

Monitoring Corporate Compliance Through Cooperative Federalism: Trends in Multistate Settlements by State Attorneys General

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Recent scholarship on U.S. regulatory federalism has tended to focus on conflict between the states and state resistance to federal initiatives. Less attention has been given to federal-state cooperation and how it affects regulatory enforcement. In this paper, we examine intergovernmental cooperation in multi-state lawsuits filed by state attorneys general to ascertain trends in multi-state regulatory enforcement through litigation over time. We pay particular attention to the increasing use of compliance monitoring by both state and federal regulators, including through monitors independent of the regulated industries. Relying upon a dataset of legal settlements, scoping interviews, and two case studies of recent multistate litigation, we find that federal-state cooperation in multi-state lawsuits has become more institutionalized over time. This increased cooperation has created a two-way street in which state and federal regulators often combine resources and learn from each other through the process of compliance monitoring.

Regulatory federalism in the United States has been characterized by patterns of conflict as well as cooperation between federal and state governments. The patterns of conflict have received much of the recent scholarly attention, as high levels of polarization have filtered from the federal level to the states (Conlan 2017; Conlan and Posner 2016), producing state resistance to federal initiatives on increasingly partisan lines (Bulman-Pozen 2014; Bulman-Pozen and Metzger 2016; Dishman 2022; Nolette 2017; Nolette and Provost 2018). Despite this partisanship, patterns of cooperation remain both between the federal government and the states (Bulman-Pozen and Metzger 2016) and among the states (Nolette 2017; Nolette and Provost 2018). State AGs, while increasingly involved in partisan, national policy battles, have developed avenues of bipartisan cooperation during the Obama, Trump, and Biden presidencies despite the growth of federalism conflicts across many policy venues. Recent examples include significant multi-state investigations and lawsuits involving opioids, robocallers, financial misconduct, and data breaches.

This increasing pattern of federal-state cooperation has grown more sophisticated over time, with state AGs pursuing new reforms designed to improve corporate governance and compliance within defendant companies as a condition of regulatory settlements. These requirements have been evident for some time in *federal* settlements, as Department of Justice (DOJ) negotiators have utilized the tool of “compliance monitoring” (CM) in the wake of Enron’s dissolution and the passage of the 2002 Sarbanes-Oxley Act (Arlen 2011; Baer 2009; Ford and Hess 2009, 2011; Garrett 2014; Root-Martinez 2014).¹ The purpose of CM is to provide additional oversight of corporate activities to prevent the recurrence of legal violations in the future. CM is often performed by an independent, third-party monitor, tasked with overseeing the implementation of the settlement, but the job of monitoring may also fall to government regulators or to monitors who are employees of the defendant company – a process of self-monitoring.²

Recently, the use of CM has increased at the *state* level, particularly the use of independent, third-party CM (Cooper and Leatherman 2018; Fox 2019). In 1997-98, major tobacco companies agreed to pay over \$200 billion to the states and reform their advertising and marketing practices, while an independent monitor verified tobacco companies' compliance with settlement terms and payments to states (Derthick 2002; Spill, Licari and Ray 2001). However, tobacco was an outlier to the typical pattern of AG regulatory oversight until more recently, as AGs have become willing to apply CM to a variety of regulatory domains. This has been particularly true in coordinated federal and state settlements, but states are also using CM independently of federal enforcers (Cooper and Leatherman 2018).

In this article, we attempt to understand how federal-state cooperation affects the use of CM by the states. While much scholarship has focused on CM in federal agencies, there has been virtually no scholarly attention paid to CM originating from multi-state settlements negotiated by state AGs, or to settlements jointly negotiated by federal and state enforcers. CM is an important reform to regulatory governance, and scholars continue to grapple with how it affects business compliance with the law (e.g., Baer 2009; Barkow and Barkow 2011; Ford and Hess 2009, 2011; Garrett 2014). We seek to understand the role of federal and state cooperation in this process.

We argue that the motivation to use third party CM is shaped primarily by factors related to the specific case, defendant, and nature of the federal-state cooperation. The likelihood of seeking an independent, third-party monitor is determined by the type, severity, and pervasiveness of the misconduct and depth of the need for reform to a company's corporate governance (Cooper and Leatherman 2018; Fox 2019). However, defendant companies, fearing the large expense of third-party CM, may attempt to limit both the use and scope of third-party CM (Root Martinez 2014), requiring state AGs to be selective about requiring third-party monitoring. Additionally, we argue that the use of independent, third-

party CM by state AGs will be driven by factors related to the state-federal cooperation: the ability of federal partners to share resources with state AG personnel, the jurisdictional capabilities of state and federal regulators, and the ability of state and federal regulators to use these differential capabilities to learn from each other and enhance cooperative efforts.

Our analysis proceeds in four parts. First, we explore the degree of cooperation between state AGs and federal regulatory agencies by examining federal agency participation within all multi-state settlements brought by state AGs between 1982 and 2019. Second, to understand the prevalence of third-party monitoring, we coded documents gathered from multi-state cases settled between 2007 and 2021 and compared the use of independent, third-party CM against the use of government monitoring and company self-monitoring. We performed this coding for cases with and without federal cooperation. Third, to corroborate the findings from these data, we conducted six scoping interviews with assistant AGs with extensive experience in negotiating the terms of multi-state settlements. Finally, in order to understand how resources and federal jurisdictional capabilities matter, we examine CM in the context of two policy areas that involve federal-state cooperation: data privacy and health care. Specifically, we argue that jurisdictional roles have produced a complementary relationship between federal partners and states in data privacy, while the same roles have produced parallel state and federal settlements in the opioid litigation.

This article makes several key contributions to the literatures on American federalism and regulatory governance and compliance. First, we integrate research on regulatory federalism with research on CM and regulatory enforcement to understand how federal-state partnerships influence CM. Second, we shed light on CM in the multistate context, which has received little attention compared to federal enforcement. Third, CM is a crucially important “New Governance” regulatory technique (e.g. Lobel 2004) which overlaps with “management-based regulation” (Coglianese and Lazer 2003), and “meta-regulation” (Gilad

2010; Parker 2002). Our focus on learning between states and the federal government has the potential to help scholars understand how CM operates as a form of meta-regulation in the U.S. system of regulatory federalism. Finally, even though the success of CM as a tool of regulatory governance has been hotly contested (Arlen 2011; Baer 2009; Ford and Hess 2009, 2011; Garrett 2014), this fact has not stopped various forms of CM from spreading to other jurisdictions, such as the UK (Cheung 2018; Grasso 2016) and Australia (Bronitt 2017; Campbell 2021), among other jurisdictions. Given its importance as a tool of regulatory enforcement and compliance, it is crucial to map its use in the federal system and understand how it is being used.

