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The Supreme Court's Assault on Litigation: Why (and How) It Might Be a Good Thing for Health Law

Abigail R. Moncrieff, Boston University School of Law

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ABSTRACT

In recent years, the Supreme Court has narrowed or eliminated private rights of action in many legal regimes, much to the chagrin of the legal academy. That trend has had a significant impact on health law; the Court’s decisions have eliminated the private enforcement mechanism for at least three important healthcare regimes: Medicaid, employer-sponsored insurance, and medical devices. In a similar trend outside the courts, state legislatures have capped noneconomic and punitive damages for medical malpractice litigation, weakening the tort system’s deterrent capacity in those states. This Article points out that the trend of eliminating private rights of action in the four stories I consider is actually a trend of shifting regulatory authority from state judicial forums to federal executive forums, which is (I argue) a wise reallocation of authority for healthcare regulation. In all four stories, federal executive regulators are (and have been, throughout the stories’ timelines) poised to take over the regulatory job, but they have not yet done so. The Article urges completion of the shift—a consolidation of regulatory authority in the federal executive and a full disarming of state judicial enforcement power.

∗ Peter Paul Career Development Professor and Associate Professor of Law, Boston University School of Law. J.D. 2006, University of Chicago. Thanks to Allison Hoffman, Christopher Robertson, Vincent Chiao, Nancy Moore, Jack Beermann, Gary Lawson, Larry Yackle, Ken Simons, David Seipp, Anup Malani, and Kevin Outterson for helpful comments and suggestions.
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INTRODUCTION

Consider the following scenarios:

- A state Medicaid agency refuses to pay its doctors at the reimbursement rate required by federal statute. ¹
- An employer-sponsored health insurer refuses to cover medically necessary services that ought to be covered under the insurance contract. ²
- A medical device manufacturer refuses to pull from the market—or to add warnings to the label of—an FDA-approved product that has injured patients. ³
- A doctor refuses to take cost-justified precautions against injuring patients. ⁴

How can the legal system bring these actors into compliance with the law?

Since the country’s founding, the predominant answer in the United States has been that individuals harmed by such violations could sue such wrongdoers for individual compensation, yes, but also for systemic deterrence. That is, the American legal system has largely relied on private litigation—primarily on common law claims in state courts—to deter wrongdoing through punitive damages or court-ordered regulatory change. In the last few decades, however, the Supreme Court has, in a wide range of regulatory regimes, curbed individuals’ and courts’ ability to play that role.

This change, although certainly not limited to healthcare law, ⁵ has been significant for healthcare regulation. With three Supreme Court cases and one widely enacted state statutory reform, the private enforcement model has disappeared from at least four important realms of healthcare law—the four alluded to in the stories above. First, Medicaid. In Gonzaga University v. Doe, ⁶ the Supreme Court narrowed the availability of 42 U.S.C. § 1983 for enforcing federal statutes, especially those that were enacted under Congress’s spending power. That holding, as applied in the lower courts, has made it impossible for individuals to sue the heads of state agencies for certain violations of the federal Medicaid Act, including violations of the essential “Equal Access Provision” that governs

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provider reimbursement. Second, employer-sponsored insurance (ESI). In *Aetna v. Davila*, the Court gave a broad reading and application to the preemption provision of the Employee Retirement Income Security Act of 1974 (ERISA). That holding, combined with the Court’s narrow reading of ERISA’s remedial provision, has made it impossible for patients with certain kinds of employer-sponsored insurance to hold their insurers accountable for injuries resulting from wrongful benefits denials. Third, medical devices. In *Riegel v. Medtronic*, the Court held that Food and Drug Administration (FDA) premarket approval of the riskiest (“Class III”) medical devices preempts state tort suits challenging those products’ safety and labeling. Because there is no federal cause of action to replace preempted state laws, that holding has made it impossible for patients to sue manufacturers for injuries resulting from unsafe devices. Finally, medical error. In a similar trend outside the Court, several state legislatures have capped noneconomic and punitive damages in medical malpractice litigation, limiting their own tort systems’ capacity to deter iatrogenic (or physician-caused) injuries. Of course, medical malpractice litigation still serves compensatory purposes in those states, but caps limit the tort system’s regulatory capacity.

Healthcare regulation has thus lost several of its private enforcement mechanisms over the past decade, largely to the chagrin of the legal academy. But should those losses actually worry us? Is it problematic that private litigation is

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7 See Nicole Huberfeld, Bizarre Love Triangle: The Spending Clause, Section 1983, and Medicaid Entitlements, 42 U.C. Davis L. Rev. 413, 445–51 (noting that federal appellate courts have applied *Gonzaga* to limit or prohibit claims against state Medicaid agencies and predicting that the Roberts Court will further limit such claims).

8 542 U.S. 200, 221 (2004) (holding that ERISA preempts state laws that would have provided causes of action against insurance companies denying benefits under “medical necessity” clauses)

9 See id. at 221 n.7 (reserving the question of whether one of ERISA’s remedial provisions, § 502(a)(3), might allow for consequential or punitive damages); Great-West Life & Annuity Insurance Co. v. Knudson, 534 U.S. 204 (2001) (interpreting § 502(a)(3) extremely narrowly); Davila, 542 U.S. at 222 (Ginsburg, J., concurring) (arguing that the Court’s “encompassing interpretation of ERISA’s preemptive force” coupled with its “cramped construction of the ‘equitable relief’ allowable under § 502(a)(3)” creates a “‘regulatory vacuum’ in which no remedy exists”); David A. Hyman, Regulating Managed Care: What’s Wrong With a Patient Bill of Rights, 73 So. Cal. L. Rev. 221, 229 (2000) (noting that ERISA, while preempting state-law remedies, “contains no substantive regulation of its own, and provides only an exceedingly limited set of remedies”).


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no longer an option for enforcing federal Medicaid rules, contractual insurance provisions, or common law safety standards?

The answer to that question ought to depend on the existence and nature of alternatives to private litigation.\textsuperscript{12} If market forces or administrative enforcement works as well as or better than private litigation, then we ought to embrace rather than resist the Court’s assault on private actions since those private actions might inefficiently replicate regulatory deterrence. This premise is neither new nor radical; scholars of law and economics have long recognized that common law and administrative law are substitutes, such that a rising administrative state justifies and even necessitates diminishment of common law remedies.\textsuperscript{13} But this premise and mode of analysis is one that the literature—especially the health law literature—has largely overlooked (or actively ignored?) in its considerations of the Supreme Court’s recent holdings. This Article fills that analytic void, asking not whether the disappearance of litigation is bad in itself but whether the disappearance of litigation is bad given the broader regulatory environment for healthcare and given the particular regulatory needs that healthcare markets present. That is, this Article asks and answers the comparative question: whether litigation is better or worse at setting incentives than its available substitute, administrative regulation.

An important first step in answering that comparative question is to note that, in all four stories considered here, administrative regulators already exist and are already authorized to regulate. For Medicaid, the federal Centers for Medicare and Medicaid Services (CMS) already has the authority to enforce federal standards against state agencies. For ESI, the Department of Labor (DOL) already has authority to govern employer-provided healthcare plans, including authority to regulate administrators’ claims processing. For medical devices, FDA already has authority to monitor approved devices and to require manufacturers to change safety labels or to pull unsafe products. For medical error, CMS already has authority to serve a regulatory role by changing Medicare and Medicaid quality rules or by establishing an administrative adjudication system for medical injuries,\textsuperscript{14} and professional associations already have authority to serve a regulatory role by changing minimum quality standards for medical licensure.

Why, then, have so many commentators complained of “regulatory vacuums” left in the wake of the Supreme Court’s holdings? The current regulatory


\textsuperscript{14} Bill Sage and Eleanor Kinney have already proposed at least a limited version of this idea, arguing that CMS should adjudicate malpractice claims brought by Medicare and Medicaid beneficiaries. See Eleanor D. Kinney and William M. Sage, Dances With Elephants: Administrative Resolution of Medical Injury Claims by Medicare Beneficiaries, 5 Ind. Health L. Rev. 1 (2008); William M. Sage, The Role of Medicare in Medical Malpractice Reform, 9 J. Health Care L. & Pol’y 217 (2006); Eleanor D. Kinney and William M. Sage, Resolving Medical Malpractice Claims in the Medicare Program: Can It Be Done?, 12 Conn. Ins. L.J. 77 (2005–2006).
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environment does not lack authoritative figures, and the authoritative figures that exist do not lack legal tools for regulation. The regulatory space, then, is not at all vacuous, despite the abolition of private rights of action; federal executive agencies are well equipped to engage in the regulatory project, even though individuals and courts are no longer allowed to pursue it.

The commentators, though, are not completely off-base; they are simply over-stating the problem. The problem today is not a lack of regulatory presence but rather a lack of regulatory rigor. The existing administrative regulators simply don’t do the jobs that the Supreme Court and state legislatures have left for them: CMS hardly ever withdraws funding from or refuses approval to state Medicaid plans that violate federal standards; DOL neither provides an administrative system for claims review nor punishes abusive MCOs; FDA rarely monitors the safety of devices that have gone through premarket approval and have entered the market; and neither CMS nor professional medical associations actively enforce quality standards for practicing providers. For now, thus, the Supreme Court and state legislatures have left health law not so much with regulatory vacuums as with enforcement vacuums, in which Medicaid agencies, employer-sponsored insurers, device manufacturers, and sloppy doctors can shirk legal obligations with relative impunity despite the existence of a robust regulatory structure.

Unlike a true regulatory vacuum, an enforcement vacuum does not strongly suggest that the best solution is to restore the status quo ante, re-establishing private rights of action (the solution that most scholars have advocated so far). Instead, the enforcement vacuum presents a choice between two clear and easy alternatives: (1) re-empowering the enforcement mechanism that was working before (private litigation) or (2) motivating (and funding) the enforcement mechanisms that are not yet working today (administrative regulation).

