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In Aetna Health Inc. v. Davila, *the Supreme Court held that two individuals' suits against their respective managed care organizations ("MCOs") for injuries allegedly arising from coverage denials were completely preempted by the Employee Retirement Income Security Act of 1974 ("ERISA"). This decision may encourage a structural separation between physicians and MCOs, effectively creating two independent sources of medical information about a patient's treatment—the physician's conversation with the patient and the MCO's coverage decision. As MCOs increase their involvement in creating, evaluating, and disseminating medical information, patients will begin to rely more heavily on MCOs' provision of medical information. Subjecting this information provision to standards created by a state tort law regime would provide an incentive to improve informational quality. At the same time, retaining ERISA regulation of MCOs' ultimate coverage decisions would help to preserve the current legal regime's benefits with respect to regulatory uniformity and cost control. A bifurcated legal regime would thus reinforce the movement toward consumer-driven health care.*

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INTRODUCTION

In the 2004 case *Aetna Health Inc. v. Davila*,[1] the Supreme Court held that two individuals' suits against their respective MCOs for failure to exercise ordinary care were completely preempted under the federal ERISA statute, which regulates employee benefit plans.[2] The plaintiffs, who alleged that they had suffered injuries as a result of their MCOs' refusal to cover the care recommended by their physicians, had sued their MCOs under a Texas statute that imposes on managed care entities a "duty to exercise ordinary care when making health care treatment decisions."[3] The Supreme Court unanimously concluded that the MCOs had made "pure eligibility

1. 542 U.S. 200, 124 S. Ct. 2488 (2004).

2. *Id.* at 2502. "Managed care" refers to a form of health insurance that "attempt[s] not just to pay for, but also to control the cost of, health care services." BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 567 (5th ed. 2004). Managed care organizations include health maintenance organizations, preferred provider organizations, and point-of-service plans. Russell Korobkin, *The Failed Jurisprudence of Managed Care, and How to Fix It: Reinterpreting ERISA Preemption*, 51 UCLA L. REV. 457, 459 n.1 (2003). ERISA is the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (codified as amended at 29 U.S.C. §§ 1001–1461 (2000)).

3. TEX. CIV. PRAC. & REM. CODE ANN. § 88.002(a) (Vernon 2004).

decisions" rather than treatment decisions or "mixed eligibility and treatment decisions," and that the plaintiffs sought "only to rectify a wrongful denial of benefits promised under ERISA-regulated plans."[4] It then held that the plaintiffs' cause of action was completely preempted by section 502(a)(1)(B) of ERISA.[5] Thus, the Court dashed MCO enrollee[6] advocates' hopes of recovering compensation under state law for injuries resulting from improper MCO denials of care.[7] Because ERISA does not permit consequential damages that would compensate enrollees for injuries resulting from denied benefits,[8] the *Davila* holding also precluded the plaintiffs from obtaining a meaningful remedy under federal law.

The *Davila* decision is troubling both because it leaves injured enrollees to bear much of the burden stemming from improper MCO decisionmaking and because it undermines MCO incentives to improve the quality of the coverage decisionmaking process. Not surprisingly, newspaper editorials critical of the result in *Davila* (although not necessarily its legal reasoning) appeared soon after the decision was issued.[9] One editorial said that the decision "leaves most Americans helpless" and "puts the public at the mercy of the insurance industry."[10] A second referred to the "intolerable

4. *Davila*, 124 S. Ct. at 2498, 2502.

5. *Id.*

6. This Article uses the term "enrollee" broadly to apply to any ERISA plan participant or beneficiary whose benefits depend on medical necessity decisions of the sort typically made by MCOs. The term therefore includes a plan participant whose employer self-insures but hires a third party administrator to perform utilization review functions. For descriptions of the roles of third parties in ERISA plan administration, see Karen A. Jordan, *Coverage Denials in ERISA Plans: Assessing the Federal Legislative Solution*, 65 MO. L. REV. 405, 443–44 (2000); Korobkin, *supra* note 2, at 486.

7. While the Texas statute at issue in *Davila* may continue to apply to MCO enrollees whose health plans are not subject to ERISA regulation (such as those who purchase coverage individually), many Texans have ERISA-regulated coverage. *See* TEX. DEP'T OF INS., HEALTH INSURANCE REGULATION IN TEXAS: THE IMPACT OF MANDATED HEALTH BENEFITS 38, 41 (1998), *available at* http://statecoverage.net/pdf/tx2.pdf (stating that ERISA applies to "virtually *all* private-sector employee benefit plans" and estimating that in 1996 over fifty-seven percent of Texans had employment-based health coverage); *see also infra* note 31 (documenting the prevalence of ERISA plans).

8. See *infra* note 35 and accompanying text for a discussion of the remedies available under ERISA.

9. For a synopsis of selected *Davila*-related editorials, see Kaiser Daily Health Policy Report, *Editorials Respond to Supreme Court Decision to Limit Lawsuits Against HMOs in State Courts*, June 23, 2004, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=24375.

10. Editorial, *Where Are Patients' Rights?*, TENNESSEAN (Nashville), June 22, 2004, at 6, *available at* 2004 WLNR 16170046.

situation" existing in the wake of *Davila*.[11] A third called the result "bad news" for those harmed by health plans' coverage denials and suggested that the plaintiffs "surely deserved a day in court."[12] The editorials expressed concerns about the lack of MCO accountability that have long been articulated by health policy analysts, legal scholars, and judges.[13] They frequently advocated that Congress fill the ERISA-created regulatory void,[14] echoing the message of Justice Ginsburg, who, in a concurring opinion in *Davila*, urged that Congress "revisit what is an unjust and increasingly tangled ERISA regime."[15] Scholarly commentary on the *Davila* case highlights similar themes.[16]

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11. Editorial, *A "Regulatory Vacuum,"* ST. PETERSBURG TIMES, June 23, 2004, at 14A, *available at* 2004 WLNR 3726078.

12. Editorial, *A Blow to Health Plan Patients*, N.Y. TIMES, June 23, 2004, at A22.

13. *See, e.g.*, DiFelice v. Aetna U.S. Healthcare, 346 F.3d 442, 459 (3d Cir. 2003) (Becker, J., concurring) ("ERISA . . . creates strong incentives for HMOs to deny claims in bad faith .... ERISA's remedial scheme gives HMOs every incentive to act in their own and not in their beneficiaries' best interest."); Peter J. Hammer, Pegram v. Herdrich: *On Peritonitis, Preemption, and the Elusive Goal of Managed Care Accountability*, 26 J. HEALTH POL. POL'Y & L. 767 *passim* (2001) (analyzing the Supreme Court's *Pegram* opinion described *infra* in Part I and its implications for accountability).

14. *See, e.g.*, Editorial, *supra* note 12 ("[T]he only real remedy may lie with Congress .... This page has long endorsed a strong patients' rights bill that would allow managed care plans to be held accountable in state courts."); Editorial, *supra* note 11 ("[T]he decision puts the responsibility to fix this intolerable situation where it belongs: on Congress."); Editorial, *supra* note 10 ("This ruling should be all the evidence that Congress should need to put passage of a real Patients Bill of Rights at the top of its agenda.").

15. Aetna Health Inc. v. Davila, 124 S. Ct. 2488, 2503 (2004) (Ginsburg, J., concurring) ("I also join 'the rising judicial chorus urging that Congress and [this] Court revisit what is an unjust and increasingly tangled ERISA regime.' ") (citing *DiFelice*, 346 F.3d at 453 (Becker, J., concurring)). Justice Ginsburg explained that Congress had intended to incorporate a make-whole standard of relief into ERISA, and that she "anticipate[d] that Congress, or this Court, will one day so confirm." *Davila*, 124 S. Ct. at 2504. In support of the argument that the Supreme Court had previously erred in denying plaintiffs make-whole relief, the Ginsburg opinion cited John Langbein, *What ERISA Means by "Equitable": The Supreme Court's Trail of Error in* Russell, Mertens, *and* Great-West, 103 COLUM. L. REV. 1317 (2003). *Davila*, 124 S. Ct. at 2503.

16. *See, e.g.*, Wendy K. Mariner, *The Supreme Court's Limitation of Managed-Care Liability*, 351 NEW ENG. J. MED. 1347, 1351 (2004) ("Congress should amend ERISA to ensure that ERISA plans and their MCOs are just as accountable to patients for medical decisions as physicians are."); Theodore W. Ruger, *The United States Supreme Court and Health Law: The Year in Review*, 32 J.L. MED. & ETHICS 528, 531 (2004) (suggesting that *Davila* will "create institutional debate, probably result in federal legislative or judicial action, and possibly produce a very different regime of managed care regulation than the immediate status quo"); *The Supreme Court, 2003 Term—Leading Cases*, 118 HARV. L. REV 456, 462–63 (2004) [hereinafter *Leading Cases*] ("*Davila*, coupled with ERISA's limited remedial scheme, leads to a troubling incentive structure in managed care utilization review .... Either the judiciary or the legislature must act to correct this incentive structure."). *See generally* M. Gregg Bloche, *Back to the '90s—The Supreme*

This Article proposes a legal regime that would increase MCO accountability and provide remedies to some injured enrollees, but at the same time would preserve the benefits of ERISA, including those resulting from the *Davila* decision itself. As several commentators have recognized, the *Davila* opinion may affect the structure of health plan decisionmaking.[17] In a previous opinion, the Supreme Court left open the possibility that MCOs could be held liable under state law for certain coverage decisions made on their behalf by treating physicians,[18] while in *Davila* it determined that MCOs that do not act through treating physicians receive ERISA-based protection against such liability.[19] Thus, *Davila* gives MCOs an incentive to maintain a functional separation from treating physicians. If a physician recommends a proper course of treatment, but the MCO denies coverage, both will be protected from tort liability—the physician by compliance with the standard of care, and the MCO by ERISA preemption.

If *Davila* results in a greater functional separation of MCO administration and physician care, it may benefit MCO enrollees by increasing the information available to patients faced with a treatment choice. The treating physician is the most obvious source of medical information for a patient, but not the only one. When an MCO's coverage determination involves the exercise of medical judgment, such as in a "medical necessity"-based coverage denial, the MCO becomes another source of medical information. The MCO announces its assessment that a treatment is not medically necessary and describes the medical basis for its decision. Just as treating physicians influence patients' decisions through the information they provide as part of the treatment process, MCOs may influence patients' decisions through the information they provide as part of the coverage determination process. If changes in the health care industry expand the role of the MCO as an information provider, and thus increase MCO influence over patient decisionmaking, it will

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Court Immunizes Managed Care, 351 NEW ENG. J. MED. 1277 (2004) (commenting on the implications of *Davila* for health plans, patients, and providers); Timothy Stoltzfus Jost, *The Supreme Court Limits Lawsuits Against Managed Care Organizations*, HEALTH AFF. WEB EXCLUSIVE, Aug. 11, 2004, http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.417v1 (noting that *Davila* will protect plans from liability related to their utilization review decisions unless Congress intervenes).

17. *See* Mariner, *supra* note 16, at 1350; Ruger, *supra* note 16, at 530; *Leading Cases*, *supra* note 16, at 462–63.

18. *See* Pegram v. Herdrich, 530 U.S. 211, 231–37 (2000); *infra* Part I.A (describing *Pegram*).

19. *See infra* text accompanying notes 79–83.

become more important to hold MCOs accountable for the quality of the information they provide, just as physicians are held accountable.

One way to achieve MCO accountability is to eliminate ERISA preemption of state law as applied to coverage determinations involving the exercise of medical judgment. This approach would subject medical necessity determinations to the scrutiny of tort law; suits like Davila's would be allowed to proceed. For medical necessity decisions based on purely medical criteria, this may be a desirable approach. As numerous scholars have pointed out, however, medical necessity determinations may reflect resource allocation decisions as well as the exercise of purely medical judgment.[20] This Article proposes a bifurcated regulatory regime under which only the medical information underlying discretionary exercises of medical judgment, not resource allocation decisions, would be subject to challenge under tort law.[21] The ultimate coverage decision, and the process used to reach it, would remain subject to ERISA's uniform regulatory framework.

Part I of this Article describes managed care organizations, the nature of litigation against them, and the effects of ERISA preemption. Part II traces the evolution of the roles of patients, physicians, and health insurers in the medical decisionmaking process, and explores the legal implications of this evolution. Part III considers how two recent trends in health care, an increased focus on information processing as a means of achieving health care quality and an increased emphasis on consumer participation in decisionmaking, might further affect these roles. It explains that both trends magnify the importance of MCO accountability for information provision. Part IV proposes that while MCO coverage denials based on express plan terms or cost-effectiveness

20. *See, e.g.*, PETER D. JACOBSON, STRANGERS IN THE NIGHT: LAW AND MEDICINE IN THE MANAGED CARE ERA 8–10 (2002) (commenting generally on the role of cost considerations in health plan and physician decisionmaking and noting that health plan administrators must weigh the impact of medical decisions for individual plan members on the availability of resources for the treatment of other members); E. HAAVI MORREIM, HOLDING HEALTH CARE ACCOUNTABLE 110–16 (2001) (exploring variant definitions and applications of medical necessity criteria and how they may affect members' access to services).

21. E. Haavi Morreim has forcefully argued that resource decisions should be subject to a contract regime, while decisions involving expertise should be subject to a tort regime. *See generally* MORREIM, *supra* note 20. The proposed bifurcated regime is supported by much of the reasoning that Morreim offers in her thorough analysis of her own proposal. It differs from Morreim's recommended legal regime, however, in its narrow focus on ensuring accountability through tort law only for MCOs' provision of medical information. *See infra* note 191.

determinations should continue to be subject to challenge only under ERISA, the medical information provided as part of the coverage determination process should be subject to tort suits. It argues that while the proposed regime would have some drawbacks, it would benefit patients in the short term by encouraging the dissemination of high-quality medical information, and in the long term by increasing awareness of MCO resource allocation decisions. Part V concludes by pointing out that this proposed bifurcated legal regime's emphasis on informational quality as a tool for enhanced decisionmaking is well-suited for an era of consumer-driven health care.[22]

I. MANAGED CARE LAWSUITS AND ERISA PREEMPTION

A. *Managed Care and ERISA Before* Davila

In the late 1980s and 1990s, millions of Americans enrolled in MCOs,[23] which sought to control the costs of care through selective contracting, negotiated payment rates, provider financial incentives, preauthorization requirements, utilization review, and other techniques.[24] During this period, the rate of growth in national health care expenditures slowed dramatically.[25] At the same time, however, MCO enrollees became increasingly wary of the effects of MCOs' cost-control mechanisms on health care choice and quality.[26] While managed care critics sought legislation to protect enrollees against

22. Relative to traditional managed care arrangements, "consumer-driven health care" features greater choice but increased financial responsibility. *See* John V. Jacobi, *Consumer-Directed Health Care and the Chronically Ill*, 38 U. MICH. J.L. REFORM 531, 543–47, 549–55 (2005) (describing consumer-directed health plans); Jon R. Gabel et al., *Employers' Contradictory Views About Consumer-Driven Health Care: Results from a National Survey*, HEALTH AFF. WEB EXCLUSIVE, Apr. 21, 2004, http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.210v1.pdf (defining consumer-driven health care). See *infra* Part III.B for further discussion of the recent expansion of the role of the consumer-enrollee-patient in the health care decisionmaking process.

23. *See* M. Susan Marquis & Stephen H. Long, *Trends in Managed Care and Managed Competition, 1993–1997*, 18 HEALTH AFF., Nov./Dec. 1999, at 75, 76 (noting the rapid growth in managed care enrollment in the late 1980s and 1990s).

24. *See* David A. Hyman, *Regulating Patient Care: What's Wrong with a Patient Bill of Rights*, 73 S. CAL. L. REV. 221, 228–29 (2000) (listing prevalent managed care practices).

25. *See* Marquis & Long, *supra* note 23, at 76; *see also* Aaron S. Kesselheim & Troyen A. Brennan, *The Swinging Pendulum: The Supreme Court Reverses Course on ERISA and Managed Care*, 5 YALE J. HEALTH POL'Y L. & ETHICS 451, 451 (2005) (suggesting that managed care led to a decrease in health care costs).

26. *See Leading Cases*, *supra* note 16, at 456, and the sources cited therein (describing managed care practices and the accompanying backlash).

practices they believed would erode the quality of care,[27] enrollees who believed they had been harmed by MCO practices sought remedies through the legal system.[28]

Many enrollees who took the lawsuit route soon found themselves facing a major roadblock: ERISA.[29] In addition to regulating pensions, this federal statute regulates employer-sponsored health benefit plans,[30] through which many Americans receive their health insurance coverage.[31] ERISA was intended both to guarantee individual beneficiaries the benefits they were promised and to encourage employers to promise benefits in the first place by minimizing the burden of administration, particularly for multistate employers.[32] To accomplish these goals simultaneously, ERISA section 514 expressly preempts state law related to benefit plans (thus allowing employers to avoid potentially inconsistent regulatory demands),[33] while ERISA section 502(a) provides a comprehensive federal remedial framework for beneficiaries who are denied benefits due.[34]

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27. *See generally* Frank A. Sloan & Mark A. Hall, *Market Failure and the Evolution of State Regulation of Managed Care*, 65 LAW & CONTEMP. PROBS. 169 (2002) (describing managed care regulations).

28. *See, e.g.*, Kesselheim & Brennan, *supra* note 25, at 453 ("[P]atients brought increasingly potent suits alleging harm by MCOs for denying them appropriate benefits.").

29. 29 U.S.C. §§ 1001–1461 (2000). For a description of ERISA's preemptive effects, see Korobkin, *supra* note 2, at 466–70. For a discussion of the history of ERISA litigation, see Jost, *supra* note 16, at W4-419 to -23.

30. *See* 29 U.S.C. § 1002 (defining "employee benefit plan" as "an employee welfare benefit plan or an employee pension benefit plan," and defining an "employee welfare benefit plan" to include "any plan, fund, or program . . . maintained by an employer . . . for the purpose of providing for its participants or their beneficiaries . . . medical, surgical, or hospital care or benefits"); *id.* § 1003 (defining ERISA's scope of coverage to include any "employee benefit plan").

31. In 2003, approximately sixty percent of the United States population (and more than eighty-five percent of the privately-insured population) received insurance coverage through their employers. CARMEN DENAVAS-WALT ET AL., U.S. CENSUS BUREAU, CURRENT POPULATION REPORTS, P60–226, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2003, 16 (2004), *available at* http://www.census.gov/prod/2004pubs/p60-226.pdf. Nationally, more than 140 million people are insured through ERISA plans. Mariner, *supra* note 16, at 1347.

32. *See, e.g.*, Korobkin, *supra* note 2, at 464–65 ("The primary purpose of the statute was to regulate private-sector pension plans at the federal level and thus guarantee the solvency and integrity of such plans for the benefit of employees . . . . By federalizing employee benefits law . . . ERISA's drafters sought to provide legal uniformity for employers that administrate benefit plans. Uniformity was intended to reduce the administrative cost and inconvenience to multistate employers . . . ." (citations omitted)); *see also infra* Part IV.C.2.

33. ERISA § 514, 29 U.S.C. § 1144.

34. *Id.* § 502(a), 29 U.S.C. § 1132(a). For example, ERISA section 502(a) permits a beneficiary to bring a civil action "to recover benefits due to him under the terms of his

While a comprehensive federal remedial framework might at first seem appealing to enrollees harmed by MCO wrongdoing, ERISA's remedial and preemption features together have proved a formidable obstacle to obtaining legal remedies for enrollees' injuries. In particular, the Supreme Court has established that ERISA's remedial framework does not permit consequential or punitive damages for denied benefits.[35] Thus, while an enrollee could sue under ERISA for an injunction ordering the provision of a benefit, or for reimbursement for a service financed by the enrollee after coverage was improperly denied by the plan,[36] the same enrollee could not recover under ERISA for harm caused by the MCO's improper denial or delay of coverage. For example, the enrollee could not recover for the increased medical costs or pain and suffering resulting from the failure to obtain care for which coverage was denied.

Because of this limitation on remedies available under ERISA, enrollees have often pursued state law remedies for their injuries. But soon after filing a suit in state court, they have had to confront the challenge of shielding themselves from ERISA's powerful preemptive effects.[37] Even if the enrollee-plaintiffs made only state law claims in their complaint (based on negligence, for example), defendants would argue based on Supreme Court precedent that the cause of action was essentially federal in nature, was completely preempted by ERISA, and was therefore removable to federal court.[38] Courts would often find that a cause of action dependent on

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plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan." *Id.* § 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B).

35. *See* Korobkin, *supra* note 2, at 469 (citing Mass. Mut. Life Ins. Co. v. Russell, 473 U.S. 134 (1985) and Mertens v. Hewett Assocs., 508 U.S. 248 (1993), among other cases, for the proposition that an employee denied a benefit due may not recover for consequential or punitive damages); *see also* John Langbein, *What ERISA Means by "Equitable": The Supreme Court's Trail of Error in* Russell, Mertens, *and* Great-West, 103 COLUM. L. REV. 1317 *passim* (2003) (discussing the cases in which the Supreme Court determined that ERISA prohibited compensation for consequential injury, and arguing that the Court's view of ERISA is in error because it fails to account for trust law's traditional make-whole remedial standard).

36. *See* Aetna Health Inc. v. Davila, 124 S. Ct. 2488, 2497 (2004).

37. *See, e.g.*, Korobkin, *supra* note 2, at 495–97 (describing tort litigation arising from utilization review decisions).

38. The Supreme Court has stated:

> Congress has clearly manifested an intent to make causes of action within the scope of the civil enforcement provisions of § 502(a) removable to federal court .... Accordingly, this suit, though it purports to raise only state law claims, is necessarily federal in character by virtue of the clearly manifested intent of Congress. It, therefore, 'arise[s] under the ... laws ... of the United States,' 28

a coverage denial was a claim within the scope of ERISA section 502(a) and therefore completely preempted.[39] Because section 502 was intended to serve as the exclusive remedial scheme for all benefits improperly denied, state attempts to supplement section 502 would be preempted.[40] Given the limits on damages available under ERISA, plaintiffs would then be left without a viable remedy, and their claims would be dismissed.[41]

Patient advocates looked for a way to work around the preemption problem. One way was to frame their state law claim not as a claim based on a denied benefit, but instead as a claim based on poor treatment. In *Dukes v. U.S. Healthcare*,[42] the plaintiff filed a negligence suit against a health maintenance organization ("HMO") in state court, arguing that it was vicariously liable for poor quality care provided by physicians and others, and that it was directly liable for its negligence in selecting providers.[43] The HMO removed the case to federal district court, arguing that the claims were completely

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U.S.C. § 1331, and is removable to federal court by the defendants, 28 U.S.C. § 1441(b).

Metro. Life Ins. Co. v. Taylor, 481 U.S. 58, 66–67 (1987); *see also Davila*, 124 S. Ct. at 2494–96 (discussing the complete preemption doctrine).

39. *See, e.g.*, Jass v. Prudential Health Care Plan, Inc., 88 F.3d 1482, 1485, 1488–90 (7th Cir. 1996) (recharacterizing a vicarious liability claim as a denied benefit claim and finding the claim completely preempted).

