9-2004

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Wendy K. Mariner
Boston University School of Law

LEGAL ISSUES IN MEDICINE

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Wendy K. Mariner, J.D., M.P.H.

On June 21, 2004, in the combined cases of *Aetna Health Inc.* v. *Davila* and *CIGNA HealthCare of Texas Inc.* v. *Calad*, the U.S. Supreme Court effectively immunized managed-care organizations (MCOs) from liability for negligent decisions about the care of patients in private employer-sponsored health plans.[1] It found that when MCOs decide to deny benefits, they are simply applying the terms of an insurance contract and are not making decisions regarding the care of patients, even when their decisions are based on a finding that the care is not medically necessary. The decision interprets the federal Employee Retirement Income Security Act (ERISA), which governs private employer-sponsored health plans.[2] It limits the remedies available to the more than 140 million people under the age of 65 years in these ERISA plans.[3] MCOs are responsible only for the cost of wrongfully denied treatment. Liability for negligent medical judgment remains almost exclusively with treating physicians and hospitals. The cases demonstrate why ERISA, which was originally enacted in 1974 to protect employee pensions, is not well suited to protecting patients or their health benefits today.

THE *DAVILA* AND *CALAD* CASES

Ruby Calad obtained health care coverage through her husband's employee group health plan, an ERISA plan administered by CIGNA HealthCare of Texas. CIGNA paid for Calad's hysterectomy, with rectal, bladder, and vaginal repair. However, CIGNA authorized payment only for one day in the hospital, against the recommendation of Calad's physician. Calad claimed she could not pay for a longer stay herself and was discharged. Within days, she had complications that brought her to the hospital's emergency department.

Juan Davila, who has the postpolio syndrome and diabetes, was enrolled in Aetna U.S. Healthcare of North Texas, an MCO offered through Davila's employer. Davila's physician recommended that he take the brand-name drug Vioxx to alleviate severe pain from rheumatoid arthritis, because it had a lower incidence of gastrointestinal toxicity than other arthritis drugs in Aetna's formulary. Aetna denied coverage for Vioxx. According to Davila, Aetna's prescription-drug formulary precludes a prescription for Vioxx unless the patient has a "contraindication, intolerance, allergy to or a documented adequate trial of at least two formulary [nonsteroidal antiinflammatory drugs]."[4] Therefore, Davila received naprosyn, but within a few weeks was taken to a hospital emergency department, where he received seven units of blood for severe internal bleeding, was kept in critical care for five days, and was readmitted once later.[5]

Calad and Davila sued their MCOs under the Texas Health Care Liability Act, a Texas statute that holds MCOs liable for negligence when they fail to exercise ordinary care in making decisions about whether treatment is medically necessary for a patient.[6] CIGNA and Aetna argued that ERISA preempted the Texas law and that the cases should be moved from state to federal court. The MCOs claimed that the plaintiffs were really suing for denial of insurance benefits, not negligence in making medical decisions, and that because they were enrolled in ERISA plans, their only remedy lay in a lawsuit under ERISA to recover insurance payments due.

Section 502(a)(1)(B) of ERISA allows a lawsuit by a plan participant "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan."[7] When an ERISA plan wrongfully denies benefits to a participant, Section 502 allows, in essence, a claim of breach of contract to be brought under the federal law, instead of ordinary state contract law. The U.S. Supreme Court has interpreted Section 502 as preempting any claim of denial of benefits under state law.[8,9] It has also suggested that Section 502 prevents the patient from recovering more than the value of the benefits denied.[10] In Davila's case, this payment would be what Aetna would have paid for

a Vioxx prescription. In Calad's case, it would be what CIGNA would have paid for an additional day or two in the hospital. Courts have interpreted Section 502 to mean that plan participants cannot obtain compensation for any additional financial losses, such as unpaid medical expenses for the treatment of problems that arise from denial of the correct treatment, lost wages resulting from the inability to work, or noneconomic damages to compensate for disability or "pain and suffering."[11,12]

