Law and the Public's Health

AETNA HEALTH, INC. V. DAVILA: IMPLICATIONS FOR PUBLIC HEALTH POLICY

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This installment of *Law and the Public's Health* discusses the United States Supreme Court's June 2004 opinion in *Aetna Health, Inc. v. Davila*[1] and considers the decision's implications for public health policy and practice. This long-awaited case clarifies that the Employment Retirement Income Security Act (ERISA) completely shields health insurers from liability under state law for injuries incurred by patients as a result of medically negligent coverage decisions. At the same time, *Davila* clarifies that when acting in a health care capacity, health insurers and health maintenance organizations (HMOs) remain liable for the consequences of negligent medical conduct. But because the central business of health insurers is *coverage decision-making* as opposed to medical care provision, *Davila* has far-reaching implications for access to remedies by patients who are harmed by substandard coverage determination practices.

BACKGROUND AND OVERVIEW

Approximately 150 million workers and their families receive health coverage through a benefit plan established by a private employer. Enacted in 1974, the Employee Retirement Income Security Act (ERISA) was established to protect employee pensions and "welfare plans" (which include health benefits) from fraud and improper plan administration, including denials of benefits to which individuals are entitled under their plan. ERISA applies to virtually all privately employed individuals in the United States, while exempting federal, state, and local public employees.[2]

To protect pensions and benefits, ERISA imposes "fiduciary" obligations on the companies (typically insurers or HMOs) that administer plans and have the power to make final decisions about who gets what. In addition, ERISA sets uniform nationwide rules governing the protection of pension benefits and plan administration procedures. Importantly, while there is a considerable body of pension standards, ERISA contains almost no substantive standards governing the design or structure of health plans and leaves almost total discretion to employers.[2]

Finally, ERISA contains a "federal right of action" on the part of participants and beneficiaries, meaning that individuals can sue in court to enforce their claims for benefits in the event of inappropriate denial.[3] ERISA's statutory remedies include recovery of a denied benefit or a court-issued injunction to force the prospective granting of a denied benefit. Both remedies have been used by litigants to force health plans to pay for denied treatment.[2] ERISA does not provide for either compensatory or punitive damages in the event that an individual is injured as the result of the wrongful denial of a benefit.

In the seminal 1987 case of *Pilot Life v. Dedeaux*,[4] the United States Supreme Court held that ERISA's "right of action" provision constituted not merely *a* remedy, but in fact the *exclusive* remedy for benefit maladministration. As a result, the plan enrollee in *Pilot Life* who suffered serious injuries as a result of the wrongful denial of disability benefits was precluded from bringing a state law damages action against his ERISA plan to recover for the harm he suffered when the plan negligently denied him his disability coverage. The Court held that ERISA's remedial provision "preempted" (i.e., superceded) all state remedies otherwise available to ERISA plan participants.

The underlying logic of *Pilot Life* was essentially that the *quid pro quo* for extending federal standards to employer-sponsored welfare and pension plans was protection of plan assets against the type of high payouts that could result from exposing ERISA plans to damages actions under state law. Even with this powerful justification for the preemption of state law, ERISA remains nearly unique among American federal laws in its broad displacement of state laws; indeed, in a type of government such as that found in the United States, the fundamental approach to government is to treat federal law as additive to state law, not as its replacement.[2]

While the logic of ERISA preemption might make some sense in a cash benefit context such as disability payments, it appears to make less sense where the benefit at issue is health care, which is heavily regulated under state law, and where there are no liquid assets as such to deplete. (While medical negligence actions might affect health costs, evidence of such effects is quite unclear). Nonetheless, a federal appeals court in 1992 extended the *Pilot Life* preemption rule to a case involving the death of an unborn child. In *Corcoran v. United Health Plan*[5] (which was subsequently affirmed by the Supreme Court), the court dismissed a plaintiff's state law claims for wrongful death damages in connection with the death of her fetus following the company's allegedly negligent denial of coverage for appropriate preterm labor management services. The court held that, regardless of any negligence in medical judgment exhibited by the plan's utilization management staff, state law damages actions in connection with coverage decisions were completely preempted under ERISA in accordance with the Supreme Court's decision in *Pilot Life*.

Several years later, in the face of a virtual flood of cases following the *Corcoran* decision, another federal appellate court ruled in *Dukes v. U.S. Healthcare*[6] that although ERISA participants may not be able to secure damages for the negligent *denial of a covered benefit*, they do not lose their state law remedies where they claim negligence in connection with *the provision of health care*. The *Dukes* court reasoned that health care quality has historically been within the purview of states to regulate, and that nothing in ERISA suggested Congressional intent to displace state laws that regulate the practice of medicine itself. Liability law covering health professionals and health care corporations is considered a form of medical quality regulation.