40. *See, e.g.*, Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355, 388 (2002) (Thomas, J., dissenting) ("This Court has repeatedly recognized that ERISA's civil enforcement provision, § 502 . . ., provides the exclusive vehicle for actions asserting a claim for benefits under health plans governed by ERISA, and therefore that state laws that create additional remedies are pre-empted."); *see also* Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 52, 57 (1987) (concluding that a plaintiff's state law claim was preempted under ERISA section 514(a) based in part on a finding that ERISA section 502(a) was the "exclusive vehicle for actions by ERISA-plan participants and beneficiaries asserting improper processing of a claim for benefits").

41. *See, e.g.*, DiFelice v. Aetna U.S. Healthcare, 346 F.3d 442, 452 (3d Cir. 2003) ("Because . . . DiFelice's claim that Aetna was negligent in determining that the special tube was 'medically unnecessary' could have been the subject of a suit under section 502(a) . . . his claim is preempted . . . . We will therefore affirm the District Court's exercise of removal jurisdiction and subsequent dismissal of the claim . . . ."); *Jass*, 88 F.3d at 1485 ("We conclude that Jass' state law negligence claim . . . and her vicarious liability claim . . . are within the scope of § 502(a) of ERISA and therefore completely preempted . . . . The district court also properly dismissed those claims because as written Jass failed to state a claim for which ERISA provides relief."); *see also* Corcoran v. United Healthcare, Inc., 965 F.2d 1321, 1339 (5th Cir. 1992) ("[W]e find that ERISA pre-empts the Corcorans' tort claim against United and that the Corcorans may not recover damages for emotional distress under § 502(a)(3) of ERISA. Accordingly, the judgment of the district court [summary judgment for the defendant] is affirmed.").

42. 57 F.3d 350 (3d Cir. 1995).

43. *Id.* at 352.

preempted under section 502(a).[44] The Third Circuit held, however, that the claims were not completely preempted. Because the claims challenged the quality of care provided and not the quantity of benefits received, they fell outside of the scope of section 502(a).[45] *Dukes* thus offered hope to MCO enrollees that if their claims challenged only the quality of care provided, they might be able to overcome the ERISA preemption hurdle. Overcoming this hurdle would not be easy, however. In particular, as the court acknowledged, it might be difficult to distinguish between the quantity and quality of benefits provided.[46]

The Supreme Court adopted language echoing that of the *Dukes* court in *Pegram v. Herdrich*,[47] a case concerning the nature of ERISA plans' fiduciary duties.[48] The plaintiff's appendix ruptured after her physician, a part owner of her HMO, recommended a test at a distant location where services would not be available until after a considerable delay.[49] The plaintiff prevailed on a malpractice claim against the physician, but also alleged that her HMO had breached its fiduciary duty under ERISA by instituting financial incentives to limit care.[50] The Court rejected this claim on the ground that the decision she questioned was not fiduciary in nature.[51] In reaching its decision, the Court distinguished "eligibility decisions," such as whether a plan covers acupuncture, from "treatment decisions," such as which treatment would be appropriate for a person with particular symptoms.[52]

While the eligibility/treatment distinction sounds much like the *Dukes* quantity/quality distinction, the Supreme Court went one step further than the *Dukes* court by creating a third category for "mixed eligibility and treatment" decisions.[53] Mixed decisions could not properly be classified as solely "eligibility" or solely "treatment"

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44. *Id.* at 352–53.

45. *Id.* at 356–57. After finding that the plaintiffs' claims were not completely preempted, the court instructed the district court to remand the case to the state court. The Third Circuit left open the possibility, however, that the state court might still find the plaintiffs' negligence claims preempted under ERISA section 514. *See id.* at 361.

46. *Id.* at 358–59.

47. 530 U.S. 211 (2000).

48. *Id.* at 214.

49. *See id.* at 215 ("Dr. Pegram did not order an ultrasound diagnostic procedure at a local hospital, but decided that Herdrich would have to wait eight more days for an ultrasound, to be performed at a facility . . . more than 50 miles away.").

50. *Id.* at 215–17.

51. *Id.* at 237.

52. *See id.* at 228.

53. *See id.* at 229.

decisions because they were in fact both. The decision at issue in *Pegram* was such a decision. The physician made a judgment that immediate treatment was not required, and thus dictated the result that immediate treatment would not be covered.[54] The Court concluded that mixed decisions were not fiduciary in nature, thus preventing a flood of fiduciary duty claims that could have destroyed the incentive-based HMO model of care.[55]

The part of the decision most intriguing for those frustrated with enrollees' lack of remedies under ERISA, however, was dicta offering a justification for the Court's refusal to find mixed decisions fiduciary.[56] If mixed decisions were fiduciary and subject to ERISA claims, then a defendant might try to show that it had fulfilled its fiduciary duties by demonstrating that it had complied with the medical standard of care. The ERISA suit would therefore resemble a traditional malpractice action in state court. The resemblance would be even more striking if the suit were brought against not just the HMO, which bears the ultimate responsibility for the mixed decision, but also the physician-employee who acted as a fiduciary when making the mixed decision on behalf of the HMO. The possibility of a physician defendant is troubling because if ERISA litigation requires scrutiny of a physician's compliance with the standard of care, ERISA's provisions preempting laws related to employee benefit plans[57] would seem to mandate the preemption of state malpractice law.[58] The Supreme Court also noted, however, that "in the field of health care, a subject of traditional state regulation, there is no ERISA preemption without clear manifestation of congressional purpose."[59] By rejecting the argument that mixed decisions were fiduciary decisions, the Supreme Court avoided the possibility of this sort of preemption. At the same time, it left open the possibility that enrollees harmed by an MCO's mixed eligibility and treatment decision could escape the effects of ERISA preemption by bringing an action in state court alleging that the MCO had provided substandard treatment.

54. *Id.* at 229–30.

55. *Id.* at 232–34.

56. *See id.* at 235–37.

57. ERISA § 514, 29 U.S.C. § 1144 (2000).

58. *See Pegram*, 530 U.S. at 236 ("On its face, federal fiduciary law applying a malpractice standard would seem to be a prescription for preemption of state malpractice law, since the new ERISA cause of action would cover the subject of a state-law malpractice claim.").

59. *Id.* at 237.

B. *The* Davila *Case*

The Supreme Court's reasoning in *Pegram* became the basis for the appeals court decision that was ultimately reversed by *Davila.* The *Davila* case resulted from the consolidation of the suits of Juan Davila and Ruby Calad. Davila, who was afflicted with arthritis, received a prescription for Vioxx from his primary care physician.[60] Vioxx has been shown to cause fewer gastrointestinal problems (such as bleeding) than other painkillers.[61] The rules of Davila's Aetna HMO, however, required him to try two alternatives to Vioxx before it would approve coverage for Vioxx, unless medical necessity required otherwise.[62] After taking one of the alternative painkillers,

60. Aetna Health Inc. v. Davila, 124 S. Ct. 2488, 2493 (2004).

61. *See* Claire Bombardier et al., *Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis*, 343 NEW ENG. J. MED. 1520 *passim* (2000) (reporting the results of a randomized trial comparing gastrointestinal events in patients receiving Vioxx to those in patients receiving naproxen (the generic form of Naprosyn)); Press Release, FDA, FDA Approves New Indication and Label Changes for the Arthritis Drug, Vioxx (Apr. 11, 2002), http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01145.html (announcing FDA approval of label text concerning risk of gastrointestinal events based on the Vioxx Gastrointestinal Outcomes Research (VIGOR) study). Neither of these documents had been published before the spring of 2000, when Juan Davila was prescribed Vioxx, Brief of Appellant Juan Davila at 6, Roark v. Humana, Inc., 307 F.3d 298 (5th Cir. 2002) (No. 01-10905), and Vioxx had been approved only the year before, *see* FDA, DRUG APPROVALS FOR MAY 1999 (June 11, 1999), http://www.fda.gov/cder/da/da0599.htm. Researchers and physicians were generally aware of the potential gastrointestinal benefits of Vioxx before 2000, however. *See, e.g.*, Michael J. Langman et al., *Adverse Upper Gastrointestinal Effects of Rofecoxib Compared with NSAIDs*, 282 JAMA 1929, 1931–32 (1999) (finding that Vioxx had fewer adverse gastrointestinal effects than nonsteroidal anti-inflammatory drugs such as ibuprofen). The same comparative study that supported the FDA's approval of label text concerning the beneficial gastrointestinal effects of Vioxx showed early evidence of Vioxx's problematic cardiovascular effects; in 2004, after a more definitive study, Merck withdrew Vioxx from the market. *See* David H. Solomon & Jerry Avorn, Editorial, *Coxibs, Science, and the Public Trust*, 165 ARCHIVES INTERNAL MED. 158, 158 (2005). While some experts continue to believe that naproxen may present fewer cardiovascular risks than Vioxx, *see, e.g.*, Bridget M. Kuehn, *FDA Panel: Keep Cox-2 Drugs on Market*, 293 JAMA 1571, 1571 (2005), recent studies have associated naproxen with cardiovascular risks, *see, e.g.*, Soren P. Johnsen et al., *Risk of Hospitalization for Myocardial Infarction Among Users of Rofecoxib, Celecoxib, and Other NSAIDs*, 165 ARCHIVES INTERNAL MED. 978, 983 (2005) (reporting results of a study of the relationship between nonaspirin nonsteroidal anti-inflammatory drugs and myocardial infarction). The FDA has become concerned that the cardiovascular effects of Vioxx may be attributable to a broader class of drugs that includes naproxen. *See* Memorandum from John K. Jenkins, Director, Office of New Drugs, and Paul J. Seligman, Director, Office of Pharmacoepidemiology and Statistical Science, to Steven Galson, Acting Director, Center for Drug Evaluation and Research 2 (Apr. 6, 2005), http://www.fda.gov/cder/drug/infopage/COX2/NSAIDdecisionMemo.pdf.

62. See Aetna's Member Medication Formulary Guide, January 2000, which describes Aetna's "step-therapy" program:

Naprosyn, Davila was admitted to a hospital's critical care unit for bleeding ulcers and internal bleeding.[63]

Like Davila, Calad suffered an injury after her HMO intervened in her care. Calad was admitted to the hospital for a hysterectomy. Her physician recommended an extended post-operative hospital stay, but a CIGNA nurse determined that a one-day stay in the hospital was sufficient.[64] Calad was discharged but later readmitted with complications that allegedly stemmed from her early discharge.[65]

In both cases, the plaintiffs claimed that they had suffered injury as a result of MCO actions that conflicted with the recommendations of their treating physicians. More specifically, the plaintiffs brought suits under the Texas Health Care Liability Act ("THCLA"), which established that HMOs had a duty of ordinary care with respect to health care treatment decisions.[66] They argued that their HMOs had failed to exercise ordinary care in making medical necessity decisions and that this failure resulted in their injuries.[67]

The Fifth Circuit relied on the language of *Pegram* in determining that Davila's and Calad's claims were not preempted under ERISA. First, the court determined that the plaintiffs' disputes involved mixed eligibility and treatment decisions.[68] The disputed HMO actions were not pure eligibility decisions about the availability of coverage for Vioxx or hospital stays in general; instead, they were coverage determinations based on the MCOs' judgments about whether Davila had received the proper medication or whether Calad

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> If step-therapy applies to your benefit plan, you must try one or more 'prerequisite therapy' medications before a 'step-therapy' medication will be covered. However, if it is medically necessary for you to be initially treated with a step-therapy medication, your doctor can contact the Pharmacy Management Precertification Unit to request coverage as a medical exception.

Brief for Petitioner Aetna Health Inc. at 8, *Davila*, 124 S. Ct. 2488 (No. 02-1845) (citing Joint Appendix at 34a, *Davila*, 124 S. Ct. 2488 (No. 02-1845)).

63. *See* Roark v. Humana, Inc., 307 F.3d 298, 303 (5th Cir. 2002), *rev'd sub nom.* Aetna Health Inc. v. Davila, 124 S. Ct. 2488 (2004).

64. *Id.* at 302.

65. *Id.*

66. TEX. CIV. PRAC. & REM. CODE ANN. §§ 88.001–88.003 (Vernon 2004) (effective Sept. 1, 1997). Section 88.002(a) states that a "health insurance carrier, health maintenance organization, or other managed care entity ... has the duty to exercise ordinary care when making health care treatment decisions and is liable for damages for harm to an insured or enrollee proximately caused by its failure to exercise such ordinary care."

67. *Roark*, 307 F.3d at 302–03.

68. *Id.* at 307.

had spent enough days in the hospital.[69] The mixed character of the decisions meant that they could not be fiduciary decisions under the reasoning of *Pegram*. As a result, the plaintiffs' claims could not be preempted under section 502(a)(2) of ERISA, which imposes liability for breach of fiduciary duty.[70] Furthermore, the court determined that section 502(a)(1)(B), which permits suits to recover benefits due, had no preemptive effect because the plaintiffs' claims were tort claims rather than contract claims.[71] In addition to citing *Dukes* for the proposition that claims against an HMO for failure to exercise reasonable care were not preempted,[72] the court cited *Pegram*: "[a]ny doubts we might have [about the conclusion that the THCLA is not preempted] are eliminated by *Pegram*'s admonition that ERISA should not be interpreted to preempt state malpractice laws or to create a federal common law of medical malpractice."[73]

In a unanimous opinion, the Supreme Court reversed the Fifth Circuit's decision, holding that the plaintiffs' causes of action were preempted.[74] The Court explained that "if an individual, at some point in time, could have brought his claim under ERISA section 502(a)(1)(B) and where there is no other independent legal duty that is implicated by a defendant's actions, then the individual's cause of action is completely pre-empted by ERISA section 502(a)(1)(B)."[75] While Davila and Calad might have argued that THCLA imposed an independent legal duty to exercise ordinary care in treatment decisions, this duty was not truly independent because it applied only to care covered under plan terms.[76] As a result, the plaintiffs were left

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69. *Id.*

70. *See id.* at 306–08. ERISA section 502(a)(2), 29 U.S.C. § 1132(a)(2), allows civil actions under § 1109 of the same title, which says in part that "[a]ny person who is a fiduciary with respect to a plan who breaches any of the responsibilities . . . imposed upon fiduciaries by this subchapter shall be personally liable to make good to such plan any losses to the plan resulting from each such breach." 29 U.S.C. § 1109.

71. *See Roark*, 307 F.3d at 308–11. ERISA section 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B), permits suits to recover benefits due, enforce rights, or clarify rights to future benefits under the terms of a plan.

72. *Roark*, 307 F.3d at 309–10.

73. *Id.* at 311.

74. *See* Aetna Health Inc. v. Davila, 124 S. Ct. 2488, 2502 (2004) (finding the plaintiffs' causes of action preempted under ERISA section 502(a)(1)(B)). The Supreme Court declined to consider whether the causes of action might also be preempted under ERISA section 502(a)(2). *See id.* at 2494 n.1.

75. *Id.* at 2496.

76. *See id.* at 2497–98. THCLA provides that the standards imposed under the statute "create no obligation on the part of the health insurance carrier, health maintenance organization, or other managed care entity to provide to an insured or enrollee treatment which is not covered by the health care plan of the entity." TEX. CIV. PRAC. & REM.

with what was effectively a claim alleging wrongful denial of benefits due under the plan, a claim that falls within the scope of section 502(a)(1)(B). The Court found that it did not matter that the plaintiffs chose to allege tort claims, or that the remedies they sought would not be available under ERISA.[77] Congress intended to make ERISA's remedial scheme exclusive, so state causes of action supplementing remedies available under ERISA were impermissible.[78]

The Supreme Court also rejected the use of *Pegram*'s reasoning in support of a conclusion that the plaintiffs' claims were not preempted.[79] It explained that discretionary benefit determinations under ERISA were fiduciary acts, even if they involved the exercise of medical judgment.[80] The Court clarified that it was not the exercise of medical judgment in *Pegram* that meant that the challenged decision was a mixed eligibility and treatment decision; a decision involving medical judgment was not the same thing as a treatment decision.[81] Instead, the decisions in *Pegram* were "truly 'mixed eligibility and treatment decisions' "[82] because the medical necessity decisions were "made by the plaintiff's treating physician *qua* treating physician and *qua* benefits administrator."[83] By contrast, the decisions at the heart of the plaintiffs' suits in *Davila* were made by their health plans, not by their treating physicians or their physicians' employer, and therefore could only be eligibility decisions. Because no treatment decisions were implicated in the Davila or Calad cases, the reasoning of *Pegram* did not apply.[84]

C. *Treatment and Eligibility in an ERISA Framework*

Davila's and Calad's THCLA claims had been premised on the assertion that their MCOs had made treatment decisions; the duty of ordinary care imposed by the THCLA applied to "health care treatment decisions," not eligibility decisions.[85] In their Supreme Court brief, Davila and Calad suggested that the impetus for the

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CODE ANN. § 88.002(d) (Vernon 2004); *see infra* notes 145–49 and accompanying text for further discussion of the independent legal duty issue.

77. *See Davila*, 124 S. Ct. at 2498–2500.
78. *Id.* at 2499–2500.
79. *Id.* at 2500–02.
80. *Id.* at 2501–02.
81. *Id.*
82. *Id.* at 2502 (citing Pegram v. Herdrich, 530 U.S. 211, 229 (2000)).
83. *Id.*
84. *Id.* at 2502.
85. *See supra* note 3 and accompanying text.

Texas statute was the lack of traditional malpractice protection for "a patient whose treatment was in practice being shaped, not by his or her doctor, but by the entity engaging in utilization review."[86] They argued that the Texas Legislature intended to address the situation where "the patient-insured follows the course of treatment charted—and in many instances controlled—by his or her HMO, and the HMO's decision ends up being a medically imprudent one that causes significant harm."[87] Consistent with this theory, Calad's original petition to the state court alleged that "[m]edical services were actually provided to Plaintiffs by the Defendants: they controlled, influenced, participated in, and made medical necessity decisions which affected the quality of the diagnosis[,] care, and treatment provided to Plaintiffs, violating the duty of ordinary care set forth in §§ 88.001 and 88.002."[88]

In other words, Davila and Calad argued that their health plans themselves made treatment decisions by *influencing* the care provided. The Texas statute contemplates the MCO role as an entity that influences care: in part, it defines a "health care treatment decision" as one that "affects the quality of the diagnosis, care, or treatment provided to the plan's insureds or enrollees."[89] Even if the MCO did not directly provide care or employ an enrollee's treating physician, it might become liable under the Texas statute for the care ultimately provided to the enrollee because of its role in altering that care.[90] In *Davila*, MCO determinations that the sought-after care was not medically necessary ultimately resulted in Davila taking Naprosyn rather than Vioxx and in a shorter hospital stay for Calad. The

86. Brief for Respondents at 4, *Davila*, 124 S. Ct. 2488 (Nos. 02-1845 & 03-83).

87. *Id.* at 2. During the Supreme Court oral arguments, David C. Mattax, Assistant Attorney General for Texas, stated that "[t]he reason the Texas statute was passed was because managed care entities, HMOs and other varieties and forms, had decided to exercise medical judgment. And it is that duty that the state is regulating." Transcript of Oral Argument at 39, *Davila*, 124 S. Ct. 2488 (Nos. 02-1845 & 03-83), *available at* http://www.supremecourtus.gov/oral_arguments/argument_transcripts/02-1845.pdf.

88. Joint Appendix at 187, *Davila*, 124 S. Ct. 2488 (No. 02-1845).

89. TEX. CIV. PRAC. & REM. CODE ANN. § 88.001(5) (Vernon 2004).

90. Under the Texas statute, a "health care treatment decision" is a "determination made when medical services are actually provided by the health care plan and a decision which affects the quality of the diagnosis, care, or treatment provided to the plan's insureds and enrollees." *Id.* The "determination made when medical services are actually provided by the health care plan" language arguably could be interpreted to require direct MCO involvement in the provision of care. The proper interpretation of this language is unclear, however. In particular, it is not clear what it means for a "health care plan" (as opposed to a "managed care entity," another defined term within the statute, *id.* § 88.001(8)) to "actually provide[]" services. Nor is it clear if this part of the definition is relevant when an MCO's decision affects the quality of care provided.

plaintiffs alleged that these changes in their course of treatment, changes that stemmed from their MCOs' actions, resulted in their injuries.[91]

The precise mechanisms by which the medical necessity determinations might have influenced the plaintiffs' care are mentioned but not fully explored in the parties' briefs. Davila's Supreme Court brief argued that after "Aetna insisted, as a medical-necessity decision, that Davila first receive a generic substitute for Vioxx .... [H]e could not even get his pharmacy to fill the prescription [for Vioxx]."[92] This contention, which implies that Aetna somehow had direct control over whether a prescription issued by Davila's physician would be filled, was rejected by Aetna; it is not clear how Aetna could have exercised such control, if Davila had offered to pay for the Vioxx himself.[93] Calad similarly emphasized her insurer's degree of control: "Ruby Calad was prematurely forced out of the hospital by CIGNA's discharge nurse . . . ."[94]

But Calad's arguments also acknowledged the effect of another factor that influenced her course of treatment: her financial condition. Calad's Supreme Court brief alleged that "her financial condition did not make days of appeal feasible,"[95] while her petition stated that she "was unable to incur the expense personally" for an extension of her hospital stay.[96] The Supreme Court oral arguments also highlighted the role of financial constraints in determining care:

> *Question*: But to say that the plan condemned them to not using Vioxx is simply not true. All you're talking about here is money. The claimant didn't want to lay out the additional money for the Vioxx.
>
> *Mr. Young* [George P. Young, counsel for respondents Calad and Davila]: Well, the truth is, Your Honor, that neither of these claimants would have needed health insurance if they had

91. Brief for Respondents, *supra* note 86, at 4–6.

92. *Id.* at 6.

93. Aetna stated: "Davila remained free to have the Vioxx prescription filled at his own expense . . . Nothing in the record—or in common sense or experience—suggests that the *pharmacist* would not 'fill' (*i.e.*, dispense) a valid prescription provided that Davila agreed to pay for it . . . ." Reply Brief for Petitioner Aetna Health Inc. at 4–5 n.5, Aetna Health Inc. v. Davila, 124 S. Ct. 2488 (2004) (No. 02-1845).

94. Brief for Respondents, *supra* note 86, at 5.

95. *Id.*

96. Joint Appendix, *supra* note 88, at 181.

> the independent means to just whip out a gold card and pay for the drug.[97]

Thus, while some of the language in court documents suggests that the MCOs exercised direct control over their enrollees' course of treatment,[98] other statements in Calad's brief and the oral arguments suggest that the real source of the MCOs' influence was the combination of their denial of coverage and the financial limitations that precluded or discouraged the plaintiffs from financing their own care. The plaintiffs wanted to follow their physicians' treatment advice, but could not. From an ERISA perspective, the trouble with this scenario is that the plaintiffs' claims depend on the denial of coverage. Since ERISA is supposed to provide a comprehensive remedial framework for those improperly denied coverage, it seems entirely reasonable to conclude that such claims must be preempted by ERISA.

