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The Role of State Attorneys General in Improving Prescription Drug Affordability

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THE ROLE OF STATE ATTORNEYS GENERAL IN IMPROVING PRESCRIPTION DRUG AFFORDABILITY

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ABSTRACT

Impact litigation initiated by state attorneys general has played an important role in advancing public health goals in contexts as diverse as tobacco control, opioids, and healthcare antitrust. State attorneys general also play a critical role in helping governors and legislatures advance health policies by giving input into their drafting and defending them against legal challenges. State attorneys general have entered the prescription drug affordability arena in both these ways—for example, by initiating lawsuits relating to price fixing by generic drug manufacturers and defending state

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laws requiring disclosures of pharmaceutical prices. Yet the scope of their collective efforts is not well understood, and little is known about factors that facilitate and hinder them in their pursuit of policy objectives relating to drug affordability. In this Article, we report findings from an empirical study of state attorney general activities relating to pharmaceutical pricing. Drawing from key informant interviews with attorneys working on drug pricing issues as well as a scoping review, we report on how state attorneys general are working to address the problem of drug affordability, how they make decisions about resource investments in this area, what positions state attorneys general to be effective change agents in this space, and what challenges they confront in this work. We situate our results within the broader literature on state attorneys general as policy actors, and we suggest measures that could extend their capacity to successfully tackle the complex issues that give rise to unaffordable drugs.

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INTRODUCTION

Prescription drug affordability has risen to the very top of the policy agenda for lawmakers and the public. Even during the peak of the COVID-19 pandemic in January 2021, a national poll ranked taking action to lower prescription drug prices as Americans' second-highest domestic policy priority, with eighty-seven percent of participants rating the issue "extremely important."[1] Nearly one in four Americans reports difficulty affording their prescription medications, and patients may respond by delaying filling their prescriptions, cutting pills in half, or skipping doses.[2] Despite partisan

1. POLITICO & HARV. T.H. CHAN SCH. OF PUB. HEALTH, THE AMERICAN PUBLIC'S PRIORITIES FOR THE NEW PRESIDENT AND CONGRESS, POLITICO & HARV. T.H. CHAN SCH. OF PUB. HEALTH 2 (2021).

2. Ashley Kirzinger, Lunna Lopes, Bryan Wu, & Mollyann Brodie, *KFF Health Tracking Poll—February 2019: Prescription Drugs*, KAISER FAM. FOUND. (Mar. 1, 2019), http://www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs [http://perma.cc/H75W-

divisions among voters in many areas of health policy, a bipartisan supermajority of Americans—nearly four in five—believes that prescription drug costs are "unreasonable."[3]

Notwithstanding both this bipartisan support and pledges by leaders of both parties to take action on the issue following the 2016 election,[4] few substantive reforms have become law at the federal level in recent years, either through legislation or regulation.[5] Rather, states have become the locus of policy action on prescription drug costs. States' interest in this area arises not only because high drug prices harm consumers, but also because state budgets are directly affected when drug costs for the Medicaid program or state employee health plans rise. Unlike the federal government, states face special financial pressures due to requirements that they balance their budgets.[6] Since 2017, 166 prescription drug pricing bills have become law in forty-eight states, tackling everything from price transparency to regulation of pharmacy benefit managers (PBM) to drug affordability boards.[7] State legislatures are even taking inspiration from bold proposals being introduced at the federal level by considering bills that would adopt international reference pricing approaches within their own states.[8] Despite this energetic activity, state legislative interventions adopted to date have had only modest impacts on drug pricing.[9]

There has been little scholarly attention paid to the drug affordability

RSS2].

3. *Id*.

4. Stacie B. Dusetzina & Michelle M. Mello, *Drug Pricing Reform in 2021—Going Big or Going Bipartisan?*, JAMA HEALTH F. (July 8, 2021), http://jamanetwork.com/journals/jama-health-forum/fullarticle/2781947 [http://perma.cc/397H-9M5N].

5. Rachel E. Sachs, *The Rhetorical Transformations and Policy Failures of Prescription Drug Pricing Reform Under the Trump Administration*, 46 J. HEALTH POL., POL'Y & L. 1053 (2021). Some small reforms that would attempt to eliminate anticompetitive abuses, such as the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, did become law. *See* Further Consolidated Appropriations Act, 2020 § 610, 21 U.S.C. § 355-2; U.S. FOOD & DRUG ADMIN., ACCESS TO PRODUCT SAMPLES: THE CREATES ACT (2020), http://www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act [http://perma.cc/YZ2B-QJ7T].

6. *See, e.g.*, David Gamage, *Preventing State Budget Crises: Managing the Fiscal Volatility Problem*, 98 CALIF. L. REV. 749, 755 (2010).

7. Trish Riley, *Celebrating Five Years of State Action to Lower Drug Prices*, NAT'L ACAD. FOR ST. HEALTH POL'Y (May 18, 2021), http://www.nashp.org/celebrating-five-years-of-state-action-to-lower-drug-prices [http://perma.cc/8YJZ-L7PW].

8. Lev Facher, *States Still Can't Import Drugs from Canada. Now, Many are Seeking to Import Canadian Prices*, STAT (Feb. 18, 2021), http://www.statnews.com/2021/02/18/states-canada-drug-prices [http://perma.cc/AW6E-VLT9].

9. Michelle M. Mello & Trish Riley, *To Address Drug Affordability, Grab the Low-Hanging Fruit*, JAMA HEALTH F. (Feb. 25, 2021), http://jamanetwork.com/journals/jama-health-forum/fullarticle/2777036 [http://perma.cc/E5FD-N6RW] (summarizing data on recent price increases). For a discussion of legal limitations on what states can regulate in the drug affordability space, see *infra* note 233 and accompanying text.

activities of another state-level policy actor with an important role to play: offices of state attorneys general (AGs).[10] State AGs are important players both in using affirmative tools, including litigation, to advance important policy goals and in defending states against the inevitable legal challenges to state legislative efforts on prescription drug affordability.[11] Past examples of state AG involvement in critical public health issues, including tobacco control and the opioid epidemic,[12] suggest that state AG litigation can be a powerful force in combating business practices that cause health harms. In many states, AGs also have a critical role to play in providing advice to legislatures trying to make progress on drug pricing amidst ever-present threats of lawsuits challenging their enactments. Building on their past experiences, as well as a successful history of addressing high drug prices using healthcare fraud-and-abuse statutes, state AG offices have recently expanded their activities in the drug affordability space to include a variety of interesting, creative approaches leveraging state and federal antitrust laws, state consumer protection laws, emergency price-gouging statutes, and other authorities.

In this Article, we report findings from an empirical study of state AG activities relating to pharmaceutical pricing. Few empirical analyses of state AGs' activities have been conducted,[13] and to our knowledge, this is the first

10. Hereinafter, we use the term "AGs" to refer both to the state's top attorney and to the attorneys who staff the AG's office.

11. *See, e.g.*, Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 666 (4th Cir. 2018) (invalidating a Maryland statute regulating excessive price increases for essential off-patent and generic drugs).

12. See *infra* Part I for discussions of these specific examples.

13. See *infra* Part I for discussions of these specific examples. Danielle Keats Citron, *The Privacy Policymaking of State Attorneys General*, 92 NOTRE DAME L. REV. 747, 751–52 (2016) (analyzing interview data and documentary evidence obtained from Freedom of Information Act requests to study how AGs are working on data privacy issues). Most empirical work has analyzed predictors of AGs' participation in multistate litigation. Colin Provost, *An Integrated Model of U.S. State Attorney General Behavior in Multi-State Litigation*, 10 ST. POL. & POL'Y Q. 1, 2–3 (2010) [hereinafter Provost, *Integrated Model*]; Colin Provost, *The Politics of Consumer Protection: Explaining State Attorney General Participation in Multi-State Lawsuits*, 59 POL. RES. Q. 609, 612 (2006) [hereinafter Provost, *Politics of Consumer Protection*]; Colin Provost, *State Attorneys General, Entrepreneurship, and Consumer Protection in the New Federalism*, 33 PUBLIUS 37, 43–44 (2003) [hereinafter Provost, *Entrepreneurship*]; Joseph F. Zimmerman, *Interstate Cooperation: The Roles of the State Attorneys General*, 28 PUBLIUS 71, 72–73 (1998); Thomas A. Schmeling, *Stag Hunting with the State AG: Anti-Tobacco Litigation and the Emergence of Cooperation Among State Attorneys General*, 25 LAW & POL'Y 429, 430–31 (2003). A few studies have modeled predictors of states' decisions to join amicus briefs. *See* Shane A. Gleason, *The Dynamics of Legal Networks: State Attorney General Amicus Brief Coalition Formation*, 39 JUST. SYS. J. 253, 254 (2018); Margaret H. Lemos & Kevin M. Quinn, *Litigating State Interests: Attorneys General as Amici*, 90 N.Y.U. L. REV. 1229, 1242–43 (2015); Cornell W. Clayton, *Law, Politics and the New Federalism: State Attorneys General as National Policymakers*, 56 REV. POL. 525, 544–48 (1994); Thomas R. Morris, *States Before the U.S. Supreme Court: State Attorneys General as* Amicus Curiae, 70 JUDICATURE 298, 301–02 (1987). Other studies have analyzed characteristics of cases in which states have enforced federal consumer protection statutes, *see, e.g.*, Amy Widman & Prentiss Cox, *State Attorneys General's Use of Concurrent Public Enforcement Authority in Federal Consumer Protection Laws*, 33 CARDOZO L. REV. 53, 54–55 (2011); state AGs' decisions to bring nonpharmaceutical

to focus on drug pricing. Through key informant interviews with attorneys working on drug pricing issues within state AG offices as well as a scoping review, we sought to learn more about how state AGs are addressing the problem of prescription drug affordability, how they make decisions about resource investments in this area, what positions state AGs to be effective change agents in this space, and what challenges they confront in this work. We situate our results within the broader literature on state AGs as policy actors, and we suggest measures that could extend their capacity to successfully tackle the complex issues that give rise to overpriced drugs.

Part I of this Article surveys the existing literature on the role of state AGs, considering key elements of their institutional role and exploring how those elements were instantiated in specific activities in the health context. Part II presents the methods we used in conducting this project. Part III presents the results of our analysis, including the major activities of state AGs in the prescription drug affordability space and key findings relating to how they carry out this work and the factors that empower and constrain them. Part IV reflects on these results, and Part V offers recommendations for strengthening state AGs' role in this important area.

I. SITUATING THE ROLE OF STATE ATTORNEYS GENERAL IN PUBLIC HEALTH POLICY

In the prescription drug pricing arena, as in other policy areas, attorneys general are "an important and underappreciated force."[14] As the chief legal officer of their state or territory, AGs have several functions: providing legal advice to the governor and executive agencies, stewarding affirmative and defensive litigation concerning the state, issuing opinions clarifying the law for other branches of the government, administering public outreach and advocacy programs (for example, consumer-protection programs and child-support enforcement), enforcing the criminal law, participating in law reform and legislative advocacy, and conducting investigations.[15] Over the past

healthcare antitrust suits in the 1970s and early 1980s, *see, e.g.*, Ronald C. Lippincott, *Redressing the Imbalanced Political Market for Health Policy: A Role for the State Attorney General?*, 9 J. HEALTH POL., POL'Y & L. 389, 391 (1984); strategies employed in consumer-protection lawsuits, *see, e.g.*, Prentiss Cox, Amy Widman & Mark Totten, *Strategies of Public UDAP Enforcement*, 55 HARV. J. ON LEGIS. 37, 79–85 (2018); and changes in the types of lawsuits AGs have brought over time, *see e.g.*, Paul Nolette & Colin Provost, *Change and Continuity in the Role of State Attorneys General in the Obama and Trump Administrations*, 48 PUBLIUS 469, 471–73 (2018).

14. PAUL NOLETTE, FEDERALISM ON TRIAL: STATE ATTORNEYS GENERAL AND NATIONAL POLICYMAKING IN CONTEMPORARY AMERICA, at vii (2015).

15. NAT'L ASS'N OF ATT'YS GEN., STATE ATTORNEYS GENERAL: POWER AND RESPONSIBILITIES 12–14 (Lynne M. Ross ed., 1990). For a logic model depicting how these core functions can improve public health, see Lainie Rutkow & Stephen P. Teret, *The Potential for State Attorneys General to Promote the Public's Health: Theory, Evidence, and Practice*, 30 ST. LOUIS U. PUB. L. REV. 267, 271 (2011).

several decades, most of these roles have expanded as state and federal legislatures grant AGs new authorities, responsibilities, and funding, including the authority to bring actions to enforce specific federal statutes.[16] AGs have increasingly become seen as "political entrepreneurs" pressing their own policy agendas.[17] On the other hand, their participation in drafting and reviewing legislation has contracted somewhat as state legislatures have employed their own legal support staff.[18]

Investigating and litigating potential violations of state and federal law are central to AGs' work. Most have a legal duty to litigate affirmatively and defensively on behalf of state agencies.[19] AGs may litigate pursuant to a constitutional provision, statutory provision, or common-law prerogative.[20] Of particular relevance to prescription drug pricing, AGs may bring *parens patriae* suits to vindicate interests of their state's citizens;[21] have authority to enforce both state and federal antitrust laws as well as capacious state consumer-protection laws;[22] and have been actively encouraged by federal lawmakers to litigate against drug companies.[23]

Prior legal and political science literature has considered several dimensions of the ways in which state AGs engage in litigation or other policymaking activities, both in general[24] and in particular substantive areas.[25] Additionally, public health scholars have cataloged a series of important health-related areas in which state AGs have undertaken focused litigation and other activity.[26] This Part begins by highlighting three important themes from the existing literature on state AG enforcement

16. NAT'L ASS'N OF ATT'YS GEN., *supra* note 15, at 40; NOLETTE, *supra* note 14, at 4, 7–8, 36–40.

17. *See, e.g.*, Provost, *Entrepreneurship*, *supra* note 13, at 43–44.

18. NOLETTE, *supra* note 14, at 93, 96–97.

19. *Id.* at 84, 86.

20. *Id.* at 76.

21. Richard P. Ieyoub & Theodore Eisenberg, *State Attorney General Actions, the Tobacco Litigation, and the Doctrine of* Parens Patriae, 74 TUL. L. REV. 1859, 1863–64 (2000); NOLETTE, *supra* note 14, at 40–41.

22. NOLETTE, *supra* note 14, at 223; *see generally* Cox et al., *supra* note 13, at 42–47 (describing the breadth of state UDAP laws). A key tool in the antitrust arena is the Hart-Scott-Rodino Antitrust Act of 1976, 15 U.S.C. § 15c, which provides that state AGs may represent their state's citizens as *parens patriae* in antitrust cases. NOLETTE, *supra* note 14, at 234.

23. NOLETTE, *supra* note 14, at 44.

24. *See generally, e.g.*, Elysa M. Dishman, *Enforcement Piggybacking and Multistate Actions*, 2019 BYU L. REV. 421 (2019); Margaret H. Lemos & Ernest A. Young, *State Public-Law Litigation in an Age of Polarization*, 97 TEX. L. REV. 43, 67–85 (2018); Margaret H. Lemos, *State Enforcement of Federal Law*, 86 N.Y.U. L. REV. 698 (2011) [hereinafter Lemos, *State Enforcement*]; Margaret H. Lemos, *Aggregate Litigation Goes Public: Representative Suits by State Attorneys General*, 126 HARV. L. REV. 486 (2012) [hereinafter Lemos, *Aggregate Litigation*].

25. *See* Citron, *supra* note 13, at 747; NOLETTE, *supra* note 14, at 13–17.

26. *See generally* Lainie Rutkow & Stephen P. Teret, *Role of State Attorneys General in Health Policy*, 304 JAMA 1377 (2010).

efforts: the role of multistate cooperation, the ability to use litigation to create policy, and the federalism implications of state action. This Part then goes on to explain how these three aspects of state AG action have played out in the public health arena—specifically, in major initiatives by AGs in the tobacco, drug pricing, and opioid contexts.

A. KEY ELEMENTS UNDERLYING STATE AG ACTIVITIES

Scholars have explored the ways in which state AGs engage in litigation to enforce a variety of laws,[27] to make substantive policy,[28] and to represent the interests (at least purportedly) of both their citizens[29] and their state as a whole.[30] They have also explored some of the problematic incentives that might impact state AG activities across these domains.[31] In this literature, three strengths stand out as important for state AGs seeking to influence public health policy; each also involves attendant challenges.

1. The Role of Multistate Cooperation

Scholars and attorneys consistently emphasize the role of multistate cooperation in state AG activity of various types,[32] and multistate action has become increasingly common in AG litigation.[33] Multistate partnerships enable states to pool their limited resources and share expertise and information.[34] These collaborations can be particularly important for small states, which may lack the resources to take on large corporate actors or investigative matters by themselves.[35] Through multistate cooperative efforts, state AGs can more easily initiate large-scale investigations, file and litigate challenges to allegedly unlawful business practices, and achieve broad settlements, such as those explored in Section II.B of this Article. State AGs may also engage in other types of collaborative activities, such as filing amicus briefs.[36]

27. *See generally* Dishman, *supra* note 24.
28. *See generally* Citron, *supra* note 12.
29. *See generally* Lemos, *Aggregate Litigation*, *supra* note 24.
30. *See generally* Lemos & Quinn, *supra* note 13.
31. *See generally* Dishman, *supra* note 24; Margaret H. Lemos & Max Minzner, *For-Profit Public Enforcement*, 127 HARV. L. REV. 853 (2014).
32. *See, e.g.*, NAT'L ASS'N OF ATT'YS GEN., *supra* note 15, at 215 (characterizing multistate action as an "extremely effective tool for combatting fraud [on consumers] perpetrated on a multistate basis").
33. NOLETTE, *supra* note 14, at 21 (presenting data on number of multistate cases resolved per year).
34. Citron, *supra* note 12, at 790–91; Dishman, *supra* note 24, at 429, 448–50.
35. Citron, *supra* note 12, at 790–91. Regulated entities may even prefer to face a single investigation backed by a large majority of states, rather than multiple investigations by a variety of regulators. *See id*. at 796–97.
36. Lemos & Quinn, *supra* note 13, at 1233–34.

Many of these collaborative efforts are facilitated by the National Association of Attorneys General (NAAG), a "nonpartisan national forum" providing "a community for attorneys general and their staff to collaboratively address issues . . . and resources to support attorneys general."[37] NAAG has devoted resources to supporting state AGs in special types of practice, such as Supreme Court litigation,[38] and has also developed a broad range of topic-specific working groups and task forces.[39] As one example, Professor Danielle Citron has explored the ways in which NAAG's Privacy Working Group helps facilitate collaboration among state AGs in substantive privacy law matters.[40]

Multistate actions are not without their challenges, however, only some of which the parties involved can manage. Coordinating dozens of states in enforcement actions or settlement proceedings may be unwieldy or impossible, so as a result, many multistate actions are led by one or a few states, with other states contributing resources as needed but not taking a leadership role.[41] Some scholars have expressed concern about the potential for overenforcement, including in situations when "states with weak claims . . . piggyback on other states' stronger legal claims."[42] In the case of amicus briefs, when particularly partisan issues arise, these issues may pit groups of states against each other,[43] altering the signaling function communicated when state AGs form a united front on a particular issue.[44]

37. *About the National Association of Attorneys General*, NAT'L ASS'N OF ATT'YS GEN. (2021), https://www.naag.org/about-naag [http://perma.cc/7PFZ-KC9U].

38. Clayton, *supra* note 13, at 540, 542; NOLETTE, *supra* note 14, at 34; NAT'L ASS'N OF ATT'YS GEN., *supra* note 14, at 333–35 (describing a clearinghouse implemented by NAAG that, among other things, assists states in finding other AGs to join amicus briefs).

39. NOLETTE, *supra* note 14, at 33–34 ("Other more recently created groups have included, among others, a Craigslist Working Group, an Internet Safety Task Force, a Committee on Financial Practices, and a State-Federal Task Force on Mortgage Enforcement.").

40. Citron, *supra* note 12, at 790–91.

41. Dishman, *supra* note 24, at 452–53. It is not clear that this organizational structure represents a weakness of multistate litigation. Indeed, it may often be an efficient division of labor that allows states with the strongest expertise, resources, and motivation to lead, while benefiting from the political optics of having a large number of signatories on their lawsuit.

42. *Id.* at 455.

