

# MANAGED CARE'S CRIME: MEDICAL NECESSITY, THERAPEUTIC BENEFIT, AND THE GOALS OF ADMINISTRATIVE PROCESS IN HEALTH INSURANCE

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Reading news headlines, one would think that the managed care wars were over. By the end of 2001, forty-two states had enacted laws subjecting coverage determinations by managed care companies to “external” or “independent” review, with twenty-seven states adopting them in the preceding three years.<sup>1</sup> In June 2002, the Supreme Court held that the federal ERISA statute<sup>2</sup> did not preempt an Illinois law requiring health maintenance organizations (HMOs) to submit coverage denials to binding independent review.<sup>3</sup> In February

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1. KAREN POLLITZ ET AL., ASSESSING STATE EXTERNAL REVIEW PROGRAMS AND THE EFFECTS OF PENDING FEDERAL PATIENTS' RIGHTS LEGISLATION v (rev. 2002) (report to the Henry J. Kaiser Family Foundation), available at [http://www.kff.org/insurance/external\\_reviewpart2rev.pdf](http://www.kff.org/insurance/external_reviewpart2rev.pdf); see also RACHEL BEVINS MORGAN, 2003 STATE BY STATE GUIDE TO MANAGED CARE LAW § 5.2 (Donald R. Levy ed., 2003) (compiling state independent external review laws). Independent review is “a formal process for resolving disputes between health plans and consumers [after exhaustion of remedies internal to the plan] . . . [It] generally is independent of disputing parties and has the capacity to evaluate and resolve at least those disputes involving medical issues.” POLLITZ ET AL., *supra*, at v. Although independent review can, in theory, apply to any dispute, most such review programs focus on situations in which health plans have denied coverage as not medically necessary, usually in advance of patients' receiving treatment (termed “preauthorization” or “prospective utilization review”). The first independent review law was adopted in Michigan in 1978. See *id.* Under federal law, HMOs that participate in Medicare must offer independent review to beneficiaries whose claims are denied. See 42 C.F.R. § 422.592 (2002) (requiring independent review of adverse determinations by Medicare+Choice plans).

2. Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001–1461 (2000).

3. Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355 (2002). The degree to which ERISA preempts both state regulatory efforts and private tort claims involving private health coverage remains unsettled. See POLLITZ ET AL., *supra* note 1, at vii–x. In the 1980s, the Court uniformly held that state laws challenged under ERISA “related to” employee benefit plans,

2003, the Second Circuit joined a growing number of federal courts of appeals in allowing individual plaintiffs to sue managed care health plans in state court alleging that faulty decisionmaking caused physical harm.<sup>4</sup> In May 2003, Aetna settled a nationwide class action brought by physicians by agreeing, among other things, to apply generally accepted medical standards in determining the medical necessity of proposed treatments.<sup>5</sup> Congress has all but abandoned efforts to enact a "Patients' Bill of Rights," and has placed managed care on a legislative back burner in order to deal with medical malpractice reform and a Medicare prescription drug benefit. Doctors who only a few years ago were clamoring for expanded rights to sue health plans are now standing shoulder-to-shoulder with the managed care industry against the predations of the personal injury bar.

Can one conclude from these events that the era of lawless managed care has ended? Is the relationship among patients, physicians, and health insurers now governed by a well-accepted framework of contractual obligations and readily available independent administrative review, with predictable recourse to private litigation as a last resort? Hardly. Although many of these regulatory and self-regulatory developments hold promise for improving both health insurance and medical care, they suffer from three substantial infirmities. First, they oversimplify the economic and clinical effects of managed care by focusing attention primarily on the determination of "medical necessity," a term of art in health insurance contracts used to distinguish, at the margin, covered from

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were not saved as "laws regulating insurance," and were therefore preempted. Beginning in 1995, however, the Court reversed course and began to narrow the scope of ERISA preemption by limiting the reach of the statute's "relating to" language and relaxing its definition of insurance laws. *New York State Conference of Blue Cross and Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645 (1995). In April 2003, the Court continued its string of pro-regulatory rulings involving managed care by permitting Kentucky to enforce its any-willing-provider statute, notwithstanding ERISA. *Ky. Ass'n of Health Plans, Inc. v. Miller*, 123 S. Ct. 1471 (2003).

4. See *Cicio v. Does*, 321 F.3d 83, 90 (2d Cir. 2003). The Supreme Court is currently reviewing a group of Fifth Circuit cases involving personal injury claims against employer-sponsored health plans. See *Aetna Health Inc. v. Davila*, 124 S. Ct. 462 (2003) (granting certiorari); *CIGNA Healthcare of Texas, Inc. v. Calad*, 124 S. Ct. 463 (2003) (granting certiorari); see also *Roark v. Humana, Inc.* 307 F.3d 298 (5th Cir. 2002) (consolidated opinion).

5. Joseph B. Treaster, *Aetna Agreement with Doctors Envisions Altered Managed Care*, N.Y. TIMES, May 23, 2003, at A1. According to Archie Lamb, lead counsel for the plaintiffs, Aetna promised in the agreement "to commit to external review, transparency, clearly defined coding guidelines and a meaningful enforcement mechanism." Press Release, Aetna, Physicians and Aetna Begin New Era of Cooperation (May 22, 2003), at [http://www.aetna.com/news/2003/prtptr\\_20030522.htm](http://www.aetna.com/news/2003/prtptr_20030522.htm) (on file with the *Duke Law Journal*) (quoting Archie Lamb).

noncovered services.<sup>6</sup> Second, their universality is easily exaggerated; the Supreme Court in *Rush Prudential HMO v. Moran*<sup>7</sup> strongly suggested that, without new federal legislation, states may not mandate independent review for the tens of millions of patients covered by “self-funded” ERISA plans,<sup>8</sup> and that the state law in question applied narrowly to HMOs, not all health insurance.<sup>9</sup> Third, they take insufficient account of underlying variation in health plan structure, financial incentives, and clinical acumen and resources.<sup>10</sup> Second-best theory suggests that layering a uniform review and appeals system atop such a variable decisionmaking process may, at the end of the day, make access to medical care less—rather than more—consistent.<sup>11</sup>

This Essay explores the concept of medical necessity as it has evolved in the judicial and administrative oversight of managed care. The goals of the Essay are to illustrate the range of plausible rationales for establishing administrative procedures to govern medical necessity disputes, and to demonstrate the difficulty of incorporating into those procedures the most important professional and social responsibilities of managed care in today's health care system. Part I of the Essay explains the ideological and practical significance of medical necessity as managed care has evolved. Part II examines medical necessity as a legal problem, and questions whether current independent review programs match social needs. Part III

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6. See Mark A. Hall & Gerard F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637, 1663–65 (1992) (describing a trend among insurers, since the mid-1970s, to control costs by scrutinizing medical necessity).

7. 122 S. Ct. 2151 (2002).

8. See *id.* at 372 n.6 (“ERISA’s ‘deemer’ clause provides an exception to its saving clause that prohibits States from regulating self-funded plans as insurers.”).

9. 215 ILL. COMP. STAT. 125/4-10 (2000); see also *Rush*, 536 U.S. at 361, 361 n.1 (discussing the scope of the statute).

10. For example, the right to independent review under the Illinois statute challenged in *Rush* only arose if the patient's primary care physician, who was part of the health plan's network, had the courage and incentive to disagree with the health plan's denial decision. See 215 ILL. COMP. STAT. 125/4-10 (granting a right to an independent review only “in the event of a dispute between the primary care physician and the [HMO] regarding the medical necessity of a covered service proposed by a primary care physician”); see also *Rush*, 536 U.S. at 361 (quoting the statute).

11. Second-best theory holds that if one condition of a complex system cannot be fulfilled, a second-best solution can be obtained only by departing from all the other optimal conditions. See, e.g., Andrew P. Morriss, *Implications of Second-Best Theory for Administrative and Regulatory Law: A Case Study of Public Utility Regulation*, 73 CHI.-KENT L. REV. 135, 136 (1998) (quoting a statement of this theory in R.G. Lipsey & R.K. Lancaster, *The General Theory of Second Best*, 24 REV. ECON. STUD. 11, 12 (1956–57)).

offers an alternative perspective on oversight of decisionmaking in managed care that emphasizes therapeutic effect rather than contractual enforcement. Part IV describes improvements in both independent review and overall medical necessity policy that would better serve therapeutic objectives. Among other things, the Essay suggests that independent review procedures should be different for insured individuals who are severely or chronically ill than for those who are only occasional users of health care services.

## I. MEDICAL NECESSITY IN THEORY AND PRACTICE

The most important thing to appreciate about “medical necessity” is that it has always operated at two levels: symbolic and substantive. Health policy debates over medical necessity are sometimes about the benefits to which insured patients should be entitled, but they are just as often about ideology or political advantage. The rise of managed health care and the subsequent backlash against it are frequently portrayed in simplistic fashion as a struggle between corporate interests and individual health professionals for control over health care decisions, and by extension as a referendum on the legitimacy of allowing cost considerations to override clinical judgment. The determination of medical necessity is a convenient emblem of, or metaphor for, this struggle.<sup>12</sup>

History buffs can think of medical necessity as managed care’s “Crimea”—and not only because health plans have gotten trapped and wounded in it from time to time. An oddity of the Crimean War was that nobody much cared about capturing the Crimean Peninsula (which is in southern Ukraine near the Black Sea).<sup>13</sup> It was mainly a convenient place for the armies to fight. Few soldiers fought for territory. More fought for honor. Many suffered casualties. As a French general is said to have remarked of the Light Brigade’s famous charge, it was “magnificent[,] but not war.”<sup>14</sup> A popular war ideologically, the Crimean campaign as actually conducted was fraught with ambiguities that eventually came to haunt the British

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12. See, e.g., Sara Rosenbaum et al., *Who Should Determine When Health Care Is Medically Necessary?*, 340 *NEW ENG. J. MED.* 229, 229 (1999) (framing the discussion of medical necessity as central to “a radical shift in power” from physicians to insurers since the late 1970s).

13. On the Crimean War generally, see TREVOR ROYLE, *CRIMEA* (2000). The Crimean War was fought in the 1850s, and involved Russia on one side and England, Turkey, France, and Sardinia on the other. Britain and France declared war on Russia in 1854, see *id.* at 127, and by 1856 Russia had been decisively beaten, *id.* at 501.

14. *Id.* at 274.

public.<sup>15</sup> Similarly, one must temper the image of medical necessity as a fierce battlefield between physicians and insurers with an evaluation of actual legal and public policy importance in order to offer meaningful suggestions for improving its implementation and oversight.<sup>16</sup>

#### A. *The Meanings of Medical Necessity*

“Medical necessity” is an unfortunate term that we seem to be stuck with. In this respect, it is hardly unique in health policy—“managed care” is worse. Unlike “managed care,” however, the excess baggage of “medical necessity” is not its pejorative connotation, but rather its multiplicity of meanings. In today’s health care system, parties with a range of backgrounds and biases are involved in medical necessity decisions. To many physicians, the phrase “not medically necessary” means “not clinically indicated,” which makes them question why a seemingly nonprofessional party such as a health plan has the right to challenge their professional opinion. To many health plans, it means “not covered even though not expressly excluded from coverage,” which gives them a degree of comfort issuing denials based on established insurance practice even though such decisions outrage physicians. Consequently, decisions involving medical necessity are frequently characterized by inconsistent administration, poor communication, distrust and, if disputes arise, relatively unprincipled, results-oriented judicial resolution.<sup>17</sup>

Managed care caused wrenching change to the American health care system, and altered forever the economic landscape of medical practice. But if managed care ever was as polarized in operation as the overheated political rhetoric of “patient protection” would suggest, that time has passed. Therefore, the stereotyped image of

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15. See ASA BRIGGS, *THE AGE OF IMPROVEMENT 1783–1867*, 376–85 (1979).

16. Some disclaimers are warranted. First, as befits a law professor, I am interested more in the forest than the trees. I devote much of this Essay to brush-clearing—hacking away at various aspects the business of insurance, the practice of medicine, the political environment, and the law to uncover what I believe are essential but neglected aspects of the medical necessity debate. Second, as space does not permit a comprehensive analysis of all the issues raised in the Essay, I am selective about the issues discussed. Third, I offer an informed opinion about medical necessity; I do not present all sides of the question or document in detail the current state of the law.

17. See William M. Sage, *Judicial Opinions Involving Health Insurance Coverage: Trompe L’Oeil or Window on the World?*, 31 *IND. L. REV.* 49, 66 (1998) (“Coverage cases are notorious for results-oriented reasoning.”).

physicians and insurers battling over medical necessity is potentially misleading for policymakers. Today, greater concordance exists between organizational and professional perspectives than is generally credited. Specifically, decisions about health care have become responsibilities of the health plan or other system that also determines coverage, and not merely of that system's constituent physicians. This convergence of coverage with care necessarily blends managerial and clinical roles, and exists in part because the United States has rejected centralized controls over health care resources. Instead, American health care places private insurance organizations in positions with high public visibility and attendant social obligations.

A striking aspect of recent discussions I have had with health plans about medical necessity was a dog that didn't bark—that is, an argument *not* made.<sup>18</sup> For decades, a standard move by insurers in contractual language, lobbying activity, and courtroom defense tactics was to maintain that coverage is about money, not about access to health care. If coverage is denied, the argument goes, an insured individual is free to finance the desired care in other ways, and a physician or hospital is welcome to provide it gratis. This was arguably true of indemnity insurance; however, it has always seemed disingenuous in managed care, whose *raison d'être* is to give insurers a voice in determining what care is actually delivered to patients. Still, I recall a 1994 workshop involving health plans from around the country where several hours were spent arguing the point. By contrast, in meetings I have attended since 2000, no health plan took this position. Instead, they were willing to acknowledge their influence over clinical care, and seemed to have abandoned the fiction that medical necessity determinations are merely payment decisions.

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18. The source of this metaphor is Sir Arthur Conan Doyle's short story *Silver Blaze*. SIR ARTHUR CONAN DOYLE, *Silver Blaze*, in THE MEMOIRS OF SHERLOCK HOLMES 1, 1–44 (D. Appleton & Co. 1902) (1893). Holmes surmises that no stranger was present at a racing stable because “[t]he dog did nothing in the night-time,” *id.* at 34, leading him to conclude that a groom was killed by the eponymous racehorse while trying to steal it, *id.* at 40. For readers who might feel that this digression into Victorian literature is a perfect example of how law review articles love to cite tangential material, please rest assured that there is a substantive connection. A subsequent chapter of the same book tells the story of a prison break aboard a convict ship bound for Australia, which only occurred because the better secured vessels usually employed for such purposes were being used for transporting troops in the Black Sea, as “[i]t was the year [18]55, when the Crimean war was at its height.” SIR ARTHUR CONAN DOYLE, *The “Gloria Scott”*, in THE MEMOIRS OF SHERLOCK HOLMES, *supra*, at 108, 129.

Furthermore, health plans appear receptive to discharging these responsibilities “professionally.” For example, participants in a recent Stanford study of coverage decisionmaking in California, for which I served as a consultant, unanimously and unquestioningly supported the consensual development of “best practices” for medical necessity determinations.<sup>19</sup> This is a distinctively professional, self-regulatory approach to a problem that could equally have been left to consumer preferences expressed in the market, democratically determined legislative mandate, or regulatory specification. Through 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.

However, the professionalization of decisions about medical necessity does not imply that a single professional paradigm is being applied. Health plans, medical groups, individual physicians, patients, and courts have varying views of the term’s meaning and its interaction with the contractual, clinical, and regulatory structures that govern the health care system. Relatively little of this disagreement is purely mercenary or self-interested. Rather, most everyone involved tries to do the “right thing,” but their ethical and practical frameworks differ substantially.

For example, in a series of “key informant interviews,” the Stanford study asked health plans and delegated provider groups in California to state the difference between a “medical necessity decision” and a “coverage decision.”<sup>20</sup> The question elicited a much greater range of responses than would have been the case twenty years ago, when all such decisions were rendered by indemnity insurers after treatment had already been administered. One view was that the two terms were identical. A second was that medical necessity decisions determined clinical availability, while coverage decisions determined payment. A third was that medical necessity decisions determined the level and intensity of care (e.g., the right to see a specialist with particular skills), while coverage decisions merely verified the existence of some benefit. A fourth was that medical

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19. See Sara J. Singer & Linda A. Bergthold, *Prospects for Improved Decision Making About Medical Necessity*, HEALTH AFF., Jan.–Feb. 2001, at 200, 203 (“In virtually all cases, workshop participants ranked recommendations higher on impact than on feasibility”); Sara Singer et al., *Decreasing Variation in Medical Necessity Decision Making: Final Report to the California Healthcare Foundation 23* (1999), available at <http://www.chcf.org/documents/policy/medicalnec.pdf> (on file with the *Duke Law Journal*).