But what if the MCOs' denial of coverage did not cause the plaintiffs' injuries? What if MCOs' influence over their enrollees' treatment were to emanate not from the financial consequences of their coverage determinations, but instead from their provision of information to enrollees? The more direct that MCOs' influence over enrollees becomes—the less that MCOs' influence is mediated through financial mechanisms or the decisions of contracting providers—the more that MCOs begin to resemble treating physicians. The closer the resemblance, the weaker the logic of *Davila* (that treating physicians make treatment decisions, but MCOs do not), and the stronger the justification for treating MCOs like other health care providers rather than just payers in assessing liability.

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97. Transcript of Oral Argument, *supra* note 87, at 25.

98. In addition to the statements implying direct MCO influence, *see supra* text accompanying notes 92–94, the plaintiffs argued that the MCOs' control might extend to affiliated entities: "Through their contracts with providers, HMOs often require that doctors, hospitals, and pharmacies in their provider networks 'comply' or 'cooperate' with the HMO's medical necessity decisions .... In many instances the hospital or other provider may refuse to provide the treatment until the HMO gives the green light ...." Brief for Respondents, *supra* note 86, at 3. It seems unlikely that a provider would refuse to provide treatment it had previously recommended, however, if a patient were to agree to fund the care. In such a case, it is once again financial constraints, rather than the MCO's direct control over treating providers, that influences the patient's course of treatment.

II. PATIENT, PHYSICIAN, AND PLAN ROLES IN THE TREATMENT PROCESS

A. *Who Makes Treatment Decisions?*

To assess the degree of resemblance between MCOs and treating physicians in their interactions with patients, it is important to understand the nature of the treatment process. Variations on the word "treat" appear frequently in court opinions in ERISA health benefit cases; discussion of "treatment" and "treatment decisions" proliferated after *Pegram*.[99] The precise definition of these terms, however, is unclear. A dictionary, for example, defines "treat" as "to care for or deal with medically or surgically."[100] But what exactly is involved in "caring for" or "dealing with"?

One way to give more content to the term "treatment" is to consider the myriad tasks of today's "treating physician," the physician who "cares for" or "deals with" a particular patient. When a patient arrives at a physician's office seeking treatment for a specific health problem, the physician will collect whatever information may be necessary, including a description of the nature of the problem and the patient's medical history. The physician may physically examine the patient, and then may recommend and/or perform tests to collect additional information. On the basis of all of the information collected, the physician may formulate a diagnosis of the patient's problem. The treating physician may provide information about potential medical or surgical responses to the health problem, offering a brief assessment of the merits and drawbacks of each alternative, and may make a recommendation about the best course of action. The physician may write a prescription or perform a surgery. Throughout this process, physicians exercise medical judgment, using their medical knowledge and experience to determine which question to ask, which diagnostic procedure to order, which step to take during surgery.[101]

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99. For example, an August 2005 search in Westlaw's ALLFEDS database using the search terms "ERISA" and "treatment decision" identified eighteen pre-*Pegram* opinions containing these terms. In contrast, it identified sixty-three such opinions in the years following the 2001 *Pegram* decision.

100. *See* MERRIAM-WEBSTER ONLINE, http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=treat&x=0&y=0 (last visited Dec. 5, 2005).

101. Professor Morreim emphasizes that "the heart and soul of medicine as a learned profession is judgment," and describes the many actions of physicians that involve medical judgment. E. Haavi Morreim, *Playing Doctor: Corporate Medical Practice and Medical Malpractice*, 32 U. MICH. J.L. REFORM 939, 962 (1999).

Yet, by focusing on the tasks of the treating physician, this description obscures the roles that others, including patients and health plans, may play in the treatment process as a whole. These roles, and indeed the treatment process itself, have evolved over time. In particular, while physicians have always guided the treatment process, participation of both patients and plans has expanded.

Fifty years ago, insurer involvement in the treatment process was minimal. The role of the indemnity insurer was often limited to reimbursing patients for payments the patients had made directly to their physicians.[102] Insurers generally did not question the nature of care that had been provided; they simply paid the physician charges reflected in the claim that had been submitted.[103] Insurers eventually required that care provided be "medically necessary" to be reimbursable, but the term had limited practical effect on the course of treatment, both because many courts interpreted the term to accommodate whatever care the treating physician recommended,[104] and because the determination was made only after the treatment was provided.[105]

Patients' involvement in determining the course of treatment was also once quite limited. Patients have always participated in the treatment process by seeking physicians' medical and surgical services and following physician advice, but this form of participation does not necessarily entail significant control over treatment decisionmaking. Traditionally, physicians tended to give patients little information about the treatment process, and "were often accused of paternalism—making decisions on behalf of their patients . . . ."[106] In the 1970s, however, the development of the doctrine of informed consent elevated the patient's role. Courts began to require that physicians provide information about a variety of factors, including the patient's diagnosis and the nature, purpose, risks, and likely outcomes of a particular treatment and its feasible alternatives,

102. *See* Jeffrey E. Shuren, *Legal Accountability for Utilization Review in ERISA Health Plans*, 77 N.C. L. REV. 731, 735–37 (1999) (describing insurance plans before the 1980s).

103. *See* MORREIM, *supra* note 20, at 4 (commenting on reimbursement practices and the economics of health care between the 1950s and the 1980s).

104. *See* JACOBSON, *supra* note 20, at 43 (describing courts' treatment of medical necessity provisions).

105. *See* Morreim, *supra* note 101, at 965–66 n.65 (explaining the differing implications of prospective and retrospective review for a patient's course of treatment).

106. JACOBSON, *supra* note 20, at 53; *see also* BARRY R. FURROW ET AL., HEALTH LAW § 6-9, at 311 (2d ed. 2000) ("The function of disclosure historically was to get patients to agree to what the doctors wanted.").

before obtaining consent from a patient to perform medical procedures.[107]

The emergence of the informed consent doctrine highlighted the role of the physician as information provider and the role of the patient as decisionmaker. With the information they receive through the informed consent process, patients can participate in determining the course of their own care in a much more meaningful way.[108] By encouraging the dissemination of information, the informed consent doctrine increases the autonomy of patients. It also introduces a new perspective on the term "treatment decision," which *Pegram* and *Davila* attribute to physicians (who make "choices about how to go about diagnosing and treating a patient's condition"[109]) and the THCLA attributes to MCOs (which make decisions that "affect[] the quality of the diagnosis, care, or treatment provided to the plan's . . . enrollees").[110] It is certainly true that physicians regularly exercise medical judgment during the treatment process without input from patients (by deciding which questions to ask, which treatment alternatives to recommend, or which surgical steps to take, for example), and that MCOs regularly make decisions that affect care (by denying coverage, for example). But the essence of the notion of consent is that it is ultimately the patient who makes the treatment decision; it is the patient who decides whether to pursue a given course of treatment by following up on a referral, undergoing a diagnostic test or surgery, taking a drug, or adhering to medical advice.[111] The courts' embrace of the informed consent doctrine[112] has arguably altered the treatment process by amplifying the importance of information provision and increasing the likelihood of meaningful participation by patients.

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107. *See* FURROW ET AL., *supra* note 106, § 6-11 (describing factors to be disclosed); JACOBSON, *supra* note 20, at 53 (describing the development and application of the doctrine of informed consent).

108. For a discussion of the theoretical benefits and practical shortcomings of the informed consent process, see generally Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899 (1994). *See also* Jan Hoffman, *Awash in Information, Patients Face a Lonely, Uncertain Road*, N.Y. TIMES, Aug. 14, 2005, at A1 (describing the increase in information provided to and sought by patients, and the difficulties they face in making decisions about their own care).

109. Pegram v. Herdrich, 530 U.S. 211, 228 (2000).

110. *See supra* note 89 and accompanying text.

111. *See* MORREIM, *supra* note 20, at 108 (explaining the role of the patient in the treatment process).

112. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772, 782 (D.C. Cir. 1972) ("We now find, as a part of the physician's overall obligation to the patient, a . . . duty of reasonable disclosure of the choices with respect to proposed therapy and the dangers inherently and potentially involved.").

The growth of managed care in the late 1980s and 1990s further altered the treatment process by increasing the participation of health insurers.[113] Trying to stem the rapid growth of health care costs, health care payers adopted a variety of mechanisms designed to change the way that care was provided.[114] One such mechanism was utilization review.[115] No longer willing to pay after the fact for whatever care a physician deemed appropriate, MCOs began to actively evaluate medical necessity as a condition of coverage for care, before the care was provided. The possibility that a plan might ultimately deny reimbursement for a particular type of care through a process of retrospective utilization review, forcing patients and/or physicians to absorb the costs for care that had already been provided, would naturally tend to deter the provision of the care. The prospective utilization review methods favored by MCOs would further strengthen the plans' influence by informing physicians and patients in advance of treatment about whether reimbursement would be denied. A patient apprised about the financial consequences of a medical treatment might choose not to proceed. While this "treatment decision" is ultimately made by the patient, not the MCO, the potential influence of the MCO's refusal to provide financing on the patient's course of treatment is clear.

When a denial of coverage is based on the exercise of medical judgment, however, the MCO's influence may extend beyond that associated with the financing of care. In making determinations of medical necessity, the MCO evaluates information specific to an individual patient's condition. According to the Certificate of Coverage that Aetna provided to Davila, for example, in determining whether a requested service was medically necessary, the medical director was supposed to consider not only the opinion of the patient's physicians, but also information on the patient's health status, reports in peer-reviewed literature, reports by nationally recognized health care organizations, professional standards, the opinions of health professionals, and other relevant information.[116]

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113. *See supra* Part I.A.

114. *See id.*

115. *See* Shuren, *supra* note 102, at 737–48 (describing payer cost-containment techniques and prospective and retrospective utilization review). As used in this Article, the term "utilization review" refers to the process by which payers (including MCOs) determine whether to pay for medical services that have been recommended for or provided to a particular patient. *See, e.g., id.* at 740 (defining "utilization review" as "the process whereby patients' needs are evaluated in light of objective criteria to determine whether to pay for an individual's medical care").

116. Joint Appendix, *supra* note 88, at 55.

Thus, while an MCO utilization reviewer is unlikely to replicate the myriad tasks of a treating physician—the reviewer may never take the patient's history, or physically examine the patient, or provide surgical services—in theory, the reviewer evaluates the patient's need for care much as a physician would.[117] The recent settlement of a class action suit by physicians who had contracted with Aetna further highlights the resemblance between utilization reviewers' and physicians' tasks by requiring that medical necessity be defined in part as "health care services that a Physician, exercising prudent clinical judgment, would provide to a patient."[118] In other words, the utilization reviewer is expected to use criteria that would generate a necessity determination consistent with the result that would be reached by a physician exercising medical judgment in an individual patient's case. Ultimately, MCO reviewers and treating physicians both exercise medical judgment in performing their duties.

B. *The Legal Implications of MCO Influence on the Treatment Process*

Many commentators have suggested that the MCOs' exercise of medical judgment during the utilization review process should remove MCOs from the protection of ERISA preemption and subject them to state tort liability.[119] In fact, the pre-*Davila* Second Circuit

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117. *See, e.g.*, William M. Sage, *Managed Care's Crimea: Medical Necessity, Therapeutic Benefit, and the Goals of Administrative Process in Health Insurance*, 53 DUKE L.J. 597, 603 (2003) (describing health plans' varying approaches to coverage decisions and observing that "[t]hrough both internal discussion and delegation to physician groups, managed care seems to be evolving a quasi-medical model for what used to be considered a decision about the business of insurance").

118. Settlement Agreement, by and among Aetna, Inc., The Representative Plaintiffs, The Signatory Medical Societies and Class Counsel (May 21, 2003), http://www.aetna.com/legal_issues/pdf_documents/settlement.pdf.

119. *See, e.g.*, Peter D. Jacobson & Scott D. Pomfret, *Form, Function, and Managed Care Torts: Achieving Fairness and Equity in ERISA Jurisprudence*, 35 HOUS. L. REV. 985, 1063–67 (1998) (noting that utilization review requires individualized medical judgment and proposing a functional analysis-based ERISA preemption framework under which claims stemming from utilization review decisions would not be preempted); Wendy K. Mariner, *Slouching Toward Managed Care Liability: Reflections on Doctrinal Boundaries, Paradigm Shifts, and Incremental Reform*, 29 J. L. MED. & ETHICS 253, 268 (2001) ("If MCOs do in fact exercise judgment about the appropriate type of care to provide or who should provide it, they should be held responsible for negligence in making that determination."). Other commentators have examined the role of medical decisionmaking in ERISA preemption analysis. *See, e.g.*, Phyllis C. Borzi, *Distinguishing Between Coverage and Treatment Decisions Under ERISA Health Plans: What's Left of ERISA Preemption?*, 49 BUFF. L. REV. 1219, 1271 (2001) (arguing that *Pegram* implied that plan decisions premised on medical judgment were subject to state law); Jordan, *supra* note 6, at 415–32 (explaining the role of medical decisionmaking in benefit

decision in *Cicio v. Does*[120] took just such an approach.[121] The treating physician in the case had requested HMO approval for a tandem stem cell transplant for a patient who had blood cancer.[122] The HMO's medical director initially rejected the request on the basis that the procedure was experimental or investigational and therefore not covered.[123] In response to the treating physician's appeal, the medical director once again rejected the request, but this time approved a single stem cell transplant.[124] The patient died soon after the HMO's decision was issued.[125] The patient's wife brought a malpractice claim against the HMO in state court, and the defendants removed to federal court, arguing that the claim was preempted by ERISA.[126] In analyzing the preemption argument, the court noted that utilization review involved the exercise of medical judgment, and that the decisions made could potentially determine the patient's course of care.[127] Citing *Pegram*, the court classified the HMO's decision as a "mixed decision because it allegedly involved both an exercise of medical judgment and an element of contract interpretation," and it held that the plaintiff's tort claim was not preempted.[128]

As previously discussed,[129] the Supreme Court rejected this reasoning in *Davila*, and the Second Circuit vacated its opinion soon after *Davila* was decided.[130] The fact that a medical necessity determination involved the exercise of medical judgment is irrelevant to the ERISA analysis when the judgment occurs during the course of a coverage determination made by the MCO itself. If, as in *Pegram*, the treating physician simultaneously exercises medical judgment and makes an eligibility decision, then there is a mixed eligibility and treatment decision, but when the MCO performs similar tasks, there is only an eligibility decision.[131] The Supreme Court cited the dissent in *Cicio* in support of this conclusion: "the reasoning of *Pegram* 'only

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determinations and the implications of this role for (pre-*Davila*) ERISA preemption analysis).

120. 321 F.3d 83 (2d Cir. 2003), *vacated per curiam*, 385 F.3d 156 (2d Cir. 2004).
121. *Id.* at 104.
122. *Id.* at 87.
123. *Id.* at 88.
124. *Id.*
125. *Id.*
126. *Id.* at 88–89.
127. *Id.* at 98–99.
128. *Id.* at 102, 104.
129. *See supra* Part I.B.
130. Cicio v. Does, 385 F.3d 156 (2d Cir. 2004) (per curiam).
131. *See supra* text accompanying notes 79–83.

make[s] sense where the underlying negligence also plausibly constitutes medical maltreatment by a party who can be deemed to be a treating physician or such a physician's employer.' "[132] The dissent in *Cicio* had elaborated on this argument by explaining that when the alleged negligence does not constitute malpractice by a treating physician, "there is no apparent reason ... for treating the unlawful coverage decision any differently from any other unlawful coverage decision that is *not* based on medical error."[133]

To the extent that claims like those of Davila and Calad stem from injuries caused by the MCOs' denial of payment, this argument has considerable appeal. From the perspective of such plaintiffs, the reason for the denial of payment is completely irrelevant; it is the denial of payment itself that precludes the access to the services they need. The reason for an improper denial also has no effect on the availability (or unavailability) of remedies for the denial under ERISA.

This does not mean, however, that the reason for denial will always be irrelevant. MCOs act like treating physicians not only when they exercise medical judgment in determining what patients need,[134] but also when they *communicate* their determination to patients.[135] When MCOs deny a claim on the basis of medical necessity, they provide information to the patient in the form of an announcement that a particular treatment is not needed. Some MCOs have acknowledged an informational role. For example, one plan's documents stated that "[t]he Quality Care Program ... assists you ... in securing quality medical care .... They do this by providing you with information which will permit you (in consultation with your doctor) to evaluate alternatives to surgery and hospitalization when those alternatives are medically appropriate."[136] The documents also stated that the Quality Care Program "[p]rovides independent, professional review when surgery or hospitalization is

132. Aetna Health Inc. v. Davila, 124 S. Ct. 2488, 2502 (2004) (citing *Cicio*, 321 F.3d at 109 (Calabresi, J., dissenting)) (alteration in original).

133. *Cicio*, 321 F.3d at 109 (Calabresi, J., dissenting).

134. Numerous articles have examined the legal debate over whether utilization review constitutes the practice of medicine. *See generally* J. Scott Andresen, *Is Utilization Review the Practice of Medicine?*, 19 J. LEGAL MED. 431 (1998); David L. Trueman, *The Liability of Medical Directors for Utilization Review Decisions*, 35 J. HEALTH L. 105 (2002).

135. Indeed, Ohio defines the practice of medicine to include "through the use of any communication ... advis[ing], recommend[ing] ... for compensation ... a drug or medicine ... or treatment." OHIO REV. CODE ANN. § 4731.34(A)(3) (LexisNexis 2003).

136. Corcoran v. United Healthcare, Inc., 965 F.2d 1321, 1323 (5th Cir. 1992).

recommended—to assist you in making an enlightened decision regarding your treatment."[137]

By providing information in this way, MCOs, like physicians, may influence patients' treatment decisions. As the doctrine of informed consent underscores, physicians' communication to patients about the benefits of treatment is one of the critical components of the treatment process. Physicians have a duty to comply with a state standard of care when communicating this information. Why should a state not be permitted to impose a similar duty on MCOs?[138]

Consider the following hypothetical. A treating physician recommends a particular surgery and seeks pre-approval as required from the patient's employer-sponsored managed care plan. The MCO's medical director determines that the surgery is unnecessary and communicates her determination to both the patient and physician, pointing to a decade-old small-scale study that failed to identify a significant benefit of the surgery. Pursuant to plan terms that permit but do not require the MCO to deny coverage for unnecessary procedures, the MCO announces that the surgery will be covered despite the surgery's lack of proven effect. The patient, however, decides to abandon the surgery on the basis of the MCO's unequivocal statement that the surgery is unnecessary. Soon after refusing the surgery, the patient suffers an injury that several five-year-old large-scale studies demonstrate the surgery would likely have prevented. The patient then sues the MCO in state court, alleging negligence in its medical necessity determination. What result?

Although the MCO made an error in the process of coverage determination, its ultimate decision to grant coverage was not in error. Unlike Davila,[139] the patient would not likely have a claim within the scope of ERISA section 502(a)(1)(B), because the plan has

137. *Id.* at 1324.

138. An exchange during the *Davila* oral argument before the Supreme Court highlights the distinction between injuries caused by the necessity determination and injuries caused by the coverage denial. After David Mattax, the Assistant Attorney General for Texas, explained the role of MCOs in treatment and coverage decisions, a Justice said, "[I]t's simply a statement, we will not pay for it . . . ." Mattax responded, "Well respectfully the statement is we don't think it's good for you. We don't think this care is appropriate for your particular situation." Transcript of Oral Argument, *supra* note 87, at 44.

139. *See* Aetna Health Inc. v. Davila, 124 S.Ct. 2488, 2497 (2004) (observing that Davila and Calad could have funded treatment themselves and then obtained reimbursement through an action under ERISA section 502(a)(1)(B)).

not denied any benefits due.[140] Perhaps the patient could bring a suit under ERISA for violation of the plan's fiduciary duty. However, the very same action that would provide a basis for such a claim—the poor quality of the MCO's "recommendation" to the patient—could also conceivably provide a basis for a state tort action against the MCO. The Supreme Court's logic with respect to treating physicians in *Pegram* suggested that such a situation would be problematic, contributing to its determination that the treating physician's decision was not fiduciary in character, and therefore not subject to liability under ERISA's fiduciary duty provisions.[141] The same logic could apply to MCOs that take on treatment-related tasks by making medical necessity decisions. Thus, the patient would not likely have any ERISA claim, and the patient would need to seek a remedy through a tort claim.

While this hypothetical situation is admittedly unlikely to arise in practice, it illustrates that if enrollees rely on their MCOs as providers of information, then it really does matter whether an improper coverage decision stems from a medical error or from an administrative error. When an MCO communicates erroneous medical information, its influence on patients' well-being may extend beyond that associated with the coverage decision itself. Consider again the hypothetical, with just two changes to the fact pattern. First, instead of granting coverage for the surgery, the MCO denies coverage due to lack of medical necessity. Second, the patient just happens to be someone sufficiently wealthy to easily finance surgery after the MCO has denied coverage. Once again, the patient is injured after refusing the surgery on the basis of the plan's justification for its medical necessity determination—not the coverage denial itself—and sues in state court. Should the patient be entitled to pursue a recovery in tort?

On the one hand, the reasoning of *Davila* suggests that such a suit would be preempted. The relationship between the patient and the MCO was shaped by the terms of the ERISA plan. The patient's claim emanated from a coverage determination process governed by ERISA, and were it not for the fact that ERISA mandates disclosure

140. Interestingly, the patient would have no recourse under the THCLA, either, since an MCO that approves benefits cannot be held liable under the statute. *See* TEX. CIV. PRAC. & REM. CODE ANN. § 88.002(c)(2) (Vernon 2004). Note that this feature of the statute tends to reinforce the conclusion that the statute is aimed primarily at coverage decisions, rather than treatment decisions.

141. *See supra* text accompanying notes 56–59.

of the reasons for a negative benefit determination,[142] the MCO might have said nothing at all about the efficacy of surgery. Furthermore, unlike the first version of the hypothetical, the result of the MCO's faulty determination process was an improper eligibility decision, one that the enrollee could have forced the MCO to revisit by bringing a challenge under ERISA. The fact that ERISA supplies no remedy for the injury that resulted after the patient failed to challenge the decision or to seek care elsewhere is irrelevant.

On the other hand, ERISA is intended to address the failure of ERISA plans to allocate their financial resources in accordance with plan terms, not their failure to provide medical information of sufficient quality.[143] This patient's injury was completely unrelated to the plan's allocation decision. Just as in the first version of the hypothetical, the injury stemmed from the MCO's provision of poor information, not from the coverage determination under the terms of the plan.[144] In fact, the plan's coverage terms are relevant to the patient's claim only in the sense that the medical necessity criteria they contain prompted the plan to use medical information in making an eligibility determination, and to disclose its analysis to the patient. The patient's claim in this hypothetical, however, would be based not on whether the plan contains a necessity term, but instead on whether the statement that the plan has offered—"this surgery has no significant benefits"—is consistent with the plan's state-imposed duty of quality information provision.

Perhaps the information duty could be viewed as sufficiently independent from the plan's terms so as to differentiate this case from *Davila*. As described in Part I.B, the Supreme Court held in *Davila* that "if an individual, at some point in time, could have brought his claim under ERISA § 502(a)(1)(B), and where there is no other independent legal duty that is implicated by a defendant's actions, then the individual's cause of action is completely pre-empted by ERISA § 502(a)(1)(B)."[145] The plaintiffs tried to avoid preemption by arguing that the THCLA created an independent legal duty of ordinary care in treatment.[146] Because the THCLA does not impose an obligation to provide care outside of the scope of the plan terms,

142. *See infra* notes 216–20 and accompanying text.