This paper argues for the latter approach. The Supreme Court’s and state legislatures’ assault on litigation, if understood as a vote of confidence for administrative regulators over judicial regulators, can be understood to embody a growing skepticism towards state judicial forums and an emerging trust in national executive forums for creating and enforcing healthcare rules. Each story considered here suggests a straightforward reallocation of regulatory responsibilities from the judiciary to the executive as well as a less-straightforward-but-nevertheless-real reallocation of regulatory responsibilities between the state and federal governments. (In the stories of employer-sponsored insurance and drug and device manufacturers, the federalist reallocation is a simple shift from state to national governance; in the Medicaid and medical malpractice stories, the federalist reallocation is more muddled, but like the others, those two stories involve a shift of authority away from state forums.)

Particularly in healthcare, this balance of skepticism towards judicial and state forums and trust in executive and national forums may be well-founded. As we have long recognized, generalist juries and judges are bad at understanding,
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evaluating, and creating healthcare regulations—and expert agencies might be much better. Furthermore, federal regulation of healthcare might make more sense than state regulation for a variety of reasons, especially including the economies of scale that we gain from operating nation-wide.

The shift from state courts to federal agencies therefore seems a wise shift, such that the mere re-creation of private rights of action—the rejection of this reallocate trend—does not seem the best solution to our current enforcement vacuums. Instead, we should embrace the reallocations, and the federal executive bodies that are poised to regulate should start doing the jobs that the Supreme Court and state legislatures have left to them. Doing so will probably require some restructuring of administrative bodies and some additional funding and resources for the federal regulators, but the move should not require any substantive amendments to the regulatory statutes.

This Article proceeds as follows. Part I fleshes out the four stories identified here, noting the assaults on litigation and the curbing of private rights of action in the four exemplar healthcare realms. Part II fleshes out the problem of enforcement vacuums, identifying the entity in each story that could regulate in the absence of litigation, noting that those entities have not yet stepped in to fill the regulatory role, and identifying the market failures that persist in the absence of legal regulation. Part III fleshes out the judicial-to-executive and state-to-federal reallocation trends that each story represents and discusses the reasons that we might like those trends for health law. Part IV identifies the range of possible solutions for filling enforcement vacuums and argues that our general preference should be for federal executive regulation, even to the full exclusion of state judicial regulation. Part V concludes.

I. THE ASSAULT ON LITIGATION

In recent years, the Supreme Court has closed courthouse doors to many litigants, particularly those alleging generalized statutory violations or otherwise attempting to use the court system for systemic regulation. This trend has affected a wide range of regulatory regimes, including disabilities law, employment and labor law, and civil rights law. It has also had a significant impact

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15 Cites
17 See generally Chemerinsky, supra note 5, at 537–39 (listing cases from 2001 and 2002 that limited civil rights plaintiffs’ access to courts).
18 See, e.g., Board of Trustees of the University of Alabama v. Garrett, 531 U.S. 356 (2001) (holding that state governments cannot be sued for violating the Americans with Disabilities Act); Buckhannon Board & Care Home, Inc. v. West Virginia Department of Health and Human Services, 532 U.S. 598 (2001) (making attorneys’ fees unavailable for successfully catalyzing a change in the state’s disability policy); Barnes v. Gorman, 536 U.S. 181 (2002) (holding that punitive damages are unavailable under the Americans with Disabilities Act and the Rehabilitation Act).
on health law. The Court’s recent jurisprudence has disarmed private litigation for Medicaid enforcement, employer-sponsored insurance regulation, and medical device regulation.

Beyond the Supreme Court, another major trend against private enforcement mechanisms in health law has been the state legislatures’ limitation or elimination of noneconomic and punitive damages in medical malpractice litigation. Those damages caps at least attempt to serve the same purpose, dissuading individual litigants in their attempts to deter physician negligence.

This Part fleshes out the four stories of health law’s trend away from the private enforcement model.

A. Gonzaga and Medicaid

In Gonzaga University v. Doe22 (a decision that Chief Justice Rehnquist called his “sleeper case” of 200223), the Supreme Court narrowed the availability of 42 U.S.C. § 1983 for enforcing federal statutes.24 Section 1983 provides a private right of action against state actors for deprivations “of any rights, privileges, or immunities secured by the Constitution and laws” of the United States.25 Because the provision refers to laws as well as the Constitution, plaintiffs have long used § 1983 to sue state actors for violating federal statutes.

But in Gonzaga, the Court held that § 1983 did not provide a right of action for a violation of the Family Educational Rights and Privacy Act (FERPA),26 noting that FERPA did not create any “personal rights”27 that could be vindicated through a § 1983 action. In so holding, the Court announced a more restrictive test for the availability of § 1983 for correcting federal statutory violations, allowing private enforcement of only those federal statutes that intended to create and confer individual rights in the plaintiff. In other words, the Court announced that plaintiffs could use § 1983 only to protect their own rights, not to enforce a general statutory scheme (even when such enforcement would provide the plaintiff a direct and tangible benefit).


21 The empirical evidence so far indicates that damages caps have had little if any effect on awards recovered in medical malpractice cases and have had little impact on healthcare costs. See Moncrieff, supra note 4, at 855 & n. 37.


24 536 U.S. at 276.


27 Id. at 276.
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Importantly, two of the Court’s central considerations—beyond the text of the relevant provision—in holding that FERPA did not create and confer individual rights were, first, that FERPA was a Spending Clause statute and, second, that FERPA specified a regulatory enforcement scheme that charged the Secretary of Education with withdrawing federal funds from noncompliant institutions. Because Congress passed the statute merely as a grants program for the states and because Congress intended for the statute to be enforced through regulatory funding decisions, the Court reasoned, the legislature must not have intended to allow individual private enforcement through § 1983.

Since Gonzaga was decided, several federal courts of appeal have applied the decision to preclude individual enforcement of several federal Medicaid provisions, including a central requirement known as the “Equal Access Provision.” The Equal Access Provision is a federal statutory requirement that state Medicaid agencies reimburse providers at a rate that is “consistent with efficiency, economy, and quality of care and [is] sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.” In short, it requires state agencies to pay doctors at a rate that is competitive with private market payments. The fear that motivates the provision is a fear that doctors will refuse to treat Medicaid patients if the program pays too little.

Before Gonzaga was decided, providers and patients could (and did) use § 1983 to enforce the Equal Access Provision. They sued state Medicaid agencies for cutting reimbursement rates, alleging that the cut rate would be too low to meet federal statutory requirements. Since Gonzaga, however, most courts of appeal have held that the Equal Access Provision does not create and confer enforceable rights and have therefore held that providers and patients lack standing to enforce the provision.

Of course, that holding seems right under the Gonzaga logic. Like FERPA, the Medicaid Act is a spending statute; its central creation is not a substantive

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28 Gonzaga, 536 U.S. at 278–79.
29 Of course, Congress can pass provisions even within Spending Clause statutes with regulatory enforcement mechanisms that still confer individual rights. The text of the provision is the first line of inquiry, and if it seems to be rights-creating text, then the courts will still allow private enforcement. See generally Huberfeld, supra note X, at 446–47 (noting that several circuits still allow Medicaid beneficiaries to use § 1983 to enforce the “minimum services” provision, which vests individual rights in beneficiaries).
32 See Moncrieff, supra note 1.
33 Id.
34 CITES: but see Independent Living Center of Southern California, Inc. v. Maxwell-Jolly, 572 F.3d 644 (9th Cir. 2009) (upholding a preliminary injunction against California’s rate reduction legislation on the ground that it would violate the Supremacy Clause).
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federal program like Medicare but rather a set of grants to subsidize state-run pub-
lic health insurance. Also like FERPA, the Medicaid Act’s substantive require-
ments—including the Equal Access Provision—are “requirements” only insofar as states that refuse to comply will risk losing their Medicaid grants. That is, the substantive requirements are merely conditions for receipt of federal funds. And finally, like FERPA, the Medicaid Act charges a federal administrator—the Centers for Medicare and Medicaid Services (CMS)—with enforcing the Act’s substantive requirements by denying federal funding to any noncompliant Medicaid plan.

Given that the structure of the Medicaid Act is so similar to the structure of FERPA, the conclusion is rightly the same: that the Medicaid Act did not in-
tend to create or confer privately enforceable rights. But, of course, that holding strips individuals of the power to enforce Medicaid rules through liti-
gation, even when those individuals have been harmed by the statutory violation. In other words, the holding disarms private litigation in Medicaid regulation.

B. Davila and Employer-Sponsored Insurance

In the second story, the Supreme Court did not narrow or eliminate private rights of action per se but rather interpreted the Employee Retirement Income Secu-
urity Act of 1974 (ERISA) in a way that effectually foreclosed private actions against employer-sponsored managed care organizations (MCOs). In Aetna v. Davila, the question before the Court was whether ERISA preempts state laws that expose employer-sponsored MCOs to consequential and punitive damages for injuries that result from claim denials. It held that it did.

In Davila, a Texas doctor had recommended that his patient, Juan Davila, take Vioxx for his arthritis pain rather than a cheaper alternative drug, Naprosin. The doctor’s recommendation was based on Davila’s history of stomach ulcers and the knowledge that Naprosin could, as a side-effect, aggravate Davila’s gastrointestinal condition. Despite the doctor’s recommendation, Davila’s employer-sponsored MCO, Aetna, denied the claim for Vioxx but agreed to cover Naprosin, asserting that Davila should try the cheaper option first. Rather than paying out-
of-pocket for Vioxx, Davila accepted Aetna’s direction and started on Naprosin. As the doctor had feared, the Naprosin severely worsened Davila’s gastrointestinal problems, causing serious and lasting injury. Davila sued Aetna under Texas statute, asserting that Aetna was negligent in denying the claim for Vioxx against the doctor’s recommendation and asserting on that basis that the MCO was liable for his injuries, a claim that the Texas statute explicitly allowed.

The case made it to the Supreme Court, which held that ERISA preempted the state statute. Because ERISA itself provides a cause of action “to recover

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35 [Consider and maybe contrast the provisions of the Medicaid Act that HAVE been found to confer individual rights.]
37 This case looks ironic in retrospect, given what we now know about Vioxx and its impact on heart health. CITE
benefits due,” the Court held that the Texas statute fell “within the scope” of ERISA and thereby triggered ERISA’s preemption provision. With that holding, the Court shielded employer-sponsored MCOs from any and all state tort liability for coverage decisions that proximately cause injury to patients.