20. *Id.* at 23. I read and evaluated deidentified transcripts of these interviews.

necessity decisions assessed existing practices, while coverage decisions assessed new technologies. A fifth view was that medical necessity decisions were based on individual patients' clinical circumstances, while coverage decisions applied generally to the insured group. A sixth view was that coverage decisions were explicit contractual matters, whereas "medical necessity" was a deliberately ambiguous term because individual judgments at the margin cannot as a practical matter be specified contractually. One respondent referred to this as "conditional eligibility," suggesting that care that was not "medically necessary" still might be covered under special circumstances, but not indicating on what basis—principled, compassionate, or discriminatory—such "exceptions" might be made.

In the legislative or administrative context, moreover, medical necessity attracts stakeholders like honey breeds flies. When Medicare, Medicaid, or private health insurance is debated, special interest groups battle fiercely over the details of coverage language because, literally, coverage is where the money is. The resultant logrolling may serve the stakeholders involved, but generally muddies any logic that the statutory or regulatory language might have had. Furthermore, political tactics often exacerbate the ambiguity inherent in "medical necessity" by forcing it to do more work than principles of good drafting would dictate. Savvy legislators often prefer to bury the deals they have cut in seemingly neutral provisions so that they are hard to spot and even harder to delete. For example, pro-choice advocates in the 1993-94 health care reform debate paid close attention to which word was chosen to govern the proposed national benefits package—medically "necessary" or medically "appropriate"—rather than trying to fight an uphill battle for explicit abortion coverage.

All in all, these factors suggest that ambiguity in the interpretation of medical necessity is inevitable, especially in the private, pluralistic health care system that will exist in the United States for the foreseeable future. This counsels against mandating intricate, but supposedly less ambiguous, definitions of medical necessity, as some commentators have suggested.<sup>21</sup> Furthermore,

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21. See, e.g., David M. Eddy, *Benefit Language: Criteria That Will Improve Quality While Reducing Costs*, 275 JAMA 650, 653-54 (1996) (recommending the adoption of language more detailed than "medically necessary," which suffers "from gross imprecision and conflicting interpretations," but acknowledging that new language should still be flexible enough for individual plans to define and amend definitions of their local methods).



prevailing views of the term are both substantively different and emotionally laden, which both adds to the contentiousness of disputes and limits the usefulness of standardized definitions. If the serious problems of resource allocation underlying the notion of medical necessity are not well-suited either for free-market contracting or political resolution, but are more matters of professional ethics and social norms, one should not rely on medical necessity to set strict boundaries. Instead, one should look for other ways to control costs and assure quality in insured systems.

### *B. Medical Necessity and Benefit Design*

A serious problem is that, because of its symbolic importance, health professionals and policymakers often regard “medical necessity” as a coverage standard unto itself, rather than entwined with a historically determined, legally stylized insurance document that itself operates within an increasingly complicated set of relationships among purchasers, health plans, and providers. When the standard for coverage seems to be “necessity,” answering the question “Is it necessary?” with “It’s not covered” is inviting conflict. Accordingly, a prerequisite for improving medical necessity is understanding the term’s role in benefit design and what alternatives exist to employing it in its current form.

Health insurance contracts are based on broad categories of covered services such as hospital care, physician care, care by other health professionals, diagnostics, medical equipment, and prescription drugs. This structure arose because comprehensive health insurance is an aggregation of previously separate strands of coverage—some originally sponsored by specific providers (e.g., Blue Cross for hospital services, Blue Shield for physician services), others layered on to accommodate new technologies or allied and alternative professionals (e.g., chiropractors).

Within many of these categories, services may still be denied coverage if they are deemed “not medically necessary” (or categorized under related terms such as “experimental,” “investigational,” “cosmetic,” or “for the convenience of the patient or family”). These vague, general exclusions were the result of cost pressures beginning in the 1960s that forced health plans to make their own determinations of appropriateness rather than rely exclusively on the judgment of treating physicians. Deferring to physicians was less tenable because the principal source of

questionable spending had become high-cost technologies, procedures, and inpatient services from the medical mainstream, rather than “unconventional” therapies and practitioners. In part because of this history, and in part because regulators feared making intricate insurance policies even more complicated, insurers adopted broad coverage standards based on supposedly objective indicia of appropriateness—such as “medical necessity”—rather than listing specifically included or excluded services.

In other words, the same pressures that expanded reliance on medical necessity for retrospective review of claims for insurance benefits also eventually produced the principal tools of managed care: preauthorization, selective contracting with providers, and physician financial incentives.<sup>22</sup> All of these devices help insurers to protect themselves against moral hazard, which manifests itself in health coverage as overutilization of services rather than excessive risk-taking, and therefore afflicts medical providers as well as consumers. Consequently, emphasis on one tool generally reduces the need for the others. For example, greater use of selective contracting or physician financial incentives permits less reliance on preauthorization and hence medical necessity to address provider moral hazard, and vice versa. On the consumer side, as described in greater detail below,<sup>23</sup> the principal counterweights to moral hazard are cost-sharing (which can be done in innovative ways that incorporate attributes of medical necessity) and more explicit contracting over the scope of coverage. Because it is safe to assume that technological change will continue to generate increases in medical spending, the key questions are what balance among these strategies health plans will likely employ in the future, and what new strategies will be devised.

What will be the future of medical necessity? Recently, many health plans have beaten a hasty and well-publicized retreat from preauthorization, and have even offered relatively generous support

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22. Preauthorization conditions coverage on having the provider or patient notify the health plan in advance, and is usually imposed for hospital admissions and surgical procedures. Selective contracting either restricts coverage to certain providers (e.g., in traditional HMOs), or gives insured individuals financial incentives to utilize providers who have agreed contractually with the health plan to discounted fees (e.g., in preferred provider organizations). Financial incentives are intended to restrain physicians' tendencies to offer as many services as possible, usually by paying physicians the same monthly amount no matter how often the patient is seen (capitation), or by reducing physician fees if aggregate spending exceeds certain benchmarks (withholds).

23. See *infra* notes 147–150 and accompanying text.

for care in clinical trials that was previously excluded as “investigational.”<sup>24</sup> Does this mean that medical necessity is fading in importance? Probably not. There are larger market and legal forces at work. Financial incentives have also been diminishing in popularity, partly because apparent conflicts of interest provoked concern in the media and the courts,<sup>25</sup> and partly because risk-bearing by poorly capitalized, inexperienced physicians spawned insolvency. All else being equal, this adds to the need for some type of medical necessity review. Similarly, selective contracting is less prominent now than a decade ago. It was widely (though not universally) believed from the 1970s through the early 1990s that large, brand-identifiable, tightly integrated managed care organizations eventually would dominate the health care system.<sup>26</sup> To most everyone’s surprise, what emerged from the spectacular failure of the Clinton health plan,<sup>27</sup> and the extraordinarily rapid transformation of the health care system to a private, competitive model in the mid-1990s, was the “disintegration” of managed care into health plans with broad, overlapping networks of physicians. Although a few large “closed-panel” organizations survive (e.g., Kaiser Foundation Health Plan and Group Health Cooperative of Puget Sound), choice became the mantra for managed care. Selective contracting—the heart of the

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24. See Milt Freudenheim, *Big H.M.O. to Give Decisions on Care Back to Doctors*, N.Y. TIMES, Nov. 9, 1999, at A1 (describing United Health Group’s renunciation of preauthorization); Milt Freudenheim, *Medical Insurers Revise Cost-Control Efforts*, N.Y. TIMES, Dec. 3, 1999, at A1 (describing similar changes in other HMOs); Robert Pear, *Managed-Care Plans Agree to Help Pay the Costs of Their Members in Clinical Trials*, N.Y. TIMES, Feb. 9, 1999, at A21 (spotlighting the American Association of Health Plans’ agreement to encourage managed-care plans to cover routine costs associated with clinical trials).

25. See, e.g., *Herdrich v. Pegram*, 154 F.3d 362, 373 (7th Cir. 1998) (holding that financial incentives paid to physician-owners of an HMO “can,” but do not “automatically,” violate ERISA’s fiduciary duty provisions), *rev’d on other grounds*, 530 U.S. 211 (2000); Carl T. Hall, *Kaiser Dumps Bonus Plan: Program Rewarded Doctors for Containing Medical Costs*, S.F. CHRON., Dec. 20, 1995, at B1 (reporting on Kaiser Permanente’s incentive system and other cost-cutting efforts).

26. See ALAIN C. ENTHOVEN, *HEALTH PLAN: THE ONLY PRACTICAL SOLUTION TO THE SOARING COST OF MEDICAL CARE* (1980) (presenting the paradigmatic statement of this position); Clark C. Havighurst, *How the Health Care Revolution Fell Short*, 65 LAW & CONTEMP. PROBS. 55, 56–57 (Autumn 2003) (describing expectations based on the Kaiser model).

27. On the demise of the Clinton health plan, see generally HAYNES JOHNSON & DAVID S. BRODER, *THE SYSTEM: THE AMERICAN WAY OF POLITICS AT THE BREAKING POINT* (1996); JACOB S. HACKER, *THE ROAD TO NOWHERE: THE GENESIS OF PRESIDENT CLINTON’S PLAN FOR HEALTH SECURITY* (1997); THEDA SKOCPOL, *BOOMERANG: CLINTON’S HEALTH SECURITY EFFORT AND THE TURN AGAINST GOVERNMENT IN U.S. POLITICS* (1996).

original HMO model—currently signifies little more than acceptance of discounted fees.

How much of this is lasting change, and how much is historical accident? The primacy of choice in political rhetoric was a reaction to the Clintons' heavy-handedness, and much of the enthusiasm for expensive "patients' rights" was arguably a luxury of economic prosperity, a tight labor market, relatively stable health care costs, and aggressive premium pricing to gain market share and forestall political intervention. Furthermore, although the legal system made a lot of noise about constraining managed care, it did not significantly curtail the use of particular management techniques.<sup>28</sup> Now that the economic boom has faltered and double-digit health care inflation has apparently resumed, the market may move managed care once again toward stricter controls.

The general lesson is that care and cost management will track "macro" cycles of economics and politics. A productive approach to medical necessity therefore should accommodate various combinations of management strategies, rather than locking itself into any single model. If provider contracting becomes truly selective, for example, health plans will have better ways to address physician moral hazard than by using general exclusions for lack of medical necessity (e.g., provider profiling with "gold-carding" that focuses utilization review on outliers). On the other hand, if "consumer-directed care"—the current darling of benefits consultants—actually takes hold, the "necessity" of smaller-ticket items will depend on consumer information and patient preference more than contractual provisions in insurance contracts.<sup>29</sup>

Planning for a range of actors to make medical necessity decisions is an equally important aspect of sound policy. An irreversible consequence of the 1990s is the end of centralized decisionmaking by medical directors of managed care organizations

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28. See, e.g., *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000) (refusing to regard "mixed eligibility decisions" as fiduciary decisions under ERISA, thereby condoning physician financial incentives); see also Peter D. Jacobson, *Legal Challenges to Health Care Cost Containment Programs: An Initial Assessment*, HEALTH AFF., July–Aug. 1999, at 69 (reviewing earlier cases permitting cost-containment techniques); William M. Sage, *UR Here: The Supreme Court's Guide for Managed Care*, HEALTH AFF., Sept.–Oct. 2000, at 219 (discussing *Pegram*).

29. See Jon Gabel et al., *Consumer-Driven Health Plans: Are They More than Talk Now?*, HEALTH AFF., Jan.–Feb. 2003, at W395, W396 (describing the "heart" of consumer-directed programs as "combin[ing] incentives with information to enable consumers to make informed choices about non-life-threatening health care"), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.395v1.pdf> (on file with the *Duke Law Journal*).

at corporate headquarters. One reason is that prospective review of treatments that patients want but have not yet received adds urgency and emotional content to coverage decisions that are not well addressed from a distance. Another reason is that the structure of managed care has evolved such that insurance decisions are no longer being made only by insurers. Increasingly, preauthorization is delegated by contract to medical groups and other provider organizations, many of which also bear financial risk for utilization of services under capitation arrangements. Medical professionals differ from insurers in their interpretation of coverage criteria, and in today's market they have so many arrangements with health plans that it is impractical for them to master the practices of each. Surprisingly, cash-strapped medical partnerships may be even more restrictive in their coverage policies than large insurers with strong reserves and greater familiarity with the underwriting cycle. As a result, health plans and employers sometimes reverse roles with physicians and play the part of "patient advocate," persuading medical groups to reconsider their coverage denials. This type of marketplace dynamic requires a simplified, consensual understanding of medical necessity that can be applied relatively consistently, notwithstanding the cultural and contractual chasms that potentially separate different organizational actors.

## II. LAW AND MEDICAL NECESSITY

A system of health care liability and dispute resolution that creates optimal incentives for technical quality, appropriately compensates injured victims, ensures that professionals and organizations on which people rely act in their best interests, and operates at acceptable monetary and psychic cost is not a realistic goal in the short term. Existing mechanisms of legal accountability in health care are historically determined and sector-specific. Insurance liability, for example, is based on the law of contracts,<sup>30</sup> and includes regulatory oversight to ensure solvency.<sup>31</sup> Because people who attempt to draw on insurance are often hurt and vulnerable, several states also allow tort suits against insurers, but it is usually a distinct

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30. See ROBERT H. JERRY, II, UNDERSTANDING INSURANCE LAW 165–79 (2002) (examining contract doctrine in a chapter devoted to sources of insurance law).

31. See *id.* at 69 ("One rationale for regulation . . . [i]n the insurance industry . . . [is that] it is feared [excessive competition] could lead to insurer insolvencies.").

brand of tort liability for intentional conduct resembling fraud.<sup>32</sup> The tort liability that hospitals and other institutional health care providers face, by contrast, typically involves unintentional but avoidable injuries. Physicians and other licensed practitioners also have fiduciary obligations to patients,<sup>33</sup> which involve both technical competence and notions of loyalty. Unlike other areas of fiduciary law (e.g., corporate law) that focus mainly on loyalty and allow defendants considerable leeway regarding competence, medical law emphasizes the tort of malpractice, which is based entirely on technical failure, and relegates loyalty to poorly enforced professional disciplinary processes. Although these legal doctrines in the aggregate contain ample raw material for a system of accountability in managed care, there is no easy way to combine them.

Moreover, because of the popular backlash against managed care, technical disputes over medical necessity in courtrooms and legislatures have spilled over into public discourse and have been imbued with ideological significance. Before managed care, who other than health care lawyers (and not even all of them) could have identified ERISA as a law governing health plans?<sup>34</sup> Now, ERISA is referenced in most news accounts of suits against managed care or congressional maneuvering over patient protection. However, trends and tensions within the law not obviously connected to managed care also influence coverage litigation. Two of these important issues are the balance of authority between Congress and the states (federalism), and the relative competence of legislatures and courts as lawmakers.

#### A. *Medical Necessity Litigation*

The conventional wisdom about medical necessity litigation is that judges disregard contractual language in order to allow sympathetic plaintiffs access to potentially lifesaving therapies, or to

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32. *See id.* at 196–212 (“[I]nsurers can be held liable in tort for bad faith performance of their duties to insureds.”).

33. *See* PETER D. JACOBSON, *STRANGERS IN THE NIGHT: LAW AND MEDICINE IN THE MANAGED CARE ERA* 222–49 (2002) (detailing the physician’s fiduciary duty); *see also* Maxwell J. Mehlman, *Fiduciary Contracting: Limitations on Bargaining Between Patients and Health Care Providers*, 51 U. PITT. L. REV. 365, 389–90 (1990) (attributing physicians’ fiduciary obligation to their “superior information and expertise”).