Calad and Davila had sued under Texas law, not ERISA, because their complaint was with their MCOs' choices of medical care, and ERISA offered no compensation for personal injury. ERISA was enacted to protect employees from losing their pensions as a result of inadequate funding or mismanagement of pension plans.[13,14] Congress replaced ineffective state laws with a single federal regulatory system, which works reasonably well for pensions.[15] Employees who are wrongfully denied pension benefits in the form of monthly cash payments can be fully compensated for that harm ("made whole") by receiving the dollars denied. In contrast, denying health benefits in the form of medical care can result in physical as well as financial harm. ERISA's remedy of a cash benefit reimbursement may have suited traditional indemnity health insurance plans, but it proved ill suited for managed care. In the 1990s, courts began to distinguish between the types of decisions that MCOs made to determine whether they should be held responsible under state malpractice law or under ERISA.[16-18] Decisions about patient care were generally considered medical judgments that could be challenged under state malpractice law,[12,19-23] whereas decisions about benefit coverage were viewed as contract decisions that could be challenged only under ERISA.[11,12,24-26]

In *Pegram* v. *Herdrich*,[27] the Supreme Court classified decisions made by MCOs and physicians into three categories. Eligibility decisions determined whether an insurance contract covered a particular medical condition or therapy. Treatment decisions were medical judgments about "how to go about diagnosing and treating a patient's condition." Mixed decisions were described as "when-and-how" decisions, in which benefit coverage depended on the type of treatment needed, such as inpatient hospital care. Even though *Pegram* dealt with the separate claim of fiduciary duties, it led to speculation about whether the Supreme Court expected that claims of negligent treatment and mixed decisions should be heard in state courts under state malpractice law, rather than in federal court under ERISA.[28-30] The Fifth Circuit Court of Appeals used *Pegram* to conclude that Davila and Calad's claims involved mixed decisions that belonged under state law.[31] The Supreme Court rejected that conclusion.

THE SUPREME COURT'S DECISION

In a unanimous decision written by Justice Clarence Thomas, the Supreme Court held that Section 502 of the act provides the "exclusive" remedy for patients in ERISA plans when an MCO denies benefits — even if the denial is based on a decision that the disputed care is not medically necessary for the particular patient. The Court said, "If an individual, at some point in time, could have brought his claim under ERISA Section 502(a)(1)(B), and where there is no other independent legal duty that is implicated by a defendant's actions, then the individual's cause of action is completely pre-empted by ERISA Section 502(a)(1)(B)."[1] The Court rejected the patients' argument that the Texas law created an independent legal duty — that of making medical decisions with ordinary care. Ultimately, it found, everything turns on whether the health plan covers the treatment sought. MCOs, like other insurers, owe patients only what the contract covers. The MCO would not be legally responsible for denying care that the contract excluded, no matter what happened to the patient, because it had no contractual duty to provide that care in the first place. Therefore, it is always necessary to determine whether the contract covers the disputed treatment before deciding whether the MCO made the wrong treatment decision. This means that decisions by MCOs about what kind of care to pay for must be regarded as eligibility or benefit determinations, not treatment decisions.

The Court then found that since ERISA provided a federal remedy for benefit denials, Davila and Calad could not sue the MCOs under state law.[1] Although the text of Section 502 says nothing about preempting state law, the Court concluded that giving members of ERISA plans recourse to remedies under state law would conflict with Congress's intent to create a comprehensive federal regulatory scheme for employee benefit plans under ERISA. Thus, patients who challenge an MCO's determination that a treatment is not medically necessary are limited to a Section 502 claim. If they ultimately win, the most they can recover is the dollar amount of the insurance payment for the care they were de-

nied — such as extra inpatient days or a prescription for Vioxx. (Calad and Davila had elected to pursue their appeal to the Supreme Court instead of filing a claim under Section 502 and therefore recovered nothing.)

The Court left open the possibility that patients could sue MCOs for breach of fiduciary duty.[32] An employer typically designates a person or company to be its ERISA plan fiduciary. But others are also deemed to be fiduciaries if they have "any discretionary authority or discretionary responsibility in the administration" of an ERISA plan.[33] The Court said that MCOs would be considered fiduciaries if they made final benefit-coverage decisions that were binding on the ERISA plan — even when the decisions were "based extensively on medical judgments."[1] But this simply confirmed that MCOs can be sued for benefit denials. Few wrongful benefit denials amount to a breach of fiduciary duty, which typically involves the use of plan assets for personal gain.[34] Moreover, in the case of such a breach, the fiduciary must reimburse the ERISA plan, not the patient.[10] Thus, these alternatives do not compensate the patient for personal injury.