Standing alone, of course, that decision does not entirely disarm private litigation since it allows individual suit under the ERISA civil action provision. But in a prior decision, the Court had also held that ERISA’s remedial provision, which provides for “equitable relief” in the case of a wrongful benefits denial, allows patients to recover only the value of the denied benefit. In other words, if Davila had sued under ERISA instead of the Texas statute, he could have recovered only the cost of Vioxx coverage. He could not have recovered any consequential damages for the injury to his gastrointestinal system, nor could he have recovered punitive damages to deter Aetna from denying valid claims in the future.

Given ERISA’s broad preemptive force and narrow remedial scheme, patients are now completely unable to use litigation for regulation when their employer-sponsored health insurers abuse discretion in claims processing. When an MCO denies a claim, the patient can use ERISA to enforce the contract—can get specific performance—but she cannot recover make-whole damages for resulting injuries nor effect punishment for the violation or deterrence of future violations.

C. Medtronic and Medical Devices

Like the ERISA story, the medical devices story centers on federal pre-emption of state-law causes of action, rather than on direct limitations of private enforcement. In Riegel v. Medtronic, the Supreme Court held that federal statute preempts common-law products liability suits against those medical devices that have been approved for the market through the Food and Drug Administration’s (FDA) premarket approval process.

The question in Riegel was whether an express preemption provision in the Medical Device Amendments to the Food, Drug, and Cosmetics Act (FDCA) preempted Charles Riegel’s common law complaints against Med-
tronic’s balloon catheter. Riegel’s doctors had used the Medtronic catheter to open his arteries, despite the fact that it was contraindicated for a patient in Riegel’s condition. 46 The catheter exploded, causing serious injury. Because FDA had found the catheter to be safe and effective through its premarket approval process (the most extensive and rigorous of FDA’s safety and efficacy inquiries) and because the FDCA provision governing premarket approvals expressly preempted state-based safety and efficacy requirements, Medtronic argued that it could not be held liable under state-based common-law theories of strict liability, breach of warranty, or negligence.

The Court agreed with Medtronic, holding that common law duties constitute state-based safety and efficacy “requirements” and therefore fall within the scope of the FDCA’s preemption provision. This holding has the same effect as the Davila holding; Riegel prevents individuals from raising an alarm in state court when medical devices malfunction, just as Davila prevents individuals from raising an alarm in state court when employer-sponsored MCOs misbehave. Also like the holding in Davila, the holding in Riegel entirely prevents individuals from using litigation as regulation because the federal alternative FDCA (like ERISA) does not allow federal actions to recover consequential or punitive damages for malfunctioning devices. Indeed, the situation after Riegel is even starker than that after Davila because the FDCA does not provide any cause of action to replace the preempted state torts. It is thus entirely impossible after Riegel for individuals harmed by medical devices to enforce legal safety requirements against the devices’ manufacturers.

D. State Legislatures and Medical Malpractice

The fourth story of disappearing private enforcement is different in kind and scope from the others, but it marks the same trend of limiting private enforcement. It is the story of state statutory limits on damages arising from medical malpractice. Since the 1970s, which marked the first medical malpractice “crisis” of the modern era, 47 state legislatures have sought to limit costs arising from medical malpractice litigation. One of the most popular reform measures among state legislatures, following California’s lead with its Medical Injury Compensation Reform Act of 1975, has been to cap or otherwise limit noneconomic and punitive damages that a plaintiff can recover foriatrogenic injuries. 48 As of 2007, forty-one states limit noneconomic or punitive damages in some way. 49

46 128 S.Ct. at 1005.
47 Cites
49 NCSL, supra note 48. Of the nine states that do not currently have damages caps, two have had such caps declared unconstitutional, and one has a constitutional provision specifically prohibiting
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This story is different in scope and kind from the others for two reasons. First and most obviously, its source is different. The story is a political one rather than a judicial one and a state-based one rather than a federal one. The medical malpractice caps might therefore bear greater political legitimacy than the Court’s limits on private enforcement, and the caps obviously are not uniform across the country, as the Court’s limits are. The second reason for difference is slightly subtler: Whereas the Court’s holdings have firmly closed courthouse doors to individual litigants, the medical malpractice caps have not. Patients can still bring medical malpractice claims in every state; the caps merely decrease patients’ incentive to litigate and their ability to use such litigation to penalize misbehaving doctors.

Despite these differences, the caps mark the same trend as the Courts’ decisions. By decreasing individual litigants’ incentive to sue and ability to penalize, medical malpractice damages caps limit the effectiveness of private enforcement in deterring medical negligence. Furthermore, because the limits apply only to noneconomic and punitive damages, the caps do not primarily limit the tort system’s compensatory role but rather its deterrence goal. This feature of the caps places them squarely in the relevant trend away from litigation as a mechanism for regulation; as the Supreme Court made clear in its definition of § 1983’s scope, the motivation for the trend is not to eliminate individuals’ ability to vindicate their own legal rights but rather to shift systemic regulation and enforcement out of the state court systems.

II. ALTERNATIVES AND VACUUMS

If that’s right—if the goal of these limits on private litigation is to shift systemic regulation and enforcement out of state courts—then the obvious next question is where those functions are supposed to shift to. The answer needn’t be legal (in the traditional sense); competitive private markets and their reputational sanctions might suffice to prevent inefficiencies, such that the answer could be “out of state courts and into the market.” But since some disciplining force is necessary to restrain self-interested actors, we need to ask whether the private market works in each case and, if not, whether our public regulators are working to correct market failures.

In each of the stories considered here, an alternative to individual litigation already exists—and has existed throughout each story’s timeline. Unfortunately, however, the alternative public regulators have not yet fully taken the disciplining role that the Supreme Court and state legislators have left to them. That failure represents a real problem in each of these four stories because healthcare markets are fraught with information and agency costs that cause those markets to fail. Part II.A identifies the alternative regulator in each story and demonstrates that none of these regulators has fully filled the role left to it. Part II.B describes the such caps. In Oregon, the monetary cap was deemed unconstitutional, but the state continues to prohibit punitive damages absent a showing of malice. Id.
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information and agency costs that cause each of these markets to fail in the resulting enforcement vacuums.

A. The Alternative Regulators

1. Medicaid and CMS

In the Medicaid story, the alternative regulator is the federal agency charged with administering the Medicaid program: the Centers for Medicare and Medicaid Services (CMS). Since Medicaid’s creation in 1965, CMS (or one of its predecessors, the Health Care Financing Administration or the Department of Health, Education, and Welfare) has had statutory authority to approve or reject “state plans for medical assistance,” i.e. state Medicaid plans.

At its inception, the federal statute specified twenty-two conditions that state plans had to meet in order to qualify for federal funding, codified in 42 U.S.C. § 1396a(a). Today, the § 1396a(a) list has grown to seventy-three requirements, and countless new statutory sections have joined company with § 1396a(a) in conditioning federal funds. But the basic structure of the program has been the same since 1965: States submit plans for medical assistance, and the Medicaid Administrator (now in CMS) reviews those plans for compliance, either approving or rejecting federal funds.

Given this structure, it might make sense to ask why we ever allowed private lawsuits to enforce the federal statute. If CMS is doing its job, then no plan will receive federal funds and go into effect under the Medicaid moniker if it does not, in CMS’s opinion, comply fully with the federal statute. Under such a program, it seems nonsensical to allow suit against the state agency for violating the federal law; it would make more sense to allow an administrative suit or complaint against CMS for poor judgment in measuring the states’ compliance—perhaps a claim of arbitrariness or capriciousness in approving state plans.

If § 1983 had never been in the picture, that enforcement mechanism might well have developed. Perhaps because § 1983 suits were permitted and sufficed to police violations, however, CMS and its predecessors have never served much of a gatekeep-
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...ing function and have never answered for that failure in administrative litigation. Instead, CMS tends to rubber-stamp state plans and to pass the buck to state agencies when providers and beneficiaries complain.\textsuperscript{56} And CMS directs most of its resources at policing individual providers’ compliance with Medicaid fraud and abuse laws rather than policing state agencies’ compliance with the federal statute.\textsuperscript{57} On the occasions that CMS does reject state plans or insist on amendments thereto, it almost always does so to protect its own funds from perceived state raids; as a result, CMS is unlikely to enforce something like the Equal Access Provision, which would, in its violation, \textit{save} federal funds. Furthermore, CMS has never developed a robust administrative remedy for individuals wanting to challenge CMS approval of Medicaid plans.\textsuperscript{58} Although some administrative processes exist for raising challenges to Medicaid plans, including challenges to reimbursement rates, Medicaid’s administrative process (unlike Medicare’s) has never been an effective means of enforcing the federal statute.\textsuperscript{59} 

In the end, then, although CMS has the authority (the duty, really) to enforce the federal statute against state agencies, it has never chosen to direct its resources towards that project. Section 1983 suits have historically been the only effective means of enforcing the Medicaid Act against disobedient state agencies and state legislatures. Now, there seems to be no legal mechanism for doing so.

2. ESI and DOL

In the employer-sponsored insurance (ESI) story, the alternative legal regulator is the Department of Labor (DOL), which is charged with administering the Employee Retirement Income Security Act (ERISA).\textsuperscript{60} ERISA gives DOL broad statutory authority to enforce its terms, and the agency could use that authority to regulate ESI, including employer-sponsored MCOs’ claims processing decisions, through a variety of mechanisms. First, the agency could set up an administrative complaints process, adjudicating individuals’ claims itself and ordering the “equitable relief” (however defined) that ERISA provides for benefits denials.\textsuperscript{61} Second, it could issue a formal interpretation of the statutory term “equitable relief,”\textsuperscript{62} holding that ERISA allows make-whole relief for not only the denied benefits but also the injuries resulting from the benefits denial. (Such an interpretation would,
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of course, be entitled to deference if it were challenged in court and would thereby create a private enforcement mechanism in federal court. Third, DOL could monitor employer-sponsored MCOs’ claims decisions and seek penalties against abusive firms, without itself providing or ordering any compensation to harmed patients beyond that which is currently available in federal court. Any of these options would provide a reasonable substitute for state tort claims against injurious MCO benefits denials.