34. When my wife clerked for a federal district court judge in Los Angeles in 1997, she heard a prominent litigator react as follows to the judge’s dismissal of her state law claim: “My case *can’t* be preempted by ERISA, your honor. I don’t *know* anything about ERISA.”

jury-awarded damages if they have already suffered physical harm. There are many anecdotes to support this view. In a series of blatantly results-oriented decisions during the late 1980s and early 1990s, for example, women with advanced breast cancer were granted coverage of high-dose chemotherapy with autologous bone marrow transplantation (HDC-ABMT) that had been denied by their insurers as “experimental” or “investigational.”<sup>35</sup> Even health plans that had explicitly excluded “transplants” found themselves obligated to cover much of the cost of the procedure and attendant hospitalization, on the grounds that their policies listed “chemotherapy” (i.e., drugs) as an explicitly covered category and were, therefore, ambiguous.<sup>36</sup> The irony of these decisions was apparent a decade or so later when randomized clinical trials failed to show clinical benefits from HDC-ABMT.<sup>37</sup> Because courts are structured to address the needs of individual plaintiffs, they are institutionally incapable of learning from this history and are probably doomed to repeat it in cases involving other medical innovations absent legislative intervention. For example, the plaintiff who prevailed before the Supreme Court in *Rush* had traveled out of state to receive a controversial, extremely expensive surgical procedure that the health plan had considerable scientific justification for refusing to cover.<sup>38</sup>

At the same time, conventional wisdom allows for harsher results in cases alleging denials of benefits under ERISA, because that statute precludes extracontractual damages (e.g., compensation for pain and suffering or punitive damages),<sup>39</sup> renders unavailable most

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35. See HEALTH, EDUC., & HUMAN SERVS. DIV., U.S. GEN. ACCOUNTING OFFICE, GAO/HES-96-83 HEALTH INSURANCE: COVERAGE OF AUTOLOGOUS BONE MARROW TRANSPLANTATION FOR BREAST CANCER 9 (1996) (“Overall, the insurers had not been very successful in these [ABMT] cases . . .”).

36. See, e.g., *Bailey v. Blue Cross & Blue Shield of Va.*, 67 F.3d 53, 55 (4th Cir. 1995) (affirming summary judgment for the plaintiff even though the insurance policy excluded “[a]utologous bone marrow transplants . . . with high dose chemotherapy”).

37. See Michelle M. Mello & Troyen A. Brennan, *The Controversy over High-Dose Chemotherapy with Autologous Bone Marrow Transplantation for Breast Cancer*, HEALTH AFF., Sept.–Oct. 2001, at 101, 101–02 (“[Recent studies have] found no survival advantage to HDC-ABMT relative to standard-dose chemotherapy . . .”).

38. See E. Haavi Morreim, *ERISA Takes a Drubbing: Rush Prudential and Its Implications for Health Care*, 38 TORT TRIAL & INS. PRAC. L.J. 933, 947–48 (2003) (describing justifications for Rush Prudential’s refusal to cover the procedure).

39. See, e.g., *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 148 (1985) (“[T]he relevant text of ERISA, the structure of the entire statute, and its legislative history all support the conclusion that in [§ 409(a), 29 U.S.C. § 1109(a) (2000)] Congress did not provide . . . a cause of

state law claims that relate to employee benefit plans, and limits judicial inquiry when an employee benefit plan explicitly confers discretion on the administrator.<sup>40</sup> ERISA undoubtedly keeps many disputes out of court because the monetary upside for plaintiffs' lawyers is so slight. Courts certainly seem to labor mightily to free plaintiffs from ERISA's constraints where possible. Even cases in which judicially conservative courts rule in favor of health plans contain impassioned pleas to Congress to cure the inequities of ERISA.<sup>41</sup> This hardly persuades the public that medical necessity decisions are being rendered fairly. The last line of Judge William Young's memorable opinion in *Andrews-Clarke v. Travelers Insurance Co.*<sup>42</sup> reads, "Does anyone care? Do you?"<sup>43</sup>

Are these perceptions accurate? It is very difficult to determine the empirical truth regarding coverage law. Studies suggest that the notion of judges and juries handing weeping plaintiffs a handkerchief and the insurance company's money is a caricature, but so is the idea that ERISA bars the courthouse door to injured victims. A study by Professors Hall and Anderson, and colleagues, concludes that plaintiffs prevailed more often when cases are not in federal appeals court, when the insurance contract failed to reserve discretion to the insurer, and when the medical condition at issue was serious.<sup>44</sup> It did not, however, find that ERISA cases systematically favored defendants.<sup>45</sup> A more recent study, by Professor Jacobson and colleagues, concludes that courts are largely sympathetic to cost-

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action for extra-contractual damages caused by improper or untimely processing of benefit claims.").

40. See *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989) (requiring *de novo* review when "a denial of benefits is challenged under [29 U.S.C.] § 1132(a)(1)(B) "except when "the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits").

41. See, e.g., *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321, 1338 (5th Cir. 1992) ("The result ERISA compels us to reach means that the Corcorans have no remedy, state or federal, for what may have been a serious mistake. This is troubling for several reasons.").

42. 984 F. Supp. 49 (D. Mass. 1997).

43. *Id.* at 65.

44. See Gerard Anderson et al., *When Courts Review Medical Appropriateness*, 36 MED. CARE 1295, 1298 (1998) (charting the predictiveness of these and other factors); see also Mark A. Hall et al., *Judicial Protection of Managed Care Consumers: An Empirical Study of Insurance Coverage Disputes*, 26 SETON HALL L. REV. 1055, 1065 (1996) ("We interpret this finding [from authors' empirical study of disputes ending in published judicial opinions] as suggesting that insurers are more cautious in denying coverage for life threatening conditions.").

45. *Id.* at 1067.



containment efforts, especially in ERISA cases.<sup>46</sup> Jacobson has speculated that courts accommodate managed care as an important stage of “industrial development” in health care much as they shielded railroads from litigation in the nineteenth century.<sup>47</sup> However, empirical studies of judicial decisions are always vulnerable to criticism, because the way in which cases are selected, litigated, and reported is not random.<sup>48</sup> Furthermore, in contrast to medical malpractice “reform,” the various stakeholder groups with dogs in the political fight over coverage liability have not yet recruited many researchers to their cause.

Absent empirical research, one must employ less precise tools to explain medical necessity. Reading judicial opinions in medical necessity disputes conveys several distinct impressions. First, there is relatively little law in these cases. This is true even though, unlike medical malpractice cases, their rationales are fully stated in published text instead of being hidden in a jury’s unexplained verdict regarding liability.<sup>49</sup> Second, the facts of principal interest to courts concern clinical benefit to the specific patient bringing suit, not “population health,” “cost-effectiveness,” or the prudent use of pooled social resources—in other words, identified rather than statistical lives. Third, the time pressures created by disputes over preauthorization and the potential conflicts of interest that beset both insurers and providers in managed care seem to make courts apprehensive that the facts before them are incomplete or untrustworthy. Fourth, and relatedly, hallmarks of procedural fairness at early stages of the dispute—such as clear explanations regarding denials, timely access to internal appeal mechanisms with competent systems of gathering evidence, and unbiased external review—tend to reassure courts that coverage cases can be viewed as contractual matters and make courts less likely to reverse the health plan’s determination.

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46. See Peter D. Jacobson et al., *The Role of the Courts in Shaping Health Policy: An Empirical Assessment*, 29 J.L. MED. & ETHICS 278, 285 (2001) (concluding that “it is difficult to win a challenge to a benefit denial under ERISA,” and that, in such cases, “courts are deferring to cost/efficiency arguments”).

47. Peter D. Jacobson & Scott D. Pomfret, *Establishing New Legal Doctrine in Managed Care: A Model of Judicial Response to Industrial Change*, 32 U. MICH. J.L. REFORM 813, 822–31 (1999).

48. See Sage, *supra* note 17, at 62–66 (describing selection and publication biases).

49. See *id.* at 66–67 (recognizing that decisionmaking rationales may be opaque even in published judicial opinions).

What about ERISA? “Preemption”—the extent to which federal ERISA law protects defendants from suit under state law—matters greatly to the medical necessity debate. For the vast majority of privately insured Americans who might choose to file lawsuits, ERISA is the main difference between a dismissal and a generous award or settlement. Before 1995, ERISA preemption was interpreted broadly, essentially immunizing insurers from tort liability under state law and shielding self-funded plans from state regulation.<sup>50</sup>

However, preemption law has undergone dramatic if not entirely logical shifts in recent years, mainly because the Supreme Court has been caught between a rock and a hard place. On the one hand, the Rehnquist Court believes that states should be entitled to enact and enforce their own laws unless Congress explicitly asserts its authority to overrule them and has the constitutional right to do so.<sup>51</sup> On the other hand, the Supreme Court dislikes “judicial activism,” and strongly prefers that legislatures rather than courts turn social policy into law. Accordingly, the Court has cut back ERISA’s preemptive reach, allowing state legislatures greater leeway to regulate health coverage unless and until Congress steps in and clearly defines the boundary between state and federal law. But Congress has not stepped in very far, partly because the Supreme Court’s actions emboldened state and federal courts to narrow preemption even further—in essence providing through judicial activism a safety valve that took the political pressure off Congress to act.<sup>52</sup> The result has been an uncomfortable mix of state-level legislative sleight of hand that tries to accomplish indirectly what ERISA still will not permit it to do openly, and court cases that generally reach morally acceptable results through various legal contortions that stop just short of insubordination to the Supreme Court.

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50. *See, e.g.*, *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983); *see also* Jacobson et al., *supra* note 46, at 280 (discussing this interpretive trend).

51. *See, e.g.*, *City of Boerne v. Flores*, 521 U.S. 507 (1997) (holding unconstitutional the federal Religious Freedom Restoration Act of 1993).

52. 514 U.S. 645 (1995).

53. *See, e.g.*, *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350, 352 (3d Cir. 1995) (reversing the district court’s refusal to remand the plaintiff’s case to state court, concluding that the plaintiff’s claim was not subject to “complete preemption,” even though the plaintiff’s decedent was insured through an ERISA-covered welfare plan); *Pappas v. Asbel*, 768 A.2d 1089, 1096 (Pa. 2001) (treating an HMO’s refusal to admit a patient to the first available university hospital as a “mixed eligibility and treatment decision,” such that it is subject to state malpractice law and is not preempted by ERISA).

The turning point in ERISA preemption doctrine was the Supreme Court's 1995 opinion in *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.*<sup>54</sup> In *Travelers*, the Court in essence limited ERISA preemption to state laws that directly, or indirectly but substantially, affect employee benefit plans.<sup>55</sup> This vague but intuitive standard allowed courts to react ad hoc to the rapid growth of managed care. Although *Travelers* did not specifically address preemption of tort claims, which is still governed by a 1987 decision, *Pilot Life Insurance Co. v. Dedeaux*,<sup>56</sup> the case and those that followed it constituted an unmistakable signal to lower courts that liability could be imposed on health plans.

Two lines of argument have been used to justify this result, both of which are evident in a 1995 Third Circuit decision, *Dukes v. U.S. Healthcare*.<sup>57</sup> First, when an individual physician commits garden-variety malpractice, a health plan that is vicariously responsible for her actions by virtue of the law of agency should not be protected merely because of the tangential presence of ERISA.<sup>58</sup> Second, because ERISA deals with the *availability* of benefits, a claim about the *quality* of benefits is not a claim under ERISA and is therefore not "completely preempted."<sup>59</sup> (Note that there is an important technical difference between "complete preemption," which is a jurisdictional standard, and preemption itself.<sup>60</sup> Nevertheless, finding a state claim not "completely preempted" usually induces a defendant to settle because it shifts the claim to state court, where it is more likely to be held not preempted as a substantive matter.)

There are logical problems with both interpretations. Under the first interpretation, requiring preauthorization and then denying coverage is less likely to generate liability than granting an affiliated physician discretion to determine what is best for the patient. Therefore, a health plan gains, rather than loses, legal protection by

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54. 514 U.S. 645 (1995).

55. *See id.*

56. 481 U.S. 41 (1987).

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

58. *See id.* at 357 (rejecting the defendant's preemption argument, because the plaintiffs did not allege "that [their ERISA] welfare plans in any way withheld . . . benefits due . . . [but rather] argue[d] that the [defendant] should be held liable [for poor quality care] under agency and negligence principles").

59. *See id.* ("Quality control of benefits . . . is a field traditionally occupied by state regulation[,] and we interpret the silence of Congress [on quality of care (in § 502(a)(1)(B) of ERISA)] as reflecting an intent that it remain such.").

60. *See id.* ("The difference between preemption and complete preemption is important.").

taking a harmful action directly, instead of waiting to be blamed vicariously for the actions of its physicians. Under the second interpretation, abysmal quality—so poor as to amount to a constructive denial of a benefit—generates less liability than mere substandard quality. Furthermore, separating the existence of benefits from their quality makes little sense if a given level of quality is a deliberately designed component, and not merely an accidental byproduct, of an insurance benefit package.

Despite such problems, courts have used these doctrinal devices, which allow them to emphasize the clinical influence of health plans and downplay managerial considerations, to achieve rough justice for injured patients. In a series of cases from various jurisdictions, nearly always citing *Travelers* and *Dukes*, health plans have been denied a preemption defense against vicarious liability claims.<sup>61</sup> Health plans also face increasing direct liability for conduct such as limiting hospital length of stay or mismanaging referrals.<sup>62</sup> These rationales seem to make direct preauthorization of benefits a “safer” strategy for health plans than indirect care management techniques such as selective contracting and financial incentives. Nonetheless, a few courts have held utilization review for medical necessity by the health plan itself to be outside the scope of ERISA preemption on a “quality” theory.<sup>63</sup> ERISA therefore still protects health plans in the abstract, but cases with real injuries reasonably attributable to errors by health plans will likely escape preemption and take their toll on health plans’ reputations and reserves.

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61. See David L. Trueman, *Managed Care Liability Today: Laws, Cases, Theories, and Current Issues*, 33 J. HEALTH L. 191, 206 (2000) (discussing *Rice v. Panchal*, 65 F.3d 637 (7th Cir. 1995), as an example of this trend). But see *id.* at 207 (recognizing that *Jass v. Prudential Health Care Plan, Inc.*, 88 F.3d 1482 (7th Cir. 1996), goes against this trend).

62. See, e.g., *In re U.S. Healthcare, Inc.*, 193 F.3d 151 (3d Cir. 1999) (recognizing state court jurisdiction when a newborn died at home after being discharged prematurely from the hospital); *Ouellette v. Christ Hosp.*, 942 F. Supp. 1160 (S.D. Ohio 1996) (rejecting the defendant health plan’s complete preemption defense when the plaintiff alleged that its two-day limit on hospitalization following ovary removal caused the hospital to discharge her prematurely, causing injury); *Pappas v. Asbel*, 768 A.2d 1089 (Pa. 2001) (holding that ERISA did not preempt the patient’s complaint against his health plan when the health plan delayed authorizing the patient’s referral to a university hospital for treatment of spinal cord compression).

63. See, e.g., *Cicio v. Does*, 321 F.3d 83, 104 (2d Cir. 2003) (classifying decisions as “mixed eligibility and treatment decisions,” and stating that “preemption does not obtain with regard to those claims predicated on the violation of a state tort law by a failure to meet a state-law defined standard of care”).

There are additional avenues available to the courts to expand health plan liability, even if the congressional stalemate over amending ERISA continues. Because *Rush* determined that the challenged independent review statute was saved from preemption because it was a “law regulating insurance,”<sup>64</sup> lower courts may become receptive to the argument that the new managed care liability statutes that a dozen or so states have enacted are also “insurance laws,” despite *Pilot Life*. Somewhat more speculatively, there are hints in the Supreme Court’s decision in *Pegram v. Herdrich*<sup>65</sup> (which was not a preemption case) that the “employee benefit plan” that triggers an ERISA preemption analysis may in some cases be limited to the contract between employer and health plan.<sup>66</sup> If the case law heads in this direction, even self-funded employee benefit plans may find their coverage arrangements subject to state regulation and liability arising from the health plan’s relationship with providers and beneficiaries.<sup>67</sup> Of course, all these clever arguments will become irrelevant if Congress enacts patient protection legislation, either increasing the damages available for improperly denied benefits under ERISA itself or, more likely, curtailing preemption and explicitly allowing tort suits relating to medical necessity to be brought under state law.