Regulation and Cooperation in a Federalist System

We situate our discussion of regulatory enforcement and CM in the context of cooperation between the federal and state governments. The use of CM to ensure that defendants comply with the terms of legal settlements has increased at the federal level (Garrett 2014; Root Martinez 2014) and at the same time, similar compliance mechanisms are being deployed in multi-state settlements. (Cooper and Leatherman 2018). Additionally, the willingness to cooperate and utilize CM has also increased among federal and state enforcers. In the early 1980s, multi-state litigation was perceived as a substitute for federal inaction (Lynch 2001), but cooperation with federal agencies increased as multi-state litigation became institutionalized. Lynch argues that even though the regulatory climate of the Reagan Administration provided the impetus for state AGs to pursue multi-state cases, “the eventual rise of multistate litigation...seems in retrospect to have been inevitable” (2001: 2005). State AGs could more effectively take on corporations when allied with other AGs, while they often lacked the necessary resources on their own. The widening use and scope of multi-state litigation has paved the way for greater partnership with federal agencies.

Cooperation has increased for several overlapping reasons. First, President Obama signed into law broad, sweeping laws, such as the Affordable Care Act and the Dodd-Frank Act, that enlisted the states as active partners in implementing and enforcing the laws (Bulman-Pozen and Metzger 2016; Metzger 2011; Totten 2015). State partners in enforcing these specific laws have tended to be Democratic, as Republican AGs have repeatedly attempted to have the Affordable Care Act invalidated. However, state AGs have displayed a bipartisan spirit of cooperation in multi-state lawsuits involving data privacy (Citron 2016; Dishman 2021), pharmaceuticals (Nolette 2015b) and antitrust cases (Provost 2014), among other issues. Consequently, it has also been easier for federal agencies to work with a broad range of state AGs on these issues as well.

Second, the patterns of polarization and partisan conflict in American federalism have indirectly enabled greater policy coordination between federal agencies and the states. Gridlock is prominent in Congress, leading to difficulty in enacting significant legislation across several policy domains. Polarization at the state level now tends to mirror polarization at the federal level (Conlan 2017; Conlan and Posner 2016; Lemos and Young 2018) and a key example of this phenomenon has been litigation brought by state AGs against federal initiatives (Bulman-Pozen 2014; Bulman-Pozen and Metzger 2016; Dishman 2022; Nolette 2015a; Nolette and Provost 2018). While such litigation is a prime example of how states often conflict with federal policymakers, political polarization can also be effective in generating cooperation between federal agencies and state AGs.

Legislative polarization at the federal level often produces gridlock that in turn opens space for federal agencies to operate. Presidential administrations that seek active regulatory enforcement are more likely to employ an administrative strategy of relying on federal agencies when gridlock impedes a president's legislative agenda. Additionally, federal agencies often possess the legal authority or political capability to push policymaking beyond

what the president might want (Freeman and Spence 2014; Metzger 2015; Strauss 1984). Consequently, while it is likely reasonable to expect higher levels of federal-state cooperation during Democratic presidential administrations, some agencies may be able to push their own policy initiatives beyond the president's policy objectives and enlist states as partners in the process, even during Republican administrations (Metzger 2015).

In summary, studies of American federalism have focused upon the circumstances under which cooperation and conflict are likely to occur between and within branches of government, as well as with and between the states. Research on CM has been more concerned with the legal and administrative tools that can reform business organizations and achieve settlement compliance. Few scholars have attempted to bridge this gap and demonstrate how federal-state cooperation in regulatory enforcement has affected the joint use of CM by federal and state regulators.

The Origins and Importance of Compliance Monitoring

To understand the motivations and constraints behind the use of third-party monitors, it is necessary to understand the history and purpose of CM. The first instance of CM in a U.S. federal agency occurred because of a 1995 DOJ criminal settlement (Cooper and Leatherman 2018; Lissack et al. 2020) and since then, CM has expanded dramatically in U.S. federal agencies when negotiating both criminal and civil settlements (Garrett 2014; Ford and Hess 2009, 2011; Root Martinez 2014). CM is designed to ensure that defendant companies are accountable for implementing settlement terms including reforms to their corporate governance. Companies that enter settlements with the government may have inadequate safeguards or corporate cultures that enable or condone illegal behavior. Entering the inner workings of corporations to reform their cultures or governance structures is seen by many observers as a bold regulatory reform. Garrett (2014, 7) argues that it “represents an

ambitious approach to governance in which federal prosecutors help reshape the policies and culture of entire institutions...”, while Ford and Hess say, “in theory, we believe monitorships have significant potential as a form of new governance regulation focused on reforming corrupt corporate cultures,” although they argue that monitorships in practice ultimately fall short of this lofty potential (2009, 2011).

Government enforcers are more likely to demand an independent monitor as a term of settlement when certain factors are present. There are a variety of means to oversee compliance with a settlement such as allowing the company to designate an employee to oversee reforms or for government enforcers to ensure compliance. Designating an independent monitor is substantively different, in that the monitor is a third party separate from both the defendant company and the government. Company culture and leadership are driving factors in whether an independent monitor is necessary. Lissack et al. (2020) interpret guidance from the DOJ to say that independent monitors may be required if a company is not able to reform on its own. They also suggest that outside monitoring should be used if the “tone at the top” of a company undermines compliance and encourages law-breaking. Changing the tone at the top of a company is very challenging, as it possibly means reforming the entire corporate culture. Van Rooij and Fine (2018, 1) analyze “toxic corporate culture” and argue that “detoxing corporate culture...requires addressing the structures, values and practices that enable violations and obstruct compliance within an organization.” The collapse of companies like Enron, Worldcom and Global Crossing are historically considered spectacular corporate failures, generating enormous losses of jobs, investments, pensions and savings. The collective desire to avoid disasters like this again has led prosecutors to think about reforming corporate governance as a condition of regulatory settlements.

The complexity of the matter and the severity and pervasiveness of the misconduct are also factors that weigh heavily in favor of an independent monitor. Complex settlements or regulatory requirements where there has been severe and pervasive misconduct may require the expertise and supervision of an independent monitor. For example, the Master Tobacco Settlement Agreement signed in 1998 is a long-term complex settlement agreement aimed at addressing severe and pervasive misconduct in the tobacco industry. Specifically, the MSA required that the companies subject to it would not lose market share, which meant that existing market structures had to be monitored and maintained (Fox 2019). It was also necessary to ensure that tobacco taxes were paid and that the interstate movement of tobacco was regulated. Consequently, nearly every state AG office has had staff devoted to enforcing the MSA in their state (Cooper and Leatherman 2018).

Cooper and Leatherman (2018) therefore argue that “it was only a matter of time before state attorneys general incorporated the use of monitors into multistate settlements to supervise compliance with new industry-wide standards...” They also provide the salient example of the 2012 National Mortgage Settlement with the five largest U.S. banks as the right conditions for an independent monitor, due to the settlement’s complexity. Not only did it involve the distribution of billions of dollars in settlement funds, but “it required banks to comply with over 300 servicing standards and involved law enforcement of a new federal law and laws of 49 states” (Cooper and Leatherman 2018). In an interview with Tom Fox (2019), a former Rhode Island Assistant Attorney General, Gerry Coyne argues that the shifting focus towards supervising compliance is a positive development: “taking away money is not enough to change behavior...you have to find a way to regulate the business going forward, so that the conduct is not engaged in, in the future.”