43. Lemos & Quinn, *supra* note 13, at 1257–60 (reporting an increase in partisanship in AGs' amicus briefs since 2000); Gleason, *supra* note 13, at 266 (finding that ideology became a key predictor of whether AGs joined amicus briefs in the 2000s).

44. For a helpful discussion of this signaling or "catalyst" function of litigation, see Nora Freeman Engstrom & Robert L. Rabin, *Pursuing Public Health Through Litigation*, 73 STAN. L. REV. 285, 354 (2021).

2. The Ability to Use Litigation to Create Policy

In some cases, state AGs may bring lawsuits with the goal of obtaining monetary penalties for legal violations.[45] But state AGs often sue (and, specifically, bring multistate actions of the type described above) with the goal of creating policy by forcing the company or industry involved to the bargaining table.[46] As political scientist Paul Nolette has described, in these cases, "the AGs' goal is not to win in court but rather to use the threat of active litigation to achieve comprehensive out-of-court settlements with their litigation targets."[47] These settlements have the ability to force the targeted industries to adopt comprehensive new regulatory regimes beyond existing requirements, thus bypassing the difficulties of creating new legislation or regulations.[48]

Policy-creating litigation has been used effectively by multistate coalitions of state AGs to change behaviors in a wide range of industries. A settlement reached by the federal government and forty-nine state AGs with the nation's five largest mortgage servicers in the wake of the foreclosure crisis resulted in those servicers adopting important new homeowner protections against foreclosure going forward.[49] The Master Settlement Agreement signed by fifty-two state and territory AGs with the nation's four largest tobacco companies (discussed in more detail below) significantly restricted tobacco advertising and marketing, particularly regarding youth audiences.[50] Thirty-one state AGs reached a settlement with the three main credit reporting agencies in which those agencies agreed to make a range of changes to improve the accuracy of the credit reporting process and improve

45. Dishman, *supra* note 24, at 421, 449–50.

46. For a broader analysis of this phenomenon, see generally Matthew C. Turk, *Regulation by Settlement*, 66 U. KAN. L. REV. 259 (2017).

47. NOLETTE, *supra* note 14, at 23. Nolette also identifies the phenomenon of "policy-forcing litigation," in which AGs bring suits against federal agencies in an attempt "to force the federal government to take a more active regulatory approach"—particularly in the environmental context—and "policy-blocking litigation," in which AGs bring "legal challenges to regulatory actions by federal policymakers"—prominent in the environmental context as well, but also in other fields. *Id*. at 30–33. Although these strategies are important pieces of a state AG's toolkit, they are not our focus in this Article, which is aimed at lawsuits against companies in a regulated industry.

48. *Id.* at 22–23, 44–45, 91–92.

49. *Federal Government and State Attorneys General Reach $25 Billion Agreement with Five Largest Mortgage Servicers to Address Mortgage Loan Servicing and Foreclosure Abuses*, U.S. DEP'T OF JUST. (Feb. 9, 2012), http://www.justice.gov/opa/pr/federal-government-and-state-attorneys-general-reach-25-billion-agreement-five-largest [http://perma.cc/Z5KB-PP69] ("The agreement requires new servicing standards which will prevent foreclosure abuses of the past, such as robo-signing, improper documentation and lost paperwork, and create dozens of new consumer protections. The new standards provide for strict oversight of foreclosure processing, including third-party vendors, and new requirements to undertake pre-filing reviews of certain documents filed in bankruptcy court.").

50. *The Master Settlement Agreement*, NAT'L ASS'N OF ATT'YS GEN. (2021), http://www.naag.org/our-work/naag-center-for-tobacco-and-public-health/the-master-settlement-agreement [http://perma.cc/SE8H-4XFB].

their responsiveness to consumers.[51]

There are limitations to what policy-creating litigation can achieve, however. First, state AGs' ability to force companies to the bargaining table depends on the strength of the underlying legal tools, and the potential costs—both financial and otherwise—to the companies of simply defending the lawsuit. In some areas, state AGs' legal tools may be too weak or too difficult to exercise to create the conditions necessary for a policy-creating negotiation. There may be concerns regarding the lack of public scrutiny of the arrangements or the confidentiality of the negotiations supporting these settlements,[52] particularly if they enable defendants to avoid making public statements of wrongdoing.[53] More generally, scholars have critiqued state AG suits as having the potential to inadequately represent the interests of their state's citizens,[54] which may contribute to state AGs' willingness to reach settlements that may be insufficient in a range of ways.[55]

3. Federal-State Relationships and Federalism Implications

The federalist nature of our constitutional structure creates additional opportunities—and challenges—for state AGs. AGs may work not only with each other, but also with the federal government to conduct investigations and bring enforcement actions of various types. State AGs may also have the authority to enforce federal statutes, expanding the range of legal authorities at their disposal.[56] State AGs, who are generalists, may experience themselves as representing different constituencies or bringing different areas of expertise to the table when compared with specialist agency officials

51. Press Release, Off. of the Att'y Gen. of Ohio, Attorney General DeWine Announces Major National Settlement with Credit Reporting Agencies (May 20, 2015), http://www.ohioattorneygeneral.gov/Media/News-Releases/May-2015/Attorney-General-DeWine-Announces-Major-National-S [http://perma.cc/4JR3-Y36S]; *see also* Citron, *supra* note 12, at 779–80 (describing this and other state settlements involving credit reporting agencies, including settlements arising out of actions brought by individual states).

52. *See, e.g.*, Elysa M. Dishman, *Settling Data Protection Law: Multistate Actions and National Policymaking*, 72 ALA. L. REV. 839, 846 (2021). In some ways, this concern is the flip side of one of the strengths of policy-creating litigation: it can bypass the challenges associated with the creation of new legislation or regulation, as noted above. *See, e.g.*, Turk, *supra* note 46, at 318.

53. *See* Turk, *supra* note 46, at 315; Urska Velikonja, *Securities Settlements in the Shadows*, 126 YALE L.J.F. 124, 128–29 (2016). These concerns may be more or less acute depending on the type of settlement involved: regulatory settlements (in administrative proceedings) may be able to escape review by third parties entirely, while settlements filed in federal court often need to be approved by the presiding judge. Velikonja, *supra*, at 128; *see also* SEC v. Citigroup Glob. Mkts., Inc., 827 F. Supp. 2d 328, 330 (S.D.N.Y. 2011) (rejecting the proposed settlement); Zachary Kouwe, *Judge Rejects Settlement Over Merrill Bonuses*, N.Y. TIMES (Sept. 14, 2009), http://www.nytimes.com/2009/09/15/business/15bank.html [http://perma.cc/V5PQ-3R2G].

54. Lemos, *Aggregate Litigation*, *supra* note 24, at 491.

55. *Id*. at 525.

56. Lemos, *State Enforcement*, *supra* note 24, at 700.

as well.[57] State AGs' generalist practice plus the sheer number of state AGs' offices may also make it more difficult for regulated industries to evade enforcement actions through regulatory capture or other forms of influence on the federal regulator alone.[58]

Federal law commonly empowers state AGs to bring enforcement actions in situations involving consumer protection laws of various types.[59] For instance, the Dodd-Frank Wall Street Reform and Consumer Protection Act authorizes state AGs to enforce its federal consumer protection laws.[60] As explored by Professor Citron, the Federal Trade Commission (FTC) in particular not only supported the passage of state Unfair and Deceptive Acts and Practices (UDAP) laws,[61] but also has worked with state AGs to enforce consumer protection laws, especially in the privacy context.[62]

Federalism also may create significant challenges for state AGs, however.[63] Perhaps most obviously, federal laws or regulations may preempt states from passing their own laws in a particular area or may preempt state AGs from bringing enforcement actions in a particular area.[64] Some scholars have expressed concern about overlapping enforcement actions, on various grounds. One set of concerns focuses on the potential for overlapping enforcement actions to result in excessive, inefficient overenforcement,[65] particularly where the addition of so many different state regulators to existing federal authority runs the risk of creating a one-way ratchet toward

57. *Id*. at 701.

58. *Id*. at 702–03; *see also* Citron, *supra* note 12, at 803–04; Mark Totten, *The Enforcers & the Great Recession*, 36 CARDOZO L. REV. 1611, 1658 (2015) ("No individual state AG is per se resistant to capture . . . but understood collectively it is likely that at least a few states will act. Resistance is a feature of the whole, not any one part.").

59. For a comprehensive treatment of the issue, see Lemos, *State Enforcement*, *supra* note 24. *See also* Widman & Cox, *supra* note 13 (exploring issues in consumer-protection law enforcement).

60. Dodd-Frank Wall Street Reform and Consumer Protection Act, 12 U.S.C. § 5552.

61. Citron, *supra* note 12, at 791. These laws are sometimes colloquially referred to as "baby FTC Act[s]," as they are intended to create analogous state causes of action to those established by the federal law. *See, e.g.*, J. THOMAS ROSCH, DECEPTIVE AND UNFAIR ACTS AND PRACTICES PRINCIPLES: EVOLUTION AND CONVERGENCE, FED. TRADE COMM'N (2007).

62. Citron, *supra* note 12, at 792–93.

63. Some have argued that state AGs' efforts to engage in impact litigation may even run counter to important justifications in support of federalism. *See* Claire McCusker, *The Federalism Challenges of Impact Litigation by State and Local Government Actors*, 118 YALE L.J. 1557, 1561 (2009).

64. *See generally* Trevor W. Morrison, *The State Attorney General and Preemption*, *in* PREEMPTION CHOICE: THE THEORY, LAW, AND REALITY OF FEDERALISM'S CORE QUESTION 81 (William W. Buzbee ed., 2009); *see also* Citron, *supra* note 12, at 801–03. *But see* Dishman, *supra* note 24, at 463–64 (arguing that preemption is a potential solution to reduce problems of overenforcement or piggybacking in a multi-enforcer system).

65. Dishman, *supra* note 24, at 421, 458–59; Lemos, *State Enforcement*, *supra* note 24, at 754 ("State enforcement also may be undesirable in areas where the optimal level of enforcement lies somewhere below maximum enforcement."); Lemos, *State Enforcement*, *supra* note 24, at 753–61 (summarizing and critiquing concerns about overenforcement).

greater enforcement.[66] Other concerns focus on the potential for one state's enforcement to spill over and impact conduct in other states, posing concerns that are more in tension with key principles of federalism.[67]

B. IMPORTANT STATE AG ACTIVITIES IN THE HEALTHCARE CONTEXT

State AGs have previously engaged in a substantial number of important litigation efforts in the health arena. Although a full exploration of these examples is outside the scope of this Article,[68] three examples—involving tobacco, the average wholesale price (AWP) of prescription drugs, and opioids—provide especially useful contexts for this Article's analysis. These three examples not only embody the above-described themes in the existing state AG literature (multistate collaborations, policy-creating litigation, and federalism implications) but also illustrate some of the complexities states may encounter when pursuing litigation against large industries in the healthcare context, including the pharmaceutical industry.

1. Tobacco Litigation

In the wake of hundreds of unsuccessful private lawsuits brought against the tobacco manufacturers for the harms their products had caused,[69] Michael Moore of Mississippi was the first state AG to file suit against the industry in 1994. Instead of focusing on the health-related harms experienced by individuals, Moore focused on the financial harms smoking had caused to the state, attempting to recover costs Mississippi's Medicaid program had incurred in treating smoking-related illnesses.[70] Unlike at least some of today's state AG actions, Moore's suit did not begin as a multistate effort.

66. Lemos, *State Enforcement*, *supra* note 24, at 749.

67. Citron, *supra* note 12, at 762; Jason Lynch, Note, *Federalism, Separation of Powers, and the Role of State Attorneys General in Multistate Litigation*, 101 COLUM. L. REV. 1998, 1998–2001 (2001) (discussing claims that state AGs' litigation violates principles of federalism). Empirical evidence suggests that at least for consumer protection laws, state enforcement is more likely to complement federal enforcement than conflict with it. *See* Widman & Cox, *supra* note 13, at 81–88; Lemos, *State Enforcement*, *supra* note 24, at 760–61.

68. For broad discussions, see, for example, NOLETTE, *supra* note 14, at 66–87 (discussing litigation involving prescription drug marketing); Rutkow & Teret, *supra* note 15 (discussing several important efforts).

69. Engstrom & Rabin, *supra* note 44, at 295 ("From the 1950s through the early 1990s, plaintiffs filed hundreds of personal injury and wrongful death claims against the tobacco industry. Yet no plaintiff—not one—prevailed."). Although some of these lawsuits were brought by individual smokers, others were brought by private organizations (such as unions) attempting to bring claims that were more like those of the state AGs. Courts in those cases, however, ruled that the private organizations' injuries "were too remote" to establish standing. John C. Coffee, Jr., *"When Smoke Gets in Your Eyes": Myth and Reality About the Synthesis of Private Counsel and Public Client*, 51 DEPAUL L. REV. 241, 241–42 (2001).

70. Rutkow & Teret, *supra* note 15, at 280; *see also* Hanoch Dagan & James J. White, *Governments, Citizens, and Injurious Industries*, 75 N.Y.U. L. REV. 354, 363 (2000).

But other states soon followed Moore, with over forty state AGs filing suit against tobacco manufacturers by 1997.[71] Four states would settle their lawsuits individually,[72] but in 1998, the remaining states and territorial AGs—fifty-two in all—signed the Master Settlement Agreement (MSA) with the four largest tobacco companies.[73]

The MSA recovered much of the healthcare costs state Medicaid programs had incurred in treating smoking-related illnesses, sending more than $200 billion back to the states.[74] But it also had a significant policy-creating function.[75] The MSA was designed for the purpose of "reduc[ing] smoking in the [United States], especially in youth,"[76] and included a broad range of provisions to restrict the advertising and marketing of tobacco. Companies could no longer use cartoons in their advertising, sponsor events with significant youth audiences, promote their products in media, or take other actions targeting youth.[77] Ultimately, the state AGs created a new national regulatory system for tobacco companies, without any legislative or federal government involvement.[78] The MSA also appears to have had important impacts on rates of youth smoking—for instance, because it was associated with increases in the price of cigarettes.[79]

The MSA also served as an important catalyst for the expansion of multistate AG initiatives. Scholars argue that both the success of the MSA and its "unprecedented"[80] degree of multistate collaboration helped "generate a cascade in which each successful settlement provided momentum for further settlements."[81] State AGs built on their experience

71. Rutkow & Teret, *supra* note 15, at 280–81.
72. *Id*. (listing the four states as Florida, Minnesota, Mississippi, and Texas).
73. *The Master Settlement Agreement*, *supra* note 50.
74. NOLETTE, *supra* note 14, at 23.
75. *See id*.
76. *The Master Settlement Agreement*, *supra* note 50.
77. *See id*.
78. NOLETTE, *supra* note 14, at 23–24. As one state AG put it, "there are many things that this agreement accomplishes, particularly in the public health arena, that we could not achieve through our lawsuit." Rutkow & Teret, *supra* note 15, at 282.
79. *See* ALLAN M. BRANDT, THE CIGARETTE CENTURY: THE RISE, FALL, AND DEADLY PERSISTENCE OF THE PRODUCT THAT DEFINED AMERICA 434–35 (2007). To be sure, tobacco remains a significant public health problem, even with these reduced levels. *See, e.g.*, *Smoking & Tobacco Use: Tobacco-Related Mortality*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 28, 2020), http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm [http://perma.cc/9AKR-8DC6] (noting that smoking is estimated to cause more than 480,000 deaths per year in the United States).
80. Richard P. Ieyoub & Theodore Eisenberg, *State Attorney General Actions, the Tobacco Litigation, and the Doctrine of* Parens Patriae, 74 TUL. L. REV. 1859, 1860 (2000); *see also id*. at 1861 ("[M]uch of the success was based on the fact that the attorneys general acted in concert.").
81. NOLETTE, *supra* note 14, at 214.

with the tobacco industry to "target the practices of many other industries,"[82] particularly including the types of multistate actions and settlements mentioned above involving mortgage servicers and credit reporting agencies.[83]

There have also been strong criticisms of the MSA. Perhaps the most trenchant concerns states' use of their $200 billion recovery. Although the intention was for states to use these funds for health-related initiatives, the MSA itself did not formally restrict the funds for those purposes, and many states used the money to balance their general budgets or for other purposes.[84] Others have criticized the use of private counsel on a contingent-fee basis by many state AGs,[85] including the private lawyers' focus on monetary recovery as compared to regulatory changes.[86] In considering the policy-creating aspect of the MSA, Nolette has inquired whether the agreement's inclusion of the entire industry might "limit the prospects for future regulatory innovation" as the settlement "becomes locked in place," as compared to a piecemeal settlement approach providing for more regulatory and legal experimentation.[87]

2. AWP Litigation

Another important state AG initiative in the healthcare context focused directly on prescription drug pricing. The target here was the use of the Average Wholesale Price (AWP) as a reimbursement benchmark, which AGs claimed was fraudulent under state and federal law.[88] In its role as an insurer through the Medicare and Medicaid programs, the government typically does not directly reimburse pharmaceutical companies for their products. Instead, it pays providers that dispense drugs (including hospitals, physicians, and pharmacies) according to the AWP. Those providers purchase the products from pharmaceutical companies (or intermediaries).

Although the AWP was intended to mirror the average price at which

82. *Id.* at 24.

83. *See* Dishman, *supra* note 24, at 448.

84. Lemos, *State Enforcement*, *supra* note 24, at 734; Engstrom & Rabin, *supra* note 44, at 343.

85. *See, e.g.*, Coffee, *supra* note 69, at 242; Margaret H. Lemos, *Privatizing Public Litigation*, 104 GEO. L.J. 515, 519–21 (2016). The controversial question of the amount of fees owed to private attorneys after the MSA was even the subject of a congressional hearing, in which members of Congress questioned whether "public policy considerations should prevent the recovery of grossly excessive fee awards." *Attorneys' Fees and the Tobacco Settlement: Hearing Before the Subcomm. on Cts. & Intell. Prop. of the Comm. on the Judiciary*, 105th Cong. 2 (1997).

86. NOLETTE, *supra* note 14, at 100.

87. *Id.* at 94.

88. This litigation followed on a longer history of using fraud statutes to address business practices that inflated costs for the Medicaid program. *See* NAT'L ASS'N OF ATT'YS GEN., *supra* note 15, at 291–98 (describing AGs' history of action against Medicaid fraud).

providers made these purchases, policymakers became concerned that the AWP represented an inflated price because it did not reflect discounts obtained by the providers.[89] As pharmaceutical industry observers phrased it, AWP stood for "ain't what's paid."[90] Policymakers worried that the "spread" between the higher, reimbursed AWP price and the lower, actual purchase price was causing a range of problems within the drug pricing ecosystem, including driving up overall spending and encouraging providers to prescribe drugs with high spreads.[91]

Initially, there were federal legislative efforts to reform the system and eliminate the use of the AWP as a benchmark for reimbursement, particularly toward the end of the Clinton administration.[92] But after these efforts failed under lobbying pressure, a broader range of actors joined in efforts to investigate and bring lawsuits regarding the use of the AWP. Many of these suits were brought by state AGs on their own, in response to concerns about overpayments in state Medicaid programs.

Between 2000 and 2013, twenty-seven state AGs brought lawsuits, sometimes against a single defendant and sometimes against dozens of them, alleging that the use of AWP as a basis for reimbursement in state Medicaid programs was fraudulent.[93] These state AGs did not act alone, however. They often collaborated with federal prosecutors on these investigations.[94] And because the legal authority underlying many of these investigations was the False Claims Act (FCA),[95] its qui tam provisions (authorizing private actors to sue on the government's behalf and retain a portion of the suit's proceeds)[96] incentivized plaintiffs' firms to investigate and bring AWP claims of their own.[97]

The nature of the FCA claims strongly motivated pharmaceutical firms to settle rather than go to trial because one potential consequence of a criminal fraud verdict against the firms would be exclusion from Medicare

89. As Nolette has explained, "the AWP is similar to the sticker price for vehicles in the automobile industry." NOLETTE, *supra* note 14, at 47.

90. Patrick Mullen, *The Arrival of Average Sales Price*, 4 BIOTECH. HEALTHCARE 48, 48, 53 (2007).

91. NOLETTE, *supra* note 14, at 47.

92. *See id.* at 48–49.

93. *See id.* at 56, table 3.1.

94. *See id.* at 49–51.

95. 31 U.S.C. § 3729 (2012).

96. David Freeman Engstrom, *Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of Qui Tam Litigation Under the False Claims Act*, 107 NW. U. L. REV. 1689, 1706–07 (2013).