That Congress seemingly prefers sending medical necessity litigation to the states, rather than authorizing it directly, reflects two larger issues in the realpolitik of legal institutions. The first is a can of worms called medical malpractice. The battle lines over medical malpractice were drawn decades ago as a problem of state law, and each state has reached a compromise unique to its political and legal

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64. See *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 373 (2002) (“[T]he Illinois HMO Act is a law ‘directed toward’ the insurance industry, and an ‘insurance regulation’ under a ‘commonsense’ view.”).

65. 530 U.S. 211 (2000).

66. See *id.* at 223 (“[W]hen employers contract with an HMO to provide benefits to employees subject to ERISA, the provisions of documents that set up the HMO are not, as such, an ERISA plan; but the agreement between an HMO and an employer who pays the premiums may, as here, provide elements of a plan by setting out rules under which beneficiaries will be entitled to care.”).

67. See *Sage*, *supra* note 28, at 221 (stating that restrictions on selective contracting, even those applied to self-insured arrangements, may not be preempted if the term “ERISA plan” is “interpreted as excluding the HMO or other contracting vehicle directly subject to regulation”); Russell Korobkin, *The Failed Jurisprudence of Managed Care, and How to Fix It*, 51 UCLA L. REV. 457, 470–488 (2003) (describing various hypothetical outcomes based on the provider, the beneficiary, and their relationship with the health plan).

environment.<sup>68</sup> None of the patient protection stakeholders involved want to reopen the can by suggesting a uniform federal standard for managed care liability. Even the Supreme Court is afraid to impose accountability on health plans that might end up diverting a torrent of routine malpractice litigation to federal courts.<sup>69</sup> In *Pegram*, the Court justified its holding—that “mixed eligibility-treatment decisions” (possibly including medical necessity determinations, but not specific, explicit contractual exclusions) do not implicate ERISA’s fiduciary duties—partly on the grounds that cases involving those decisions should be heard in state court.<sup>70</sup>

The second barrier to improving legal accountability in managed care is the Supreme Court’s distrust of judge-made law in the lower federal courts.<sup>71</sup> Unlike state law, much of which was imported from England in colonial times and adapted in the courts without legislative intervention, federal law is largely statutory in nature, for the most part enacted by Congress under enumerated constitutional powers. Furthermore, federal statutes are usually specific—seldom does Congress legislate with the expectation that the courts will flesh out the details.<sup>72</sup> One of the unpleasant side effects for the Supreme Court of relaxing ERISA preemption has been the willingness of lower federal courts to immerse themselves in the details of specific clinical situations, in essence evolving a “common law” unconnected with Congress.

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68. The current crisis in cost and availability of malpractice insurance has forced the issue of tort reform to the front of state and federal legislative agendas, but mainly in terms of limiting liability for patient injury. With Republicans in control of Congress, the vigorous debate of the last few years over expanding liability to managed care organizations has been conveniently forgotten. For an overview of the malpractice crisis, see William M. Sage, *Understanding the First Malpractice Crisis of the 21<sup>st</sup> Century*, in 2003 HEALTH LAW HANDBOOK 185 (Alice Gosfield ed., 2003).

69. *Pegram*, for example, held unanimously that a “mixed eligibility-treatment decision” that arguably resulted in patient injury did not implicate the fiduciary duties that ERISA assigns to health plans. 530 U.S. at 237. One of the Court’s stated reasons was that courts would have to evaluate medical practice in order to determine whether a fiduciary duty was violated, and medical malpractice litigation should be kept out of federal court. *See id.* at 235.

70. *See id.* at 237 (“[W]hat would be gained by opening the federal courthouse doors for a fiduciary malpractice claim, save for possibly random fortuities such as more favorable scheduling [than in state court], or the ancillary opportunity to seek attorney’s fees[?]”).

71. *See, e.g.*, Peter L. Strauss, *Courts or Tribunals? Federal Courts and the Common Law*, 53 ALA. L. REV. 891, 924 (2002) (observing that “[e]very [Supreme Court] Justice [currently sitting], save perhaps Justice Breyer, has subscribed to an opinion raising questions in one or another context about the common law functions of federal courts”).

72. The Sherman Antitrust Act, 15 U.S.C. §§ 1–7 (2001), is an important exception.

The Court's bias against federal common law is particularly detrimental to managed care accountability because it interferes with the evolution of fiduciary oversight. Explicating fiduciary duties is a common law enterprise, meaning that it is better suited to being developed over time through a series of decisions in individual cases than to being codified in a detailed statute or set of regulations. In fact, ERISA provides a useful template for combining contractual and fiduciary duties in managed care. Employers are free to set or change the terms of employee benefit plans as part of general negotiations with workers over compensation,<sup>73</sup> but they take on fiduciary responsibilities of loyalty, fairness, and transparency when administering the plans that they have established.<sup>74</sup> Interestingly, the fiduciary duties that ERISA imposes are for the benefit of the plan as a whole, not individual members,<sup>75</sup> which is relevant to the problem of adapting the individually oriented obligations of traditional medical ethics to group settings such as managed care. Furthermore, one can infer from ERISA's structure that Congress considered the "conflict of interest" between employers and their workers over the cost of benefits an inevitable and acceptable one, despite the existence of fiduciary duties with respect to the administration of individual claims. This insight suggests that, over time, case law could help resolve the tension between arm's-length negotiation over coverage by informed purchasers and reliance on the care associated with that coverage by sick and needy beneficiaries. However, ERISA's fiduciary duties are governed by the nearly moribund federal common law of trusts,<sup>76</sup> which, based on its opinion in *Pegram*, the Supreme Court seems unwilling to risk resuscitating even if it could generate progress in managed care oversight.

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73. 29 U.S.C. § 1102(b)(3) (1999); *see also* *Curtiss-Wright Corp. v. Schoonenjongen*, 514 U.S. 73, 78 (1995) ("Employers or other plan sponsors are generally free under ERISA, for any reason at any time, to adopt, modify, or terminate welfare plans.").

74. *See* 29 U.S.C. § 1106 (prescribing loyalty by prohibiting transactions between health plans and "parties in interest"); *id.* § 1133; *see also* *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 142–43 (1985) (discussing fiduciary duties under ERISA).

75. *See Russell*, 473 U.S. at 140–42 (explaining that although, under 29 U.S.C. § 1132(a), individual health plan beneficiaries or participants may bring actions against plans for breach of fiduciary duty, a health plan's duty is to participants and beneficiaries as a whole).

76. *See* John H. Langbein, *The Secret Life of the Trust: The Trust as an Instrument of Commerce*, 107 *YALE L.J.* 165, 169 (1997) ("ERISA's legislative history makes clear that Congress meant to track the common law of trusts.").

*B. Independent Administrative Review*

The ambiguities of medical necessity in insurance practice and coverage litigation carry over to independent administrative review under state law. Much as medical necessity carries a well-accepted symbolic meaning apart from its practical significance, so too has independent review generated broad support while eliding important questions about its purpose and effect. What, exactly, is the goal of independent review? There are several possibilities.

One explanation is that independent review is a system for screening and controlling litigation. Independent review operates in the shadow of coverage litigation, and cutbacks in ERISA preemption send more and more cases to state court. Litigation is an inefficient process that expends scarce public resources and imposes uncertainty and cost on potential plaintiffs and defendants. Interposing an administrative adjudicatory mechanism between informal negotiation and formal courtroom proceedings related to insurance contracts can help contain meritless claims by changing strategic incentives for plaintiffs; can divert justifiable claims into less costly forms of dispute resolution; and can focus any remaining, unsettled issues for judicial consideration. Proponents of alternative dispute resolution also emphasize the psychological benefits to the parties of private conciliation over traditional courtroom proceedings, which tend to be highly adversarial. In addition, critics of generalist judges and lay juries might argue that, in areas such as medicine, an expert administrative process will generate more accurate determinations than conventional litigation.<sup>77</sup> On the other hand, litigation is both scrupulously fair and oriented to building public legal precedent; other adjudication systems might not retain these advantages.

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77. In the current malpractice crisis, considerable attention is being paid to the need to improve technical expertise in dispute resolution, such as by requiring medical screening panels to evaluate claims or chartering specialized medical courts. See CATHERINE T. STRUVE, EXPERTISE IN MEDICAL MALPRACTICE LITIGATION: THE ROLE OF PROCEDURAL REFORM 55-80 (2003) (monograph from the Pew Project on Medical Liability in Pennsylvania) (discussing screening panels and specialized medical courts). Although there are undoubted benefits to improving the factual base for making legal determinations in both areas, the debate over procedural reform in health care also reflects a longstanding problem in the regulation of professions generally: how to hold experts accountable to nonexperts. See Jay Alexander Gold, *Wiser than the Laws?: The Legal Accountability of the Medical Profession*, 7 AM. J.L. & MED. 145, 150 (1981) (underscoring this dilemma).



A second possible explanation for independent review of managed care decisions is that it represents an extension of health care regulation rather than litigation management.<sup>78</sup> This perspective focuses on the low likelihood of litigation to remedy imbalances of power, conflicts of interest, and other inadequacies of decisionmaking processes within health plans. Particularly because of ERISA's preemptive effect (accompanied by the failure of federal regulators to enforce ERISA's duties directly), few disputes over coverage give rise to formal legal claims. Many legitimate claimants therefore have no practical recourse when coverage is denied, and the deterrent effect of litigation on health plan conduct is weak. Independent review requirements potentially empower beneficiaries, while simultaneously educating and incentivizing health plans and providers to honor contractual commitments and general duties.<sup>79</sup> Accumulated experience with claims brought to external review can also inform regulators about the need for more intrusive oversight, and can provide new enrollees with information about existing members' satisfaction with health plan decisionmaking.

A third justification for independent review is that it offers a standard process for resolving socially contentious entitlement issues that, in Professor Fiss's phrase, builds "public values."<sup>80</sup> Public trust in the health care system has collective importance, and fair deliberative

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78. The relationship between regulation and litigation is complex, particularly in health care. See William M. Sage, *Unfinished Business: How Litigation Relates to Health Care Regulation*, 28 J. HEALTH POL. POL'Y & L. 387, 397 (2003) ("The interplay between regulation and litigation in health care may be subtle . . ."); see also W. Kip Viscusi, *Overview, in REGULATION THROUGH LITIGATION 1* (W. Kip Viscusi ed., 2002) (presenting an overview of the complex relationship between regulation and litigation in several contexts, including health care).

79. A related role for independent review would be in connection with federal and state due process requirements. Although managed care organizations are usually private entities, many enroll beneficiaries of public entitlement programs or otherwise take on arguably governmental functions that might induce legislators to build in appropriate procedural safeguards. However, the Supreme Court has rejected the claim that HMOs serving Medicaid beneficiaries are "state actors" subject to constitutional due process oversight by the courts. See *Shalala v. Grijalva*, 526 U.S. 1096, 1096 (1999) (vacating and remanding the case for consideration in light of *American Manufacturers Mutual Insurance Co. v. Sullivan*, 526 U.S. 40 (1999)). For an analysis of managed care as state action, see ELEANOR DEARMAN KINNEY, *PROTECTING AMERICAN HEALTH CARE CONSUMERS* 51–53, 171 (2002); Gillian Metzger, *Privatization as Delegation*, 103 COLUM. L. REV. 1367, 1380–83, 1487–92 (2003). Medicare and Medicaid themselves have separate rules for adjudicating grievances and appeals in their fee-for-service programs. See KINNEY, *supra*, at 136.

80. Owen Fiss, *Against Settlement*, 93 YALE L.J. 1073, 1085 (1984) (arguing that adjudication gives voice to public values).

procedures reassure individuals as consumers, patients, and citizens that health plans, even as private actors, are seeking a reasonable balance between access to (or quality of) health care and its cost. Professors Daniels and Sabin emphasize “accountability for reasonableness” as crucial to assuring legitimacy, and observe that fair procedures such as independent review help make up for lack of social consensus over distributive justice in American health care.<sup>81</sup> Health plans are immersed in these debates. In one recent study, only one-third of appeals heard within health plans (prior to applicable external review) sought *clinical* consensus on the appropriateness of requested services (in effect asking the question, “Is it necessary?”).<sup>82</sup> The remaining two-thirds sought *social* consensus on appropriateness (in effect asking the question, “Is it medical?”).<sup>83</sup> Indeed, the earliest programs of external review were developed for disputes over “last-chance” therapies that raised moral concerns about rationing and cost-effectiveness, as well as issues of contractual performance. According to Daniels and Sabin, the voluntary model of external review developed by Aetna and Kaiser in the early 1990s was instituted not to solve a competence problem, but to ensure trust.<sup>84</sup> Similarly, the first managed-care-oriented independent review legislation, California’s 1996 Friedman-Knowles Experimental Treatment Act,<sup>85</sup> applied only to coverage denials of “experimental” treatment for serious illness.<sup>86</sup>

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81. See NORMAN DANIELS & JAMES E. SABIN, SETTING LIMITS FAIRLY: CAN WE LEARN TO SHARE MEDICAL RESOURCES? 169–74 (2002) (highlighting these points in summarizing the book’s discussion of limits to care that the public should consider legitimate).

82. See David M. Studdert & Carol Roan Gresenz, *Enrollee Appeals of Preservice Coverage Denials at 2 Health Maintenance Organizations*, 289 JAMA 864, 864, 866 (2003) (documenting that 36.9 percent of pre-service appeals involved medical necessity determinations).

83. See *id.* (recording that 36.6 percent of appeals related to questions of contractual limits of coverage). Among the examples the authors provide of treatments tending to raise such disputes are foot orthotics, physical therapy, dental care, alternative medicine treatments, infertility treatment, obesity surgery, breast alteration, and varicose vein removal. See *id.* at 868–69.

84. See DANIELS & SABIN, *supra* note 81, at 74.

85. CAL. HEALTH & SAFETY CODE § 1370.4 (West Supp. 2003). The Friedman-Knowles Act is also codified at CAL. INS. CODE § 10,145.3 (West Supp. 2003).

For an analysis of the act’s early impact, see Institute for Medical Quality, Independent Medical Review Experiences in California, Phase I: Cases of Investigational/Experimental Treatments (2002), at <http://www.chcf.org> (on file with the *Duke Law Journal*) (report to the California HealthCare Foundation).

86. See CAL. HEALTH & SAFETY CODE § 1370.4(a) (requiring independent review for “decisions regarding experimental or investigational therapies”); *id.* § 1370.4(a)(1)(A) (limiting

The preceding characterizations of independent review emphasize health insurers' roles as regulated business entities and as administrators of socially important programs. A different set of possible objectives for external review involves the quality of health care delivered to patients. In the health services literature, quality is sometimes divided into "technical" and "interpersonal" components.<sup>87</sup> On the technical side, it has become apparent in recent decades that American medicine, which at its best is extraordinary, suffers from widespread inconsistencies in practice that compromise safety and quality, and also wastes resources.<sup>88</sup> An argument for independent review of health plan decisions, especially when new or life-saving therapies are involved, is that expert reviewers can bring the best scientific evidence to bear on individual cases. This is different from the traditional self-regulatory preferences of professions described above<sup>89</sup>—the concern here is not the vagaries of lay courts but the need to make sure that both treating physicians and plan-based claims reviewers get it right. Programs taking this approach would take seriously the obligation to educate health plans and physicians as well as assure optimal treatment for individual patients.

On the interpersonal side of quality, independent review can strengthen therapeutic relationships by reducing adversarial tensions, building patients' trust in their health plans and providers, and rewarding compassionate behavior. Review procedures oriented to these goals would also encourage patient participation, furthering individual autonomy by offering information and making patients feel in control of decisions that affect them.

How compatible are the features of current independent review programs with these explanations? Researchers at Georgetown University have compiled comprehensive information about

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the independent review requirement to decisions affecting health plan enrollees with "life-threatening or seriously debilitating condition[s]").

87. AVEDIS DONABEDIAN, *THE DEFINITION OF QUALITY AND APPROACHES TO ITS ASSESSMENT* 4 (1980).

88. *See, e.g.*, *THE DARTMOUTH ATLAS OF HEALTH CARE IN THE UNITED STATES* 54–80 (John E. Wennberg & Megan McAndrew Cooper eds., 1998) (showing dramatic "small-area" variation in medical care that cannot be explained by patient characteristics or medical outcomes); *INSTITUTE OF MEDICINE, TO ERR IS HUMAN: BUILDING A SAFE HEALTH SYSTEM* 26 (Linda T. Kohn et al. eds., 2000) (attributing as many as 98,000 deaths annually to avoidable medical error).

