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**THE SUPREME COURT’S ASSAULT ON LITIGATION:  
WHY (AND HOW) IT MIGHT BE GOOD  
FOR HEALTH LAW**

**ABIGAIL R. MONCRIEFF\***

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\* Peter Paul Career Development Professor and Associate Professor of Law, Boston University School of Law. J.D. 2006, University of Chicago. Thanks to Jack Beermann, Vincent Chiao, Allison Hoffman, Gary Lawson, Kristin Madison, Fran Miller, Nancy Moore, Kevin Outterson, Ken Simons, David Seipp, Larry Yackle, and the students in BU’s Health Law and the Constitution seminar for helpful comments and suggestions. Thanks to Namrata Kotwani and Mary Carter for excellent research assistance.

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*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, although certainly not limited to health law, has had a significant impact on the field; 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 non-economic and punitive damages for medical malpractice litigation, weakening the tort system's deterrent capacity in those states. This Article suggests that the trend of eliminating private rights of action should be evaluated not as an elimination of legal enforcement (and creation of a "regulatory vacuum") but rather as a shift of regulatory authority from state judicial forums to federal executive forums. The Article then argues that such a shift might be a wise one for healthcare, given the particular market failures that justify the regulatory intervention. In all four stories, federal executive regulators are poised to take over the regulatory job, and federal executive regulators have the capacity to do a better job than courts. The Article therefore urges completion rather than reversal of the reallocation – a consolidation of regulatory authority in the federal executive and a further disarming of state judicial enforcement power.*

#### INTRODUCTION

Consider the following scenarios:

- A state Medicaid agency refuses to pay its doctors at the reimbursement rate required by federal statute.<sup>1</sup>
- An employer-sponsored health insurer refuses to cover medically necessary services that ought to be covered under the insurance contract.<sup>2</sup>
- 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.<sup>3</sup>

<sup>1</sup> See Nicole Huberfeld, *Bizarre Love Triangle: The Spending Clause, Section 1983, and Medicaid Entitlements*, 42 U.C. DAVIS L. REV. 413, 415-18 (2008); Abigail R. Moncrieff, Comment, *Payments to Medicaid Doctors: Interpreting the "Equal Access" Provision*, 73 U. CHI. L. REV. 673, 673 (2006).

<sup>2</sup> See, e.g., *Aetna Health Inc. v. Davila*, 542 U.S. 200, 204-05 (2004).

<sup>3</sup> See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319-21 (2008); Catherine T. Struve, *The Food and Drug Administration and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 588 (2005) (explaining how in recent years, because "policymakers have stressed the need to bring innovative medical treatments to market," greater deference is paid to FDA's product

- A doctor refuses to take cost-justified precautions against injuring patients.<sup>4</sup>

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 wrongdoers not only for individual compensation but also for systemic deterrence. That is, the American legal system has largely relied on private litigation – primarily brought under common law theories 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,<sup>5</sup> 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*, the Supreme Court narrowed the availability of 42 U.S.C. § 1983 for enforcing federal statutes, especially those enacted under Congress's spending power.<sup>6</sup> That holding, as applied in the lower courts, has made it impossible for individuals to sue state agencies (or, more precisely, the heads of the agencies) for certain violations of the federal Medicaid Act, including violations of the essential "Equal Access Provision" that governs provider reimbursement.<sup>7</sup> Second, employer-sponsored insurance (ESI). In *Aetna Health Inc. v. Davila*, the Court gave a broad reading and application to the preemption provision of the Employee Retirement Income Security Act of 1974 (ERISA).<sup>8</sup> That holding, combined with the Court's narrow reading of ERISA's remedial provision, has made it impossible for some patients to hold their insurers accountable for injuries resulting from wrongful benefits denials.<sup>9</sup> Third,

approval).

<sup>4</sup> See Abigail R. Moncrieff, *Federalization Snowballs: The Need for National Action in Medical Malpractice Reform*, 109 COLUM. L. REV. 844, 855-61 (2009) (reviewing the literature on medical malpractice reform).

<sup>5</sup> See Erwin Chemerinsky, *Closing the Courthouse Doors to Civil Rights Litigants*, 5 U. PA. J. CONST. L. 537, 537-39 (2003) (listing a long line of Rehnquist Court decisions that prevent individuals from suing to enforce civil rights).

<sup>6</sup> *Gonzaga Univ. v. Doe*, 536 U.S. 273, 273 (2002).

<sup>7</sup> See Huberfeld, *supra* note 1, at 445-51 (observing 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).

<sup>8</sup> *Aetna Health Inc. v. Davila*, 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).

<sup>9</sup> 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 Ins. Co. v. Knudson*, 534 U.S. 204, 209-18 (2002) (interpreting § 502(a)(3)

medical devices. In *Riegel v. Medtronic, Inc.*, the Court held that Food and Drug Administration (FDA) pre-market approval of the riskiest (“Class III”) medical devices preempts state tort suits challenging those products’ safety and labeling.<sup>10</sup> 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 non-economic and punitive damages in medical malpractice litigation, limiting their own tort systems’ capacity to deter iatrogenic (i.e., physician-caused) injuries. Of course, medical malpractice litigation still serves compensatory purposes in those states, but caps limit the tort system’s regulatory capacity.<sup>11</sup>

Healthcare regulation has thus lost several of its private enforcement mechanisms over the past decade, largely to the chagrin of the legal academy.<sup>12</sup> But should those losses actually worry us? Is it problematic that

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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 (citations omitted)); David A. Hyman, *Regulating Managed Care: What’s Wrong with a Patient Bill of Rights*, 73 S. CAL. L. REV. 221, 229 (2000) (explaining that ERISA, while preempting state-law remedies, “contains no substantive regulation of its own, and provides only an exceedingly limited set of remedies”).

<sup>10</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 312-13 (2008).

<sup>11</sup> Granted, the tort system probably wasn’t doing a good job at deterring iatrogenic injury before the caps. See INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 1 (Linda T. Kohn et al. eds., 2000) (summarizing statistical evidence that suggests that the frequency of iatrogenic deaths in U.S. hospitals is much higher than commonly believed). But caps certainly decrease the system’s potential for that kind of regulation.

<sup>12</sup> For representative examples of scholarly chagrin at the curbing of private enforcement in each of the four stories described here, see TOM BAKER, THE MEDICAL MALPRACTICE MYTH 1 (2005) (arguing that attempts to limit medical malpractice litigation are fundamentally misguided); David Brennan, *Federal Preemption of All State Law Tort Claims in Riegel v. Medtronic: A Need to Undo a Serious Wrong*, 36 W. ST. U. L. REV. 137, 165-66 (2008) (“Consumer organizations and groups were quick to realize that users of Class III medical devices had been effectively disenfranchised from any reasonable remedy for dangerous or defective devices by a sweeping doctrine of federal preemption doctrine.”); Margaret Cyr-Provost, *Aetna v. Davila: From Patient-Centered Care to Plan-Centered Care, a Signpost or the End of the Road?*, 6 HOUS. J. HEALTH L. & POL’Y 171, 179 (2005) (describing the fact that today’s legal climate lacks “legal and moral accountability” and leaves health care consumers without recourse); Huberfeld, *supra* note 1, at 414 (urging “legislative responses to the possible demise of the Medicaid entitlement”); Mark Andrew Ison, Note, *Two Wrongs Don’t Make a Right: Medicaid, Section 1983 and the Cost of an Enforceable Right to Healthcare*, 56 VAND. L. REV. 1479, 1516-18 (2003) (highlighting the potentially “catastrophic” harms to beneficiaries that might result from under-enforcement after *Gonzaga*); Theodore W. Ruger, *The United State Supreme Court and Health Law: The*

private litigation is 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.<sup>13</sup> 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. In that case, 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.<sup>14</sup> But this premise and mode of analysis is one that the health law literature has largely overlooked in considering the Supreme Court's recent holdings. This Article fills that analytic void, asking not whether the curbing of healthcare litigation is bad in itself but whether the curbing of that litigation is bad given the broader regulatory environment for healthcare and given the particular regulatory needs that healthcare markets present. That is, I ask and answer the comparative question: whether litigation is better or worse at setting incentives than its available substitute, administrative regulation.

An important first step in answering the 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) (as well as a handful of other agencies since the passage of the Patient Protection and Affordable Care Act (PPACA)<sup>15</sup>) already has authority to

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*Year in Review: The Supreme Court Federalizes Managed Care Liability*, 32 J.L. MED. & ETHICS 528, 529 (2004) ("ERISA's remedial provisions are so penurious that *Aetna's* holding of complete preemption produces a legal regime that vastly under-compensates plan members who suffer a wrongful denial of care.").

<sup>13</sup> See RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 383-84 (6th ed. 2003) (outlining circumstances in which we ought to prefer common law to administrative regulation and vice versa).

<sup>14</sup> For a recent elaboration of this point, see Kyle D. Logue, *Coordinating Sanctions in Tort* (Univ. of Mich. Law Sch., Olin Ctr. for Law & Econ. Working Paper Series, Paper No. 105, July 2009), available at <http://ssrn.com/abstract=1430596>.

<sup>15</sup> The Employee Benefits Security Administration (EBSA), an agency of the Department of Labor, is primarily responsible for administering the provisions of ERISA. The enactment of the Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education Reconciliation Act, signed into law in March 2010, made some significant changes to the regulatory structure for employer-sponsored insurance. In particular, EBSA now shares "interpretive jurisdiction" with the Department of Treasury and the Department of Health and Human Services (HHS) over PPACA provisions applicable to employer-sponsored insurance. EBSA Unified Agenda, Regulations Implementing the Patient Protection and Affordable Care Act of 2010 (PPACA), available at <http://www.dol.gov/>

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,<sup>16</sup> 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 environment does not lack authoritative figures, and the existing authoritative figures do not lack legal tools for regulation.<sup>17</sup> 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.

These anxious 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;<sup>18</sup> DOL

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ebsa/regs/unifiedagenda/spring-2010/1210-AB41.htm (last visited Oct. 10, 2010). The EBSA Unified Agenda states that the three departments "are proceeding concurrently to provide regulatory guidance regarding [implementation of PPACA] provisions." *Id.* Thus, the agencies will jointly issue interpretations of relevant PPACA provisions. *Id.* According to EBSA, initial regulatory action will likely require insurers to extend dependent coverage and cover preventive health services without cost sharing and address PPACA provisions that prohibit insurers from establishing lifetime or annual limits on benefits, rescinding health coverage after coverage begins, excluding potential beneficiaries based on pre-existing conditions and health status, and discriminating in favor of highly compensated individuals. *Id.* PPACA also imposes requirements on internal claims appeal and external review procedures that are applicable to group health plans. *See infra* note 86 and accompanying text.

<sup>16</sup> Eleanor Kinney and Bill Sage 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 & William M. Sage, *Dances with Elephants: Administrative Resolution of Medical Injury Claims by Medicare Beneficiaries*, 5 IND. HEALTH L. REV. 1, 2 (2008); Eleanor D. Kinney & William M. Sage, *Resolving Medical Malpractice Claims in the Medicare Program: Can It Be Done?*, 12 CONN. INS. L.J. 77, 90 (2005-2006); William M. Sage, *The Role of Medicare in Medical Malpractice Reform*, 9 J. HEALTH CARE L. & POL'Y 217, 225-28 (2006).

<sup>17</sup> That said, the relevant administrative agencies do not have sufficient financial resources to engage in the projects that I urge here. That is, they have legal tools but lack practical resources. For more on this point, see *infra* Part IV.B.3.

<sup>18</sup> Jon Donenberg, *Medicaid and Beneficiary Enforcement: Maintaining State*

neither provides an administrative system for claims review nor punishes abusive MCOs; FDA rarely monitors the safety of devices that have gone through pre-market approval and have entered the market; and neither CMS nor professional medical associations actively enforce quality standards for practicing providers.<sup>19</sup> In short, to the extent that the executive already regulates these fields, it does far too little to make up for a lack of parallel private enforcement. For now, thus, the Supreme Court and state legislatures have left health law not so much with *regulatory* vacuums as with *enforcement* vacuums, within which Medicaid agencies, employer-sponsored insurers, device manufacturers, and sloppy doctors can shirk legal obligations with relative impunity – all 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 Article urges the latter approach, primarily for reasons of comparative institutional competence. The federal agencies have greater capacity to regulate well than courts and juries.

The Supreme Court's and state legislatures' assaults on litigation, if understood as a vote of confidence for administrative regulators over common law and other 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, these 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.

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*Compliance with Federal Availability Requirements*, 117 YALE L.J. 1498, 1501 (2008) (finding that CMS's withdrawal power is "rarely, if ever, invoked" (quoting Lisa E. Key, *Private Enforcement of Federal Funding Conditions Under § 1983: The Supreme Court's Failure to Adhere to the Doctrine of Separation of Powers*, 29 U.C. DAVIS L. REV. 283, 293 (1996))).

<sup>19</sup> For discussion of CMS's growing interest in quality regulation, particularly including its "never events" and "pay for performance" policies, see *infra* Part II.A.4.

As we have long recognized, generalist juries and judges are bad at understanding, evaluating, and creating healthcare regulations<sup>20</sup> – and expert agencies might be much better.<sup>21</sup> Furthermore, federal regulation of healthcare might make more sense than state regulation for a variety of reasons, especially considering the economies of scale that we gain from operating nation-wide.<sup>22</sup>

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 reallocative 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. Fulfilling this shift will probably require some restructuring of administrative bodies and will certainly require additional funding for the federal regulators, but the move should not require substantive amendment of the regulatory statutes.

The 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 regimes. 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 regulation. Part III fleshes out the judicial-to-executive and state-

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<sup>20</sup> See Lawrence Gostin, *The Formulation of Health Policy by the Three Branches of Government*, in *SOCIETY'S CHOICES: SOCIAL AND ETHICAL DECISION MAKING IN BIOMEDICINE* 335, 339-40 (Ruth Ellen Bulger et al. eds., 1995) (describing the limits of courts in healthcare policymaking); William M. Sage & Rogan Kersh, *Introduction to MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM* 4 (William M. Sage & Rogan Kersh eds., 2006) (outlining potential changes to the medical malpractice litigation process which could substantially increase the “accuracy and consistency of outcomes”); NEIL VIDMAR, *MEDICAL MALPRACTICE AND THE AMERICAN JURY* 3-6 (1995) (reviewing criticism of juries by American Medical Association and others); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 319-20, 332-33 (1985) (arguing that juries are institutionally unable to make risk choices and that decisions should be made by regulatory agencies); Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 370 (2000) (“[P]opular perceptions of juror incompetence and bias have caused commentators to argue that the role of the jury in patent litigation should be severely limited, and many alternatives have been proposed.”); David M. Studdert & Michelle M. Mello, *When Tort Resolutions Are “Wrong”: Predictors of Discordant Outcomes in Medical Malpractice Litigation*, 36 J. LEGAL STUD. S47, S48-52 (2007). *But see* VIDMAR, *supra*, at 161-82 (arguing that juries are competent and that medical malpractice liability system is generally sound).