97. Hagens Berman, *Pharmaceutical AWP Litigation*, HAGENS BERMAN (2020), http://www.hbsslaw.com/cases/pharmaceutical-average-wholesale-price-litigation [http://perma.cc/YTP7-HHDU].

and Medicaid,[98] a serious financial penalty sometimes referred to as a "corporate death sentence."[99] As a result, states (and private litigants) have been able to recover significant amounts through settlements. One of the earliest settlements, in which the federal government brought charges against TAP Pharmaceuticals for its pricing of a single product, the cancer drug Lupron, yielded an $875 million settlement in October 2001.[100] At the time, that was the largest health care fraud settlement in history.[101]

But the AWP settlements were not only monetary. Like the tobacco settlement, they often functioned as policy-creating tools themselves.[102] In January 2001, Bayer reached an AWP settlement with forty-five states and the federal government that not only required Bayer to pay $14 million,[103] but also to report additional information to both the state and federal governments about the "average sale price" (ASP) of its products, a term defined specifically in the settlement agreement to include the types of customary discounts left out of AWP reporting.[104]

Future settlements were able to build on the Bayer agreement. The later settlement with TAP over the pricing of Lupron similarly included an ASP reporting requirement, as well as supervision of TAP's sales and marketing practices for seven years.[105] It also empowered the Centers for Medicare & Medicaid Services (CMS) and state Medicaid programs to use the ASP data rather than AWP information to set reimbursement rates for TAP's products[106]—a goal that legislative efforts in the 1990s had tried but failed

98. *See* 42 U.S.C. § 1320a-7 (2012).

99. Engstrom, *supra* note 96, at 1695.

100. *TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay $875 Million to Settle Charges*, U.S. DEP'T OF JUST. (Oct. 3, 2001), http://www.justice.gov/archive/opa/pr/2001/October/513civ.htm [http://perma.cc/5BC9-Q2UD]. Roughly $95 million of the settlement went to the whistleblowers, as specified under the FCA. *Id*.; Melody Petersen, *2 Drug Makers to Pay $875 Million to Settle Fraud Case*, N.Y. TIMES (Oct. 4, 2001), http://www.nytimes.com/2001/10/04/business/2-drug-makers-to-pay-875-million-to-settle-fraud-case.html [http://perma.cc/KTB7-WP4U].

101. NOLETTE, *supra* note 14, at 53.

102. Ohio Attorney General Betty Montgomery, the first leader of NAAG's Pharmaceutical Task Force, stated that "our major task is to change behavior. Money is incidental." *Id*. at 58.

103. Press Release, U.S. Dep't of Just., Bayer to Pay $14 Million to Settle Claims for Causing Providers to Submit Fraudulent Claims to 45 State Medicaid Programs (Jan. 23, 2001), http://www.justice.gov/archive/opa/pr/2001/January/039civ.htm [http://perma.cc/NU44-HHAX].

104. U.S. DEP'T HEALTH & HUMAN SERVS.: OFF. INSPECTOR GEN., CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND BAYER CORPORATION 11–12 (2001), https://oig.hhs.gov/fraud/cia/agreements/BayerCorporation120301.PDF [https://perma.cc/FMH7-4KH8].

105. U.S. DEP'T HEALTH & HUMAN SERVS.: OFF. INSPECTOR GEN., CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND TAP PHARMACEUTICAL PRODUCTS INC. 2, 9 (2001), https://oig.hhs.gov/fraud/cia/agreements/tap_pharmaceutical_products_92801.pdf [https://perma.cc/ELQ2-RZYB].

106. *Id*. at 11.

to accomplish. Dozens of additional follow-on lawsuits and settlements accomplished these same goals, on a firm-by-firm, state-by-state basis,[107] until Congress ultimately succeeded in adopting the use of the ASP through legislation.[108]

Like the tobacco litigation, the AWP litigation initially featured individual AGs filing their own lawsuits in state courts. But unlike that litigation, it did not culminate in a single, industry-wide settlement with nearly all states. It therefore allowed for greater regulatory experimentation.[109] However, there was still significant interstate coordination on the AWP litigation, facilitated by NAAG's Pharmaceutical Pricing Task Force. Established in 2002, the Task Force aimed to "encourage communication and collaboration among the states, federal enforcement agencies, and the private bar."[110] Information-sharing through NAAG working groups would later come to support additional multistate investigations and lawsuits against the pharmaceutical industry, including in the pharmaceutical advertising context.[111]

Also like the tobacco litigation, private counsel continued to play a significant role in the AWP litigation. Because of the qui tam nature of the FCA, it would have been difficult to exclude them entirely, even if states had wanted to. States went into the AWP litigation cognizant of the criticism of the use of contingent-fee arrangements with private counsel in the MSA.[112] In the AWP context, Nolette has argued that states' efforts to work with a small number of plaintiffs firms, including Hagens Berman and Beasley Allen, "made it easier to achieve consistency across the states"[113] in the AWP litigation and therefore helped coordinate the legal arguments around the fraudulent nature of AWP reimbursement. This coordination helped to change the political environment for AWP reimbursement, supporting the subsequent Congressional shift to ASP reimbursement.

3. Opioid Litigation

State AG efforts to investigate and bring suits against opioid manufacturers and others in their distributional chain are the most recent example of large-scale AG involvement in healthcare litigation, and many of

107. NOLETTE, *supra* note 14, at 53–55, 58.
108. *Id*. at 62; 42 U.S.C. § 1395w-3a (2012).
109. NOLETTE, *supra* note 14, at 93–94. To be sure, there were multistate settlements, as with the Bayer settlement described above. A private class action brought against twenty-eight drug companies was also consolidated with several state AG lawsuits. *Id*. at 57–58, 63.
110. *Id*. at 56.
111. *Id*. at 57, 73.
112. *Id*. at 100.
113. *Id*. at 57.

these cases are still ongoing. These lawsuits were a response to the nationwide opioid epidemic, which has only grown over time (to nearly 50,000 deaths in 2019).[114] The first wave of these lawsuits began in the early 2000s. Like the initial lawsuits against the tobacco manufacturers, these lawsuits were primarily brought on behalf of individuals who had died of opioid overdoses. They mostly targeted Purdue Pharmaceuticals, the manufacturer of OxyContin, alleging that Purdue had failed to take care in designing, marketing, and labeling the product, particularly downplaying its addictive qualities.[115] Also like the individual suits against the tobacco companies, these lawsuits failed, largely due to weaknesses in the legal doctrines underlying their claims.[116]

Darrell McGraw Jr., West Virginia's AG, was the first AG to bring suit against Purdue in June 2001.[117] West Virginia's *parens patriae* suit included several causes of action closely resembling those brought in the individual suits,[118] but the state's posture allowed it to avoid some of Purdue's defenses against those individual claims, and the state may have been able to marshal its resources more effectively.[119] As a result, West Virginia's AG was able to succeed where individual suits had failed, and in 2004, Purdue ultimately settled for $10 million, though with no admission of fault.[120] Encouraged by the settlement, twenty-six states and the District of Columbia brought suit against Purdue on similar legal grounds.[121] Purdue settled the case for $19.5 million in May 2007, but also agreed to make a number of policy changes, including restrictions on its marketing, staff training, and compensation

114. *Overdose Death Rates*, NAT'L INST. ON DRUG ABUSE (Jan. 29, 2021), http://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates [http://perma.cc/4MKF-XWR8].

115. Engstrom & Rabin, *supra* note 44, at 310–11.

116. *Id*. at 311–12 (noting legal issues involving defective-design claims, the learned intermediary doctrine, causation, and the wrongful-conduct rule, among others). The private class action suits brought on behalf of people who had taken OxyContin were generally not more successful, often failing to meet the class certification requirements. *Id*. at 313.

117. Engstrom & Rabin, *supra* note 44, at 314; Landon Thomas Jr., *Maker of OxyContin Reaches Settlement with West Virginia*, N.Y. TIMES (Nov. 6, 2004), http://www.nytimes.com/2004/11/06/business/maker-of-oxycontin-reaches-settlement-with-west-virginia.html [http://perma.cc/AEX3-JCAQ]; Complaint, West Virginia *ex rel.* McGraw v. Purdue Pharma L.P., No. 01-C-137 (W. Va. Cir. Ct. June 21, 2001).

118. Richard C. Ausness, *The Role of Litigation in the Fight Against Prescription Drug Abuse*, 116 W. VA. L. REV. 1117, 1148 (2013).

119. *Id*. at 1121 ("[G]overnmental litigants are not subject to the conduct-based defenses that have been invoked to defeat individual plaintiffs in product misuse cases.").

120. Thomas, *supra* note 117. This "comparatively small sum" may have been due to the perceived weaknesses in the legal doctrines underlying the case. Ausness, *supra* note 118, at 1149.

121. Ausness, *supra* note 118, at 1149.

systems.[122] Kentucky's October 2007 suit was the final civil[123] public action brought against Purdue in this first wave of litigation,[124] settling in December 2015 for $24 million.[125]

The second wave of litigation, beginning in 2014, is much broader in scope. These lawsuits now target a large number of opioid manufacturers, as well as distributors (including AmerisourceBergen, Cardinal Health, and McKesson), retailers (including Walmart, Walgreens, Costco Wholesale, and CVS), and consulting firms (McKinsey & Company).[126] These suits have added new causes of action, including claims that the distributors and retailers have violated their obligations under the Controlled Substances Act.[127] Separately, approximately 2,700 cases brought by local governments (such as cities and counties), Native American tribes, and hospitals[128] proceeded in consolidated fashion in a massive federal multidistrict litigation (MDL) action, still ongoing[129] and currently pending in the Northern District of Ohio.[130] Several hundred cases also remain pending at the state level, including cases filed by state AGs. As with the tobacco litigation, Mississippi

122. *Id.*; Shannon Henson, *Purdue Pharma Settles with States over OxyContin*, LAW360 (May 8, 2007), http://www.law360.com/articles/24311/purdue-pharma-settles-with-states-over-oxycontin [http://perma.cc/WBD6-VD3P].

123. Federal prosecutors were pursuing simultaneous criminal investigations of Purdue, which included $600 million in fines from the company itself. Engstrom & Rabin, *supra* note 44, at 315.

124. *Id*. at 316 (noting that the lawsuit also included Abbott as a defendant); Ausness, *supra* note 118, at 1150 (noting that these legal grounds were broader, including claims that "the defendants' wrongful marketing and promotion practices caused the state to pay for unnecessary prescriptions and provide medical services that would not have otherwise been required" and including Medicaid and false advertising claims).

125. Settlement Agreement and General Release at 7, Commonwealth *ex rel.* Conway v. Purdue Pharma, L.P., No. 07–CI–01303 (Ky. Cir. Ct. 2015); *see also* Ausness, *supra* note 118, at 1150–56 (describing several of the procedural reasons for the delay).

126. Engstrom & Rabin, *supra* note 44, at 316–18; Michael Forsythe & Walt Bogdanich, *McKinsey Settles for Nearly $600 Million over Role in Opioid Crisis*, N.Y. TIMES (Nov. 5, 2021), http://www.nytimes.com/2021/02/03/business/mckinsey-opioids-settlement.html [https://perma.cc/SK35-3UEG].

127. Engstrom & Rabin, *supra* note 44, at 318. Several Controlled Substances Act claims have also been brought by the federal government and have been settled. *See* Michelle Llamas, *Opioid Lawsuits*, DRUGWATCH (Sept. 24, 2021), http://www.drugwatch.com/opioids/lawsuits [http://perma.cc/7SUH-TX3A] (listing settlements by Mallinckrodt, McKesson, Costco Wholesale, and Cardinal Health).

128. Engstrom & Rabin, *supra* note 44, at 319. Some such suits are also proceeding individually or in smaller groupings of plaintiffs. For example, a lawsuit brought by three California counties recently resulted in a verdict for defendants; an appeal is planned. Robert Jablon & Donald Thompson, *Drug Companies Win in California Opioid Crisis Lawsuit*, ASSOCIATED PRESS (Nov. 2, 2021), http://apnews.com/article/business-health-lawsuits-california-los-angeles-308ad46ecb6e08d57fc08ed78870c187 [https://web.archive.org/web/20211103010135/https://apnews.com/article/business-health-lawsuits-california-los-angeles-308ad46ecb6e08d57fc08ed78870c187].

129. Many defendants have resisted efforts to settle the case. *See, e.g.*, Jeff Overley, *Opioid MDL Judge Picks New Bellwethers, Denies Retaliating*, LAW360 (Apr. 7, 2021, 10:32 PM), http://www.law360.com/articles/1373167/opioid-mdl-judge-picks-new-bellwethers-denies-retaliating [https://perma.cc/9ZBL-EXFM].

130. Jan Hoffman, *Can This Judge Solve the Opioid Crisis?*, N.Y. TIMES (Mar. 5, 2018), http://www.nytimes.com/2018/03/05/health/opioid-crisis-judge-lawsuits.html [http://perma.cc/X479-ZLGK].

was again the first to file, and it has been followed by nearly every state.[131]

Some of these cases have been resolved or are nearing completion, and where states have obtained settlements, they have typically combined monetary awards with provisions requiring the companies to change their conduct going forward. A few of the evolving settlements are especially notable for their scale. Johnson & Johnson settled with Texas and New York for $297 million and $263 million, respectively.[132] Another manufacturer, Mallinckrodt, has entered into a global settlement framework with nearly all states,[133] in which the manufacturer would owe $1.6 billion but also would be subject to restrictions on marketing and other practices going forward.[134] Forty-seven states, the District of Columbia, and five territories reached a $573 million settlement with McKinsey & Company; Washington and West Virginia also reached separate settlements with the firm.[135] New York has reached a $1 billion settlement with the three distributors: McKesson, Cardinal Health, and AmerisourceBergen.[136] In July 2021, a deal was announced that cleared the way for a $4.5 billion global settlement for Purdue Pharma.[137] Most significantly, a $26 billion global settlement was

131. Engstrom & Rabin, *supra* note 44, at 319; Grant Schulte & Geoff Mulvihill, *Nebraska's AG Is Lone Holdout in Pursuing Opioid Cases*, ASSOCIATED PRESS (June 12, 2019), http://apnews.com/article/prescription-opioids-wv-state-wire-ne-state-wire-us-news-ap-top-news-2ca3e7d1501643b7aea0feeb2bed3929 [http://perma.cc/T8WL-G7MP].

132. Nate Raymond, *J&J Strikes $297 Million Texas-Specific Opioid Settlement*, REUTERS (Oct. 26, 2021, 12:50 PM), http://www.reuters.com/legal/litigation/jj-strikes-297-million-texas-specific-opioid-settlement-2021-10-26; *Johnson & Johnson Reaches Opioid Settlement Agreement with New York State Consistent with Terms of Previously Announced Broader Settlement Agreement in Principle*, JOHNSON & JOHNSON (June 26, 2021), http://www.jnj.com/johnson-johnson-reaches-opioid-settlement-agreement-with-new-york-state-consistent-with-terms-of-previously-announced-broader-settlement-agreement-in-principle [https://perma.cc/MGR5-VYXX].

133. Mallinckrodt Pharmaceuticals, *Mallinckrodt Provides Update on Proposed Global Opioid Settlement*, MALLINCKRODT PHARMS. (Mar. 11, 2020), http://mallinckrodt.com/about/news-and-media/news-detail/?id=26566 [http://perma.cc/VNN8-DH2Z].

134. Press Release, Off. of the Att'y Gen. of Connecticut, Attorney General Tong Announces $1.6 Billion Settlement with Opioid Manufacturer Mallinckrodt (Oct. 12, 2020), http://portal.ct.gov/AG/Press-Releases/2020-Press-Releases/AG-Tong-Announces-Settlement-with-Opioid-Manufacturer-Mallinckrodt [http://perma.cc/L77Z-AY2X]. Although this and other settlement proposals would impose policy-creating requirements on the different defendants, some scholars have expressed pessimism about the ability of ideas like these to either ameliorate the current overdose epidemic or prevent the next one. *See, e.g.*, Nicolas P. Terry, *The Opioid Litigation Unicorn*, 70 S.C. L. REV. 637, 638–39, 663–66 (2019).

135. Forsythe & Bogdanich, *supra* note 126.

136. Sara Randazzo & Jared S. Hopkins, *Opioid Settlement of $26 Billion Between Drug Companies, States Expected This Week*, WALL ST. J. (July 19, 2021), http://www.wsj.com/articles/26-billion-opioid-settlement-among-states-and-drug-industry-expected-this-week-11626745448 [http://perma.cc/QB5X-KSKG].

137. Specifically, fifteen states agreed to drop their opposition to a proposed bankruptcy reorganization plan for Purdue in exchange for additions to a proposed settlement—discussed in more detail *infra* note 142—to be voted on by more than 3,000 plaintiffs with pending claims against the company. Eight states continued to oppose the bankruptcy plan. Jan Hoffman, *15 States Reach a Deal with Purdue Pharma, Advancing a $4.5 Billion Opioids Settlement*, N.Y. TIMES (July 8, 2021), http://www.nytimes.com/2021/07/08/health/purdue-pharma-opioids-settlement.html [http://perma.cc/M

announced the same month between states and Johnson & Johnson and the three distributors.[138] The funds would be earmarked for opioid treatment and related services, and the distributors would create a new clearinghouse to strengthen their ability to detect suspicious opioid orders.[139]

In contrast to the collaborative approach state AGs seem to have used in previous litigation efforts, in the opioid context, state AGs appear to be more at odds with both local governments and the federal government. Many of the local governments in the MDL, represented by private counsel working on contingency fees, have sought a settlement that would allow them to secure funds directly, rather than relying on the state to disburse any eventual settlement money to them. This concern is founded on the local governments' experience with the tobacco MSA, which, as noted above, often did not direct money to smoking prevention or treatment programs.[140] But in 2019, a bipartisan group of thirty-nine state AGs opposed the local governments' proposed settlement, with the Ohio AG writing to the judge overseeing the MDL and arguing that the local governments' push created both "structural and constitutional" concerns, and that it is the responsibility of the states, not local governments, to secure a binding national settlement.[141] The dispute between the state and federal governments, most recently over Purdue's bankruptcy deal with the federal government, involves similar arguments.[142]

HQ4-KCFV].

138. *See* Jan Hoffman, *Drug Distributors and J.&J. Reach $26 Billion Deal to End Opioid Lawsuits*, N.Y. TIMES (July 21, 2021) [hereinafter Hoffman, *Drug Distributors*], http://www.nytimes.com/2021/07/21/health/opioids-distributors-settlement.html [http://perma.cc/WCP5-6QNC]. Purdue Pharma was formally dissolved on September 1, 2021, after a bankruptcy court approved the controversial settlement. Jan Hoffman, *Purdue Pharma Is Dissolved and Sacklers Pay $4.5 Billion to Settle Opioid Claims*, N.Y. TIMES (Sept. 1, 2021), http://www.nytimes.com/2021/09/01/health/purdue-sacklers-opioids-settlement.html [https://perma.cc/CHG4-TCKS].

139. Hoffman, *Drug Distributors*, *supra* note 138.

140. Jan Hoffman, *States Clash with Cities over Potential Opioids Settlement Payouts*, N.Y. TIMES (Aug. 5, 2019), http://www.nytimes.com/2019/08/05/health/opioids-litigation-settlement.html [http://perma.cc/7LZM-EXC5].

141. *Id.*; *see also* Letter from Ohio Att'y Gen. Dave Yost to the Hon. Dan Aaron Polster (July 23, 2019).