89. *See supra* note 19 and accompanying text.

independent review in design and operation.<sup>90</sup> Several themes emerge. First, most review programs have a distinct regulatory flavor. All programs originated in legislative activity, and are linked more closely to managed care regulation than to alternative dispute resolution or judicial resources. However, essentially all states require exhaustion of internal plan appeals before proceeding to external review, and substantial variation exists in the timing and conduct of those processes.<sup>91</sup> This reduces patients' sense of external review as part of cohesive overall regulation. On the other hand, half of states with external review provide for exceptions to or time limits on the internal review process.<sup>92</sup>

Second, the programs focus on resolving conflicts between physicians and health plans. In thirty-two states, independent review is limited to disputes involving medical necessity, which is a clinical judgment, as opposed to disputes over other contractual terms that require legal, rather than medical, expertise to interpret.<sup>93</sup> Only seven states require the reviewer to apply the definitions of medical necessity and other relevant terms contained in the contract of insurance.<sup>94</sup>

Third, external review does not resemble litigation procedurally. Only eight states require or permit a hearing with the potential for representation.<sup>95</sup> Neither party is assigned a formal burden of proof in review proceedings. Review is intended to be widely available, regardless of the potential for litigation. Of the forty-two states with review programs, thirty-one states have no dollar thresholds for reviewing claims, while the remaining eleven states have dollar thresholds ranging from \$100 to \$1,000.<sup>96</sup> The cost of review, usually \$400–1,500, is paid by the health plan in thirty states, with nine states providing public funding and only Rhode Island imposing a

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90. See POLLITZ, *supra* note 1 (updating the previous reports by the Kaiser Family Foundation on external review boards); see also KAREN POLLITZ ET AL., EXTERNAL REVIEW OF HEALTH PLAN DECISIONS: AN OVERVIEW OF KEY PROGRAM FEATURE IN THE STATES AND MEDICARE (1998), at [www.kff.org](http://www.kff.org) (on file with the *Duke Law Journal*) (compiling the initial findings by the Kaiser Family Foundation and Georgetown University on characteristics of the first thirteen external review laws).

91. POLLITZ, *supra* note 1, at 5–7.

92. *Id.* at 12. Federal law also provides for time limits in connection with claims for ERISA plan benefits. See 29 C.F.R. § 2560.503-1 (2004).

93. POLLITZ, *supra* note 1, at 8.

94. *Id.* at 18–19.

95. *Id.* at 20.

96. *Id.* at 13–14.

substantial cost on the consumer.<sup>97</sup> As litigation risk increases, however, independent review helps manage it. Eight states that have enacted specific statutes authorizing liability suits against managed care organizations require exhaustion of external review procedures prior to filing a complaint.<sup>98</sup> In thirty-eight states, the decision of the independent reviewer is binding on the health plan.<sup>99</sup>

Fourth, fairness seems to be a top priority, suggesting a public values agenda. All states have strong prohibitions on conflicts of interest affecting reviewers.<sup>100</sup> On the other hand, reviewers are invariably physicians (or chiropractors); no state has lay participation in its review process.<sup>101</sup> In twenty-seven programs, the reviewers are qualified as experts by an independent review organization under contract to the state.<sup>102</sup> Twenty-eight states apply their programs to all private health plans (with the important exception of self-insured ERISA plans),<sup>103</sup> a practice that serves public values as well. The remainder are targeted to a subset of insurance products (e.g., HMOs) that raise specific concerns.<sup>104</sup> The availability of independent review seems to matter more than the degree to which it is actually used. Utilization is low in every state; New York has the highest appeals rate at 10.7 cases/100,000 enrollees.<sup>105</sup> Dispositions vary from state to state but, on average, 45 percent of external appeals are decided in favor of consumers (ranging from 21 percent in Arizona and Minnesota to 72 percent in Connecticut).<sup>106</sup>

Despite a veneer of expertise, little in the design of review programs clearly improves clinical quality. For example, in states that do not defer to the health plan's definitions, no formal evidence regarding the effectiveness of a proposed treatment is required (e.g., peer reviewed studies). Instead, the basis for decisions is left to the discretion of the reviewers.<sup>107</sup> Programs are divided between an adversarial model and one that takes fuller advantage of the

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97. *Id.* at 25–26.

98. *Id.* at 28.

99. *Id.* at 25.

100. *Id.* at 17–18.

101. *Id.* at 15.

102. *Id.* at 15–16.

103. *Id.* at 8.

104. *Id.*

105. *Id.* at 3.

106. *Id.*

107. *Id.* at 18–19.

reviewers' expertise. In sixteen states, the reviewer may only uphold or reverse the plan's decision.<sup>108</sup> In twenty-two states, the reviewer may also modify the decision.<sup>109</sup>

There is essentially no support in the data for the interpersonal quality argument for independent review. Administrative review is less conflict-laden than outright litigation, but it similarly assumes that an adversarial relationship exists between the treating physician and the health plan. No feature of current programs seems designed to further therapeutic trust or patient participation. As noted, paper review of submitted materials is the norm.<sup>110</sup> Although thirty-nine states require written disclosure of external review rights in enrollment material, only eleven require notice to be given in the initial denial letter sent to the beneficiary.<sup>111</sup>

Additional support for a quality-related interpretation of independent review, at least on the technical side, is authoritative but probably accidental. In *Rush*, the Supreme Court addressed whether an Illinois law imposing binding independent review on HMOs was preempted by ERISA.<sup>112</sup> The Court easily disposed of the question of express preemption by holding that the Illinois law at issue regulated HMOs as insurers and was therefore saved under ERISA section 514(b).<sup>113</sup> However, the question of conflict preemption remained, which under applicable precedent required the Court to determine whether state independent review constituted an impermissible alternative to the enforcement mechanism specified in ERISA.<sup>114</sup>

The Court correctly noted that independent review, unlike a state tort claim, can result only in the beneficiary obtaining the disputed service, and therefore does not expand remedies beyond those provided under ERISA section 503.<sup>115</sup> Less logically, however, the Court rejected the petitioner's characterization of the Illinois law as akin to mandatory arbitration, which would impinge unduly on

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108. *Id.* at 18. However, in two states, Indiana and Michigan, regulators have permitted modified determinations in some cases. *Id.* at 19 n.1.

109. *Id.* at 18.

110. *Id.* at 20.

111. *Id.* at 10.

112. *Rush Prudential HMO, Inc. v. Moran*, 122 S. Ct. 2151, 2156 (2002).

113. *Id.* at 2163–64; see ERISA § 514(b)(2)(A), 29 U.S.C. § 1144(b)(2)(A) (2000) (“[N]othing in this title shall be construed to exempt or relieve any person from any law of any State which regulates insurance . . .”).

114. *Rush*, 122 S. Ct. at 2166.

115. *Id.* at 2167.

ERISA's own procedures.<sup>116</sup> Instead, the Court likened independent review to a "second opinion."<sup>117</sup> The Court emphasized that the review panel was intended to consider clinically relevant facts, rather than to interpret the respondent's insurance contract.<sup>118</sup> In other words, the Court seemingly regarded independent review, at least in Illinois, as a source of medical expertise.

The problem with the Court's preferred analogy is that state laws requiring health, disability, or workers compensation insurers to allow "second opinions" typically provide only that the insurer must pay for an additional consultation, not that it must pay for services that the consultant recommends.<sup>119</sup> The Illinois law, which mandates coverage if an independent reviewing physician deems the treatment necessary, does refer to the process as a second opinion, but refers in its title to dispute resolution as well, which undercuts the Court's assertion that no enforcement mechanism beyond ERISA was involved.<sup>120</sup>

In fact, the Court's position more likely reflected the difficult task of reconciling prior precedent with a preference for deferring to seemingly sensible and popular state regulation, rather than any deep appreciation of medical uncertainty. One reason for granting certiorari in *Rush* was to resolve a circuit split between the Seventh and Fifth Circuits.<sup>121</sup> In *Corporate Health Insurance, Inc. v. Texas Department of Insurance*,<sup>122</sup> the Fifth Circuit had affirmed a district court ruling invalidating Texas's independent review requirement on ERISA preemption grounds.<sup>123</sup> The trial court had acted essentially

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116. *Id.*

117. *Id.* at 2169.

118. *Id.*

119. *See, e.g., CAL. INS. CODE* § 10,123.68 (West Supp. 2003) (mandating coverage of a second opinion upon the request of an insured, who must pay a standard copayment, but not requiring insurers to cover services recommended by a second opinion); *FLA. STAT. ch. 641.51(5)(c)* (Supp. 2003):

The organization's physician's professional judgment concerning the treatment of a subscriber derived after review of a second opinion shall be controlling as to the treatment obligations of the health maintenance organization. Treatment not authorized by the health maintenance organization shall be at the subscriber's expense.

120. *See* 215 ILL. COMP. STAT. 125/4-10 (2000) ("In the event that the reviewing physician determines the covered service to be medically necessary, the Health Maintenance Organization shall provide the covered service.").

121. *See Rush*, 122 S. Ct. at 2158.

122. 215 F.3d 526 (5th Cir. 2000).

123. *Id.* at 539.

sua sponte with respect to independent review.<sup>124</sup> The ERISA litigation giving rise to its opinion had principally attacked provisions of a new state law authorizing tort claims against managed care organizations, and had only challenged the external review program established by the same law because the inclusion of that program seemed to bolster the plaintiffs' argument that the liability provisions were preempted. The unhappy result for the plaintiffs was that the tort provisions were upheld but the state's external review program, which the managed care industry had favored, was overturned.<sup>125</sup> After *Rush* was decided, the Fifth Circuit modified its prior opinion to hold independent review preempted only as applied to self-funded ERISA plans.<sup>126</sup>

### III. A THERAPEUTIC APPROACH TO COVERAGE DECISIONS

In an interview shortly before his death, medical quality pioneer Avedis Donabedian reaffirmed his support for managed care in principle, but expressed great concern about commercialism in medicine. "Systems awareness and systems design . . . are enabling mechanisms," he said, but "[u]ltimately, the secret of quality is love."<sup>127</sup> Obviously, one cannot write an insurance policy to cover love, legislate love, or even train health professionals to love. Indeed, calls for "ethics" and "professionalism" are often the last refuge of the nostalgic, outcompeted, elitist, or merely confused, and therefore should be regarded skeptically. Images of professional virtue depicted by early sociologists such as Talcott Parsons are now regarded as naïve, and it has become common to depict professionals instead as

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124. *Corporate Health Ins., Inc. v. Tex. Dep't of Ins.*, 12 F. Supp. 2d 597, 622 (S.D. Tex. 1998) (noting that in order to examine the plaintiff's claim that the Texas act's definition of "appropriate and medically necessary" unlawfully changed the terms of an ERISA plan, "the Court must examine this term in conjunction with the procedure provided by the Act for the review of claims relating to an adverse benefit determination by an independent review organization"), *aff'd in part*, 215 F.3d 526 (5th Cir. 2000); *id.* at 625 (finding that the Texas act's independent review provisions "improperly mandate[d] the administration of [ERISA] employee benefits").

125. See Charles Ornstein, *Judge Upholds State Law that Lets Patients Sue over HMO Denials: But Ruling Strikes Much of Independent Review Process*, DALLAS MORNING NEWS, Sept. 19, 1998, at 1A ("Ironically, Aetna and other insurers had advocated the external appeals process during the 1997 Legislature.").

126. *Corporate Health Ins., Inc. v. Texas Dep't. of Ins.*, 314 F.3d 784, 786 (5th Cir. 2003).

127. Fitzhugh Mullan, *Interview: A Founder of Quality Assessment Encounters a Troubled System Firsthand*, HEALTH AFF., Jan.-Feb. 2001, at 137, 140.



stubborn protectionists.<sup>128</sup> On the other hand, as economist Kenneth Arrow observed forty years ago, professional norms play an essential role in filling “optimality gaps” caused by lack of information in health care markets.<sup>129</sup>

Recognizing the limitations of the current processes described in Parts I and II, this Part of the Essay proposes an alternative perspective on decisionmaking in managed care. It argues that health plans should make a serious attempt to identify traditional ethical values associated with healing and build them into coverage determinations.

Because interpretations of medical necessity are so variable, the *process* of making coverage decisions has arguably the most predictable effect on both clinical outcomes and patient satisfaction. Currently, the experience of requesting coverage of a proposed treatment, receiving a response, and negotiating or formally appealing an adverse decision is complex, impersonal, time-consuming, adversarial, and mysterious. These qualities have emerged in large part from a predictable tug-of-war between corporate inertia and regulatory zeal. The result is at best formalistic, at worst Byzantine. At meetings conducted in connection with the Stanford study, it was apparent that particular legal or contractual definitions of medical necessity had far less impact on actual practice than the manner in which decisionmakers (whether health plans or medical groups) gathered information, reached a preliminary conclusion, communicated with the patient and the treating physician, and modified their policies and procedures over time.<sup>130</sup> Furthermore,

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128. Compare TALCOTT PARSONS, *THE SOCIAL SYSTEM* 464 (1951) (“[T]he relationship is expected to be one of mutual ‘trust,’ of the belief that the physician is trying his best to help the patient and that conversely the patient is ‘cooperating’ with him to the best of his ability.”), with PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 20–21 (1982) (emphasizing that the “social structure is based, not purely on shared expectations about the roles of physicians and the sick, but on institutional arrangements [and reinforcement of professional authority] that often impose severe costs on people who wish to behave in some other way”).

129. Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 *AM. ECON. REV.* 941, 947, 965–66 (1963); see also Peter J. Hammer, *Arrow’s Analysis of Social Institutions: Entering the Marketplace with Giving Hands?*, 26 *J. HEALTH POL. POL’Y & L.* 1081, 1087–88 (2001) (analyzing Arrow’s insights).

130. See Singer et al., *supra* note 19, at 7 (“The reliance on contractual definitions of *medical necessity* in decision making is conspicuously absent . . .”); Singer & Bergthold, *supra* note 19, at 202 (“[E]ach medical director relies to a different extent on coverage policies, scientific evidence, expert opinion, committee consensus, personal experience, and patient characteristics and preferences when making daily decisions, while the contractual definition remains on the

specific legal requirements were often impediments to sound process, because they reduced the leeway available to decisionmakers or increased the potential liability associated with taking a novel, flexible approach.

An alternative conception of coverage decisionmaking is to model the interaction among an insured individual, her physicians, and her health plan so that it resembles—to the greatest extent possible—the classic doctor-patient relationship. One can call this approach “therapeutic coverage.”<sup>131</sup> For example, therapeutic considerations apply to the exchange of information. An obvious step is for the health plan to communicate with the patient through her physicians whenever possible, and in any event to coordinate information flow so that the health professional with whom the patient has the closest relationship is kept fully informed, regardless of whether the subject matter of the communication is nominally clinical or administrative. Physicians should be compensated for playing this more intensive role, and should be provided with information technology and other administrative support.

The policy rationales favoring this approach have not been fully appreciated. Economists tend to focus on information as a tool. Consumer advocates in managed care have agreed with this formulation, calling for extensive disclosure by health plans to assist patients with enrollment and treatment decisions.<sup>132</sup> In contrast, activists in other policy areas, such as the environment, understand that a “right to know” has dignitary value as well as practical value,

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shelf as a reminder of legal obligations and risks.”). The current author served as a legal consultant to the Stanford study and attended stakeholder meetings held in Sacramento, California in 1999 and Annapolis, Maryland in 2001.

131. Recasting health insurance coverage as a therapeutic process is related to “therapeutic jurisprudence,” an umbrella term that encompasses efforts in various legal fields, such as mental health law, to craft rules and procedures that alleviate suffering and improve physical and psychological well-being. See generally DAVID B. WEXLER, THERAPEUTIC JURISPRUDENCE (1990); see DAVID B. WEXLER & BRUCE J. WINICK, ESSAYS IN THERAPEUTIC JURISPRUDENCE ix (1991) (explaining therapeutic jurisprudence and “the extent to which substantive rules, legal procedures, and the roles of lawyers and judges produce therapeutic or antitherapeutic consequences” in health care decisions). The connection between health law and medical benefit has begun to attract scholarly attention. See, e.g., M. Gregg Bloche, *The Invention of Health Law*, 91 CAL. L. REV. 247, 254–56 (2003) (arguing that social values, rather than economic reasoning, should underlie health law decisions by courts); Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 525 (2002) (“Health care law can (and does) enforce trust-related expectations, punish violations of trust, facilitate the psychology of trust, and undermine trust.”).