<sup>21</sup> Timothy Stoltzfus Jost, *Health Law and Administrative Law: A Marriage Most Convenient*, 49 ST. LOUIS U. L.J. 1, 16-30 (2004) (describing the executive’s comparative advantages over both the judiciary and the market for regulating healthcare); Huber, *supra* note 20, at 285, 307-26.

<sup>22</sup> See Moncrieff, *supra* note 4, at 848.



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.

### 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.<sup>23</sup> This trend has affected a wide range of regulatory regimes, including disabilities law,<sup>24</sup> employment and labor law,<sup>25</sup> and civil rights law.<sup>26</sup> It has also had a significant impact 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 non-economic and punitive damages in medical malpractice litigation. These damages caps at least attempt to serve the same purpose, dissuading courts and litigants in their attempts to regulate physician negligence.<sup>27</sup>

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

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<sup>23</sup> See Chemerinsky, *supra* note 5, at 537-39 (listing cases from 2001 and 2002 that limited civil rights plaintiffs' access to courts).

<sup>24</sup> See, e.g., *Barnes v. Gorman*, 536 U.S. 181 (2002) (holding that punitive damages are unavailable under § 202 of the Americans with Disabilities Act and § 505(a)(2) of the Rehabilitation Act); *Bd. of Trs. of the Univ. of Ala. v. Garrett*, 531 U.S. 356 (2001) (holding that state governments cannot be sued for violating the Title I of the Americans with Disabilities Act).

<sup>25</sup> See, e.g., *Circuit City Stores, Inc. v. Adams*, 532 U.S. 105, 119 (2001) (requiring arbitration of employment-related claims of state discrimination).

<sup>26</sup> *Porter v. Nussle*, 534 U.S. 516, 532 (2002) (requiring prisoners to exhaust administrative remedies before filing suit alleging excessive force by corrections officers); *Booth v. Churner*, 532 U.S. 731, 740-41 (2001) (finding that prisoners must exhaust prison administrative remedies before seeking money damages in court); *Alexander v. Sandoval*, 532 U.S. 275, 293 (2001) (finding that Title VI of the Civil Rights Act of 1964 does not contain a private right of action).

<sup>27</sup> 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. That said, the spirit of the caps is the same as the spirit of the other limits on private enforcement; the attempt is to dissuade litigation.

A. *Gonzaga and Medicaid*

In *Gonzaga University v. Doe*<sup>28</sup> (a decision that Chief Justice Rehnquist called his “sleeper case” of 2002<sup>29</sup>), the Supreme Court narrowed the availability of 42 U.S.C. § 1983 for enforcing federal statutes.<sup>30</sup> 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.<sup>31</sup> Because the provision refers to laws as well as the Constitution, plaintiffs have long used § 1983 to enforce federal statutes against state agents.

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),<sup>32</sup> finding that FERPA did not create any “personal rights”<sup>33</sup> 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).

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 the statute specified a regulatory enforcement scheme, charging the Secretary of Education with withdrawing federal funds from noncompliant institutions.<sup>34</sup> Because Congress passed the statute merely as a grants program for the states, because Congress intended for the statute to be enforced through regulatory funding decisions, and because the relevant provision did not clearly create and confer an enforceable right in the plaintiff, the Court reasoned, the legislature must not have intended to allow individual private enforcement through § 1983.<sup>35</sup>

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<sup>28</sup> 536 U.S. 273 (2002).

<sup>29</sup> Erwin Chemerinsky & Martin A. Schwartz, *Section 1983 Litigation: Supreme Court Review*, 19 *TOURO L. REV.* 625, 663 (2003).

<sup>30</sup> *Gonzaga*, 536 U.S. at 276.

<sup>31</sup> 42 U.S.C. § 1983 (2006).

<sup>32</sup> 20 U.S.C. § 1232g (2006).

<sup>33</sup> *Gonzaga*, 536 U.S. at 276.

<sup>34</sup> *Id.* at 278-79.

<sup>35</sup> Of course, even after *Gonzaga*, Congress can pass provisions under its Spending Clause power that create and 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 Huberfeld, *supra* note 1, at 446-47 (observing that several circuits still allow Medicaid beneficiaries to use § 1983 to enforce the “minimum services” provision, which vests individual rights in beneficiaries).

Since *Gonzaga* was decided, all but one of the federal courts of appeal that have considered the question have applied *Gonzaga* to preclude individual enforcement of several Medicaid provisions, including a central Medicaid requirement known as the Equal Access Provision.<sup>36</sup> The Equal Access Provision is a part of the federal Medicaid Act, requiring state agencies to 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.”<sup>37</sup> In short, it requires state agencies to pay doctors at a rate that is competitive with private market payments.<sup>38</sup> The fear that motivates the provision is that doctors will refuse to treat Medicaid patients if the program pays too little.<sup>39</sup>

Before *Gonzaga* was decided, providers and patients could (and did) use § 1983 to enforce the Equal Access Provision, suing heads of state Medicaid agencies for cutting reimbursement rates on the ground that the cut rate would be too low to meet federal statutory requirements.<sup>40</sup> 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.<sup>41</sup>

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 federal program like Medicare but rather a set of grants to subsidize state-run

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<sup>36</sup> See Andrew R. Gardella, Note, *The Equal Access Illusion: A Growing Majority of Federal Courts Erroneously Foreclose Private Enforcement of § 1396a(a)(30) of the Medicaid Act Using 42 U.S.C. § 1983*, 38 U. MEM. L. REV. 697, 733-42 (2008) (discussing cases in which the First, Fifth, Sixth, Ninth, and Tenth Circuits have held that the Equal Access Provision does not create an individual right enforceable under § 1983 while only the Eight Circuit has held that it does).

<sup>37</sup> 42 U.S.C. § 1396a(a)(30)(A) (2006).

<sup>38</sup> See Moncrieff, *supra* note 1, at 685-87.

<sup>39</sup> *Id.* at 684-85 (explaining that the basic purpose of the Equal Access Provision was to avoid a “dual-tracked” medical system in which Medicaid beneficiaries would have access to different and worse doctors than patients with non-Medicaid insurance).

<sup>40</sup> See *id.* at 677-78 (describing pre-*Gonzaga* cases).

<sup>41</sup> See *AlohaCare v. Haw. Dep’t Human Servs.*, 572 F.3d 740, 746 (9th Cir. 2009) (finding that AlohaCare did not have a private right of action under several Medicaid sections related to the state’s ability and limitations in contracting with providers); *Equal Access for El Paso, Inc. v. Hawkins*, 509 F.3d 697, 703 (5th Cir. 2007); *Long Term Care Pharmacy Alliance v. Ferguson*, 362 F.3d 50, 51, 57-59 (1st Cir. 2004); Devi M. Rao, Note, “*Making Medical Assistance Available*”: *Enforcing the Medicaid Act’s Availability Provision Through § 1983 Litigation*, 109 COLUM. L. REV. 1440, 1461-62 n.155. *But see* *Indep. Living Ctr. of S. Cal., Inc. v. Maxwell-Jolly*, 572 F.3d 644, 655-57 (9th Cir. 2009) (upholding a preliminary injunction against California’s rate reduction legislation on the ground that it would violate the Supremacy Clause).

public health insurance.<sup>42</sup> Also like FERPA, the Medicaid Act's substantive requirements – 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.<sup>43</sup> And finally, like FERPA, the Medicaid Act charges a federal administrator – the head of the Centers for Medicare and Medicaid Services – with enforcing the Act's substantive requirements by denying federal funding to any non-compliant Medicaid plan.

Given that the Medicaid Act's structure is so similar to FERPA's structure, the conclusion is rightly the same: the Equal Access Provision did not intend to create or confer privately enforceable rights.<sup>44</sup> But, of course, that holding strips individuals of the power to enforce certain Medicaid rules through litigation, even when those individuals have been harmed by the statutory violation. In other words, the holding disarms private litigation in Medicaid regulation.<sup>45</sup>

#### 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 Security Act of 1974 (ERISA)<sup>46</sup> in a way that effectively foreclosed private actions against employer-sponsored managed care organizations (MCOs). In

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<sup>42</sup> See Jerry L. Mashaw & Dylan S. Calsyn, *Block Grants, Entitlements, and Federalism: A Conceptual Map of Contested Terrain*, 14 YALE L. & POL'Y REV. 297, 304-05 (1996) (describing the interactions of state and federal funding in Medicaid and the interactions of state and federal law in Medicaid before *Gonzaga*).

<sup>43</sup> See *South Dakota v. Dole*, 483 U.S. 203, 206 (1987) (stating that Congress has constitutional authority to “attach conditions on the receipt of federal funds”).

<sup>44</sup> There are, however, several individual provisions of the Medicaid Act that have been found to confer individual rights. See *Grammer v. John J. Kane Reg'l Ctrs.-Glen Hazel*, 570 F.3d 520, 527 (3d Cir. 2009) (finding that Medicaid's Federal Nursing Home Reform Amendments created individuals rights); *Rabin v. Wilson-Coker*, 362 F.3d 190, 201-02 (2d Cir. 2004) (holding that an eligibility provision codified as § 1396r-6 does create and confer enforceable rights); *Gean v. Hattaway*, 330 F.3d 758, 772-73 (6th Cir. 2003) (finding that the “right to fair hearing” provision, § 1396a(a)(3), “creates an obligation on the part of the State and is phrased in terms of benefitting Medicaid recipients”); see also Brian J. Dunne, Comment, *Enforcement of the Medicaid Act Under 42 USC § 1983 After Gonzaga University v Doe: The “Dispassionate Lens” Examined*, 74 U. CHI. L. REV. 991, 996-1012 (2007) (discussing the circuit courts' various interpretive methodologies for determining whether an enforceable right exists and noting some provisions that continue to be enforceable after *Gonzaga*); Rao, *supra* note 41, at 1463-80 (explaining that the Medicaid Act's Availability Clause has been found enforceable under *Gonzaga* and urging that Clause's continued enforcement even after recent amendments to the Medicaid Act).

<sup>45</sup> See Mashaw & Calsyn, *supra* note 42, at 304 (describing the importance of § 1983 litigation, before *Gonzaga*, for enforcing federal Medicaid requirements).

<sup>46</sup> Employee Retirement Income Security Act, Pub. L. No. 93-406, § 502(a)(1)(B), 88 Stat. 891 (1974) (codified at 29 U.S.C. § 1132(a)(1)(B) (2006))

*Aetna Health Inc. v. Davila*,<sup>47</sup> the question before the Court was whether ERISA preempts state laws that expose employer-sponsored MCOs to consequential and punitive damages for injuries resulting from claim denials. The Court held that it did.

In *Davila*, a Texas doctor had recommended that his patient, Juan Davila, take Vioxx for arthritis pain rather than a cheaper alternative drug, Naprosin.<sup>48</sup> 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 statutory law, 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 reached the Supreme Court, which held that ERISA preempted the state statute. Because ERISA itself provides a cause of action "to recover benefits due,"<sup>49</sup> the Court held that the Texas statute fell "within the scope" of ERISA and thereby triggered ERISA's preemption provision.<sup>50</sup> 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.<sup>51</sup>

Standing alone, of course, the *Davila* decision does not entirely disarm private litigation because it allows individual suit under the ERISA civil action and remedial provisions.<sup>52</sup> But in a prior decision,<sup>53</sup> the Court had also held

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<sup>47</sup> 542 U.S. 200, 204 (2004).

<sup>48</sup> This case looks ironic in retrospect, given what we now know about Vioxx and its impact on heart health. See Juhana Karha & Eric J. Topol, *The Sad Story of Vioxx, and What We Should Learn from It*, 71 CLEV. CLINIC J. MED. 933, 933 (2004) (discussing the implications of the Vioxx scandal on the prescription drug market); Editorial, *Vioxx: An Unequal Partnership Between Safety and Efficacy*, 364 LANCET 1287, 1288 (2004) (describing one study on the use of Vioxx that "revealed a significant increase in the number of myocardial infarctions in patients taking rofecoxib [(Vioxx)] compared with those receiving naproxen [(Aleve)]"); Peter Loftus & Jonathan D. Rockoff, *Merck Settles Some Vioxx Suits*, WALL ST. J., Feb. 11, 2010, at B4 ("[Merck] removed Vioxx from the market in 2004, after a study showed the painkiller doubled the risk of heart attack or stroke.").

<sup>49</sup> ERISA, Pub. L. No. 93-406, § 502(a)(1)(B), 88 Stat. 891, 891 (1974) (codified at 29 U.S.C. § 1132(a)(1)(B) (2006)).

<sup>50</sup> *Davila*, 542 U.S. 200, 210-14.

<sup>51</sup> *Id.* at 221 n.7 (holding that ERISA preempts state law but reserving the question of whether one of ERISA's remedial provisions, 29 U.S.C. § 1132(a)(3), might allow for consequential or punitive damages).

<sup>52</sup> See ERISA § 502.

that ERISA's remedial provision, which provides for "equitable relief"<sup>54</sup> 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 future valid claims.

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.<sup>55</sup> 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 nor deterrence of future violations.

### C. *Medtronic and Medical Devices*

Like the ERISA story, the medical devices story centers on federal preemption 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.<sup>56</sup>

The question in *Riegel* was whether an express preemption provision in the Medical Device Amendments to the Food, Drug, and Cosmetic Act (FDCA)<sup>57</sup> preempted Charles Riegel's common law complaints against Medtronic's balloon catheter. Riegel's doctors had used the Medtronic catheter to open his arteries, despite the fact that the catheter was contraindicated for a patient in Riegel's condition.<sup>58</sup> 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)<sup>59</sup> and because the FDCA provision governing premarket

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<sup>53</sup> *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 209-18 (2001) (interpreting ERISA's remedial provision extremely narrowly).

<sup>54</sup> ERISA, § 502(a)(3).

<sup>55</sup> *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 (citations omitted)).

<sup>56</sup> *Riegel v. Medtronic*, 552 U.S. 312, 320-29 (2008).

<sup>57</sup> 21 U.S.C. § 360k(a) (2006).

<sup>58</sup> *Riegel*, 552 U.S. at 320.

