56%, with a nationwide impact of $6.2 billion increased spending annually. Visante, \textit{Proposed MAC Legislation May Increase Costs Of Affected Generic Drugs By More Than 50 Percent}, January, 2015, on file with author. Importantly, this estimate captures only the immediate fiscal impact, and not the more long-term indirect consequences.

The second study was performed by the Washington Health Care Authority (“WHCA), and involved “scoring” the financial impact of proposed legislation that prohibited PBMs from paying pharmacies less than their actual acquisition cost. WHCA concluded the proposed legislation would make MAC lists much less effective, and would dramatically reduce pharmacies’ incentive to acquire generic drugs at the lowest possible cost. WHCA Fiscal Note, SSB – 5857. Although WHCA did not settle on a single number for the fiscal impact of SB 5857, it presented a range of figures, up to and including a 10% increase in the cost of pharmaceuticals. WHCA specifically determined that the legislation would “significantly increase” costs for public employee benefits and would also have a cost-increasing impact on Medicaid.
H. How The Empire Struck Back: The Political Economy of MAC Legislation

How did such overtly anti-competitive legislation get enacted in such short order, by so many states? One of the most important insights to understanding U.S. health policy is that every dollar of health care spending is a dollar of income for some health care provider. To the extent MACs are effective at reducing pharmaceutical spending on generic drugs, they reduce the amounts that pharmacies receive for dispensing those same drugs. Not surprisingly, pharmacists feel aggrieved that their services are not being compensated at the handsome level that they believe their expertise and professionalism justifies – and they lobby for relief from the hardships imposed by competitive markets.

Pharmacists began these lobbying campaigns with at least three distinct advantages. First, like funeral directors and car dealerships, there are one or more pharmacies in every legislative district – many of which are small independent pharmacies. These small independent pharmacies are pillars of the local business community. Second, if a legislator has to pick sides, the small independent local pharmacy is a much more appealing entity than a large out-of-state PBM. Third, many legislators believe there is a serious problem with access to pharmacy care in rural areas, where most pharmacies are small and independent.

Although chains account for a near-majority of pharmacies in most states, the protection of small independent local pharmacies from the depredations of large out-of-state PBMs was the basis of the lobbying campaign. The flames were fanned by references to the rebates that PBMs were receiving from drug companies. Given these dynamics, it is not surprising that we went from no states with MAC legislation at the beginning of 2013 to thirty-eight states having such legislation only three and a half years later.

Three features of the MAC statutes listed in the Appendix deserve further attention. First, although the legislative campaign was built around the protection of independent (mostly rural) pharmacies, state MAC statutes were not so limited. Instead, in all of these jurisdictions, every single

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50 Hyman, supra note 16, at 280 (noting “the reality that every dollar of health care spending by someone is a dollar of income for someone else.”)

51 These rebates are paid on branded drugs – not generics – so it is difficult to see the relevance of this argument to a dispute over whether PBMs are paying pharmacies the right amount for dispensing generic drugs. And, the fact that PBMs may have multiple sources of revenue does not translate into an obligation to share any of that revenue with pharmacies, unless doing so is necessary to induce the pharmacies to participate in the PBM’s network.
pharmacy – including chain drugstores in urban locations – receives the benefits of the legislation. That strategy means the legislation is not well targeted to address the supposed problem that it is allegedly remedying. Stated differently, MAC legislation puts money in the pockets of all pharmacies in a state – whether they “need” it or not. (Need is in quotes because the issue is simultaneously an empirical question, and also a matter of opinion). That is an exceedingly peculiar understanding of consumer protection – to say the least.

Second, in thirty-six of the thirty-eight states, the state Medicaid program is excluded from the requirements imposed by the MAC legislation. Many of these states also exclude state employees from the “consumer protections” contained in the MAC statutes. The only thing these two groups have in common is that the costs of their health coverage are on-budget expenses, borne (either in whole or in part) by the state in its sovereign capacity. By excluding these populations from the scope of MAC legislation, state legislators made it clear that they thought that the supposed consumer protections were worth doing -- right up until the moment the state would bear the costs of doing so. This pattern is certainly not unique to MAC legislation – but it provides a useful (albeit under-inclusive) signal of legislation that is provider protection masquerading as consumer protection.