DOL has, however, done none of these things. The agency has set standards for claims processing by health benefits plans and has set rules for internal appeals, but it has not created an enforcement mechanism for punishing plan administrators that fail to comply with those rules. Nor has it ever monitored claims denials itself or sought to punish abusive plans. Although DOL seems aware that claim denials can be a problem, it has not created a regulatory enforcement scheme to avoid that problem. Furthermore, DOL apparently believes that “equitable relief” ought to be interpreted to allow for make-whole damages, having filed amicus briefs to that effect (which are not entitled to deference), but it has not issued a formal rule advancing that interpretation. At the time of the Supreme Court’s decisions in Davila and Great West, therefore, private enforcement was the only operational mechanism available for punishing a health benefits plan that refuses to honor claims for health benefits, and the Supreme Court eliminated that mechanism.

3. Medical Devices and FDA

For medical devices, the alternative regulator is, of course, the Food and Drug Administration (FDA). Not only is FDA responsible for ensuring a device’s safety and efficacy before it goes to market, but also it has the authority to monitor that device’s safety and efficacy once on the market as well as an obligation to withdraw approval from devices that prove unsafe or ineffective over time. Furthermore, FDA obliges device manufacturers to report instances of death or injury

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63 See Chevron v. Natural Resources Defense Council, 467 U.S. 837 (1984) (holding that an agency’s interpretation of its governing statute is entitled to judicial deference as long as the statute’s meaning is ambiguous and the agency’s interpretation is reasonable).
64 ERISA and DOL already require employer-sponsored benefits plans to submit annual reports with information about their financial and accounting statuses and practices, see 29 U.S.C. § 1132(c) (2006); 29 CFR § 2520.103–1(b) (2008), and it has authority to impose civil penalties against non-complying plans, see 29 U.S.C. § 1132(c)(2); 29 CFR § 2560.502c–2 (2008). It does not, however, require any reporting related to claims processing or claim denials.
66 Indeed, DOL holds that exhaustion of internal appeals to the benefits plan constitutes exhaustion of administrative remedies for purposes of litigation. 29 CFR § 2560.503–1 (l).
67 CITE
68 Mead
69 See Riegel, 128 S.Ct. at 1005 (“The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling.”) (citing 21 U.S.C. § 360(c)(1); § 360h(e)).
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that may have resulted from the device’s use and to report instances of device malfunction that might contribute to death or injury in the future.\(^{70}\)

If this regulatory structure operated effectively, the tort system—at least in its whistleblower and deterrent capacities—might well be unnecessary. Manufacturers must blow the whistle on their own devices or risk losing their premarket approval for failure to comply with FDA regulations,\(^{71}\) and FDA can (without the aid of punitive damages) prevent the continued sale of unsafe devices by withdrawing premarket approval. Granted, this scheme leaves the individuals harmed by unsafe devices without compensation for their injuries, but the point here is only that the plaintiffs’ role as regulators is perhaps unnecessary given FDA’s authority to force whistle-blowing and to effect deterrence. Furthermore, FDA could almost certainly establish an administrative hearing process and an administrative remedy to recompense injured patients without relying on state tort systems.

The problem is that FDA doesn’t actually play these roles with the vigor required to supplant the tort system and to prevent injuries. Although FDA is perhaps the best of the four alternative regulators considered here (at least insofar as it acknowledges post-market regulation as one of its central duties), the agency does not yet have the resources necessary to watch its preapproved devices to ensure that they do not have post-market problems.\(^{72}\) Again, therefore, the Supreme Court’s opinion seems to leave behind a vacuum in which manufacturers can continue to market and sell dangerous devices with legal impunity.

4. Medical Error and CMS or Professional Associations

In the story of medical error, there are two alternative regulators that could enforce quality standards against licensed providers: CMS and state licensure boards. To some extent, CMS already plays this role. It has created a “never events” policy, by which it refuses to reimburse providers that make certain listed errors; and it has instituted a variety of “pay for performance” initiatives, by which it calibrates hospitals’ and providers’ reimbursement formulae based on evidence of the providers’ success rates and general quality.\(^{73}\) State licensure boards, too, play this role to a certain extent, revoking licenses from providers that commit egregious violations (such as practicing the wrong kind of medicine).

Neither CMS nor licensure boards, however, engage in the kind of intensive quality regulation that the tort system has intended to provide. The central

\(^{70}\) Id. (citing 21 U.S.C. § 360i; 21 CFR §§ 803.50(a), 814.84(b)(2)).

\(^{71}\) See 21 CFR § 814.46(a)(2) (authorizing FDA to withdraw market approval if manufacturer has failed to meet “any postapproval requirement imposed by . . . regulation”).

\(^{72}\) See Statement of Richard M. Cooper before the Subcommittee on Health of the House Committee on Energy and Commerce, May 12, 2009, at 14 (admitting, in the context of testimony supporting the Court’s decision, that “better systems and methods are needed generally to monitor the safety of medical products after they have been approved”), online at http://energycommerce.house.gov/Press_111/20090512/testimony_cooper.pdf; see also FDA’s Sentinel Initiative, http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm.

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problem here is that the regulators don’t hear or register individual patients’ claims, which for medical malpractice is necessary not only for individual justice but also for systemic regulation. Many individual instances of negligence and of resulting iatrogenic injury do not fall on the categorical list of “never events,” do not constitute evidence of poor quality under the “pay for performance” program, and are not egregious enough to provoke license revocation. The reason for those programmatic gaps is that many instances of patient injury are extremely hard to judge; for a large percentage of bad outcomes in healthcare, the causal link between the patient’s injury and the physician’s care (or lack thereof) is hard to prove and is dangerous to impute. Did the patient get sick after surgery because the surgeon did something wrong, or just because she got sick, like people do? We can’t answer that question without looking into the circumstances of the individual patient.

The strategies, thus, that CMS and licensure boards have developed so far for deterring negligence—refusing reimbursement, altering reimbursement formulas, and revoking licenses—would dramatically over-deter negligence if triggered by every bad outcome. Unfortunately, though, they under-deter negligence in their current form, triggered as they are by limited categories of bad outcomes (those that could result from nothing but negligence, such as amputation of the wrong leg) without punishing any instances of negligence that fall outside of those categories.

B. Market Failures and Enforcement Vacuums

Of course, the lack of a legal mechanism for enforcement of laws and contracts does not automatically prove the lack of any mechanism for such enforcement; markets, including political ones, sometimes suffice to prevent violations and inefficiencies. In each of the stories presented here, however, political and private markets systematically fail to achieve optimal deterrence and regulation. The problem is that healthcare markets of all kinds are fraught with information and agency costs that prevent individual voters and consumers from representing their own interests. Each of these stories thus presents a true vacuum in which actors can violate rules with impunity despite the presence of regulators, and in each story, a legal regulator ought to start working to fill the void.

1. Medicaid

Medicaid, of course, is not subject to many private market pressures. Although the rise of Medicaid managed care has allowed some private companies to serve as Medicaid intermediaries and although individual providers have the option of refusing to serve Medicaid patients (which might force the program to respond to providers’ interests), the process for setting reimbursement rates is a decidedly public, political process. We must therefore look to political markets rather than private markets to restrain inefficiency.

Unfortunately, however, the political market for Medicaid regulation fails in two significant ways, both of which arise from its “cooperative federalist”
structure. First, because both state and federal lawmakers affect Medicaid decisions, the two levels of government can (and do) engage in a constant cycle of buck-passing that destroys ordinary mechanisms of political accountability (a severe information cost). Second, because states have flexibility in setting reimbursement rates, they can engage in some Tiebout competition74 for the best policy bundles, but that competition would likely result not in optimality but rather in a “race to the bottom” (an agency cost of a sort).

(a) Information Costs. The most obvious political check on states’ violations of federal law is voting. Medicaid decision-makers at the state level are all politically accountable; they are either state legislators who are directly subject to electoral incentives or state administrators who answer to an elected governor. If those decision-makers change their Medicaid programs in a way that violates federal law—and does so to the chagrin of state residents—those residents can (at least theoretically) punish their officials in the next election cycle.75

But in Medicaid, it is often hard for voters to know whom they should punish, and gathering accurate information on that score is extremely costly. First, because state Medicaid plans are subject to a complicated web of federal requirements, state decision-makers can often blame their unpopular moves on federal rules (disingenuously, of course, in the relevant case of a move that violates federal statute). In a mere political marketplace, the lie probably would not get caught; information about the web of regulations is too costly to collect and verify, and individual voters (with their limited influence) act rationally in remaining ignorant of those regulations. A more frequent strategy for state decision-makers is to blame the paucity of their programs on the paucity of federal funding. Because states are budget constrained, federal funding often determines the generosity of state Medicaid plans. The most common tale from state Medicaid agencies accused of federal statutory violations is that they lack the financial resources to do any better. According to the states, the federal statute requires generous reimbursements and benefits (perhaps to the point of being aspirational), but the federal government refuses to put its money where its mouth is.76 The states’ political answer, then, is that Congress and the President, rather than the state legislature and the Governor, should be punished for Medicaid problems.

The federal government, in its turn, points out that the states demand and receive a great deal of flexibility in designing their Medicaid programs, including access to waivers that would allow eligibility or benefit cuts rather than reimbursement reductions. If a particular strategy for reducing the budget is unpopular, the federal government says, the state should try other options available for realizing savings. (What the federal government misses, perhaps strategically, is that any budget-cutting strategy is likely to be just as unpopular.) Voters again have a hard time judging or verifying the reality of the situation because informa-

74 Tiebout
75 This point assumes, of course, that the Medicaid violations are politically unpopular. If such cuts are politically popular, then we need to ask whether the statutory violation is a problem at all and whether either the state should continue to engage in the Medicaid program at all.
76 Cases in which states cut reimbursements for budgetary reasons.
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tion about these programs is costly to gather, and voters are rationally ignorant of
details.

In the end, then, voters have a difficult time apportioning blame between
state and federal governments, and political accountability therefore fails as a me-
chanism for cabining Medicaid abuses.