<sup>59</sup> *See id.* at 316-20 (describing the premarket approval process for Class III medical devices); Jordan Paradise et al., *Evaluating Oversight of Human Drugs and Medical Devices: A Case Study of the FDA and Implications for Nanobiotechnology*, 37 J.L. MED. &

approvals expressly preempted state-based safety and efficacy requirements,<sup>60</sup> Medtronic argued that it could not be held liable under state-based common-law theories of strict liability, breach of warranty, or negligence.<sup>61</sup> 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.<sup>62</sup>

This holding has the same effect as the *Davila* holding; *Riegel* prevents individuals from raising an alarm and compelling disclosures in state court when medical devices malfunction, just as *Davila* prevents individuals from raising an alarm in state court when employer-sponsored MCOs misbehave.<sup>63</sup> Also like the holding in *Davila*, the holding in *Riegel* entirely prevents individuals from using litigation as regulation because the federal alternative – the FDCA (like ERISA) – does not provide for federal actions to recover consequential or punitive damages for malfunctioning devices.<sup>64</sup> Indeed, the medical device situation after *Riegel* may be even starker than the ESI situation 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 certain medical devices to enforce legal safety requirements against the devices’ manufacturers.<sup>65</sup>

#### 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,<sup>66</sup> state legislatures have sought to limit

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ETHICS 598, 601-02 (2009) (describing FDA approval processes for medical devices in various classes).

<sup>60</sup> See 21 U.S.C. § 360k(a), quoted in *Riegel*, 552 U.S. at 316.

<sup>61</sup> See *Riegel*, 552 U.S. at 319-21.

<sup>62</sup> *Id.* at 322-23.

<sup>63</sup> See Lawrence O. Gostin, *The Deregulatory Effects of Preempting Tort Litigation: FDA Regulation of Medical Devices*, 299 JAMA 2313, 2315 (2008) (outlining the benefits of a tort system for device regulation, including tort’s ability “through the discovery process . . . [to] compel corporations to disclose everything they know, or reasonably should know, about [a medical device’s] safety and effectiveness”).

<sup>64</sup> See *id.* at 2313 (explaining that *Riegel* “removes all means of judicial recourse for most consumers injured by defective medical devices”).

<sup>65</sup> *But see* Bruce Patsner, *Riegel v. Medtronic, Inc.: Revisiting Preemption for Medical Devices*, 37 J.L. MED. & ETHICS 305, 306 (Summer 2009) (describing the limits of the *Riegel* holding); Malika Kanodia, Note, *The Fate of the Injured Patient in the Wake of Riegel v. Medtronic: Should Congress Interject?*, 32 HAMLINE L. REV. 791, 813-14 (2009) (explaining that the FDCPA does not preempt some limited tort claims as long as the requirements of the tort claim are sufficiently similar to federal requirements).

<sup>66</sup> See, e.g., Martin H. Redish, *Legislative Responses to the Medical Malpractice*

costs arising from medical malpractice litigation. One of the most popular reform measures among state legislatures, following California's Medical Injury Compensation Reform Act of 1975, has been to cap or otherwise limit noneconomic and punitive damages that a plaintiff can recover for iatrogenic injuries.<sup>67</sup> As of 2010, forty-one states limit noneconomic or punitive damages in some way.<sup>68</sup>

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 Court's decisions. By decreasing individual litigants' incentive to sue and ability to penalize, medical malpractice damages caps limit the potential of private enforcement to deter medical negligence.<sup>69</sup> 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

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*Insurance Crisis: Constitutional Implications*, 55 TEX. L. REV. 759, 759-61 (1977); Comment, *An Analysis of State Legislative Responses to the Medical Malpractice Crisis*, 1975 DUKE L.J. 1417, 1417 (1975). *But see, e.g.*, NEAL C. HOGAN, UNHEALED WOUNDS: MEDICAL MALPRACTICE IN THE TWENTIETH CENTURY 129-33 (Eric Rise ed., 2003) (recounting the emergence of the malpractice crisis and dating it back to the 1950s); Cecilia Loh, *An Overview of Medical Malpractice and the Tort Reform Debate*, CASE WESTERN (Apr. 23, 2003), <http://www.case.edu/med/epidbio/mphp439/Malpractice.htm> (dating the first medical malpractice "crisis" to 1840).

<sup>67</sup> See Ronen Avraham, Database of State Tort Law Reforms (DSTLR, 3rd) (Apr. 1, 2010) (unpublished manuscript) (on file with author), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=902711](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=902711) (listing several state limitations on punitive and noneconomic damages); *Medical Malpractice/Medical Liability*, NAT'L CONFERENCE OF STATE LEGISLATURES, <http://www.ncsl.org/default.aspx?tabid=18516> (last updated Mar. 22, 2010) [hereinafter NCSL].

<sup>68</sup> NCSL, *supra* note 67. 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 such caps. In Oregon, the monetary cap was deemed unconstitutional, but the State continues to prohibit punitive damages absent a showing of malice. *Id.*

<sup>69</sup> As previously noted, these caps have not been terribly successful at limiting malpractice awards, according to most empirical studies. Nevertheless, the motivation for the legislation seems to be the same as the motivation for the Supreme Court's holdings. See *supra* note 27.



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 judicial system.

## 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 (rather than simply to prevent litigation) – 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 because *some* disciplining force is necessary to restrain self-interested actors, we need to ask whether the private market performs that function in each case and, if not – if the market will fail, whether our non-judicial public regulators can work to correct market failures.

In each of the stories considered here, private markets are extremely likely to fail, due to high information and agency costs.<sup>70</sup> But an alternative to individual litigation already exists – and has existed throughout each story's timeline – with the tools necessary to correct market failures. Unfortunately, the alternative public regulators have not yet fully taken the disciplining role that the Supreme Court and state legislators have left to them, and that lag represents a serious problem in each of these four stories. Part II.A identifies the alternative regulator in each story and demonstrates that none of these regulators has fulfilled the role left to it. Part II.B describes the 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.<sup>71</sup> Since Medicaid's creation in 1965, CMS (or one of its predecessors, the Health Care Financing Administration or the Department of

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<sup>70</sup> *But see* Richard A. Epstein & David A. Hyman, Controlling the Cost of Medical Care: A Dose of Deregulation 1-2 (Feb. 17, 2010) (unpublished manuscript), *available at* <http://ssrn.com/abstract=1158547> (arguing that private markets will provide better results for the healthcare industry, at least in terms of cost controls, than public regulators).

<sup>71</sup> CMS is a division of the Department of Health and Human Services. *See* CENTERS FOR MEDICARE & MEDICAID SERVICES, [www.cms.hhs.gov/home/medicaid.asp](http://www.cms.hhs.gov/home/medicaid.asp) (last visited Sept. 12, 2010).

Health, Education, and Welfare) has had statutory authority to approve or reject “state plans for medical assistance,” i.e., state Medicaid plans.<sup>72</sup>

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).<sup>73</sup> Even before the 2010 Medicaid expansion that accompanied President Obama’s healthcare reform legislation, the § 1396a(a) list had grown to seventy-three requirements<sup>74</sup>; the 2010 legislation adds even more. Furthermore, countless new statutory sections have joined company with § 1396a(a) in conditioning federal funds.<sup>75</sup> 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.<sup>76</sup>

Given this structure, it might make sense to ask why we ever allowed litigation against state agents 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 head of 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.<sup>77</sup> 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 gatekeeping function and have never answered for that failure in administrative litigation.<sup>78</sup> Instead, CMS tends to rubber-stamp state plans and to pass the

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<sup>72</sup> Pub. L. No. 89-97, § 1901, 79 Stat. 343, 344 (1965) (codified at 42 U.S.C. § 1396-1 (2006)) (“The sums made available under this section shall be used for making payments to States which have submitted, and had approved by the Secretary, State plans for medical assistance.”).

<sup>73</sup> § 1902, 79 Stat. at 344-48 (listing twenty-two requirements).

<sup>74</sup> 42 U.S.C.A. § 1396a(a)(1)-(73) (West 2009)

<sup>75</sup> For example, 42 U.S.C. § 1396a passed in 1965 with three subsections, (a)-(c); even before the Patient Protection and Affordable Care Act (PPACA) passed, the list went all the way through subsection (ee). The Medicaid statute as a whole consisted of five sections when first passed: §§ 1901–1905. Even before PPACA, the statute included forty-five sections, codified between 42 U.S.C. § 1396a and 42 U.S.C. § 1396w-2. PPACA adds even more.

<sup>76</sup> See Dunne, *supra* note 44, at 994-95 (discussing the options available to CMS for enforcing federal Medicaid requirements).

<sup>77</sup> See Administrative Procedure Act, 5 U.S.C. § 706(2)(A) (2006).

<sup>78</sup> See Edward A. Tomlinson & Jerry L. Mashaw, *The Enforcement of Federal Standards in Grant-in-Aid Programs: Suggestions for Beneficiary Involvement*, 58 VA. L. REV. 600, 619-20 (1976) (describing the weakness of the federal agency’s incentives to enforce federal requirements against state agencies); Dunne, *supra* note 44, at 994-95 (explaining that CMS

buck to state agencies when providers and beneficiaries complain.<sup>79</sup> In fact, CMS directs more of its Medicaid resources to policing individual providers' compliance with Medicaid fraud and abuse laws than policing state agencies' compliance with the federal statute.<sup>80</sup> 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.<sup>81</sup> In that framework, CMS is unlikely to enforce something like the Equal Access Provision, which would, in its violation, *save* federal money. Furthermore, CMS has never developed a robust administrative remedy for individuals wanting to challenge CMS approval of Medicaid plans.<sup>82</sup> 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.<sup>83</sup>

In the end, then, although CMS has the authority (the duty, really) to enforce the federal statute against state agencies, it has never created an enforcement scheme that would work to police state failures. 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 primary alternative legal regulator is the Department of Labor (DOL),<sup>84</sup> which is charged with administering the Employee Retirement Income Security Act (ERISA).<sup>85</sup>

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rarely, if ever, enforces federal requirements "in a punitive sense" and discussing reasons for that failure).

<sup>79</sup> See sources cited *infra* note 107.

<sup>80</sup> See Huberfeld, *supra* note 1, at 466.

<sup>81</sup> See generally U.S. GEN. ACCOUNTING OFFICE, GAO-04-574T, MEDICAID: INTERGOVERNMENTAL TRANSFERS HAVE FACILITATED STATE FINANCING SCHEMES (2004) (describing CMS and Congressional efforts to curtail state financing schemes that inappropriately increase federal Medicaid matching payments).

<sup>82</sup> See Huberfeld, *supra* note 1, at 465.

<sup>83</sup> *Id.* Part of the reason for this failure, as many commentators have noted, is that the only regulatory tool that CMS has in the Medicaid program is withdrawal or withholding of funds. Dunne, *supra* note 44, at 994-95. That enforcement mechanism would have perverse effects if CMS's goal were to force states to provide more generous – rather than less generous – coverage; the withdrawal of federal funding would obviously harm the states' capacity to be generous.

<sup>84</sup> The Department of Health and Human Services has become an important secondary regulator with the passage of the Patient Protection and Affordable Care Act, which charges the HHS Secretary with enforcing external review requirements. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1104(4), 124 Stat. 119, 151 (2010).

<sup>85</sup> 29 U.S.C. § 1135 (2006) (authorizing the Secretary of Labor to promulgate regulations for interpretation and enforcement of ERISA); Dietz et al., *Pensions and Retirement Funds*,

ERISA gives DOL broad statutory authority to enforce its terms, such that the agency has a variety of mechanisms available for regulating ESI generally and for regulating employer-sponsored MCOs' claims processing decisions in particular.<sup>86</sup> 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.<sup>87</sup> Second, it could issue a formal interpretation of the statutory term "equitable relief,"<sup>88</sup> holding that ERISA allows make-whole relief not only for the denied benefits but also for the injuries resulting from the benefits denial. (Such an interpretation would, of course, be entitled to judicial deference and would thereby create a private enforcement mechanism in federal court.<sup>89</sup>) 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.<sup>90</sup> 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 and external review,<sup>91</sup> but it has not created an enforcement

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60A AM. JUR. 2D *Pensions* § 764 (2009) (outlining DOL's authority and obligations as ERISA administrator).

<sup>86</sup> Between 1995 and 2001, Congress regularly considered legislation to increase DOL's regulatory authority, but the legislation, commonly known as the "patients' bill of rights," never made it to the President's desk. Frances H. Miller, *Why Don't Doctors & Lawyers (Strangers in the Night) Get Their Act Together?*, 102 MICH. L. REV. 1295, 1303 (2004). Some of those regulatory provisions made it into the PPACA, but even without those changes, the Department's authority has been sufficiently broad to allow it to regulate employer-sponsored MCOs. The Department has simply chosen not to engage in the project.

<sup>87</sup> 29 U.S.C. § 1132(a)(5) (2006) (allowing the Secretary of Labor to bring a civil action against the administrator of an employee benefit plan for an injunction against ERISA violations or for other equitable relief). *See also supra* text accompanying notes 52-53 (explaining that individuals have the same access to civil actions as the Secretary under the terms of the statute, 29 U.S.C. § 1132(a)(3)).

<sup>88</sup> § 1132(a)(5).

<sup>89</sup> *See Chevron v. Natural Res. Def. Council*, 467 U.S. 837, 842-43 (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).

<sup>90</sup> 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); DOL Administration and Enforcement of ERISA, 29 C.F.R. § 2520.103-1(b) (2010). DOL has authority to impose civil penalties against non-complying plans. *See* 29 U.S.C. § 1132(c)(2); DOL Administration and Enforcement of ERISA, 29 C.F.R. § 2560.502c-2 (2010). ERISA and DOL do not, however, require any reporting related to claims processing or claim denials.

<sup>91</sup> For pre-PPACA regulations, *see* 29 C.F.R. § 2560.503-1 (2010); Employee Retirement

mechanism for punishing plan administrators that fail to comply with those rules.<sup>92</sup> 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.

Additionally, although DOL apparently believes that “equitable relief” ought to be interpreted to allow for make-whole damages, having filed amicus briefs to that effect<sup>93</sup> (a litigating position that is not entitled to deference<sup>94</sup>), it has not issued a formal rule advancing that interpretation. At the time of the Supreme Court’s decision in *Davila*, therefore, private enforcement was the only operational mechanism available for punishing a health benefits plan that refused to honor coverage claims, 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 FDA has the authority to monitor that device’s safety and efficacy once it is *on* the market. FDA is then statutorily obliged to withdraw approval from devices that, after marketing, prove unsafe or ineffective over time.<sup>95</sup> Furthermore, FDA obliges

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Income Security Act of 1974; Rules and Regulations for Administration and Enforcement, 65 Fed. Reg. 70,246 (Nov. 21, 2000) (codified at 29 C.F.R. § 2560 (2010)). PPACA set additional rules for external review and involved HHS in the enforcement of those rules. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1001(4), 124 Stat. 119 (2010).

