The Adverse Consequences of Mandating Reimbursement of Pharmacies Based on Their Invoiced Drug Acquisition Costs

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Executive Summary

Public and private payers routinely rely on "Maximum Allowable Cost" programs ("MACs") to determine the reimbursement level for dispensed generic pharmaceuticals. MACs are set at a level reflecting the average acquisition cost of a well-run pharmacy. MACs encourage pharmacies to purchase generics at the lowest possible cost, thereby intensifying competition among wholesalers and drug manufacturers, and lowering overall pharmaceutical spending.

Various states have enacted or are considering legislation limiting the circumstances under which MACs may be used. Arkansas recently enacted legislation that contains a novel provision, which requires pharmacy benefit managers ("PBMs") to pay pharmacies at least their invoiced acquisition cost – irrespective of whether a lower priced option was available in the marketplace.[1] Other states are considering similar legislation.

This provision will effectively function as a "guaranteed profits" term: no matter how much a pharmacy spends to acquire a drug, they are guaranteed they will be repaid at least that amount, and likely more. And, because of rebates and discounts, invoiced prices may not reflect actual drug acquisition costs – further inflating the guaranteed profits.

The inflationary consequences of similar cost-based reimbursement systems are well known. For many years, the federal government relied heavily on cost-based procurement for defense contracts, only to discover that this approach resulted in large cost over-runs, because defense contractors knew their costs would be reimbursed, *however much they were.*

In the pharmaceutical setting, such legislation is likely to have a number of specific undesirable consequences, including:

- Increased spending on pharmaceuticals and the cost of pharmaceutical coverage;
- Reduced competition at the wholesaler and manufacturer level;
- Increased use of off-invoice discounting, thereby decreasing transparency of pharmaceutical pricing and reducing pricing competition;
- Guaranteed profits for pharmacies, irrespective of their actual efficiency;
- Reduced consumer welfare.

Apart from heavily regulated natural monopolies and government mandated agricultural cartels, we generally do not observe government-mandated guaranteed profits at the expense of third parties. And, natural monopolies and government mandated agricultural cartels are heavily regulated – so they do not get to unilaterally determine their cost structure, and the level of guaranteed profits they will receive. Arkansas' legislation, and similar legislation being considered in other states, is designed to benefit pharmacies, at the expense of consumers, employers, and PBMs.

[1] The legislation was challenged in a lawsuit filed in federal district court in Arkansas. PCMA v. Rutledge, Case No. 4:15-CV-00. I was retained by PCMA as an expert in that case.

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Why Payers Developed MACs

Payers developed Maximum Allowable Cost programs ("MACs") to avoid overpaying for generic pharmaceuticals. Generics currently account for 86% of filled prescriptions. At one time, payers reimbursed pharmacies for dispensed pharmaceuticals based on list price. But, for a variety of reasons, the list price for many generics routinely exceeds the actual acquisition costs incurred by pharmacies in obtaining those drugs. Depending on a variety of factors, pharmacies can obtain a generic drug for anywhere from 20% - 95% off list price. And even invoiced prices do not necessarily reflect actual acquisition costs, because of the effect of various rebates, charge-backs, and discounts. In response, payers developed reimbursement strategies that were based on average actual acquisition costs, and not list or unadjusted invoice prices.

The Rise of MACs

Medicaid was a leader in the move toward reimbursement strategies that incorporated the estimated average acquisition cost of an efficient pharmacy. Beginning in 1987, Medicaid programs were required to pay pharmacies a flat amount for dispensing certain drugs, *irrespective of their actual acquisition cost*.[2] This payment limit was computed mechanically. However, there were serious concerns that these payment limits were still too high. Many states responded by adopting MAC programs, which implemented low reimbursement levels on a broad array of drugs.[3] PBMs emulated state Medicaid programs, and adopted their own MAC programs. MACs are now a pervasive feature of the pharmaceutical reimbursement landscape.

MACs have had at least five distinct effects on pharmaceutical markets.[4] First, MACs encourage pharmacies to dispense the generic version of applicable pharmaceuticals. Second, MACs heighten competition among generic manufacturers. Third, MACs 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.

Arkansas' Mandating of Reimbursement of Pharmacies Based on Drug Acquisition Costs

In April, 2015, Arkansas enacted Senate Bill 688 (also called Act 900).[5] The legislation stated that its purpose was "to create accountability in the establishment of prescription

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[2] 42 C.F.R. sec. 447.301 et seq.