(b) Agency Costs. The theory of Tiebout competition is that political
subdivisions, such as states, will compete for resident taxpayers by providing ap-
pealing bundles of public goods, public services, and taxes. In other words, they
will set themselves up as good agents of the public interest in order to attract prin-
cipals (and their concomitant revenue).\(^{77}\) Potential taxpayers will then sort them-
seves among those subdivisions according to their preferences regarding those
bundles. Theoretically, this process should result in taxing and spending policies
that optimally reflect the preferences of the states’ residents (an optimal principal-
agent relationship). The Tiebout theory fails, however, when the good or service
at issue is one that will attract unappealing residents, such as those that take out of
the tax system more than they put in. If the public good or service is one that the
country as a whole would benefit from providing but is one that each state would
benefit from sloughing off onto its neighbors, then the states will compete to
avoid the good or service and its consumers. They will race to the bottom.

With respect to Medicaid, just such a failure occurs. The people that ben-
efit from Medicaid and that would flock to a state with generous Medicaid spend-
ing are, by programmatic definition, poor and sick. They are overwhelming liv-
ing at or below the Federal Poverty Line; they are taking Supplemental Security
Income; and they are not paying state taxes. Medicaid recipients are therefore net
losses for state tax systems. While it’s good for the economy as a whole if such
people have pre-paid access to the medical market, no single state wants to attract
those people to its jurisdiction. Tiebout’s interjurisdictional market, therefore,
imposes on the states the opposite incentive of the one that the federal govern-
ment intended to impose with the Medicaid Act, and it is the opposite of the in-
centive that taxpayer-principals ought collectively (i.e. nation-wide) to prefer.
Each state’s incentive is to make its program as small as possible, at least relative
to its neighbors’ programs, so that Medicaid eligible residents will move out.

It is possible that providers as resident taxpayers might counteract that ef-
fect by choosing to leave states with low Medicaid reimbursements in favor of
states with higher Medicaid reimbursements. But that effect seems unlikely to
correct the problem given that most providers (unlike Medicaid beneficiaries) do
not depend on the Medicaid program. They can make enough money from pri-
ately insured and Medicare patients to run a good business, even to the point that
they could opt out of Medicaid entirely if reimbursement rates were too low.

Interstate competition, thus, probably does not provide enough of a check
on state violations of the Medicaid statute. In fact, it may be counter-productive,
incentivizing states to make their Medicaid programs as unappealing to benefici-
aries as possible.

\(^{77}\) Tiebout
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2. ESI

In the case of ESI, a robust private market exists that could, if operating efficiently, cabin abuses on the part of managed care organizations (MCOs), including abuses in claims processing. That private market has two critical parts: insurance companies competing for employers and employers competing for labor. Unfortunately, both components of that market suffer from high transaction costs that destroy the market’s regulatory capacity. The first—the insurance market—is fraught with information costs, preventing individual patients and even large employers from judging the quality of a given insurance contract. Employers could bear those costs with sufficient investment, but they will be willing to do so only if they are good agents for their employees, which (despite the robust labor market) is often not the case.

(a) Information Costs. The market for employer-sponsored health insurance is undoubtedly a competitive one, with many MCOs and other insurers trying to sell their products to many employers. In that market, employers ought to be trying to maximize value. If they are good agents for their employees, then they will try to spend as little as possible but as much as necessary to get a healthcare plan that operates honestly and well, optimizing the cost-benefit trade. Part of that value in the case of an MCO (which is charged with determining eligibility for benefits under “medical necessity” review) would undoubtedly be the MCO’s claims processing habits; an MCO that habitually denies claims—deeming them medically unnecessary—ought to fail in the competitive ESI market.

But in order to determine whether an MCO is abusive in claims processing, one needs to aggregate information across patients and over time; individual complaints or stories are insufficient to draw conclusions. Because we want MCOs to deny claims for medical services that are unnecessary and because both doctors and patients have incentives to over-consume medical care, we cannot deem every denial of benefits about which a patient or doctor complains to be negligent or abusive. Furthermore, because causation is difficult to prove, we cannot impute MCO malice or negligence from a patient’s bad outcome. Only by examining trends in claims processing can an MCO consumer determine whether the insurer has a bad or abusive habit of denying claims. Part of the value of the ESI system, then, is that employers (and other large-group purchasers) are well-positioned to aggregate information across employees and over time. Unlike individual consumers, large-group purchasers have the capacity to become well-informed consumers in the MCO market.78

But such information aggregation is expensive. Employers would need to establish reporting mechanisms so that they would know when claims were denied, and they would need to analyze trends in claims denials. They would also need to investigate causation—a tricky question in any medical case—when a denial correlated to an injury.

78 This distinction is, incidentally, part of why the individual market for MCOs fails so completely, and it is a good reason for maintaining private actions against MCOs that are not employer-sponsored.
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The good news is that employers do play this role to some extent.\textsuperscript{79} The bad news is that they probably do not monitor MCOs sufficiently to eliminate abuses or even to optimize regulation, even though it would certainly be in their employees’ interests for them to avoid bad MCOs.

\textsuperscript{79} Temin et al.
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(b) Agency Costs. The natural next question is whether we have any reason to believe that employers are investing less in this information than their employees would choose to invest if they were deciding for themselves. In other words, is there agency slack between employers and employees that results in sub-optimal investment? And the answer is probably yes. Economists typically agree that the cost of employees’ health insurance premiums comes out of employees’ wages, not shareholders’ profits, so that employers should be willing to spend any amount that their employees are willing to spend on insurance premiums. But the administrative cost of monitoring a health insurance company and the administrative cost of punishing insurers for abuses might be much harder to pass on to employees in the form of decreased wages. Although there is evidence that employees will choose an employer based on general generosity of the benefits package, it is much less likely that labor will choose an employer based on a specific MCO’s quality or based on the employer’s efforts to ensure MCO quality. Those things are simply harder for prospective employees to see and measure than the general scope of the benefits package and the premiums paid there for, particularly given the need to aggregate information about MCO quality. Even in a competitive labor market, therefore, the employer might not have much of an incentive to invest in information about MCO quality in order to compete for good labor, and the employer might not be able to charge its employees for the service of aggregating information if it chooses to do so on the employees’ behalf. The employer’s incentive might, therefore, be to do what’s cheapest, not what’s best.

Employers thus have the capacity to “regulate” MCO abuses through market competition, and they do play that role to some extent. Their abilities are limited, however, by the information costs of monitoring MCO behavior and by the failures in the agency relationship between the employers and their employees.

3. Medical Devices

As with ESI, there are several competitive markets that might cabin device manufacturers’ ability to sell unsafe products. First, manufacturers must sell their products to doctors and hospitals, both of which have incentives to provide good care in order to attract insurance contracts and patients. And second, manufacturers must convince public and private insurance companies to cover their new technologies, and those insurers have incentives to avoid costly injuries to their patients. Those markets, however, fail in essentially identical ways to the ESI markets, with the providers, hospitals, and insurance companies rather than employers serving as the agents and the actors positioned to aggregate information about device quality.

(a) Information Costs. As with MCOs, devices are hard to judge based on individual stories. In any given case, a patient’s bad outcome might not have been the device’s fault at all, and even when the device clearly malfunctions, its failure might have been the doctor’s fault or simply a single bad device whose malfunction will not be replicated. In order to draw the conclusion that a device
is generally unsafe or ineffective, one needs to see a trend of harmful malfunctions or a trend of unsatisfactory patient outcomes. Individual patients, of course, cannot easily see those trends when deciding whether or not to use a particular device.

Fortunately, doctors, hospitals, and insurance companies are (at least somewhat) well-positioned to see such trends. Not only does each individual doctor gain experience with a given device as she uses it across patients but also each hospital and insurer can see the device’s utility and success across doctors. If a device is unsafe or ineffective, doctors and hospitals can simply stop buying it and stop using it on their patients, regardless of whether the device retains FDA approval or not, and insurance companies can refuse to reimburse for such devices.

As in the ESI case, though, such information aggregation is expensive. Doctors, hospitals, and insurance companies would need to establish mechanisms for monitoring device malfunctions and bad outcomes, and they would need to analyze the individual cases of malfunction to ensure that they were actually attributable to the device rather than to the doctor or patient. Although the benefits of that information for patients might be quite high, there is no doubt that the information is extremely costly.

(b) Agency Costs. The question, then (as in the employer case), is whether the actors that are positioned to aggregate information have the right balance of incentives to optimize their investment. Will they invest the same amount that their patients collectively would choose to invest in gathering information about device quality? And the answer, once again, is probably not. Most of the costs of malfunctioning devices are borne by patients, not doctors, hospitals, or insurers, so that the agents in this case do not internalize the costs to their principals.

Perhaps counter-intuitively, doctors and hospitals might be worse agents for their patients in this case than insurers. Although the Hippocratic Oath and the markets for doctors and hospitals prevent egregious abuses, all providers have incentives to provide as much care as they can, especially if they are reimbursed on a fee-for-service basis. Even if not on fee-for-service, providers have incentives to provide the care that brings them the highest possible profits. Doctors and hospitals, thus, might have incentives to continue using risky devices for as long as possible in order to bill for the extra intervention, and they might therefore want to avoid information about the devices’ malfunctions. To take the point even further, in the current system, doctors and hospitals often get paid more for injuring their patients than for curing their patients. If they use a device that malfunctions, they get paid for the initial intervention as well as for any interventions that become necessary to fix resulting injuries (excepting reimbursement for the consequences of “never events”).

Insurers’ incentives, by contrast, at least follow the same vector as their patients’ incentives since they often get stuck with higher costs when their patients get injured. Unlike doctors, the insurers pay for all interventions, including post-injury interventions. Unfortunately, though, most insurers (indeed, all insurers but Medicare) do not keep their patients long enough to suffer the full cost
of disabling injuries, for example, and private insurers often find ways to terminate coverage rather than bearing consequential costs. In the end, then, insurers’ incentive might be better aligned with patients’ interests than doctors’ and hospitals’ incentives, but because insurers often do not bear the full costs of dangerous devices, they do not have a full incentive to avoid them.

Of course, patients usually get to choose their doctors, hospitals, and insurance companies, so maybe patients could use those markets to encourage monitoring on the part of the providers and insurers. But as in the case of ESI, patients are ill-positioned to enforce their preferences through their agents because they lack the information necessary to hold their agents accountable. Again, an individual patient who has a bad experience with a medical device does not have a credible story to tell about the device’s general safety or efficacy, which prevents patients from determining whether the doctors’, hospitals’, and insurers’ purchasing decisions are good or not.