<sup>92</sup> Indeed, DOL holds that exhaustion of internal appeals to the benefits plan constitutes exhaustion of administrative remedies for purposes of litigation. 29 C.F.R. § 2560.503-1 (l) (2010).

<sup>93</sup> *See, e.g.*, Brief for the United States as Amicus Curiae at 8-15, *Amschwand v. Spherion Corp.*, 128 S. Ct. 2995 (2008) (No. 07-841) (signed by the United States Solicitor General as well as the Department of Labor’s Solicitor, Associate Solicitor, and Counsel for Appellate and Special Litigation, urging the Supreme Court to grant certiorari); Brief of Amicus Curiae Elaine L. Chao, Sec’y of the U.S. Dep’t of Labor as Amicus Curiae supporting Appellee Requesting Affirmance at 20-21, *Ferrer, Poirot & Wansbrough PC v. Bombardier Aerospace Emp. Welfare Plan*, 541 U.S. 1072 (2004) (No. 03-10195).

<sup>94</sup> *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988) (“We have never applied [deference rules] to agency litigating positions that are wholly unsupported by regulations, rulings, or administrative practice.”); *see also* *United States v. Mead Corp.*, 533 U.S. 218, 226 (2001) (holding that agency enactments are entitled to deference only if they carry the “force of law”).

<sup>95</sup> *See* *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319-20 (2008) (“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(e)(1), 360h(e) (2006)).

device manufacturers to report instances of death or injury 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.<sup>96</sup>

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, and FDA can (without the aid of punitive damages) prevent the continued sale of unsafe devices by withdrawing premarket approval.<sup>97</sup> Granted, this scheme leaves the individuals harmed by unsafe devices without compensation for their injuries, but the point here is only that the plaintiffs' and courts' 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 insofar as it acknowledges post-market regulation as one of its central duties,<sup>98</sup> the agency does not yet have the resources necessary to watch its preapproved devices for post-market problems and to correct the problems that arise.<sup>99</sup> Again, therefore, the Supreme Court's opinion seems to leave behind an enforcement 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

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<sup>96</sup> *Id.* (citing 21 U.S.C. § 360i (2006); 21 C.F.R. § 803.50(a) (2005); 21 C.F.R. § 814.84(b)(2) (2007)).

<sup>97</sup> See FDA Premarket Approval of Medical Devices Rule, 21 C.F.R. § 814.46(a)(2) (2010) (authorizing FDA to withdraw market approval if manufacturer has failed to meet "any postapproval requirement imposed by . . . regulation").

<sup>98</sup> See, e.g., Richard Platt et al., *The New Sentinel Network – Improving the Evidence of Medical-Product Safety*, 361 NEW ENG. J. MED. 645, 645 (Aug. 13, 2009) (describing FDA's new efforts, congressionally authorized in 2007, to use electronic medical records to monitor medical product safety).

<sup>99</sup> See Gostin, *supra* note 63, at 2314 (describing FDA's severe "resource deficits" and observing that those deficits "have resulted in high-profile regulatory failures"); *The Medical Device Safety Act of 2009: Hearing on H.R. 1346 Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 111th Cong. 14 (2009) (statement of Richard M. Cooper), [http://energycommerce.house.gov/Press\\_111/20090512/testimony\\_cooper.pdf](http://energycommerce.house.gov/Press_111/20090512/testimony_cooper.pdf) (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").

boards. To some extent, CMS has already started playing this role, and PPACA will strengthen CMS's hand in quality control in the coming years. Even prior to PPACA's passage, CMS had created a "never events" policy, by which it refuses to reimburse providers that make certain listed errors;<sup>100</sup> and it had 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.<sup>101</sup> PPACA requires both the Medicare and Medicaid programs to expand these and similar policies and to study their usefulness in quality control.<sup>102</sup>

State licensure boards also play a quality-controlling role to a certain extent, revoking licenses from providers that commit egregious violations (such as practicing the wrong kind of medicine).<sup>103</sup>

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<sup>100</sup> See NAT'L QUALITY FORUM, SERIOUS REPORTABLE EVENTS IN HEALTHCARE 2006 UPDATE: A CONSENSUS REPORT 8-16 (2007) (examples of "never events" include surgery performed on the wrong body part, surgery performed on the wrong patient, and wrong surgical procedure performed on patient.).

<sup>101</sup> See *Details for: Medicare "Pay for Performance (P4P)" Initiatives*, CTRS. FOR MEDICARE & MEDICAID SRVS. (Jan. 31, 2005), <http://www.cms.hhs.gov/apps/media/pres/s/release.asp?counter=1343> (describing CMS's initiatives that link hospital and physician reimbursement rates to quality measures).

<sup>102</sup> PPACA prohibits Medicaid plans from paying for services associated with hospital-acquired conditions (HACs), i.e., complications or co-morbidities contracted by patients during a hospital stay. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2702, 124 Stat. 119, 318-19 (2010). The Secretary is required to identify HACs and implement appropriate regulations by July 1, 2011. *Id.* Similarly, PPACA also adjusts Medicare payments for hospitals to incentivize reductions in HACs. Beginning January 1, 2015, hospitals in the top quartile of all hospitals, relative to the national average of HACs, will receive ninety-nine percent of applicable Medicare payment at discharge. *Id.* at § 3008. Prior to 2015, HHS must provide confidential reports to such hospitals, and inform the public regarding HACs at such hospitals. *Id.* This public information must be posted to the Hospital Compare website. *Id.* Further, PPACA requires the DHHS to conduct a study on expanding the HAC payment reduction policy to other facilities that receive Medicare payments. *Id.* DHHS must submit this study and associated recommendations to the Congress by January 1, 2012. *Id.*

<sup>103</sup> See, e.g., MED. BOARD CAL. (last visited Sept. 16, 2010), <http://www.medbd.ca.gov/> ("The mission of the Medical Board is to protect health care consumers through the proper licensing and regulation of physicians and surgeons and certain allied health care professions and through the vigorous, objective enforcement of the Medical Practice Act, and, to promote access to quality medical care through the Board's licensing and regulatory functions."); MINN. BOARD MED. PRAC., <http://www.state.mn.us/portal/mn/jsp/home.do?age ncy=BMP> (last visited Sept. 16, 2010) ("The mission of the Minnesota Board of Medical Practice is to protect the public's health and safety by assuring that the people who practice medicine or as an allied health professional are competent, ethical practitioners with the necessary knowledge and skills appropriate to their title and role."); *State Board of Medical Examiners*, N.J. DIV. OF CONSUMER AFFAIRS, <http://www.state.nj.us/lps/ca/bme/index.html> (last visited Sept. 16, 2010) ("New Jersey's Medical Board is responsible for protecting the public's health and safety by determining qualifications of applicants for licensure,

Neither CMS nor licensure boards, however, engage in the kind of intensive quality regulation that the tort system has intended to provide. Uniquely among these four stories, the central problem here is that the regulators do not 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. As a result, even if these programs worked well as intended (which they might not<sup>104</sup>), they would not catch or punish all instances of negligence. 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.<sup>105</sup> 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 formulae, and revoking licenses – would dramatically over-deter negligence if triggered by every bad outcome. Unfortunately, though, these strategies 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 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 vacuum in which actors can violate rules with impunity even despite the

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establishing standards for practice, and disciplining licensees who do not adhere to those requirements.”).

<sup>104</sup> See, e.g., Sandra J. Tanenbaum, *Pay for Performance in Medicare: Evidentiary Irony and the Politics of Value*, 34 J. HEALTH POL. POL'Y & L. 717, 717 (2009) (evaluating the pay for performance initiative and concluding that it does not function as intended but is instead a useful political tool).

<sup>105</sup> Studdert & Mello, *supra* note 20, at S47-49.



presence of potential private regulators. In each story, therefore, a public 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.<sup>106</sup> First, because both state and federal lawmakers affect Medicaid decisions and because the federal requirements that supposedly bind state decision-makers are so complex, 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).<sup>107</sup> Second, because states have flexibility in setting reimbursement rates, they can engage in some Tiebout competition<sup>108</sup> for the best policy bundles, but in welfare programs

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<sup>106</sup> Cooperative federalism is the "[d]istribution of power between the federal government and the states in which each recognizes the power of the other while jointly engaging in certain governmental functions." BLACK'S LAW DICTIONARY 664 (8th ed. 2004).

<sup>107</sup> See Joseph Fastiggi, *New York Medicaid: Never Can Say Goodbye*, 16 CORNELL J.L. & PUB. POL'Y 581, 609-10 (2007) (lamenting the lack of information made available to Medicaid recipients regarding "their health and the courses of recommended treatment" and discussing government administrators' propensity to shirk responsibility for Medicaid beneficiaries' well being); Joshua Tenzer, *Reaching the Final Frontiers in Medicaid Managed Care*, 62 N.Y.U. ANN. SURV. AM. L. 329, 354-57 (2006) (explaining that states shirk fiscal responsibility with Medicaid funds while the federal government "push[es] more responsibility on the states"); Sara Kay Wheeler & Tizgel K.S. High, *Medicaid Enforcement Amidst the Perfect Storm*, 9 J. HEALTH CARE COMPLIANCE 25, 25-26 (2007) (explaining how the joint regulatory nature of Medicaid forms the "perfect storm," creating a regulatory vacuum which neither CMS nor states feel compelled to fix).

<sup>108</sup> See Charles M. Tiebout, *A Pure Theory of Local Expenditures*, 64 J. POL. ECON. 416, 418 (1956); see also John D. Donahue, *Tiebout? Or Not Tiebout? The Market Metaphor and America's Devolution Debate*, 11 J. ECON. PERSP. 73, 75-77 (1997); Robert P. Inman & Daniel L. Rubinfeld, *Rethinking Federalism*, 11 J. ECON. PERSP. 43, 45-52 (1997); Moncrieff, *supra* note 4, at 869 (outlining the basic Tiebout theory); Larry Ribstein & Bruce Kobayashi, *The Economics of Federalism* 3-4 (Jan. 2006) (unpublished manuscript), available at <http://ssrn.com/abstract=875626>.

like Medicaid, that competition often results not in optimality but rather in a “race to the bottom” (an agency cost of a sort).<sup>109</sup>

*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.<sup>110</sup> 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 theoretically punish their officials in the next election cycle.<sup>111</sup>

But in Medicaid, it is often hard for voters to know whom they should punish, and gathering accurate information on that score is costly. Because state Medicaid plans are subject to an extremely large and complicated web of federal requirements, state decision-makers can 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.<sup>112</sup> The most common tale from state Medicaid agencies accused of federal statutory violations, thus, 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 aspirationalism), but the federal government refuses to put its money where its mouth is.<sup>113</sup> The states’

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<sup>109</sup> See Scott L. Greer & Peter D. Jacobson, *Health Care Reform and Federalism*, 35 J. HEALTH POL. POL’Y & L. 203, 219-21 (2010) (explaining that fiscal competition among states limits the ability of the states to raise revenue for redistributive health care programs).

<sup>110</sup> Susan Dorr Goold et al., *Choosing Healthplans All Together: A Deliberative Exercise for Allocating Limited Health Care Resources*, 30 J. HEALTH POL. POL’Y & L. 563, 594 (2005) (explaining that decisions regarding Medicaid are subject to “the usual methods of political accountability”).

<sup>111</sup> This point presupposes, 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 the state should continue to participate in the Medicaid program at all.

<sup>112</sup> Lisa Colosi, *Wilder v. Virginia Hospital Association: Making the Medicaid Reimbursement Rate Challenge a Federal Case*, 12 PACE L. REV. 139, 142 (1992) (“To cover the costs of providing medical services to the poor, states primarily rely on federal contributions . . .”).

<sup>113</sup> In many of the Equal Access Provisions cases that reached the federal appellate level, the states’ justification for cutting reimbursement rates was purely budgetary. For a list of such cases, see *Orthopaedic Hosp. v. Belshe*, 103 F.3d 1491, 1499 n.3 (9th Cir. 1997); *Ark.*

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.<sup>114</sup> 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 alternative 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 information about these programs is costly to gather, and voters are rationally ignorant of details.<sup>115</sup>

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Med. Soc'y, Inc. v. Reynolds, 6 F.3d 519, 531 (8th Cir. 1993) (rejecting 'exclusively budgetary' justification for rate cuts to Medicaid providers); AMISUB v. Colo. Dep't of Soc. Servs., 879 F.2d 789, 801 (10th Cir. 1989) (rejecting state Medicaid plan that resulted in forty-six percent reduction in provider reimbursement as being based solely on budgetary constraints: "While budgetary constraints may be a factor to be considered by a state when amending a current plan . . . budgetary constraints alone can never be sufficient"). See generally Moncrieff, *supra* note 1 (explaining the budgetary strain that Medicaid creates for states and discussing the cases in which states reduced reimbursement rates in an attempt to avoid budget overruns).

<sup>114</sup> See Frank J. Thompson & Courtney Burke, *Executive Federalism and Medicaid Demonstration Waivers: Implications for Policy and Democratic Process*, 32 J. HEALTH POL. POL'Y & L. 971, 993-95 (2007) (discussing the impact of the Medicaid waiver process on democratic transparency and legitimacy). Some of this flexibility may diminish with the Medicaid expansions in PPACA, though, of course, we do not yet know how CMS will administer the new requirements. PPACA expands Medicaid eligibility to include all individuals with income at or below 133% of the federal poverty line, who are otherwise ineligible for Medicaid or Medicare coverage, and also allows for federal matching of state expenditures associated with expanded enrollment criteria. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2001(a)(1)(C), 124 Stat. 119, 271 (2010). The statute requires states to provide this population with "benchmark" or "benchmark equivalent" benefits by January 1, 2014. *Id.* at §§ 2001(a)(1)(C), 2001(a)(2)(A). A benchmark plan is equivalent to federal employees health benefit plan coverage, state employee coverage, coverage offered by the HMO plan that has the largest insured commercial, non-Medicaid enrollment in the state, or other DHHS secretary approved coverage. 42 C.F.R. § 440.330 (2010). PPACA also establishes Federal Medical Assistance Percentage (FMAP) rate for this category of Medicaid coverage to offset related state expenditures. Patient Protection and Affordable Care Act § 2001(a)(3)(B). From 2014 to 2016, FMAP is 100%, i.e., the federal government will match 100% of states' funds used for providing Medicaid coverage to this new category of enrollees. *Id.* The FMAP is scaled downward from 2017 onwards, and will be 90% from January 1, 2020. 42 U.S.C.A. § 1396d(y)(1) (West 2010). Additionally, PPACA requires states to provide Medicaid coverage to former foster children under twenty-six years of age by 2014. Patient Protection and Affordable Care Act § 10201. Previously, this requirement was optional for states. 42 U.S.C. 1396(a)(10) (2006).