142. In October 2020, the Department of Justice announced a settlement agreement with Purdue that would restructure the manufacturer as a public benefit company, in which it would be publicly owned and continue to sell OxyContin. Brian Mann, *Purdue Pharma Reaches $8B Opioid Deal with Justice Department over OxyContin Sales*, NAT'L PUB. RADIO (Oct. 21, 2020), http://www.npr.org/2020/10/21/926126877/purdue-pharma-reaches-8b-opioid-deal-with-justice-department-over-oxycontin-sale [http://perma.cc/VDC2-93VR]. Twenty-five state AGs initially opposed the settlement on the grounds that "[a] business that killed thousands of Americans should not be associated with government," and that a range of concerning consequences might follow from that reorganization. Letter from State Att'ys Gen. to Att'y Gen. of the U.S. William Barr (Oct. 14, 2020) ("[T]he business should be sold to private owners, so the government can enforce the law against it with the same impartiality as for any other company."). An additional source of opposition to the deal was that it allowed company officials and members of the Sackler family, who own the company, to avoid prison time. *See* Letter from Members of Cong. to Att'y

Although far more could be said about the opioid, AWP, and tobacco litigation as exemplars of the power of state AG activity in the public health space, the key points for our purposes can be summarized briefly. First, these lawsuits all imparted to state AGs experience in mobilizing multistate collaborations for purposes of litigation, and also showed the potential for such collaborations to be more than the sum of their parts. Second, the settlements demonstrated not only the financial upside for states of investing in complex, long-term litigation but also the potential to use settlement agreements to create policy. In the case of the AWP litigation, for instance, the settlement initially circumvented legislative failures to adopt the ASP as the basis for reimbursing providers, and later served as a catalyst for Congress to formally impose that new rule. In the case of tobacco and opioids, settlements and judgments required companies to take steps that no agency or legislature had or could have required them to do (for example, imposing restrictions on tobacco advertising that may have gone beyond what the First Amendment permits, and expanding surveillance of opioid shipments beyond the requirements of the Controlled Substances Act) and funded new programs (such as a large-scale neonatal abstinence treatment program at Oklahoma hospitals[143]). Third, the lawsuits illustrated the complex state-federal dynamics that can arise in litigation. In the opioid litigation, for example, states and the federal government pursued parallel actions synergistically, but at times clashed over strategy, as in the example of the Purdue bankruptcy plan. More generally, in all three pieces of litigation, the states were able to leverage federal statutes as causes of action to vindicate harms within their borders while also bringing state-law causes of action.

This history of successful collaboration sets up state AGs well to tackle the complex problem of prescription drug affordability using antitrust and consumer-protection law. With this context in mind, we now turn to our empirical exploration of recent AG actions in that arena.

II. STUDY METHODS

Our approach blended two study methods: (1) a scoping review of state AG activities relating to drug affordability between 2016 and 2020; and (2) a key informant interview study of attorneys in state AG offices. We describe the methodology employed for each in this Part.

Gen. Barr (Oct. 15, 2020). A judge approved the federal settlement over these objections. Brian Mann, *Federal Judge Approves Landmark $8.3 Billion Purdue Pharma Opioid Settlement*, NAT'L PUB. RADIO (Nov. 17, 2020), http://www.npr.org/2020/11/17/936022386/federal-judge-approves-landmark-8-3-billion-purdue-pharma-opioid-settlement [http://perma.cc/HFD5-E4H5].

143. *See* Judgment After Non-Jury Trial at 12, Oklahoma *ex rel.* Hunter v. Purdue Pharma, No. CJ-2017-816, 2019 Okla. Dist. LEXIS 3486, at *17 (Cnty. Dist. Ct. Aug. 26, 2019).

A. SCOPING REVIEW

In addition to reviewing scholarly articles and books on state AG activity in the public health sphere, we searched online sources of information about initiatives by state AGs relating to prescription drug pricing or affordability within the previous five years. The objective was not to describe the legal claims and merits of these activities in depth, but rather to form a general picture of the nature of state AGs' activities.

LexisNexis and internet searches were used to gather news articles, blog posts and newsletters, industry news digests, government press releases, and other sources of information on lawsuits, investigations, and other state AG activities. The scope of the search included both affirmative activities such as lawsuits and amicus briefs filed, and also activities in support of work by other branches of state government, such as defending the state in lawsuits filed by drug companies, analyzing proposed legislation, and producing reports. A profile was developed for each state's activities, including its participation (or nonparticipation) in multistate activities such as lawsuits, amicus briefs, and letters to federal agencies.

B. KEY INFORMANT INTERVIEW STUDY

1. Study Design

We sought to interview attorneys in each of the fifty states regarding their activities relating to prescription drug affordability. We also sought to interview leaders of NAAG interest groups working on issues relevant to drug costs.

To identify appropriate participants, we searched materials uncovered in the scoping review for attorneys who had direct involvement in one or more reported activities. Where no such person could be identified, or the involved individuals no longer worked for the state AG's office, we sought to identify knowledgeable individuals through several methods. First, one of us (T.R.) compiled a list of individuals the National Academy for State Health Policy (NASHP) had worked with in the past on drug affordability issues, some of whom were state AG attorneys and some of whom had other policy roles but could provide information on knowledgeable state AG attorneys. Second, we consulted NAAG Pharmaceutical Interest Group leaders for recommendations. Third, where these approaches did not yield an appropriate participant, we searched state AG office directories for individuals in the consumer protection, antitrust, or healthcare division.

We sent interview invitations by email beginning in December 2020. We sent up to three email reminders to nonresponders. Participants were not

compensated for their time spent on the interview. We asked invitees to suggest a colleague if they felt they were not knowledgeable about drug affordability issues, and we then invited a person to whom we were referred. If an invitee indicated that they were too busy to participate but did not state that the AG's office itself did not wish to participate, we invited another attorney in the office. For those who had not responded after three reminders, we asked two colleagues with extensive personal contacts in state policymaking to make personal appeals where they had a prior professional connection. Occasionally an invitee asked to include a colleague in the interview, and these requests were honored.

Interviews were conducted by Zoom and lasted thirty to forty minutes. Two investigators (M.M.M. and R.E.S.) conducted the first three interviews together to calibrate interviewing approaches and then conducted subsequent interviews solo. Interviews followed a detailed, semi-structured interview guide that was developed in partnership with individuals at NASHP who were seasoned in working with state officials on drug affordability issues.[144] Interview questions were also informed by a discussion at a December 2019 meeting convened by NASHP of state AG attorneys and legal academics working on drug affordability issues, the purpose of which was to identify opportunities for additional AG activities and felt needs among AGs. Interview questions spanned the following domains: (1) how the office prioritizes issues and initiatives; (2) activities relating to drug affordability (both affirmative and supportive activities); (3) institutional strengths and other factors empowering AGs in pursuing these activities; (4) institutional limitations and challenges encountered in pursuing these activities; and (5) resources that would enable AGs to expand their activities relating to drug affordability.

Interviews were audio recorded and automatically transcribed by Zoom. After an investigator redacted identifying information, the transcripts were edited for accuracy by a law student research assistant who listened to the audio recordings. Transcripts were analyzed using standard methods of thematic content analysis.[145] Two investigators (M.M.M. and R.E.S.) independently coded a random sample of five transcripts, using the interview guide as the initial basis for the draft coding scheme and revising the nodes as necessary. The two coding schemes were then compared and discussed and a final version agreed upon. All transcripts were then independently coded by the two investigators. The textual snippets coded

144. The interview guide is appended to this Article.

145. *See generally* KLAUS KRIPPENDORFF, CONTENT ANALYSIS: AN INTRODUCTION TO ITS METHODOLOGY (Margaret H. Seawell et al. eds., 2d ed. 2004); BARNEY G. GLASER & ANSELM L. STRAUSS, THE DISCOVERY OF GROUNDED THEORY: STRATEGIES FOR QUALITATIVE RESEARCH (1967).

under each node were compared and discrepancies were identified and resolved. For each node, one investigator then analyzed and summarized the snippets coded within.

The study was reviewed and deemed exempt by the institutional review boards of Stanford University School of Medicine and Washington University. All interview participants received written, informed consent materials and the interview questions in advance of the interview, and they verbally confirmed their consent to participate in the study after being given an opportunity to have their questions about the research answered.

2. Interview Sample

Individuals in forty-nine states were invited for interviews.[146] A total of twenty-one individuals were interviewed in eighteen interviews, for an interview completion rate of 35.3%.[147] The relatively low completion rate even after extensive follow-up attempts with nonresponders may relate to the fact that interview recruitment was conducted during the peak of the COVID-19 pandemic (December 2020 to April 2021).

The twenty-one participants were fairly evenly distributed across U.S. Census regions (seven West, five South, five Midwest, and four Northeast) and about evenly divided between Blue and Red states.[148] Four participants worked within antitrust divisions, ten sat within consumer protection divisions, and seven had roles that spanned more than one division. Job titles varied, but most were seasoned attorneys, with many reporting long tenures within their respective state AG's offices. Nine identified as male and twelve identified as female. Three of eighteen interviews were conducted with two respondents and the remainder with one respondent.

3. Methodological Limitations

Our study methods have limitations. First, only about one-third of states are represented in our sample. Although the sample was geographically and

146. No potentially knowledgeable participants from one state could be identified after extensive online searches and personal inquiries.

147. Attorneys from an additional three states agreed to be interviewed but were not responsive to multiple attempts to schedule the interview. Fourteen states declined to participate; of these, respondents in five indicated that they could not answer the interview questions due to confidentiality policies, two stated that they could not identify anyone knowledgeable in their office to participate, and seven did not give a reason. In fifteen states, we received no response to the study invitation even after several follow-up attempts.

148. Red and Blue designations were taken from FiveThirtyEight partisan lean scores. Nathaniel Rakich, *How Red or Blue Is Your State?*, FIVETHIRTYEIGHT (May 27, 2021, 6:00 AM), http://fivethirtyeight.com/features/how-red-or-blue-is-your-state-your-congressional-district [http://perma.cc/7TKQ-7WR9].

politically diverse, different responses may have been obtained from a larger sample. In particular, state AG offices with a special interest in drug affordability issues may be overrepresented in the sample, leading to bias in how attorneys ranked drug affordability among their office's priorities.

Second, AGs' work on drug affordability issues is often split across antitrust and consumer protection bureaus, and many of our respondents sat within one or the other of those bureaus and were not joined in the interview by a representative from another bureau. In larger offices, respondents occasionally reported limited knowledge of the activities of other divisions. To reduce the risk that relevant activities would not be discovered, we triangulated interview data with other sources of information about AGs' activities from our scoping review.

Finally, the policies of many AG offices restricted attorneys from discussing some aspects of their work. In some states, attorneys were unable to be interviewed at all. More typically, attorneys declined to discuss information about pending litigation and investigations that was not publicly available. On one or two occasions, participants also expressed reluctance to discuss weaknesses in the legal authorities on which their lawsuits were based, out of concern that, if the defendants became of aware of their comments, it could undermine their success in the litigation.

III. RESULTS

A. RECENT ACTIVITIES OF STATE AGS IN THE DRUG AFFORDABILITY SPACE

Our scoping review revealed a range of activities state AGs have recently engaged in regarding prescription drug affordability. A large majority of these activities are affirmative, in which state AGs initiated various types of actions against actors in the prescription drug production and distribution pipeline. But some activities are more supportive, with state AGs defending acts of their state legislature, governor, or agencies in the drug affordability space.

Several of the AGs' affirmative activities are rooted in antitrust law. Perhaps the most significant is the multistate action led by Connecticut alleging a widescale price-fixing conspiracy in the generic drug industry.[149] One interview participant suggested that "it's probably going to be the

149. Press Release, Off. of the Att'y Gen. of Connecticut, Att'y Gen. Tong Leads Coalition Filing 3rd Complaint in Ongoing Antitrust Price-Fixing Investigation into Generic Drug Industry (June 10, 2020), http://portal.ct.gov/AG/Press-Releases/2020-Press-Releases/AG-Tong-Files-3rd-Complaint-in-Antitrust-Price-Fixing-Investigation-Into-Generic-Drug-Industry [http://perma.cc/YN9Z-N85C].

largest price-fixing case that's ever been brought in the United States." The complaint, filed in 2018 on behalf of forty-six AGs, alleged that eighteen generic drug companies had worked to increase the prices of fifteen drugs.[150] The second complaint, filed by forty-four states in 2019, was broader in scope, naming twenty drug companies as defendants and identifying more than one hundred drugs at issue.[151] The third and most recent complaint, filed in 2020 by fifty-one states and territories, focused on eighty generic topical dermatological drugs and twenty-six companies.[152]

Another multistate action, filed by thirty-six state AGs regarding the opioid addiction treatment Suboxone, alleged that Suboxone's manufacturer had engaged in a "product hop,"[153] aiming to block generic competition for Suboxone by switching the drug's formulation from a tablet to a film.[154] The AGs further alleged that, after switching Suboxone's formulation, the manufacturer "made unfounded claims to physicians that [the] tablets were dangerous" in an effort to discourage their prescribing.[155] As a result, the AGs argued, Suboxone's manufacturer ultimately obtained nearly a billion dollars in profits it would not otherwise have received.[156] This lawsuit is ongoing, but a parallel FTC settlement involving Suboxone led to nearly $60 million being returned to patients who were overcharged for film versions of the product.[157]

150. Press Release, Off. of the Att'y Gen. of Connecticut, Att'y Gen. Jepsen Leads Coalition in New, Expanded Complaint in Federal Generic Drug Antitrust Lawsuit (Oct. 31, 2017), http://portal.ct.gov/AG/Press-Releases-Archived/2017-Press-Releases/AG-Jepsen-Leads-Coalition-in-New-Expanded-Complaint-in-Federal-Generic-Drug-Antitrust-Lawsuit [http://perma.cc/NVG5-HQV2]; Consolidated Amended Complaint, State of Connecticut v. Aurobindo Pharma USA, Inc., No. 2:17-cv-03768 (E.D. Pa. June 18, 2018).

151. Press Release, New York Att'y Gen., Att'y Gen. James Joins 44 State Coalition in Motion to Unseal Generic Drug Price Fixing Complaint (June 6, 2019), http://ag.ny.gov/press-release/2019/attorney-general-james-joins-44-state-coalition-motion-unseal-generic-drug-price [http://perma.cc/3U97-HUDA]; Complaint, Connecticut v. Teva Pharm. USA, Inc., No. 3:19-cv-00710 (D. Conn. May 10, 2019).

152. Press Release, Off. of the Att'y Gen. of Connecticut, *supra* note 150; Complaint, Connecticut v. Sandoz, Inc., No. 3:20-cv-00802 (D. Conn. June 10, 2020).

153. *See* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 168 (2016) (defining product hopping).

154. Susan Scutti, *States Sue Suboxone Drugmaker, Claiming Antitrust Violations*, CNN (Sept. 23, 2016), http://www.cnn.com/2016/09/23/health/suboxone-lawsuit-antitrust/index.html [http://perma.cc/RQ29-MYGS].

155. Press Release, California Dep't of Just., Att'y Gen. Kamala D. Harris Files Lawsuit Against Pharmaceutical Company for Inflating Prices for Opioid Addiction Treatment (Sept. 22, 2016), http://oag.ca.gov/news/press-releases/attorney-general-kamala-d-harris-files-lawsuit-against-pharmaceutical-company [http://perma.cc/P8VP-3LVV].

156. *Id.*

157. Press Release, Fed. Trade Comm'n, FTC Returns Nearly $60 Million to Those Suffering from Opioid Addiction Who Were Allegedly Overcharged in Suboxone Film Scheme (May 10, 2021), http://www.ftc.gov/news-events/press-releases/2021/05/ftc-returns-nearly-60-million-those-suffering-opioid-addiction [http://perma.cc/8ZGS-YV68].

A smaller number of states—seven—brought a similar lawsuit in collaboration with the FTC against the manufacturers of the antiparasitic drug Daraprim for their efforts to block generic entry.[158] Daraprim and Martin Shkreli, who led the company that acquired the drug, rose to notoriety when the price of a single tablet of Daraprim was raised overnight from $13.50 to $750.[159] The lawsuit focuses on the manufacturer's subsequent conduct to block potential generic competitors, such as by "craft[ing] unlawful restrictive distribution agreements to keep competitors from buying the Daraprim samples they needed to conduct FDA-required tests."[160]

State AGs have also been involved in a range of pay-for-delay suits, in which branded pharmaceutical firms reach agreements with generic or biosimilar firms to delay their market entry, thereby retaining the originators' monopoly for longer than they might have otherwise.[161] As just one example, fifty state AGs obtained a $125 million settlement against the relevant companies for the deals they used to retain their monopoly on the narcolepsy drug Provigil.[162] California, which had not been part of the original settlement, secured a separate $69 million Provigil settlement as well as a ten-year injunction prohibiting manufacturer Teva from engaging in pay-for-delay arrangements.[163]

Although antitrust actions have focused on collusive price fixing and abuses of the patent system to block competition, other state AG lawsuits are based more in consumer-protection or fraud causes of action, as were the

158. Press Release, Fed. Trade Comm'n, Six More States Join FTC and NY Att'y Gen.'s Case Against Vyera Pharmaceuticals, Martin Shkreli, and Other Defendants (Apr. 14, 2020), http://www.ftc.gov/news-events/press-releases/2020/04/six-more-states-join-ftc-ny-attorney-generals-case-against-vyera [http://perma.cc/8ZLJ-G8Z5].

159. Andrew Pollack, *Drug Goes From $13.50 a Tablet to $750, Overnight*, N.Y. TIMES (Sept. 20, 2015), http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html [http://perma.cc/CDP8-XE48].

160. Press Release, Fed. Trade Comm'n, *supra* note158.

161. *See* Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 504–05 (2016) (defining pay-for-delay deals and noting their evolution over time from simple payments to more complex deals).

162. Press Release, Off. of the Att'y Gen. of Connecticut, State Joins $125 Million Multistate Antitrust Settlement with Cephalon for Efforts to Delay Provigil Competition (Aug. 4, 2016), http://portal.ct.gov/AG/Press-Releases-Archived/2016-Press-Releases/State-Joins-125-Million-Multistate-Antitrust-Settlement-with-Cephalon-For-Efforts-to-Delay-Provigil [http://perma.cc/NEJ2-Y4WU]. This settlement was facilitated by a much larger action brought by the FTC, which secured a $1.2 billion settlement of its own. Press Release, Fed. Trade Comm'n, FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go to Purchasers Affected by Anticompetitive Tactics (May 28, 2015), http://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill [http://perma.cc/J56F-Y3CT].

163. Press Release, California Dep't of Just., Att'y Gen. Becerra Secures Nearly $70 Million Against Several Drug Companies for Delaying Competition and Increasing Drug Prices (July 19, 2019), http://oag.ca.gov/news/press-releases/attorney-general-becerra-secures-nearly-70-million-against-several-drug [http://perma.cc/3QYA-YSQY].

Medicaid AWP lawsuits of the early 2000s. The actions typically involve claims that a company's pricing practices are deceptive and result in harm to consumers or state health programs. In some cases, it is alleged that multiple companies, such as manufacturers and pharmacy benefit managers (PBMs) colluded to perpetrate a deceptive practice. For instance, Mississippi recently became the first state to file suit against both drug companies and PBMs specifically for their practices regarding insulin, alleging that the state had overpaid for insulin as a result of violations of the Mississippi Consumer Protection Act in methods of pricing and delivering different insulin products.[164] Several state AGs have begun investigations into the conduct of PBMs, and particularly into whether PBMs may have been overpaid under state contracts.[165] Ohio and Mississippi have already obtained significant settlements ($88 and $55 million, respectively) from Centene for pharmacy services it provided to the states.[166] Specifically, the suits alleged that PBMs managing their states' Medicaid pharmacy benefits engaged in abusive "spread pricing," in which the PBM pockets a portion of the difference between what the health plan pays the PBM for a given prescription and the amount the PBM pays the retail pharmacy.[167]

Short of filing lawsuits, state AGs frequently engage in other types of activities in the drug affordability arena, including drafting multistate letters and amicus briefs. In August 2020, a bipartisan group of thirty-four state and territorial AGs sent a letter to the Trump Administration in response to the COVID-19 pandemic, urging the administration to take legal action to ensure

164. Ed Silverman, *Mississippi Becomes the First State to Jointly Sue Drug Makers and PBMs Over the Cost of Insulin*, STAT (June 14, 2021), http://www.statnews.com/pharmalot/2021/06/14/insulin-mississippi-novo-lilly-sanofi-cvs-pbm [http://perma.cc/DV5H-HJ67]. Notwithstanding that action, for reasons described later in the Article, interview participants indicated that "it's quite rare that we've tried to use our consumer protection law to directly go after effectively price gouging in prescription drugs." *See infra* Section III.D.3.

165. Anna Wilde Mathews, *States Probe Business Practices of Pharmacy Benefit Managers*, WALL ST. J. (May 11, 2021, 7:00 AM), http://www.wsj.com/articles/states-probe-business-practices-of-pharmacy-benefit-managers-11620730804 [http://perma.cc/JZX4-U2PA]. PBMs are middleman organizations that develop lists of covered drugs (called formularies) for health insurers, purchase drugs in bulk from manufacturers, using their purchasing power to negotiate rebates and discounts, and contract with pharmacies to reimburse them for drugs dispensed to insured patients. PBMs have come under scrutiny for contributing to high drug costs because of perverse incentives arising from the way they make money based on the "spread" between the discounted price they pay for drugs and the price at which they resell them. For details, see *Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 22, 2019), http://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending [http://perma.cc/ZRX3-D8BY].