In the case of medical devices, then, the private market actors that are best situated to gather information about unsafe and ineffective devices probably do not have sufficient incentive to bear the considerable cost of doing so. Even as agents for their patients, their incentives are not aligned because there is too much agency slack. The market, thus, fails to protect patients from unsafe and ineffective devices.

4. Medical Error

As in the prior cases, there is a private market that could cabin medical negligence, but as in the prior cases, that market fails. In this story, doctors compete for insurance contracts (meaning that they compete for “preferred provider” status with large insurance companies), and they compete for individual patients. (Some doctors choose not to compete for the insurance status and throw their fates to the individual patients’ choices; others compete for insurance status and then compete for patients within those insurer pools.) The failure in the medical malpractice case is again virtually identical to the failures in ESI and devices; it is that individual experience is insufficient to draw conclusions about doctor quality, and the actors positioned to aggregate information—the insurers, in this case—are poor agents for their patients.

(a) Information Costs. As in the prior stories, the primary information cost here is the need for aggregate data. In this case, one cannot draw reliable conclusions about provider quality without knowing something about the provider’s overall injury and error rates; all doctors make some mistakes, and many patients have bad outcomes through no fault of their provider’s. But the information cost is actually a bit higher here than in the prior cases. Even comprehensive data about a provider’s morbidity and mortality rates would not tell us enough about that provider’s quality because we would need to risk adjust those statis-

\footnote{Note changes that the federal bill will effect if it passes.}

\footnote{Undercut somewhat by “any willing provider” laws, but even under those laws MCOs can place conditions on participating providers, presumably including quality controls.}
tics—to account for the possibility that the individual provider habitually treats sicker, riskier patients who are simply more likely to experience bad outcomes. That is, unlike with devices that regularly malfunction or MCOs that regularly deny claims, we cannot confidently conclude that a doctor that regularly fails to save her patients’ lives is a malfunctioning or abusive doctor. We need to account for the possibility that any doctor treating the particular patients at issue would have had the same mortality rate because those patients were simply beyond medical help. Such risk adjustment requires conclusions about causation that cannot be reached without close, expert analysis of individual outcomes. Clearly, that task would outstrip an individual patient’s capacity, even if the patient had access to lots of data.

Of course, one good reason to buy an MCO, such as a preferred provider organization, is to delegate the task of choosing doctors to an insurance company, which has better capacity to aggregate and analyze information. Insurance companies have good access to data about doctors’ successes across patients, and they have reasonable access to data about individual patients’ risk factors as well as excellent infrastructural capacity to gauge risk in the form of actuarial departments. Perhaps, then, the private market could work to regulate doctor error if MCOs would stop reimbursing—or would cut reimbursements for—doctors that have high error rates that seem attributable to doctor failure rather than patient risk. As previously noted, CMS is leading the way on just such a project with its “pay for performance” and “never events” initiatives, but private insurers have not yet adopted these programs.

That said, if insurers were truly to supplant medical malpractice as a regulatory mechanism, their reimbursement programs would need to be rigorous and precise. Insurers would need to be careful to deny payment for avoidable errors while continuing to pay for unavoidable ones and to refuse contracts to sloppy doctors while continuing to contract with doctors that take on high-risk patients. Such a system would be costly to implement and execute.

(b) Agency Costs. Consumers, of course, might be willing to bear the cost of such a system if it prevented patient injury, and if that were the case, then insurance companies would theoretically be able to pass the cost of their monitoring systems on to their patients in the form of higher premiums. There are two problems, though, that stymie this possible market innovation: first, patients would have a hard time evaluating the MCOs’ efforts and might therefore get hoodwinked into paying more for an MCO that doesn’t actually regulate quality well, and second, patients might irrationally undervalue such a system out of optimism bias (either because every patient thinks she’s unlikely to get sick or because ever patient thinks her doctor is better than average). Once again, then, agency costs in the form of information asymmetry come into play. Patients lack necessary information to demand and evaluate this service.

Nor do insurance companies’ incentives align with their patients’ incentives sufficiently for the insurance companies to play a paternalistic role, monitoring doctor quality absent patient insistence and forcing patients to accept resulting costs. Insurers’ incentives are somewhat aligned with their patients’, of course,
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since insurers suffer some costs from patient injury if they wind up paying for post-injury care. But, as in the device case, they often avoid such costs by terminating coverage or by shifting patients to other insurance companies.82 And even if insurance companies could never avoid paying for post-injury care, they still would not have a full incentive to avoid patient injuries; the most the insurance company has to pay is the medical cost of treating the iatrogenic injury, but they internalize none of the non-monetary costs (like pain).

The insurance company, thus, does not have a full incentive to protect its patients from bad doctors, and because patients are not good at judging doctor quality themselves, they are not good at evaluating insurance companies’ relevant policies. Even if the market for health insurance were perfectly competitive, therefore, there still would be agency slack between insurers and patients.

In the end, then, the private market, even with MCOs as agents for their patients, does not suffice to regulate doctor quality. Individual patients are bad at evaluating individual doctors, and they are bad at evaluating MCO quality-control programs.

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Note that the four markets considered here—and, in fact, most if not all healthcare markets—suffer from the same two sets of transaction costs: information costs and agency costs. Indeed, we can be more precise. In the three private market cases, the informational problem has two components: (1) a need for aggregation of information across patients and doctors and (2) a need for critical (and difficult) evaluation of causation in individual cases. The agency costs also have two components in the three private market cases: (1) an asymmetry of information between patients and their agents and (2) a misalignment of incentives between patients and their agents (or a failure of agents to internalize their patients’ costs). In all four cases, information and agency costs cause healthcare markets to fail, necessitating regulatory intervention.

III. FROM STATE JUDICIAL TO FEDERAL EXECUTIVE ENFORCEMENT

Given that healthcare markets require legal regulation to operate efficiently, we ought now to ask the comparative institutional competence question: Which legal entity is best situated to correct healthcare’s information and agency costs? The Court’s and state legislatures’ decisions to eliminate private enforcement suggest part of the answer: not state courts. And the presence of the alternative regulators suggests the other part of the answer: federal agencies. In all four of the stories considered here, the assault on litigation and the presence of federal regulatory alternatives present an opportunity. Without much statutory change or congressional action, we can fill our enforcement vacuums by embracing the trend from state judicial to federal executive regulation, further empowering the federal executive to fulfill its regulatory role. This Part fleshes out that

82 Again, not changes that federal bill might effect.
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reallocating trend as it arises in our four stories and considers the pros and cons of the shift for Medicaid, ESI, devices, and medical malpractice.

A. The Reallocation Trend

The migration of regulatory authority from judicial to executive forums is quite clear in our four stories; in all four, the problem is that private litigation (i.e. judicial action) is no longer available, and in all four, the apparent solution is to let the alternative regulators (all executive entities) supplant private litigation. The migration of authority from state to federal forums is clear in two of our stories and real (though less clear) in the other two; the device and ESI cases, premised as they are on federal preemption of state law, present clean shifts of authority from state to federal forums while the Medicaid and medical malpractice cases represent more-muddled shifts in the general direction of federal forums.

1. Separation of Powers

In limiting private enforcement, the Supreme Court and state legislatures also effectively limit judicial enforcement. The point may be obvious, but: without individual lawsuits, the judiciary is powerless to make or alter healthcare regulations. The judicial branch’s regulatory power—in common law systems by creating rules and in statutory regimes by interpreting them—is always contingent on case-by-case adjudication, the resolution of private litigation. And in all four cases considered here, private litigation has disappeared in favor of executive enforcement through rulemaking. Courts can no longer here any challenges to Medicaid compliance, any claims for consequential or punitive damages against abusive employer-sponsored MCOs, any allegations of dangerousness against preapproved medical devices, or large claims for noneconomic or punitive damages against negligent providers.

That said, the elimination of private causes of action—if we shift from pure litigation to executive enforcement—does not completely obliterate the judiciary’s role in the regulatory regime. First, administrative agencies’ rules, regulations, and interpretations are subject to Article III review for both procedural and substantive compliance. Second, in the four cases considered here, as Part III.B will argue, the relevant agencies would be well advised to establish adjudicatory processes for individual claims, which would allow for private, individual challenges to executive decision-making, and the agencies’ resolution of such claims would then be subject to Article III review.

The judiciary will therefore retain some role in these four regulatory regimes even if the executive fully displaces private litigation as the regulatory mechanism, but the judiciary’s role will be significantly weaker. Courts will owe deference to many of the agency rules and adjudications that reach Article III review, and many of the quotidian regulatory decisions that might have belonged

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83 APA for procedure, Chevron basics for substantive (must comply with organic statute).
84 Chevron and Mead
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to the judiciary in the past will never reach the courts, having been sufficiently settled through administrative processes.

The judiciary, thus, has largely ceded to the executive the power to enforce federal Medicaid rules, ESI contracts, and medical device safety, and the state legislatures have largely shifted the power to enforce medical malpractice standards out of the judiciary.

2. Federalism

The federalist shift is obvious for ESI and medical devices, though less so for Medicaid and medical malpractice. In the regulatory regimes for ESI and medical devices, private enforcement mechanisms have disappeared only because the Supreme Court held that federal law preempts state law (even where federal law fails to provide its own private right of action). Davila and Riegel prohibit states from setting rules for MCO negligence and for products liability, leaving that responsibility entirely with the federal government, with only ERISA and the FDCA—federal statutes—available for constraining MCO and manufacturer abuses.

In Medicaid, the entity responsible for enforcing the statute prior to Gonzaga was usually a federal entity; federal courts could have heard (and heard most if not all of) the § 1983 suits against state Medicaid agencies. Regulatory authority itself, therefore, did not as clearly shift away from state governments in the Medicaid story since state courts were never solely responsible for enforcing the statute. But the effect of Gonzaga has been to absolve state agencies from liability or responsibility for their violations of the federal statute and to shift responsibility for the statute’s enforcement entirely to the federal agency, CMS. The story therefore represents a shift of responsibility from state to federal entities, just not the same shift of active regulatory oversight that is at issue in the ESI and device cases.