<sup>115</sup> Beneficiaries who are harmed by federal violations, of course, act rationally when

Additionally, even if we assumed that all voters knew whom to blame for Medicaid policy choices, for the political marketplace to work, a large percentage of the electorate – beyond just beneficiaries and physicians – would need to understand and care about Medicaid decision-making enough to vote against legislators and governors that favored an ungenerous program. Even assuming that Medicaid was a voting issue for most of the electorate, an average voter would have a hard time evaluating the wisdom of a given Medicaid policy choice. Cutting reimbursements might be unquestionably bad for physicians – and might even be unidirectionally bad for already-covered beneficiaries – but it might be a good choice if it allows more people to be covered. Such complicated policy tradeoffs are hard for voters to evaluate without a lot of information about the policy landscape.

In the end, then, voters have a difficult time apportioning blame between state and federal governments and have a hard time evaluating Medicaid policy choices even when they know whom to blame for them. Political accountability therefore fails as a mechanism for cabining Medicaid abuses.

*Agency Costs.* The theory of Tiebout competition is that political subdivisions, such as states, will compete for resident taxpayers by providing appealing bundles of public goods, public services, and taxes. In other words, states will set themselves up as good agents of the public interest in order to attract principals and their concomitant revenue.<sup>116</sup> Potential taxpayers will then sort themselves 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).<sup>117</sup>

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.<sup>118</sup> 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.

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they collect information about statutory violations, so long as the harm of the violation is sufficiently costly to outweigh the cost of the information. This point is one reason that litigation – or administrative adjudication – is a useful tool; it allows individuals who have an incentive to monitor lawfulness to blow a whistle, rather than relying on general voting populations.

<sup>116</sup> Tiebout, *supra* note 108, at 418; Moncrieff, *supra* note 4, at 869.

<sup>117</sup> Tiebout, *supra* note 108, at 418.

<sup>118</sup> See Jan K. Brueckner, *Welfare Reform and the Race to the Bottom: Theory and Evidence*, 66 S. ECON. J. 505 (2000); Craig Volden, *The Politics of Competitive Federalism: A Race-to-the-Bottom in Welfare Benefits?*, 46 AM. J. POL. SCI. 352 (2002) (explaining that some have argued interjurisdictional competition may lead to an undersupply of welfare services as jurisdictions cut services to repel undesirable welfare recipients).

With respect to Medicaid, just such a failure occurs.<sup>119</sup> The people that benefit from Medicaid and that would choose a state with generous Medicaid spending are, by programmatic definition, poor and sick. They are overwhelmingly living at or below the Federal Poverty Line; they are taking Supplemental Security Income; and they are *not* paying state taxes.<sup>120</sup> Medicaid recipients are therefore net losses for state tax systems. While it is good for the economy of the country 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 government intended with the Medicaid Act, and it imposes the opposite incentive of the one 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 effect by choosing to leave states with low Medicaid reimbursements in favor of states with higher Medicaid reimbursements, causing a dearth of practicing physicians in states with low Medicaid reimbursement rates. But that effect seems unlikely to correct the problem given that most providers (unlike Medicaid beneficiaries) do not depend on the Medicaid program and are thus less likely to uproot themselves to find a better Medicaid system. Providers generally can make enough money from privately-insured and Medicare patients to run a good business, allowing them simply to opt out of Medicaid if reimbursement rates fall 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 beneficiaries as possible, regardless of what federal law requires.

## 2. Employer Sponsored Insurance

In the case of employer-sponsored insurance (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.<sup>121</sup> That private market has two critical parts: insurance companies competing for employers and employers competing for labor.<sup>122</sup> Unfortunately, both

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<sup>119</sup> See Greer & Jacobson, *supra* note 109, at 219; Paul E. Peterson, *Devolution's Price*, 14 YALE L. & POL'Y REV. 111, 118 (1996).

<sup>120</sup> See 42 U.S.C. § 1396(a)(10) (2006) (listing eligibility groups).

<sup>121</sup> See David Blumenthal, *Employer-Sponsored Health Insurance in the United States – Origins and Implications*, 335 NEW ENG. J. MED. 82, 82 (2006) (“More than 159 million Americans – 62.4 percent of the nonelderly population – had health care coverage through employer-sponsored insurance in 2004.”).

<sup>122</sup> See James Maxwell & Peter Temin, *Corporate Management of Quality in Employee Health Plans*, 28 HEALTH CARE MGMT. REV. 27, 27 (2000) [hereinafter *Corporate*

components of that market suffer from high transaction costs that weaken the market's regulatory capacity.<sup>123</sup> 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 information costs with sufficient investment, but they will be willing to optimize that investment only if they are good agents for their employees, which (despite the robust labor market) they often are not.<sup>124</sup>

*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.<sup>125</sup> In the relevant case – in the only case that is governed by the ERISA shield – the employer does not hire the MCO to bear the financial risk of its employees' healthcare losses. ERISA protects from liability only those employer-sponsored plans that are "self-insured," in which the employer is financially responsible for its employees' healthcare claims. The employer-sponsored MCO, then, is responsible only for administering benefits, deciding whether a claim is payable or not; it does not bear any financial risk.

In that market for MCO administration, employers ought to be trying to maximize value. That is, if employers are good agents for their employees, they will try to spend as little as possible but as much as necessary to get a healthcare administrator that operates honestly and well, optimizing the cost-benefit trade.<sup>126</sup> Part of that value in the case of an MCO (which is charged

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*Management*] (finding that employers have been "conducting intensive price negotiations with health plans"); see also JAMES MAXWELL ET AL., CORPORATE HEALTH CARE PURCHASING AMONG THE FORTUNE 500, at 8 (2001) [hereinafter FORTUNE 500] ("Large companies have a competitive need to attract and retain skilled employees, especially in today's tight labor markets.").

<sup>123</sup> See Robert S. Galvin & Suzanne Delbanco, *Why Employers Need to Rethink How They Buy Healthcare*, 24 HEALTH AFF. 1549, 1550 (2005) ("Quantitative data are critical to procurement, yet fewer than half of firms perform financial analysis on their health care costs, and fewer than a third use hard-dollar 'return-on-investment' calculations in their decisionmaking.").

<sup>124</sup> See, e.g., *Corporate Management*, supra note 122, at 28 (finding that Fortune 500 employers use a broader definition of health care quality that focuses more on service quality and less on clinical quality).

<sup>125</sup> See James Maxwell et al., *Corporate Health Care Purchasing and the Revised Social Contract with Workers*, 39 BUS. & SOC'Y 281, 287 (2000) [hereinafter *Revised Social Contract*] ("Consumers (employees) keep down the cost of health care by forcing health plans to compete among themselves, just as the producers of other goods and services do.").

<sup>126</sup> See Galvin & Delbanco, supra note 123, at 1549 (arguing that employers' economic interest and expertise in supply-management chain "should result in employers' using their procurement expertise to increase the value of their health care expenditures"); Pamela B. Peele et al., *Employer-Sponsored Health Insurance: Are Employers Good Agents for Their Employees?*, 78 MILBANK Q. 5, 7 (2000) (hypothesizing that if employers are good agents, they will "understand[] their employees' health plan preferences" and "establish mechanisms for . . . providing useful information to their employees about their health

with determining eligibility for benefits on a case-by-case basis under “medical necessity” review) would undoubtedly be the MCO’s claims processing habits. An MCO that habitually denies valid claims – maliciously or negligently deeming them medically unnecessary<sup>127</sup> – ought to fail in the competitive ESI market.<sup>128</sup>

But in order to determine whether an MCO is abusive or arbitrary in claims processing, one needs to aggregate information across patients and over time; individual complaints or stories are insufficient to draw conclusions.<sup>129</sup> 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,<sup>130</sup> 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.<sup>131</sup> Unlike individual consumers, large-group purchasers have the capacity to become well-informed consumers in the MCO market.<sup>132</sup>

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insurance offerings”); WATSON WYATT WORLDWIDE, 12TH ANNUAL NATIONAL BUSINESS GROUP ON HEALTH/WATSON WYATT SURVEY REPORT 2 (2007), *available at* [http://www.corp.syn.net/Special/images/SPC\\_090607\\_WatsonWyatt.pdf](http://www.corp.syn.net/Special/images/SPC_090607_WatsonWyatt.pdf) (declaring that “best-performing companies” have significantly lower annual expenditure increases for their health care programs).

<sup>127</sup> One reason that the ERISA shield applies only to self-insured employer plans – i.e., plans under which employers directly bear the risk of their employees’ healthcare losses – is that the MCO that processes claims in the relevant case does not have a financial incentive to deny claims. Because the MCO’s finding that a claim is “medically necessary” and therefore valid will cause the employer rather than the MCO to lose money, the likelihood of malicious denial is relatively low in the relevant case, as compared to the non-relevant case of a fully insured employer.

<sup>128</sup> See Stephen Blakely, *The Backlash Against Managed Care*, NATION’S BUS. At 16 (July 1998), *available at* [http://findarticles.com/p/articles/mi\\_m1154/is\\_n7\\_v86/ai\\_20797610/?tag=content;coll](http://findarticles.com/p/articles/mi_m1154/is_n7_v86/ai_20797610/?tag=content;coll) (describing patients’ growing discontent with managed care).

<sup>129</sup> See Peele et al., *supra* note 126, at 15-16 (finding that employees were hesitant about making plan choices on their own and felt that employers “were much better equipped to sort through the plans and options than they were individually”).

<sup>130</sup> For a thorough review of health care consumer and provider incentives, see generally CHARLES E. PHELPS, HEALTH ECONOMICS (Addison Wesley 3d ed. 2002).

<sup>131</sup> Peele et al., *supra* note 126, at 15-16.

<sup>132</sup> See *Corporate Management*, *supra* note 122, at 38 (stating that Fortune 500 companies “routinely collect large amounts of data and use them in their purchasing decisions”). 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.

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. Employers would also need to investigate causation – a tricky question in any medical case – when a denial correlated to an injury, in order to determine whether the MCO should have known *ex ante* that denying the claim would likely cause harm.

The good news is that employers do play this role to some extent.<sup>133</sup> Particularly large corporate purchasers are aware of quality differentials among MCOs, and many large employers do have reporting systems in place that allow their employees to file complaints when their claims are denied. The bad news is that employers 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.<sup>134</sup>

*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, relative to employees' preferences? And the answer is probably yes.

The cost of employees' health insurance premiums comes out of employees' wages, not shareholders' profits.<sup>135</sup> As a result, when it comes to spending on insurance premiums, employers should be willing to spend any amount that their employees are willing to spend. That is, employers have no incentive to under-invest in *premiums* relative to their employees' preferences. But the administrative cost of monitoring a health insurance company and the administrative cost of punishing insurers for abuses might be a different story; those costs might be much harder to pass on to employees in the form of decreased wages. Although there is evidence that employees will choose an

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<sup>133</sup> See, e.g., Blumenthal, *supra* note 121, at 86 ("Pressed by rising costs, private employers have pushed insurance companies to develop new approaches to organizing and financing care that they hope will limit expenses without alienating their employees."); Galvin & Deblanco, *supra* note 123, at 1550 ("[A] minority [of employers] factor quality information into health plan selection and contracting."); James Maxwell et al., *Corporate Health Care Purchasing Among Fortune 500 Firms*, 20 HEALTH AFF. 181, 186 (2001) [hereinafter *Corporate Health Care Purchasing*] ("The study documents relatively widespread awareness of quality measurement among the Fortune 500, with companies reporting the routine collection of large amounts of quality related data.").

<sup>134</sup> See, e.g., Galvin & Deblanco, *supra* note 123, at 1550 (arguing that employers do not focus enough resources or the right resources for employees' ESI plans).

<sup>135</sup> See, e.g., Blumenthal, *supra* note 121, at 85 ("This dynamic leads economists to argue that ultimately employers pass the costs of health care on to workers who pay for their own health insurance in the form of wages or others benefits foregone."); Peele et al., *supra* note 126, at 5 ("Economists argue that employees effectively pay for most of their nonwage benefits through lower wages.").



employer based on general generosity of the benefits package,<sup>136</sup> it is much less likely that employees 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 for insurance, particularly given that prospective employees lack the aggregate information needed to judge 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.<sup>137</sup>

The bottom line here is that employers have the capacity to "regulate" MCO abuses through market competition, and they do play that role to some extent. But employers' abilities are limited by the information costs of monitoring MCO behavior and by the failures in the agency relationship between employers and their employees.

### 3. Medical Devices

As with ESI, there are several competitive markets operating in the medical device story that might cabin 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. 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 ways essentially identical to the ESI markets, with the providers, hospitals, and insurance companies serving as the agents positioned to aggregate information about device quality.

*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 to use a particular device. In fact, at the point of purchase, individual consumers are not likely to have any basis for judging the device's safety; consumers have not

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<sup>136</sup> FORTUNE 500, *supra* note 122, at 9 ("Health benefits were viewed as contributing most to employee attraction . . .").

<sup>137</sup> *Corporate Health Care Purchasing*, *supra* note 133, at 186 (suggesting that employers care more about driving down cost than quality of care).

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yet had any experience with the device themselves, and few will have had exposure to other patients who have used the 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, this process of aggregating information and learning from emerging trends is not free. 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 those cases 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.

*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,<sup>138</sup> so that the agents in this case do not internalize the full cost 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 (as most doctors still are).<sup>139</sup> 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 want 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.

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<sup>138</sup> See James T. O'Reilly, *Pin the Tail on the Other Donkey: Allocating and Avoiding Injury Losses After Drug or Device Approval*, 62 FOOD & DRUG L.J. 559, 571 (2007) ("No one looks forward to being an injured plaintiff, no one aspires to be the subject of Form FDA-3500 adverse experience reports, so the loss from medical and product error stays with the least effective lobbying force, the patients.").

<sup>139</sup> INST. OF MED., *REWARDING PROVIDER PERFORMANCE: ALIGNING INCENTIVES IN MEDICARE 4* (2006) (suggesting that fee-for-service pay structures encourages over use and thus higher costs and substandard care).

To take the point to a macabre extreme that one hopes and expects to be rare: doctors and hospitals in the current system actually get paid more for injuring their patients than for curing them. If doctors or hospitals 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” from payers with such policies<sup>140</sup>). Even after discovering new evidence of a device’s risks, therefore, an unscrupulous doctor might continue to use it.