[3] Richard G. Abramason et al, *Generic Drug Cost Containment in Medicaid: Lessons from Five State MAC Programs*, 25 Health Care Financing Review 25 (2004); Office of Inspector General, Medicaid Drug Pricing in State Maximum Allowable Cost Programs (August 29, 2013), available at https://oig.hhs.gov/oei/reports/oei-03-11-00640.asp

[4] David A. Hyman, The Unintended Consequences of Restrictions on the Use of Maximum Allowable Cost Programs ("MACs") for Pharmacy Reimbursement, PCMA White Paper, at http://www.pcmanet.org/research/the-unintended-consequences-of-restrictions-on-the-use-of-maximum-allowable-cost-programs-macs-for-pharmacy-reimbursement.

[5] *See* http://www.arkleg.state.ar.us/assembly/2015/2015R/Pages/BillInformation.aspx?measureno=SB688

drug pricing."[6] Like similar legislation in other states, SB 688 places limits on when a pharmaceutical can be placed on a MAC list; requires PBMs to update their MAC lists on a periodic basis and make those lists available to pharmacies; and specifies an administrative appeals process that must be made available to pharmacies that are dissatisfied with the amount they were paid pursuant to a MAC. These provisions are likely to undermine the effectiveness of existing MAC programs, while simultaneously increasing pharmaceutical spending and the cost of prescription drug coverage.[7]

SB 688 also contains a novel provision that requires PBMs to pay pharmacies at least their actual acquisition cost – irrespective of whether a lower priced option was available in the marketplace. This provision will effectively function as a "guaranteed profit" term: no matter how much a pharmacy spends to acquire a drug, they are guaranteed they will be repaid at least that amount, and likely more.

The "guaranteed profit" term is implemented through the administrative appeal process in SB 688. Pharmacies are entitled to appeal any MAC payment that is below their actual acquisition.[8] The guaranteed profits that will result are not accidental: the original version of SB 688 provided that a pharmacy could appeal if the MAC is "below the cost at which the pharmacy *may* obtain the drug" (emphasis supplied) -- but this language was stricken, and replaced with a provision that allows a pharmacy to appeal if the MAC is "below the pharmacy acquisition cost."[9] Thus, SB 688 was amended to make it crystal clear that pharmacies must be paid based on their actual acquisition costs, even if the pharmacy could have obtained the pharmaceutical in question for far less.

A brief example helps clarify the incentive problems that result from this approach. Assume that a drug is available from two Wholesalers: A, and B.[10] Wholesaler A charges $10 if the pharmacy purchases 100 tablets, and $35 if the pharmacy purchases 500 tablets. Wholesaler B charges $15 if the pharmacy purchases 100 tablets, and $60 if the pharmacy purchases 500 tablets. Table 1 shows the price per tablet for both wholesalers for each of the two offered unit sizes.

Table 1

Price per Tablet		Wholesaler A	Wholesaler B
Unit Size (Tablets)	100	10¢	15¢
	500	7¢	12¢

Absent SB 688, the PBM will set the MAC at a level that reflects the average acquisition cost of a well-run pharmacy – i.e., it will set the MAC at just over 7¢ per tablet, creating a very strong incentive for the pharmacy to purchase the drug only from Wholesaler A, and to do so in lots of 500 tablets. The existence of the MAC will also intensify

[6] *See* http://www.arkleg.state.ar.us/assembly/2015/2015R/Bills/SB688.pdf
[7] Hyman, *supra* note 4.
[8] SB 688 Section I(c)(4)(A)(i)(b).
[9] Id.
[10] For the sake of simplicity, this white paper focuses on Wholesalers, but the same analysis applies to pharmaceutical manufacturers, which deal directly with large pharmacy chains.

competition in the wholesale market (i.e., it will encourage wholesaler B to lower its prices, and encourage wholesalers A and B to narrow the pricing differences between unit sizes of 100 and 500 tablets). This will help drive down pharmaceutical spending, and lower the cost of pharmaceutical coverage.

However, once the "guaranteed profits" term in SB 688 takes effect, pharmacies can purchase the specified drug in whatever unit size they choose – and purchase it from either Wholesaler A or Wholesaler B, confident that they can successfully appeal if the MAC does not exceed their actual acquisition cost. PBMs know that a sizeable number of appeals are in the offing if they set the MAC below the average acquisition cost incurred by pharmacies that are now free to determine their own costs – and they will likely respond by setting higher MACs. This will result in guaranteed profits for pharmacies that purchase the drug for less than the (now inflated) MAC. The higher the MAC, the less effective it will be in constraining pharmaceutical spending and increasing competition at the wholesale level – and PBMs will still have to deal with appeals from pharmacies that have actual acquisition costs that exceed the now-inflated MAC. Because the only appeals will come from pharmacies whose costs exceed those of the MAC, SB 688 ensures that many pharmacies will be paid more than their average acquisition costs – thereby guaranteeing each of them a potentially large profit on their acquisition cost, wholly apart from any dispensing fee they receive.