Finally, in some states, the legislative history casts light on whose interests are actually being protected. When Iowa was considering MAC legislation, one overly enthusiastic legislator stated that the legislation was necessary because the lack of regulation was “eroding local pharmacies.” Another Iowa legislator explained that legislation was necessary because PBMs were engaging in “unfair business practices that hurt community pharmacies and their patients.” Similarly, when Washington enacted MAC legislation, the Office of Insurance Commissioner was instructed to conduct a study that would inter alia “discuss suggestions that recognize the unique nature of small and rural pharmacies and possible options that support a viable business model that do not increase the cost of pharmacy products.” As these examples indicate, MAC legislation is provider protection – not consumer protection.

52 The exceptions are Mississippi and Texas.
I. Some Empirical Evidence

The legislative campaign against MACs turned on whether pharmacies were being paid enough for dispensing generic drugs. As we summarize below, the two sides staked out competing positions on various factual matters.

Pharmacies insisted that PBMs were underpaying them, by setting MAC levels too low, and failing to update them quickly enough when acquisition costs increased. Pharmacies argued that the resulting shortfalls in payment placed considerable financial pressure on independent pharmacies (particularly those in rural areas) – causing closures and more limited access to pharmacy services.

PBMs insisted that they were paying the correct amounts – and pharmacies that were losing money on dispensed generic prescriptions were either paying higher acquisition costs than they needed to; were mistaken about the transactions in question; or did not realize that MACs were intended to average out across all the generic prescriptions dispensed by a well-run pharmacy, with over-payments on some drugs compensating for under-payments on others.

What do we actually know about these issues (i.e., MAC usage and levels, and access to pharmacy services)? We consider each in turn.

1. MAC Usage and Levels

In ongoing research, one of us (Hyman) interviewed personnel at four PBMs about their use of MACs. All four PBMs used MACs for most drugs that were available in generic form. MACs were typically set for each generic drug in all of the available dosing strengths. MAC levels were set based on pricing information from various sources, including Medicaid MAC and FUL lists; and price lists from wholesalers and other sources (e.g., NADAC and Medi-Span). All four PBMs used this pricing information to create their own MAC lists – each using its own proprietary methods. Each PBM maintained multiple MAC lists, which varied depending on the contracts with plan sponsors. Some MAC lists were regional, but most were applied on a national basis. All four PBMs insisted that they took account of changes in drug acquisition costs in updating their MAC lists – in some instances doing so on a daily basis.

Each PBM had its own appeals mechanism. Appeals were triggered when a pharmacy submitted documentation confirming that the drug was actually dispensed to a PBM customer, and that the MAC was below the pharmacy’s actual acquisition cost. All of the PBMs used the information derived from appeals as part of a feedback loop to inform the levels at
which MACs were set. All four PBMs reported that appeals were a small (i.e., << 1%) share of total transactions.

Of course, there are limitations to qualitative studies of this sort. None of those being interviewed were under oath. MACs are a hot issue, and those being interviewed were unlikely to volunteer information that would make their PBM-employers look bad. Qualitative research can tell us how PBMs create and maintain their MAC lists – but only quantitative research can answer the question of how often PBMs pay pharmacies less (and more) than their acquisition cost; how large those deviations actually are; whether there are any time trends in these patterns; and whether the drugs in question were available for less from a different wholesaler than the one used by the pharmacy in question.

It is exceedingly difficult to conduct such research, since the pharmaceutical marketplace is quite dynamic; data from multiple sources is required; and all of the PBMs treat their MAC lists as proprietary and confidential. Those difficulties notwithstanding, Washington’s 2016 MAC legislation required the Washington Office of Insurance Commissioner to conduct a quantitative study of these issues. The expected completion date of the study, which is being conducted by HMA and Mercer, is November, 2016. But, regardless of the results of such studies, from an economic perspective what matters is whether pharmacies are willing to participate in the networks that PBMs have created, and whether those networks are acceptable to payers.