Insurers’ incentives, by contrast, at least follow the same vector as their patients’ incentives because the insurers often get stuck with higher costs when their patients get injured. Unlike doctors, insurers lose money as the number of interventions increases; they pay for initial *and* post-injury interventions on behalf of the patients they cover. As a result, insurers might want to set incentives for doctors and patients to avoid using risky devices, such as by refusing to cover certain technologies or by setting strict guidelines for coverable uses of such technologies, in order to avoid paying consequential claims when devices malfunction. Insurers, thus, might well have the right incentives to monitor device malfunction and to tinker with the private market for device purchase and use, effectively punishing sloppy manufacturers by shrinking their market.

Unfortunately, though, most insurers (indeed, all insurers but Medicare) do not keep their patients long enough to suffer the full cost of disabling injuries. If a device malfunctions in a way that causes a lifelong disability, the insurance company will bear the cost of treatment only until the patient qualifies for public insurance, at sixty-five or at a point of coverable disability (whichever comes first).<sup>141</sup> Even if an injury is not fully disabling, private insurers often find ways to terminate coverage rather than bearing consequential costs.<sup>142</sup> For example, insurers (prior to PPACA) have placed caps on yearly and lifelong claims, and some have habitually terminated contracts when patients started consuming too much medical care. Insurers have also refused coverage for preexisting conditions – including lasting effects of prior injuries – such that an insured might lose coverage for the injury when he or she changes jobs or otherwise switches insurance. PPACA addresses all of these problems to one degree or another, though it might allow plans to terminate contracts in some cases.<sup>143</sup>

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<sup>140</sup> See *supra* Part II.A.4.

<sup>141</sup> *Who Is Eligible for Medicare?*, MEDICARE, [http://questions.medicare.gov/app/answers/detail/a\\_id/10/kw/eligibility](http://questions.medicare.gov/app/answers/detail/a_id/10/kw/eligibility) (last updated June 10, 2009).

<sup>142</sup> See *Largest U.S. Health Insurer Rewarded Employees That Cancelled Coverage Of Sick Patients – Consumer Watchdog Calls on Congress to Ban Bonuses for Canceling, Delaying or Denying Medical Care*, CONSUMERWATCHDOG.ORG (June 16, 2009), <http://www.consumerwatchdog.org/patients/articles/?storyId=27969>.

<sup>143</sup> PPACA prohibits all group health plans from establishing lifetime limits from September 23, 2010 onwards or January 1, 2011 for calendar year plans. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10101(a), 124 Stat. 119, 883-84 (2010).

In the end, then, insurers' incentive might be better aligned with patients' interests, but because insurers often avoid the full costs of exposure to dangerous devices, they do not have a full incentive to avoid those costs. Insurers might, therefore, gather some information about devices and refuse coverage to the worst ones, but their investment in the regulatory project will likely fall short of what rational patients would be willing to spend to avoid bad devices.

Of course, patients usually get to choose their doctors, hospitals, and insurance companies, so maybe patients could use competition within these groups to encourage monitoring. In other words, patients could give more business to doctors, hospitals, and insurers that invest correctly in monitoring device malfunction. But as in the case of ESI, patients are ill-positioned to enforce their preferences through their agents because patients 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. Should the doctor have known that the device was risky and refused to provide it? Or was the patient's bad experience a rare or even unique event – a fluke?

Even if patients incapable of judging individual devices knew that they should prefer insurance companies that actively monitor device safety and efficacy, it is not clear that they could determine which insurance companies were doing so – or at least which companies were doing so *well*. First, insurance contracts are so long and complicated that it would be hard to discover which devices were and were not covered, and second, even if a consumer had clear lists of covered devices for various competing insurance contracts, it would be impossible to distinguish between good and bad lists

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Plans may not set annual limits from 2014 onwards. *Id.* Prior to 2014, however, plans may only establish restricted annual limits as defined by the Secretary of Health and Human Services, to assure access to needed services with minimal impact on premiums. *Id.* With respect to benefits that are not “essential health benefits . . . a plan or issuer may impose annual or lifetime per-individual dollar limits on specific covered benefits.” Patient Protection and Affordable Care Act: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections, 75 Fed. Reg. 37,191 (June 28, 2010) (to be codified at 26 C.F.R. 54.9815–2711T, 29 C.F.R. 2590.715–2711, 45 C.F.R. 147.126). Finally, the PPACA forbids plans from rescinding coverage, except in case of fraud or misrepresentation. *Id.* at 37,192. PPACA also prohibits group and individual health plans from denying coverage based on an applicant's preexisting condition. Patient Protection and Affordable Care Act, § 2704, 124 Stat. at 154-55. Although this prohibition is generally effective for plan years beginning on or after January 1, 2014, it became effective for plan years beginning on or after September 23, 2010 for enrollees who are under nineteen. Patient Protection and Affordable Care Act: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections, 75 Fed. Reg. at 37,189-90.

(good and bad contracts) without knowing which devices *should* be covered. Again, that information is awfully hard for an individual consumer to gain.

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, does not adequately 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 due to high information and agency costs. In this story, doctors compete for insurance contracts (meaning that they compete for “preferred provider” status with large insurance companies),<sup>144</sup> 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.) But there are failures in the medical malpractice case that are again virtually identical to the failures in ESI and devices: 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.

*Information Costs.* As in the prior stories, the primary information cost here is the need for aggregate data. With respect to provider quality, one cannot draw reliable conclusions about an individual provider 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 statistics – 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.<sup>145</sup>

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<sup>144</sup> This point holds less true in states with “any willing provider” laws, which require MCOs to enlist any provider that wants to participate in the MCO’s “preferred provider” network, but even under those laws MCOs can place conditions on participating providers, presumably including quality controls.

<sup>145</sup> For an example of risk-adjusted morbidity and mortality rates, see David Emmons, *Data on Employee Physician Profiling*, 26 AM. HOSP. ASS’N J. HEALTH & LIFE SCI. L. 73

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, reasonable access to data about individual patients' risk factors, and 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 engage in intensive quality controls, such as refusing reimbursement to – or cutting reimbursements for – doctors that have high error rates and whose errors 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, and many private insurers have begun to adopt these programs.<sup>146</sup>

That said, if insurers were truly to supplant medical malpractice as a regulatory mechanism, their reimbursement and other quality control 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. As in the prior stories, such a system is possible but costly to implement and execute.<sup>147</sup>

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(1993) (outlining physician profiles created by the New York Department of Health).

<sup>146</sup> See Meredith B. Rosenthal et al., *Early Experience With Pay-for-Performance: From Concept to Practice*, 294 J. AM. MED. ASS'N 1788, 1788, 1792-93 (2005) (noting the growing adoption of pay-for-performance programs among private payers but concluding that the programs do little to increase provider quality); Devin S. Schindler, *Never Events, Defensive Medicine and the Continued Federalization of Malpractice*, 12 QUINNIPIAC HEALTH L.J. 209, 213-14 (2008-2009) (discussing CMS' advent of “never-events” and the growing trend that doctors and hospitals are not reimbursed for provider-induced injuries); Maura Lerner, *Minnesota Is First State With Policy to Stop Billing After Medical Errors*, STAR TRIB. (Minneapolis-St. Paul), Sept. 19, 2007, <http://www.startribune.com/local/11590481.html> (describing how Minnesota hospitals decided to stop charging for follow-up care caused by their own mistakes); Stephen Smith, *Medical Mistakes No Longer Billable: Bold Steps Taken to Reduce Hospital Errors*, BOSTON GLOBE, June 19, 2008, [http://www.boston.com/news/local/articles/2008/06/19/medical\\_mistakes\\_no\\_longer\\_billable/](http://www.boston.com/news/local/articles/2008/06/19/medical_mistakes_no_longer_billable/). See generally Kristin Madison, *The Law and Policy of Health Care Quality Reporting*, 31 CAMPBELL L. REV. 215 (2009) (discussing payers' use of quality “report cards” as a possible means of improving provider quality).

<sup>147</sup> And, as noted, the systems that are in place so far do not seem to be working very well. See, e.g., Rosenthal et al., *supra* note 146, at 1792-93 (concluding that current private insurers' quality improvement programs do not work well for some kinds of providers); Tanenbaum, *supra* note 104, at 722-40 (reviewing empirical studies of pay-for-performance initiatives in CMS and private insurers and concluding that they generally have not effected

*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. As noted in the ESI and device stories, MCO habits are hard to monitor, even for large group purchasers with lots of market power.<sup>148</sup> Second, patients might irrationally undervalue such a system out of optimism bias (either because every patient thinks she is unlikely to get sick or because every patient thinks her doctor is better than average).<sup>149</sup> 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, since insurers suffer some costs from doctor error if they wind up paying for post-injury care. But, as in the device case, insurers often avoid such costs by terminating coverage or by shifting patients to other payers.<sup>150</sup> Furthermore, even if insurance companies could never avoid paying for post-injury care, they still would not have a full incentive to avoid patient injuries because the most the insurance company has to pay is the medical cost of treating the iatrogenic injury. Insurers internalize less than the full monetary cost since they do not pay for lost productivity, and they internalize none of the non-monetary cost (like pain).<sup>151</sup>

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

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quality improvements).

<sup>148</sup> See *supra* Parts II.B.2 & II.B.3. Furthermore, the agency slack between employers and employees, see *supra* Part II.B.2, might cause employers to under-invest in information about MCO quality controls.

<sup>149</sup> See generally Neil D. Weinstein & William M. Klein, *Resistance of Personal Risk Perceptions to De-biasing Interventions*, in *HEURISTICS AND BIASES: THE PSYCHOLOGY OF INTUITIVE JUDGMENT* 313 (Thomas Gilovich, Dale Griffin & Daniel Kahneman eds., 2002) (describing the persistence of optimism bias in patients' judgments of their own health risks).

<sup>150</sup> See *supra* Part II.B.3.

<sup>151</sup> See generally *INST. OF MED.*, *supra* note 11 (describing and quantifying the many costs of iatrogenic injury).

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 all four 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 principals' full costs). In all four cases, these 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 Supreme 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.

Importantly, the point here is not that executive agencies are already doing a good job at regulating. In fact, our experience with federal executive regulation so far might well give readers pause in accepting my suggestions here. But the central thesis of this Article is that a regulator that can operate nation-wide through *ex ante* regulation has greater institutional *capacity* to address healthcare's particular market failures than any regulator that must operate case-by-case through *ex post* evaluation. That simple theoretical point, which seems uncontroversial in itself, strongly suggests that we should invest in strengthening our federal executive system of healthcare regulation rather than reverting to our state judicial system.

This Part fleshes out the reallocation trend as it arises in our four stories and considers the advantages and disadvantages 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, one apparent solution is to let the alternative regulators (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 hear 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 any 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.<sup>152</sup> 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 as well as private claims for compensation. The agencies' resolution of such claims would then also 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 different and lesser. Courts will owe deference to many of the agency rules and adjudications that reach Article

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<sup>152</sup> See Administrative Procedure Act of 1946, Pub. L. No. 89-554, §§ 701-706, 80 Stat. 392, 392 (1966) (codified at 5 U.S.C. §§ 701-706 (2008)); *Chevron v. Natural Res. Def. Council*, 467 U.S. 837, 844 (1984) (“Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute.”).

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III review,<sup>153</sup> and many of the quotidian regulatory decisions that might have belonged to the judiciary in the past will never reach the courts, having been sufficiently settled through administrative processes. The judiciary will therefore retain a role as a mediator of executive regulation, but it will not be a creator of regulatory rules.

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.<sup>154</sup> 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 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 reform

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<sup>153</sup> See *Chevron*, 467 U.S. at 844.

<sup>154</sup> See Donenberg, *supra* note 18, at 1520 n.131 (citing *Pa. Pharmacists Ass'n v. Houston*, 283 F.3d 531, 543-44 (3d Cir. 2002); *Evergreen Presbyterian Ministries, Inc. v. Hood*, 235 F.3d 908, 927-28 (5th Cir. 2000); *Visiting Nurse Ass'n v. Bullen*, 93 F.3d 997, 1004 n.7 (1st Cir. 1996); *Ark Med. Soc'y, Inc. v. Reynolds*, 6 F.3d 519, 528 (8th Cir. 1993)).

proposals.<sup>155</sup> 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.

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 have significant advantages over state judicial forums in the project of correcting information and agency costs. Most importantly, federal agencies will be significantly better than state courts at aggregating and evaluating information. That said, state judicial forums might retain some advantage in correcting agency costs, and any future design changes to administrative regulation ought to try to minimize the regulators' agency failures.

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, over time, become expert in the project, as DOL staffers would develop skill at identifying abusive claim denials. The same would be true 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,<sup>156</sup> the jurors' evaluations of that testimony would be less sophisticated and more error-prone

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<sup>155</sup> Moncrieff, *supra* note 4, at 857-58 (describing congressional and presidential interest in medical malpractice reform).

<sup>156</sup> Which it certainly doesn't seem to do. See Christopher T. Robertson, *Blind Expertise*, 85 N.Y.U. L. REV. 174, 177-78 (2010) (discussing how biased expert witnesses deprive factfinders of a clear view of the facts, leading to wrong decisions).

than expert bureaucrats' own evaluations of individual cases, especially because the adversarial process encourages countervailing testimony that jurors might have a particularly hard time judging.

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, the most expert of experts may not be able to conclude with confidence that the device was responsible for the injury, and the expert certainly would hesitate to conclude from a single story that a device is generally unsafe and should be recalled or relabeled. Likewise for a single story of provider negligence, from which we might not be able to conclude that the provider was solely to blame for the injury and 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 might not be able to conclude that the MCO was to blame and ought not to conclude that the MCO is generally abusive and should be put out of business.<sup>157</sup> In order to draw final 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. Indeed, the final evaluation drawn from a body of data becomes increasingly likely to be correct as the body of data grows, as long as the evaluating experts that produce the data are (on average) better than random in their individual evaluations.<sup>158</sup>

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 often – 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.<sup>159</sup> A court's ability to aggregate information

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<sup>157</sup> Admittedly, the tort system does not generally draw such wholesale conclusions; liability rules do not put manufacturers, MCOs, or providers out of business. Instead, the damages recoverable in tort are specifically designed to allow injuries where efficient, such that a device manufacturer, MCO, or doctor will go out of business only if held liable on several occasions.

<sup>158</sup> See MARQUIS DE CONDORCET, *Essay on the Application of Mathematics to the Theory of Decision-Making*, in CONDORCET: SELECTED WRITINGS 33, 52-55 (Keith Michael Baker ed., 1976) (stating a mathematical theorem that voting groups become increasingly likely to choose correct results as the groups grow in membership, as long as the groups' members are, on average, more likely to vote for the right answer than the wrong one); see also Adrian Vermeule, *Forward: System Effects and the Constitution*, 123 HARV. L. REV. 4, 13 (2009) (“[W]here a group votes sincerely on two alternatives, one of which is correct, and the members of the group are even slightly more likely to be right than wrong, then as the number of members in the group increases, the probability that a majority vote of the group is correct tends towards certainty.”).