In medical malpractice, the state legislatures have merely disarmed their own common law systems without proactively encouraging the federal government to step in. The effect, however, has been to leave CMS, through its reimbursement formulae, primarily responsible for ensuring provider quality. Furthermore, the states’ actions in the medical malpractice arena have accomplished little if anything in terms of improving provider quality, which has emboldened Congress to step in with federal medical malpractice legislation. The legislative caps have therefore effected a shift in governance, though probably unintentionally and certainly indirectly.

In all four stories, therefore, the federal government has taken over large swaths of regulatory responsibility from the states. In the two preemption cases, the shift is clear and obvious; in the other two stories, the shift is perhaps less clear but nevertheless real.

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85 Federal question jurisdiction; examples.
86 Moncrieff, Fed Snowballs; bills.
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B. Advantages and Disadvantage of the Shift

The best regulatory forum in each of these cases will be the one that is best situated to address and correct the information and agency costs that confound healthcare markets. In all four stories considered here—and probably in most healthcare contexts—federal executive forums will be significantly better at aggregating and evaluating information, while state judicial forums might retain some advantage in correcting agency costs.

1. Information Costs

Federal executive forums bring two significant advantages to the project of gathering and evaluating information: expertise and scale. As Part II.B made clear, the biggest informational problem in healthcare markets is the need to aggregate data. This need arises primarily from causal uncertainty that pervades healthcare stories; in an individual case, we can rarely determine with confidence the cause of a patient’s bad outcome. It might have been provider sloppiness, device malfunction, or MCO abuse, or it might have been simply that the patient was sick and didn’t get better. Distinguishing among possible causes requires a high level of medical expertise.

That expertise, then, is the first advantage of executive forums over judicial forums. If DOL took over ESI regulation, the department created for evaluating MCO claims processing would become quite expert in the project and would get better and better at identifying abusive claim denials. Similarly for an FDA department devoted to monitoring devices and a CMS department devoted to evaluating provider quality: the staff of those departments presumably would come in with some expertise and would develop even greater expertise over time. This institutional learning contrasts starkly with lay juries that have been charged, one panel at a time, with evaluating plaintiffs’ individual claims. Even if expert testimony worked flawlessly to inform lay jurors,

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which it doesn’t. See Christopher Robertson, Blind Expertise.

Of course, even when experts are charged with evaluating individual outcomes, their conclusions are limited to individual cases and might still be error-prone. From a single story of device malfunction, even an expert may not be able to conclude with confidence that the device is generally unsafe and should be pulled or relabeled. Likewise for a single story of provider negligence, from which we ought not to conclude that the provider is generally sloppy and should be punished; and likewise for a single story of wrongful benefits denial, from which we ought not to conclude that an MCO is generally abusive and should be put out of business. In order to draw such conclusions, we need to gather several stories—to aggregate data. That process of gathering large swaths of data allows
evaluation of trends and also helps to smooth error that might occur in expert evaluations of individual cases since the final evaluation drawn from a large body of data is extremely likely to be right as long as the experts are better than random in their individual evaluations.\textsuperscript{88}

Hence the second advantage of federal executive forums (and the true advantage of federal over state forums): scale. It would be theoretically possible, of course, for a state court to watch for repeat offenders—for MCOs, devices, and providers that get sued a lot—and perhaps to assign high punitive damages to those repeat offenders in an effort to put them out of business. But an individual state court has limited jurisdiction and does not communicate all that well with other jurisdictions.\textsuperscript{89} A court’s ability to aggregate information across stories is therefore limited. A federal agency, by contrast, gathers stories nation-wide and could even take note of stories from other countries in the case of internationally marketed devices. Because the agency sees all individual stories in the nation, the federal regulator reaches more accurate conclusions\textsuperscript{90} and faster conclusions. Federal executive agencies can therefore take more decisive action.

A word about Medicaid: The informational problem in Medicaid is obviously different from the informational problems in the other three stories; for Medicaid, the problem is not that aggregate information is needed. Instead, the informational need for correcting Medicaid violations includes knowledge of the complicated web of federal regulations, understanding of the interactions between state and federal decision-makers, and appreciation for the programmatic trade-offs that are necessary in running public insurance for the poor. Under the Equal Access Provision, for example, courts are asked to determine whether a given reimbursement rate reduction will cause Medicaid recipients to lose access to needed services, but determining the long-term effects of a reimbursement rate reduction is difficult if not impossible for a single, non-expert court to make.\textsuperscript{91} The problem is exacerbated by the need to consider programmatic trade-offs that become necessary in the face of budgetary restrictions; will Medicaid eligible people have better access to services if rates are low and benefits are generous, or vice versa? These systemic evaluations are better made in expert agencies than in generalist courts.

In all four stories, thus, federal executive regulators have significant advantages over state judicial regulators in their ability to correct informational failures. In the three private market stories, a single expert body, operating nation-wide, will do the best job of identifying and punishing bad actors. In Medicaid, consolidating power in a single body will help providers and beneficiaries to hold public decision-makers accountable.

\textsuperscript{88} Condorcet jury theorem.
\textsuperscript{89} States have high courts that can gather and see cases from all jurisdictions in the state, but they are not usually in the habit of punishing repeat tortfeasors more harshly because of the repetition. Furthermore, although it would not be difficult for one state court to see what other state courts have decided, they are certainly not bound by one another’s law and probably do not bother to research foreign jurisdictions’ experience and decisions.
\textsuperscript{90} Condorcet again.
\textsuperscript{91} Moncrieff comment.
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2. Agency Costs

With respect to agency cost, the benefits of federal executive regulation are less clear. Individual enforcement in state courts might better correct those costs by allowing individual victims to stand up for themselves (eliminating the need for an agent), while federal executive enforcement might replicate agency failures if it falls prey to interest group capture. That said, state courts are not immune to capture, and federal agencies can use individual enforcement mechanisms to counteract (at least somewhat) their agency failures.

As noted in Part II.B, the agency failures in healthcare markets occur for two reasons: an asymmetry of information and a misalignment of incentives between principals and agents. To correct those failures fully, a legal regulator should not itself be subject to them, but as public choice theory makes clear, all legal regulators are at least somewhat subject to both of them. Since we have a choice between two possible regulators, though, the relevant question is which of the two—state courts or federal agencies—does a better job along those dimensions.

On the first, information asymmetry, state courts do better than federal agencies, but that’s more a curse than a blessing. A judicial proceeding is almost entirely transparent; the litigants are involved in the case from the word go, and the court decides the case based entirely on the information that the litigants present. As a result, patients can accurately judge the decision-making quality of state courts without much difficulty and can hold elected judges accountable for their regulatory decisions. The federal executive, by contrast, makes its decisions based on expert evaluations and aggregated data that are hard for patients to understand. And even though the Administrative Procedure Act forces a certain degree of transparency in executive proceedings, affected parties are not as intimately involved in executive regulatory decisions as they are in judicial ones. Executive agencies, thus, have more leeway—less accountability—in regulating.

The state courts’ success here, though, is not necessarily something to celebrate; it is merely the flip side of the courts’ failure to aggregate information. True, state courts make transparent decisions based entirely on individuals’ presentations. But that’s exactly why they don’t do a very good job of reaching optimal decisions for healthcare regulation. In the end, information asymmetry is the price we pay for better-informed healthcare regulation.

State courts probably do a bit better on the second dimension of agency cost, too: misaligned incentives. Here, the biggest risk is capture; moneyed interests like insurers, doctors, and manufacturers can gain disproportionate influence over elected officials, especially as compared to dispersed, unorganized interests like patients. Regulators’ incentive, then, is to please the organized lobbies rather than to serve the public interest, creating a misalignment of incentives between patients and federal agencies. State judges, of course, are usually elected and therefore lack the political insulation of Article III judges, but they might be able to avoid upsetting moneyed interests simply by making small, case-by-case decisions. Because they do not usually effect broad-sweeping regulatory change,
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even elected state judges might not attract the attention or the pressure of interest groups, at least not nearly to the same extent as federal agencies.

That said, even in individual litigation and even in litigation before insulated judges, the playing field is not exactly level. Just as moneyed interests can gain an advantage in wholesale regulation by donating to officials’ campaigns and by monitoring regulatory processes, so too can they gain an advantage in litigation by outspending their individual opponents—by hiring better lawyers, filing more motions, dragging out trials, etc. This failure is not a traditional capture story, but it is a similar story of process failure that causes a similar distortion in regulatory incentives. State courts, thus, are not immune to distortion and probably would do only a marginally better job than agencies of basing regulatory decisions on the general public interest.

One possible (though only partial) correction for agency failures in the federal executive would be to allow individual administrative claims. An individual claims process would allow patients to inform the executive of their experiences, to have more direct contact with the decision-making process, and to influence the development of the regulatory environment in the same small way that the state courts allow them to do so. Such a process would, in short, give individuals some power to act as their own agents, as they do in state courts. It therefore seems wise, if we do shift entirely to federal executive enforcement in these stories, to encourage federal agencies to establish administrative claims (like those available to Medicare beneficiaries).

Again, a word on Medicaid: The agency problem for Medicaid is that state governments will not adequately represent the collective interest in providing insurance to the poor because their incentive instead will be to send poor and sick residents to neighboring states by making their own Medicaid programs less generous than their neighbors—a race to the bottom. Will courts or agencies do a better job of representing the interests of poor residents in enforcing federal statutory requirements? In this case, courts’ advantage in providing access to dispersed interests and avoiding capture by organized interests is less clear than in the other cases; for Medicaid, organized interests such as doctors and hospitals actually prefer generous Medicaid programs, just as their patients do. They are therefore unlikely to pressure CMS to cut the program. The only lobbies that oppose Medicaid generosity are the state-based lobbies, such as the National Governors Association and the National Conference of State Legislatures, and those lobbies cannot “buy” federal agencies the way that insurers, manufacturers, and doctors can.