143. *See supra* note 32 and accompanying text.

144. Note that a finding that the injury did not stem from the coverage decision would distinguish this case from *Davila*. *See Davila*, 124 S. Ct. at 2497 ("It is clear, then, that respondents complain only about denials of coverage promised under the terms of ERISA-regulated employee benefit plans.").

145. *Id.* at 2496.

146. *See id.* at 2497.

however, a court would need to examine these terms as well as the substance of the necessity decision to determine whether the MCO had fulfilled its duty.[147] For this reason, the duty could not be independent of the plan.[148]

In contrast, the cause of our hypothetical patient's injury is informational quality, not the plan's terms or the MCO's application of those terms. Furthermore, the informational quality duty would apply to all MCOs' interactions with individual enrollees, regardless of whether the enrollees are insured through an ERISA plan, and regardless of the other ways in which plan terms might shape those interactions. Given these differences, perhaps the *Davila* preemption analysis would not apply, and enrollees would be permitted to pursue informational quality-based tort claims. Other aspects of the opinion, however, suggest that ERISA's preemptive effect is broad and the "independent legal duty" category narrow, giving substantial reason to doubt that an informational quality claim would survive ERISA preemption.[149]

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147. *See id.* at 2498.

148. *See id.* The Court also suggested that if the MCO had correctly denied coverage, it would be the policy's failure to cover the treatment, not the denial of coverage, that caused the injury. *Id.* at 2497. If establishing causation requires scrutiny of the ERISA plan terms, then a court's determination of liability under the THCLA would not be independent of the plan.

149. For example, the opinion noted that "THCLA liability would exist here only because of petitioners' administration of ERISA-regulated benefit plans." *Id.* at 2498. In the surgery example, information provision liability would exist only because the MCO communicated information to a specific enrollee, and the only reason that the MCO communicated with the enrollee was that it made a medical necessity-based denial in the course of administering the enrollee's ERISA-regulated benefit plan. In addition, *Davila* cited *United Steelworkers of America v. Rawson.* In that case, the Supreme Court held that the Labor Management Relations Act preempted a claim by survivors of deceased miners against a union they alleged had been negligent in inspecting a mine. United Steelworkers of Am. v. Rawson, 495 U.S. 362, 372 (1990). The Idaho Supreme Court had reasoned that it was "not faced with looking at the Collective Bargaining Agreement to determine whether it imposes some new duty upon the union—rather it is conceded that the union undertook to inspect and, thus, the issue is solely whether that inspection was negligently performed under traditional Idaho tort law." *Id.* at 367–68 (citing Rawson v. United Steelworkers, 770 P.2d 794, 796 (Idaho 1988)). Similarly, the argument that the information duty is independent is that the plan undertook to provide information supporting its decision, and the issue is whether that information was negligently offered, as determined by state law. In rejecting the Idaho Supreme Court's approach, the U.S. Supreme Court noted that duty did not apply to all who inspected mines or protect all who might be injured. *Id.* at 367. Rather, the duty arose from a collective bargaining agreement defining the relationship between the parties. Similarly, just as malpractice law generally applies only when a physician has established a relationship with a patient, *see* FURROW ET AL., *supra* note 106, § 6-1, the information duty applies only when the MCO has established a relationship with an enrollee. It is not a duty that anyone who provides medical information owes to society as a whole. If the fact that the relationship is created

Regardless of the answer a full ERISA preemption analysis would yield, a policy analysis suggests that the answer to this question *should* be that claims based on deficiencies in the medical information generated as part of the coverage determination process are subject to state tort law and not preempted, while the ultimate coverage determination itself is subject to suit only under ERISA. The remainder of this Article explores the benefits of adopting such a policy proposal. This proposal in some ways resembles previous efforts to define the scope of ERISA preemption narrowly. Several commentators have suggested that MCO coverage determinations involving the exercise of medical judgment should be regulated by tort law rather than ERISA.[150] Recent congressional bills, too, have proposed a legal regime in which ERISA would not preempt state law allowing recovery of damages resulting from "medically reviewable" decisions, such as benefit denials based on medical appropriateness.[151] This Article's proposal also identifies a particular MCO function that should be governed by a state regulatory regime rather than a federal one. Yet the function it identifies is different. The proposal would not permit states to regulate the coverage decision. Instead, it would permit states to regulate the provision of

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by an ERISA plan is enough to result in preemption, then no malpractice-like claim against an MCO by an ERISA plan beneficiary can survive preemption. (On the other hand, the Supreme Court also observed that the Idaho Supreme Court had "acknowledged that the Union's representatives were participating in the inspection process pursuant to the provisions of the collective-bargaining agreement, and that the agreement determined the nature and scope of the Union's duty," *Rawson*, 495 U.S. at 371, suggesting that the analysis may depend on the degree to which the ERISA plan, as opposed to state tort law, determines the nature and scope of the plan's informational duties.) Note that this discussion by no means exhausts potential preemption issues. For example, the fact that the MCO provided information in the course of claim administration would also tend to support a finding of preemption under ERISA section 514. *See, e.g.*, Darcangelo v. Verizon Commc'ns, Inc., 292 F.3d 181, 188 (4th Cir. 2002) (finding that state law claims arising out of the dissemination of an employee's medical information "would be 'related to' the ERISA plan under § 514 and would therefore be preempted" if the company disseminating the information had obtained it "in the course of processing a benefits claim or in the course of performing *any* of its administrative duties under the plan"). A full ERISA preemption analysis of the proposed regime is beyond the scope of this Article.

150. *See supra* note 119; *cf.* MORREIM, *supra* note 20, at 121–25 (arguing that health plans sometimes practice medicine and that when they do, they should be subject to medical malpractice liability).

151. Patients' Bill of Rights Act of 2005, H.R. 2259, 109th Cong. §§ 104(d)(2), 402(b)(2) (2005). Although the bill permits state causes of action to proceed, it limits the award of punitive damages. *Id.* The Senate has previously considered similar bills. *See, e.g.*, Bipartisan Patient Protection Act of 2004, S. 2083, 108th Cong. §§ 104(d)(2), 402(b)(2) (2004).

medical information produced as a byproduct of the coverage determination process.

III. THE IMPORTANCE OF TAILORING PREEMPTION FOR AN INFORMATION AGE

Two recent developments in the health care world underscore the importance of fashioning an appropriate regulatory regime to govern MCOs' provision of medical information. First, as explained in Part III.A, health insurers have become increasingly involved in the collection and processing of medical information, partly in an attempt to improve the quality of medical care. Second, as explained in Part III.B, new forms of health plans have begun to shift more decisionmaking responsibility to patients, increasing their need for medical information.

A. The Increasing MCO Role as a Medical Information Provider

In theory, the primary goal of health maintenance organizations should be to "maintain" the "health" of their enrollees. In practice, this health maintenance function was largely pushed aside in the 1990s as managed care entities focused on controlling medical care costs.[152] Recently, however, there has been a resurgence in MCO involvement in health promotion activities. This increased involvement probably stems in part from MCOs' technological capabilities and in part from changes in the nature of the practice of medicine. Increasing emphasis on the practice of evidence-based medicine and the rapid proliferation of new treatment technologies together place a premium on the ability to collect, process, and synthesize large amounts of information.[153] Often large institutions

152. On MCOs' previous focus on costs and renewed focus on the nature of care provided, see, for example, Glen P. Mays et al., *Managed Care Rebound? Recent Changes in Health Plans' Cost Containment Strategies*, HEALTH AFF. WEB EXCLUSIVE, Aug. 11, 2004, at W4-427, W4-433, http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.427v1 (commenting that health plans have designed new payment systems "as replacements for capitated provider payment methods that had been used previously in HMOs" and noting that "[w]hereas capitation was used primarily as a cost containment strategy, these new incentives are being used to address cost and quality issues").

153. Evidence-based medicine has been defined as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." David L. Sackett et al., *Evidence Based Medicine: What It Is and What It Isn't*, 312 BMJ 71 (1996); *see also* Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POL. POL'Y & L. 327, 327–28 (2001) (citing this definition and describing the use of large databases to support evidence-based medicine).

with sophisticated data management systems already in place, MCOs tend to be well-suited to take on such tasks.

For example, Aetna, CIGNA, and other health care plans have established a partnership with the federal Agency for Healthcare Research and Quality to improve data collection with respect to race and ethnicity, with the goal of finding ways to reduce disparities in the provision of health care.[154] UnitedHealth Group recently announced that it would make available claims data for millions of patients in order to facilitate research on potential drug complications.[155] Once it has data on at least one thousand patients taking a particular drug, it plans to compare claims of these patients against the claims of other patients taking similar drugs, in order to identify any problematic side effects.[156] UnitedHealth Group and several other organizations have contracted with the FDA to provide patient records that can be used to conduct drug safety analyses.[157] Medicare also has proposed supplying its claims data to the FDA to improve monitoring of pharmaceuticals.[158]

While these information-gathering projects are in their early stages, in the past, health plans have acted on the information they have collected. For example, Kaiser Permanente worked with the FDA to study the risk of myocardial infarction associated with COX-2 drugs (such as Vioxx) and non-selective non-steroidal anti-inflammatory drugs (such as naproxen). The preliminary results of

154. Press Release, Agency for Healthcare Research and Quality, Major Health Plans and Organizations Join AHRQ to Reduce Racial and Ethnic Disparities in Health Care (Dec. 14, 2004), *available at* http://www.ahrq.gov/news/press/pr2004/dispcolpr.htm.

155. Vanessa Fuhrmans, *Early-Warning Tool for Unsafe Drugs*, WALL ST. J., Apr. 28, 2005, at D4. This innovation raises the possibility that while MCOs and other entities with superior access to claims databases may be well-suited to process information, they are not the only entities that could do so. MCOs could in theory limit their functions to claims processing and simply turn their claims data over to other experts (such as university researchers, government entities, or physician organizations) for analysis, evaluation, and communication of the results. The examples reviewed in this section, however, suggest that MCOs have for now chosen to take a more active role in reviewing claims and other information and communicating this information to their enrollees.

156. *Id.*

157. *See* David Phelps, *FDA Turns to Industry To Help Track Drug Safety, Effectiveness*, STAR TRIB. (Minneapolis, Minn.), Sept. 29, 2005, at 1D (reporting that the FDA selected UnitedHealth Group, the Kaiser Foundation Research Institute, Vanderbilt University, and Harvard Pilgrim Health Care "to help it monitor drug effectiveness and safety by sifting through large computerized volumes of patient records").

158. *See* Ricardo Alonso-Zaldivar, *Medicare's Will May Be FDA's Way*, L.A. TIMES, June 5, 2005, at A1. For an analysis of how Medicare records might be used to monitor the effects of "high-risk medical devices," see generally David J. Malenka et al., *Postmarketing Surveillance of Medical Devices Using Medicare Claims*, 24 HEALTH AFF. 928 (2005).

this study, released in the months prior to the withdrawal of Vioxx, contributed to concerns about the drug's safety.[159] Kaiser limited its use of Vioxx more than a year before the drug was withdrawn, because its evidence-based reviews indicated that Vioxx did not work better than older pain relievers for many patients.[160] As MCOs and other health care payers become more active in collecting and examining information, they will become more likely to use this information in their coverage determination process, and to communicate their findings to physicians and patients.

Medicare has expressly acknowledged the potential informational benefits of the data-gathering process underlying some of its financial coverage decisions. In particular, it has begun to tie coverage decisions for certain items and services to the systematic collection of data showing the health effects of these items and services. Medicare has justified this approach in part by explaining that it would generate evidence that would

> assist doctors and patients in better understanding the risks, benefits and costs of alternative diagnostic and treatment options .... These additional data may alter the course of patient treatment based on the best available evidence, and may lead a physician to reconsider the use of the item or service or otherwise alter a patient's management plan, potentially improving health outcomes.[161]

The more that information gathered pursuant to payer operations influences patient treatment, the more important payer accountability for the dissemination of that information becomes.

Recent trends in quality reporting may increase pressure on MCOs to influence the treatment process through any available mechanism, including information dissemination. Greater

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159. *See Hearing on FDA, Merck and Vioxx: Putting Patient Safety First? Before the S. Comm. on Finance*, 108th Cong. (2004) (statement of Sandra Kweder, Deputy Director of the Office of New Drugs, Center for Drug Evaluation & Research, U.S Food and Drug Administration), *available at* http://finance.senate.gov/hearings/testimony/2004test/111804sktest.pdf. The Vioxx study, released on September 30, 2004, is available at http://www.fda.gov/cder/drug/infopage/vioxx/vioxxgraham.pdf.

160. *See* Barry Meier, *Doctors, Too, Ask: Is This Drug Right?*, N.Y. TIMES, Dec. 30, 2004, at C1. The Mayo Clinic and the Department of Veteran Affairs similarly limited the use of Vioxx. *See id.*

161. CTRS. FOR MEDICARE & MEDICAID SERVS., DEP'T OF HEALTH & HUMAN SERVS., DRAFT GUIDANCE FOR THE PUBLIC, INDUSTRY, AND CMS STAFF: FACTORS CMS CONSIDERS IN MAKING A DETERMINATION OF COVERAGE WITH EVIDENCE DEVELOPMENT 4 (2005), *available at* http://www.cms.hhs.gov/coverage/download/guidanceced.pdf.

technological capabilities increase both MCOs' ability to monitor the quality of care delivered to enrollees, and enrollees' ability to monitor the quality of their MCOs. The National Committee for Quality Assurance ("NCQA"), a health plan accreditation organization, issues report cards on health plans.[162] The reported scores reflect not only enrollee satisfaction with plan administration, but also objective measures of clinical quality, such as whether enrollees have received recommended preventive care such as immunizations or mammograms, or whether enrollees who have suffered from heart attacks have received beta blocker drugs.[163] To the extent that MCOs are regularly evaluated on measures of the quality of care received by enrollees, they have an incentive to influence the treatment of enrollees. In other words, MCOs have both the ability to use information to improve the treatment of their enrollees, and the reason to do so.

The expansion of MCOs' involvement in collecting, evaluating, and disseminating medical information, both in generalized form and as applied to specific patients, demonstrates that MCOs are capable of serving as information providers to their health plan enrollees. Some plans already provide information to enrollees outside of the coverage decision context. CIGNA, for example, recently introduced a website that not only allows enrollees to compare pharmaceutical prices, but also notifies them of potentially problematic interactions between medications.[164] Furthermore, some MCOs have begun to provide information to enrollees through disease management programs, particularly for chronic health conditions such as congestive heart failure and diabetes.[165] As more enrollees come to

162. *See* NAT'L COMM. FOR QUALITY ASSURANCE, HEALTH PLAN REPORT CARD, http://hprc.ncqa.org/index.asp (last visited Dec. 5, 2005).

163. *See* NAT'L COMM. FOR QUALITY ASSURANCE, HEALTH PLAN REPORT CARD—LIVING WITH ILLNESS, http://hprc.ncqa.org/living.asp (describing NCQA's criteria for the "Living With Illness" health plan grade) (last visited Dec. 5, 2005); NAT'L COMM. FOR QUALITY ASSURANCE, HEALTH PLAN REPORT CARD—STAYING HEALTHY, http://hprc.ncqa.org/stayinghealthy.asp (describing the NCQA's criteria for the "Staying Healthy" health plan grade) (last visited Dec. 5, 2005).

164. *See Cigna Offers Its Customers Drug Data*, INDIANAPOLIS STAR, Aug. 24, 2005, *available at* http://www.indystar.com/apps/pbcs.dll/article?AID=/20050824/BUSINESS/508240384&SearchID=73218346172234; *see also* Press Release, CIGNA, CIGNA Pharmacy Management Makes It Easier for Consumers to Comparison Shop for Prescription Drugs, Aug. 23, 2005, *available at* http://www.prnewswire.com/news/index_mail.shtml?ACCT=104&STORY=/www/story/08-23-2005/0004092803&EDATE= (announcing new web pharmacy tools).

165. Typical components of such programs include educating patients about treatment plans, monitoring patients' symptoms and treatment, and coordinating care across multiple providers. *See* Mays et al., *supra* note 152, at W4-431 to -32; *see also* CONG.

recognize their MCOs' involvement in such functions, they may begin to rely more on their MCOs as independent sources of information.

Enrollees may also begin to rely less on their treating physicians. Treating physicians will always play a critical role in the treatment process because so much of the practice of medicine requires professional judgment and personal interaction with patients. At the same time, the increasing complexity and rapid expansion of our knowledge about medicine poses a considerable challenge to physicians, particularly generalist physicians.[166] Extensive data comparing the actual provision of care to current medical standards demonstrates that patients do not always receive high-quality care.[167] A recent study reviewing medical records, for example, found that patients had received less than sixty percent of recommended care as determined by expert panels based on national treatment guidelines and the medical literature.[168] Although the discrepancy should not be attributed solely to the actions of physicians, these data suggest that there may be a role for outside intervention in the treatment process.

BUDGET OFFICE, AN ANALYSIS OF THE LITERATURE ON DISEASE MANAGEMENT PROGRAMS 2–3 (Oct. 13, 2004), *available at* http://www.cbo.gov/ftpdocs/59xx/doc5909/10-13-DiseaseMngmnt.pdf (describing disease management programs). MCOs have also become involved in patient care indirectly by developing and disseminating practice guidelines to physicians. *See, e.g.*, KAISER PERMANENTE'S CARE MGMT. INST. CORONARY ARTERY DISEASE GUIDELINES WORKGROUP, EVIDENCE-BASED GUIDELINES AND TECHNICAL REVIEW FOR THE SECONDARY PREVENTION OF CORONARY ARTERY DISEASE (rev. 2004), http://members.kaiserpermanente.org/kpweb/pdf/feature/247clinicalpracguide/CMI_CADGuidelines_public_web102604.pdf (providing treatment guidelines for cardiac care).

166. *See, e.g.*, John Z. Ayanian et al., *Knowledge and Practices of Generalist and Specialist Physicians Regarding Drug Therapy for Acute Myocardial Infarction*, 331 NEW ENG. J. MED. 1136, 1136 (1994) (finding that cardiologists were more likely than family practitioners to report prescribing certain drugs that had been shown to be associated with improved survival and suggesting that differential knowledge about clinical trials may have contributed to this result). For a general evaluation of the relative strengths and weaknesses of generalists and specialists in providing high-quality care, see Martin T. Donohoe, *Comparing Generalist and Specialty Care: Discrepancies, Deficiencies, and Excesses*, 158 ARCHIVES OF INTERNAL MED. 1596, 1596–1608 (1998). *See also* E. Haavi Morreim, *A Dose of Our Own Medicine: Alternative Medicine, Conventional Medicine, and the Standards of Science*, 31 J.L. MED. & ETHICS 222, 224–26 (2003) (reviewing evidence on the disconnect between clinical practice and medical science and observing that rapid change in medicine, among other factors, impedes efforts to address this disconnect).

167. *See, e.g.*, Morreim, *supra* note 166, at 225 & nn.36–45 (providing examples of studies documenting overprovision and underprovision of medical care).

168. Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 NEW ENG. J. MED. 2635, 2641 (2003).

Through use of their expertise, MCOs could potentially improve the quality of care received by patients.[169]

The physicians of both Calad and Davila allegedly recommended a course of care that the MCO declined to recognize as medically necessary.[170] In many such cases, it will be natural for patients to want to follow the course of care recommended by their treating physicians. First, MCOs may have a financial incentive to decline to cover recommended care. As long as benefit denials do not lead to a net increase in health care costs during the enrollee's coverage period,[171] MCOs may benefit financially from denials.[172] To the extent that physicians are paid for each service they deliver, rather than a fixed amount per patient, they do not face a similar financial incentive to limit care.[173] As a result, patients concerned about the underprovision of care will tend to be less skeptical of their physicians' advice than their MCO's advice.[174] Second, patients know that their physicians have personally examined them, while the MCO and its utilization reviewers have not. To the extent that physicians possess more information about patients than MCOs do, patients are

169. For a similar argument that independent external review mechanisms could improve patient treatment through the provision of information, see Sage, *supra* note 117, at 623 (arguing that American medicine "suffers from widespread inconsistencies in practice that compromise safety and quality," and that independent review can "bring the best scientific evidence to bear" and could "take seriously the obligation to educate health plans and physicians as well as assure optimal treatment for individual patients").

170. *See supra* Part I.B; *see also* Roark v. Humana, Inc., 307 F.3d 298, 302–03 (5th Cir. 2002), *rev'd sub nom.* Aetna Health Inc. v. Davila, 124 S. Ct. 2488 (2004) (describing the recommendations of Calad's and Davila's physicians, the MCOs' refusal of coverage, and Calad's and Davila's allegations that their MCOs "had failed to use ordinary care in making medical necessity decisions").

171. Denials may increase health care costs by causing injuries that require further treatment.

172. More specifically, the entity financially responsible for funding the care (possibly the employer) would benefit from denials. Of course, MCOs may refrain from denying claims if they believe that denials will harm their reputation and result in a loss of profitable customers.

173. In the past, many MCOs used a payment system known as "capitation," under which they paid certain physicians a fixed fee per enrollee for a fixed period of time (such as a month), rather than paying for each service provided. *See* Mark A. Hall, *Rationing Health Care at the Bedside*, 69 N.Y.U. L. REV. 693, 758–79 (1994) (defining capitation and discussing its implications). Because the fee did not depend on the number of services provided, physicians compensated on a capitated basis, like MCOs, faced a financial incentive to limit the care provided. In recent years, however, the use of capitation has declined, so that physicians are more likely to be paid for each service they provide. *See* Mays et al., *supra* note 152, at W4-430 (reporting that many health plans abandoned capitated payment arrangements in 2000 and 2001 in favor of fee-for-service systems).

174. On the other hand, if physicians are paid for each service they provide, patients concerned about *over*provision of care have reason to be skeptical about their physicians' advice.

likely to rely more heavily on their physicians' judgment. Third, trust is an important part of physician-patient interactions, and patients will tend to trust physicians to recommend appropriate care. Still, the more that enrollees perceive MCOs to be engaged in activities related to medical information and the provision of care, rather than just the processing of claims, the more likely they will take seriously the information provided by their MCOs.[175]

B. The Increasing Patient Role as a Medical Information User

The likelihood that enrollees will actively evaluate the information provided by MCOs is enhanced by a second, very recent trend in the health care world: the increasing role of patients in choosing the level of care that they receive. Rapid increases in health care expenditures and health plan premiums have prompted employers and MCOs to redesign health plans to place a larger fraction of the cost burden on enrollees.[176] One approach has been to increase deductibles significantly, which from employers' perspectives has the dual cost-saving effect (at least in the short term) of shifting costs from the plan to the enrollee and discouraging the enrollee from using care. Under a "consumer-directed" health plan, for example, enrollees would have relatively unfettered control over the care they receive and the identity of the providers from whom they receive it. The plan might have a very high deductible, however, perhaps $2,000; even if the employer were to create an account to cover some expenditures, enrollees would likely bear a significant proportion of the cost burden associated with the treatment decisions they make.[177] The recent creation of Health Savings Accounts ("HSAs"), which "combine[] a tax-free account to pay for medical expenses with a high-deductible health plan with low premiums,"[178] will undoubtedly reinforce the trend toward high-deductible plans. Fifty insurers have

175. Direct informational influence on an enrollee's decisionmaking has been alleged in at least one case involving utilization review: "[the enrollee's surgeon] alleged that [the insurance company medical director's] decision caused [the enrollee] to question [the surgeon's] professional judgment and to waver in her decision to proceed with surgery that was not covered by insurance." Murphy v. Bd. of Med. Exam'rs, 949 P.2d 530, 533 (Ariz. Ct. App. 1997).