132. On the disclosure debate generally, see William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701 (1999).

and is empowering in both respects.<sup>133</sup> Similarly, physicians give information to patients not only to help patients make decisions but to promote trust, which has both intrinsic health benefits and instrumental effects on health by inducing patients to share relevant facts about themselves with their providers and improving compliance with therapy.<sup>134</sup> In particular, when doctors convey their professional opinion that a specific therapy is not advisable, they also maintain hope, offer explanations and alternatives, and assure patients that they will not abandon them. Health plans should try to follow this example when relaying determinations of medical necessity or other coverage matters. For example, written and oral communications denying coverage or requesting additional information should be compassionate, should be forthcoming about reasons for the health plan's action, should take responsibility for the consequences instead of disclaiming them in anticipation of litigation, should offer alternatives to the denied treatment, and should avoid giving the impression of abandonment.

The therapeutic implications of choice also bear mentioning, although health plans probably lack sufficient credibility in the short term to constrain choice of physician or treatment for therapeutic purposes. Psychological studies of choice tend to reveal a Goldilocks problem: People are unhappy about having either too little choice or too much choice, but what intermediate level of choice is "just right"?<sup>135</sup> When selecting treatments, patients want structured choices and, ultimately, an expert recommendation.<sup>136</sup> Health plans might take

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133. For a discussion of environmental information disclosure, see Bradley C. Karkkainen, *Information as Environmental Regulation: TRI and Performance Benchmarking, Precursor to a New Paradigm?*, 89 GEO. L.J. 257 (2001).

134. For a study attempting to model and measure trust, see Mark A. Hall et al., *Trust in Physicians and Medical Institutions: What Is It, Can It Be Measured, and Does It Matter?*, 79 MILBANK Q. 613 (2001) (reviewing the literature on trust as an essential factor in therapeutic encounters between doctor and patient). For an explanation of how medical beneficence and trust may be more important to patients than formal autonomy, see CARL F. SCHNEIDER, *THE PRACTICE OF AUTONOMY: PATIENTS, DOCTORS, AND MEDICAL DECISIONS* xi–xiii (1998) (arguing that while patients may crave autonomy, it is hard for them to accept the responsibility of making medical decisions without the input of medical professionals).

135. See Sheena S. Iyengar & Mark R. Lepper, *Choice and Its Consequences: On the Costs and Benefits of Self-Determination*, in *SELF AND MOTIVATION: EMERGING PSYCHOLOGICAL PERSPECTIVES* 71, 85 (Abraham Tesser et al. eds., 2002) (“[A]lthough the provision of extensive choices may initially be perceived as desirable, the actual exercise of choice [when there are many options] may hamper rather than enhance choosers’ intrinsic motivation.”).

136. Informed consent law in some countries outside of the United States recognizes this need and directs physicians to recommend a course of action. See, e.g., Ron Paterson, *A ‘Code of Patients’ Rights’ for New Zealand*, 5 HEALTH CARE ANALYSIS 43, 46 (1997) (discussing New

this trait into account when addressing coverage issues, both in their own dealings with patients and with respect to the psychological effect on patients of having a health plan countermand their treating physicians' recommendations. The therapeutic impact of choice also counsels against allowing enrollees to choose among markedly different rationing schemes (sometimes called "economic informed consent"), with subsequent disputes judged according to different standards of care.<sup>137</sup> Neither the public nor the law has rushed to discard the notion of a unitary, unalterable standard of medical care, in large part because openly acknowledging that medical practice can be varied for economic reasons reduces trust in health care for everyone. In other words, unconstrained choice can have significant negative externalities.

Avoiding conflict where possible, and managing conflict where inevitable, are also hallmarks of a therapeutic approach to coverage decisions. Scholars of dispute resolution distinguish "positional bargaining," which views outcomes as zero-sum and is typical in courtroom situations, from "interest-based bargaining," which attempts to look beyond articulated positions to determine whether a creative approach might produce mutual gains.<sup>138</sup> Currently, medical necessity determinations are framed in adversarial terms, which leads the public to assume that all participants are aligned on a partisan basis with one side or the other, and to expect a final decision to be rendered by a scrupulously neutral party. Consequently, patients increasingly look to physicians as their "advocates," and regard any action of the health plan with suspicion. Studies have shown that physicians cast in this role may withhold or fabricate information regarding medical necessity, especially if the decisionmaking

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Zealand's informed consent statute). American informed consent law, which emphasizes autonomy over beneficence, does not. *See generally* GEORGE J. ANNAS, STANDARD OF CARE: THE LAW OF AMERICAN BIOETHICS (1993) (discussing how standards of care are strongly influenced by law and how they should be based more on protecting the patient).

137. *See* MARK A. HALL, MAKING MEDICAL SPENDING DECISIONS 193–227 (1997) (discussing when resource allocation mechanisms should be disclosed to patients); Mark A. Hall, *A Theory of Economic Informed Consent*, 31 GA. L. REV. 511, 556 (1997) ("The theory of economic informed consent reasons that when consumers make fully informed purchasing decisions to join a constrained insurance plan rather than an unlimited one, they knowingly opt into an economizing style of medicine in exchange for lower premiums or more comprehensive coverage.").

138. *See, e.g.*, ROGER FISHER & WILLIAM URY, GETTING TO YES: NEGOTIATING AGREEMENT WITHOUT GIVING IN 14 (Bruce Patton ed., 1991) ("[I]n contrast to positional bargaining, the principled negotiation method of focusing on basic interest, mutually satisfying options, and fair standards typically results in a *wise* agreement.").

processes established by health plans seem illegitimate.<sup>139</sup> Furthermore, over time patients' trust in the medical profession may erode because the posturing and exaggeration expected of an advocate is detrimental to one's role as a healer.<sup>140</sup> Legalistic procedures for dispute resolution may assure fairness, but they do not necessarily restore therapeutic trust.

Health plans can enhance therapeutic benefit by adopting procedures that are less adversarial. For example, health plans can use mediation to defuse conflict when coverage of a requested service may not be forthcoming, and can hire administrative staff whose job is to anticipate and answer questions likely to arise in connection with particular health conditions. By reducing confrontation, health plans also promote truth-telling and help ensure that the information necessary to build the base of clinical evidence underlying medical necessity decisions is comprehensive and accurate.

Another way to appreciate the harm caused by making health care into an adversarial process is to recognize that the relationship between health plan and beneficiary is potentially a lasting and dependent one. Medicine deals with continuing relationships relatively well. In particular, medical ethics emphasizes non-abandonment of those who are sick, a tenet that is increasingly important now that chronic disease rather than acute illness dominates health care.<sup>141</sup> Tort law and medical ethics reinforce this behavior by holding physicians accountable for continuing care once

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139. See M. Gregg Bloche, *Fidelity and Deceit at the Bedside*, 283 JAMA 1881, 1882 (2000) (“[P]hysicians crafted their presentations to utilization managers with an eye toward gaining coverage. Particularly in cases in which clinical findings are subjective and ambiguous (or fall within the intricacies of plan coverage rules) the possibilities for advocacy-driven interpretation and presentation of clinical data are great.”); Matthew K. Wynia et al., *Physician Manipulation of Reimbursement Rules for Patients: Between a Rock and a Hard Place*, 283 JAMA 1858, 1858 (2000) (“A sizable minority of physicians report manipulating reimbursement rules so patients can receive care that physicians perceive as necessary.”).

140. See William M. Sage, *Physicians as Advocates*, 35 HOUS. L. REV. 1529, 1616 (1999) (“Ironically, reconstituting the physician as advocate—that is, as the patient’s champion in the struggle against cost-conscious society and its corporate representatives—might have the effect of reducing rather than increasing the intimacy of the physician/patient relationship.”).

141. See BD. ON HEALTH CARE SERVS., INST. OF MED., FOSTERING RAPID ADVANCES IN HEALTH CARE: LEARNING FROM SYSTEM DEMONSTRATIONS 28 (2002), at <http://www.nap.edu/openbook/0309087074/html/27.html> (on file with the *Duke Law Journal*) (noting that an estimated 120 million Americans have chronic conditions, and that people with chronic conditions account for the majority of overall health care spending).

a doctor-patient relationship has been formed.<sup>142</sup> By contrast, most other forms of insurance are aimed at single, catastrophic occurrences which, in the unlikely event they occur, render subsequent coverage unavailable or substantially more expensive. Fiduciary obligations are few, and, if they exist, run to the insured pool as a whole rather than to individual beneficiaries.<sup>143</sup> Considerable miscommunication results from this difference in perspective. Health insurers lament the fact that consumers want to “use” their coverage regularly, which would be absurd for property or casualty insurance. On the other hand, physicians, patients, and often regulators regard as shameful insurers’ tendency to exclude or surcharge people who have suffered medical misfortune.

If health coverage is to operate effectively, therefore, it must develop forms of relational contracting that blend actuarial integrity with responsiveness to patients’ continuing needs. One priority should be accessibility. A good doctor is there for a patient, even if she cannot offer a cure. And doctors are available on a continuing basis, not just during a single catastrophic event. By contrast, even the property-casualty insurer that advertises itself as a “good neighbor” is at best there to help when the flood or tornado hits, and may not stay long. All too often, managed care organizations have shortchanged consumers looking for information and assistance by understaffing help lines and adding bureaucratic barriers to resolving claims. Recent regulatory changes to ERISA have reduced the time within which health plans must respond to requests for coverage or appeals of initial denials.<sup>144</sup> These measures, however, merely recognize that the leisurely pace with which pre-managed care disputes over financial responsibility could be resolved is incompatible with prospective review under managed care, which potentially leaves patients untreated for as long as they are uncovered. Health plans

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142. *O’Neill v. Montefiore Hosp.* 202 N.Y.S.2d 436, 440 (1960) (“[A] physician who undertakes to examine or treat a patient and then abandons him, may be held liable for malpractice.”); AM. MED. ASS’N, PRINCIPLES OF MEDICAL ETHICS, E-10.01: FUNDAMENTAL ELEMENTS OF THE PATIENT-PHYSICIAN RELATIONSHIP (“The physician may not discontinue treatment of a patient as long as further treatment is medically indicated, without giving the patient reasonable assistance and sufficient opportunity to make alternative arrangements for care.”).

143. See JERRY, *supra* note 30, at 262–63, 514 (noting that, in contrast to health insurance, most other insurance policies tend to cover major, catastrophic events that occur only rarely, and that only under special circumstances do insurers have fiduciary duties to their insureds).

144. See 29 C.F.R. 2560.503-1 (setting forth new claims procedures, effective January 1, 2003, for employer-sponsored health plans).

should work much harder to emulate the medical profession's commitment to timely access and prompt response.

#### IV. RECOMMENDATIONS FOR MEDICAL NECESSITY POLICY

Independent review programs spend surprisingly little time on preserving or improving medical relationships. Current conceptions of medical necessity steer a middle course between legal fairness and accuracy on the one hand and medical fairness and accuracy on the other, a course that serves both professional systems poorly. Legal fairness demands due process, often through adversarial advocacy, and impartial decisionmaking. Outcomes of a fair legal process are generally deemed accurate. Medical fairness, on the other hand, demands beneficence and respect for persons, while medical accuracy requires a scientific foundation that is largely independent of fairness. This Part of the Essay argues for a more deliberately therapeutic design to medical necessity and coverage procedures. Many of the benefits of approaching medical necessity in this fashion would accrue to individual patients, but the approach also provides a vehicle for extending these private conversations into the public realm in order to tackle difficult social problems of resource allocation.

##### *A. Implications for Benefit Design*

How should current practices involving medical necessity be modified to improve credibility, trust, and therapeutic effect? The probable answer is to reduce reliance on “medical necessity” as a legally binding criterion for coverage and to unpack the term into two components: a customized menu of contractual specifications for particular treatments, and a set of general principles regarding beneficial, cost-effective care.

It is critical to judge a proposed treatment's appropriateness using scientific evidence that demonstrates the treatment's clinical benefit. A commitment to scientific evidence should be emphasized at each system interface—health plan/physician, health plan/enrollee, and physician/patient—through explicit disclosure and discussion of the centrality of science to sound practice. However, health plans should avoid conflating evidence-based medicine with complete predictability of treatment expense. Variation is a core characteristic of professional activity. Variation in medicine derives from the incompleteness of scientific knowledge, the rapidity of technologic innovation, the complex determinants of illness, and the different

emotional needs and responses of patients. Put differently, health coverage differs from the classic model of insurance because loss is uncertain as well as risky.<sup>145</sup> Vague terms like medical necessity reflect the underlying uncertainty of medicine, and are a prominent example of the health care system's reliance on inevitably ambiguous contracts.<sup>146</sup>

The existence of uncertainty suggests one reason why managed care has not lived up to its promise that has by and large escaped notice. Reducing unwarranted variation in clinical practice has been the holy grail of managed care since its inception, and it remains a mantra for reformers who seek to expand insurance coverage without greatly increasing national health expenditures. Insurers find this idea attractive in part because it accords well with the actuarial approach to risk that is their core competency. However, they may overestimate the ease of standardizing medical practice. Medical professionals take pride in their individual judgment, and have substantial reservations about rule-like approaches to health care quality. Medical liability law reflects the paradox of wanting health insurers to be objective and consistent about coverage decisions when underlying medical practice is often neither. For example, the professional standard of care that governs medical malpractice suits leaves room for much greater variability than the strict contractual standard applied in insurance coverage litigation.

A principal goal of reconfiguring medical necessity, therefore, is to promote efficient care while still accommodating uncertainty and variation. Accordingly, evidence-based practices and the descriptive language that captures them in contracts of insurance and provider agreements should be guidelines rather than requirements, with the health plan acting more as facilitator than as monitor in providing feedback to treating physicians in individual cases. By the same token, physician profiling (evaluating the general practices of network providers over a large range of cases) should be used in preference to strict utilization review by health plans of individual treatment recommendations. Implicit in this approach is that the

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145. In standard economic analysis, "risk" denotes a known probability distribution of possible outcomes, and therefore can be managed actuarially, whereas "uncertainty" means that the probabilities themselves are unknown. SHERMAN FOLLAND ET AL., *THE ECONOMICS OF HEALTH AND HEALTH CARE* 232 n.1 (2d ed. 1997).

146. See CLARK C. HAVIGHURST, *HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM* (1995) (arguing for improved contracting in health care and the use of private contracts to specify the legal rights of enrollees).



health plan should accept, and pay for, occasional divergence from modal practice for compassionate, beneficent reasons. To channel these instances into professionally virtuous activities and to create institutional dialogue and accumulated wisdom, it makes sense for health plans to use ethics committees, peer review panels, and ad hoc advisory bodies drawn from the plans' own providers. These would supplement outside technology assessments and other purely technical systems for adducing and weighing scientific evidence.