In sum, state courts might do better than federal administrators at internalizing and representing the public interest if they are less subject to capture than federal agencies, but their advantages are marginal, come at the expense of informational deficits, and are at least partially overcameable through administrative claims processes. For the three private markets, therefore, state courts might be slightly better for correcting the markets’ agency failures, but that advantage may not be worth its cost. (For Medicaid, the federal agency seems no worse than courts at representing patients.)
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IV. WHAT NEXT?

Given that the status quo for these four realms of health law is one of failing markets and inadequate regulation, we must now consider regulatory alterations and solutions. Of course, the Article up to this point has identified many weaknesses of state judicial regulation and many strengths of federal executive regulation, strongly implying a conclusion that federal agencies should simply take over the regulatory job. I hereby explicitly and wholeheartedly endorse that conclusion. But I must also address one compelling question that ought to arise in the critical reader’s mind: Why not both? Why not encourage the federal executive to fill its regulatory role while still preserving a full judicial role, at least in the federal judiciary if not in the state judiciaries? This Part will tackle that question and will offer compliance and error costs as an answer. It will then lay the landscape of exclusive executive authority and make suggestions for its improvement.

A. The Possibility of Concurrent Authority

Before we get to compliance and error costs, we must first consider whether judicial authority can be reinstated after the Supreme Court’s holdings and state legislatures’ decisions. The answer, of course, is that it can be in all four stories, though it requires congressional action in one story, executive or congressional action in two, and state legislative action in the last.

For Medicaid, the Supreme Court’s holding applied to § 1983, holding that the general right of action provided in that statute did not allow private enforcement of Spending Clause conditions against state agencies. (Remember, it was not even a Medicaid case that caused the vacuum here; it was FERPA.) Congress, however, could insert an explicit right of action into the Medicaid statute or could amend § 1983 to allow private enforcement of Spending statute conditions. (Either of those options would create a right of action in federal rather than state courts, but either amendment would reauthorize judicial regulation of Medicaid conditions.)

For ESI, Congress could obviously amend ERISA to allow for consequential and punitive damages against insurers. It could do so either by amending the “equitable relief” restriction in ERISA’s federal cause of action or by amending ERISA’s preemption provisions to allow for state tort suits against employer-sponsored insurers. Indeed, Congress came very close to passing the latter approach in 2001, when the so-called Patients’ Bill of Rights passed both chambers but stayed stuck in conference committee after the September 11 attacks consumed the national dialogue. Alternatively, as noted, the Department of Labor could issue a formal rule, establishing that ERISA’s “equitable relief” provision allows for consequential and punitive damages in federal court.

The story is the same for medical devices. Congress could either create a federal right of action for device-related injuries or amend the FDCA’s preemp-
tion provision to allow for state tort suits. In this case, too, it is possible that the federal executive could change the meaning of the preemption provision by issuing a formal rule that state tort suits are not “requirements” for device safety. Given that FDA has changed its position on that question several times in the past, though, the Supreme Court might deem the interpretation to be unreasonable and thereby refuse deference. In any event, the provision could certainly be changed, whether or not the change would require congressional action.

For medical error, the reinstatement of full judicial authority would simply require the state legislatures to repeal their damages caps. It is also possible that Congress could create a federal cause of action for medical torts, empowering the federal judiciary rather than state judiciaries, though such an approach would be vulnerable to constitutional challenges, particularly on the ground that medical practice does not constitute “interstate commerce.”

In any event, there is no impenetrable barrier to the reauthorization of judicial regulation in these four regimes—or in any regime. Congress and state legislatures can certainly create rights of action to reempower private enforcement. And a decision to reempower the judiciary would not be fundamentally incompatible with a decision to encourage the relevant executive agencies to play a greater regulatory role. At a minimum, the judiciary can adjudicate claims for compensation without playing the full regulatory game that comes with punitive damages. We could, then, choose to divide responsibility between the two branches, with the executive deterring systemic abuse and the judiciary compensating victims. And at most, we could allow both branches to have full regulatory authority, with punitive damages available in courts and regulatory oversight vested in agencies. Other regulatory regimes follow this model with success, and there is no inherent structural problem with allowing the branches to exercise concurrent authority.

B. The Problems with Concurrent Authority

But to argue that we should allow concurrent authority is to miss the point. State judicial bodies are not simply failing to get the job done; their flaws are actively detrimental to the system, creating high and unnecessary costs for regulated entities. For our four stories and probably for healthcare generally, state judicial regulation creates high compliance costs (a problem with state regulation) and injects high error costs (a problem with judicial regulation).

1. Compliance Costs

The first problem with state judicial regulation hinges on the state-ness of it; with fifty independent jurisdictions creating rules, some regulated entities will suffer higher-than-necessary compliance costs. This problem is, of course, the

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93 Chevron Step 2.
94 Sources cited in Snowballs.
95 Examples?
motivation behind the preemption rules in ERISA and in the FDCA. Medical device manufacturers benefit significantly from regulatory uniformity since they sell their devices nation-wide, and employers benefit significantly from such uniformity since they employ labor and provide benefits across jurisdictions (if not nation-wide). Given that federal agencies have authority to take over from the states and have superior capacity to the states’ to reach regulatory optimality, there is no good reason to continue suffering the compliance costs that come with state judicial regulation. Even if state courts were simply settling claims for compensation, they would necessarily impose regulatory duties for manufacturers and employers that might vary across jurisdictions. Concurrent jurisdiction between state and federal regulators, thus, does not solve the uniformity need for manufacturers and employers.

Of course, that uniformity need is less acute for medical malpractice and Medicaid. In those stories, variation among states probably would not be a significant problem since providers tend to operate in a single state. Even in a country with fifty different legal regimes, individual providers (including hospitals) would need to learn and to abide by only one set of negligence rules and only one set of Medicaid reimbursement formulae because their practice is ordinarily confined to a single state. Similarly, liability insurers probably do not benefit much from national medical malpractice standards since they write state-specific policies for actuarial reasons. If compliance costs were the only reason to eliminate state judicial regulation, then, we might consider maintaining state courts’ role in medical malpractice and state agencies’ answerability for Medicaid.

2. Error Costs

The second problem with state judicial regulation—and the problem with allowing federal judicial regulation rather than moving entirely to the executive—hinges on the judicial-ness of it; juries and judges make bad decisions when confronted with single healthcare cases, leading to systemic error costs. This problem is significant for all four of our stories, as should be apparent from the pervasive discussion of information costs. For ESI, devices, and malpractice, the source of the error has been well-canvassed in the Article so far: courts (especially juries) do a bad job of evaluating causation. As a result, they issue both false positives and false negatives. Good MCOs, devices, and providers get punished, and bad ones go free; inevitable injuries get compensated while preventable ones do not. Regulated entities then invest in avoiding liability in a completely arbitrary system, a wasteful investment since arbitrary rules fail to incentivize greater safety or welfare.

Snowballs

It is a reasonable question whether this is an artifact of fifty different legal regimes, whether nation-wide providers would emerge if the federal government took over regulation.

This point is perhaps best-known in the malpractice context, where arbitrary litigation rules incentivize defensive medicine on the part of individual providers rather than appropriate precaution on the part of systemic entities.

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96 Snowballs
97 It is a reasonable question whether this is an artifact of fifty different legal regimes, whether nation-wide providers would emerge if the federal government took over regulation.
98 This point is perhaps best-known in the malpractice context, where arbitrary litigation rules incentivize defensive medicine on the part of individual providers rather than appropriate precaution on the part of systemic entities.
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For Medicaid, too, the problem with courts is they lack the wide-angle lens necessary to evaluate something like a reimbursement rate reduction. The systemic evaluations necessary to shape a Medicaid program are better made in expert agencies than in generalist courts, and the cost of error could be significant if courts unwittingly move Medicaid eligibles into emergency rooms.

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The problem with concurrent authority here, thus, is not at all inherent to concurrency. The problem is that state and judicial decision-making, whether occurring alongside federal executive decision-making or not, imposes costs on the system. Those costs might be worth bearing if state courts were the only option for regulation, but given the presence of superior regulators in the federal executive, we might be able to avoid completely the compliance and error costs that come with judicial rulemaking by vesting exclusive authority in federal agencies.

C. Exclusive Executive Authority

We ought, then, to shift entirely to federal executive authority. As noted, the groundwork for that shift is already laid; in each of our four regulatory regimes, some federal agency already has authority to regulate. But the federal agencies do not yet play that role. The question, thus, is what needs to be done to optimize federal executive regulation of Medicaid, ESI, medical devices, and medical malpractice.

The short answer is money. The biggest barrier to robust federal executive regulation right now is the agencies’ shortage of resources for enforcing their statutes. To engage in robust regulation, the agencies need bigger staffs and more money. Those provisions need to come from Congress.

The longer answer is restructuring. All three agencies—CMS for Medicaid and malpractice, DOL for ESI, and FDA for devices—have structured themselves with different goals in mind, other than the regimes at issue here, and they operate in complex regulatory environments in which they sometimes compete with other agencies for jurisdiction over single healthcare problems.99 If we want the federal executive to become the exclusive regulator for these regimes, we need to consolidate power not only in the executive but also within the executive in a single department, giving a single agency—probably a single office within a single agency—the task of monitoring each of these regimes.

Furthermore, the federal executive should structure its regulations to address the most common objection to administrative regulation: the lack of individual compensation. Each agency ought to establish an administrative claims process that will allow injured patients to seek redress for their injuries. Such a system could replicate the one true advantage of judicial regulation—agency correction—without necessarily replicating the error costs that come with generalist judges and juries.

99 See e.g. Farrell
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These changes to the federal executive regulatory environment would require some congressional action, but they would not require substantive amendments to the relevant regulatory statutes, all of which already authorize administrative regulation. The move, therefore, should be relatively easy to implement and therefore seems well worth the effort.

V. CONCLUSION

Although the Supreme Court’s and state legislatures’ decisions might be a bit premature—predating robust federal executive involvement—the instinct they represent is a good one. Particularly for health law, an area that has a long history of administrative regulation, the shift from state judicial regulation to federal executive regulation is a wise shift. At this point in the history of health law, we should embrace the reallocation of regulatory authority, recognizing healthcare regulation as an aggregate rather than individual project, shifting authority to a big-picture regulator. For that project, federal executive agencies are significantly better positioned than state courts.