176. *See* Mays et al., *supra* note 152, at W4-433.

177. *See* Anne K. Gauthier & Carolyn M. Clancy, *Consumer-Driven Health Care—Beyond Rhetoric with Research and Experience*, 39 HEALTH SERVICES RES. 1049, 1049 (2004) (defining consumer-driven health care); Shari Roan, *More Choice, at a Cost: Consumer-Directed Health Plans Give Patients Freedom to Choose—and a Larger Bill*, L.A. TIMES, Aug. 16, 2004, at F1 (describing consumer-directed health plans).

178. Louise Story, *Health-Savings Accounts Gain Momentum*, WALL ST. J., Sept. 9, 2004, at D2.

already introduced high-deductible health policies in anticipation of the spread of HSAs.[179]

Another new health plan feature combining increased consumer choice with increased cost-sharing is provider "tiering." One of the reasons for the managed care backlash was the limited size of MCOs' provider networks.[180] By channeling their enrollees to fewer providers, MCOs were able to negotiate lower payment rates. But consumers wanted to keep their previous physicians and receive services at their preferred hospitals, so MCOs loosened restrictions on providers. The tiering model is a compromise between this post-backlash open network model and the pre-backlash closed network model. Health plans place hospitals and physicians into tiers based on the cost as well as the quality of the care they provide. Enrollees are free to choose their providers, but face copayments or deductibles that differ depending on the tier of the provider they choose.[181] Pharmaceutical coverage, too, may be tiered, with different levels of copayments depending on whether the drug is generic or branded, and the price of the brand.[182]

High-deductible/HSA and tiered-design health plan features impose a considerable burden on consumers. While fully insured enrollees have little reason to be concerned about the cost of the care they receive, enrollees who must pay for a significant proportion of care directly will want to be informed of the cost of a proposed course of treatment. Health plans are currently developing tools that will assist enrollees in determining costs.[183] Enrollees will also want to understand the likely health consequences of a proposed course of treatment so that they may make an informed decision about whether the treatment is cost-justified.

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179. *Id.*

180. *See, e.g.*, Alain C. Enthoven et al., *Consumer Choice and the Managed Care Backlash*, 27 AM. J.L. & MED 1, 1, 8 (2001) (hypothesizing that the managed care backlash was related to consumer choice and concluding based on an empirical analysis that "one approach to reducing the backlash against HMOs ought to include policies that encourage employers to offer a choice of plans, including a wide-access plan, to their employees").

181. *See* Robert Steinbrook, *The Cost of Admission—Tiered Copayments for Hospital Use*, 350 NEW ENG. J. MED. 2539, 2539–40 (2004); Robert Kazel, *Aetna Targets Costs, Expands Tiered Network of Specialists*, AM. MED. NEWS, July 26, 2004; James C. Robinson, *Hospital Tiers in Health Insurance: Balancing Consumer Choice with Financial Incentives*, HEALTH AFF. WEB EXCLUSIVE, Mar. 19, 2003, at W3-135, W3-135 to -139, http://hpm.berkeley.edu/pdfs/hospital%20tiers.pdf.

182. Barbara Martinez, *Drug Co-Pays Hit $100*, WALL ST. J., June 28, 2005, at D1.

183. *See* Sarah Rubenstein, *Patients Paying for Medical Care Struggle To Divine the Costs*, WALL ST. J. ONLINE, Feb. 16, 2005, http://www.wsj.com (subscription service).

The development of consumer-directed health plans thus represents another step in the evolution of the plan-patient-physician relationship, one that will greatly enhance enrollees' demand for information. Enrollees with financial responsibility for their own treatment will likely collect relevant information from a variety of sources. Enrollees faced with claim denials, for example, may need to decide whether to use money in an HSA to purchase care directly. Their decisions may turn on the information they receive from their treating physicians, their health plans, the Internet, and other sources. Admittedly, if devices such as HSAs or tiers prove to be successful in limiting the growth in health care costs without sacrificing quality, they may eventually reduce the prevalence of utilization review, decreasing the information that MCOs provide as part of the benefit determination process.[184] Some scholars have argued, however, that HSAs and managed care may ultimately coexist and may even generate synergies that benefit patients.[185] In the meantime, they create a climate that encourages enrollees to seek out regularly any information that is available with respect to recommended treatments, including information provided by their MCOs.[186] The fact that information provision is likely to become a significant component of consumer-directed health plans is an important reason to start defining standards with respect to MCO information provision.

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184. Even if consumer-directed health insurance reduces the use of traditional forms of utilization review, however, it may promote information provision in conjunction with other financing arrangements, such as tiering. Along these lines, Professor Sage has suggested that "[n]ecessity-based exclusions in health insurance . . . should be reoriented to influence consumer decisionmaking directly" by "factor[ing] medical necessity into a system of graduated cost-sharing" based on cost-effectiveness. Sage, *supra* note 117, at 639.

185. *See* Mark A. Hall & Clark C. Havighurst, *Reviving Managed Care with Health Savings Accounts*, 24 HEALTH AFF. 1490, 1490 (2005) ("HSAs and managed care are not antithetical, however, and are already being integrated by health plans to create synergies that should benefit consumers and bring new cost-consciousness and discipline to the health care marketplace."); *see also id.* at 1497–98 (discussing the continued relevance of coverage decisions within an HSA framework). Hall and Havighurst conclude that the "consumer-directed movement's greatest contribution may be to make it finally clear to the public at large that health plans' coverage decisions differ . . . from treatment decisions and that benefit administration is an essential part of a larger process by which people make choices about spending." *Id.* at 1498–99.

186. *See, e.g.*, Jon B. Christianson et al., *Consumer Experiences in a Consumer-Driven Health Plan*, 349 HEALTH SERVICES RES. 1123, 1126 (2004) (describing the informational features of consumer-driven health plans, including Internet-based access to measures of physician qualifications and hospital performance and "educational resources . . . relating to health promotion, disease management, and general medical information").

Thus, with each additional task that health plans have taken on—first simply financing care, then managing costs based in part on medical judgment, and now managing quality more directly—they have become a more significant source of medical information for patients. With each additional task that patients have taken on—first complying with a prescribed course of care, then helping to determine that course of care under the doctrine of informed consent, and now weighing cost, quality, and convenience in selecting a course of care—their reliance on medical information has grown. Together, these changes make it imperative that MCOs be held accountable for the quality of information that they provide.

C. *Information Benefits of the Post-*Davila *ERISA Regime*

The post-*Davila* ERISA regime ultimately may increase the information available to patients. It is true that *Davila* undermines the goal of accountability by precluding the application of state law in an environment in which ERISA offers no meaningful remedy. Under *Davila*, if an MCO does not delegate coverage decisions to treating physicians, its coverage decisions are subject to challenge only under the ERISA regime. As the Fifth Circuit commented before the *Davila* decision, "HMO's [sic] can escape all liability if they instruct their doctors to recommend every possible treatment and leave the real decision to HMO administrators."[187] Plans that want the protection of ERISA preemption will therefore be careful to ensure that the coverage determination process remains separate from the treating physician's interaction with the patient.

From the patient's perspective, the effect of the separation is the creation of two potentially independent sources of information: the treating physician and the MCO. When the physician recommends a treatment for which the MCO denies coverage on the basis of lack of medical necessity (or other medical criteria), the patient can resolve the conflict in information provision in several ways. First, the patient may pursue internal appeals, or, in some cases, seek an independent external review; many states have mandated that medical necessity-based HMO coverage decisions be subject to review by an independent party.[188] Second, the patient may seek

187. Roark v. Humana, Inc., 307 F.3d 298, 315 (5th Cir. 2002), *rev'd sub nom.* Aetna Health Inc. v. Davila, 124 S. Ct. 2488 (2004).

188. *See, e.g.*, Aaron Seth Kesselheim, *What's the Appeal? Trying To Control Managed Care Medical Necessity Through a System of External Appeals*, 149 U. PA. L. REV. 873, 886–91 (2001) (describing the external review process); Korobkin, *supra* note 2, at 507 (stating that at least forty-one states mandate external review); *see also* Rush Prudential

additional information from his or her treating physicians, or third parties, and decide to finance the recommended care him or herself.

In either case, if there is room for legitimate disagreement over medical necessity, the patient may ultimately make a less informed decision when the treating physician makes both coverage and treatment decisions than when the treating physician makes only treatment recommendations and the MCO makes eligibility decisions. This is true regardless of whether the treating physician ultimately approves or declines coverage. If the treating physician were to make a mixed decision recommending treatment, for example, the patient might never become aware of any doubt about medical necessity. Alternatively, a treating physician closely affiliated with an MCO may face a *Pegram*-like financial incentive to deny coverage, perhaps a stronger financial incentive than a typical non-affiliated physician. The physician may then fail to recommend care initially, leaving the patient unaware of at least a potentially beneficial treatment option.

Thus, if *Davila* encourages MCOs to retain the responsibility for coverage decisions while preserving the independence of treating physicians, *Davila* may ultimately increase the availability of information to enrollees. If the enrollee uses the additional information gathered to choose the best possible course of treatment, clinically speaking, the enrollee will be less likely to need the remedies of the tort system, because physical injury will be less likely to occur. If the initial MCO coverage denial were faulty, an enrollee could pursue treatment based on the physician's recommendation and then seek compensation for that care through the ERISA regime, either prospectively, or, if the enrollee finances treatment him- or herself, retrospectively. Enrollees would be uninjured and indemnified, while MCOs would be held accountable for poor-quality coverage decisions.

If the post-*Davila* regime achieved its full potential, there would be little need to consider a change in the law. The regime faces significant obstacles, however, including several raised by the *Davila* case. For example, patient-enrollees may be unable to finance care themselves. If they are also unable to finance prospective litigation to obtain treatment, not an unrealistic assumption, the MCO coverage decision will essentially be determinative. In addition, for an enrollee like Calad who is very ill, navigating the appeals process within the

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HMO, Inc. v. Moran, 536 U.S. 355, 359 (2002) (holding that an Illinois statute mandating independent medical review of HMO benefit denials was not ERISA preempted). *But see* Haw. Mgmt. Alliance Ass'n v. Ins. Comm'r of Haw., 100 P.3d 952, 954 (Haw. 2004) (holding that the Hawaii external review statute was ERISA preempted).

timeframe dictated by the enrollee's medical needs will be very difficult.[189] These obstacles, while real and important, are not the focus of this Article.

Instead, this Article focuses on another potential impediment to achieving the full potential benefit of the post-*Davila* regime: information of substandard quality. If enrollees are unable or unwilling to seek a third opinion, but have sufficient funds to finance their own care, they must weigh the information they have been given by the treating physician against the information given by the MCO in determining whether to pursue treatment. While many patients are likely to follow the recommendation of their physicians, others will follow the recommendation of their MCOs. For reasons discussed in Parts III.A and III.B, patient reliance on MCOs for the provision of information is likely to be greater in the future than it was in the past. MCOs have become increasingly involved in collecting and disseminating information related to the quality of care, while at the same time patients are being asked to take on more responsibility in determining the course of their own care. If an MCO is incorrect in its determination of medical necessity, however, a patient choosing a course of care based on that determination will likely be harmed. The current ERISA regime's limitation on the award of consequential damages would preclude a remedy for this harm. By combining a tort regime with an ERISA regime we can increase the likelihood that the patient will be compensated and, through tort remedies' incentive effects, reduce the likelihood that injury will occur in the first place.

IV. A PROPOSAL FOR A BIFURCATED LEGAL REGIME

A. Enhancing ERISA with Liability for Information Provision

The challenge is to shape a bifurcated legal regime that would take advantage of the strengths of both ERISA and the tort system while containing their weaknesses. One option is to take the route rejected by *Davila* as a matter of current law but considered by Congress as a matter of future law: to allow medical necessity-based coverage decisions to be subject to tort law.[190] The analysis in this Article lends support to such an approach. The expansion in MCOs' actual and potential roles as providers of medical information

189. *See, e.g.*, Mariner, *supra* note 16, at 1349–50 (noting the difficulty of pursuing claims while ill).

190. *See supra* note 151 and accompanying text.

enhances the importance of accountability for actions that convey medical information, and liability for coverage decisions based on medical criteria is one means of achieving accountability. This is not the only possible approach, however.[191] Consider the following proposal.

MCOs can make coverage decisions in an individual case in several ways. One way is to apply clearly defined, contractually specified criteria to a disease or condition identified by a treating physician, or to the procedure, equipment, drug, or other treatment recommended by the treating physician.[192] So, for example, if a contract specifically excludes coverage for bariatric surgery, then, regardless of any offered medical justification, the MCO could properly refuse to approve reimbursement for it.[193] Alternatively, the

191. E. Haavi Morreim has proposed a different sort of bifurcated regime: she would subject MCOs' (and physicians') breaches of expertise to tort law, and "breaches of resource duties" to contract law. *See* MORREIM, *supra* note 20, at 11; *see also supra* note 21. While Professor Morreim's analysis does not focus on ERISA, she does consider the potential implications of her analysis for ERISA preemption. MORREIM, *supra* note 20, at 160–83. Writing before *Davila*, she notes the existing similarities between the courts' quality-quantity distinction and her expertise-resource distinction. She then argues that a full adoption of the expertise-resource analysis would make the courts' ERISA preemption analysis more coherent. *Id.* at 162–63. While this Article's information provision duty would arguably fall within Morreim's expertise category, and coverage determinations would often fall within Morreim's resource category, the two bifurcated ERISA regimes would nonetheless differ in important ways. The expertise category, for example, extends far beyond information provision, encompassing "business and administrative activities," among others. *Id.* at 143. It would therefore alter existing law to a greater extent than the regime proposed here, harnessing the benefits of tort law, but sacrificing some of the flexibility and uniformity benefits of ERISA.

192. Health plans decline coverage requests for a variety of reasons. A study of nearly 150,000 coverage requests made in 1997 through 1999 to a California medical group that had taken on responsibility for utilization review showed that 10% of all coverage requests, and 6% of prospective coverage requests, had been denied. Of the denied prospective requests, 42% were denied because they were not for a contractually covered service, and 22% were denied because of the identity of the provider selected by the enrollee. Kanika Kapur et al., *Managing Care: Utilization Review in Action at Two Capitated Medical Groups*, HEALTH AFF. WEB EXCLUSIVE W3-275, W3-275 to -280 (2003), http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.275v1.

193. Insurers' flexibility with respect to the breadth of coverage may be limited by state law. *See, e.g.*, MD. CODE ANN., INS. § 15-839 (West, Westlaw through 2005 Reg. Sess.) (requiring MCOs and other insurers to cover surgical treatment of obesity under certain circumstances); Metro. Life Ins. Co. v. Massachusetts, 471 U.S. 724, 727–32, 758 (1985) (describing mandated benefit laws generally, and holding that a Massachusetts statute requiring inclusion of mental health benefits in insurance policies was not preempted by ERISA). *But see infra* note 294 (explaining that ERISA preempts such state mandates with respect to self-insured ERISA plans). On bariatric surgery, see generally Mark A. Hall, *State Regulation of Medical Necessity: The Case of Weight-Reduction Surgery*, 53 DUKE L.J. 653 (2004). Hall reports that plans have taken a variety of approaches with

contract could specify that all bariatric surgery recommended by a treating physician is covered if the patient's body mass index ("BMI") is greater than forty. A claim for bariatric surgery under either of these rules would generate the sort of "yes-or-no" coverage decision identified as a pure eligibility decision in the *Pegram* case.

Under the proposed bifurcated legal regime, such a coverage decision would be treated just as it is now: as an eligibility decision governed by ERISA. The eligibility decision has been effectively predetermined by the plan terms. The plan terms reflect the judgment of the plan creators about how best to allocate plan resources among plan beneficiaries. An employer might have decided to favor coverage for one type of procedure (acupuncture, for example), but only by sacrificing coverage for another (bariatric surgery for enrollees with BMIs under forty). Thus, the coverage determination conveys little or no medical information to an individual enrollee; it indicates only that the creator of the plan, for whatever reason, has decided not to fund the care. This resource allocation decision is precisely the sort of decision traditionally made by trustees and those who create trusts. Thus, its fit with ERISA, which is based on trust law, is a natural one.

A second type of coverage decision involves an exercise of judgment by the MCO.[194] While the MCO administrator's decision may be influenced by internal guidelines, the decision with respect to a given case might not be dictated by specific contractual terms. So, for example, the contractual terms might say nothing at all about bariatric surgery, but may say that the plan covers only care that is "medically necessary."[195] In determining whether bariatric surgery fulfills the necessity criterion, the MCO must exercise its medical judgment. Perhaps in its judgment, bariatric surgery is a cosmetic procedure that is never medically necessary. Alternatively, it might use internal guidelines to determine that surgery is not medically

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respect to coverage of weight-reduction surgery, including excluding it from coverage entirely, and specifying coverage criteria in the plan terms. *Id.* at 662.

194. MCOs sometimes delegate the coverage decision to another entity, such as a physician group. *See, e.g.*, Sage, *supra* note 117, at 609 (noting that "[i]ncreasingly, preauthorization is delegated by contract to medical groups and other provider organizations"). If so, the same bifurcated legal regime should apply to this entity.

195. A study of utilization review by a medical group found that twenty-nine percent of prospectively denied benefits were denied on the basis of lack of medical necessity. *See* Kapur et al., *supra* note 192, at W3-280. For an excellent discussion of the issues surrounding the definition and application of medical necessity criteria, see AM. HEALTH LAWYERS ASS'N, PUBLIC INTEREST COLLOQUIUM, MEDICAL NECESSITY: CURRENT CONCERNS AND FUTURE CHALLENGES *passim* (2005), *available at* http://www.healthlawyers.org/docs/pubs/Colloq05.pdf.

necessary unless the patient has a BMI of more than forty. Or the MCO might leave the judgment of necessity entirely to the discretion of its medical director or other utilization reviewer, who would decide how much weight to give the BMI criterion in the medical necessity determination on a case-by-case basis.

When the MCO's exercise of judgment involves the evaluation of medical criteria, it necessarily communicates medical information to the individual enrollee that has made the claim. The determination that recommended care is not medically necessary—or for that matter, that it *is* medically necessary—announces in a broad sense whether recommended care is needed. But the exact content of the information conveyed will depend on the meaning of "medically necessary." Some enrollees will undoubtedly interpret a negative MCO determination to mean that a recommended treatment would not be medically beneficial[196]—that bariatric surgery has no medical benefit[197]—but enrollees who read their plan terms more carefully may realize that in reality the message is more complicated.

Some health plans leave the term "medically necessary" or "medical necessity" completely undefined.[198] Others use definitions that suggest that the MCO should consider only the criteria a physician would consider in recommending care; such definitions may consist "merely of a reference to the standards of the medical community."[199] More generally, common contractually-specified criteria of medical necessity include whether the intervention is in accordance with community or national standards, whether it is consistent with accepted principles of medical practice, and whether the treating physician believes it should be provided.[200] To the extent that physicians base their decisions on purely medical criteria, the resulting MCO determination would communicate only medical information. Similarly, a medical necessity definition based solely on the existence of scientific evidence showing improvement in health

196. For an example where it was argued that an MCO necessity determination caused a patient to question the need for surgery, see *supra* note 175.

197. *Cf.* Sage, *supra* note 117, at 601 ("To many physicians, the phrase 'not medically necessary' means 'not clinically indicated' . . . .").

198. Hall, *supra* note 193, at 665.

199. CLARK C. HAVIGHURST, HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM 126 (1995).

200. CTR. FOR HEALTH POL'Y, STANFORD UNIV., STATE-BY-STATE COMPENDIUM OF MEDICAL NECESSITY REGULATION, SURVEY OF STATE MANAGED CARE REGULATORS 15 (2001), http://www.hcfo.net/pdf/stanford.pdf.

outcomes[201] would generate a determination that was purely medical in nature.

To find a service or supply medically necessary, the Aetna contract at issue in the *Davila* case required in part that it "be care or treatment as likely to produce a significant positive outcome as, and no more likely to produce a negative outcome than, any alternative service or supply."[202] To be considered medically necessary, a diagnostic procedure must have been "indicated by the health status of the Member and be as likely to result in information that could affect the course of treatment as, and no more likely to produce a negative outcome than, any alternative service or supply."[203] Moreover, the contract stated that in determining medical necessity, the director was to consider, in addition to the enrollee's health condition, peer-reviewed medical literature, national guidelines, professional standards, the opinion of professionals in the relevant specialty, and the opinion of the attending physicians.[204] To the extent that these sources consider only the medical consequences of medical interventions, a coverage determination based on such criteria would convey purely medical information.

In some cases, however, the term "medical necessity" may reflect more than just an assessment of the medical benefits of a proposed treatment, or a balancing of the medical benefits and risks of a treatment relative to alternatives. It may also incorporate a consideration of cost.[205] Some plans incorporate cost considerations obliquely, using terms such as "a prudent use of plan resources" or the "most appropriate level of service."[206] Other contract terms incorporate cost more explicitly. They may define an intervention as medically necessary in part based on whether it is "furnished in the most cost-effective manner that may be provided safely and effectively," whether "[t]here is no other equally effective course of treatment available which is less costly," or perhaps even whether "benefits and harms relative to costs for the treatment represent an

201. *See id.*

202. Joint Appendix, *supra* note 88, at 54.

203. *Id.* at 54–55.

204. *Id.* at 55.

205. *See, e.g.*, Timothy P. Blanchard, *"Medical Necessity" Determinations—A Continuing Healthcare Policy Problem*, 37 J. HEALTH LAW 599, 601 (2004) ("Historically . . . the individual's treating physician decided what services were 'medically necessary.' As these . . . plans confronted high-cost new technology and burgeoning total costs, however, they have sought to narrow the concept of 'medical necessity' . . . to incorporate an element of cost-effectiveness.")

206. Sara J. Singer & Linda A. Bergthold, *Prospects for Improved Decision Making About Medical Necessity*, 20 HEALTH AFF. 200, 202 (2001).

economically efficient use of resources for patients with this condition compared to alternative treatments."[207] The Aetna contract at issue in *Davila* incorporated cost-related considerations in its definition of "medically necessary": "To be Medically Necessary, the service or supply must: . . . as to diagnosis, care and treatment be no more costly (taking into account all health expenses incurred in connection with the service or supply) than any equally effective service or supply in meeting the above tests."[208]

Thus, a determination that a particular service is not medically necessary may reflect not just an assessment of the medical advantages and drawbacks of the proposed intervention, but also its costs. In other words, medical necessity decisions may embody not just a judgment about the likely health effects of a treatment, but also a decision about how a plan's resources should be spent. Ideally, a bifurcated legal regime would distinguish between the medical assessment and resource allocation components of the decision. As in the pure coverage decision case, the resource allocation decision would be subject to review under ERISA. The medical assessment portion of the decision, however, should be subject to a state legal regime, just as a treating physician's medical assessment and recommendation would. The challenge is to separate the two components.