For several years, this *Corcoran/Dukes* distinction between quality and quantity held sway among the lower courts. In 2000, however, the United States Supreme Court appeared to significantly change the framework for analyzing when ERISA preemption applies and when it does not. The case in which this change took place was *Pegram v. Herdrich*,[7] in which a treating physician who also was part-owner of an HMO group practice negligently failed to order a timely diagnostic test and thus failed to detect what turned out to be appendicitis. The plaintiff's appendix ruptured, and she subsequently sued for damages. In the course of deciding whether physician incentive plans violate ERISA's fiduciary duty standards, the Court had occasion to pass on the conduct of the physician in the case. A unanimous Court observed that there are two types of health plan decisions: "pure eligibility" decisions, in which no medical judgment is exercised; and "mixed eligibility" decisions, in which treatment and coverage are inextricably intertwined. Where a mixed eligibility decision is present, the Court said, state medical liability remedies are not preempted because the conduct retains its essential characterization as medical conduct.

Pegram was both far-reaching and ambiguous in its suggestion that coverage and care could co-exist. Nonetheless, because the reasoning in *Pegram* appeared to restore remedies for negligence that previous cases had removed, lower courts began to rapidly embrace the decision in order to avoid the type of situation in *Pilot Life* or *Corcoran*, in which badly injured individuals were literally left without any meaningful remedy. In fact, in managed care it is often difficult to distinguish between coverage and care, since coverage is prospective and so heavily affects the course of care. At the same time, however, *Pegram* was remarkably unclear regarding how far its "mixed eligibility" rule could be extended (i.e., at what point would the plan conduct be deemed pure coverage decision-making rather than an amalgam of coverage and care?). For example, what if the health care decision maker was an HMO medical director rather than a treating physician? In *Pappas v. Asbel*,[8] decided two years after *Pegram,* the Supreme Court of Pennsylvania assigned "mixed eligibility" status to a case involving extensive medical involvement in treating a patient by an HMO medical director. Similarly, in *Cicio v. Does*,[9] a federal appeals court similarly assigned mixed eligibility status upon a finding of extensive medical involvement by the medical director in care decisions, not merely coverage determinations.

In *Roark v. Humana* (the name of the *Davila* case in the lower courts), a federal appeals court extended *Pegram* still further, applying "mixed eligibility" status to situations in which very routine, first-level utilization management decisions resulted in the denial of care. Thus, the case before the Court was one in which a routine coverage decision was classified as the type of medical decision to which "mixed eligibility" status would be assigned.

THE *DAVILA* DECISION

In *Aetna v. Davila* (which was consolidated with a companion case, *Cigna v. Calad*),[2] Juan Davila was a participant and Ruby Calad was a beneficiary in ERISA employee benefit plans administered by Aetna and Cigna, respectively. Davila nearly died after Aetna, in administering its pharmacy benefit, substituted naprosyn for the more expensive brand name Vioxx to treat his arthritis pain. (Like many insurers, Aetna has a "prior failure" rule that precludes access to more expensive drugs unless a less expensive equivalent drug is ineffective.) Calad experienced post-surgery complications after an allegedly premature hospital discharge under the company's standing one-day-hospitalization rule for her particular condition. In effect, the cause of the injuries suffered by both individuals was a negligent health plan design that established pre-set rules regarding coverage and that failed to consider individual patient circumstances in the application of these routine coverage standards to a particular patient's case. Unlike in *Pappas*, there was no medical director involvement in *Davila*, and no appeal was taken. The denials in *Davila* were effectively first-level and automatic.

Rather than appealing their denials with their respective insurers, both individuals brought suit under the Texas Health Care Liability Act (THCLA), which, they argued, authorizes suits for any lapse in medical decision-making, even at the initial stage of coverage determination. Their main argument was that the insurers' refusal to cover the requested items or services violated a duty under THCLA to exercise ordinary care when making health care treatment decisions, and that such refusals "proximately caused" their injuries.

A unanimous Court (there were two concurring Justices) rejected their claim. Reiterating the continued vitality of *Pilot Life,* the Court held that ERISA preempts suits for damages against ERISA fiduciaries for negligence in connection with coverage decisions, even when that negligence involves the flawed exercise of medical judgment. To the degree that *Pegram* appeared to draw a distinction, for purposes of preemption, between medical judgment-based decisions and non-medical decisions (i.e., pure eligibility decisions such as whether an individual in fact is a member of a particular plan), the Court ruled that this was too broad a reading of *Pegram.* The Court suggested that a "mixed eligibility" situation depends on the existence of actual treatment by a health plan medical employee, not simply utilization management conduct. Where the only conduct complained of is routine coverage management, (i.e., where the injury is the denial of a claim for benefits), ERISA shields health plans from liability for negligence, even where medical judgment might have been involved.

IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

Davila has many implications. First, it clarifies that no matter how severe the injury, an ERISA plan participant or beneficiary suing over the wrongful denial of a benefit cannot recover even basic compensation for injury. Claimants are limited to the value of the denied benefit. Put another way, if a patient were to die from a brain tumor following a routine denial of a diagnostic procedure, the patient's survivors could recover no more than the value of the test itself. Under ERISA's appeals rules, the claimant could immediately appeal the denial of what he or she believes to be an essential medical test, but there can be no recovery of damages where a test denial ultimately leads to illness or death.

As a result, ERISA plan fiduciaries are shielded from any serious financial consequences for what may be an arbitrary and capricious denial of coverage. Since there is virtually no oversight by the U.S. Department of Labor of the quality of health plan coverage decision-making, this liability shield is problematic. Under an earlier Supreme Court decision,[10] states can in fact establish procedures for reviewing health plan coverage denials in cases where employers covered by ERISA buy insurance coverage. However, under other ERISA preemption principles, self-insuring employers are completely immune from this type of external review process.[11] This leaves a complete void in terms of quality oversight for coverage decision-making in the case of self-insuring employers, and approximately half of all employers in the U.S. self-insure. While the health plan accreditation process establishes certain procedural safeguards (including external review) in order to ensure that plan decision-making is conducted fairly, ERISA does not require employers to buy accredited health plans.

Second, *Davila* throws into confusion the status of managed care liability laws in those states that, in addition to Texas, have enacted such legislation (Arizona, California, Georgia, Maine, Oklahoma, Washington State, West Virginia, and New Jersey).[12] To the extent that courts in these states interpret the laws as authorizing corporate and vicarious medical malpractice claims against health plans for medical *practice*, these state laws may survive, since the remedies they offer could be interpreted as relating to medical practice, not coverage. But the *Davila* decision is confusing regarding how to distinguish between coverage and care, and thus how to know when state powers to regulate medical care apply. For example, *Davila* leaves open the question of what happens once an HMO medical director gets extensively involved in a patient's treatment as part of what might have begun as a coverage appeal. Does the fact that the director is now making judgments about what is proper care in a specific patient case elevate the situation above a routine coverage matter?

Third, the decision underscores the implications flowing from Congress's failure to enact compromise legislation in 2001 that would have established clearer standards of liability and allowed all patients to recover at least compensatory damages for injuries caused by their managed care plans. The compromise legislation would have allowed state remedies to apply in cases involving medical negligence (in coverage or in care), and a federal damages remedy would have been established for "pure eligibility" cases (i.e., cases in which negligence occurred, but no medical judgment was involved in reaching the erroneous decision). Chances for passage of this legislation ended when a House-crafted compromise fell apart and was succeeded within weeks by the events of September 11, 2001. In an election year, there is little chance that a compromise could again be reached, particularly because the issue is so controversial. It is possible that the question of compensation for coverage-related injuries could make it back on the federal agenda when the 109th Congress convenes in January 2005, but no one is sure.

Finally, from many vantage points, the decision illustrates the complex nature of American health care. Is it possible in an era of extraordinarily high health costs to treat a coverage decision "simply" as coverage and not as a decision about the treatment itself? Who can afford medically necessary health care if there is no coverage? The decision also serves as a reminder of how important it is for patients and their treating professionals to aggressively pursue appeals of coverage denials in any situation in which health care is of great importance. Finally, the decision also illustrates the irrationality of a legal system that grants patients fundamental remedies for injuries caused by the wrongful denial of medical coverage based only on whom those patients work for.

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REFERENCES

1. 2004 WL 1373230 (June 21, 2004).
2. Rosenblatt R, Law S, Rosenbaum S. Law and the American health care system. New York: Foundation Press; 1997.
3. ERISA §502(a).
4. 481 U.S. 41 (1987).
5. 965 F. 2d 1321 (5th Cir. 1992), cert. den. 506 U.S. 1033 (1992).
6. 57 F. 2d 350 (3d Cir. 1995), cert. den. 516 U.S. 1009 (1995).
7. 530 U.S. 211 (2000).
8. 768 A.2d 1089 (Pa. 2001).
9. 321 F.3d 83 (2nd Cir. 2003), pet. for cert. filed 72 USLW 3093 (July 11, 2003).
10. Moran v. Rush Prudential HMO, 536 U.S. 355 (2002).
11. Metropolitan Life Insurance Co. v. Massachusetts, 471 U.S. 724 (1985).
12. Butler P. Key characteristics of state managed care organization liability laws: current status and experience. Available at http://www.kff.org/insurance/upload/13845_1.pdf.