While independent monitors might be appropriate for implementing deep reform within businesses, there may also be reasons for why their use would be constrained. The

costs of monitorships are typically borne entirely by the defendant company and these costs can often run into the millions of dollars (Khanna and Dickinson 2007; Root Martinez 2014). Ford and Hess (2011) argue, “the cost of a monitorship is also easier to justify where more pervasive, serious, persistent, corporate-level problems are identified.” If firms disagree about the nature of the problems identified, they may push back in negotiations over a monitor. Or they may agree to the monitor but insist on concessions elsewhere, such as lower monetary penalties or a hindered ability to bring new legal actions in the face of future complaints. Thus, the need to be strategic regarding the use of independent monitors may prevent state AGs from requiring independent monitors more frequently.

Research Design

This article examines trends in federal-state cooperation with respect to regulatory enforcement and how CM has evolved as part of this cooperation. We employ a mixed methods approach that utilizes both quantitative and qualitative data. First, we look at all multi-state settlements from 1982 through 2019 to gauge the degree of federal-state cooperation in multi-state settlements. Second, we analyze a sample of cases that took place between 2007 and 2021 for which we could locate specific settlement data. We categorized three types of CM in enforcement settlements: 1) independent third-party monitors, 2) government oversight, and 3) company self-monitoring. We code settlement data according to the type of CM used to ascertain how often independent monitors are employed in multi-state settlements. These two sets of quantitative data are designed to illuminate how federal-state cooperation has evolved in multi-state litigation, as well as how the use of CM has evolved in more recent years.

To provide additional support to our data on CM categories, we conducted several scoping interviews with assistant attorneys general to understand better the use of CM and the

circumstances under which it is used. Assistant AGs play an active role in negotiating multi-state settlements and our interviews are with AGs from states that are active in multi-state litigation. Each of the interviews were conducted in a semi-structured fashion – with a set list of questions and follow-up questions regarding CM, its use, and its perceived effectiveness. While the sample size is small, the interviews generated useful data to help us understand the circumstances under which independent, third-party monitors are used.

Building upon the findings from the quantitative and interview data, we present two qualitative case studies. First, we present evidence from data privacy and security cases to show how compliance is monitored in settlements that are negotiated by state AGs and the Federal Trade Commission (FTC). Second, we examine the case of health care, specifically the settlements reached with pharmaceutical companies, commonly known as the “opioid settlements.” We choose data privacy and opioid cases for several reasons. First, state AGs and the DOJ have attempted to achieve structural reform in these areas, building upon pioneering efforts by state AGs to do so in the tobacco and financial services industries. These broader efforts to regulate significant sectors of the national economy are different than ad hoc efforts to respond to areas involving frequent consumer complaints, such as robocalls. Second, settlements in both types of cases typically require changes in a company’s governance, compliance, and operations and will therefore require a monitoring mechanism to oversee those changes. Third, both areas involve complexity in the settlements, whether in terms of technical complexity in the data protection context that requires expertise to oversee or in terms of addressing the complexity of regulating a vast pharmaceutical industry and compensating many states and localities. Fourth, both case studies have significant federal and state involvement, providing the opportunity to explore federal and state cooperation and CM at the same time.

Federal State Cooperation in Multi-State Litigation

To examine federal-state cooperation in multi-state litigation, we examine all multi-state settlements settled between 1982 and 2019³ -- data that come from the Nolette Multi-State Settlement Database. The database classifies whether there was federal involvement in each case and which federal agencies were involved, if any. Federal involvement includes federal joint or parallel enforcement actions. Additionally, the database lists the general policy area of each case: antitrust, consumer protection, environmental or health care. Antitrust cases involve mergers, monopolies and price-fixing; consumer protection cases involve advertising, data privacy and finance; environmental cases deal with violations of state and federal environmental law, while health care cases primarily involve different forms of fraud involving the Medicaid program.

In Figure 1, we present the raw number of multi-state lawsuits settled between 1982 and 2019, as well as the raw number of cases involving federal agencies, broken down by policy area. For ease of interpretation, utilizing the data in Figure 1, we discuss the data in terms of percentages of multi-state cases with federal involvement by each presidential administration. First, the figure demonstrates a clear increase in multi-state cases over time, with cases increasing beyond twenty per year starting in 2000. The figure also demonstrates a gradual increase in federal agency involvement over time, a trend which then dramatically escalates at the start of the Obama Administration. The early years of multi-state litigation are characterized by very little federal involvement,⁴ as multi-state litigation from this period was perceived almost exclusively as a reaction to federal regulatory inaction (Lynch 2001). Federal involvement increases during the George H.W. Bush Administration to 12.5 percent of total cases, but then jumps markedly to 33 percent during the Clinton Administration, before falling slightly to 30 percent during the George W. Bush Administration. The 1990s

tobacco litigation is a major driver of increased multi-state litigation and CM during the Clinton Administration.

[FIGURE 1]

The most notable shift that we see however with respect to federal participation is an increase during the Obama Administration in federal participation to 57 percent of all multi-state cases. Much of the overall increase appears to be driven by health care cases, where state AGs see increased collaboration with HHS, typically to crack down on Medicaid fraud. However, the number of consumer protection cases with Obama Administration federal involvement also reaches its highest level during the series. This increase is most likely driven by increased coordinated enforcement in financial regulation, as well as more data privacy cases in which the FTC and state AGs work jointly. Finally, the number of cases with federal involvement decreases during the Trump Administration and the proportion of cases with federal involvement is 40 percent. This is a substantial drop from the Obama Administration level of federal participation, but it is notably higher than the level of federal involvement under every other president in the series.

In Figure 2, we utilize the same data, but look at federal involvement in each type of case (antitrust, consumer protection, environmental and health care) as a proportion of the total number of multi-state cases each year. The data reveal a bit more volatility with respect to overall federal involvement, but this is partly due to the smaller number of overall multi-state cases in the 1990s and early 2000s. These data support the finding from Figure 1 that federal involvement in multi-state cases experienced bursts in the 1990s and 2000s, while also confirming dramatically higher federal involvement during the Obama Administration. Finally, Figure 2 also demonstrates that a high proportion of the cases with federal

involvement are in the areas of health care and consumer protection, particularly during the Obama Administration.

[FIGURE 2]

There are some key takeaways regarding federal and state enforcement trends. As the annual number of multi-state cases rose during the 1990s, federal involvement rose as well. Nolette database data reveal that DOJ and FTC are responsible for much of the federal involvement through the Bush Administration, while HHS is the primary federal partner in health care cases, dealing with cases of Medicaid fraud. The start of the Obama Administration reveals a paradigm shift, as multi-state cases and federal involvement both increase dramatically. Additionally, Nolette database data also reveal several other federal agencies, beyond DOJ, FTC and HHS, joining the action during the Obama Administration. Finally, the data appear to indicate greater federal involvement in multi-state cases during Democratic administrations, but this pattern does see some exceptions.