It is possible that the MCO itself would distinguish the medical information component of the decision from the cost-based component of the decision. In particular, the MCO can separately identify each portion by explaining the medical evidence underlying its decision and then rendering the actual coverage decision. So, for example, in response to a treating physician's recommendation of Vioxx, an MCO might have said, "Vioxx is as likely to produce a significant positive outcome as, and no more likely to produce a negative outcome than, alternative medications. However, because naproxen is equally effective in meeting this test, and is less costly, we decline to cover Vioxx."[209]

In this example, the MCO's ultimate refusal to cover Vioxx would be subject to challenge only under ERISA. If the enrollee decided to take the Vioxx anyway, then the enrollee could challenge

207. CTR. FOR HEALTH POL'Y, *supra* note 200, at 19.

208. Joint Appendix, *supra* note 88, at 55.

209. I make no claims as to the accuracy of these statements; on the status of Vioxx at the time this Article was written, see *supra* note 61. See *infra* note 210 on the potential consequences under the proposed legal regime of an overly sanguine assessment of the effects of a recommended treatment.

the benefit determination component of the decision under ERISA to obtain funding for the Vioxx.[210]

If the enrollee chose to take naproxen, however, then the enrollee should be entitled to sue the MCO for any resulting injury in state court.[211] More specifically, the MCO's statement about the relative effectiveness of Vioxx and naproxen should be subject to challenge under tort law. The enrollee should be entitled to rely on this information as a reasonably accurate summary of medical evidence. If (a) the enrollee chose to take naproxen because of this statement or the supporting evidence provided, (b) naproxen was significantly more likely to produce a negative outcome than Vioxx, (c) the MCO should have known and communicated this fact to the enrollee (or at least, not communicated the opposite), and (d) the enrollee's injury was proximately caused by the use of naproxen, then the enrollee should be able to bring a state law claim against the MCO to receive compensation for his or her injuries.

It is also possible that the MCO would choose not to specify the medical basis for its ultimate coverage decision. In the *Cicio* case, for example, the initial denial of the treating physician's request for coverage "stat[ed] only that the procedure sought was 'not a covered benefit according to this member's plan which states [that] experimental/investigational procedures are not covered.' "[212] Similarly, a plan might state simply that an intervention is not medically necessary, and that therefore coverage is denied. Observers have commented that in the past plans frequently offered

210. If the enrollee were injured after taking Vioxx, then under the proposed bifurcated regime, the enrollee might instead bring an action under state law for poor quality information provision. For example, an enrollee might allege that the MCO's positive assessment of the effects of Vioxx prompted the enrollee to take the drug, and that the drug caused a heart attack. If a court were to accept these arguments, and to determine that the MCO's statement that Vioxx "was no more likely to produce a negative outcome than" alternatives was inconsistent with the standard of care, then it would hold the MCO liable for the harm the enrollee suffered. It might be difficult, however, for the enrollee to convince the court that it was the MCO's information (rather than the treating physician's) that led to the enrollee's treatment choice.

211. More precisely, under the proposed regime, the enrollee should be able to sue the entity that provided the substandard-quality medical information. Thus, if a third-party administrator were responsible for supplying the beneficiary of a self-insured ERISA plan with medical information supporting a negative benefit determination, the beneficiary should be able to sue the administrator. *Cf.* Jordan, *supra* note 6, at 444 (arguing that the proper defendant in a tort suit stemming from a "negligent medical determination" could be the third party administrator or other entity responsible for utilization review services).

212. Cicio v. Does, 321 F.3d 83, 88 (2d Cir. 2003), *vacated*, 385 F.3d 156 (2d Cir. 2004) (per curiam).

little reasoning for their decisions.[213] Given that many enrollees would naturally assume such a statement to mean that the MCO had decided that the procedure would not benefit them, state courts should be entitled to treat the determination as a statement to that effect. MCOs wanting to avoid this presumption could do so by providing more specific information about the medical basis for their decision.

The likelihood that ERISA plans would issue such a sparse determination, however, has been significantly diminished by the most recent Department of Labor regulations, which were intended in part to improve enrollees' access to information.[214] These regulations require the plan administrator to notify claimants of adverse benefit determinations.[215] The notification must include the "specific reason or reasons for the adverse determination," and "[r]eference to the specific plan provisions on which the determination is based."[216] The plan must also disclose upon request any "internal rule, guideline, protocol, or other similar criterion" relied upon.[217] Most importantly, if the determination is based on medical necessity or experimental treatment status, the plan must provide "an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request."[218] These basic rules will simplify enrollees' and courts' tasks of separating the medical information underlying coverage decisions from the resource-based choices underlying coverage decisions. Once separated, the medical information alone would be subject to public scrutiny under a tort regime.

In the Vioxx hypothetical discussed earlier, as in Davila's and Calad's experiences, the MCO denied a claim for treatment that a treating physician had recommended. The bifurcated liability regime protects an enrollee who decides not to pursue treatment as a result

213. *See* Rules and Regulations for Administration and Enforcement of Employee Retirement Income Security Act of 1974, 65 Fed. Reg. 70,246, 70,251 (Nov. 21, 2000) (to be codified at 29 C.F.R. pt. 2560) ("Commenters asserted that the reasons given in these circumstances were frequently 'cursory' and 'vague and open ended.' . . . The Department agrees that claimants would benefit from receiving fuller explanations when a claim is denied because the care is not medically necessary . . . .").

214. *See id.* at 70,246.

215. 29 C.F.R. § 2560.503-1(g)(1) (2004).

216. *Id.* § 2560.503-1(g)(1)(i)–(ii).

217. *Id.* § 2560.503-1(g)(1)(v)(A).

218. *Id.* § 2560.503-1(g)(v)(B).

of the information provided by the MCO. In most cases, however, the MCO will approve treatment that a treating physician has recommended.[219] Such cases raise the question of whether the MCO could be held liable for information provided pursuant to a coverage approval. In particular, if a physician makes an inappropriate recommendation of treatment that the MCO then covers, an injured enrollee may wish to sue a deep-pocketed MCO in addition to the physician, on the theory that by covering the care, the MCO implicitly conveyed the information that the care was medically necessary.[220]

The frequency with which such situations occur would be limited by MCOs' financial incentives, which would discourage them from approving costly but ineffective or harmful treatments. MCOs may have a financial incentive to approve a substandard recommended treatment, however, when an alternative is more costly. Moreover, MCOs might simply improperly evaluate available medical evidence, resulting in an improper approval of recommended treatment. Alternatively, MCOs may choose to approve a request rather than risk resistance from the recommending physician or patient (even if that resistance is ill-informed). Recognizing claims against MCOs that approve coverage in such situations might benefit enrollees by encouraging MCOs to scrutinize treatment recommendations more carefully.

On the other hand, it would be difficult for the enrollee to prevail in such a suit, because the enrollee would have to show that the information provided through the MCO's coverage determination (and not just the treating physician's recommendation) was the proximate cause of the patient's injury, despite the fact that the MCO likely gave no detailed information in support of its decision. (ERISA regulations do not require MCOs to provide information in support of *positive* benefit determinations.)[221] The MCO might also be able to avoid this form of liability if plans give it discretion (rather than imposing an obligation) to deny care that it deems medically

219. *See* Kapur et al., *supra* note 192, at W3-276 (reporting that previous studies showed low coverage denial rates); *id.* at W3-277 (finding that two groups contracting with health plans to make coverage decisions had denied eight and ten percent of coverage requests, respectively).

220. *But see* Mark A. Hall & Gail Agrawal, *The Impact of State Managed Care Liability Statutes*, 22 HEALTH AFF. 138, 143 (2003) (noting that adding a deep-pocketed health plan may increase the cost and complexity of litigation and that plaintiffs may prefer to sue only providers).

221. *See* 29 C.F.R. § 2560.503-1(g)(1) (requiring the plan administrator to provide the "specific reason or reasons for the adverse determination" but not specifically mentioning positive benefit determinations (in a provision with the heading "Manner and Content of Notification of Benefit Determination")).

unnecessary, thus precluding the inference that covered care is necessary. In addition, a treating physician who has personally interacted with the patient is likely to have more information about the patient's condition and preferences than the patient's MCO. An MCO that chooses to defer to the treating physician's recommendation might therefore be conceding the physician's informational advantage in recommending treatment, rather than supplying an independent assessment of medical necessity. For this reason, from a policy perspective, it may not be appropriate to hold the MCO liable for information provision when it approves coverage.[222] The complexities that these considerations would introduce into the litigation process, as well as the possibility that the injured patient could obtain compensation from the treating physician if the care was indeed substandard, militate in favor of limiting the applicability of tort liability to information provided during the course of a negative coverage determination.[223]

B. Benefits of a Bifurcated Regulatory Regime

The advantages of this bifurcated regime fall into two general categories: the benefits of imposing accountability in tort for the provision of poor quality medical information and the benefits of retaining the ERISA regime to govern eligibility decisions.

1. Benefits of Imposing Tort Liability

The benefits of holding MCOs accountable in tort for the provision of medical information mirror those produced by the tort regime generally. One such benefit is compensation of the injured. The ERISA regime, as currently structured, fails to provide compensation to those injured by poor MCO decisionmaking.[224] In contrast, a tort regime would provide compensation to enrollees injured by an MCO's failure to comply with a medical information duty.

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222. In contrast, when an MCO declares that a physician's recommended treatment is not medically necessary on the basis of medical or scientific evidence (as opposed to cost considerations), an enrollee may view the declaration as an assertion that the MCO has superior information or a superior ability to evaluate information relative to the patient's treating physician. In this situation, it seems more appropriate to hold the MCO accountable for the quality of its information provision.

223. As MCOs become more adept in identifying appropriate treatments for individuals, as opposed to simply determining whether recommended treatments are inappropriate, this aspect of the bifurcated liability regime should be revisited.

224. *See supra* note 35 and accompanying text.

Additionally, a tort regime would provide a greater incentive to health plans to take care in providing medical information to enrollees. If there were no financial consequences associated with denying coverage for care, MCOs that focused exclusively on minimizing costs or maximizing profit would have little reason to be concerned about erroneous denials. While external review laws and ERISA do impose financial consequences on MCOs that have improperly denied care, the financial consequences are limited.[225] Suits for improperly denied coverage under these statutes may result in an order to pay for the requested care. If this is the only sanction that MCOs face, it may be in their financial self-interest to deny coverage initially, particularly if only a subset of these denials will ever be appealed. It is true that MCOs may face other financial consequences when they deny coverage; denials may increase litigation-related costs, lead to the loss of customers to competitors with more generous coverage policies, or result in higher expenses, if the denials cause injuries that require medical treatment during the contractual coverage period. Such consequences are likely to discourage indiscriminate denials of coverage. By expanding the magnitude of MCOs' potential liability, however, tort law would provide an even greater financial incentive to reform coverage determination processes: MCOs would face full tort liability for denial-related injuries. They could be liable for treatment costs, including those incurred after the enrollee's coverage period has expired, pain and suffering, and lost wages.[226] The potential for such liability would encourage MCOs to provide higher-quality medical information.

More specifically, the availability of a tort suit based on the provision of medical information would encourage MCOs to meet the informational quality standard recognized by law. The shape of this duty would be determined by state courts, which can take advantage of the expertise they have developed through their historic

225. External review statutes permit MCO enrollees to appeal adverse coverage determinations to outside reviewers. *See supra* note 188 and accompanying text. ERISA permits employee benefit plan beneficiaries to sue to obtain a benefit for which the MCOs have improperly denied coverage. *See supra* note 34 and accompanying text.

226. The Restatement (Second) of Torts states that "[o]ne whose interests of personality have been tortiously invaded is entitled to recover damages for past or prospective (a) bodily harm and emotional distress; (b) loss or impairment of earning capacity; (c) reasonable medical and other expenses; and (d) harm to property or business caused by the invasion." RESTATEMENT (SECOND) OF TORTS § 924 (1979).

responsibility for determining the contours of similar duties.[227] Courts seeking guidance could consider the tort of misrepresentation; the information provided should not mislead the enrollee with respect to the likely outcome of a treatment that has been recommended by a physician. However, courts are even more likely to draw upon cases in which patients alleged that by neglecting to properly disclose information relevant to treatment decisions, their physicians failed to obtain informed consent.

The information standard applied to MCOs would likely be somewhat different from and more stringent than that applied to physicians, however.[228] Treating physicians typically devote much of their time to personal interactions with patients, examining them, performing procedures, or discussing treatment plans in face-to-face conversations. While physicians may be required to describe alternatives to surgical interventions as part of an informed consent process, because of the nature of the interaction and the time constraints involved, the amount of information they provide will tend to be limited. MCOs, on the other hand, often interact with enrollees through written communication. MCOs can thus provide a more thorough assessment of the scientific basis (or lack thereof) for any given recommended treatment. For example, MCOs might be expected to offer summary statements about the nature of the evidence, and then provide citations to medical articles or published medical consensus-based guidelines that provided the foundation for their statements. As previously explained, because of their administrative capabilities and regular interactions with large numbers of physicians and enrollees, MCOs are well-positioned to collect, evaluate, and disseminate this kind of medical information. While both physicians and MCOs are information providers, the tort

227. It would also be possible for Congress to create a federal cause of action for substandard information provision, enabling enrollees to pursue compensation for their injuries in federal courts. Requiring such claims to be heard in federal instead of state court might increase the uniformity of decisionmaking, and might therefore address one of the concerns underlying ERISA. On the other hand, permitting state tort actions, as proposed here, allows litigants to take advantage of the existing expertise of state courts in resolving tort claims. Requiring federal litigation over the quality of information provision would impose a substantial new burden on federal courts.

228. In advocating malpractice liability for MCOs that practice medicine, Professor Morreim similarly suggests that the duties of MCOs will differ from the duties of physicians. *See* MORREIM, *supra* note 20, at 124. She explains that while MCOs cannot perform physicians' hands-on functions, they must seek information from persons who can. *See id.* She concludes that "tort litigation will focus heavily on the quality of evidence and the quality of reasoning behind the plan's decision." *Id.* at 125.

law standard should account for the differences in the nature of their interactions with patients.[229]

A tort law-based standard for information provision may be important because although ERISA regulations dictate that information be provided,[230] they do not and probably cannot articulate in detail the content or quality of that information. The availability and nature of relevant medical and scientific information will vary widely depending on the individual enrollee's condition. Thus, bright line rules governing the magnitude and nature of information provision would be difficult to formulate. In areas where the regulations do not provide specific guidance, the tort standard can give shape to our expectations about the quality of information to be provided.

By encouraging the development and provision of high-quality information, a tort regime could significantly increase the quality of care that enrollees receive. First, to the extent that improper benefit denials are a function of poor-quality information gathering by MCOs, an information provision standard might improve the mechanics of MCO decisionmaking. If the information provision standard facilitates the introduction of additional information into the benefit determination process itself, it may increase the likelihood that MCOs take full account of the medical risks and benefits of proposed treatments, resulting in more accurate benefit determinations. As a result, enrollees may be more likely to obtain needed care.

Second, regardless of the nature of MCOs' ultimate benefit determinations, an information standard would reduce the likelihood that enrollees would be misled by MCOs about the necessity of care recommended by physicians. An information standard modeled after the reasonable patient standard sometimes applied in the informed consent context, for example, would require provision of information

229. Some commentators have gone further in suggesting that MCO utilization review processes should be reshaped to more closely resemble the interaction between physicians and patients. William Sage, for example, has suggested that health plans should make "a serious attempt to identify traditional ethical values associated with healing and build them into coverage determinations," thus adopting a therapeutic approach to coverage decisions. Sage, *supra* note 117, at 629; *see also* Kathy L. Cerminara, *Dealing with Dying: How Insurers Can Help Patients Seeking Last-Chance Therapies (Even When the Answer Is "No")*, 15 HEALTH MATRIX 285, 286–87 (2005) (proposing that "insurers incorporate interdisciplinary counseling and mediation techniques" into the coverage decisionmaking process for last-chance therapies, to "help those patients deal with dying in a more therapeutic way, even when the answer to their pleas for coverage of particular treatments must be 'no' ").

230. 29 C.F.R. § 2560.503-1(g)(1) (2004).

that patients would consider material to their decisions about whether to adhere to their physicians' recommendations.[231] By combining this information with information they glean from the Internet and other sources, motivated and educated enrollees could make more informed decisions about which course of care to pursue—even if they must pay for the care themselves. An enrollee with an employer that selects a health plan with stringent cost-effectiveness requirements, for example, may choose to purchase out-of-pocket care for which the MCO (properly) denies coverage.

Admittedly, many enrollees would find themselves unable to take full advantage of the information the MCO provides. Millions of Americans are functionally illiterate; many have difficulty understanding even their own physicians' instructions.[232] Only enrollees with significant education and time to devote to the task would be able to understand the medical evidence provided by MCOs and the reasons for which MCO and treating physician assessments differed. After all, one reason that patients consult their physicians in the first place is that they do not possess the necessary information and training to make treatment decisions on their own. On the other hand, not every enrollee needs to have the capacity to evaluate the MCO information for the bifurcated regime to produce substantial benefits. Enrollees may discuss the information with more informed friends, family members, or caregivers; even better, they may discuss it with their own physicians or other physicians in order to reconcile conflicting views. Even if only a subset of enrollees actually used the information provided, the fact that the MCO might be held accountable for informational quality creates an incentive to improve MCO decisionmaking.[233]

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231. *See* Canterbury v. Spence, 464 F.2d 772, 786 (D.C. Cir. 1972) ("The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is the information material to the decision."); *see also* FURROW ET AL., *supra* note 106, § 6-10(b) (describing the reasonable patient standard of disclosure).

232. *See* Shoou-Yih D. Lee et al., *Health Literacy, Social Support, and Health: A Research Agenda*, 58 SOC. SCI. & MED. 1309, 1309 (2004) (summarizing literacy statistics); *see also* Julie A. Gazmararian et al., *Health Literacy Among Medicare Enrollees in a Managed Care Organization*, 291 JAMA 545, 545 (1999) (finding that more than one-third of English-speaking and more than one-half of Spanish-speaking survey respondents in a Medicare MCO had "inadequate or marginal health literacy").

233. The proposed regime would offer a remedy only to persons who were injured as a result of their reliance on the information the MCO provided. *See infra* Part IV.C.1 (discussing limitations on the effectiveness of the proposed regime). Nevertheless, the potential for liability in some cases will give MCOs a greater incentive than they otherwise would have to improve their information provision to all enrollees.

Furthermore, even if enrollees did not themselves consider the information produced during the coverage determination process, treating physicians might be able to take advantage of the consolidated source of information. While the MCOs' evaluations may not always provide physicians with new information—after all, the MCOs' evaluations would be based on studies conducted or guidelines conceived by physicians—they may on occasion prove helpful, particularly for treating physicians who are not specialists in the relevant field. Higher quality information may thus improve the treatment of not only an individual enrollee, but also future patients. As commentators such as E. Haavi Morreim have noted, increased MCO accountability for their exercise of expertise could improve the enrollees' quality of care not just through improved MCO coverage decisions, but also through improved MCO involvement in care.[234]

2. Benefits of Preserving ERISA Regulation

In enacting ERISA, Congress decided to dictate very little of the substantive content of health plans.[235] Just as the settlors of trusts are free to determine the nature and size of the trust, employers are free to determine the nature and generosity of their health plans through their purchase of existing insurance products or the design of their own plans. The rules of the plan determine how the employers' resources are allocated among plan beneficiaries. ERISA protects beneficiaries not by dictating or second-guessing this resource allocation, but by providing remedies for those seeking to enforce the allocation specified by plan terms.[236] Congress also decided that plan enforcement should be regulated primarily by the federal Department of Labor[237] and the federal courts,[238] which would

234. MORREIM, *supra* note 20, at 144–47 (arguing that health plans' duties of expertise include setting and overseeing patterns of good care and identifying and responding to patterns of poor care); *see also* Jennifer Arlen & W. Bentley MacLeod, *Malpractice Liability for Physicians and Managed Care Organizations*, 78 N.Y.U. L. REV. 1929, 1935 (advocating MCO liability in part on the basis of "MCOs' ability to use authority both to influence treatment choice directly and to indirectly affect the quality of physician-selected care").

235. *See* MORREIM, *supra* note 20, at 160–61.

236. *See supra* note 34 (explaining beneficiary remedies).

237. The Secretary of Labor has the authority to create regulations necessary to protect employee benefits. 29 U.S.C. §§ 1002(13), 1135 (2000). At the same time, ERISA's preemptive effects limit states' abilities to enact their own benefit plan regulations. *See supra* note 33 and accompanying text.

238. Federal courts have exclusive jurisdiction over most types of civil suits brought to protect employee benefits, 29 U.S.C. § 1132(e)(1) (2000), but state and federal courts have concurrent jurisdiction with respect to suits to recover benefits due under § 1132(a)(1)(B). *Id.* Even if the enrollee brings a claim within the scope of § 1132(a)(1)(B) in state court,

promote uniformity in regulation. These two decisions assist employers in limiting the costs of their benefit plans.

Restricting the reach of state tort law to suits based on the provision of medical information, rather than to suits based on the coverage decision, the decisionmaking process, or MCO operations as a whole, ensures that resource allocation decisions continue to be regulated under ERISA. By doing so, the proposed bifurcated regime may facilitate plans' ability to take costs into account in their current decisionmaking processes and may encourage greater use of cost effectiveness criteria in the future.

Proposals that would permit enrollees to sue their plans under state tort law for medical necessity-based coverage decisions may not share these cost-related advantages. As discussed in Part IV.A, "medical necessity" may be defined partly based on cost-related criteria. Thus, if a necessity-based benefit determination were to engender a tort suit, the state court would need to determine liability based not only on the medical criteria underlying the decision, but also on the cost criteria underlying the decision. In other words, a jury might ultimately evaluate the health plans' resource allocation decisions, as well as their exercise of medical judgment. The jury entanglement with the necessity determination process as a part of a tort liability determination stands in contrast to the current regime, under which allocation decisions are subject to review only under ERISA.

In theory, juries could be permitted to determine whether plans have properly applied cost-related criteria, just as they determine whether a physician has committed malpractice or not. However, particularly when a patient has allegedly been harmed as a result of a plan's actions, jurors may find it natural to second-guess resource allocation decisions. While ERISA permits employers to tailor their benefit packages as they choose, thus limiting the cost of the benefits they provide,[239] jurors may focus on the physical harm to a particular

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however, the defendant will often exercise its right under 28 U.S.C. § 1441(a) to remove the case to federal district court. For examples of cases filed in state court that the defendant then attempted to remove to federal court, see Aetna Health Inc. v. Davila, 124 S. Ct. 2488, 2493 (2004); Land v. Cigna Healthcare of Fla., 381 F.3d 1274, 1276 (11th Cir. 2004); DiFelice v. Aetna U.S. Healthcare, 346 F.3d 442, 459 (3d Cir. 2003).