166. Rebecca Pifer, *Centene Shells Out $143 to Settle PBM Disputes in Ohio, Mississippi*, HEALTHCARE DIVE (June 15, 2021), http://www.healthcaredive.com/news/centene-shells-out-143m-to-settle-pbm-disputes-in-ohio-mississippi/601773/ [http://perma.cc/A5HZ-2C7G].

167. Rachel Dolan & Marina Tian, *Management and Delivery of the Medicaid Pharmacy Benefit*, KAISER FAM. FOUND. (Dec. 6, 2019), http://www.kff.org/medicaid/issue-brief/management-and-delivery-of-the-medicaid-pharmacy-benefit [http://perma.cc/32F4-VGJJ].

that the antiviral drug remdesivir could be supplied in sufficient quantities and at affordable prices for COVID-19 patients who may need it.[168] At the time, remdesivir was one of a small number of therapies to have demonstrated any efficacy in treating patients with COVID-19,[169] and the limited supply when combined with the drug's price tag in the United States—over $3,000 per course—threatened patient access.[170] The letter asked the Administration either to take action on its own, using authorities granted under the Bayh-Dole Act, or to permit the states to use those legal authorities to increase the supply and lower the price of the drug.[171]

Another bipartisan letter to the Trump Administration in 2020 focused on the federal drug discount program known as 340B, the goal of which is to provide prescription drugs at a discount to eligible healthcare organizations serving vulnerable patient populations, including community health centers and critical access hospitals, for distribution to their patients.[172] In their letter, AGs from twenty-eight states and the District of Columbia argued that several pharmaceutical companies were unlawfully refusing to provide drugs at the required 340B discount to eligible entities, imposing significant cost burdens on those safety-net providers.[173] As one interview participant explained:

168. Jake Johnson, *34 State Attorneys General Urge Trump to End "Outrageous" Gilead Monopoly on COVID-19 Drug*, SALON (Aug. 6, 2020), http://www.salon.com/2020/08/06/34-state-attorneys-general-urge-trump-to-end-outrageous-gilead-monopoly-on-covid-19-drug_partner [http://perma.cc/R35R-QKXB].

169. Press Release, U.S. Food & Drug Admin., Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment (May 1, 2020), http://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment [http://perma.cc/FG6F-AAGV]. Other therapies demonstrating such evidence, such as dexamethasone, were already widely available at low prices. Dylan Scott, *How the UK Found the First Effective COVID-19 Treatment—and Saved a Million Lives*, VOX (Apr. 26, 2021), http://www.vox.com/22397833/dexamethasone-coronavirus-uk-recovery-trial [http://perma.cc/M8C4-HEA7].

170. Matthew Herper, *Gilead Announces Long-Awaited Price for COVID-19 Drug Remdesivir*, STAT (June 29, 2020), http://www.statnews.com/2020/06/29/gilead-announces-remdesivir-price-covid-19 [http://perma.cc/UU73-EZXU].

171. Press Release, California Dep't of Just., Att'ys Gen. Becerra and Landry Lead Bipartisan Coalition Urging Federal Government Action to Increase Access and Affordability for Remdesivir (Aug. 4, 2020), http://oag.ca.gov/news/press-releases/attorneys-general-becerra-and-landry-lead-bipartisan-coalition-urging-federal [http://perma.cc/E5TP-B6G3].

172. *340B Drug Pricing Program*, HEALTH RES. & SERVS. ADMIN. (2021), http://www.hrsa.gov/opa/index.html [http://perma.cc/X32C-QFRL]. Despite the laudable goals of the 340B program, it has been criticized for its inclusion of wealthier entities, given the distortionary effects it may have. *See, e.g.*, Rena M. Conti & Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding to Reach More Affluent Communities*, 33 HEALTH AFFS. 1786, 1786 (2014).

173. Kyle Blankenship, *Attorneys General Ask HHS to Punish 340B Program Bilkers— but Pharma Claims It's Fighting 'Waste and Abuse,'* ENDPOINTS NEWS (Dec. 14, 2020), http://endpts.com/attorneys-general-ask-hhs-to-punish-340b-program-bilkers-but-pharma-claims-its-fighting-waste-and-abuse [http://perma.cc/SSE9-XX4U].

> This was putting low-income patients at risk of losing access to affordable medications, . . . right in the middle of the COVID-19 pandemic. . . . We reacted by thinking this is wrong. There must be something we can do. . . . So, we built this team with expertise and the capacity to handle the 340B issues and to consider whether or not this might be some kind of a multistate issue that we needed to work on. And we went to work. So, the first thing we did was tee up a letter directly . . . to the manufacturers, you know, "What are you doing here, what's going on?" . . . "Is this true?" and giving them a chance to respond. And we were not pleased with the responses we received. And so, you know, we began to engage our multistate counterparts . . . . [If federal regulators are] not doing what we think they should be doing, what can we do to raise the temperature here to ask them to do more?

The AGs asked the Department of Health and Human Services (HHS), which administers the 340B program, to render a determination that such refusal was unlawful, which would have implications for the manufacturers' continued ability to participate in the Medicare and Medicaid programs.[174] Just two weeks after the AGs' letter was sent, HHS issued a formal advisory opinion that did just that.[175]

State AGs have also collaborated to file bipartisan amicus briefs, such as in the 2020 Supreme Court case of *Rutledge v. Pharmaceutical Care Management Association*.[176] In 2015, Arkansas had passed a law aiming to regulate PBM pricing practices, which was swiftly challenged in court by the PBM trade association. The trade association argued that the state law was preempted by existing federal laws, limiting the state's ability to adopt additional legislation impacting the industry.[177] A group of forty-six state AGs filed an amicus brief in support of Arkansas' side. These states argued Arkansas' law was not preempted, a position which would preserve their own ability to legislate in this area.[178] In December, the Supreme Court ruled unanimously in Arkansas' favor.[179]

State AGs have also engaged in supportive work for the legislature and executive agencies, although interview responses indicate that the frequency and scope of such supportive activities are significantly outweighed by AGs'

174. *Id.*

175. Dep't of Health & Hum. Servs., Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020), http://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf [http://perma.cc/L4WF-REXR].

176. Rutlegde v. Pharm. Care Mgmt. Ass'n, 141 S. Ct. 474 (2020).

177. *Id.* at 476.

178. Brief for California et al. as Amici Curiae in Support of Petitioner at 1, Rutledge v. Pharm. Care Mgmt. Ass'n, 141 S. Ct. 474 (2020) (No. 18-540) [hereinafter Brief for California].

179. *Rutledge*, 141 S. Ct. at 478.

affirmative activities.[180] Most notably, some AGs have been called upon to defend acts of the state legislature, as with Attorney General Rutledge's defense of Arkansas' PBM law as described above,[181] the Maryland AG's defense of that state's law prohibiting price gouging for essential off-patent and generic drugs,[182] or the California AG's defense of that state's pay-for-delay legislation,[183] to name a few examples. "We're the law firm for the state," one interview participant observed, representing state agencies when they are engaged in rulemaking, sued, or threatened with suit. However, some interview participants noted that, in their state, the AG is not necessarily tasked with defending the state in court; other offices might instead serve as counsel.

A number of participants also described more supportive work "behind the scenes" to assist the legislative process, such as "meeting with legislators, answering their questions, talking with advocates on all sides who are either filing the bill or filing amendments to the bill." Some of this consultative activity is more traditionally legal in nature, with participants describing being asked to determine "would this bill be preempted" or "whether the proposed statute would conflict with other existing state law." But other participants were involved in "informing and educating" the legislature about the need for certain legislation, including "explain[ing] to them what we were seeing at the Attorney General's office in the form of consumer complaints."

B. PRIORITY SETTING AND DRUG AFFORDABILITY

Participants ranked prescription drug affordability as a high-priority issue for the AG's office. On a scale of one ("among our highest priorities") to five ("not a priority at all"), the median score was two, and only one participant ranked it below a three. This high rating is particularly striking in light of several major competing priorities at the time the interviews were conducted, including the COVID-19 pandemic, opioid litigation, and—for some states—challenges to policies of the Trump Administration. One participant noted that in the past four years, "we've not only taken on the traditional duties of an attorney general's office, we've been playing the role of the federal government" and "pulling [attorneys] off [traditional activities] so they can defend . . . the ACA."

180. Relatively few states have been sued over drug pricing legislation.

181. *Rutledge*, 141 S. Ct. at 476.

182. Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 664 (4th Cir. 2018).

183. Press Release, California Dep't of Just., Att'y Gen. Becerra Fights Latest Challenge to California's Landmark Anti-Pay-for-Delay Law (Oct. 16, 2020), http://oag.ca.gov/news/press-releases/attorney-general-becerra-fights-latest-challenge-california%E2%80%99s-landmark-anti-pay [http://perma.cc/L9HX-7U46].

When asked what influenced their prioritization of the drug affordability issue, respondents mentioned two interrelated factors: the priorities of the AG and the financial burden on consumers and state programs, such as Medicaid. Respondents spoke about the "immense consumer impact . . . that touches almost everybody," but particularly affects vulnerable groups such as seniors, low-income individuals, and persons with chronic illnesses. Several explained that their AG had prioritized the issue because of the cost burden. Some AGs had signaled a special interest in equity and protecting "those in our most vulnerable communities," while others had a longstanding, general interest in healthcare regulation.

In addition to the AG's own priorities, several respondents mentioned that a more "organic," bottom-up process of issue spotting by frontline "trench warriors" also contributed to priority setting. Long-serving frontline attorneys often developed considerable interest, expertise, and experience in prescription drug pricing issues, especially as many of them worked closely with counterparts at state Medicaid agencies, and senior managers reportedly took up their suggestions as to worthwhile problems to explore. One attorney noted that they had been working on drug issues for nearly two decades under three different AGs, and observed that for new AGs, issue prioritization is "not necessarily that refined." Although incoming AGs may lack awareness of some issues, "there's an institutional memory and skill set that lives its way through various new AGs."

In describing how their office chose among potential activities that could address prescription drug costs, the theme of potential consumer impact again surfaced prominently. The generic price-fixing litigation, for example, was described as a "no brainer" not only because of the "strong evidence of outright collusion" but also because it involved "over a hundred drugs that Medicaid reimburses for, tens of thousands of [state residents] using these drugs," and taxpayers "forking out a lot of money" for the drugs.

A related theme was that the office prioritized activities that could deliver "the most bang for the buck" with the limited resources they had. "These cases are expensive," one attorney commented, "They cost money, . . . they cost staff time. And so we have to make a value judgment, you know, is this one where we should be letting someone else lead . . . ?" Attorneys from small offices, in particular, recognized that joining multistate actions involved "tremendous yield." Some cases offered a double benefit: addressing a particular business practice that contributed to high drug costs while also empowering states to regulate in other health-related areas or strengthening their position in future litigation. The most prominent example of such a transsubstantive issue is preemption. AGs prioritized joining the amicus brief in *Rutledge* because of the case's potential to undercut

preemption defenses raised by a variety of defendants—not only PBMs, but also drug manufacturers and tobacco companies.[184] "Most state attorneys general view themselves as having broad authority," one respondent explained, and wish to avoid judicial decisions restricting it. Making progress on this cross-cutting problem not only bolstered the bang-for-the-buck factor of certain cases, but also served as a uniting force across AGs. The same respondent explained that "law enforcement are usually similarly situated in viewing themselves as having broad jurisdiction and not wanting the Federal Government to intrude on their jurisdiction."

Good "bang for the buck" could also arise from activities that had more modest potential impact but involved little effort for AGs—for instance, signing on to a letter to a federal agency. "Doesn't take that much to agree to it," one participant observed. "You read it, you make comments, maybe tweak it [to make it] a little bit better, but there's not a lot of investment of resources. But I do think collectively it can make a difference." States were generally willing to join a low-effort, multistate initiative such as a brief or letter as long as "there's merit to it" and they could think of no reason *not* to support it. "We usually have a pretty decent opinion of our fellow states," one explained, "and so if they're doing something, we would take it pretty seriously. . . . The general proposition of working in a multistate fashion is to agree." But one participant noted that a state's failure to sign on to a letter is not necessarily due to disagreement with the letter's goals or substance: "these letters sometimes get lost" in terms of finding the right attorney, and "sometimes they have to go pretty quickly," meaning that states may sometimes miss a window to sign on.

C. INSTITUTIONAL ADVANTAGES OF STATE AG ACTION ON DRUG AFFORDABILITY

Interviewers asked attorneys about factors that facilitated their office's success in particular drug affordability activities or made AGs effective policy actors on drug affordability issues more generally. Four themes emerged in the responses: (1) their ability to leverage multistate collaborations; (2) their nonpartisan status; (3) their investigative and litigation powers; and (4) their deep institutional knowledge.

1. Capacity for Multistate Action

The most dominant theme concerning facilitators of success was multistate cooperation. Although several respondents from antitrust

184. AGs have a long history of banding together to challenge federal preemption of states' regulatory authority. For a summary of early activities, see Clayton, *supra* note 13, at 548–52.

divisions also mentioned the benefits of collaboration with federal partners (in particular, the Federal Trade Commission and Department of Justice), more important were the strong working relationships among state AGs, which were fostered and leveraged by NAAG. Multistate cooperation sometimes occurred during supportive activities—for example, states sued over laws that were similar to one another "look very much to see what's being argued and . . . how other folks are handling things." However, collaboration was of greater importance in affirmative activities.

Multistate action helped establish the value proposition for launching big litigation by spreading costs and effort across states. Participants from small states, in particular, emphasized that multistate action allowed them to "amplify our voice" and "bat a little bit above our league" by tackling problems that were too large to take on solo. The forty-two-state Suboxone litigation, for instance, was a case where "I don't know that it could be done without NAAG because of the amount of a lift that case is."

Multistate collaboration was also reportedly helpful with issue spotting. Through NAAG-organized monthly calls, speaker series, and newsletters, states shared observations about business practices that were potentially problematic and identified commonalities in their observations, often sparking a mutual decision to "take a closer look here" and compare findings. NAAG leaders "keep an eye on issues" on which AGs may wish to "weigh in." The organization "takes complaints that anybody has received [about potentially illegal conduct] and tries to determine if there are other complaints or anyone's done an investigation." Sharing information about activities of one state often inspired others. For example, a NAAG working group participant reported that when one state filed lawsuits relating to insulin prices, it "got people interested in insulin, so then a group of states started an insulin investigation."

These conversations not only built coalitions of states pursuing particular issues, but also built strong and trusting relationships across offices over time. Participants in working groups focused on pharmaceuticals, health care fraud, and antitrust got to know one another well. "NAAG provides the phone lines, NAAG provides the format," one member explained, "but it is the relationships that the AGs create with each other through NAAG that [achieve concerted multistate action]. . . . It is a platform, if you will, to create that unity."

States had reportedly developed a "well-oiled system" for circulating letters to federal regulators, amicus briefs, and legal complaints to garner sign-on from other states. Doing so was perceived to add considerable power to the signal that state AGs sent to federal regulators when they wrote about

problematic situations. "If you can get even a handful of states to all agree that something's wrong here and speak up, I think that has to get the attention of the federal regulators," one commented. "And in [one case] we had twenty-seven on board, so I think it was hard for them . . . to ignore and not do something." Recruiting a bipartisan group of signatories was a core part of the strategy because "as soon as the company can say that this is only Republican AGs doing this or Democratic AGs doing this, you've lost so much credibility with the courts." For amicus briefs, for example, an AG from each political party ideally would propose the brief and then circulate it for additional signatories.

NAAG also served as a platform for organizing the management of multistate litigation. The organization was variously described as "very much like a law firm," "a congressional model," and the United Nations: leaders and committees organized and delegated work among states that had opted to join particular teams.[185] It was reportedly effective in allowing a "real synergistic relationship" among states to develop and leveraging the distinctive resources of each state. "If you collaborate and coordinate, they can be a very powerful force," one attorney observed. In addition to managing work within cases, NAAG reportedly smoothed the distribution of states' resources across cases, "looking to see which case needs resources and to kind of call for more help on those cases needing more help."

Thus, NAAG served several critical roles: (1) catalyzing action within AG offices on particular issues by hosting educational workshops and conversations about matters that had come across states' radar screens; (2) creating opportunities to recruit attorneys to take the lead in writing multistate briefs and other documents; (3) facilitating relationship-building among AG offices through regular information-sharing conference calls; and (4) providing a management structure for multistate litigation. Participants repeatedly stressed the value of all of these activities in empowering AGs and ensuring that "together the sum is greater than the individual parts." "Honestly, I can't reiterate how helpful NAAG is," one said. The collaboration ensures "that we're not all in our own corner of the world, unaware."

2. Nonpartisanship

Interviewers inquired about whether AGs perceived political barriers to their participation in affirmative activities on drug affordability. Partisan divides in state AG activities have been observed elsewhere in the healthcare

185. Prior work has also invoked the metaphor of a law firm. *See* Lynch, *supra* note 67, at 2008.

space,[186] most recently in the 2021 Supreme Court case *California v. Texas*,[187] in which eighteen Republican state AGs had filed a suit attempting to invalidate the entire Affordable Care Act, an effort in which they were opposed by seventeen AGs from Democratic states and the District of Columbia.[188] Although some interview participants acknowledged that they "wouldn't say that we're necessarily insulated from politics," only a few reported challenges in this area. The vast majority reported that their offices were perceived as nonpartisan (even if not *apolitical*) organizations and enjoyed substantial political independence.

In seven of the fifty U.S. states, AGs are appointed, usually by the governor; in the other forty-three, they are elected.[189] Only interview participants from states with appointed AGs reported political constraints. For instance, one long-serving attorney commented that some administrations had greater appetite than others for bringing consumer claims against large companies, and that the legislature also would "push back, sometimes, when we're pursuing things that just don't sort of cohere with certain ideology regarding the free market and the regulatory state." Similarly, another respondent believed that "the legislature has an eye on the work that we do," especially in the consumer protection space, which is "a little bit unfortunate." In contrast, respondents in states with elected AGs did not perceive that political pressure affected what work attorneys were able to do, even though their AGs had to think about reelection.

Attorneys spoke about the political neutrality of the AG's office as an

186. To be sure, partisan divides in AG activity have also been observed outside the healthcare space, though that is not our focus in this project. *See, e.g.*, Margaret H. Lemos, *Foreword: State Enforcement in an Interstate World*, 2019 BYU L. REV. 1427, 1430–31 (2019).

187. California v. Texas, 141 S. Ct. 2104 (2021).

188. *Id.* at 2112–13.

189. *Attorney General Office Comparison*, BALLOTPEDIA, http://ballotpedia.org/Attorney_General_office_comparison [http://perma.cc/R2YK-6MV6] (reporting that AGs are appointed by the governor in five states, appointed by the legislature in one state, and appointed by the state supreme court in one state); *see also* NOLETTE, *supra* note 14, at 19 (commenting that being elected affords AGs "considerable political independence"). Although some scholars have argued that electoral pressure may impinge on AGs' independence, others have maintained that the need to impress voters weighs in favor of more and bolder action by AGs, rather than less. *See* Rutkow & Teret, supra note 15, at 278; Lemos, *Aggregate Litigation*, *supra* note 24, at 514; Totten, *supra* note 58, at 1659; Provost, *Entrepreneurship*, *supra* note 13, at 38, 43; Provost, *Politics of Consumer Protection*, *supra* note 13, at 615 (reporting supportive quantitative findings); Lippincott, *supra* note 13, at 403. Empirical evidence also suggests that AGs find their office's resources and their chances of prevailing in a lawsuit to be more important influences than public opinion on their decisions to initiate or join litigation. Provost, *Entrepreneurship*, *supra* note 13, at 47–52 (reporting empirical findings that AG partisanship and state government ideological leaning did not predict AGs' involvement in particular multistate lawsuits); Provost, *Politics of Consumer Protection*, *supra* note 13, at 615; Cox et al., *supra* note 13, at 100–01 (examining UDAP suits). *But see* Provost, *Integrated Model*, *supra* note 13, at 1 (finding evidence that both electoral considerations and policymaking goals predict AGs' decisions to join multistate consumer protection lawsuits).

asset in garnering bipartisan support for their initiatives within their state and in multistate initiatives. One explained, "It's easier [to forge bipartisan relationships] in the AG world because . . . you're law enforcement, you're tough on wrongdoers, and so even a Republican can sort of get behind that. Or, you're filling your state's coffers with money, and everyone can get behind that."