Impact on Off-Invoice Discounting and Pricing Transparency

In order to pay a pharmacy its actual acquisition cost, the PBM must determine the "right" amount to pay. SB 688 provides a simple answer: the PBM must pay "the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice."[11]

The problem with this approach is that it creates a significant incentive for wholesalers and manufacturers to use off-invoice discounting, thereby reducing pricing transparency and decreasing the effectiveness of price competition. Wholesalers and manufacturers already rely on rebates and discounts to help drive sales, but SB 688 is likely to supercharge these efforts, and move them off-invoice.

The United States has already experienced the problems that can result from relying solely on the figures that appear on invoices to determine acquisition cost. For several decades, public and private payers relied on publicly reported average wholesale prices ("AWPs") to set the level of reimbursement for pharmacies. AWPs appeared in authoritative commercial publications, and also often appeared on the invoices that pharmacies received. But, AWPs did not reflect the actual acquisition costs incurred by pharmacies – in part because they did not reflect various rebates, charge-backs, and discounts.[12] The result was that AWPs often dramatically overstated the true acquisition costs incurred by pharmacies. Relying on AWPs resulted in massive overpayments by public and private payers, followed by years of litigation and the recovery of billions of dollars in damages.

[11] SB 688 Section I(a)(6).

[12] As explained in an earlier white paper, AWPs also overstated the actual acquisition costs for generic drugs, because AWPs were not updated on a timely basis to reflect the impact of generic entry on pricing.

Once it became clear that AWPs did not reflect actual acquisition costs, public and private payers experimented with various payment formulas (including MACs), to address this problem. For example, in 2003, Congress enacted legislation requiring Medicare Part B to replace its AWP-based payment system for drugs with one based on the Average Sales Price ("ASP"), as reported quarterly by drug manufacturers.[13] ASP is computed net of any price concessions, including volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates.[14] Congress also specified that the definition of ASP could be updated administratively, to reflect the impact of any "other price concessions. . . that would result in a reduction of the cost to the purchaser."[15] As this example illustrates, Congress explicitly rejected the use of a cost-based payment system for pharmaceuticals that did not take account of *all* rebates, discounts, and price concessions -- whether they appeared on the face of an invoice or not. SB 688 is a significant step back down a path that Congress decisively rejected in 2003.

To summarize, if the goal is to determine the actual acquisition cost for a particular pharmaceutical, it is necessary to take account of all discounts and rebates associated with all pharmaceutical purchases -- whether they appear on the face of a particular invoice, or are recorded and reconciled elsewhere. Because SB 688 fails to do that, it creates a virtual license for wholesalers, manufacturers, and pharmacies to collude at the expense of public and private payers. This will result in increased pharmaceutical spending and higher costs for pharmaceutical coverage.

Lessons From Past Experiences with Cost-Based Reimbursement

The inflationary consequences of cost-based reimbursement are well known, and help explain why such reimbursement schemes have fallen into disfavor. For example, 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.[16] 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

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[13] *See* Use of Average Sales Prices Payment Methodology, 42 U.S.C. 1395w–3a, available at https://www.law.cornell.edu/uscode/text/42/1395w-3a.

[14] *See Id.* at 42 U.S.C. 1395w–3a (c)(3) ("In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1396r–8 of this title).")

[15] *See Id*. ("For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.")

[16] 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.

there have been issues with the implementation of PPS, there has been no serious discussion of a return to cost-based reimbursement for hospitals.[17]

The same dynamic has played out in the context of government procurement. 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 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.