239. *See* Korobkin, *supra* note 2, at 465 & n.30 (noting ERISA's limited substantive requirements for benefit plans). In addition, ERISA's "deemer clause" has been interpreted to allow self-insured plans to avoid state regulation of the content of insurance policies, thus giving self-insuring employers flexibility in designing their insurance plans. *See infra* note 294. For an explanation of the deemer clause and its relationship to state-imposed benefit mandates, see Russell Korobkin, *The Battle over Self-Insured Health*

enrollee resulting from a particular policy, rather than the cost savings that the policy has produced for all enrollees.[240]

Subjecting the ultimate coverage determinations to an ERISA regime, rather than state tort law, could help to limit these problematic effects.[241] One potentially relevant argument is that juries may be more susceptible to hindsight bias than judges. If this argument is correct,[242] one reason to subject coverage determinations to ERISA rather than state law is ERISA's more limited use of juries. ERISA never expressly addresses the availability of jury trials,[243] and there is some conflict in the courts on this question.[244] But numerous courts have rejected jury trials after deeming the relief sought under ERISA to be equitable in nature.[245] Thus, even if equitable remedies

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Plans, or "One Good Loophole Deserves Another," 5 YALE J. HEALTH POL'Y L. & ETHICS 89, 92–98 (2005).

240. *See* Richard A. Ippolito, *Freedom To Contract in Medical Care: HMOs, ERISA and* Pegram v. Herdrich, 9 SUP. CT. ECON. REV. 1, 50 (2001) (describing jury reactions to the use of cost criteria in the contexts of medicine and safety devices). In an article exploring the potential consequences of MCO tort liability for coverage decisions, Gail Agrawal and Mark Hall express similar concern about court involvement in determining the reasonableness of resource allocation decisions. *See* Gail B. Agrawal & Mark A. Hall, *What If You* Could *Sue Your HMO? Managed Care Liability Beyond the ERISA Shield*, 47 ST. LOUIS U. L.J. 235, 289 (2003). They stress "the risks of hindsight bias and the potential chilling effect on efforts to contain costs" inherent in applying substantive state law standards to coverage determinations. *Id.*

241. While observing that "[i]t is very difficult to determine the empirical truth regarding coverage law," William Sage notes that a recent empirical study "concludes that courts are largely sympathetic to cost-containment efforts, especially in ERISA cases." *See* Sage, *supra* note 117, at 612–13. The cited study concluded that its empirical results "confirm[ed] the conventional wisdom that MCOs will be more vulnerable to liability if ERISA preemption is weakened," and suggested that "[b]y applying ERISA preemption expansively . . . courts have protected the growth and development of managed care." Peter D. Jacobson et al., *The Role of the Courts in Shaping Health Policy: An Empirical Analysis*, 29 J.L. MED. & ETHICS 278, 286–87 (2001).

242. It is not clear that judges are able to control hindsight and other biases to a greater extent than juries. In fact, at least one study has found that judges may be as susceptible to hindsight bias as others, and suggests that juries have the advantage of being able to correct for hindsight bias by working together as a group. *See* Chris Guthrie et al., *Inside the Judicial Mind*, 86 CORNELL L. REV. 777, 816, 827 (2001). The article reports the results of an experimental study involving 167 federal magistrate judges. It evaluates "five common cognitive illusions (anchoring, framing, hindsight bias, the representativeness heuristic, and egocentric biases)," and finds that the judges were less susceptible than other decisionmakers to only two: framing effects and the representative heuristic. *Id.* at 778. It also discusses mechanisms for avoiding cognitive biases. *Id.* at 822–26, 828–29.

243. *See* Langbein, *supra* note 35, at 1355.

244. *See* Frank Cummings, *ERISA Litigation: An Overview of Major Claims and Defenses*, *in* ALI-ABA COURSE OF STUDY MATERIALS: ERISA LITIGATION 56 n.199 (2004).

245. For example, the United States Court of Appeals for the Second Circuit has stated:

were eventually determined to encompass make-whole damages,[246] enrollees' claims for injuries due to improper coverage determinations under ERISA would likely be heard by judges rather than juries. To the extent that judges are ultimately better-equipped to respect the resource allocation decisions made by health plans, this approach will help to achieve the goals of ERISA.

Relatedly, the ERISA regime would help to limit the problematic effects of hindsight bias because it mandates the application of a deferential standard of review when plan administrators have been given discretionary authority to make coverage decisions.[247] The deferential standard tends to discourage second-guessing of an administrator's resource allocation decisions. It therefore helps to preserve employers' flexibility in determining the scope of benefits provided to employees.

Gail Agrawal and Mark Hall seek to alleviate the hindsight problem through a different approach, the application of process-based, rather than substantive, standards of tort liability to MCO decisionmaking processes. More specifically, they argue that tort liability for coverage decisions should arise "only if an incorrect coverage decision was caused by 'defects in the design or

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> [T]his Court now joins its sister circuits and decides that there is no right to a jury trial in a suit brought to recover ERISA benefits. A persuasive factor in favor of finding no right to a jury trial is that: "The significance of the [arbitrary and capricious] standard, while second nature to a judge, is not readily communicated to jurors."

Sullivan v. LTV Aerospace & Def. Co., 82 F.3d 1251, 1258 (2d Cir. 1996) (quoting Berry v. Ciba-Geigy Corp., 761 F.2d 1003, 1006–07 (4th Cir. 1985)).

246. *See generally* Langbein, *supra* note 35 (arguing that equitable remedies include make-whole relief).

247. In *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 112–15 (1989), the Supreme Court rejected the argument that benefit denials should necessarily be reviewed under an arbitrary and capricious standard because ERISA fiduciaries by definition exercise discretion, *id.*, and instead held that "a denial of benefits challenged under § 1132(a)(1)(B) is to be reviewed under a *de novo* standard," *id.* at 115. However, the Court added the caveat that the de novo standard would apply "unless the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan." *Id.* Thus, if the plan administrator is given discretionary authority, decisions are to be reviewed under an arbitrary and capricious standard. *See also* JACOBSON, *supra* note 20, at 136–38 (describing court review of coverage decisions). The degree of deference the court gives to a plan administrator exercising discretionary authority may depend on the court's assessment of whether the plan administrator has a conflict of interest. *See Firestone*, 489 U.S. at 115; *see also* Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355, 384 n.15 ("An issue implicated by this case ... is the degree to which a plan provision for unfettered discretion in benefit determinations guarantees truly deferential review. In *Firestone Tire* itself, we noted that review for abuse of discretion would home in on any conflict of interest ....").

implementation of the [coverage determination] mechanisms.' "[248] This approach, like the medical information approach, helps to preserve cost-containment mechanisms by limiting second-guessing of the substance of the decision. However, it may do so at the cost of sacrificing another of the advantages of ERISA regulation: its uniformity.

In particular, as previously discussed, one of the goals of ERISA was to ensure that multistate employers could administer their ERISA plans uniformly across states.[249] Many aspects of the coverage determination process, such as the timeframes for decisionmaking,[250] are currently regulated under ERISA. The wider the scope of liability of health plans for other aspects of their coverage decisions, however, the more likely they will be subject to the varied determinations of state courts about the appropriateness of their decisionmaking processes. While similar criticism could be lodged against malpractice liability for the provision of medical information,[251] because the provision of medical information is only one subset of the coverage determination process, the scope of liability is necessarily more limited. For this reason, it may be preferable to allow for medical information-based tort liability while continuing to preempt suits based on other aspects of the coverage determination process.

C. *Concerns About a Bifurcated Regulatory Regime*

1. Potential Limits on the Effectiveness of the Regime

There are a number of reasons to question whether a bifurcated regulatory regime would actually be able to realize all of its potential benefits. In particular, while this Article's analysis of the bifurcated regime suggests that the regime could obtain the compensation and incentive benefits associated with tort law, this suggestion is premised on the presumption that enrollees would be able to bring successful tort claims for substandard medical information provision. Plaintiff-enrollees may encounter multiple obstacles, however, in their efforts to bring a successful tort suit. First, courts may be unwilling to recognize an informational duty; second, the availability of alternative mechanisms for information provision may undermine tort claims;

248. Agrawal & Hall, *supra* note 240, at 289 (quoting Wickline v. State, 239 Cal. Rptr. 810, 819 (Cal. Ct. App. 1986)).

249. *See supra* note 32 and accompanying text.

250. *See* 29 C.F.R. § 2560.503-1(f) (2004).

251. *See infra* Part IV.C.

third, MCOs may try to avoid liability through contract; and fourth, the causation element of the tort claim may not always be satisfied. Each of these obstacles raises an important concern, but none ultimately provides a reason to abandon the proposed bifurcated regulatory regime.

Consider the first potential obstacle, courts' possible lack of willingness to impose an informational duty on MCOs. While there have been few examples thus far of courts holding MCOs liable in tort for their provision of services, a couple of recent cases suggest that courts are moving in this direction.[252] In *Shannon v. McNulty*,[253] a Pennsylvania court reasoned that "[w]here the HMO is providing health care services rather than merely providing money to pay for services their conduct should be subject to scrutiny" and held that an HMO had a duty to ensure that the advice provided by nurses staffing its emergency phone line was medically reasonable.[254] In *Jones v. Chicago HMO Ltd.*,[255] which involved a claim that an HMO had assigned too many patients to a contracting physician, the Illinois Supreme Court held that an HMO may be liable for institutional negligence.[256]

A willingness to recognize MCO duties in general is not sufficient for proper functioning of the proposed legal regime, however; courts must be willing to recognize the medical information duty itself. *Shannon* and *Jones* draw on case law holding hospitals liable for institutional negligence as a basis for imposing duties on MCOs.[257] A classic formulation of hospitals' legal responsibilities toward patients describes four duties: (1) a duty to use reasonable care in maintaining facilities and equipment; (2) "a duty to select and retain only competent physicians;" (3) a duty to oversee persons practicing medicine inside the hospital; and (4) a "duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for the patients."[258] The first duty relates to the physical facilities

252. *See* Agrawal & Hall, *supra* note 240, at 237–49.

253. 718 A.2d 828 (Pa. Super. Ct. 1998).

254. *Id.* at 835–36.

255. 730 N.E.2d 1119 (Ill. 2000).

256. *Id.* at 1135.

257. *See, e.g.*, *id.* at 1128–29 (citing a hospital liability case, *Darling v. Charleston Community Memorial Hospital*, 211 N.E.2d 253 (Ill. 1965), in support of its imposition of institutional liability on an HMO); *Shannon*, 718 A.2d at 835–36 (citing a hospital liability case, *Thompson v. Nason Hospital*, 591 A.2d 703 (Pa. 1991), in support of its imposition of corporate liability on an HMO); *see also* Agrawal & Hall, *supra* note 240, at 241–42 (explaining that courts have "looked to hospital liability cases . . . to develop the doctrinal bases for managed care liability).

258. Thompson v. Nason Hosp., 591 A.2d 703, 707 (Pa. 1991) (citations omitted).

used by a patient, rather than medical services provided directly to the patient. The second and third duties arise from hospitals' interactions with patients' caregivers, rather than the hospitals' delivery of medical services. MCOs' medical information duties would extend beyond these traditional institutional duties, since they would arise from the MCOs' direct interaction with patients in the role of an information provider.

Although the fourth duty, like the second and third duties, could be interpreted to govern hospitals' interactions with medical professionals, rather than the hospitals' interactions with patients,[259] it could also conceivably encompass rules governing direct interactions between institutions and patients. Thus, tort suit plaintiffs might use it to establish the existence and nature of MCOs' duties with respect to information provision.

Furthermore, state legislatures have evidenced a willingness to extend MCOs' liability beyond their actions as intermediaries to their actions in the course of making health care coverage and treatment decisions. At least ten states have passed legislation similar to the THCLA, which expressly created a right of enrollees to sue their MCOs based on their MCOs' influence on care.[260] While cases like *Shannon* and *Jones* emphasize the similarities between MCOs and hospitals, these statutes underscore the similarities between MCOs and physicians.[261] The extension of tort liability to MCOs based on information provision is thus less far-fetched than it may seem.

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259. *See, e.g.*, Graham v. Barolat, No. Civ. A. 03-2029, 2004 WL 2668579, at *4 (E.D. Pa. Nov. 17, 2004) (stating that the plaintiff had alleged that a hospital "breached the fourth *Thompson* duty" by failing "to 'properly instruct its agents, servants, workmen, employees and/or ostensible agents in the procedures for properly evaluating and treating the Plaintiff' " (citation omitted)).

260. *See* Kesselheim & Brennan, *supra* note 25, at 462 n.68; *see also* Agrawal & Hall, *supra* note 240, at 271 ("Since 1997, eleven states have enacted variants of laws that create a 'right to sue your HMO.' "). State statutes imposing liability on managed care entities include: CAL. CIV. CODE § 3428 (West 2005); ME. REV. STAT. ANN. tit. 24-A, § 4313 (West, Westlaw through 2005 second special session); and OKLA. STAT. tit. 36, § 6593 (West 2005). *See* PATRICIA BUTLER, HENRY J. KAISER FAMILY FOUND., KEY CHARACTERISTICS OF STATE MANAGED CARE ORGANIZATION LIABILITY LAWS: CURRENT STATUS AND EXPERIENCE 11–15 (2001), *available at* http://www.kff.org/insurance/upload/Comparison-of-State-Managed-Care-Liability-Laws-Report.pdf (cataloging MCO liability statutes).

261. Indeed, while state statutes defining the practice of medicine do not typically refer specifically to the provision of information, they may include the provision of medical advice. For example, Ohio defines the practice of medicine to include "through the use of any communication . . . advis[ing], recommend[ing] . . . for compensation . . . a drug or medicine . . . or treatment." OHIO REV. CODE ANN. § 4731.34(A)(3) (West 2004). Numerous articles have examined the legal debate over whether utilization review as practiced by MCO employees constitutes the practice of medicine. *See, e.g.*, Andresen,

A second potential obstacle to the effectiveness of the proposed legal regime may be the availability of alternative mechanisms for obtaining information, such as independent external review. In Calad- and Davila-like settings, the enrollee often knows that there is a disagreement between the treating physician and the MCO, and that further review may be warranted. An enrollee may be able to avoid injury associated with substandard information by seeking a review, since a reviewer's disagreement with the MCO's decision would either add to or correct the information that the MCO supplied to the enrollee. Alternatively, an enrollee might be able to avoid injury by bringing an ERISA suit challenging the coverage decision. To the extent that the litigation process results in substantive discussion or argument about the justifications for the physician's and MCO's differing medical necessity determinations, the enrollee may gain additional information relevant to his or her treatment decision.[262]

If the information provided through either type of review corrects MCO misinformation, then the information initially provided by the MCO is unlikely to cause injury; either the plaintiff would suffer no injury, or if the plaintiff did suffer injury, it would stem from causes other than the MCO's misinformation, so an information-based tort remedy would be unavailable.[263] If the enrollee declines to seek review, on the other hand, a state court might limit or refuse to provide a tort remedy, either on the theory that the enrollee was

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supra note 134, *passim* (analyzing the potential for liability based on utilization review decisionmaking); Trueman, *supra* note 134, *passim* (evaluating the potential for disciplinary actions and malpractice claims against medical directors based on negligent utilization review determinations).

262. Alternatively, the enrollee could decline to pursue a formal challenge and instead seek additional information from his or her treating physician, the MCO, or a third party.

263. In fact, if the enrollee pursues a review, the enrollee demonstrates a significant doubt about the quality of the MCO's information, compromising his or her ability to recover damages later by weakening the enrollee's claim of injury causation. Strategically-minded enrollees might therefore choose not to challenge the decision, preserving the strength of their future claim by taking action consistent with the information the MCO provided. The potential payoff of this strategy, however, is limited by the fact that a claim arises only if the enrollee is injured, an undesirable state of affairs that the enrollee may be able to avoid entirely by challenging the MCO's coverage determination. For this reason, enrollees capable of navigating the initial appeals process are likely to do so. In contrast, less capable enrollees may not pursue appeals, incurring injury as a result. The combination of appeals determinations and tort verdicts would provide an incentive to MCOs to produce higher-quality information, reducing the incidence of information-related injuries.

contributorily negligent or on the theory that the enrollee had failed to mitigate damages.[264]

The application of contributory negligence and mitigation doctrines in the managed care context should be rare, however, for several reasons. First, enrollees may face a considerable burden in seeking review of an MCO coverage decision. The enrollees would likely need to devote a significant amount of time and energy to learning how to navigate the appeals process during a period in which they find themselves sufficiently ill to need medical care.[265] Enrollees such as Calad, who would have needed to pursue her appeal from her hospital bed within a very short time, would find this process particularly burdensome. While victims of negligence are expected to bear some of the burden of avoiding injury, the doctrines of

264. *See* RESTATEMENT (SECOND) OF TORTS §§ 463–466, 552A (1979) (discussing contributory negligence); *id.* § 918(1) (discussing mitigation). For a review of cases featuring contributory negligence claims in the medical malpractice context, see Kurtis A. Kemper, Annotation, *Contributory Negligence, Comparative Negligence, or Assumption of Risk, Other Than Failing to Reveal Medical History or Follow Instructions, As Defense in Action Against Physician or Surgeon for Medical Malpractice*, 108 A.L.R. 5th 385 (2005). The contributory negligence theory would appear better suited to a claim based on an MCO's utilization review decision than to a standard malpractice claim based on a physician's recommendation. In the conventional physician treatment context, the patient has little basis for questioning the physician's recommendation and so should not be expected to seek a second opinion. *See, e.g.*, DiLeo v. Nugent, 592 A.2d 1126, 1133 (Md. Ct. Spec. App. 1991) (observing that "a patient is not in a position to . . . evaluate whether the prescribed course of treatment is in her best interest. As a consequence, it is not contributory negligence for a patient to . . . rely on the doctor's advice"). In contrast, when an MCO makes a negative medical necessity determination, the patient becomes aware of a conflict between the MCO and the physician. Thus, even if a court would not preclude recovery by a victim of physician malpractice who failed to seek a second opinion, a court might consider precluding recovery against an MCO by a patient who failed to seek external review.

265. Many enrollees begin to learn about the rules of the appeals process only after care they desire has been denied. According to one survey, two-thirds of California patients who had actually participated in the independent medical review process were unaware of the availability of review before becoming involved themselves. JILL K. SILVERMAN ET AL., INDEPENDENT MEDICAL REVIEW EXPERIENCES IN CALIFORNIA, PHASE II: CASES INCLUDING MEDICAL NECESSITY 3 (2003), *available at* http://www.chcf.org/documents/policy/Phase%20II%20IMR.pdf. While the patients reported receiving helpful information about and government assistance with the appeals process, only one-third reported that the process was clearly explained, and only thirty percent reported receiving assistance in bringing their case. *Id.* More generally, factors that might make external appeals difficult vary by state, but may include requirements to exhaust MCOs' internal appeals processes before seeking review, filing fees or the fear of filing fees, and filing deadlines. *See* KAREN POLLITZ ET AL., ASSESSING STATE EXTERNAL REVIEW PROGRAMS AND THE EFFECTS OF PENDING FEDERAL PATIENTS' RIGHTS LEGISLATION 5–14 (2002), *available at* http://www.kff.org/insurance/externalreviewpart2rev.pdf (describing impediments to seeking external reviews and measures states have taken to address them).

contributory negligence and mitigation require only reasonable efforts.[266] In some circumstances, the burden of seeking appeals may exceed the bounds of reasonableness.

Second, and more importantly, given the continuing improvements in MCO capabilities with respect to the provision of medical information, it may be inefficient and unreasonable to require enrollees to continually second-guess MCO information provision through prospective appeals.[267] One of the fundamental functions of tort law is to give potential tortfeasors an incentive to avoid injuring others; the mere fact that a tort remedy might be available would reduce the prevalence of injuries by increasing the quality of information provision. If the overall quality of information provision significantly improves, whether due to the threat of tort suits or for other reasons, then frequent enrollee appeals of benefit denials would impose costs on all parties involved without significantly increasing the quality of information. Thus, it may make sense in the long term not to require enrollees to appeal, but instead to protect the small number of enrollees who do receive substandard information through tort remedies.[268]

The third potential obstacle to the application of tort liability to MCOs' provision of information is the possibility that MCOs would attempt to avoid any such liability through contract. MCOs such as those involved in the *Davila* case often insist that they make only coverage decisions and that they do not provide medical services.[269]

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266. *See* RESTATEMENT (SECOND) OF TORTS § 464 (stating that the standard of conduct for the plaintiff in a negligence case is that of a "reasonable man"); *id.* § 918(1) (stating that a tort victim "is not entitled to recover damages for any harm that he could have avoided by the use of reasonable effort").

267. In addition, external review may not always be available. Not all states have adopted external review statutes. *Leading Cases*, *supra* note 16, at 466. Moreover, ERISA's "deemer clause," which precludes the application of state insurance laws to self-insured plans, may prevent the extension of state-mandated external review to self-insured plans. *See* Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355, 371 n.6 (2002).

268. Similarly, while it could be argued that victims of improper coverage decisions should not be able to recover damages in tort for injuries that could have been avoided by funding their own care, *see* Leonard A. Nelson, Aetna v. Davila/CIGNA v. Calad: *A Missed Opportunity*, 31 WM. MITCHELL L. REV. 843, 880 (2005) (noting that "it is not irrational to expect [patients] to mitigate their damages" by seeking care after coverage has been denied), a finding of reasonable reliance on an MCO's determination that the care was not necessary should preclude the application of the mitigation doctrine.

269. *See, e.g.*, Reply Brief for Petitioner Aetna Health Inc., *supra* note 93, at 1 ("They repeatedly assert that Aetna provided 'medical treatment' to Davila or that Aetna engaged in 'medical malpractice,' when in fact and law Aetna's role was limited to making a coverage determination under the ERISA plan."). Aetna also made the common claim that it could not make treatment decisions because it is not licensed as an entity to practice medicine. *Id.* at 3. The lack of a license does not preclude the practice of medicine,

Aetna's brief to the Supreme Court emphasizes that the plan's definition of medical necessity is only "[f]or the purpose of coverage."[270] Moreover, perhaps in an effort to avoid vicarious liability for the actions of treating physicians, MCOs have often been careful to clarify in the materials they provide to members that only independent treating providers, and not the MCOs themselves, make treatment decisions.[271]

Thus, an important question is whether an MCO should be entitled to narrow its scope of potential liability by contractually disclaiming any duty with respect to the medical content of its decisions. If so, an enrollee who chose to rely on the medical information provided through the coverage decision process might be deemed to assume the risk of poor-quality information. Note, however, that while physicians may be able to define the outer limits of their duties by refusing to accept patients or by declining to practice outside their specialty, they are significantly limited in their ability to contractually waive liability for malpractice. Courts generally resist efforts by both physicians and hospitals to limit tort liability, often refusing to enforce exculpatory clauses.[272] Courts may similarly be reluctant to allow MCOs to limit liability when the medical information they provide influences a patient's choice of care, just as a physician's recommendation would.[273]

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however; it simply means that any practice of medicine that does occur is unauthorized. Yet as Professors Hall and Agrawal note: "In some states, historical precedents banning corporations from practicing medicine were interpreted as barring MCOs from being held liable for the delivery of care." Hall & Agrawal, *supra* note 220, at 138–39.