2. Access to Pharmacy Services

Pharmacists obviously care a great deal about whether their pharmacy closes its doors, and whether it is operated by a chain or is independent. But, it is less obvious that anyone else should be all that invested in those issues. We should care about whether patients have access to pharmacy services – and not nearly as much (if at all) about the specifics of how those services are delivered. And, we should know more about the relevant size of the geographic market for pharmacy services before concluding any given pharmacy closure is a problem.55

That said, there is evidence that there have been a material number of closures of rural pharmacies.56 But, this trend long pre-dates the recent

55 For example, when Illinois was debating tort reform in 2003-2005, it was routinely noted that there were no neurosurgeons south of Springfield. No one ever discussed whether we actually should be concerned about the number of neurosurgeons south of Springfield – particularly when Carbondale was closer to St. Louis (96 miles) than to Springfield (160 miles).

56 See, e.g., Kelli Todd, Fred Ullrich & Keith Mueller, Rural Pharmacy Closures: Implications for Rural Communities, RUPRI Brief No. 2012-5, at https://www.public-
dispute over MAC levels – and the number of closures was much higher in 2007-2009, with subsequent trends "not as pronounced or as clear as in earlier years."57 More importantly, a recent study of access to pharmacy services for Medicare Part D beneficiaries by the Centers for Medicare and Medicaid Services found that 99% of urban beneficiaries had access to a pharmacy within 2 miles; 99% of suburban beneficiaries had access to a pharmacy within 5 miles; and 97% of rural beneficiaries had access to a pharmacy within 15 miles.58 These findings suggest that pharmacy closures have not had a material impact on access to pharmacy services.

V. DISCUSSION

A. How Representative are MACs?

We have presented a single case study. Readers might well ask whether we have cherry-picked a particularly egregious example of rent-seeking to justify our conclusions. We do not believe that our findings are skewed by the specific example we have chosen. In related work, we examine other examples of health care regulation, including restrictions on entry (i.e., licensure and certificates of need/public necessity) and restrictions on the terms for which goods and services may be provided (i.e., mandated benefits, any willing provider legislation, and other planks in what used to be known as the “patient bill of rights.”) Our MAC-related findings are fully consistent with our findings in this larger research project.

Other scholars have reached similar conclusions about health care legislation/regulation.59 And there is a rich public choice literature, documenting that similar complaints may be lodged at legislation and regulation across jurisdictions – both over time and across substantive areas of law and policy. Whatever else one might want to say in defense of MAC statutes, they fit comfortably into a rich tradition, where “the favored


59 See e.g., Clark C. Havighurst & Barak D. Richman, Distributive Injustice(s) in American Health Care, 69 L. Contemp. Probs. 7 (2006).
pastime of state and local governments” is the “dishing out [of] special economic benefits to certain in-state industries.”

B. Balance This!

The symposium at which this article was presented is framed around the optimal balance between competition and consumer protection. That issue is obviously difficult and complex – and no one has come up with a perfect solution to the problem. That is why it provides a good subject for a symposium. Balancing competition against provider protection that is masquerading as consumer protection is another matter entirely. That problem is easy. And, as show in our larger research project, most of what passes as consumer protection in health care is, in fact, provider protection. We should stop pretending otherwise.

C. Implications of Our Analysis for State Action

Our findings obviously call into question both the scope of the state action doctrine and the deference that doctrine gives to the decisions of state legislators. MAC statutes exemplify the degree to which private economic actors are willing and able to enlist state authority to obstruct entry or otherwise restrict competitive threats to incumbent market participants. And, as noted previously, these efforts make perfect sense. The relentless expansion of the U.S. criminal enforcement of the Sherman Act’s ban on cartelization has created powerful incentives for firms to seek comfort from state legislators. Privately agree with your competitors to exclude rivals, and you may go to jail; get the state to do it for you, and it is the competitors who may face a prison sentence for failing to comply.