Monitoring in Multi-State Litigation

In this section, we examine settlement data for cases between 2007 and 2021 in order to understand the type of CM utilized in settlements and how it is affected by federal-state cooperation. We choose this date range because it allowed us to consider types of monitoring and cooperation during four presidential administrations with presidents from each party: W. Bush, Obama, Trump, and Biden. We also choose this range for the public availability of settlement documents on the internet and an increase in activity in state enforcement during the time period. To gather these data, we relied upon basic settlement information from the Nolette database to scrape the internet to locate the specific settlement documents. We then

analyzed the settlement documents to gather information regarding what type of CM is utilized in the settlement. We organized types of CM into four categories: 1) independent third-party monitors; 2) government monitoring; 3) internal company self-monitoring; and whether some combination of these types of monitors was employed.⁵

We utilized this coding scheme in order to ascertain how often state and federal regulators decide that independent, third-party monitors are needed, as opposed to government oversight or internal company supervision. While there is a spectrum of CM and combination of CM employed in settlements, we created these distinct categories to better understand specifically how independent third-party monitoring relates to federal and state cooperation. A greater reliance on third party monitors is an indicator that settlement requirements are becoming more complex, companies cannot implement the settlement terms on their own, or more companies require changes in overall tone or culture.

The data are presented in Tables 1 and 2. Table 1 presents the different monitor type data across the four types of cases (antitrust, consumer protection, environment and health care) for cases with federal agency involvement. Out of the 235 cases whose settlement documents we obtained, 142 of these had federal agencies involved. Table 2 presents the same data, but for cases without federal involvement, of which there are 93. Each number in each table represents a percentage—the proportion of settlements in which a particular type of monitor was used for a given type of case. For example, in Table 1, government monitors were utilized in 37 percent of antitrust cases with federal involvement.⁶

[TABLE 1]

[TABLE 2]

What is most noticeable in Table 1 is that despite the prevalence of third-party monitoring, government monitors still do the CM in most settlements—50 percent in consumer protection cases and 40 percent in health care cases. Only in antitrust cases is the

percentage of independent, third-party monitors higher than it is for government monitoring. Additionally, in antitrust and consumer protection cases, state AGs appear to be reluctant to delegate CM to company self-monitoring, as both government and third-party monitors are used more frequently in these cases. In contrast, internal company self-monitoring is more common in health care and environmental cases. In Table 2, where there is no federal involvement, we see that there is still a high proportion of government oversight in antitrust and consumer protection cases,⁷ but here there is also a greater reliance on company self-monitoring. A likely explanation for relying on company self-monitoring is that without federal involvement, state AGs have fewer government resources to draw upon to monitor compliance with settlement terms and may be more inclined to accept internal self – monitoring by the company. Overall, however, we still do see that government and third-party monitors are used frequently to oversee the implementation of settlement terms.

To build on our CM data and yield more nuanced insights on the use of different types of monitoring, we conducted six semi-structured interviews with assistant attorneys general from states that play lead roles in multi-state litigation. The data gathered from our interviewees largely corroborated the guidance from the DOJ which indicated that third-party monitors are appropriate when a business requires a deep change in culture and/or tone at the top. The job of state AGs is to investigate suspected wrongdoing and negotiate settlements that bring restitution to consumers, while achieving terms designed to stop illegal behavior. Because AGs do not have the time or resources to do their own extensive monitoring, independent third-party monitors are necessary when wholesale change is needed within a business. While third-party monitors are helpful to produce deep organizational change, there are a few reasons why they might not be used as frequently as some AGs would prefer. Third party monitors tend to be expensive, and the cost is typically borne by the defendant company. Multiple interviewees indicated that if companies agree to a third-party monitor,

they may push back elsewhere in the negotiations, so that the company pays less in monetary settlements to states than would have been paid otherwise.

In summary, third party monitors are essential for producing the deeper behavioral changes AGs often seek through multi-state litigation, but the commitment of time and resources is highly significant and may require AGs to make sacrifices elsewhere in the settlement process. Consequently, AGs are more likely to be strategic in their use of third-party monitoring, which is the pattern borne out by data revealed in the 235 settlement documents. As we showed in Tables 1 and 2, third party monitors are often employed to ensure companies comply with settlement terms, but overall they are employed less often than government monitors or company monitors. It is worth noting, however, that third party monitors are employed more often when the federal government is a partner. In the next section, we present case studies that discuss CM in specific contexts, data protection and opioids enforcement, to understand how state and federal cooperation relate to the use of third-party, independent monitoring.

CM and Federalism in Data Protection Enforcement

Data protection⁸ is an area where federal and state enforcers are highly cooperative, and settlements regularly require third-party monitoring (Brill 2012, Dishman 2021). Many data protection enforcement actions are pursued by multistate coalitions and the FTC in joint or parallel actions. This cooperation has allowed states to rely on the FTC's precedent of requiring independent third-party monitors to ensure compliance with data protection settlements. State AGs have increasingly brought multistate actions together in the wake of high-profile data breaches (Citron 2016; Dishman 2021), and in resolving these actions, states have learned from the FTC, by relying on its established settlement terms including the

requirement for independent monitors. At the same time, states have charted their own paths in innovating settlement terms including approaches to CM (Dishman 2021).

Enforcement settlements play a particularly important role in transmitting data standards to companies.⁹ The FTC has developed a framework of settlement terms that has been largely consistent across its data protection settlements, including monitoring settlement compliance with a “third party assessor,” another term for an independent, third-party monitor (Solove and Hartzog 2014). States have become increasingly active data enforcers both in coordination with the FTC and as multistate coalitions (Citron 2016; Dishman 2021). Additionally, states have adopted terms in settlements for independent monitoring like those adopted by the FTC, but there have also been variations in CM in federal and state data protection settlements.

Cooperation facilitates the use of the same or similar settlement terms in federal and state settlements since enforcers may participate in joint or parallel settlements. Cooperation also enables states and the FTC to learn from each other’s settlement terms. Joint actions between the states and FTC are facilitated by statutory regimes that encourage coordinated action and delegation to state enforcers. The primary statute that the FTC relies upon for data enforcement is Section 5 of the FTC Act that broadly prohibits “unfair and deceptive acts or practices” (15 U.S.C. § 45). With the FTC’s encouragement, the states have also adopted “little FTC acts” that also prohibit “unfair and deceptive acts or practices” as part of their consumer protection laws (Citron 2016). Similar state and FTC statutes facilitate cooperation between the two levels of government. In fact, a violation of a state’s “little FTC act” can be the basis for an FTC enforcement action (Evans 2015). Furthermore, several federal statutes provide overlapping authority to the FTC and states to enforce data in specific areas or industries that allow delegation of enforcement to states. Challenges to the FTC’s authority

and regulatory restrictions also provide gaps that states are well positioned to fill in data enforcement (Dishman 2021).

The FTC's reliance on settlements to regulate data practices makes CM in settlements particularly important. As a result, the FTC has long required that compliance with settlements be regularly assessed by an independent third-party monitor. FTC settlements typically require monitors to be a "qualified, objective, independent third-party professional" and have specific information security certifications and credentials or follow procedures and standards accepted by the profession.¹⁰ The monitor assesses the company's implementation and maintenance of a comprehensive information security program that is also required by the settlement. There is variation in the amount of control the company has in the selection of the monitor in FTC settlements. In some instances, the company may select a qualified assessor and in others, the FTC must approve the company's selection.¹¹ Companies are required to have initial and biennial assessments performed by the monitor, often over a twenty-year period and the assessments are required to be submitted to the FTC.