270. Brief for Petitioner Aetna Health Inc., *supra* note 62, at 7. The Aetna Certificate of Coverage says that "[f]or the purpose of coverage, HMO may determine whether any benefit provided under the Certificate is Medically Necessary." Joint Appendix, *supra* note 88, at 54.

271. *See* Agrawal & Hall, *supra* note 240, at 246.

272. *See* FURROW ET AL., *supra* note 106, § 6-5(e) (describing courts' hostility to providers' attempts to limit liability contractually); *see also* RICHARD A. EPSTEIN, MORTAL PERIL 372–74 (1997) (analyzing a California Supreme Court decision refusing to enforce a hospital exculpation clause on the basis of public policy); HAVIGHURST, *supra* note 199, at 306 ("[E]xculpatory clauses in provider-patient contracts have been regularly denied enforcement on public policy grounds."); Wendy K. Mariner, *Standards of Care and Standard Form Contracts: Distinguishing Patient Rights and Consumer Rights in Managed Care*, 15 J. CONTEMP. HEALTH L. & POL'Y 1, 11, 14–15 (1998) (explaining the mandatory nature of physician duties to patients).

273. Furthermore, a policy prohibiting exculpatory clauses with respect to information provision could be viewed as extending to a new context the hostility Congress has expressed toward attempts by ERISA fiduciaries to avoid liability. *See* 29 U.S.C. § 1110(a) (2000) ("Except as provided . . . any provision in an agreement or instrument which purports to relieve a fiduciary from responsibility or liability for any responsibility, obligation, or duty under this part shall be void as against public policy.").

A final limitation on the effectiveness of the proposed regime is that it would not offer a remedy in tort to all who have been harmed by MCO coverage denials. In particular, an enrollee pursuing a medical information-based tort action would have to allege that it was the MCO's provision of medical information, not the financial consequences of the MCO's decision, that resulted in the enrollee's injury. This regime would not expand the remedies available to enrollees who would have liked to follow their physician's treatment recommendation but did not because their circumstances precluded financing care themselves or pursuing internal or external appeals to obtain coverage. The lack of a remedy for such enrollees under both the current and proposed regimes, and the resulting limitation on financial consequences for MCOs, dampens the MCOs' incentives to make proper use of medical information in the decisionmaking process. Nevertheless, by encouraging the recognition of liability in situations in which enrollees are harmed by the provision of medical information of substandard quality, the proposed regime does increase MCO accountability in general. Some enrollees will have the financial resources and ability to pursue recommended treatment, but will decline to do so because of the actions taken by the MCO. For reasons discussed in Part III, the level of enrollee reliance on MCOs for information is likely to increase in the future. This regime offers a remedy to enrollees harmed by their reliance, while at the same time offering an incentive to MCOs to improve their information provision processes in such a way as to benefit *all* enrollees.

2. Potential Drawbacks of the Regime

An effective bifurcated legal regime would not be without drawbacks. First, an expansion of tort liability would produce the incentive benefits commonly associated with tort law, but would also impose the costs associated with the tort system.[274] In recent years, the medical malpractice system has been subject to increasing criticism, both for failing to identify and remedy real malpractice and for allowing frivolous lawsuits to proceed.[275] While an information-based lawsuit against an MCO and a malpractice lawsuit against a

274. *See* Agrawal & Hall, *supra* note 240, at 261–62 (describing the shortcomings of the tort system, as part of an evaluation of the risks and benefits of MCO accountability).

275. *See, e.g.*, David M. Studdert et al., *Medical Malpractice*, 350 NEW ENG. J. MED. 283, 285–86 (2004) (commenting on empirical evidence on malpractice claims, including a study that showed that "[o]nly 2 percent of negligent injuries resulted in claims, and only 17 percent of claims appeared to involve a negligent injury").

physician may differ in focus, they may suffer from the same shortcomings. Both may require reliance on conflicting expert testimony, and both may be decided based on a jury's desire to compensate a badly injured plaintiff, regardless of negligence. Moreover, just as malpractice liability increases insurance costs for physicians, ultimately increasing charges to payers, informational liability may increase operational costs for MCOs, ultimately increasing premiums for consumers.[276]

Second, liability exposure may discourage MCOs from providing information to enrollees in the first place. If courts only scrutinize the accuracy of the information that MCOs choose to provide (as opposed to considering the information they omit), then MCOs can limit their likelihood of liability by providing minimal information. There are several ways to limit this potential drawback, however. First, even if the information standard does not require MCOs to divulge all information relevant to a necessity determination, courts may determine that it precludes the omission of information necessary to ensure that the information provided is not misleading. Second, a failure to offer sufficient justification of a medical necessity decision may encourage appeals, a result that MCOs may wish to avoid. Third, as previously described, regulations under ERISA require MCOs to justify their negative coverage decisions.[277]

MCOs might still avoid ERISA's justification requirements, however, by avoiding the "adverse benefit determinations" that trigger them.[278] One way to do this is to cover all recommended care, which may harm enrollees by causing an increase in insurance costs.[279] Another way is to discourage the requests or challenges that make

276. Liability exposure may be greater for MCOs than for physicians, given their deeper pockets and the perhaps greater likelihood of punitive damages. While punitive damages are rarely awarded in physician malpractice cases, *see* FURROW ET AL., *supra* note 106, § 6-7(a), courts have awarded substantial damages in cases involving MCOs. In a case involving a woman who had been denied an autologous bone marrow transplant for breast cancer based on the lack of scientific evidence for the safety and effectiveness of the procedure, the jury awarded $77 million in punitive damages. *See* MORREIM, *supra* note 20, at 41. Later studies showed that the procedure was ineffective. *Id.* Several cases have had damage awards approaching $100 million. *See* Agrawal & Hall, *supra* note 240, at 270.

277. *See supra* notes 214–18 and accompanying text.

278. An "adverse benefit determination" is defined broadly to include "a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit." 29 C.F.R. § 2560.503-1(m)(4) (2004).

279. *See, e.g.*, JACOBSON, *supra* note 20, at 183 (noting that the threat of liability might cause MCOs to refrain from influencing medical decisions). This problem would be mitigated if MCOs were also held liable for providing coverage for unnecessary care.

such determinations necessary.[280] For example, MCOs might discourage physicians from making initial recommendations for treatment.[281] To reduce the likelihood of recommendations of high-cost care, they might use financial incentives such as compensation that rises as treatment costs decrease, or disincentives such as the threat of exclusion from a network or the demotion to a less-preferred tier in a tiered health plan. If physicians respond to such incentives, the enrollee may never realize that another treatment choice is available.[282] To achieve the full informational potential of the bifurcated regime, enrollees and/or their physicians must make claims for the care that they think is appropriate, and MCOs must then explain why the care is inappropriate.[283]

There are several limits, however, on MCO attempts to circumvent information provision requirements through their influence on physicians. First, treating physicians may resist negative MCO influences for ethical reasons; the American Medical Association's code of ethics requires physicians to disclose treatment options, regardless of the availability of coverage.[284] Second,

280. Calad's Supreme Court brief, for example, indicates that CIGNA never needed to issue a formal denial, "since Calad did what CIGNA wanted by leaving the hospital early." Brief for Respondents, *supra* note 86, at 8.

281. *See, e.g.*, M. Gregg Bloche, *One Step Ahead of the Law: Market Pressures and the Evolution of Managed Care*, *in* THE PRIVATIZATION OF HEALTH CARE REFORM 35 (M. Gregg Bloche ed., 2003) ("By delegating utilization management to treating physicians (and motivating them with financial rewards for withholding care), health plans could avert the risk of liability for negligent denial of benefits."); *cf.* John V. Jacobi, *Patients at a Loss: Protecting Health Care Consumers Through Data Driven Quality Assurance*, 45 U. KAN. L. REV. 705, 757–62 (1997) (discussing circumstances under which an MCO member will not recognize substandard care because of the absence of a "trigger event" such as a denial).

282. Nearly a third of respondents to a 1998 survey of physicians reported sometimes, often, or very often declining to offer useful services because of health plan rules. *See* Matthew K. Wynia et al., *Do Physicians Not Offer Useful Services Because of Coverage Restrictions?*, 22 HEALTH AFF. 190, 193 (2003). Having a significant proportion of income (at least twenty-five percent) at risk if costs were too high was only a borderline predictor of this behavior, however; the strongest predictor was receiving patient requests to deceive health insurers (presumably to obtain coverage). *Id.*; *see also* Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, 265 (1999) (explaining that physicians do not always disclose noncovered treatments).

283. In addition, for patients to receive the maximum informational benefit from physicians as well as from MCOs, it is important that physicians be permitted to provide their honest advice without fear of MCO retaliation. On this issue, see Richard A. Epstein & Alan O. Sykes, *The Assault on Managed Care: Vicarious Liability, ERISA Preemption, and Class Actions*, 30 J. LEGAL STUD. 625, 646–47 (2001).

284. *See* AM. MED. ASS'N, CODE OF MEDICAL ETHICS, POLICY E-8.135: COST CONTAINMENT INVOLVING PRESCRIPTION DRUGS IN HEALTH CARE PLANS (2002), *available at* http://www.ama-assn.org/ama/pub/category/8500.html ("If physicians exhaust

physicians who fail to disclose treatment options may face tort liability themselves.[285] Third, while the influence of financial incentives alone may not transform a physician into an MCO agent, the greater the magnitude of MCO influence over physician treatment decisions, the more likely the MCO will be held vicariously liable for these decisions.

Another way that MCOs can avoid information provision requirements is by contractually specifying coverage criteria. If an MCO's coverage decision is based not on an evaluation of medical evidence, but instead on policy terms expressly excluding coverage of the recommended treatment, then the decision provides no medical information to the enrollee requesting the treatment. The MCO reduces its liability risk because, in such a case, the enrollee could not possibly have a claim against the MCO for the negligent provision of medical information. This approach would reduce the informational benefits of the proposed regime, because an enrollee would not receive the MCO's assessment of whether the proposed treatment is medically necessary. If a policy excluded coverage for bariatric surgery, for example, then the enrollee could rely only on a treating physician's advice about whether the surgery was needed. On the other hand, this approach would generate the countervailing benefit of increased transparency of health plan decisionmaking. Rather than being subject to the vagaries of medical necessity-based claims review, prospective enrollees who read the policy terms would know that bariatric surgery would not be covered.[286] They could then

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all avenues to secure a formulary exception for a significantly advantageous drug, they are still obligated to disclose the option of the more beneficial drug to the patient, so that the patient can consider whether to obtain the medication out-of-plan."); *see also* AM. MED. ASS'N, CODE OF MEDICAL ETHICS, POLICY E-8.053: RESTRICTIONS ON DISCLOSURE IN HEALTH CARE PLAN CONTRACTS (2002), *available at* http://www.ama-assn.org/ama/pub/category/8480.html (referring to "ethical requirements demanding full disclosure of treatment options regardless of limitations imposed by plan coverage").

285. The patient may have a malpractice claim if the treatment the physician recommends is inconsistent with the standard of care. Alternatively, if failure to disclose a relevant treatment option caused a patient to choose another option that injured the patient, the patient might have a claim based on a lack of informed consent. Furthermore, at least one court has suggested in dicta that physicians may have a duty to advocate for patients potentially harmed by coverage decisions: "[T]he physician who complies without protest with the limitations imposed by a third party payor, when his medical judgment dictates otherwise, cannot avoid his ultimate responsibility for his patient's care." Wickline v. State, 239 Cal. Rptr. 810, 819 (Cal. Ct. App. 1986); *see also* MORREIM, *supra* note 20, at 94–96 (exploring the nature of physicians' duties to advocate); William M. Sage, *Physicians as Advocates*, 35 HOUS. L. REV. 1529, 1538, 1545 (1999) (describing *Wickline* and the duties of physicians as advocates in coverage disputes).

286. Mark Hall notes that in practice, some, but not all, insurers have begun to exclude coverage for bariatric surgery. He concludes that "cost considerations remain covert in

encourage their employer to offer a wider benefit package, purchase a more comprehensive policy, or set aside additional funds for uncovered care.[287]

The magnitude of tort-related increases in premiums, the extent of MCO efforts to avoid information provision, and the prevalence of other tort law-related drawbacks will depend on how effectively both the tort system and the market for health insurance function. If MCOs understand the minimum standard of care as applied by state courts, and courts are able to identify accurately compliance with the standard, MCOs can avoid liability simply by meeting the standard. There would be no need to resort to elaborate mechanisms to avoid disclosure of medical information. If purchasers of insurance value information more than the cost of its production (including the cost associated with complying with the informational standard), MCOs would have an incentive to disclose information despite the possibility of tort liability.[288]

Furthermore, if tort reform is applied to MCOs as well as to physicians, and if it proves to be effective, it will reduce the magnitude of the drawbacks associated with tort liability. For example, recent federal tort reform proposals have included caps on noneconomic and punitive damages that appear to apply to MCOs.[289] Such caps would limit MCOs' liability exposure and thus reduce any associated disincentive to provide medical information.

A third risk of recognizing tort liability deserves mention: tort liability may impede efforts to realize the fundamental objectives of

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medical necessity determinations, rather than being exposed to public scrutiny or contractual specification." Hall, *supra* note 193, at 671.

287. On the benefits of contractual specificity, see HAVIGHURST, *supra* note 199, at 27–28; MORREIM, *supra* note 20, at 132–33; Sage, *supra* note 117, at 637.

288. This Article presumes that the value of MCO information provision exceeds its cost of production. If MCOs' information costs were higher than the benefits that such information produced, both the proposed tort law-based information disclosure requirements and current ERISA requirements would be welfare-reducing, and those who fund the costs of insurance would be unlikely to demand information provision. An information standard formulated in part based on the costs and benefits of information provision would reduce the likelihood of such a result. Furthermore, improvements in information technology and the development of the Internet have likely decreased the costs of information collection and dissemination, increasing the probability that the value of such information exceeds its cost.

289. *See, e.g.*, Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2005, H.R. 534, 109th Cong. § 4(b) (2005) (limiting noneconomic damages in health care lawsuits to $250,000); *id.* § 7(b)(2) (limiting punitive damages to the greater of $250,000 or two times the amount of economic damages); *id.* § 9(7) (defining "health care lawsuit" to include health care liability claims concerning health care services brought against a health care organization); *id.* § 9(10) (defining "health care organization" to include any person or entity obligated to pay for health benefits under any health plan).

ERISA by undermining the benefits of ERISA preemption. In *Ingersoll-Rand Co. v. McClendon*,[290] the Supreme Court reasoned that

> [s]ection 514(a) was intended to ensure that plans and plan sponsors would be subject to a uniform body of benefits law; the goal was to minimize the administrative and financial burden of complying with conflicting directives among States or between States and the Federal Government .... It is foreseeable that state courts, exercising their common law powers, might develop different substantive standards applicable to the same employer conduct, requiring the tailoring of plans and employer conduct to the peculiarities of the law of each jurisdiction.[291]

Citing this language, the Fifth Circuit in *Corcoran v. United Healthcare, Inc.*[292] suggested that "there is a significant risk that state liability rules would be applied differently to the conduct of utilization review companies in different states," and that this variation would increase the costs of providing such services, decreasing plan funds available for other purposes.[293] Similarly, there is a risk that if states were to impose tort liability for MCOs' provision of information, the substantive standards would differ. While this should not cause significant additional administrative difficulties for employers that purchase health insurance packages directly from insurers—these packages are already subject to varying state statutory requirements under ERISA's "savings" clause exception to preemption—variable state standards could in theory increase the complexity of administering a multistate self-insured health plan.[294]

The courts' discussions of the uniformity issue do not detail the nature of the complexities that would result from variation in state

290. 498 U.S. 133 (1990).

291. *Id.* at 142.

292. 965 F.2d 1321 (5th Cir. 1992).

293. *Id.* at 1333.

294. *See* ERISA § 514(b)(2)(A), 29 U.S.C. § 1144(b)(2)(A) (2000) ("Nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance ...."). This savings clause provision allows states to mandate benefits in insurance packages and to impose other requirements on insurers. Under the "deemer" clause, ERISA § 514(b)(2)(B), 29 U.S.C. § 1144(b)(2)(B), however, these regulations may not be applied to self-insured benefit plans. *See* Metro. Life Ins. Co. v. Massachusetts, 471 U.S. 724, 733, 744 (1985) (holding that a Massachusetts statute mandating the inclusion of mental health benefits in insurance contracts is not ERISA-preempted and discussing the roles of the savings and deemer clauses).

standards with respect to coverage decisions.[295] If states were permitted to enact statutes regulating the structure of the decisionmaking process, the potential for variation is clear. For example, one state might require a decision within five days, another within ten days. As Professors Jacobson and Pomfret point out, however, variation in state standards need not preclude uniformity in health plans.[296] As long as requirements do not conflict, a plan can satisfy them all by complying with the strictest requirement. A plan that faced a five-day requirement in some states and a ten-day requirement in others could simply make all of its decisions nationwide within five days. If a direct conflict in requirements imposed by states did arise, Congress could remedy the conflict by creating a federal regulation that preempts state law with regard to the specific issue in question.

Furthermore, there is unlikely to be significant variation in state common law substantive standards for the MCO provision of medical information, and it is difficult to imagine a scenario under which standards regulating informational quality would directly conflict.[297] Courts have increasingly abandoned local custom-based standards of care for physicians in favor of national standards, particularly for specialists.[298] Similarly, courts should recognize a national standard of care for MCO information provision, and would likely do so. The medical research that would supply the basis for MCOs' coverage decisions would often be publicly available nationwide, and many MCOs themselves are national in scope. For this reason, variation among state tort decisions is unlikely to exceed substantially variation among decisions within a federal system. To the extent that such variation does arise, the Department of Labor could expand its rulemaking to respond to it.

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295. For example, in *Ingersoll-Rand*, the Supreme Court expressed concern about the possibility of "different substantive standards applicable to the same employer conduct," but did not provide hypothetical or actual examples of such standards. *See Ingersoll-Rand*, 498 U.S. at 142. Similarly, in *Corcoran*, the Fifth Circuit refers to the "significant risk that state liability rules would be applied differently to the conduct of utilization review companies in different states," but does not describe the nature of any such differences in application. *See Corcoran*, 965 F.2d at 1333.

296. Jacobson & Pomfret, *supra* note 119, at 1066.

297. *See* Jordan, *supra* note 6, at 444–45 (arguing that differences in substantive state law standards are unlikely to hinder interstate administration of ERISA plans).

298. *See* FURROW ET AL., *supra* note 106, § 6-2. *See generally* Jacobson & Pomfret, *supra* note 119, at 1065–68 (discounting the lack-of-uniformity argument as a justification for ERISA preemption of claims based on utilization review, in part because of increasingly national standards of care).

Thus, while there may be drawbacks to imposing tort liability for medical information provision, they are generally limited in magnitude and can be addressed through a variety of means. The benefits of imposing liability are likely to outweigh these drawbacks.

CONCLUSION

Increasing health care costs have prompted a resurgence of interest in traditional techniques for managing care.[299] Pharmaceutical "step therapy" of the sort at issue in the *Davila* case, which requires patients to first try less expensive drugs before trying more expensive drugs, is still required by the health plans of millions of Americans; one pharmacy benefit manager reports that the use of step therapy has nearly tripled among its clients in the last three years.[300] Utilization review nurses, such as the one who played a role in Calad's case, continue to monitor hospital care.[301] A number of health plans that had eliminated prior authorization requirements in the wake of the managed care backlash reinstituted at least some of them after health care utilization levels began to rise rapidly.[302] While MCO requirements on the whole may be less restrictive than they once were,[303] they nonetheless will continue to provoke controversy among patient-enrollees and treating physicians.

Denials of coverage for care that would improve the health of enrollees can have serious long-term consequences. Regardless of whether the denials are improper or proper, and regardless of whether they are based on medical judgment, they can effectively deny care for enrollees who do not themselves have the funds to pay for care. But denials of coverage that entail the communication of incorrect medical information may have an additional effect: they

299. *See, e.g.*, DEBRA A. DRAPER & GARY CLAXTON, CTR. FOR STUDYING HEALTH SYS. REFORM, MANAGED CARE REDUX: MANAGED CARE PLANS SHIFT RESPONSIBILITY TO CONSUMERS, ISSUE BRIEF NO. 79, 1–2 (2004), *available at* http://hschange.org/CONTENT/666/666.pdf (explaining that sharp increases in utilization have led to the reimposition of certain managed care controls).

300. Martinez, *supra* note 182.

301. Mays et al., *supra* note 152, at W4-430; *see also* Robert Kazel, *Tightening the Leash: Managed Care Hassle Factors Getting Bigger*, AM. MED. NEWS, Oct. 18, 2004 (stating that some "health plans have increased the presence of utilization review nurses working inside hospitals, in part to facilitate earlier discharges").

302. Mays et al., *supra* note 152, at W4-429 to -30. Some plans have introduced preauthorization requirements for imaging procedures. *See, e.g.*, Jeffrey Krasner, *Blue Cross to Require Preapproval for Scans*, BOSTON GLOBE, Sept. 6, 2005, at C1 (reporting that Blue Cross and Blue Shield of Massachusetts planned to impose such authorization requirements).

303. Mays et al., *supra* note 152, at W4-429 to -30.

may discourage enrollees, whether financially constrained or not, from seeking needed care. While an informational influence on enrollees may seem unlikely in a climate characterized by distrust of MCOs, the more significant the role that MCOs begin to play in information collection, processing, and dissemination, the more that enrollees will—and should—rely on MCOs' information provision. The goal of tort liability would be to hold MCOs accountable for the quality of this information provision.

A bifurcated legal regime will not benefit every enrollee harmed by improper MCO adverse benefit determinations. An MCO may make an improper benefit determination but nonetheless comply with the standard for information provision. Alternatively, evidence may suggest that an enrollee has failed to pursue a recommended course of treatment not because of poor information but instead solely because of a lack of funds. In neither case would the bifurcated regime offer individual enrollees an improvement over the current ERISA-based regulatory regime. It is not clear, for example, whether either Davila or Calad would benefit from this system. Additional reforms therefore may prove useful. Reforms that improve access to and increase the use of external review mechanisms and ERISA litigation would help prevent injuries due to both poor information and financial constraints. In addition, extending the remedies available under ERISA to include consequential damages would increase MCOs' incentives to prevent injury to enrollees while at the same time supplying a remedy for injuries that do occur. Congressional attempts to expand ERISA liability, however, have failed repeatedly.

A more incremental approach may meet with greater success. Subjecting information provision to state tort liability would provide an incentive to improve informational quality, while continued ERISA regulation of coverage determinations would preserve the viability of cost-based coverage criteria. A federal statute creating a bifurcated legal regime would benefit future enrollees who want to make informed choices about the care they receive. It would thus be an appropriate legal innovation for an era of consumer-driven health care.