The problems with cost-based contracts were well known by Congress, and by defense contractors. 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."[18]

Similarly, during the first Presidential debate in 2008, Senator John McCain made the following observation:

> I think that we have to return -- particularly in defense spending, which is the largest part of our appropriations -- we have to do away with cost-plus contracts. We now have defense systems that the costs are completely out of control. We tried to build a little ship called the Littoral Combat Ship that was supposed to cost $140 million, ended up costing $400 million, and we still haven't done it. So we need to have fixed-cost contracts. We need very badly to understand that defense spending is very important and vital, particularly in the new challenges we face in the world, but we have to get a lot of the cost overruns under control.[19]

In like fashion, when Senator McCain recently became the chairman of the Senate Armed Services committee, he identified the problem of cost-plus contracts as one of his top three priorities, and indicated he would try to ban them entirely.[20] The Obama

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[17] In 1997, Congress reinstated cost-based reimbursement for "critical access hospitals" located in rural areas. But, there has been no effort to broaden the use of cost-based reimbursement beyond this small number of hospitals.

[18] HENRY WAXMAN, THE WAXMAN REPORT: HOW CONGRESS REALLY WORKS (2009).

[19] The First Presidential Debate, Sep. 28, 2008, at http://elections.nytimes.com/2008/president/debates/transcripts/first-presidential-debate.html

[20] John T. Bennett, *Sen. McCain Sets Sights on 'Disgraceful' Cost-Plus Contracts,* Defense News, Dec. 5, 2014, at http://archive.defensenews.com/article/20141205/CONGRESSWATCH/312050030/Sen-McCain-Sets-Sights-Disgraceful-Cost-Plus-Contracts; John T. Bennett, *McCain Ready To Tackle Cyber Threats,*

administration is also skeptical about the merits of cost-plus contracting, as reflected in a March 4, 2009 speech on government procurement;[21] a March 6, 2009 Presidential Memorandum on Government Contracting,[22] and a March 18, 2009 letter from the Office of Management and Budget.[23]

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.[24] 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.[25] Neither of these preconditions apply to SB 688.

Efficiency Losses

As explained in an earlier white paper, MACs help make the market for pharmaceuticals more efficient:

> MAC cuts through the forest of individual list prices, and specifies the reimbursement that will be paid, regardless of. . . 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.[26]

Obviously, these efficiencies will be lost or dramatically diminished if PBMs are forced to conduct an *ex post* individualized inquiry into the actual acquisition cost of any pharmacy that appeals. Unless PBMs respond by setting MACs for each drug at the level of the most expensive bio-equivalent product obtained by the least efficient pharmacy in

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Cost-Plus Contracts as SASC Chairman, Dec. 3, 2014, at http://www.defensenews.com/article/20141203/CONGRESSWATCH/312030041

[21] Remarks by the President on Procurement, March 4, 2009, at https://www.whitehouse.gov/the-press-office/remarks-president-procurement-3409 ("First, with the presidential memorandum that I'm signing, I am instructing my administration to dramatically reform the way we do business on contracts across the entire government. So starting today, Peter Orszag, my budget director, will work with Cabinet officials and agency heads to develop tough new guidelines on contracting by the end of September. . We will end unnecessary no-bid and cost-plus contracts that run up a bill that is paid by the American people.")

[22] Memorandum on Government Contracting, March 4, 2009, at https://www.whitehouse.gov/omb/procurement_index_gov_contracting/ and https://www.whitehouse.gov/21stcenturygov/actions/reforming-government-contracting.

[23] See letter from Peter Orszag to Joseph Lieberman, March 18, 2009, at https://www.whitehouse.gov/sites/default/files/omb/assets/procurement/cost_contracting_report_031809.pdf.

[24] FAR. 16.301-2, available at https://www.acquisition.gov/sites/default/files/current/far/html/Subpart%2016_3.html. 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.

[25] FAR 16-301-3(a).

[26] Hyman, *supra* note 4.

the state, they will inevitably face at least some appeals by pharmacies that have elected to purchase the drug in question from a higher cost supplier. And, if they set a MAC significantly below this inflated level, the costs of adjudicating the inevitable appeals has the potential to swamp the benefits of using a MAC in the first instance. Thus mandating reimbursement rates based on acquisition costs will significantly weaken (if not cripple) the effectiveness of MACs, and the efficiencies associated with their use.

Financial Effects of Mandating Reimbursement of Pharmacies Based on Their Acquisition Costs

There are no studies that explicitly quantify the effect of mandating reimbursement of pharmacies based on their acquisition costs, but two studies estimate the impact of similar legislation. The first study estimated the financial impact of legislation similar to SB 688, but the legislation they were evaluating did not include a "guaranteed profits" term.[27] This study estimated that spending on the affected pharmaceuticals would increase by 31-56%, with a nationwide impact of $6.2 billion increased spending annually. Importantly, this estimate captures only the immediate fiscal impact, and not the more long-term indirect consequences. And, as noted above, this estimate excludes the financial impact of the "guaranteed profits" term in SB 688.