FTC data protection settlements established a precedent of requiring independent monitors. As states became more active in data enforcement in joint and parallel actions with the FTC, they also adopted independent monitoring as a requirement in settlements. Early state data protection enforcement actions were pursued jointly with the FTC. Joint and parallel FTC/multistate settlements relied heavily on the terms from the FTC's established framework, including those relating to CM.¹² For example, coordinated FTC/multistate settlements contain requirements for companies to establish comprehensive information security programs that are assessed by an independent third-party monitor.¹³ Monitors are often required to have specific information security certifications.¹⁴ Parallel multistate settlements to FTC actions allowed companies to meet the requirements for third party assessments in state settlements by fulfilling their obligations in FTC settlements.¹⁵ In joint

and parallel actions with the FTC, states have been able to piggyback on the FTC's requirement for third party monitoring. Because companies are already required to undergo monitoring for the FTC, there is little reason for them to push back on the requirement for a state joint or parallel settlement. As states have become increasingly active in this area, they have instigated multistate enforcement actions, often without a joint or parallel FTC action. Even without a federal partner, states continue to rely on the FTC framework for settlement terms, including the requirement that a third-party monitor assess compliance with the settlement. Many multistate settlements track requirements of FTC settlements for monitors such as requirements that they be independent third parties with specified information system certifications.¹⁶

While states have relied on the FTC's approach to CM in settlements, they have also charted new paths in settlement terms, including greater variation in terms with respect to monitoring (Dishman 2021). In some instances, multistate settlements have adopted more customized forms of assessment based on the conduct that brought about the enforcement action. For example, in one multistate settlement, assessment was based on compliance with industry standards for payment card processes and in another, it was based on internal patch management.¹⁷ Assessments of multistate settlements generally must be submitted to a lead AG or multistate executive committee who can circulate it to participating states upon request.¹⁸ In multistate settlements, the company is generally allowed to select its own monitor that meets the qualifications in the settlement; however, in some instances, states approve the selection of the assessor.¹⁹ States generally require companies to have fewer assessments by monitors than the FTC, sometimes only requiring a single assessment. CM in federal and state data protection settlements reflects cooperation among enforcers and flexibility in the ability of enforcers to innovate and adapt.

Differences in approaches to CM are reflected in the different attributes and approaches of federal and state enforcers. The FTC is consistent about requiring an independent monitor in data protection enforcement actions, while other federal agencies rely more heavily on government and self-monitoring in other enforcement contexts. States often require third party monitors in data enforcement actions, but they tend to employ greater variation in terms relating to monitors. Companies are required to have a greater number of monitor assessments performed under FTC settlements than state settlements.

This variation can be attributed to the enforcement power and institutional attributes of the FTC and states. The FTC cannot exact civil penalties in the first instance of settlement under Section 5 of the FTC Act, but can demand penalties for violation of an existing settlement (Solove and Harzog 2014). CM becomes particularly important if violation of the settlement is the only vehicle for the FTC to collect penalties. The lack of power to obtain penalties in the first instance also favors long settlement terms and more frequent assessments to ascertain compliance. In contrast, states are empowered to seek penalties for the first violation, favoring shorter duration of settlement terms and fewer assessments. The variation in CM in multistate settlements may also be attributed to companies negotiating for less expensive or onerous monitoring requirements. Furthermore, the FTC has institutional permanence, expertise, and resources to oversee settlements of longer durations with more frequent assessments while ad hoc multistate groups have less capability of providing ongoing oversight of the CM.

Cooperation between the FTC and states has allowed independent monitoring to become a common form of CM in both federal and state data protection settlements. By pursuing joint and parallel actions with the FTC, states can rely on the FTC's established practice of requiring independent monitoring. Even when states act without the FTC as a partner, they have continued to retain independent monitoring in settlements. They have also

charted new approaches to settlement terms, including in the area of CM. As states continue to be prominent data enforcers, questions remain as to whether states will continue to adopt the FTC's approach of independent monitoring or develop their own distinctive approach to CM in the future.

CM and Oversight of the Opioid Industry

Data protection is not the only area where shifting dynamics of regulatory oversight have led to states playing a more active role in monitoring industries nationwide. The state AGs' efforts to tackle the opioid crisis also help illustrate interstate cooperation and the mechanisms states are using to address a significant national problem. As in the data protection context, federal agencies were the first to use CM in corporate settlements, but as the state AGs' activity targeting the opioid expanded, so did their use of CM. They began implementing CM after closer collaboration with federal partners in the early years of opioid litigation, which they have since expanded after pursuing their own paths separate from the federal government more recently. Most significantly, this includes the opioid settlement announced in 2021 that marks the largest state AG civil settlement since the tobacco litigation.

Despite COVID-19 arising as the nation's most pressing public health emergency over the past two years, the opioid epidemic has only continued to escalate. In 2010, there were 21,088 opioid-involved overdose deaths, already a sharp increase from 8,000 deaths a decade earlier in 2000. By 2020, the crisis had become significantly worse, with nearly 70,000 Americans dying from opioid overdoses (National Center for Health Statistics 2021). The epidemic of opioid deaths has drawn increasing attention from national and state policymakers, including the DOJ and state AGs. Both have become increasingly focused on

investigating and reforming various practices of the pharmaceutical drug industry over the past two decades, including probes of the industry's role in exacerbating the opioid crisis.

Several of the earliest efforts regarding opioids were relatively limited. State AGs were mainly interested in how to address the under-treatment of pain by assuaging physicians' fears of being investigated for inappropriate prescribing of controlled substances (Edmundson 2003). This began to change with Purdue Pharma's aggressive marketing of its prescription opioid OxyContin, which the U.S. Food and Drug Administration had approved in 1996. In 2001, West Virginia AG Darrell McGraw became the first AG to sue Purdue for its allegedly illegal marketing of the drug with prescriptions increasing 20-fold in its first five years on the market. This case was settled for a relatively small sum of \$10 million in 2004, and the settlement did not contain injunctive provisions aiming to change or monitor corporate behavior moving forward.²⁰

However, McGraw's efforts spurred additional cooperative enforcement activity among government enforcers. The U.S. Department of Justice began an investigation of Purdue's marketing of Oxycontin in 2002, followed by a multistate group of AGs shortly thereafter. These efforts led in 2007 to the first federal and multistate settlements over opioid-related claims. As part of the \$600 million federal settlement, three of Purdue's top executives pleaded guilty to federal criminal charges and the company itself plead guilty to felony misbranding of a drug (Meier 2007). In a parallel settlement announced in the same week, a multistate coalition of 27 AGs settled with Purdue for \$19.5 million to settle the states' civil claims brought under state consumer protection laws.²¹

Unlike the earlier West Virginia settlement, both settlements required Purdue to change their corporate practices. The federal Corporate Integrity Agreement that accompanied Purdue's guilty plea required the company to refrain from making any deceptive or misleading claims about OxyContin and to submit regular compliance reports

regarding its sales and marketing practices over the next five years (U.S. Department of Justice 2007). The multistate settlement also required Purdue to refrain from false or misleading marketing, provide additional training of Purdue employees, and various other restrictions on the company. One difference between the two sets of settlements, however, involved the corporate compliance mechanisms. The federal agreement required Purdue to pay for an independent monitor and staff to monitor compliance with the settlement's provisions. In contrast, the multistate settlement left it to Purdue to self-report to the state AGs its compliance with the marketing restrictions.²²