The centrality of employers and other purchasing agents to managed care also has important implications for medical necessity. The use of broad terms such as medical necessity in health insurance policies derives partly from the belief among both insurers and regulators that unsophisticated consumers are incapable of understanding more detailed contractual provisions. This concern should not apply to active insurance purchasing by large employers or other repeat players acting on behalf of individual beneficiaries. If annual benefits negotiations between large employers and health plans included reaching agreement about coverage for specific treatments and disclosing that list to employees, it could substantially lessen the burden on the residual process of determining medical necessity, while also producing better informed consumers with more reasonable expectations of their coverage. Furthermore, although the political debate understandably centers on high-visibility technologies for life-threatening diseases, medical necessity provisions are often used, less dramatically, to curtail excessive lengths of stay or to shift care from higher intensity to lower intensity settings. Many of these issues could be specified contractually.<sup>147</sup>

Explicit contracting would still be difficult to accomplish because the large number of treatment permutations possible in clinical practice makes it hard to specify individual inclusions and exclusions even in single-year policies. Furthermore, as Professor Hyman points out, the violent political backlash that erupted against limits on postpartum hospitalization is a reminder to health plans that making resource allocation decisions visible to the public may provoke fiercer, better organized opposition than occurs when rationing is done quietly, despite ethicists' virtually unanimous belief in

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147. See E. HAAVI MORREIM, *HOLDING HEALTH CARE ACCOUNTABLE: LAW AND THE NEW MEDICAL MARKETPLACE* 134–35 (2001) (“[G]uidelines-based contracting. . . . permits health plans to circumscribe much more clearly what they do and do not cover and to enforce those limits in an above-board spirit of fairness to all.”).

transparency.<sup>148</sup> A possible decline in employer involvement is another problem. If employers retreat to defined contribution plans or other indirect purchasing arrangements, enrollees may find themselves once again unable to negotiate effectively.<sup>149</sup> In addition, specific legal barriers may exist to limiting coverage explicitly—not only contrary provisions in state insurance regulations, but also problems involving disease-based distinctions and the Americans with Disabilities Act (ADA).<sup>150</sup> All this suggests the need to supplement private activity with public processes that periodically identify controversial areas of medical care, offer impartial, expert assessments of the relevant science, allow health plans to share information without risking antitrust liability, and provide political cover and legal protection to health plans that take explicit contractual positions regarding coverage.

In any event, increased emphasis on individual consumers as decisionmakers is likely to be a permanent feature of the future health care system. One reason for this trend is that transferring greater financial risk to employees has been the first response of

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148. See David A. Hyman, *Drive-Through Deliveries: Is “Consumer Protection” Just What the Doctor Ordered?*, 78 N.C. L. REV. 5, 98 (1999) (“The Newborns’ Act . . . undermines the incentives to engage in appropriately visible cost-containment, while simultaneously giving the public a false sense of security about the merits of the existing care and coverage, [making it impossible] to deploy a system that is fully transparent in its cost-containment efforts.”). The ethical case for transparency is set forth in DANIELS & SABIN, *supra* note 79, at 11–12.

149. Workers save substantial amounts of money when the cost of health insurance is channeled through their employers, because compensation received in the form of health insurance is not taxable income. Employers who offer medical benefits have typically paid all or a fixed percentage of the annual cost of coverage for their workers, whatever that cost might turn out to be. An alternative to this “defined benefit” approach is to give workers a fixed dollar amount each year (a “defined contribution”), which each worker can apply to health coverage as he or she sees fit. See generally CONSUMER-DRIVEN HEALTH BENEFITS: A CONTINUING EVOLUTION? (Paul Fronstin ed., 2002) (monograph from the Employee Benefit Research Institute and the Consumer Health Education Council) [hereinafter Fronstin].

150. The ADA is codified at 42 U.S.C. §§ 12,101–12,213 (2000). For an example of case law grappling with the health insurance implications of the ADA, see *Doe v. Mutual of Omaha Ins. Co.*, 179 F.3d 557 (7th Cir. 1999) (holding that the public accommodations section of the ADA does not prohibit selective benefit caps); see also Catherine Olender, *Capping AIDS Benefits: Does Title III of the ADA Regulate the Content of Insurance Policies?*, 28 AM. J.L. & MED. 107, 109–10 (2002) (noting that although state laws generally prevent arbitrary capping of benefits by insurance companies, the ADA is a potential hurdle to capping benefits on self-insured plans subject to ERISA preemption). Broader issues are explored in Mary R. Anderlik & Wendy J. Wilkinson, *The Americans with Disabilities Act and Managed Care*, 37 HOUS. L. REV. 1163 (2000).

employers to the recent resurgence in health care costs.<sup>151</sup> Another reason is that the Internet facilitates the formation of groups with common interests and circulates information far more easily than was previously possible.<sup>152</sup> Necessity-based exclusions in health insurance therefore should be reoriented to influence consumer decisionmaking directly, rather than merely counteracting *physicians'* moral hazard when making treatment recommendations for insured patients. Specifically, one might factor medical necessity into a system of graduated cost-sharing for many treatments similar to that already in use for prescription drug benefits.<sup>153</sup> Currently, if a forty-something, male law professor in generally good health wants an expensive screening examination such as a colonoscopy or magnetic resonance imaging (MRI) scan, health plans either deny coverage as unnecessary or cover the procedure in full (sometimes based on exaggerated information regarding symptoms or risk factors submitted by the referring physician).<sup>154</sup> Moreover, if coverage is denied, the patient loses the benefit of the discounted rate negotiated by the health plan, and must pay a much higher cash price if he elects to proceed. One might instead create a system of tiered copayments based on cost-effectiveness, so that low-risk individuals pay more for the reassurance of a screening examination than high-risk individuals, but still can avail themselves of the health plan's purchasing leverage. Moreover, unlike proposals for "economic informed consent" that urge health plans to offer consumers a choice among rationing systems (i.e., binding standards of medical necessity) at the point of enrollment,<sup>155</sup> this type of approach lets consumers exercise options at the point of service, which demonstrably improves satisfaction.

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151. See Paul Fronstin, *Can "Consumerism" Slow the Rate of Health Benefit Cost Increases?*, in Fronstin, *supra* note 149, at 3–23.

152. For a general discussion of Internet consumerism with application to health care, see Mark S. Nadel, *The Consumer Product Selection Process in an Internet Age: Obstacles to Maximum Effectiveness and Policy Options*, 14 HARV. J.L. & TECH. 183, 251–52 (2000).

153. Health insurance policies commonly cover generic prescription drugs for a lower patient copayment amount than patented drugs, and many have "triple-tier" features that divide patented drugs into subcategories with different copayments based on cost and effectiveness. For an overview of pharmaceutical cost management, see Patricia M. Danzon & Mark V. Pauly, *Health Insurance and the Growth in Pharmaceutical Expenditures*, 45 J.L. & ECON. 587 (2002). Extensions of copayment strategies to other clinical areas are mentioned in Arnie Milstein, *Optimizing Cost and Quality Through Consumer-Driven Health Benefits: Where Does the Evidence Point?*, in Fronstin, *supra* note 149, at 61–66.

154. See *supra* note 139.

155. See *supra* note 137.

A norm-based rather than directive approach to medical necessity might allow cost-effectiveness to be more openly discussed than is currently the case.<sup>156</sup> Although the public thinks of managed care as cost-obsessed, virtually no health insurance policies explicitly refer to cost or cost-effectiveness in setting coverage standards or defining medical necessity.<sup>157</sup> Some combination of regulatory resistance, fear of adverse publicity, and potential legal liability probably accounts for this fact. Nonetheless, physicians and patients assume that cost is a driving factor in coverage denials by health plans, and the perception of hypocrisy when health plans fail to mention cost increases their resentment and resistance.

If the principal goal of medical necessity review is to promote awareness of the importance of using resources prudently based on sound evidence, rather than to render a binding decision in an individual case, it becomes less threatening to address cost explicitly. Coverage documents might provide illustrative examples of services that usually would or would not be covered based on cost-effectiveness, along with an explanation of the reasons for those presumptions. In order to allay fears that coverage denials merely increase corporate profits without benefiting insured patients as a group, health plans could also give enrollees some sense of the additional health services that were made financially possible by cost savings on unnecessary care. Health plans might even extend the discussion to encompass the uninsured, including those who can only afford private coverage if it is carefully managed. Introducing these issues would also acknowledge that health insurance is a social responsibility as well as a private entitlement.

Optimism that some level of shared understanding can be achieved is warranted because of a shift in the political meaning of "cost-effective." In the 1980s, when managed care was more theory than practice, the idea of applying cost-effectiveness analysis to the care of individual patients was despised by many physicians (and liberal reformers), who saw the word "cost" as violating ethical duties to individual patients and encouraging a dollar value to be placed on

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156. See SACRAMENTO HEALTHCARE DECISIONS, COST-EFFECTIVENESS AS A CRITERION FOR MEDICAL AND COVERAGE DECISIONS (2001) (arguing that a public participation model would be the most beneficial because the needs of the public would be addressed in the cost-effective health care reform) available at <http://www.sachealthdecisions.org/vf.pdf>.

157. See Singer et al., *supra* note 19, at 8 ("Only two [health plans interviewed] include a cost effectiveness criterion in their contracts . . .").

human life.<sup>158</sup> Now that managed care is *fait accompli*, however, cost-effectiveness enjoys a somewhat more positive connotation among these groups because its reference to “effectiveness” suggests evaluation by quality experts, not cost-cutters.

Applying a cost-effectiveness criterion to medical necessity might also help address shortcomings in conventional cost-effectiveness analysis. An important but seldom discussed difference between the insurance-actuarial perspective and the medical-professional perspective is that insurance is based on statistical lives, while medicine is based on identified lives. Health insurance coverage litigation is replete with cases where insurers’ collectivist arguments about population health and optimal use of health plan resources fall on deaf judicial ears, particularly when those arguments are opposed by physician testimony regarding the specific needs of the plaintiff.<sup>159</sup> This likely reflects more than just the well-known tension between *ex ante* preferences when one buys insurance and *ex post* preferences when one suffers a loss.<sup>160</sup> Scholars have observed that values not captured in traditional cost-effectiveness analysis—the “Rule of Rescue,” maintaining hope, helping the sickest even if improvement

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158. See, e.g., David M. Eddy, *Broadening the Responsibilities of Practitioners: The Team Approach*, 269 JAMA 1849 (1993) (containing a fictional dialogue in which a traditional physician is persuaded that cost-effectiveness analysis is legitimate); Jerome P. Kassirer, *Managing Care—Should We Adopt a New Ethic?*, 339 NEW ENG. J. MED. 397, 397 (1998) (arguing against population-based models of medical ethics); cf. Lisa Heinzerling, *The Rights of Statistical People*, 24 HARV. ENVTL. L. REV. 189, 207 (2000) (“In defining the monetization of, and discrimination among, human lives based on the statistical nature of those lives, economic analysts have dehumanized the suffering and death that scientific risk assessments tell us will occur due to particular hazards.”). Political stakeholders, particularly medical device manufacturers, have taken advantage of this discomfort to delay efforts by Medicare to incorporate cost-effectiveness into its coverage standards. See *Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Technology*, 54 Fed. Reg. 4302 (Jan. 30, 1989) (announcing notice of proposed rulemaking to establish criteria and procedures for making medical services coverage decisions that relate to health care technology); Susan Bartlett Foote, *Why Medicare Cannot Promulgate a National Coverage Rule: A Case of Regula Mortis*, 27 J. HEALTH POL. POL’Y & L. 707, 707 (2002) (arguing that a Medicare rule to pay for only “reasonable and necessary” expenses has been blocked by the medical device industry).

159. In *Florence Nightingale Nursing Serv., Inc. v. Blue Cross & Blue Shield of Ala.*, 832 F. Supp. 1456 (N.D. Ala. 1993), for example, the court excoriated the health plan’s claims review expert: “Dr. Holloway’s training is not only in medicine but in ‘cost containment.’ In which of these disciplines she is better trained would be an interesting question . . . .” *Id.* at 1461; see also, e.g., *Adams v. Blue Cross/Blue Shield*, 757 F. Supp. 661, 670–71 (D. Md. 1991) (rejecting the relevance of testimony of Dr. David Eddy, a national authority on cost-effective medical care).

160. For an overview of moral hazard in insurance law and regulation, see Tom Baker, *On the Genealogy of Moral Hazard*, 75 TEX. L. REV. 237 (1996).

is slight—more accurately reflect both public sentiment and professional values.<sup>161</sup> One could imagine incorporating these refinements into measures of cost-effectiveness used to inform coverage decisions.

### *B. Implications for Independent Review*

Many of the recommendations outlined above for a therapeutic conception of coverage law are not easily reducible to binding statutes or regulations. Therefore, a slow transition—an evolution, more accurately—to an improved system is probably the best that can be expected. However, some things can be done in the near term to encourage productive change. The ubiquity of support for independent review programs suggests that altering those procedures to enhance therapeutic effect has the potential to yield long-term benefits.

Independent review is generally thought to build trust between health plans and their members. In one study by Professor Schlesinger and colleagues, problem resolution was enhanced by independent review, as was satisfaction for health plan members who knew that such review was available.<sup>162</sup> Because take-up rates for independent review remain very low,<sup>163</sup> however, merely residing in a state with a review program was not associated with more effective “voice” in the Schlesinger study.<sup>164</sup> The approachability of a given health plan—a cultural attribute of the organization—was a much stronger determinant than its regulatory environment of the level of

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161. See, e.g., David C. Hadorn, *Setting Health Care Priorities in Oregon: Cost-effectiveness Meets the Rule of Rescue*, 265 JAMA 2218 (1991) (describing the reaction of physicians and consumer groups after Oregon prioritized health care procedures using a cost-effective analysis and not taking into account the duty people feel to save endangered lives); Paul Menzel et al., *Toward a Broader View of Values in Cost-Effectiveness Analysis of Health*, HASTINGS CENTER REP., May–June 1999, at 7, 11–12 (noting that cost-effective analysis should be expanded to include maintenance of hope and assurance of treatment).

162. See Mark Schlesinger et al., *Voices Unheard: Barriers to Expressing Dissatisfaction to Health Plans*, 80 MILBANK Q. 709, 737 (2002) (“Those who were aware that they resided in a state mandating third-party mediation of disputes were nearly twice as likely to report successful problem resolution.”).

163. See *supra* note 105 and accompanying text.

164. See Schlesinger et al., *supra* note 162, at 737 (“However, simply residing in states with [third-party mediation of dispute] mandates was not associated with more effective voice. Only the combination of supportive regulations and knowledge of the regulation increased the likelihood of effective voice.”).

complaints it received and the likelihood of problems being resolved.<sup>165</sup>

Unfortunately, the trust-building achievements of independent review seldom extend to core medical matters. In the Schlesinger study, patients were far more likely to express administrative complaints than clinical complaints to health plans,<sup>166</sup> a finding that is problematic considering that the primary purpose of legislation creating grievance and appeals rights in managed care is to counter health plans' growing clinical influence. Furthermore, physicians are poorly integrated into the process of independent review.<sup>167</sup> This limits both therapeutic benefit to patients and educational value for physicians. Anecdotal impressions from conversations with both health plan representatives and external review contractors suggest that the treating physician's perspective, which traditionally was the touchstone for legal analysis in coverage cases,<sup>168</sup> is increasingly either discounted as mere "patient advocacy" or dismissed as superfluous to the scientific opinion rendered by the expert panel. This is counter-therapeutic at several levels. It ignores the patient's emotional reliance on his or her physician, fails to take advantage of the physician's superior knowledge of the patient's individual goals and circumstances, and defines the relationship among physician, health plan, and reviewer as confrontational and bureaucratic rather than cooperative and instructive.

Similar shortcomings beset the communications aspects of medical necessity review. Managed care regulators have given their greatest attention to assuring that coverage denial notices sent to members are timely, contain a clear explanation of the rationale for denial, and alert members to their grievance and appeal rights.<sup>169</sup>

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165. *Id.* at 742–43, 746. Schlesinger concludes that exhaustion of remedies requirements for access to external review are counterproductive because the least responsive plans are the least likely to generate internal grievances in the first place. *Id.* at 747.

166. *Id.* at 744.

167. See JILL K. SILVERMAN ET AL., INDEPENDENT MEDICAL REVIEW EXPERIENCES IN CALIFORNIA, PHASE II: CASES INCLUDING MEDICAL NECESSITY 22–26 (2003) (detailing the lack of awareness by physicians of the existence of independent review and their lack of involvement in the process), available at <http://www.chcf.org>; see also Schlesinger et al., *supra* note 162, at 746–47 (“Although some consumers with problems with their health plan discussed them with their physician, many more did not.”).

168. See Hall & Anderson, *supra* note 6, at 1644–57 (describing courts' tendency to defer to treating physicians regardless of insurers' contractual standards).

169. See Tracey E. Miller, *Center Stage on the Patient Protection Agenda: Grievance and Appeal Rights*, 26 J.L. MED. & ETHICS 89, 91 (1998) (noting that states have instituted

These are valuable in terms of procedural fairness, but they take no account of therapeutic relationships, they marginalize physicians, and they fail to offer alternatives to outright denial of coverage or otherwise counter feelings of abandonment.<sup>170</sup>

The patina of legal fairness accorded the few individuals who avail themselves of independent review may provide reassurance and even confer a degree of dignity on patients. However, the overall tone of independent review is impersonal and adversarial. Coverage is sought and denied, following which consumers may initiate internal appeals and subsequently invoke rights to independent review.<sup>171</sup> Eventually, a distant judgment is rendered. From a therapeutic perspective, this is suboptimal in itself, but damning in combination with the low utilization rates associated with independent review programs.