The second study was performed by the Washington Health Care Authority ("WHCA), and involved "scoring" the financial impact of proposed legislation (SB 5857). SB 5857, like SB 688, prohibits PBMs from paying pharmacies less than their actual acquisition cost. WHCA concluded SB 5857 would make MAC lists much less effective, and would dramatically reduce pharmacies' incentive to acquire generic drugs at the lowest possible cost.[28] Although WHCA did not specifically quantify the fiscal impact of SB 5857, it determined that the legislation would "significantly increase" costs for public employee benefits and would also have a cost-increasing impact on Medicaid.[29] WHCA did not attempt to determine the impact of SB 5857 on private employers and unions, but there is no reason to think it would not have similar cost-increasing effects on those payers.

Structure of SB 688

SB 688 expressly excludes Arkansas' Medicaid program and Arkansas' Employee Benefits Division of the Department of Finance and Administration from its ambit, at least as long as these entities do not contract with a PBM to manage their pharmaceutical coverage.[30] The only thing these two groups have in common is that the costs of their

[27] Visante, *Proposed MAC Legislation May Increase Costs Of Affected Generic Drugs By More Than 50 Percent,* January, 2015, on file with author. The study assumed that MACs would only be permissible if there were three nationally available, therapeutically equivalent, multiple source products (i.e., the branded drug, and at least two generics), and all three were A-rated. SB 688 only requires there to be at least one available generic, which can be rated A, B, NR, or NA.

[28] *See* WHCA Fiscal Note, SSB – 5857 (concluding that pharmacies reimbursed on the acquisition cost of pharmaceuticals "would not have as strong of an incentive to acquire generic drugs at the lowest cost available. This would effectively make the maximum allowable costs (MAC) lists less effective at controlling pharmaceutical costs.")

[29] Id. ("This bill, if passed, would significantly increase the costs within the Public Employees Benefits (PEB) delivery system.")

[30] SB 688 Section I(f) – (g).

health coverage are on-budget expenses, borne (either in whole or in part) by the state of Arkansas.

The logic seems to be that it is acceptable for the state of Arkansas to pay in-state pharmacies less than their actual acquisition cost as long as the state is acting in its sovereign capacity – but if it outsources the function to a commercial PBM, in-state pharmacies will receive higher payments. The discrimination in favor of in-state concentrated interests (i.e., pharmacies) could not be more clear. And, by excluding these populations from the scope of SB 688, Arkansas' legislators made it clear that they thought it was important to ensure pharmacies were paid their actual acquisition costs -- right up until the moment the state would bear the costs of doing so.

Competition in a post-SB 688 World

From a market structure perspective, SB 688 is an extraordinary piece of legislation. Apart from heavily regulated natural monopolies and government mandated agricultural cartels, we generally do not observe government-mandated guaranteed profits at the expense of third parties. And, natural monopolies and government mandated agricultural cartels are heavily regulated – so they do not get to unilaterally determine their cost structure, and the level of guaranteed profits they will receive. In all other markets, profits (if any) are left to ordinary competition, and the impersonal workings of the marketplace. As such, SB 688 and similar bills are special interest legislation, in every sense of the word. Pharmacies, and not consumers, are the beneficiaries of this piece of legislation.

Conclusion

SB 688 and similar bills are likely to result in increased pharmaceutical spending and increase the cost of pharmaceutical coverage. The "guaranteed profits" term in SB 688 is particularly pernicious, because it imposes a cost-based approach to pharmaceutical purchasing, and undermines the competitive forces that would otherwise result from the use of MACs.

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I am a chaired professor of law and professor of medicine at the University of Illinois. Most of my academic scholarship is on the regulation of health care financing and delivery, with a particular focus on competition law and policy. Prior to my current position, I spent three years (2001-2004) serving as Special Counsel at the Federal Trade Commission ("FTC"), where I was project leader and principal author of the report jointly issued by the FTC and Department of Justice ("DOJ"), "Improving Health Care: A Dose of Competition" (2004). The report built on twenty-seven days of hearings held throughout 2003, and a two-day workshop held in 2002. While at the FTC, I worked on a number of other projects as well, including advocacy letters directed at bills being considered in Rhode Island (any willing pharmacy) and California (PBM transparency). I have been retained as an expert in cases involving pharmaceutical pricing on behalf of several state Medicaid programs, and on behalf of PCMA in litigation in Iowa and Arkansas.