However, this discrepancy has changed as both federal and state enforcers alike have been more willing to turn to independent monitoring mechanisms to ensure corporate compliance with legal settlements. These efforts have also involved a wider range of entities involved with prescription opioids. In addition to opioid manufacturers, officials began probing opioid distributors, drug wholesalers, and others involved in the prescription opioid market. These investigations were based on a variety of legal arguments, including that distributors failed to meet their obligations under the federal Controlled Substances Act to ensure that their products were not diverted to illegal uses. In 2017, the federal government finalized a landmark settlement with opioid distributor McKesson Corporation for \$150 million (U.S. Department of Justice 2017) and the growing number of lawsuits brought by state and local governments were consolidated in federal district court in Ohio.²³

These later cases have featured considerably stronger corporate monitoring provisions over time than the first settlements with Purdue Pharma. The federal McKesson settlement became the first civil Controlled Substances Act settlement to establish an independent monitor that would assess the company's compliance with the settlement's terms, which included various staffing and organizational changes to prevent diversion of prescription opioids for illegal use (U.S. Department of Justice 2017). Later federal settlements, including

with opioid distributor Rochester Drug Co-operative and health data company Practice Fusion, also instituted independent corporate monitors (U.S. Department of Justice 2019; U.S. Department of Justice 2020).

The first individual state settlements with the opioid industry beyond Purdue, including West Virginia's 2019 settlement with distributors and Oklahoma's agreement with Teva Pharmaceuticals the same year, did not include similar corporate monitoring. However, more recently multistate groups of state AGs have incorporated increasingly substantial CM provisions independent from the DOJ. In October 2020, 47 state and territorial AGs settled with opioid manufacturer Mallinckrodt in a \$1.6 billion settlement requiring the company to retain an independent monitor. This monitor would assess Mallinckrodt's compliance with the various operating injunctions, clinical data transparency requirements, and public access to Mallinckrodt documents.²⁴ As of late 2021, the monitor has produced three reports to the states detailing the company's compliance and recommendations for further corporate changes to induce compliance.²⁵

Shortly afterward in February 2021, fifty-three state and jurisdictional AGs reached a landmark \$573 million settlement with consulting firm McKinsey & Company. The settlement was significant in part because it was with a third-party consultant of opioid industry members, reflecting the AGs' increasing oversight across the entire prescription opioid landscape. The states had accused the firm of promoting marketing schemes to opioid manufacturers and engaging in illegal activity to help the industry – including destroying documents in response to government investigations of Purdue Pharma. The settlement required a variety of injunctive provisions, including the requirement that McKinsey retain a variety of opioid-related documents and produce them to the state AGs in perpetuity. The state AGs, in turn, would make the documents available to the public through a document repository.²⁶

This state and public oversight of McKinsey’s documents in perpetuity mirrored similar state AG strategies with tobacco companies in the late 1990s, but marked an innovation in the opioid context. Additional far-reaching CM of the industry was announced a few months later in July 2021, when most of the nation’s AGs announced two separate agreements with opioid manufacturer Johnson & Johnson and the three largest opioid distributors, AmerisourceBergen, Cardinal Health, and McKesson. The proposed agreements, providing for payments to the states of approximately \$26 billion, contained numerous CM provisions. Some of these were new internal monitoring provisions requiring distributors to create a new “Chief Diversion Control Officer” to oversee their internal controlled substance monitoring programs. However, the settlements also included strict external, independent monitoring as well. The independent monitor would have the responsibility to audit opioid distribution within the companies, request and review documents, and report all its findings to a State Review Compliance Committee consisting of six AG offices.²⁷

The \$26 billion settlement was finalized in February 2022 following sufficient local government sign-on to the agreement. While it remains to be seen what impact the strict CM provisions will have on the industry, it is clear from this and other recent multistate agreements that state AGs have been willing to move ahead with expansive CM innovations in the opioid industry independently of the federal DOJ. As with the data protection area, AGs began using CM following partnerships with the federal government, but then increasingly went their own way in incorporating these tools in their own settlements.

This is important for several reasons related to American federalism and the structure of state law. First, it is a good illustration of a form of bottom-up regulation that has become increasingly common as officials have worked across state lines to create mechanisms to regulate national (and international) corporate entities. State AGs, in this way, have essentially become an increasingly important *national* corporate regulator of key industries in

the United States. Second, because state consumer protection law tends to be broader and less specific than parallel federal laws, it provides AGs an opportunity to aggressively use broad interpretations of “unfair and deceptive practices” to fill “regulatory gaps,” much like in the data protection context. Third, it illustrates that despite intense and deepening polarization among state officials, areas of genuinely bipartisan cooperation remain possible.

Conclusion

The use of CM in the context of increased state-federal cooperation in multi-state litigation is an important development because of its potential to affect the way state and federal law is enforced. Monitoring is designed to change the company’s governance and operations, and the increased use of independent, third-party CM is telling as it reflects a deeper commitment on the part of state and federal officials to making potentially profound changes to the way U.S. businesses operate. Scholars who have studied CM at the federal level have, to a significant degree, expressed disappointment with the results thus far produced by federal CM. Our evidence reveals that in order to evaluate monitoring mechanisms, we need to understand them in the context of federal-state cooperation. Thus, we must understand how federal agencies and state AGs learn from each other in the process of CM, as well as what the effects are of the combined resources devoted to CM.

Federal-state cooperation has become increasingly common in enforcement actions, especially in the years since the Obama Administration, when multiple new federal laws explicitly enlisted the states as partners in regulatory enforcement. While cooperation appears to be more prevalent during Democratic administrations, levels of cooperation have also increased across Republican administrations, although to a lesser degree, as states have become increasingly active enforcers. Within the scope of this heightened intergovernmental