Further, attorneys viewed prescription drug affordability as a rare bipartisan issue. One respondent remarked, "Pharmaceuticals are, in this weird, polarized world, one of the few unifying factors—and they have been my whole tenure [working for four different AGs]." Antitrust, too, was perceived as an increasingly bipartisan field. "It's weird political bedfellows right now," said one attorney, "where the Republican Party, which has traditionally been resistant to antitrust enforcement, is suddenly sort of coming around on the issue, maybe for slightly different reasons than the Democrats have been." As a result, multistate initiatives could readily find "an R and a D" to sign on.

When asked whether they felt pressure to have their affirmative litigation yield a large enough financial return to pay for itself, all participants reported that their office's independence and the respect they had personally earned through their long service meant that it had "never been an issue." Over time, they had come to understand that their AG and legislature had a broad conception of public benefit, and thus recognized the value of even those legal wins that did not return large amounts to the state's coffers. One described a case that resulted in only a tiny settlement and concluded, "If I did that a lot earlier in my career, that would have made me feel pretty anxious. Now I don't worry. What are they going to do, fire me?" Another struck a similar note: "We get to do this work without worrying about having to yield a particular financial return or bill hours or any of those things."

3. Deep Institutional Knowledge

Several respondents mentioned the quality, dedication, and knowledge of the attorneys in their office as critical factors in their success taking on the pharmaceutical industry. Attorneys tended to stay in the AG's office for long portions of their career, between one and three decades, and reportedly "when you have that level of commitment and expertise in the office, you have a number of people who are able to issue spot just in the ordinary course of life." Many attorneys developed deep subject-matter expertise and even cultivated a special interest and expertise in the activities of particular companies. For instance, one state had an expert in PBMs, which enabled the office to take a leading role in an initiative relating to PBMs' role in

inflating drug prices; another had litigated several cases of various kinds against a large company and had intimate knowledge of what prior consent decrees committed the company to doing.

Attorneys' long tenure also provided opportunities to build strong relationships with counterparts in other states over time. "I have a lot of really, really close, long-term relationships with antitrust enforcers in other states," one commented. "And if I were new to the job, I just wouldn't be able to have that same advantage, really." Even when attorneys did leave AGs offices, the multistate collaborations ensured there would be some continuity in the knowledge base of the litigation teams: "Because we are collaborating, we can keep that institutional knowledge, even if people get picked off to go into fancy law firms and make a million dollars a year."

In summary, attorneys reported several significant strengths of AGs as policy actors in the drug affordability space, some of which arose from their collaborations with other AGs. They consistently perceived that because of these factors, they had been able to accomplish a great deal in this space with limited resources. Nevertheless, they also reported a number of challenges and obstacles to effective action on drug pricing. We turn to these challenges next.

4. Investigative Authority and Ability to Sue

Attorneys perceived that their legal authority to investigate potential violations of the law and bring lawsuits were among their chief strengths as policy actors in the drug affordability realm. Although they acknowledged that investigative powers are not unique to AGs—legislatures also conduct investigations—respondents felt they had distinctive investigative tools, experience, and expertise. For instance, they perceived that they were "closer to the ground [than legislatures], hearing more directly from consumers about what they're seeing and what their concerns are." In response to reported problems, AGs could "move relatively quickly" to investigate it and "help drive an issue."

Their investigative authority also gave them unique access to information. "We essentially become prosecutors, even though we're in the civil world," one said, "So we have a great deal of power, basically, to subpoena documents, to depose witnesses—third parties, actual targets—and that's really powerful." Another recalled with relish instances when "you turn over a document that is clear proof that there's been collusion or that's clear proof that these guys knew exactly what they were doing and did it anyway." Surfacing such information represented a unique contribution that AGs made to policy efforts to address drug affordability.

Having the power to sue was also perceived to be "impactful." Although it could sometimes feel frustrating to have to file cases one at a time, at great effort and expense, attorneys noted that the flipside was that they could

> enforce changes on a case-by-case basis, where legislators have to sort of paint with a broad brush across a lot of areas. And that can result in all sorts of problems being tied up. If you need to address a problem in the widget area but you also unfortunately affect the gadget area, the gadget people are going to be all upset. You have to kind of narrow things. Well, we can file a case against the widget manufacturers and deal with that problem directly.

One attorney who previously had worked on legislation also argued that litigation—despite its sometimes protracted nature—was often a quicker fix for a problem than legislation. "You know, you get something passed and the industry's changed or the issues change by the time you get it passed. So, you're always kind of working a little bit behind."

D. CHALLENGES ENCOUNTERED IN DRUG AFFORDABILITY ACTIVITIES

Challenges encountered in AGs' drug affordability work clustered around four themes: (1) resource constraints; (2) complexity; (3) gaps in legal authorities; and (4) limited remedies. Each of these reportedly limited AGs' ability to expand their activities relating to drug affordability and make major progress in bringing drug prices down.

1. Limited Resources

Perhaps the clearest, most prevalent theme emerging from the interviews was that limited resources were "the number one obstacle" to greater AG activism on the prescription drug costs. With the possible exception of the most populous states, which were perceived to have "massive resources" compared to smaller states, attorney bandwidth was simply too limited to take on all matters they would like to address. In states where the legislature had been active in passing drug pricing legislation, bandwidth pressure was especially intense because they were also engaged in a larger amount of defensive work. Such legislation usually inspired legal challenges by the affected companies, and defending the state "takes up time and resources . . . . We don't have like a bunch of attorneys that are just waiting" to do that work.

Although attorneys took pride in the amount they accomplished with the available resources—at being "very skilled, out of necessity, at doing more with less"—they consistently expressed that they were short-staffed. AGs' investigatory function, in particular, was cited as resource intensive. "Very seldom do we have somebody come to us and actually give us a

violation on a silver platter," one attorney noted, which necessitated difficult decisions about whether "we want to take the time and resources to investigate and see if there actually is [a problem]."

In light of the large, varied slate of work AGs are pursuing on drug affordability, it is striking to realize that in small states, AG offices may have only a single attorney handling all antitrust or all consumer protection matters, whether related to pharmaceutical companies or to other industries. Even in a medium-sized state, one participant commented, "It's a pretty bare bones operation, honestly. We have core functions we're obligated to do, and we're given just enough people and resources to get those done. And so, taking on affirmative litigation or initiatives taps into resources we really don't have." Attorneys found a certain irony in their office's limited staffing given that "this work pays for itself" and often returned significant dollars to the state's coffers. Respondents from the most populous states recognized that their offices were unusually large and well resourced but commented that this meant an atypically large share of the legwork and hiring of experts for multistate actions fell to them.

A related, common theme when participants discussed challenges encountered in their work was the vast disparity in resources between their office and the pharmaceutical companies they went up against. Hiring talented attorneys was difficult for some AG offices, notwithstanding the prestige of working for an AG, "because, you know, the state only pays so much." Further, attorneys who were drawn to public service often preferred splashy work in the civil rights arena to working on prescription drug costs. Pharmaceutical companies have "a very well-built litigation team that do this day in and day out, and then they'll just keep going and going. Infinite resources." As one attorney quipped, "The forces of darkness pay well and have overwhelming funding."

This fact lent a David-and-Goliath quality to AGs' faceoffs with drug companies. Although attorneys clearly took pride in their willingness to go up against "the best, most high-priced lawyers" and "walking into a courtroom where you're the only lawyer on your side and there's like seven suits on the other," they also acknowledged that it made litigating very rough going. "Any kind of foray that any AG wants to try to impose greater regulation on this industry is and will be met with such volcanic pushback," one said. Although this did not deter them, it did make their work difficult.

2. Complexity

Grappling with complexity in their drug affordability work was another prominent theme when attorneys talked about challenges. This complexity had two dimensions: factual and logistical.

Proving that a drug's price reflects illegal practices was reportedly often factually complex. It required AGs to uncover and analyze complicated pharmaceutical supply chains and pricing decisions, using data that were both hard to obtain and hard to interpret. "The major thing with drug pricing is that it's so opaque," one attorney commented, "It is so difficult to know how much drugs cost. . . . Yes, we can subpoena. But the market chain is so long that to even trace out all the actors between the manufacturer and the consumer" is difficult. "It's frankly really hard to get enough visibility to know what's going on," the attorney concluded. Some of the largest cases, such as the generic price-fixing litigation, involved hundreds of different drug products, all of which had to be researched. A further problem is that information privacy laws that shield prescription records, such as the Health Insurance Portability and Accountability Act, while not "insurmountable obstacles," made it hard to observe and understand which patients were being overcharged for a drug.

The complexity of the data was a particular problem, several respondents commented, because they did not have an in-house economist and had scant funds with which to hire external economic experts. In small states, even where funding was available, in-state experts could be hard to identify. Because some cases were "quite data heavy" and required both specialized experts and software, states often had to identify ways of leveraging other states' expert resources.

Attorneys litigating pay-for-delay cases faced additional challenges in understanding a complex web of settlement agreements:

> [It's] tough to tell on the face of these agreements what was happening and they would have sometimes several agreements kind of compartmentalizing the different parts of the settlement overall to make it less clear that it was a pay-for-delay. And now we're even seeing a trend where there is no settlement agreement and you have to kind of look at the various behaviors to determine that there was some sort of pay-for-delay going on.

In both the pay-for-delay arena and the PBM context, respondents reported that such challenges had limited their activities although they recognized there were problems that needed addressing. Regarding PBMs, for example, one respondent said, "[I]t's so complicated, and we just don't have the experts in our office to figure out what really can and should be done."

Logistical complexity was also described as challenging because of the sprawling nature of multistate litigation—the "number of defendants, number of issues, the amount of material that's involved." Notwithstanding the states' long experience coordinating legal personnel to divide the

workload, participants reported that leading large cases could be arduous. "It's drafting everything by committee. . . . you're spending a lot of time just figuring out how to communicate to one another without running into FOIA problems where things will have to be disclosed," commented one. Another exclaimed, "Coordinating these people! There are around a hundred lawyers on the [drug name] case. And to coordinate a hundred lawyers over whom I have no financial or legal authority, just goodwill?" Some also reported that in certain cases, challenges arose from "different statutory permissions and restrictions" across states and circumstances in which states' interests or preferences regarding litigation strategy did not align. "There are clearly divergent interests in terms of preferred path to settlement," one commented, "You know, do we sue and when, and then, how do we resolve it and when?"

3. Legal Authorities

A strong theme emerging in interview conversations about AGs' legal tools was that although the laws they invoked in enforcement actions were strong in terms of serving the core purposes for which they were adopted, they often were an imperfect fit for the types of conduct that contribute to high drug costs. "It's not uncommon that we're trying to fit a square cube into a round hole," one remarked. Another explained:

> [I]f there's fraud, we can attack that with the consumer protection laws; if there's collusion or some other unfair competition, we can address that with the antitrust laws. But there are things that fall through the cracks . . . . [For example,] situations where you have a hedge fund come in, and they buy up a drug company, and then all of a sudden they raise the price of a drug dramatically, and it can be really harmful for consumers when that happens. . . . [S]ometimes it can be difficult to find illegal activity that matches up with what the antitrust laws cover and get a fix for it in court.

Remdesivir, the COVID-19 treatment drug, was cited as another example of a problem just out of the conventional reach of existing statutes. One AG's office decided not to join the multistate letter regarding remdesivir because it "just didn't think it fit squarely within our law." Although the drug's price had incited considerable public outcry,[190] the attorney explained:

> It's my understanding that remdesivir was in the red previously. Under our price gouging statute in [State], . . . the company is allowed to charge

190. *See, e.g.*, Ekaterina Cleary, *Remdesivir's Hefty Price Tag Ignores NIH Investment in Its Creation*, STAT (Oct. 22, 2020), http://www.statnews.com/2020/10/22/remdesivir-hefty-price-tag-ignores-nih-investment-in-its-creation [http://perma.cc/T8CL-WABM] (reporting that remdesivir was priced at $3,120 per course of treatment during COVID-19, even though the manufacturer had already developed the drug for other diseases using taxpayer-funded research).

> whatever the price [necessary] to cover their expenses, so . . . if they needed to increase the price to cover their expenses then that's legal under our state law.

Another attorney summed the problem up succinctly: "We tend to regulate the thing we can regulate, which is a lot of times conduct, and not always just price."

There was varying appetite across the states for bringing actions that stretched the envelope of consumer protection and antitrust statutes. For example, one attorney reported, "We try to be conservative in our approach to . . . opening investigations. We're not going to announce that we have an investigation open unless we feel that there are very strong reasons." Others said where the law is "somewhat unsettled," they felt comfortable evaluating the case and making "a good lawyerly judgment about, yes, this is not a slam dunk case, but this is the right case to bring." It was not clear from the interview responses whether the primary force driving conservatism among some AGs was reticence to expend scarce resources on a risky venture, concerns about losing credibility with courts and the public, or simply a view that law-enforcement interventions should focus on clear violations of the law.

Even where AGs were willing to test new strategies for attacking high pharmaceutical prices, concerns about constitutional challenges loomed large. Maryland's attempt to regulate high drug prices using a price-gouging statute, which culminated in a judicial invalidation of the law by the Fourth Circuit Court of Appeals,[191] was well known, and viewed as a cautionary tale. Respondents spoke about potential challenges to state action on the basis of patent preemption and dormant Commerce Clause claims.[192]

One state AG's office had successfully proposed that the legislature strengthen the AG's legal hand in antitrust cases by adopting a statute clarifying what constituted a violation of state antitrust law. "We felt like it was such an uphill battle in terms of the various elements we needed to prove," the attorney commented, "So, that was part of the goal in a bill like that: to simplify and reduce the number of areas of expertise for the judge . . . [and] the number of areas that we could fight over." A few other respondents voiced a desire for their state's consumer protection statute to be amended to sweep in more of the types of practices at issue in drug pricing

191. *See* Ass'n for Affordable Meds. v. Frosh, 887 F.3d 664, 666 (4th Cir. 2018) (invalidating MD. CODE ANN. HEALTH–GEN. § 2-802(a) (LexisNexis 2018)).

192. *See id.*; Michelle Mello, *NASHP's Proposal for Protecting Consumers from Prescription Drug Price Gouging*, NAT'L ACAD. FOR ST. HEALTH POL'Y (July 6, 2020), http://www.nashp.org/nashps-proposal-for-protecting-consumers-from-prescription-drug-price-gouging [http://perma.cc/6H9Y-7VND] (summarizing legal claims brought in challenges to drug price-gouging laws).

cases[193]—for example, to employ a broad definition of "unfair" business practices that would provide an alternative to having to prove conduct was "deceptive."

4. Remedies

Limitations on the available legal remedies for violations of consumer protection and antitrust law were raised by a few respondents as a challenge encountered in their work. They spoke about a disconnect between the public's expectations and what could realistically be delivered. One explained:

> AG suits get three different types of remedies. . . . We get injunctive relief, we get penalties, and we sometimes can get restitution. In cases when you're dealing with, let's say, pharmaceuticals, and you have 800,000 prescriptions, the way to make restitution happen on that is a little mind boggling and probably could be done, but is very, very, very difficult. So oftentimes, an AG's office . . . will consider seeking penalties or other punitive relief rather than restitution. . . . The challenge that I think we see is that there's a disconnect: if the money is not going to consumers, then what is it going to? . . . [And] how do you make the harm of this practice on the consumer, where it's fifty cents here or a ten-dollar copay there, feel like a bad enough thing to justify penalties that give it a deterrent effect?

The lack of visibility about how AG action benefited consumers was also mentioned by another attorney in a slightly different context: "misunderstanding" on the part of the public about settlements, manifested in complaints that "you didn't solve the problem," when "many of these problems are larger than a lawsuit" and required legislative solutions.

Remedies were reportedly an active area of exploration by the NAAG Pharmaceutical Interest Group. One member commented:

> We have spent a lot of time talking about disgorgement as a more meaningful remedy than damages in making the litigation more effective and deterring conduct. Because when we have followed a damages model, everybody got discouraged by all of the discovery that was entailed. . . . So we have, for instance, a lot of speakers on disgorgement. We assembled a body of memoranda about disgorgement both under federal and state law. In the more recent cases, we pursued disgorgement

193. Attorneys were referring to their state's UDAP statute. In some states, such statutes prohibit only "deceptive" practices and may limit the prohibition to a narrow list of enumerated practices. *See* CAROLYN CARTER, NAT'L CONSUMER L. CTR., CONSUMER PROTECTION IN THE STATES: A 50-STATE EVALUATION OF UNFAIR AND DECEPTIVE PRACTICES LAWS 11–12 (2018). Others encompass "unfair" practices, but according to our interview participants, do not provide a clear line of attack for high drug prices, which are often difficult to link directly to particular practices, much less "unfair" practices.

as opposed to just damages, as in the past.

A broader point related to the shortcomings of available remedies is the inherently "reactive" nature of litigation. "The legislature and the governor, they can be proactive," said one attorney. "My experience is that we're always looking backwards. And we don't anticipate what's coming forwards. You know, for example in our settlements[,] we're always trying to craft injunctive relief. . . . But one of the problems is that we're trying to build a barn door when the barn has burned down."

To summarize, AGs pursuing drug affordability work faced challenges relating both to the legal tools at their disposal and their practical ability to handle the daunting task of litigating complex issues against a powerful adversary. It is useful to consider these perceived challenges in light of particular conceptions that AGs have about their role and the nature of the work on which they should focus.

E. COMPETING SELF-CONCEPTIONS: LAW ENFORCEMENT VERSUS POLICYMAKING

In response to a theme that emerged early in the interviews, in nine interviews the interviewers asked whether attorneys conceived of the state AG office's role as including policymaking or being limited to law enforcement. This question left room for interpretation as to what constitutes "policymaking," and interview responses suggested three kinds of interpretations. First, policymaking could consist of supporting or promoting efforts to enact prescription drug policy reforms through other agencies or programs or through legislation. Second, it could consist of identifying particular policy priorities to advance using the AG's law-enforcement powers and selecting cases based on those priorities. For example, AGs might choose to focus on promoting competitive market conditions. Third, it could consist of architecting creative policy solutions as part of settlement agreements.

Four attorneys acknowledged that they saw policymaking as within their mission, while five saw their remit as narrower. Those who were more reticent to acknowledge policy roles appeared to have the first interpretation of policymaking in mind. "Our office, my General, has said, 'I'm not in the business to do policy. I'm in the business to enforce law,' " one said. "So he does not advocate often for legislative change . . . [nor has he] ever convened a forum for drug affordability or something." "There's a reason we don't have a lot of resources in the office devoted exclusively to advancing a policy agenda," commented another. "That's sort of not the role of the office." Rather, said a third, "we go where we see violations" and where complaints have been received. The state AG's role was to "be as good lawyers as we

can be and enforce the law as we understand it."

For those who viewed themselves as law enforcers, this self-conception was seen as critical to their institutional legitimacy. "There is an understanding that the attorney general is chief law enforcement officer of [State]," one commented. "It's a very serious power that's vested in this office, we are seen with great credibility, and we never want to lose that. That's very important." Similarly, another participant commented "In our state, our office is seen as pretty straight shooters in terms of enforcing the law. I think we would lose some of that reputation if we starting [sic] advocating policy sort of matters."

On the other hand, those who felt that "clearly we're doing both" policymaking and law enforcement reported that their AG had expressly greenlighted that mission and that they had no qualms about it. Respondents in this group mentioned all three types of policymaking. "I think my boss is very much an activist, progressive attorney general and really wants to use the time he has in that office to do good and to really achieve some meaningful things to help poor people," one observed. That attorney cited as an example a drug affordability bill that the AG's office had helped craft. Another respondent, too, noted that their office had "recently moved to much more of an expansive role to look at different ways of advocating and trying to make a change, other than simply doing piecemeal litigation." Other respondents spoke of their personal motivation "to do good" or "make a difference," even if it required creative policy solutions built into settlements or engaging in "policy advocacy in various forms" and crafting solutions entirely divorced from litigation. When pressed on the issue of whether this role compromised the office's institutional legitimacy, one respondent replied that providing advice to the legislature upon request was part of their institutional responsibility, and that they were "actually functioning as a lawyer and giving legal advice and legal counsel. It's not true advocacy in my mind."