An improved system of independent review would match its procedural framework to the underlying process of ascertaining coverage and receiving medical care. This is not the case under current law. As noted, the Illinois external review law upheld in *Rush* applied only to actual HMOs, not other forms of managed health insurance, and was triggered only if there was a specific disagreement between the patient's primary care physician and the plan.<sup>173</sup> Consequently, even if the state law were totally unaffected by ERISA (i.e., if it extended to self-insured as well as insured employee benefit

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substantial requirements that HMOs must follow when informing enrollees of denials in coverage).

170. Offering an alternative, a core aspect of a therapeutic approach, may also be contrary to health plans' interests in characterizing their conduct as related to benefits, not quality, and therefore shielded by ERISA. See *Cicio v. Does*, 321 F.3d 83, 103 (2d Cir. 2003) (noting that evidence of a health plan offering a different treatment instead of an outright denial suggests a clinical role not implicating ERISA).

171. See, e.g., HEALTH PLAN BUREAU, STATE OF N.Y., 2002 HEALTH CARE HELPLINE REPORT: COMPLAINT PATTERNS, CONSUMER TIPS, REFORM RECOMMENDATIONS 11–17 (2002) (describing the different types of medical necessity coverage disputes brought before the New York Attorney General), available at [http://www.oag.state.ny.us/health/2002\\_health\\_care\\_helpline\\_report.pdf](http://www.oag.state.ny.us/health/2002_health_care_helpline_report.pdf).

172. Offering an alternative, a core aspect of a therapeutic approach, may also be contrary to health plans' interests in characterizing their conduct as related to benefits, not quality, and therefore shielded by ERISA. See *Cicio v. Does*, 321 F.3d 83, 103 (2d Cir. 2003) (noting that evidence that health plan offered a different treatment instead of an outright denial suggests a clinical role not implicating ERISA).

173. See 215 ILL. COMP. STAT. 125/4-10 (2000) ("Each [HMO] shall provide a mechanism for the timely review . . . in the event of a dispute between the primary care physician and the [HMO] regarding the medical necessity of a covered service proposed by a primary care physician.").



plans), many patients facing issues of medical necessity would be poorly protected, and in very few cases would the law improve the technical or interpersonal quality of medical care.

The most effective reform would be to bifurcate independent review proceedings according to whether the health plan member is a light user or a heavy user of medical care.<sup>174</sup> The unequal distribution of illness is a central challenge for health policy, with a relatively small percentage of patients accounting for a majority of medical expenditures.<sup>175</sup> The principal value of having independent review in place for most beneficiaries is to maintain confidence in health insurance, even though they will seldom use it and will never actually be denied coverage. These individuals are more “consumers” than “patients,” and likely receive a mild psychological benefit from believing that managed care can be administered fairly. Accordingly, an arbitration model of independent review similar to current systems in many states seems appropriate for members who encounter coverage denials but are not seriously ill. Most disputes that arise will involve services that are not clearly “medical.”<sup>176</sup> Particularly in these situations, a system that avoids obvious bias, offers some degree of expertise, but displays little compassion is sufficient.

Patients with chronic or severe illness, by contrast, should be channeled into a proactive system of publicly sponsored mediation.<sup>177</sup>

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174. The wisdom of varying procedures according to substantive features of disputes has been debated in many contexts. See, e.g., Paul D. Carrington, *Making Rules to Dispose of Manifestly Unfounded Assertions: An Exorcism of the Bogy of Non-Trans-Substantive Rules of Civil Procedure*, 137 U. PA. L. REV. 2067, 2068 (1989) (arguing that rules of civil procedure should not be customized to the substantive nature of the rights enforced). The usual risk of sacrificing political neutrality (by subjecting a defined set of disputes to more focused and intense lobbying efforts) in order to achieve technical accuracy seems less of a problem in managed care, which is already rife with special interests.

175. See SHERRY GLIED, CHRONIC CONDITION: WHY HEALTH REFORM FAILS 123 (1997) (“The 1 percent of Americans with the highest spending on health care in 1987 accounted for fully 30 percent of total health spending in that year. By contrast, the 50 percent of Americans with the least spending accounted for only 3 percent of total health spending.”).

176. See Studdert & Gresenz, *supra* note 82, at 869 (“[M]edical necessity disputes frequently converged not around life-sustaining therapies, but in areas of ongoing uncertainty about the proper limits of insurance coverage [like surgery for obesity].”).

177. The connection between mediation and medical necessity is discussed in Nancy N. Dubler, *Mediating Disputes in Managed Care: Resolving Conflicts over Covered Services*, 5 J. HEALTH CARE L. & POL’Y 479, 480 (2002) (“Mediation is a particularly useful tool in addressing bioethics conflicts because it recognizes that in the clinical setting conflict is endemic and must be managed rather than avoided, because power differentials are inevitable and because ranges of solutions are generally available in medically complex cases.”). For a discussion of mediation in the context of medical malpractice, see Edward A. Dauer & Leonard

This procedural approach would pay less attention to the formalities of due process, and would focus instead on eliciting and discussing the patient's clinical situation, values and preferences, and sources of care and emotional support. In other words, its emphasis would be less on avoiding bias and more on bringing clinical expertise to bear on difficult medical problems. It would also offer compassion to vulnerable patients who are experiencing true illness.

Separating patients by intensity of resource use is easier than it might at first appear. Large managed care organizations typically offer several insurance products to their national accounts, most of which consist of preferred provider networks (PPOs) that accept discounted fees. For members with potentially high-cost illnesses, insurers generally employ "disease management" subcontractors to oversee care.<sup>178</sup> Properly structured disease management works with patients' existing providers to offer information and coordinate care, an approach which is highly compatible with a mediation model of independent review.

Mediating these cases only makes sense, of course, if managed care can in fact improve the effectiveness and cost-effectiveness of treatment for patients with serious diseases. Disease management programs have yet to prove themselves, and may never do so.<sup>179</sup> If managed care lacks a clinical or public policy rationale beyond "negotiating lower provider prices and defining and restricting benefits," improving the specificity of insurance contracts is more useful than involving insurers in the intimate process of coping with illness.<sup>180</sup>

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J. Marcus, *Adapting Mediation to Link Resolution of Medical Malpractice Disputes with Health Care Quality Improvement*, 60 LAW & CONTEMP. PROBS. 185, 186 (Winter/Spring 1997) ("[M]ediation . . . can make claims resolution more efficient and simultaneously promotes quality improvement in health care more effectively than does the litigation/settlement process."). For a discussion of mediation in the context of bioethical dilemmas, see NANCY N. DUBLER & CAROL B. LIEBMAN, *BIOETHICS MEDIATION: A GUIDE TO SHAPING SHARED SOLUTIONS* (2004).

178. See Thomas Bodenheimer, *Disease Management—Promises and Pitfalls*, 340 NEW ENG. J. MED. 1202, 1202 (1999) (noting that "disease management is 'a systematic, population-based approach to identify persons at risk, intervene with specific programs of care, and measure clinical and other outcomes'" to control costs).

179. ASHLEY C. SHORT ET AL., *DISEASE MANAGEMENT: A LEAP OF FAITH TO LOWER-COST, HIGHER QUALITY HEALTH CARE*, CENTER FOR STUDYING HEALTH SYSTEMS CHANGE ISSUE BRIEF NO. 69 (Oct. 2003), available at [www.hschange.org](http://www.hschange.org).

180. See Robert A. Berenson, *Market Competition—Is That All There Is?*, HEALTH AFF., Nov.–Dec. 2003, at 274, 275 (reviewing GEORGE C. HALVORSON & GEORGE J. ISHAM,

A mediation model would also provide a connection between private conversations with patients and public deliberative processes regarding resource allocation in health care.<sup>181</sup> Without structured forms of public conversation that begin to overcome the “tragic choices” problem, rendering the rationing role of managed care transparent merely makes it less tolerable.<sup>182</sup> Some early forms of utilization review had a deliberative aspect, but it has largely been lost in the regulatory response to the perceived commercialization of managed care. For example, Professors Daniels and Sabin describe a “let’s talk” model used by the Oregon Blue Cross Blue Shield plan in cases involving organ transplantation.<sup>183</sup> That model, which both gauged and influenced members’ expectations, emphasized urgency of resolution, stewardship of scarce resources, and shared decisionmaking between health plan and patient.<sup>184</sup>

Similarly, properly structured external review has a potentially valuable communicative function. Under such a system, independent review organizations—in consultation with health plans, providers, patients, and public bodies—could develop, over time, a set of norms regarding coverage. When specific disputes arose, the review organizations could provide the parties with feedback about the degree to which their positions differ from the established norms. A framework for this approach already exists. In some of the patients’ rights bills that have gained support in Congress, external review organizations must “consider,” but are not required to defer to,

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EPIDEMIC OF CARE: A CALL FOR SAFER, BETTER, AND MORE ACCOUNTABLE HEALTH CARE (2003)).

181. Professor Kinney argues that a common procedural framework should govern both setting overall coverage policy and resolving specific disputes. KINNEY, *supra* note 79, at 158–73. Coordination has three advantages. First, it adds a preventive dimension to dispute resolution, moderating the pathological conflict and hindsight that plague many litigated cases. William M. Sage, *Overdue Process*, HEALTH AFF., May–June 2003, at 241, 242 (reviewing Kinney’s book). Second, it helps match process to structure within provider and payer organizations. *Id.* Third, with respect to public programs, it addresses a major failing of the patient protection movement by summoning legislators to seek justice in the health care entitlements they create as well as in the manner that existing entitlements are administered. *Id.*

182. See David Orentlicher, *The Rise and Fall of Managed Care: A Predictable “Tragic Choices” Phenomenon*, 47 ST. LOUIS U. L.J. 411 (2003) (analyzing managed care in light of the observations about social turmoil made by Judge Guido Calabresi and Professor Phillip Bobbitt in their book, *Tragic Choices*, GUIDO CALABRESI & PHILIP BOBBITT, TRAGIC CHOICES (1978)).

183. DANIELS & SABIN, *supra* note 81, at 76–78.

184. *Id.*

health plans' contractual definitions of medical necessity.<sup>185</sup> These provisions, which at first glance seem to be illogical political compromises, nonetheless point the way to meaningful improvements in independent review systems because they foster give-and-take between health plans and reviewers.

Approaching the most serious illnesses in this fashion might also promote innovation in financing high-cost, low-benefit care. "Last chance" therapies are often offered to patients for the purpose of maintaining hope, a subjective state, not to achieve objectively measurable medical results. This goal fits less well in the health insurance model of "medical necessity" than in models of insurance that provide discretionary funds when adverse events occur. For example, many life insurance policies offer "accelerated death benefits" to be spent on medical care for terminal illness. One can envision variants on these arrangements, explicitly linked to health insurance and given favorable tax treatment, that provide additional funding for desired but not "necessary" therapy.<sup>186</sup>

State legislation is needed to move independent review for heavy users of medical services toward a mediation model. After *Rush*, managed care organizations find themselves subject to state insurance law for a large percentage of their enrollees. It is likely that many will take a path of least resistance and comply voluntarily with state external review laws even for enrollees covered by self-insured ERISA plans. This will remove much of the incentive to develop innovative approaches to external review within the private sector. To reverse this trend, at least a handful of states need to begin experimenting with alternative forms of external review, ideally with the aid of demonstration funding from private foundations or the federal government.<sup>187</sup>

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185. See, e.g., Health Care Coverage Expansion and Quality Improvement Act of 2003, S. 10, 108th Cong. § 114(d)(3)(E) (2003) ("[A] qualified external review entity and an independent medical reviewer shall . . . consider, but not be bound by, the definition used by the plan or issuer of 'medically necessary and appropriate' . . .").

186. See Alexander Eremia, *Viatical Settlement and Accelerated Death Benefit Law: Helping Terminal, But Not Chronically Ill Patients*, 1 DEPAUL J. HEALTH CARE L. 773 (1997); Wayne M. Gaxur, *Death and Taxes: The Taxation of Accelerated Death Benefits for the Terminally Ill*, 11 Va. Tax Rev. 263 (1991).

187. Cf. BD. ON HEALTH CARE SERVS., INST. OF MED., *supra* note 141, at 27–37 (urging the federal Department of Health & Human Services to support demonstration projects in many areas, including chronic care).

## CONCLUSION

This Essay has argued that traditional uses of “medical necessity” as a coverage criterion and the regulatory apparatus that has grown up around them are inadequate to address individual and social needs surrounding expensive medical treatment in a managed health care system. In particular, regulatory requirements entitling consumers to independent review of coverage denials are incompletely theorized and, despite their tremendous popularity, may prove ineffective.

Three insights provide guideposts for improving the design of coverage standards and the process for making coverage determinations. First, medical necessity cannot do the heavy lifting of cost control, or of quality assurance, in health care. Too many different actors with varying perspectives and incentives are involved in creating, implementing, and policing medical necessity for the term to develop a unitary meaning that can be applied consistently when insurance arrangements are entered into, when treatment is proposed, and when disputes are resolved. At best, standards for medical necessity can be incorporated into ethical principles that are clearly understood—if not wholeheartedly endorsed—by the major participants in the health care system. This implies that the financial “meat” of today’s medical necessity language should be placed elsewhere in the design of insurance benefits. Options for this restructuring include reworking current categories of covered services, rethinking specific inclusions and exclusions, reevaluating the role of employers and other purchasing agents in promoting contractual fairness, and revisiting both consumer cost-sharing and the structure and compensation of provider networks.

Second, where individual subscribers and patients are concerned, health plans and policymakers have paid too much attention to standardized rules for coverage decisions and too little attention to therapeutic effect. Health care is both an outcome and a process,<sup>188</sup> and all parts of the process, including those involving insurers, need to be caring as well as efficient. Medical necessity determinations should indeed be scientific and equitable, but, like good medicine, should also demonstrate compassion, offer hope, promote trust, and avoid abandonment.

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188. Cf. Arrow, *supra* note 129, at 949 (“[M]edical care belongs to the category of commodities for which the product and the activity of production are identical.”).

Third, decisions about medical necessity create important political and social opportunities for communication, discussion, and consensus-building. In the United States, private insurance companies are implicitly asked to take on significant public responsibilities for accessing and allocating medical services, but they have no clear mandate to do so and few tools at their disposal. Health plans and government can use the issue of medical necessity to talk to the public about how health insurance works. The goal of this dialogue should be to integrate core social values relating to medical care into the everyday understanding of physicians and patients, rather than isolating them in a business or legal paradigm outside of, and hence largely irrelevant to, clinical practice. These include the appropriate purpose of medical care, its scope, and the evidence of benefit and cost-effectiveness needed to support its administration.

Under the “therapeutic” approach endorsed by this Essay, both health plans and physicians would focus on the process of ascertaining coverage and accessing care, with the goal of maintaining trust and communication between patient and health system. The proposed model would also address cost, but not through individual determinations of “necessity.” Instead, the model encourages health plans to engage in clearer contracting regarding specifically covered and noncovered services, and to foster a new professional and public consensus that clinical decisions at the margin should be sensitive to resource constraints.

This is a task that health plans will largely have to undertake voluntarily. As has been true with respect to professional endeavors generally, law is too blunt an instrument to prescribe a single set of coverage standards and procedures that serve both therapeutic and systematic objectives. However, law can play an important facilitative role. Partitioning independent review mechanisms into an arbitration-like system for light users of medical care and a mediation-like system for heavy users—who require a more compassionate and technically informed approach—would be an important first step.

In all, this suggests a more hopeful interpretation of what it means for medical necessity to be “managed care’s Crimea.” What do most people remember about the Crimean War? Florence Nightingale and her nurses.<sup>189</sup> If the legacy of the early years of managed care and the ideological battles over medical necessity it

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189. The modern nursing profession arguably originated during the Crimean War. See generally F.B. SMITH, FLORENCE NIGHTINGALE: REPUTATION AND POWER (1982).

produced is similar—a reprofessionalized cadre of health care providers, health plan administrators, and public officials who earn patients' trust, educate them, and heal them—we will have all done very well.