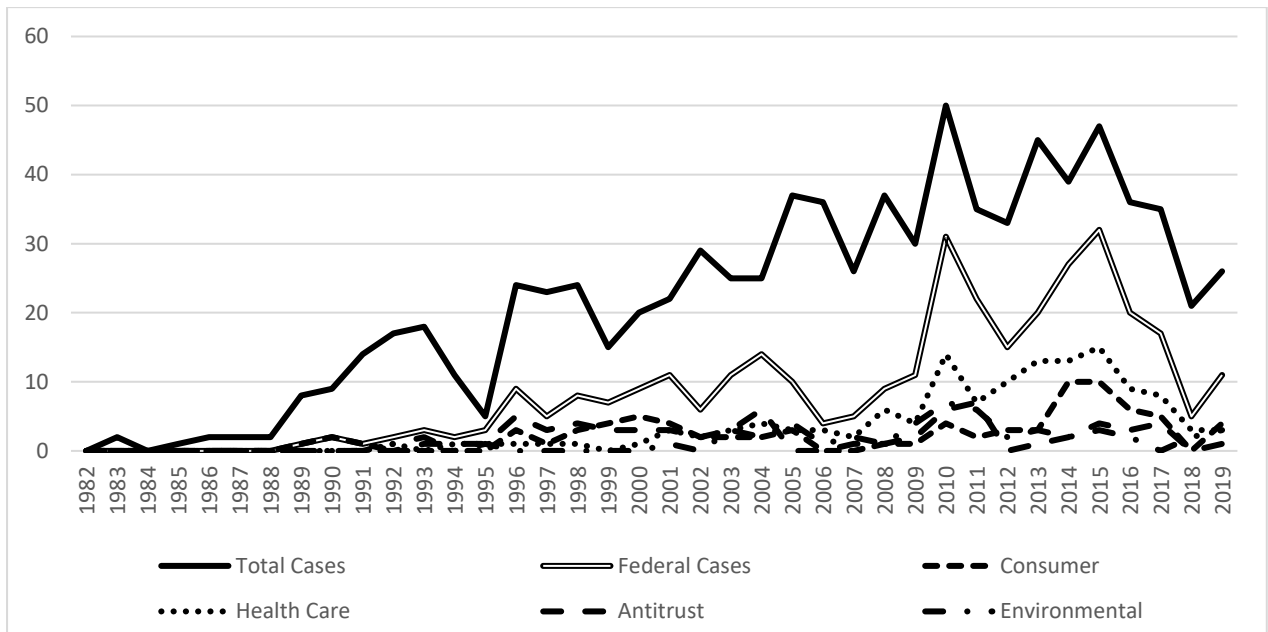
cooperation, both federal agencies and state AGs have developed approaches to ensure compliance with regulatory settlements. Independent third-party monitoring has become an increasingly more common form of CM, especially when there is federal involvement in a multistate settlement. However, we also found that the task of monitoring frequently falls to government officials or companies to self-monitor. This last finding reflects the fact that third party monitoring can be costly, which in turn means that enforcers will be strategic about its use, rather than opting for it in every settlement.

Despite this dynamic of monitor selection, the evidence still reflects the idea that when companies need to make significant changes to their culture and corporate governance, third party monitors are often chosen to achieve these far-reaching goals. Our two case studies examined the areas of data privacy and the marketing of opioids. There has been extensive third-party monitoring in these areas, as the need to reform data handling and pharmaceutical marketing practices respectively requires deep change within business organizations. Additionally, the case studies showed different, but highly engaged patterns of cooperation between federal agencies and state AGs in these policy areas. Agency-specific resources and legal capabilities result in a complementary, cooperative relationship in the case of data privacy, whereas in the opioid cases, they were more likely to produce parallel, sometimes competing cases. These cases illustrate how federal-state cooperation has increased, specifically in the use of CM, but patterns of cooperation vary depending on the policy area and the legal capabilities of the actors involved.

In this article, we have attempted to bridge different literatures on regulatory enforcement and on federalism to understand how CM has intertwined with federal-state cooperation in regulatory enforcement. Previously, one school of research has focused closely on CM as a mechanism of regulatory enforcement, while other research has examined cooperation and conflict in U.S. regulatory federalism. Our data protection and opioid case

studies show different ways in which cooperation has facilitated the use of third-party monitoring and how states and the federal government can learn from one another's approaches to CM. While our research has unearthed some of the specific patterns witnessed in the use of CM by federal agencies and state AGs, our research also raises important new questions regarding these subjects. For example, how have patterns of learning evolved between federal agencies and state AGs in other policy areas, such as antitrust law? In which other policy areas do we see close cooperation? Finally, and perhaps most importantly, are third party monitors achieving lasting reform in corporate governance structures and are these modes of enforcement having broader effects on the industries in question? And how specifically does intergovernmental cooperation enhance the capability of CM? Regulatory enforcement reforms, such as CM, ought to be evaluated in the context of intergovernmental relationships to gather a more complete picture of their effects.

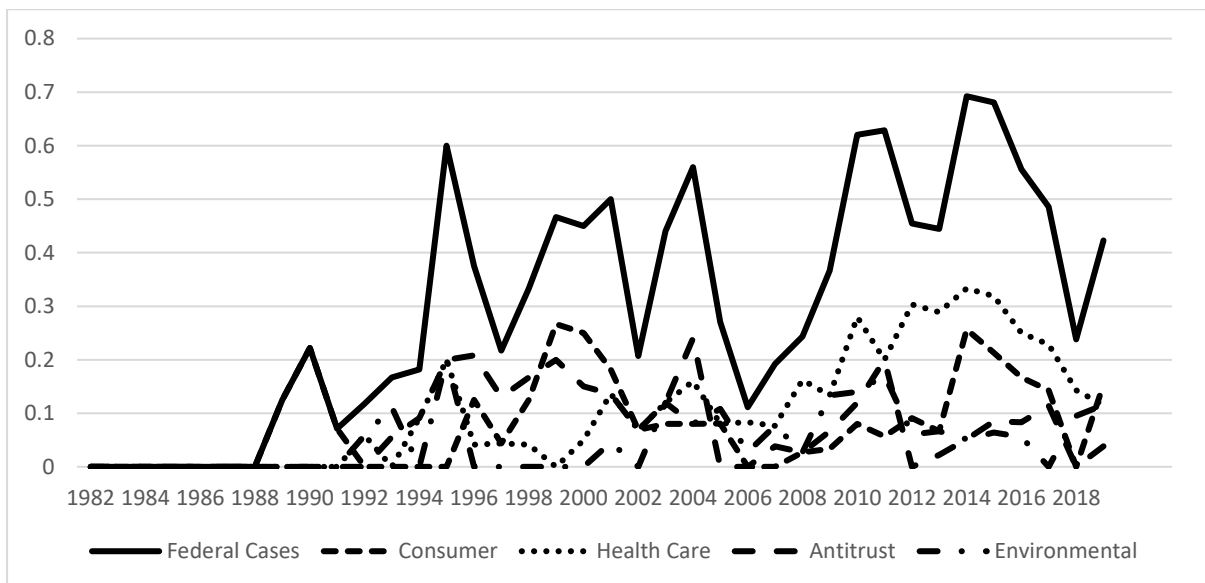
Figure 1: Multi-State Cases with Federal Involvement, by Policy Area, 1982-2019



--Vertical axis represents the number of multi-state cases

--Horizontal axis represents the year

Figure 2: Multi-State Cases with Federal Involvement as a Proportion of Total Annual Cases, by Policy Area, 1982-2019



--Vertical axis represents different proportions of multi-state cases

--Horizontal axis represents the year

Table 1: Monitor Incidence in Multi-State Cases with Federal Involvement, 2007-2021

	<i>Monitor Type</i>	Govt.	Company	3 rd Party	Multi
<i>Case Type</i>					
Antitrust		37%	05%	42%	16%
Consumer Protection		50%	13%	29%	07%
Environment		25%	38%	17%	17%
Health Care		40%	19%	14%	23%

Table 2: Monitor Incidence in Multi-State Cases without Federal Involvement, 2007-2021

	<i>Monitor Type</i>	Govt.	Company	3 rd Party	Multi
<i>Case Type</i>					
Antitrust		29%	21%	21%	29%
Consumer Protection		43%	18%	23%	16%
Environment**		0%	100%	0%	0%
Health Care**		100%	0%	0%	0%

**Environment cases without federal involvement number only two, while health care cases without federal involvement number only three. The low denominators are partly responsible for these percentages of 0 and 1.