Under ERISA Section 502(a)(3), patients can sue for a breach of other fiduciary duties or a violation of the plan or the statute.[35,36] However, the Court has said that persons cannot obtain money damages for such violations.[37-39] In a concurring opinion, Justice Ruth Bader Ginsburg suggested that the Court could reinterpret the remedy offered by Section 502(a)(3) of the act to include "make-whole" relief, which would provide some compensation for personal injury.[1] Only Justice Stephen G. Breyer joined her opinion, however, which suggests that the Court will leave any changes to Congress.

IMPLICATIONS OF THE DECISION

When *Davila* was decided, the president of the American Medical Association was quoted as saying, "This is a sad day for America's patients and the physicians who care for them."[40] Consumer organizations fear that the decision will encourage MCOs to impose tighter restrictions on benefits or increase denials.[41] They worry that MCOs will have little incentive to make medically appropriate decisions if the only penalty for wrongful conduct is no more than what they should have paid in the first place.

Most state insurance laws authorize "bad faith" lawsuits for just that reason. Insurers who deny valid claims in bad faith can be liable for punitive damages.[42,43] Such damages are intended to counterbalance any financial incentive for insurers to force claimants to sue when there is no bona fide reason to deny the claim.[44,45] However, in the 1987 case of *Pilot Life* v. *Dedeaux*, the Supreme Court ruled that ERISA preempts the remedy of punitive damages under state law for improper processing of benefit claims, including bad-faith claims.[8] The Court relied heavily on *Pilot Life* as a precedent for *Davila* and did not address the incentive effects of available remedies.

Like the Texas statute in *Davila*, liability laws in all states — whether in the form of legislation or of common law — cannot be used to hold MCOs liable for causing personal injury to patients in ERISA plans when their actions are taken as part of a benefit-coverage decision. The only medical judgments that are subject to state liability law are those made by treating physicians. The only legal mechanism for enforcing an MCO's obligation to pay for treatment is a lawsuit brought under ERISA. In theory, it remains possible to hold MCOs vicariously liable for medical malpractice committed by treating physicians who are MCO employees or agents.[46] The liability of MCOs would depend on proof of the physician's negligence, not that of the MCO.[47] In practice, however, MCOs rarely employ physicians to treat patients or authorize them to act as their agents.

In 2002, the Court found that states may require that MCOs submit to independent external review to resolve some disputes about medical necessity.[48,49] In addition, U.S. Department of Labor regulations now require that MCOs provide more specific appeal procedures.[50] If an MCO fails to abide by an external reviewer's decision, however, the *Davila* ruling prevents participants in ERISA plans from using state law to enforce the decision. This may dilute the effect of independent-review laws enacted in 42 states and the District of Columbia.

The Court emphasized that ERISA gave Davila and Calad a remedy for wrongful decisions.[1] They could have challenged the MCOs' decisions when they were first made or paid for the care they wanted and then sued for reimbursement. The ruling thus creates an incentive for patients to challenge every MCO decision they disagree with. However, such remedies may prove illusory. Many patients cannot pay for expensive treatment out-of-pocket in the hope of future reimbursement, and few patients

have the physical or emotional energy to pursue a challenge when they are sick. More important, patients may not realize that there are grounds for appeal unless their physicians tell them that there are. Physicians' ethical and legal obligation to explain all reasonable treatment options thus assumes critical importance.[47] Patients may also expect that their physicians will help them appeal MCO denials of recommended treatment. Physicians should be prepared at least to substantiate their recommendations. At the same time, they should resist pressure to recommend anything they believe to be medically inappropriate.