State action also has distributional consequences – including spill-over anti-competitive effects in other states. The benefits of MAC legislation are captured by in-state pharmacies, but the costs are largely externalized to out-of-state PBMs – particularly during the term of lock-in contracts between PBMs and payers. Previous commentators have noted the

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60 Powers v. Harris, 379 F.3d 1208, 1221 (10th Cir. 2004).
61 See Burnham v. Superior Court, 495 U.S. 604 (1990) (“Perhaps the adage about hard cases making bad law should be revised to cover easy cases.”) (Stevens, J., concurring in the judgment).
63 See supra note 1, and accompanying text.
65 PBMs contract with plan sponsors on either a “pass-through” or a “lock-in” basis. A
importance of limiting state action immunity to laws that have little or no spillovers into other states.\textsuperscript{66} Retrenchment of the state action doctrine, and closer and more skeptical scrutiny of state-based restrictions on competition, would reflect the reality that the limits imposed by one state routinely damage the interests of citizens in other states – particularly when electronic commerce has diminished the amount of commerce that is truly “local.”

For those who are concerned with distributive (in)justice, health care regulation exemplifies the various ways in which “the haves come out ahead.”\textsuperscript{67} Of course, such reverse-Robin Hood schemes are not limited to health care. Many of the state restrictions that have been challenged by the DOJ and FTC, whether through litigation or competition advocacy, have perversive (i.e., upside-down) distributional effects.\textsuperscript{68}

Perhaps there is something to be learned from the ways in which other countries handle these matters. Many countries closely scrutinize anti-competitive state measures, and intervene forcefully to strike them down.\textsuperscript{69} Other jurisdictions do allow political subdivisions to restrict competition, but they subject such interventions to more demanding standards and more frequently invalidate them.\textsuperscript{70} For example, the European Commission places sharp limits on when a jurisdiction can provide “state aid,” including an\textit{ex ante} approval process that is back-stopped by the availability of recoupment and restitution.\textsuperscript{71} These approaches more fully address the destructive potential of state curbs on competition than the “nothing to see here, move along” approach taken by the U.S. in its implementation of the state action doctrine.

VI. CONCLUSION

Our proposal is modest. We should begin by acknowledging two simple facts: (i) virtually everything that is billed as “consumer protection” lock-in contract obligates the PBM to hit the contractually specified targets throughout the contractual term, irrespective of changes in the pharmaceutical market – including changes in the amounts that must be paid to dispensing pharmacies because of the effect of state MAC statutes.

\begin{itemize}
\item \textsuperscript{67} See supra note 16, and accompanying text.
\item \textsuperscript{68} Cooper & Kovacic, supra note 64, at 1565.
\item \textsuperscript{69} Eleanor M. Fox & Deborah Healey, \textit{When the State Harms Competition – The Role for Competition Law}, 79 Antitrust L.J. 769 (2014).
\item \textsuperscript{70} Cooper & Kovacic, supra note 64, at 1584-85.
\item \textsuperscript{71} See European Commission, State Aid Control, http://ec.europa.eu/competition/state_aid/overview/index_en.html
\end{itemize}
in the health care space is actually “provider protection;” and (ii) the state action doctrine insulates such conduct, as well as other forms of rent-seeking from antitrust scrutiny – at least as long as the state can satisfy the minimal hurdles created by the clear articulation and active supervision requirements.

The antitrust laws work reasonably well in dealing with private anti-competitive conduct, but the state action doctrine turns the antitrust laws into a goalie that only guards half the net.\textsuperscript{72} That approach isn’t working, and can’t be made to work. To continue our metaphor, players quickly learn to shoot at the unguarded half of the net.\textsuperscript{73} We should treat provider protection as a form of state aid, and use the competition laws to strike down a substantially greater share of the rent-seeking statutes that emerge from the legislative process. Of course, the toolkit for fixing these problems is not limited to competition law. The list of “fixes” should also include greater public scrutiny; routine-sun-setting; and a healthy dose of skepticism about the operations of the administrative state.\textsuperscript{74}

What about the problem of striking the proper balance between true consumer protections and competition? And, the obligations imposed by federalism? Get back to us once the system has been purged of provider protection. Until then, we all have bigger fish to catch, kill, and fry.

\textsuperscript{72} We leave it up to the reader to decide whether the hypothetical goalie is playing hockey, lacrosse, soccer, or water polo.

\textsuperscript{73} See Muris, supra note 1 (stating, as a competition policy theorem, the idea that “as a competition system achieves success in attacking private restraints, it increases the efforts that firms will devote to obtaining public restraints.”)

\textsuperscript{74} See Hyman & Svorny, supra note 7.
Appendix: States With MAC Statutes