<sup>159</sup> States, of course, have high courts that can gather and see cases from all jurisdictions

across stories is therefore limited. A federal agency, by contrast, gathers stories nation-wide.

Furthermore, a federal agency can take note of any and all relevant information, including, for example, stories from other countries in the case of internationally marketed devices. This point presents another stark contrast with judicial systems, which must constrain their review to the information provided by the parties. Even in an adversarial system in which the parties have incentives to present as much information as possible, the parties' ability to collect and present information will be resource constrained; they will be able to collect only the information that they can afford to gather, and they will likely choose to dedicate much of their resources to trial strategy rather than information gathering. By contrast, executive agencies that have information aggregation and expert regulation as their primary mandate will be more likely to expend their resources on gathering and monitoring data.

In short, because the agency sees all individual stories in the nation and because the agency has a greater incentive than litigants to gather information, the federal regulator can reach more accurate conclusions<sup>160</sup> and faster conclusions than the state court. Federal executive agencies can therefore take more decisive action.

A word about Medicaid: The informational problem in Medicaid is somewhat 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 tradeoffs that are necessary in running public insurance for the poor. Under the Equal Access Provision, for example, litigants ask courts 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.<sup>161</sup> The problem is exacerbated by the need to consider programmatic tradeoffs 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? Will public health policy be better if lots of people are covered but are given only limited public benefits or if only the very poorest people are covered but are given

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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' experiences and decisions.

<sup>160</sup> See *supra* note 158 and accompanying text.

<sup>161</sup> Moncrieff, *supra* note 1, at 687-88 (discussing the difficulty that courts faced in determining whether Medicaid patients actually had "equal access" to healthcare services).

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generous public benefits? These systemic evaluations are better made in expert agencies than in generalist courts.

In all four stories 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, agencies will do a better job than either courts or voters at making decisions about complicated policy tradeoffs.

## 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; healthcare regulations might be less subject to capture than fields like telecommunications and environmental law; and, to the extent that capture is a problem, federal agencies can use individual enforcement mechanisms to counteract (at least somewhat) their agency failures.

As discussed 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 (patients) and agents (insurers and providers). To correct those failures, 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 these dimensions.

On the first, information asymmetry, state courts probably do better than federal agencies, but to the extent that that's true, it's more of a curse than a blessing. A single 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.<sup>162</sup> Litigants have easy access to (indeed, are usually given proactive notice of) all information provided and arguments presented on both sides, including any information that non-parties present, as through amicus briefs. As a result, all vested interests (patients, payers, and providers) can see the decision-making process of state courts without much difficulty, even if they are not particularly good at evaluating the big-picture regulatory quality of those decisions, and they can hold elected judges accountable for their regulatory decisions. Furthermore, a court's decision in a single case, if it will have precedential effect, must be published with reasons given for the decision. Parties are

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<sup>162</sup> See *infra* Part IV.B.1 for further discussion of this function of private litigation and for the suggestion that the function can be replicated in agencies.

therefore able to monitor not only the judiciary's resolutions of their particular conflicts but also the judiciary's overall regulatory approach to the relevant regime.

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,<sup>163</sup> affected parties are not as intimately involved in executive regulatory decisions as they are in judicial ones. Furthermore, because executive decision-making is open for comment from any and all parties that might be interested in the decision, the regulatory process often involves far too much information for any single party to read and evaluate. Finally, regulatory decisions, unlike judicial ones, do not have to be explained. The executive is not required to publish an equivalent to the judicial opinion: a public expression of its logic for reaching a particular regulatory outcome.<sup>164</sup> Executive agencies, thus, may 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. An agency's relatively opaque process of evaluating systemic problems and offering systemic solutions is, at worst, a necessary evil in a regime as complicated as healthcare. Information asymmetry is the price we pay for better-informed healthcare regulation.

On the second dimension of agency cost – misaligned incentives – state courts may do a bit better than federal agencies, but the state courts' advantage might be less significant in healthcare than in other regulatory regimes like telecommunications and environmental law. Here, the biggest risk is capture. The fear is that 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, would be to please the organized lobbies rather than to serve the public interest, creating a misalignment of incentives between patients and federal agencies.<sup>165</sup> State judges, of course, are usually elected and therefore lack the

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<sup>163</sup> See generally Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 586-87 (2000).

<sup>164</sup> That said, administrative law provides significant incentives for agencies to develop records of their decision-making processes and to give public reasons for their decisions. See *United States v. Mead Corp.*, 533 U.S. 218, 237-38 (2000) (holding that only formal rules, which require creation of a public record, will be entitled to judicial deference).

<sup>165</sup> See Robert W. Gordon, *A New Role for Lawyers?: The Corporate Counselor After Enron*, 35 CONN. L. REV. 1185, 1199 (2003) ("Big American business firms are not discrete and insular minorities. They have exceptional access to influence in legislatures, administrative agencies, and the courts through government advisory commissions, trade

political insulation of Article III judges,<sup>166</sup> but they might be less of a target than federal executive regulators simply because they make dispersed, case-by-case decisions. That is, because courts do not usually effect broad-sweeping regulatory change, 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 these interests gain an advantage in litigation by outspending their individual opponents – by hiring better lawyers and fancier expert witnesses, filing more motions, dragging out trials, etc.<sup>167</sup> 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 might well respond more favorably to organized interests than to disorganized ones, and they might therefore do only a marginally better job than agencies of basing regulatory decisions on the general public interest.<sup>168</sup>

Additionally, there may be reason to believe that the traditional capture story is less likely to be realized in healthcare than in other regulatory regimes. In typical regulated industries, there is a clear division between the moneyed interests and the public interest. In telecommunications law, one side of the policy debate is comprised of the regulated firms, which are organized and moneyed, while the other side is comprised of consumers, who are dispersed and unorganized. In environmental law, one side is comprised of big business polluters while the other is comprised of those that suffer from environmental degradation – a group that has become increasingly organized and moneyed over time but that still lacks the financial wherewithal and incentives of the polluting industrial lobby.

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associations, lobbies, and lawyers.”); Thomas W. Merrill, *Institutional Choice and Political Faith*, 22 *LAW & SOC. INQUIRY* 959, 961 (1997) (discussion of public choice theory in relation to business lobbies influence on regulators); Jennifer Arlen, Comment, *The Future of Behavioral Economic Analysis of Law*, 51 *VAND. L. REV.* 1765, 1785 (1998) (“[P]owerful business lobbies may induce regulators to declare as safe products that are not in fact safe.”).

<sup>166</sup> Stephen J. Choi et al., *Professionals or Politicians: The Uncertain Empirical Case for an Elected Rather Than Appointed Judiciary* (Univ. of Chic. Law Sch., Olin Ctr. for Law & Econ. Working Paper Series, No. 357, 2007), available at <http://ssrn.com/abstract=1008989> (observing that most state judges are elected, not appointed).

<sup>167</sup> See Einer R. Elhauge, *Does Interest Group Theory Justify More Intrusive Judicial Review?*, 101 *YALE L.J.* 31, 77 (1991) (“Small intensely interested groups are still likely to spend more on their litigation efforts than any large diffuse groups opposing them.”).

<sup>168</sup> We have evidence of this kind of distortion in medical malpractice litigation, where juries are significantly more likely to err on the doctor's side than on the patient's side. See Studdert & Mello, *supra* note 20, at S49-S53.



In healthcare, by contrast, there are organized and moneyed interests on both sides of the policy divide. In the medical malpractice example, doctors (an organized lobby) might prefer professional self-regulation to anything that CMS would offer and might therefore push the agency towards a laissez-faire approach. But payers, including private insurance companies that are just as organized and moneyed as doctors, have incentives to minimize patient injuries and might therefore push CMS in the opposite direction, advocating hefty regulatory intervention. Likewise for ESI, MCOs would favor laissez-faire, but employers would favor regulation; for medical devices, manufacturers would favor laissez-faire, but payers and providers would favor regulation; and for Medicaid, states (a surprisingly organized lobby) would favor laissez-faire, but providers strongly favor intervention. The relevant agencies in these four stories – and in most healthcare regimes – would therefore be subject to competing interests that would pull in opposite directions. It is possible that this environment would prevent the agency from falling capture to any given interest and would leave the agency freer than average to pursue the public interest.

Even if this image of a regulatory tug-of-war – or the conclusion of public-interest-oriented regulation – is too simplistic or rosy, it is possible for regulatory design to minimize some of the agency problems that executive regulators might face. Most importantly, the federal executive can and should 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, without requiring that actual decisions be made by generalist juries and judges. Such a process would give individuals some power to act as their own agents, as they do in state courts, and it would allow self-interested parties to present an informational record to expert decision-makers.<sup>169</sup> If we ever do shift entirely to federal executive enforcement in these stories or others like them, federal agencies ought therefore to establish administrative claims, like those already available to Medicare beneficiaries and Social Security Disability recipients, for example.

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 (if not non-existent in the unique world of healthcare), come at the expense of informational deficits, and can be at least partially overcome through administrative claims processes. For these four stories, therefore, courts might be slightly better for correcting the markets' agency failures, but that advantage may not be worth its cost.

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<sup>169</sup> Such a process would therefore replicate many of the informational successes of state courts. *See supra* note 162 and accompanying text.

## IV. WHAT NEXT?

Federal executive agencies, thus, bring many theoretical advantages to the project of healthcare regulation. But that point alone does not answer the question of how best to solve the current enforcement vacuum. There are three possible regimes that we must consider, and the choice among them turns on empirical questions about the cost-benefit tradeoff between state judicial regulation and federal executive regulation.

First, we could allow concurrent regulatory authority, gaining the advantages of federal executive regulation without losing any positive role that state judicial regulation plays. In other words, we could encourage the federal executive to fill its regulatory role while also re-empowering the judiciary, at least in the federal courts if not in the state courts.<sup>170</sup> Second, we could allow the judiciary to play a much more limited role than it did before the Supreme Court's intervention, providing compensation to injured parties without engaging in the regulatory aspects of tort. Such a system might depend on courts' acceptance of a regulatory compliance defense as an absolute bar to liability.<sup>171</sup> Third, we could completely eliminate the judicial role and shift all regulatory functions to the federal executive.

This Part will reject the first option, offering compliance and error costs as a reason to preserve and maybe enhance limits on the judiciary's role. It will then consider the other two options together, acknowledging the positive functions of the judiciary but suggesting that we could create a more efficient system by replicating those functions in the executive rather than retaining a limited judicial role.

A. *Concurrent Authority*

## 1. 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 unless those conditions clearly intended to create and confer enforceable rights.

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<sup>170</sup> See Edward Alan Miller, *Federal Administration and Judicial Oversight of Medicaid: Policy Legacies and Tandem Institutions under the Boren Amendment*, 38 *PUBLICUS: J. OF FEDERALISM* 315, 328-29 (2008) (celebrating the combination of judicial and regulatory oversight under the predecessor of the Equal Access Provision).

<sup>171</sup> See, e.g., Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 *GEO. L.J.* 2147, 2165 (1999) (arguing in favor of a regulatory compliance defense for drug and device torts).

(Remember, it was not even a Medicaid case that caused the vacuum here; it was FERPA.)<sup>172</sup> 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 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 amendment in 2001, when the so-called Patients’ Bill of Rights passed both chambers but died in conference committee.<sup>173</sup> Alternatively, without congressional action, 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.<sup>174</sup>

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 preemption 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.<sup>175</sup> 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 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.”<sup>176</sup>

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<sup>172</sup> *Gonzaga Univ. v. Doe*, 536 U.S. 273, 273 (2001).

<sup>173</sup> *Miller*, *supra* note 86, at 1303.

<sup>174</sup> *See* discussion *supra* Part II.A.2.

<sup>175</sup> Under the second step of deference analysis, the court asks whether the agency’s interpretation is “reasonable.” *See Chevron v. Natural Res. Def. Council*, 467 U.S. 837, 845 (1983). If it is not, the court will not defer. *Id.*

<sup>176</sup> *See* Perry H. Apelbaum & Samara T. Ryder, *The Third Wave of Federal Tort Reform: Protecting the Public or Pushing the Constitutional Envelope?*, 8 CORNELL J.L. & PUB. POL’Y 591, 593 (1999) (observing that federal medical malpractice reform raises difficult constitutional questions); Betsy J. Grey, *The New Federalism Jurisprudence and National Tort Reform*, 59 WASH. & LEE L. REV. 475, 534 (2002) (suggesting that medical malpractice might not be “economic activity” that can be subject to federal regulation under the Commerce Clause); Collin Sult, Note, *Questionable Medicine – Why Federal Medical*

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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 re-empower private enforcement. Furthermore, a decision to re-empower the judiciary would not be fundamentally incompatible with a decision to encourage the relevant executive agencies to play a greater regulatory role. We could, then, 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,<sup>177</sup> and there is no inherent structural problem with allowing the branches to exercise concurrent authority.

## 2. The Problems with Concurrent Authority

To argue that we should allow concurrent authority for these four stories of health law, however, would be 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).

*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 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

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*Malpractice Reform May Be Unconstitutional*, 47 ARIZ. L. REV. 195, 198 (2005) (expressing skepticism about the constitutionality of federal medical malpractice reform under the "Supreme Court's more recent pronouncements defining the scope of congressional power under the Commerce Clause").

<sup>177</sup> Environmental law and its regulatory regime is one example of such success. See Lois Schiffer & Timothy Dowling, Remark, *Reflections on the Role of the Courts in Environmental Law*, 27 ENVTL. L. 327, 331-32 (1997) (attributing the effectiveness of environmental policy to both legislation, such as the Clean Air Act, and to the courts for their "vigorous enforcement and resolution of exactly what the new [environmental] statutes required from the executive and from private parties"). But see Thomas O. McGarity, *The Complementary Roles of Common Law Courts and Federal Agencies in Producing and Using Policy-Relevant Scientific Information*, 37 ENVTL. L. 1027, 1044 (2007) (exploring the limits on communication between common law courts and EPA, and suggesting reforms to enhance information exchange).

necessarily impose regulatory duties for manufacturers and employers that might vary across jurisdictions, necessarily deciding when compensatory damages are due and when they are not. 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<sup>178</sup> 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.<sup>179</sup> 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.

*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.<sup>180</sup> 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.<sup>181</sup> As a result, they issue both false positives and false negatives. Good MCOs, devices, and providers get punished, but bad ones go free; inevitable injuries get compensated while preventable ones do not. Regulated entities then invest in avoiding liability in an arbitrary system, a wasteful investment since arbitrary rules fail to incentivize greater safety or welfare.<sup>182</sup>

For Medicaid, too, the problem with courts is that 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

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<sup>178</sup> Moncrieff, *supra* note 4, at 859-61 (reciting the arguments against a uniformity need for medical malpractice).