Today, MCOs are squeezed by rising health care costs and demands from employers to hold down premiums.[51-53] *Davila* may encourage MCOs to adopt more restrictive agreements with physicians in order to discourage them from recommending too much costly care.[54,55] If physicians complied without justification, MCOs would increasingly define the boundaries of medical judgment. Moreover, real or presumed conflicts of interest stemming from financial arrangements between MCOs and physicians may erode trust between patients and physicians.[56] Alternatively, MCOs could transfer more medical decision making to patients and physicians. A growing number of consumer-choice plans adopt the latter approach for a significant portion of their coverage.[57,58] Some plans allow patients to buy care up to a certain dollar amount directly from physicians without approval from the MCO, thereby insulating the MCO from any responsibility for injury of patients. Such plans mimic the division between benefit decisions and medical care that existed before the advent of managed care. After spending the designated amount, however, patients are likely to confront the same benefit decisions based on medical-necessity determinations that gave rise to cases like *Davila*.

The Court clarified the division between federal and state jurisdiction over MCOs serving ERISA plans. A decade of Supreme Court decisions narrowed the scope of the Section 514 preemption in ERISA and allowed the states to regulate insurers that serve ERISA plans in order to expand access to care.[48,59-63] But the Court remains convinced that ERISA requires a single, unified approach under federal law to disputes over benefits.[8] The Court emphasized its conclusion that ERISA was enacted to "ensure that employee benefit plan regulation would be 'exclusively a federal concern.'"[1] Thus, whereas states can regulate the terms of insurance contracts, they cannot provide patients in ERISA plans with remedies for a violation of that contract. This division may make it easy for courts to decide who is liable for what, but it fails to address the legitimate concerns of patients and physicians who seek high-quality care in a system that encompasses a variety of health plans.

By excluding ERISA plans from the jurisdiction of state laws governing liability, the Supreme Court decision continues the patchwork system of health care in the United States. The rights of patients and their physicians depend on the particular statute that governs their health care plan, whether that plan is Medicare, Medicaid, a military program, the Federal Employees Health Benefits Program, a state benefit program for government employees, or an individually purchased health insurance policy. The impetus for the federal Bipartisan Patient Protection bills passed but not enacted in 2001 stemmed largely from dissatisfaction with the differential treatment of participants in ERISA plans and people in other health care plans.[64,65] The resistance of MCOs to liability encouraged a growing consumer backlash, because it suggested that MCOs were unwilling to accept accountability for their decisions.[66-69] The Supreme Court's ruling in *Davila* may renew pressure for federal reform.

In her concurring opinion in *Davila*, Justice Ginsburg said she joined "the rising judicial chorus urging that Congress and [this] Court revisit what is an unjust and increasingly tangled ERISA regime."[70,71] ERISA could be amended in one of three ways to solve the intractable dispute over MCO liability.[18] The preemption of state liability law could be eliminated to give states exclusive jurisdiction over claims of personal injury brought by patients against MCOs as well as providers. Alternatively, ERISA could be amended to grant patients "make whole" compensation for personal injury. A third approach is to divide jurisdiction for personal-injury claims, with claims based on medical judgment, including claims that coverage for medically necessary treatment was denied, subject to state law, whereas pure eligibility or financial claims remain subject to ERISA. The first option is consistent with traditional principles of federalism and provides the greatest uniformity. The second is consistent with keeping ERISA plans as a separate group governed only by federal law. The third is a compromise, allowing separate, uniform administration of ERISA plans under federal law while preserving state regulation of health care quality and some insurance functions.

In 2001, the Bush administration supported the second approach but then opposed liability in an amicus curiae brief supporting the insurers in *Davila*. This opposition suggests that the administration will not initiate reforms on its own.

CONCLUSIONS

The *Davila* decision embodies a dichotomous view of health benefit plans, in which insurers administer contracts and physicians make medical judgments. In this view, insurers are responsible only for payments defined by contract, whereas treating physicians are responsible for the consequences of medical choices. In reality, the world is messier. MCOs and physicians share financial pressures to cut costs and improve quality. But MCOs will not share the physicians' responsibility for negligent decisions about the care of patients in ERISA plans.

Davila also highlights the variation in laws governing different types of health plans. Physicians and patients have the same goals for treatment, regardless of who pays the bill or which statute applies. Congress should amend ERISA to ensure that ERISA plans and their MCOs are just as accountable to patients for medical decisions as physicians are.

From the Department of Health Law, Bioethics, and Human Rights, Boston University School of Public Health, Boston.

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