Even respondents who saw the first type of policy advocacy as part of their mission acknowledged, however, that they were not well resourced to pursue it. One commented that "the enforcement role is a more natural, easier one[,] and it's reflected in the way the office is funded and resourced." Though some perceived that in the previous couple of years states had emerged as "the engine of change in the pharma space," they nonetheless recognized that federal action may be more effective. "I think it would be best maybe coming federally, because then we can have it across the board," one explained. "Because these guys, they obviously don't just work in [State]; it's a national market. We've all joked in the past that we kind of felt like gnats hovering around pharma's head, and they swat us away."

F. POTENTIAL AVENUES FOR EXPANDING STATE AGS' WORK

In response to the question, "If your office had more resources, what would you like to be doing on drug affordability that you're not doing now?," only two respondents had nothing to suggest. Six indicated they would simply take on more cases of the kind they were presently pursuing—for example, investigating some of the smaller, less widely distributed drugs that could have a problem—or would "do a better job of pushing along the cases we already have." The remainder suggested specific activities they would like to pursue. These included investigating anti-competitive effects of consolidation in the pharmaceutical industry, taking on PBMs and formulary placement decisions, framing high drug prices as price gouging in legislation and litigation, building more capacity for coordinated multistate discovery, bringing on more staff with health policy expertise to improve the office's ability "to spot these issues before they impact the community in a really negative way," and devoting more effort to help states craft legislation.

Attorneys identified three measures that they felt would increase their ability to pursue important work on drug affordability: strengthening their state's consumer protection laws, expanding attorneys' bandwidth, and augmenting their access to health policy experts. First, although attorneys generally praised the utility and scope of their state's consumer protection laws, some suggested avenues for strengthening them. Attorneys in states that had laws encompassing only deceptive trade practices acts rather than laws that also encompassed "unfair" acts and practices suggested that a broader UDAP statute would be helpful.[194] Additionally, one mentioned that statutes with minimum penalties for violations—which not all states had—helped ensure that judges "understood that acts of this magnitude were an important thing to address."

Second, creating more bandwidth for attorneys by expanding the number of attorneys in the office was at the top of most participants' wish list. They felt they had reached the limit of what could be achieved with multistate collaboration. Collaboration was already extensive and "we're all probably at the same point in terms of bandwidth . . . so even if we combine resources, we're still several people short of what we need."

State AGs reported limited or no use of outside counsel in their drug affordability work—and had little appetite for using private counsel more. Although there was some acknowledgment that private counsel could be "important" as a "leveler" in cases that were lavishly staffed on the opposing side, with some reporting that these collaborations were usually "a great

194. *See supra* note 196 and accompanying text.

experience," more common were comments deriding outside counsel as "rent-a-badge" and "just pirates" seeking to maximize their own fees. Attorneys also worried about the cost to taxpayers of hiring external counsel. They strongly preferred to be given more resources to expand their roster of in-house attorneys. There was also enthusiasm for expanding the office's use of external attorney volunteers and in-house legal interns and fellows, particularly fellowship programs that served as a bridge to permanent employment in the office. "I like that word, 'extenders,' " commented one, "We need some extenders. I need to be extended."

Third, attorneys returned to the theme of complexity in the matters they were investigating and litigating, stressing their need for more health policy expertise. One state had addressed that problem by building a special team focused on healthcare work that brought together consumer protection attorneys, antitrust attorneys, and a seasoned health policy expert. This structure broke down "silos," improving communication and collaboration across divisions, and the involvement of the health policy specialist deepened the team's ability to spot important issues. "A lot of times we'd get questions and nobody knew the answer," a team member reported. "You would have some attorneys that would try to do a thoughtful job [commenting on proposed legislation], but they weren't subject matter experts. They didn't track what was happening at the FTC [or] the state legislature." In contrast, the "multidisciplinary team" was able to look at issues "through many different lenses," which was reportedly "very empowering."

The lack of health policy expertise reportedly limited what AGs could contribute to legislative efforts in their states. One attorney observed, "I think more and more our group of litigators are appreciating that they can make more of an impact by supporting legislation than doing a single case. The cases are so labor intensive, it's absolutely scary." Legislative solutions were also seen as important for addressing the problem of health equity and access to medications, which implicated issues of insurance coverage and structural racism as well as drug prices. Yet, respondents indicated that their offices would need more expertise in health policy to be able to identify legislative solutions themselves.

All participants responded with enthusiasm to a question about whether greater collaboration with academics or other experts would be helpful in advancing their drug affordability work. Contact to date with academics had been limited in most states—generally, attorneys reached out to them when they needed to find an expert witness. Yet, attorneys recognized that academic experts potentially could serve several functions. Some spoke about academics' potential to help identify and frame problems that the AG's

office could address. "A more accessible policy analysis or sort of teeing up of the issues in a more formal way might be helpful for an attorney general's office because I think it's an area people want to do more on," said one. "It's hard for me to find time to go out and look for things," said another. A third envisioned

> academics coming to us and saying, "Oh, we've been studying the widget industry for two and a half years now, and this is really strange the way they always price the same way on the same day," or whatever. "You guys might want to look at this." They can spend some of the preliminary time looking at the industry that we sort of have to start from scratch at when the problem gets complained about.

Others spoke about the need for additional analytic capacity to better understand issues the AG's office was already investigating. There was a perceived need for "sophisticated people to go in and analyze the data and figure out what it means and what can be done with it," as well as to quantify the extent of consumer harm from drug overpricing. When they could find academics willing to donate time for that, "just because people are interested in these issues," they found it to be "an immense benefit" and an "incredible resource." One difficulty was finding individuals willing to maintain effort on matters over very long periods of time, however. Citing two examples of cases that had been in litigation for six and ten years, respectively, one attorney observed, "Academics have to publish papers and do things on a regular basis. . . . It's hard to really sustain somebody who is working for free on that kind of stuff."

IV. REFLECTIONS ON STATE AGS AS POLICY ACTORS

Our interview study and scoping review reveal that state AGs are indeed an important and energetic actor in the drug affordability policy space. Their affirmative litigation has tackled well-known drivers of prescription drug prices such as product hopping, pay-for-delay, and other tactics to delay generic entry. It has also surfaced and addressed anticompetitive activities that have attracted less attention in health policy research and lawmaking, such as collusive price-fixing. It has deployed federal and state laws against fraud to address practices, such as use of AWP, that have inflated costs to federal and state payers. In a similar vein, AGs have initiated investigations into potential overpayments to PBMs. Finally, they have joined together to write impactful letters to federal regulators expressing concerns about business practices relevant to prices for critical medications (such as remdesivir) and drugs in the 340B program. Collectively, these activities exemplify state AGs' role providing "an outlet for public demands for policy

change."[195]

Although we focus on affirmative activities in the remainder of our discussion because attorneys in our interviews reported much less supportive work than affirmative work on drug affordability,[196] it is important to note that state legislatures require vigorous legal support for their ongoing efforts on drug affordability legislation—whether from AGs or legislative counsel. In the present environment of "volcanic pushback" from the pharmaceutical industry, counsel must be willing to support the legislature in taking risks. Counsel must give a frank, well-informed assessment of the legal prospects, of course, but their role as advocates for the state also involves building the best possible case where there is legal uncertainty and the legislature is strongly motivated to act. In the absence of full-throated support from counsel, many policymakers will find the legal threats overwhelming. In Maine, for example, drug price-gouging legislation was recently vetoed by the governor over concerns about potential lawsuits,[197] notwithstanding strong arguments that Maine's legislation was distinguishable from Maryland's ill-fated price-gouging law.[198] At a public work session on the legislation, an attorney from the Maine Attorney General's office had opined that it was unclear whether the bills would withstand legal challenge and estimated the likelihood of success at 50/50.[199]

Turning now to AGs' affirmative activities, several overall themes emerged from our interviews that have implications for AG activity going forward: (1) multistate collaboration is thriving; (2) AGs find the political environment for their drug affordability work quite favorable; (3) frontline attorneys play important roles in setting AGs' agendas; (4) AGs are largely pursuing their drug-affordability work without the benefit of substantial assistance from academic researchers or private counsel; and (5) attorneys' vision for augmenting their drug-affordability work is rather narrow.

195. NOLETTE, *supra* note 14, at viii.

196. Some supportive work has been quite important—for example, the multistate amicus brief that led to an important win on the preemption challenge mounted in *Rutledge*—but overall, supportive work is a relatively small part of AGs' portfolio of work. *See* Brief for California, *supra* note 178.

197. Letter from Janet T. Mills, Governor of the State of Maine, to the 130th Legislature of the State of Maine (June 29, 2021).

198. *See* Mello, *supra* note 192.

199. Health Coverage, Ins., and Fin. Servs.—Me., *HCIFS 5/26/2021 Work Sessions*, YOUTUBE (May 26, 2021), http://www.youtube.com/watch?v=WKprxmtzACk [http://perma.cc/25UH-FCR6] (broadcasted at 4:42 via the Me. Legislature Joint Standing Comm. on Health Coverage, Ins., and Fin. Servs.). One of the authors (R.E.S.) subsequently provided additional testimony about the legal issues involved. Health Coverage, Ins., and Fin. Servs.—Me., *HCIFS 5/27/2021 11 AM Work Sessions*, YOUTUBE (May 27, 2021), https://www.youtube.com/watch?v=ypqaNExLGo8 [https://perma.cc/P2BH-JTPG?type=image] (broadcasted at 16:50 via the Me. Legislature Joint Standing Comm. on Health Coverage, Ins., and Fin. Servs).

A. THRIVING MULTISTATE COLLABORATION

Cooperative work across state AGs is vigorous and efficacious in the drug affordability space. Interview participants universally lauded NAAG for serving as a highly effective force for fostering, organizing, and leveraging states' desire to collaborate. Prior scholarship has enumerated many advantages of multistate collaboration among AGs, including the ability to divide up work and the fact that it enables small states to take on matters they could not handle alone.[200] Particularly notable are the findings of Danielle Citron's interview study concerning AGs' work on data privacy; in that realm, too, attorneys cited their collaboration as a strength of their work and credited a NAAG working group for creating a space in which AGs could "discuss best practices and emerging risks" and "coordinate responses" to privacy breaches.[201]

Some scholars have also raised concerns about multistate AG actions that constitute policymaking, such as settlements that impose new requirements on industries. A central critique is the idea that a group of AGs who share a particular ideological perspective may impose their vision of how an industry should be regulated on other AGs who do not share the views represented in their lawsuit.[202] In this vein, it is reassuring to note many of the high-profile drug pricing lawsuits have attracted wide, bipartisan AG participation—not just in settlements, but in the earlier stages of the cases.[203] This somewhat assuages concerns about a small cadre of activist AGs running the show.

B. FAVORABLE POLITICAL ENVIRONMENT

Although some areas of health policy where AGs have been deeply involved—such as the Affordable Care Act litigation[204]—are marked by sharp partisan battles, attorneys reported encountering few political barriers to their drug affordability work. This favorable political environment may owe to the fact that AGs are actually working at the intersection of three

200. *See, e.g.*, Citron, *supra* note 12, at 790–91; Lynch, *supra* note 67, at 2009.

201. *See, e.g.*, Citron, *supra* note 12, at 790.

202. NOLETTE, *supra* note 14, at 210–11; *cf.* Lemos & Young, *supra* note 24, at 48–49, 95–97 (describing "horizontal" conflicts among states in state public law litigation concerning which policies will dominate the national landscape).

203. *See supra* Section IV.A. Even scholars expressing concerns about some AGs imposing their settlements on others acknowledge that the number of multistate cases involving large numbers of AGs is increasing over time. NOLETTE, *supra* note 14, at 22; *see also* Zimmerman, *supra* note 13, at 85–86, 88–89 (concluding, based on an AG attorney survey, that neither partisanship nor other substantive criteria drove decisions about joining multistate actions).

204. Paul Nolette, *The Dual Role of State Attorneys General in American Federalism: Conflict and Cooperation in an Era of Partisan Polarization*, 47 PUBLIUS 342, 347 (2017).

different issues that enjoy broad, bipartisan support: prescription drug affordability, consumer protection, and enforcement of prohibitions on defrauding government programs.[205] In some cases such as the Suboxone matter, a fourth area of consensus is layered on: combating the opioid epidemic.[206]

With rare exceptions in states with appointed AGs, attorneys in our interviews did not report receiving pressure from branches of government. This finding comports with prior literature emphasizing that although they are not completely insulated from political pressure, AGs have substantial political independence, and the electoral pressure they do face militates in favor of bold, attention-getting action to protect consumers and bring money into the state.[207] Particularly in the consumer protection space, AGs "typically face few to no gate-keeping constraints from other actors in state government. . . . [T]hey have broad authority to enforce those laws as they see fit," because consumer protection is among their "most basic and general duties. . . . Even when governors or other state actors try to control attorneys general, appointed or elected, they often fail."[208]

C. KEY ROLE OF STAFF ATTORNEYS IN AGENDA SETTING

Although much of the literature on how AG offices become involved in litigation focuses on AGs themselves and the extent to which their ambition for higher elected office appears to drive their decisions, our interviews revealed that at least in the drug affordability space, decisions about which actions to pursue often came from frontline attorneys. Our respondents reported that the "institutional memory and skill set" of career attorneys ensured that drug affordability remained at the top of their office's agenda even as AGs came and went.[209]

Interestingly, despite this agenda setting and attorneys' strong reported motivation to protect consumers and save the state money, many attorneys did not see themselves as policymakers. Views on this point were somewhat split, but many expressed either a general concern about being a policy actor

205. *Id.* at 364; Nolette & Provost, *supra* note 13, at 481–83, 488, 489; Provost, *Entrepreneurship*, *supra* note 13, at 51. Although studies of amicus briefs have documented an erosion in bipartisanship over time, *see* Lemos & Quinn, *supra* note 13, at 1265, the fact that forty-six AGs signed the amicus brief in *Rutledge* suggests this trend may not apply to drug affordability cases, *see* Brief for California, *supra* note 178, at 34–37.

206. Nolette & Provost, *supra* note 13, at 487–88.

207. Provost, *Entrepreneurship*, *supra* note 13, at 43.

208. *Id*; *see also* Provost, *Politics of Consumer Protection*, *supra* note 13, at 615 (reporting, in a quantitative study of AGs' decisions to participate in multistate consumer protection litigation in the 1990s, that the ideology of their state's government was not a significant predictor of participation).

209. Citron has reported a similar finding concerning AGs' data-privacy activities. *See* Citron, *supra* note 12, at 786.

or specific anxieties about their office trying to design policy solutions when attorneys lacked training and expertise in health policy. Conceiving of their activities as law enforcement enables AGs to create an "apolitical shield" around activities that are actually a form of policymaking.[210]

D. LIMITED USE OF EXTENDERS

In our interviews, attorneys reported little use of extenders, despite universal concerns about their bandwidth to tackle big issues relating to drug affordability. Two dimensions of the extenders issue emerged. First, although several attorneys noted their own lack of technical expertise on health-economic and data-analysis issues, they also reported they are not well connected with the types of academics who could help supply such expertise. This poses a problem at all stages of the litigation process. It is difficult not only to spot specific factors that inflate drug prices in the incredibly complicated pricing ecosystem,[211] but also to investigate issues with deep factual complexity. Even drug pricing experts find these issues to be challenging.[212] The factors driving high prices for branded drugs are different from those driving high prices for generics, for example,[213] and companies may use different strategies to maintain high prices for biologic drugs as compared to small-molecule products.[214] AGs' lack of health policy expertise may also be problematic later in the litigation process, to the extent that settlements in these pending cases serve the policy-creating function identified in the literature.[215]

Second, most AGs also reported low use of external counsel to support their efforts, despite noting the significant resource constraints they face. Scholarly accounts of AG activities have characterized their use of private counsel as common,[216] including in the drug affordability context with the AWP litigation.[217] However, other empirical studies—such as an analysis of UDAP litigation— run contrary to these characterizations, finding relatively

210. NOLETTE, *supra* note 14, at 102 (quoting EUGENE LEWIS, PUBLIC ENTREPRENEURSHIP: TOWARD A THEORY OF BUREAUCRATIC POLITICAL POWER 17–18 (1980)).

211. NAT'L ACADS. OF SCIS., ENG'G & MED., MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 40–53 (Norman R. Augustine, Guru Madhavan & Sharyl J. Nass, eds., 2018).

212. *See, e.g.*, *id.* at xx–xxii, 40, 133.

213. Inmaculada Hernandez, Chester B. Good, David M. Cutler, Walid F. Gellad, Natasha Parekh & William H. Shrank, *The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Costs of Drugs*, 38 HEALTH AFFS. 76, 81 (2019).

214. W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023 (2016).

215. NOLETTE, *supra* note 14, at 13–14.

216. *Id.* at 35.

217. *Id.* at 100.

rare use of private counsel.[218] Efforts to limit states' reliance on external counsel may avoid some of the problems identified by scholars for private aggregate litigation, particularly regarding financial conflicts of interest.[219] But given AG attorneys' bandwidth and limited technical expertise,[220] the extreme factual complexity of drug-pricing issues, and the unavailability of help from academics, the decision not to use private counsel may create other problems.

E. VISION FOR EXPANDING DRUG AFFORDABILITY ACTIVITIES

Although AGs prioritized addressing the problem of drug affordability very highly, their vision for expanding their activities in this space was narrowly focused. Some participants suggested specific areas in which they would like to pursue more activities (including PBMs, industry consolidation, price gouging claims, and multistate discovery platforms), but many simply said that they would pursue "more of the same" work or "be more efficient at what we're already doing."

This narrow focus appeared to emerge not from a lack of urgency, but more likely because of AGs' limited bandwidth and challenges in identifying new issues. Several AGs reported learning about drug pricing problems through rather unsystematic strategies, such as reading a news article or receiving a consumer complaint. Some attorneys explicitly mentioned that they had limited ability to proactively spot issues likely to arise in the future. NAAG played a key role in circulating the identified signals from members and amplifying them to others, as well as in organizing people interested in working on them. However, NAAG is also not currently well positioned to identify issues that members have not yet reported.

Although some AGs felt as if they were not optimally anticipating and responding to new developments in the industry, others noted institutional advantages that AGs have in this area. AGs are typically nimbler than agencies because they have fewer bureaucratic hurdles to consider, and they

218. Cox et al., *supra* note 13, at 100 (finding that private counsel were used in only 1.5% of state UDAP cases in 2014).

219. *See generally* John C. Coffee, Jr., *Understanding the Plaintiff's Attorney: The Implications of Economic Theory for Private Enforcement of Law Through Class and Derivative Actions*, 86 COLUM. L. REV. 669, 724–27 (1986). Other scholars argue that these financial conflicts may still be present when AGs themselves evaluate settlement opportunities, because settlement funds may be returned to AGs' offices and large settlements may bolster AGs' political reputations. Lemos, *Aggregate Litigation*, *supra* note 24, at 516–17; Lemos & Minzner, *supra* note 31, at 856, 864–67, 870–74. Yet, one empirical study found no support for the thesis that the availability of funds from settlements substantially impacted AGs' enforcement work in the consumer-protection space. Cox et al., *supra* note 13, at 101.

220. Experts have noted that complicated cases in which "private attorneys possess special expertise that the government lacks in-house" present "perhaps the easiest case" for the use of private counsel. *See, e.g.*, Lemos, *Privatizing Public Litigation*, *supra* note 85, at 539.

are closer to frontline consumers.[221] The institutional capacity to more proactively address emerging problems exists, in other words, but AGs may need assistance identifying issues and organizing the process, with so many possible areas of focus.

There are clearly opportunities for AGs to expand their activities relating to drug affordability. But while few would disagree that bringing down high drug prices is desirable, some scholars question the desirability of policymaking through litigation.[222] In particular, they have voiced concerns about overenforcement of the law through AG litigation—that is, the pernicious effect of having more than fifty individual enforcers imposing different forms of regulation on companies. But such critiques implicitly assume that the current level of enforcement by non-AG actors is optimal.[223] For some drug antitrust issues in particular, it may not be. Further, concerns about a plethora of disparate regulatory signals have relatively low traction for drug pricing lawsuits given the very large numbers of states that sign on to them.[224]

Our interviews highlighted many institutional advantages of activity by AGs as compared to other legal and policy actors that have been described in prior work. In addition to the agility and information advantages noted above,[225] AGs are more resistant than agencies to capture.[226] Further, the advantages of using litigation settlements to regulate industries have been amply described; these include the fact that settlements are self-implementing, can specify detailed responsibilities for defendants, avoid the

221. Totten, *supra* note 58, at 1653–60.

222. *See, e.g.*, NOLETTE, *supra* note 14, at 103–04, 208–12; Dishman, *supra* note 24, at 424–30. Although a comprehensive review of this voluminous literature is beyond the scope of our report, notably, some scholars have criticized regulation by litigation for failing to provide a forum for balancing competing interests, as other regulatory processes do. *See, e.g.*, NOLETTE, *supra* note 14, at viii, 103–04. Yet other scholars have noted that AGs' obligation to represent the public interest necessarily means they must balance competing interests of different stakeholders within the state. *See, e.g.*, Lemos, *Aggregate Litigation*, *supra* note 24, at 513–14; Lemos & Young, *supra* note 24, at 113–17. There is thus a razor's-edge quality to the critiques.