<sup>179</sup> It is a reasonable question, however, whether this is an artifact of fifty different legal regimes – whether nation-wide providers (perhaps on a Kaiser-like model, but across state lines) would emerge if the federal government took over regulation.

<sup>180</sup> See ADRIAN VERMEULE, *JUDGING UNDER UNCERTAINTY* (2006) (discussing the limits of judicial decision-making and urging a greater executive role in interpreting statutes).

<sup>181</sup> See *supra* Part II.B.2 & Part II.B.4.

<sup>182</sup> 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.

expert agencies than in generalist courts, and the cost of error could be significant if, for example, courts unwittingly move Medicaid beneficiaries into emergency rooms.

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Importantly, the problem with concurrent authority here is not at all inherent to concurrency.<sup>183</sup> 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 or were a significantly better option than their available alternatives. But given the presence of alternative regulators with superior expertise in the federal executive, we might be able to avoid the compliance and error costs that come with state judicial rulemaking by vesting exclusive authority in federal agencies.

#### B. *Exclusive Executive Authority*

Ought we, then, to shift exclusively to 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 shifting to exclusive executive authority would eliminate any benefits that we get out of private litigation. Furthermore, the federal agencies that are poised to regulate in our four stories have not (yet) been doing a good job of playing the regulatory role. We must therefore ask two questions: (1) Are the benefits of exclusive executive regulation worth their costs, namely the lost values of private litigation in the state judicial system? (2) What needs to be done to motivate and optimize federal executive regulation of Medicaid, ESI, medical devices, and medical malpractice? This part of the Article will address these questions in turn, particularly considering whether courts should retain a limited, compensatory role in healthcare regulation.

##### 1. The Values of Private Litigation

The first potential problem with shifting authority fully to the federal executive is that the shift might (unless carefully designed) sacrifice the benefits of private litigation. The question, then, is what we get out of private litigation and whether those benefits are worth preserving, either by retaining a limited judicial role or by replicating the benefits in executive forums. Although there are several such benefits for healthcare regulation, a carefully designed administrative system can replicate them and might be able to improve on them.

*Information Gathering.* Perhaps the most relevant advantage of private litigation for present purposes is that it exposes information about private

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<sup>183</sup> The problem here is not merely one of “coordinating sanctions” between the executive and the judiciary, as a recent manuscript puts it. *See Logue, supra* note 14.

parties' behavior – information that administrative agencies currently have a hard time gathering and that, once revealed through litigation, can be important to executive regulation.<sup>184</sup> Although agencies currently have some investigatory tools and certainly engage in some information-gathering,<sup>185</sup> the discovery process in private litigation provides a much more extensive toolbox for information-gathering than any currently available to agencies.<sup>186</sup>

This point might seem inconsistent with the central claims of this paper – particularly the claim that information about individual cases, revealed in litigation, is insufficient for regulation. While that is certainly true – that litigation-based information is not *sufficient* for regulation – it is also true that some litigation-based information may be *necessary* (or at least very useful) for regulators. Particularly in the regulatory regimes involving corporations (MCOs and device manufacturers), tort claims allow the plaintiff to gather information about the corporation's knowledge or intent. Such information might include, for example, proof of a manufacturer's knowledge of private safety and effectiveness studies or proof of an MCO's explicit corporate policy to reject valid claims.<sup>187</sup> That information, in turn, might be highly useful to administrative regulation (even though it is potentially difficult for judicial agents to understand or to act upon such information without additional systemic information), and information about corporate knowledge or intent might give an agency new cause or new jurisdiction to intervene.<sup>188</sup> As an

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<sup>184</sup> See Gostin, *supra* note 63, at 2315 (“The tort system has another benefit that is not often fully recognized – through the discovery process, it can compel corporations to disclose everything they know, or reasonably should know, about the product’s safety and effectiveness.”); Robert L. Rabin, *Keynote Paper: Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2068-70 (1999) (describing the information-gathering and information-revealing virtues of tort). Administrative regulators can then take advantage of that information in making later regulatory decisions. Gostin, *supra*, at 2315 (“The discovery process provides a ‘feedback loop’ to the FDA, which in the past has changed its regulatory decisions in light of information revealed in court.”).

<sup>185</sup> For example, tobacco regulation is often cited as an instance in which litigation revealed information of corporate abuses, see Gostin, *supra* note 63, at 2315, but FDA was actively investigating those abuses at the same time. See DAVID KESSLER, *A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY* 357-93 (2001) (telling the story of FDA’s investigation into tobacco industry intent, leading up to FDA’s assertion of jurisdiction over tobacco products in 1997).

<sup>186</sup> See David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 492 (2008) (asserting that “the information-gathering tools lawyers have in litigation are, by any measure, more extensive than the FDA’s”).

<sup>187</sup> The Vioxx litigation is a good example of this function of tort; plaintiffs were able to discover, relevantly for FDA, that Merck knew about the heart risks of Vioxx and hid that information from FDA during the drug’s approval process.

<sup>188</sup> In the tobacco case, for example, FDA would have jurisdiction over nicotine only if the tobacco companies knew that nicotine was addictive and intended to sell tobacco products as a drug. Knowledge and intent were therefore central to FDA’s assertion of

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information-revealing mechanism, therefore, private litigation might serve an important function.

*Compensation.* The second benefit of state judicial regulation, particularly through tort, is that it provides compensation to injured parties. (This point is irrelevant to the Medicaid story, where the injury is regulatory rather than personal.) Compensation serves two important goals: First, it spreads risk among all consumers of the relevant good or service, rather than forcing the unlucky few who are injured to bear the full cost of that risk,<sup>189</sup> and second, it serves non-utilitarian values of social justice and morality, requiring an injuring party to make its victims whole. These values are independent of any *ex ante* regulatory benefit of compensation. That is, compensation does not merely provide an incentive for producers to be careful; it also forces insurers, manufacturers, and doctors to spread the risk of error among their consumers (through price increases) and to recompense their injured consumers for the harms that they cause.

*Experimentation and Responsiveness.* The third and final benefit of state judicial regulation is that it has the potential to be experimental with regulatory approaches and to be responsive to new regulatory needs. Both of these values are significantly weaker for state judicial regulation than for state executive or legislative regulation, but they might nevertheless be present to a certain extent in our four stories.

Experimentation is a known advantage of state control;<sup>190</sup> different states can try different approaches to Medicaid, ESI, and medical torts, allowing the country as a whole to learn from different experiences in different places. Of course, the judiciary is not a coordinated regulator than can engage in self-conscious experiments the way that a state executive or legislature can, and the judiciary has a harder time trying new approaches than the political branches, given the path dependence of the common law. But the possibility for variation among the states does provide some opportunity to test the relative successes of different approaches.

The state judiciary might also be better situated than the federal executive to respond to new regulatory needs since it is a smaller organ of government that is more accessible to affected parties.<sup>191</sup> The state judiciary might therefore gain information about changing circumstances faster than the federal executive. Again, though, the judiciary's tie to precedent – the path dependence of judicial regulation – might significantly weaken this advantage of state regulation in the contexts that are relevant here, all of which center on private litigation.

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jurisdiction. See KESSLER, *supra* note 185, at 355-58.

<sup>189</sup> See Rabin, *supra* note 184, at 2070-74 (describing the compensation goals of tort and their failure in most administrative regimes, but noting that some administrative schemes do replicate compensation).

<sup>190</sup> Moncrieff, *supra* note 4, at 880.

<sup>191</sup> See *id.*



## 2. Replicating Litigation Values in the Executive

Perhaps, in light of these values of private litigation, we ought to preserve at least some role for the state judiciary in regulating our four stories. At a minimum, the state judiciary could continue to play its compensatory role, allowing plaintiffs to file claims in state courts for compensatory damages and to conduct full discovery.

But we need not take it for granted that the values of state judicial regulation are better captured in the state judiciary than in the federal executive. Indeed, many of those values can be replicated quite easily in the federal executive and might ultimately operate more efficiently in that forum.

*Information Gathering.* As previously noted, agencies already conduct investigations when deciding whether and how to regulate, but the tools they currently have for that project are insufficient, particularly when compared to the tools available to lawyers in discovery. But surely regulatory agencies can be given better tools: greater subpoena powers, perhaps powers to search and seize in compliance with the Fourth Amendment, and more money to hire investigators. If given such tools, in fact, agencies might do better than lawyers at discovering relevant information since they would have a greater scope of “relevancy” than litigators; litigators advocate a single client’s interests (or, in the case of a class action, a single group’s interests) while agencies represent the collective interest.<sup>192</sup> Furthermore, agencies might do a better job than litigators of deciding whom to investigate. Plaintiffs and their lawyers have incentives to go after the deepest pockets they can find, regardless of whether those actors are the most responsible for creating unjustified risks. Agencies would have no such distortion in their incentives to investigate.

One caveat to this discussion is that litigants don’t just gather the relevant information but also serve as whistle-blowers, pointing out the actors (such as Medicaid agencies, MCOs, devices, and doctors) that are causing the most harm. Even if they might sometimes sue the wrong party from an efficiency standpoint, they still point to products and systems that are causing problems.

But the executive can set up administrative channels for injured parties to serve that same function – and can make it cheaper for injured parties to do so – by establishing an administrative claims process. Such a process would require less investment in terms of court filings and fancy lawyers, meaning that even parties with small injuries might step forward to blow the whistle – something that rarely happens in the high-cost world of tort litigation.

*Compensation.* As with information gathering, there is no reason to think that the compensation value of state judicial regulation is unique to that forum; administrative agencies can also establish victim compensation funds and can allow individual claims for damages. Indeed, models for this possibility already exist for workplace accidents and vaccines.<sup>193</sup> Administrative

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<sup>192</sup> Assuming they aren’t captured. See *supra* Part III.B.2.

<sup>193</sup> See Rabin, *supra* note 184, at 2074.

compensation funds naturally serve the risk-spreading goal of compensation, whether funded from general revenue or from targeted taxes paid by injurers, allowing cost of risk to be spread among the tax base or among consumers of the relevant product or service. And if funded by a targeted tax or if provided through claims adjudication by the agency, administrative compensation can also serve social justice goals, requiring risk-creators to internalize the cost of the injuries they cause.

*Experimentation and Responsiveness.* The experimentation and responsiveness advantages of state control are similarly replicable in federal agencies. With respect to experimentation, federal agencies can (and often do, particularly in CMS) run demonstration projects to test new policy ideas. The federal agencies, in fact, might run more useful experiments than states since they can select populations by statistically relevant criteria (rather than by arbitrary state boundaries). Regulators might also learn better from federal demonstration projects than from state judicial experimentation since data about such experiments flow to a single entity – the federal agency – rather than needing to be conveyed to dispersed state courts.

As for responsiveness, the state judiciary's relative advantage is not terribly significant given that agencies already have mechanisms by which the public can notify regulators of new circumstances, including public comment procedures when the agency is actively considering regulatory change and petitions for rulemaking when the agency is not actively considering such change. But the agency could create an even cheaper mechanism to gather information about changing circumstances and evolving needs by establishing administrative adjudication of individual claims. Through a claims process, agencies would receive the same kind of information that the state judiciary would get about harmful products or services, and they would receive that information just as quickly as the state judicial system. The federal executive might, with such a mechanism, be even more responsive than the state judiciary since it would not be path dependent in its regulatory choices.

### 3. Improving Executive Regulation

The final question to consider is what needs to be done to improve the federal executive's regulatory efforts. Importantly, this Article absolutely is not and should not be understood to be an endorsement of the current regulatory environment for Medicaid, ESI, devices, or malpractice. Although I have greater faith than some in the capacities of our federal executive regulators and although I believe that those regulators have the legal authority they need to assert control over the four healthcare regimes I address, I certainly do not mean to suggest that the agencies' status quo efforts are sufficient – or even that the status quo agencies are currently capable of assuming full regulatory control. What, then, needs to be done to enable exclusive executive regulation of these four regimes?

The short answer is that we need to give them more 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 funding.<sup>194</sup> Those provisions, of course, need to come from Congress.

The longer answer is that we probably ought to restructure the agencies to clarify the agencies' responsibilities and to signify the importance of the regulatory projects at issue here. All three relevant agencies – CMS for Medicaid and malpractice, DOL for ESI, and FDA for devices – have structured themselves with different goals in mind, other than the regulatory projects at issue here, and they operate in complex regulatory environments in which they sometimes compete with other agencies for jurisdiction over single healthcare problems.<sup>195</sup> PPACA, in fact, has made this problem worse with respect to employer-sponsored insurance.<sup>196</sup> 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, as noted above, the federal executive should structure itself so as to replicate the advantages of state judicial regulation: information gathering, individual compensation, experimentation, and responsiveness. Each agency ought to establish an administrative claims process that will allow injured patients to seek redress for their injuries, and Congress ought to give the agencies greater resources and tools for information-gathering.

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.

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<sup>194</sup> See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-581, FOOD AND DRUG ADMINISTRATION: FDA FACES CHALLENGES MEETING ITS GROWING MEDICAL PRODUCT RESPONSIBILITIES AND SHOULD DEVELOP COMPLETE ESTIMATES OF ITS RESOURCE NEEDS 34 (2009) (raising concern for the lack of funding and resources devoted to FDA's medical products oversight); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-106, WHISTLEBLOWER PROTECTION PROGRAM: BETTER DATA AND IMPROVED OVERSIGHT WOULD HELP ENSURE PROGRAM QUALITY AND CONSISTENCY 40-41 (2009) (asserting that the Department of Labor's Occupational Safety and Health Administration lacks funds to fully implement its program to investigate whistleblower complaints); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-54, CENTERS FOR MEDICARE AND MEDICAID SERVICES: INTERNAL CONTROL DEFICIENCIES RESULTED IN MILLIONS OF QUESTIONABLE CONTRACT PAYMENTS 45 (2007) (finding that CMS neglected to devote sufficient resources to appropriately process contract awards). CMS's response to its oversight deficiencies, the Recovery Audit Contractor program, came under a substantial amount of criticism during its initial years.

<sup>195</sup> See, e.g., Margaret G. Farrell, *ERISA Preemption and Regulation of Managed Health Care: The Case for Managed Federalism*, 23 AM. J.L. & MED. 251, 277-81 (1997) (observing that six federal agencies have jurisdiction over some aspect of managed care).

<sup>196</sup> See EBSA Unified Agenda, *supra* note 15.

## 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 and shifting authority to a big-picture regulator. For that project, federal executive agencies are significantly better positioned than state courts.