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NOTES:

¹ At the federal level, CM typically accompanies “deferred prosecution agreements” and “non-prosecution agreements” (DPAs and NPAs) in which businesses receive leniency in exchange for making agreed-upon changes to their corporate governance or business model—changes that may be overseen by an independent compliance monitor.

² Throughout the article, we refer to CM as compliance monitoring broadly. That is, CM may refer to monitoring done by an independent, third-party monitor, a government monitor or a monitor who is an employee of the defendant company (we refer to monitoring in this last category as “company self-monitoring”). In practice, these categories are not always mutually exclusive, as there are cases where more than one type of monitor may be appointed, but in the majority of cases, we can place monitors into one of these three categories. Much of the literature on federal CM is specifically about independent, third-party monitoring, but we broaden the scope of monitoring in this article to discuss the other types as well.

³ Two multi-state cases were settled in 1980-1981 and one of these had federal involvement, but we exclude these cases, as the low number of cases creates a distorted picture of federal involvement in these early years.

⁴ The DOJ was involved in the one multi-state case filed in 1981, but 1980-81 have been excluded from Figures 1 and 2 because of the way this misleading “100 percent federal involvement” data skew the proportional data in Figure 2.

⁵ We relied upon the invaluable assistance of research assistants both to gather settlement documents, as well as to code them.

⁶ The percentages for each case type (antitrust, consumer protection, environment and health care) should equal roughly 100 percent in each table.

⁷ Environmental and health care cases have a very small number of total cases without federal involvement in this sample (2 and 3, respectively) and therefore, these percentages are more difficult to interpret in the light of such a small sample.

⁸ The term data protection has been used to encompass both data privacy and data security (Solove & Hartzog, 2014).

⁹ The FTC does not have Administrative Procedures Act rulemaking power for section 5 of the FTC Act, so much of its regulation of data practices comes from the terms of settlement with individual companies (Solove and Hartzog 2014). Because the terms of these settlements then transmit standards to companies, scholars have called the body of FTC settlements the “common law of data protection” (Solove and Hartzog) 2014.

¹⁰ See, eg. Decision and Order, In the Matter of Facebook Inc., Docket No. C-4365 (April 23, 2020), Decision and Order, In the Matter of Uber Technologies, Inc., Docket No. C-4662 (Oct. 25, 2018).

¹¹ See, e.g., Decision and Order, In the Matter of Facebook Inc., Docket No. C-4365 (April 23, 2020)

¹² See, e.g. Assurance of Voluntary Compliance, The TJX Companies, Inc. (June 23, 2009), <https://www.nj.gov/oag/newsreleases09/pr20090623a-TJXCompaniesInc.pdf>,

Agreement to Entry of Final Consent Judgment, *Nebraska v. Ruby Corp.*, CI-4398 (Dec. 14, 2009), Final Judgment and Consent Decree, *Vermont v. Lenovo*, No. 505-9-17 (Sept. 5, 2017).

¹³ See, e.g., Assurance of Voluntary Compliance, *The TJX Companies, Inc.* (June 23, 2009), Agreement to Entry of Final Consent Judgment, *Nebraska v. Ruby Corp.*, CI-4398 (Dec. 14, 2009), Stipulated Order for Permanent Injunction and Monetary Judgment, Fed. Trade Comm'n v. *Equifax, Inc.*, No. 1:19-cv-03297-TWT (July 23, 2019).

¹⁴ See, e.g., Assurance of Voluntary Compliance, *The TJX Companies, Inc.* (June 23, 2009), <https://www.nj.gov/oag/newsreleases09/pr20090623a-TJXCompaniesInc.pdf>, Agreement to Entry of Final Consent Judgment, *Nebraska v. Ruby Corp.*, CI-4398 (Dec. 14, 2009), Final Judgment and Consent Decree, *Vermont v. Lenovo*, No. 505-9-17 (Sept. 5, 2017).

¹⁵ See, eg, Stipulated Order for Permanent Injunction and Monetary Judgment, Fed. Trade Comm'n v. *Equifax, Inc.*, No. 1:19-cv-03297-TWT (July 23, 2019), Assurance of Voluntary Compliance, *The TJX Companies, Inc.* (June 23, 2009), <https://www.nj.gov/oag/newsreleases09/pr20090623a-TJXCompaniesInc.pdf>, Final Judgment and Consent Decree, *Vermont v. Lenovo*, No. 505-9-17 (Sept. 5, 2017).

¹⁶ See, e.g., Final Judgment and Consent Decree, *Texas v. Uber Technologies*, No. D-1-GN-18-005842, (Sept. 26, 2008), Assurance of Voluntary Compliance, Investigation by Eric Schneiderman, Attorney General of the State of New York, of Target Corporation, No. 17-094 (May 2017), Assurance of Voluntary Compliance, Investigation by Letitia James, Attorney General of the State of New York, of The Home Depot Inc, No. 20-080 (Nov. 24, 2020).

¹⁷ Patches are software and operating system updates that address security vulnerabilities within a program. See Assurance of Discontinuance, *Hilton Domestic Operating Co.* (2017), Assurance of Voluntary Compliance, *Nationwide Mutual Insurance Company and Allied Property & Casualty Insurance Company* (July 25, 2017).

¹⁸ See, e.g. Proposed Final Judgment and Permanent Injunction, *California v. Premera Blue Cross*, No. SVC-264783 (Cal. App. Dep't Super. Ct. July 11, 2019).

¹⁹ *Id.*

²⁰ Complaint, *West Virginia ex rel. McGraw v. Purdue Pharma L.P.*, No. 01-C-137S (W. Va. Cir. Ct. June 11, 2001); See Christopher R. Page, Comment, These Statements Have Not Been Approved by theFDA: Improving the Postapproval Regulation of Prescription Drugs, 88 OR. L. REv. 1189, 1205(2009).

²¹ See, e.g., Consent Judgment, *State of Washington v. Purdue Pharma*, Cause No. 07-2-00917-2 (Wash. Sup. Ct., May 9, 2007).

²² *Id.*

²³ See Transfer Order, *National Prescription Opiate Litigation*, 1:17-MD-2804 (N.D. Ohio, Dec. 12, 2017).

²⁴ Mallinckrodt Injunctive Relief Term Sheet, *In re Mallinckrodt*, Case No. 20-12522 (Bankr. D. Del., Oct. 12, 2020).

²⁵ Third Report of R. Gil Kerlikowske, Independent Court-Appointed Monitor for *Mallinckrodt, LLC*, *In re Mallinckrodt*, Case No. 20-12522 (Bankr. D. Del., Oct. 12, 2020).

²⁶ See, e.g., Assented-to Motion for Entry of Judgment, *Massachusetts v. McKinsey & Co.* (Mass. Sup. Ct., Feb. 4, 2021).

²⁷ Distributor Settlement Agreement, National Prescription Opiate Litigation, 1:17-MD-2804 (N.D. Ohio, July 21, 2021).