223. Lemos, *State Enforcement*, *supra* note 24, at 760. Lemos further argues that "state enforcement [of federal statutes] offers a hedge against the possibility that federal agencies will abdicate on enforcement due to capture, bureaucratic pathologies, political influence, or resource limitations. But unlike private enforcement, state enforcement has built-in safeguards that reduce the risk of overenforcement." *Id.* at 702–03; *see also* Dee Pridgen, *The Dynamic Duo of Consumer Protection: State and Private Enforcement of Unfair and Deceptive Trade Practices Laws*, 81 ANTITRUST L.J. 911, 929–30 (2017) (endorsing a similar, positive view of state enforcement as filling gaps in federal enforcement).

224. Citron drew a similar conclusion after studying state AGs' activities relating to data privacy and security. Citron, *supra* note 12, at 796–97 (concluding that the "pile-up effect" is "more theoretical than real" in that space).

225. *See* Totten, *supra* note 58, at 1653–60; *see also* Stephen Calkins, *Perspectives on State and Federal Antitrust Enforcement*, 53 DUKE L.J. 673, 679–82 (2003) (describing state AGs' information advantages in antitrust enforcement).

226. Calkins, *supra* note 225, at 679–82.

lengthy processes of lawmaking and rulemaking and the associated doctrinal limitations (particularly in the First Amendment context),[227] and are not subject to appeal.[228] And although they must be negotiated with individual defendants, settlements may avoid the types of substantive compromises necessary to pass legislation in the face of lobbying by the entire pharmaceutical industry.

These advantages of state AG action are compelling, but assessing the actual effects of AG litigation is not straightforward. Evaluating the effectiveness of AGs' work in bringing down pharmaceutical prices is beyond the scope of our study—and not possible at this time, since so many drug-pricing lawsuits have been brought recently and are still pending. As in other areas of public health litigation, assessment efforts are also hampered by lack of empirical evidence, the difficulty disentangling the effects of AG action from other state and federal initiatives operating at the same time, and the fact that AG litigation may have indirect effects, such as when it prompts legislative action.[229]

Yet there are certainly many examples of impactful AG litigation in the public health law space.[230] In some cases, the effects have even been quantified, as in evaluations of the effect of the tobacco Master Settlement Agreement on cigarette prices and consumption.[231] AG action may also influence political and cultural environments in ways that promote public health but are not easily measurable—for example, by shifting public perceptions of an industry whose products cause harm. The tobacco litigation is a well-known example; a lesser-known one is the successful effort to persuade the motion picture industry to reduce depictions of smoking in films.[232]

Our interview findings and scoping review provide persuasive evidence that AG action is a promising vehicle for addressing practices that contribute to high drug prices, enforcing consumer protection laws, and protecting state budgets from fraud and abuse. To be sure, there are clearly limits on what AGs have authority to do in this space. Federal preemption and the dormant commerce clause can limit the scope of what states may regulate, and states

227. For example, a requirement by FDA that cigarette manufacturers include graphic warning labels encountered serious legal obstacles, *see* R.J. Reynolds Tobacco Co. v. U.S. Food and Drug Admin., 696 F.3d 1205 (D.C. Cir. 2012), whereas the same requirement imposed via settlement agreement would not have implicated the First Amendment.

228. NOLETTE, *supra* note 14, at 91–93.

229. Rutkow & Teret, *supra* note 15, at 279, 290–92.

230. *See generally, e.g.*, Engstrom & Rabin, *supra* note 44; Wendy E. Parmet & Richard A. Daynard, *The New Public Health Litigation*, 21 ANN. REV. PUB. HEALTH 437 (2000).

231. *See supra* note 79 and accompanying text.

232. Rutkow & Teret, *supra* note 15, at 295.

cannot address some of the key policy priorities in the drug affordability space, such as Medicare price negotiation.[233] AGs can go after many pharmaceutical pricing practices, but it is important to bear in mind that prescription drug affordability has two faces: pricing and insurance coverage. States in general, and state AGs in particular, have limited ability to address coverage issues. Therefore, AGs should be thought of as one component of a complex regulatory ecosystem for prescription drugs—a component that can be efficacious both through its own activities and through the influence it exerts on other actors. Congress and CMS should act more robustly to address drug affordability problems, but states struggling under prescription drug costs cannot afford to wait. Taking action through their AGs is a way for states to make progress now.

V. RECOMMENDATIONS

We offer recommendations aimed at addressing the four major challenges identified in the interviews: resource constraints, complexity, gaps in legal authorities, and limited remedies.

A. STRENGTHEN CONNECTIONS TO ACADEMIC RESEARCHERS

A leading finding from our study is the potential for stronger connections to health economists, pharmacoeconomists, and other academic researchers to augment AGs' work in the drug affordability space. Such connections would strengthen AGs' hand in several respects and address concerns raised by some scholars that AG action in the prescription drug arena is fraught because "AGs have neither the technical expertise of those in the FDA nor the incentive to worry about how pulling on one thread of the national regulatory scheme may affect the larger tapestry."[234]

Interviews revealed at least two roles that researchers could play. First, they could provide technical support for AGs' investigations and litigation, helping to analyze and interpret data on how particular business practices contribute to prices and how high prices harm consumers and state programs. Second, they could assist with "teeing up issues" for AGs to work on. AGs' existing ad hoc strategies for identifying drug pricing issues to address could be supplemented by creating a more systematic information pipeline from the academics who are studying particular problems to the AGs who could potentially take action on them. This new pipeline would advance the mission of both these groups of actors and help reorient AGs from their

233. Dusetzina & Mello, *supra* note 4.
234. NOLETTE, *supra* note 14, at 104.

primarily reactive stance to a more proactive one.[235]

An ideal structure for creating this connection would be for an organization with experience supporting state health policymaking, such as NASHP or AcademyHealth,[236] to enlist a group of academics with appropriate expertise and interests to have regular interactions with NAAG working groups addressing pharmaceutical pricing issues.[237] The organization could also serve as a connector, funneling questions from individual AGs to researchers with the right expertise to answer them. Although there will be limits on what busy academics can contribute and how quickly they can respond to requests, the increasing emphasis on policy impact in the criteria used to promote and tenured professors working in policy-related fields creates a powerful incentive to assist. Extramural funding, such as from a philanthropic foundation, would help accelerate and sustain such a connector project.

B. EXPAND ATTORNEY STAFFS AND BREAK DOWN SILOS

AGs' work on drug affordability is a high-impact activity, both in the sense of the importance of the issue to consumers and state programs, and in the sense that that AGs have had considerable success in their investigations and litigation. It strongly satisfies the "bang for the buck" criterion that attorneys suggested was important in their agenda setting. The attorneys we interviewed—many of whom spoke openly about their modest salaries—were very confident that their drug pricing work paid for itself, and more.[238] For these reasons, expanding the budgets of AGs' offices to enable them to hire more attorneys in antitrust and consumer protection would be a very sound investment.

AGs should also consider creating cross-cutting healthcare teams led by an attorney with health policy experience, as some states have done. In most

235. A past example of academic researchers helping with issue spotting in the public health space is a 2009 letter to NAAG leaders in which researchers synthesized research relating to the health hazards of caffeinated alcoholic beverages. Within days, eighteen AGs had sent an expression of concern about the issue to the FDA, citing the researchers' findings. Rutkow & Teret, *supra* note 15, at 297–98.

236. The mission of AcademyHealth, the main professional organization of health services and health policy researchers, is to act "as an objective broker of information, bringing together stakeholders to address the current and future needs of an evolving health system, inform health policy and practice, and translate evidence into action." *About AcademyHealth*, ACADEMYHEALTH, http://academyhealth.org/about [http://perma.cc/RAU2-CGJT].

237. Other public health law researchers, too, have called for academics to do more to share their research with NAAG and individual state AGs. Rutkow & Teret, *supra* note 15, at 298.

238. Scholars have drawn similar conclusions about AGs' work enforcing a variety of federal statutes. Lemos, *State Enforcement*, *supra* note 24, at 735 (citing Ralph H. Folsom, *State Antitrust Remedies: Lessons from the Laboratories*, 35 ANTITRUST BULL. 941, 958 (1990)) (noting that because settlement funds often flow back to the AG's budget, "state enforcement may be largely self-financing").

states, there is no place within the AG's office where antitrust and consumer-protection specialists come together to tackle the complex array of factors that contribute to high drug prices. Although attorneys in small offices may have frequent contacts with their counterparts in other divisions, in larger offices, siloing of antitrust and consumer-protection divisions may mean lost opportunities to discuss strategies that may not naturally occur to specialists in each area. Having a seasoned health policy expert on staff is particularly advantageous in terms of enabling teams to understand how parts of the healthcare system fit together and the full range of policy levers that may be effective in addressing problems. NAAG interest groups do facilitate cross-talk among AGs interested in drug pricing, but because many issues will be state specific, adopting a structure to foster collaboration in-house is desirable.

C. STRENGTHEN LEGAL TOOLS

Expanding the legal authorities that AGs have to work with in addressing drug pricing issues would address the "square cube in a round hole" problem that several attorneys reported. Further, if a state's laws more clearly embraced the types of practices that give rise to high drug prices, it could also help activate AGs who hesitated to initiate enforcement actions where they perceived that it would constitute policymaking rather than law enforcement.

Expansion of existing legal tools could take three forms. First, many states have room to strengthen their UDAP statute. In other consumer-protection areas such as mortgage regulation, research has demonstrated that the most effective enforcement response to identified problems has been mounted by AGs in states with broad UDAP statutes.[239] Several weaknesses in existing UDAP laws in the states have been identified; three are highly salient to addressing drug overpricing: (1) having narrow definitions of what constitutes a deceptive business practice;[240] (2) lacking a broad prohibition on unfair or unconscionable business practices,[241] and (3) specifying civil penalties that are too modest to have a meaningful impact on a large company.[242] More than half the states give rulemaking authority under their UDAP law to a state agency, such as the AG;[243] in these states, agencies

239. Totten, *supra* note 58, at 1655.

240. Carter, *supra* note 193, at 13–14 (finding, in a fifty-state review, that two states lacked a broad prohibition on deception and one required proof that the company knowingly and intentionally deceived consumers).

241. *Id.* at 14 (finding that six states lacked a broad prohibition on unfair or unconscionable acts).

242. *Id.* at 30 (finding that UDAP laws are heterogeneous in their civil penalties, with many specifying per-violation penalties as low as $1,000).

243. *Id.* at 17.

could clarify that specific pharmaceutical pricing practices constitute unfair or deceptive acts. For instance, annual price increases for already costly drugs that exceed a specified threshold and are not related to a drug maker's increased production costs could be defined as "unfair." Other statutes may require legislative amendment, but given the broad appeal of consumer-protection laws and a recent trend towards strengthening them,[244] this is not out of the question.

Second, states can follow the examples of states such as California and Maryland that have enacted statutes targeting practices that inflate drug prices. California's pay-for-delay statute, for instance, was designed and adopted for the specific purpose of reducing obstacles to successful AG enforcement actions against pharmaceutical companies. Price-gouging laws prohibiting excessive annual price increases for particular drugs are also very promising, as price increases are a major contributor to affordability problems.[245] Despite the judicial invalidation of Maryland's law by a split 2-1 Fourth Circuit, there are strong arguments that a modified approach—such as legislation proposed in Massachusetts[246]—would survive legal challenge.[247]

Third, AGs that are more comfortable pursuing policy objectives can continue to try to expand the scope of existing consumer-protection and antitrust laws by testing new theories about what constitutes a violation of those statutes.[248] Some AGs have done so successfully in other public health litigation—arguing, for example, that pharmaceutical companies' marketing practices for opioids constitute a deceptive business practice and a public nuisance. Our interview findings suggest there has been very limited invocation of UDAP laws to go after price gouging of prescription drugs to date, however.

244. *Id.* at 46–47.

245. Mello & Riley, *supra* note 9 (summarizing evidence); *see also* Trish Riley & Jennifer Reck, *NASHP's New Model Law Penalizes Drug Manufacturers for Unsupported Price Hikes*, NAT'L ACAD. FOR ST. HEALTH & POL'Y (July 28, 2020), http://www.nashp.org/nashps-new-model-law-penalizes-drug-manufacturers-for-unsupported-price-hikes [http://perma.cc/V78M-H5BZ] (proposing specific legislation).

246. COMMONWEALTH OF MASSACHUSETTS, THE GOVERNOR'S BUDGET RECOMMENDATION, FISCAL YEAR 2022 HOUSE 1, at 320 (2021) (noting, in particular, the Ch. 63E provision titled "Penalty on drug manufacturers for excessive price increases").

247. Mello, *supra* note 192.

248. Indeed, AGs may be more likely to take steps to expand the reach of regulations than other agencies charged with administering the statutes. Elected generalist actors like AGs may be more likely than appointed policy specialists like agency staff to take risks or initiate major reforms. Lemos, *State Enforcement*, *supra* note 24, at 724 (citing Roderick M. Hills, Jr., *Against Preemption: How Federalism Can Improve the National Legislative Process*, 82 N.Y.U. L. REV. 1, 4 (2007) (arguing that bureaucrats tend to resist or show indifference toward "broad policy considerations or claims of abstract justice that do not fall squarely within their regulatory specialty")). The issues Hills describes are precisely the types that drug affordability raises.

D. HEED LESSONS ABOUT BIPARTISANSHIP

A final recommendation is to build support for action by other policy actors using lessons learned from AGs. Specifically, AGs have been able to cultivate strong, bipartisan support for their drug affordability work by leveraging particular policy frames that have broad appeal. In addition to the frame of drug affordability itself, they have framed their activities in terms of combating fraud on government programs and in terms of consumer protection.[249] Both of these goals connote important law enforcement aims and are hard to argue with. Both have been instrumental in prompting congressional action on drug pricing issues—such as AWP reform—in the past. As Congress and state legislatures across the political spectrum continue to press ambitious drug affordability bills, they should draw upon these frames as much as possible.

CONCLUSION

In conclusion, in reflecting on AGs as policy actors in our federalist system, Paul Nolette has argued that AGs can serve as "a mechanism to achieve a larger and more energetic regulatory state."[250] Few areas of policymaking cry out for a more energetic regulatory presence than pharmaceutical pricing. Whether measured in terms of financial and clinical harm to patients, budgetary impact on public and private insurers, or starkness of contrast between the American approach and those of other industrialized nations, the regulatory gap is cavernous. AGs alone will not be able to close it, but they are and should be an integral part of the effort.

249. This pattern is in keeping with research suggesting that "state litigation against business interests tends to be more bipartisan than state litigation against the federal government." *See* Lemos, *supra* note 186, at 1431.

250. NOLETTE, *supra* note 14, at 203.

APPENDIX

Interview Guide

Introduction:

Thank you again for participating

[introduce yourself and your background]

As you know, the purpose of this study is to learn about what state attorneys general are doing to address the problem of prescription drug affordability and how they make decisions about what to work on.

No right or wrong answers. We hope you will feel free to be candid. We won't be reporting results in a way that links responses to individual people or particular organizations. Of course, we don't expect you to discuss privileged or confidential information.

Interview questions are designed to take about 30 minutes but you are welcome to speak longer.

We'd like to record the interview. If any privileged information or identifying information inadvertently gets mentioned, we'll redact it from the transcript. Just let us know, if it's not obvious.

OK, I am going to start recording now. **HIT RECORD (TO CLOUD) BUTTON IN ZOOM AND ON CELLPHONE**.

Begin with: "**This is interview [STUDYID]"** *(use format MMDD-01, MMDD-02, etc.)*

Do you have any questions about the information in the consent form we sent?

Do you consent to participate in the study?

Great, let's get started. In my questions, I'm going to use the term "your office" to refer to the state AG's office generally.

1. How highly would you say prescription affordability issue ranks on your office's list of policy priorities, on a scale of 1 (among our highest priorities) to 5 (not a priority at all)?

What influenced that prioritization? Whose priorities do people in your office see themselves as having a mandate to pursue?

I'd like to talk about some affirmative policy strategies that some state AGs offices are pursuing. By "affirmative," I mean things they are initiating on their own, such as filing lawsuits.

In contrast, we'll talk later about actions taken to craft or defend acts of

the legislature or governor, what I'll call "supportive work."

[If you know the state is pursuing one of the specific strategies below, rephrase to acknowledge – e.g., "I read that you are . . . ". If they talk about opioids, clarify that we are only talking about affordability work.]

2. Has your office been involved in / what has your role been in . . .

Price-fixing litigation against generic drug manufacturers?

Bringing price gouging claims against drug manufacturers?

Bringing claims against PBMs?

Efforts to ensure access to affordable remdesivir?

The multistate 340B letter?

Task Force or Working Group work on drug affordability that we haven't already talked about?

[for each "YES", follow up with:]

What has been your state's role in that?

[if not obvious:] Are you collaborating with other states in this work? How?

What influenced the decision to pursue that?

What has been difficult about pursuing this work? What kind of obstacles have your faced?

[If they are doing one or more of the above strategies, ask (2a). If none, skip to (2b)]

2a. Thinking about all the affirmative strategies you have been involved in…

What factors do you think position your office to be successful in these activities? What has empowered you?

PROBE: How confident do you feel about the strength of the legal authorities you have to pursue this work—for example, consumer protection statutes?

SKIPPABLE: You've talked about difficult aspects of particular activities, but are there any other, cross-cutting challenges for your office in bringing lawsuits and pursuing other affirmative strategies on the drug affordability issue?

PROBES: For example, workload? Lack of political support?

Have you found it useful to collaborate with others outside your office,

including other states, private counsel, nonprofit organizations, and academics? [Explain?]

SKIPPABLE: When money damages come out of successful actions, how are decisions made about how the dollars will be spent?

[SKIP if you asked (2a)]

2b. What have been the most important reasons why your office has not pursued affirmative strategies like these on the drug affordability issue?

[Probes: lack of interest; political obstacles; resources; lack of legal authority]

3. Now let's talk about supportive work—work your office has done <u>to craft or defend acts of the legislature, governors, or agencies</u> in the prescription drug affordability space.

Are there particular laws or actions that you have helped craft and or/defend? To the extent you're able, could you discuss specifics?

What has been the nature of your work in this space—for example, responding to litigation, providing advice to other policymakers, helping with implementation of legislation, promoting the drug affordability issue on the state legislature's or governor's agenda?

[If they are doing one or more of the above strategies, ask (4a). If none, skip to (4b)]

4a. Thinking about this supportive work as a whole . . .

What has been difficulty about pursuing this work? What kind of obstacles have you faced?

PROBE: How confident do you feel about the strength of the legal tools you have available?

PROBE: Political obstacles? Is your AG elected or appointed? Same or different party than governor?

PROBE: Resources / workload?

What factors do you think position your office to be successful in these activities? What has empowered you?

How useful has it been to collaborate with others outside your office, including other states, private counsel, nonprofit organizations, and academics? [explain?]

SKIPPABLE: How (if at all) do you think the lobbying and litigation tactics of the pharmaceutical industry differ from tactics employed by other

entities?

[SKIP if you asked (4a)]

4b. What have been the most important reasons why your office has not undertaken activities like these?

[Probes: no proposals/legislation that needed defending; lack of interest within office; political obstacles; resources; lack of legal authority]

I have just a few concluding questions.

5. **MUST ASK: If your office had more resources, what would you like to be doing on drug affordability that you're not doing now?**

6. **MUST ASK: Are there practical needs that could be met through means *other* than an increased budget (for example, through support from external pro bono lawyers; academics; inter-state AG collaborations)?**

7. **MUST ASK: What institutional strengths and limitations do you think state AG offices have in this policy context, compared to legislatures and governors?**

I'm aware of the time and don't want to keep you longer than we promised. Is there anything else you want to add about things your office is doing, or not able to do, in this space?

Thank you so much. I'd be glad to send you a copy of our study findings when they are read.