Nos. 02-1845 and No. 03-83

In The Supreme Court of the United States

AETNA HEALTH INC.,

Petitioner,

v.

JUAN DAVILA,

Respondent.

CIGNA HEALTHCARE OF TEXAS, INC.,

Petitioner,

v.

RUBY R. CALAD, et al.,

Respondents.

On Writs Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

BRIEF *AMICUS CURIAE* OF THE AMERICAN COLLEGE OF LEGAL MEDICINE IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether ERISA is intended to preempt remedial relief provided by state law when an HMO entity, acting through one or more of those in its employ or on its behalf, denies on a prospective basis a request for care and treatment as not medically necessary where the denial results from medical decision-making based upon the exercise of discretionary judgment.

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INTEREST OF THE *AMICUS CURIAE*

The American College of Legal Medicine ("ACLM") respectfully submits this brief as an *Amicus Curiae* pursuant to Rule 37 of the Rules of the Supreme Court of the United States, and submits it in each of these two consolidated cases. ACLM supports respondents in both cases. ACLM has received the consent of all parties to submit this brief pursuant to the applicable rules of this Court[1]

The ACLM has been in existence now for 44 years and is an educational, non-profit organization with nearly 1300 members. It is the only organization within the United States the majority of whose members possess degrees in medicine and in law. Its membership also consists of attorneys, physicians, nurses, those in health care administration, in government service and those who hold full time academic positions in health care and in health care law. It is also within the network of organizations worldwide whose members possess degrees, background and interest in the fields of medicine, forensic science and in law or jurisprudence.

The mission of the ACLM is to educate, train and advance dialogue and discussion for those who have a sustained interest in issues at the crossroads of law, medicine and health care delivery. This includes promoting the administration of justice and assisting jurists in deciding issues, such as the ones presented in these cases.

[1] Petitioners and respondents have consented to the filing of this brief in letters filed with the clerk. No counsel for a party authored this brief in whole or in part. No persons or entities other than the *amicus* made a monetary contribution to the preparation or submission of this brief.

SUMMARY OF ARGUMENT

By affirming the court below in both cases, this Court will incorporate within the fabric of federal jurisprudence a recognition that managed health care entities, i.e., HMOs or generically, those entities which provide or administer care through ERISA health plans, do, indeed, make medical decisions made prospectively based on discretionary judgment – as do other healthcare providers – for which these entities are held as accountable as all others who make medical decisions as to what care and treatment a patient should receive. In so doing as well, this Court will pronounce that remedial relief for such accountability remains venued in state and territorial forums, rather than in federal jurisdictions due to the constructs of ERISA.

The HMO market for providing and delivering medical care and treatment had its genesis at the federal level roughly three decades ago, when the HMO Act of 1973[2] was enacted by Congress. Neither this Act, nor ERISA,

[2] 42 U.S.C. §300c *et seq*., more completely known as the Health Maintenance Organization and Resources Development Act of 1973, PL. 93-222. Nowhere in the legislative history (Senate Report No. 93-129) is there a suggestion to federalize medical decision-making made by those acting in the employ or on the behalf of HMOs. This is notwithstanding a specific section (pp. 3057-3059) on "Preemption of State Law." Additional evidence that Congress did not wish to interfere with states' rights in the area of health care is when there was stated, "It is not the intent of the [Senate Labor and Public Welfare] Committee that the Commission [on Quality of Health Care Assurance] engage in the setting of standards for, or the regulation of, the practice of medicine." *Id.* at 3074. Congress also emphasized that creation and enforcement of standards for health care and providers of that care should remain with the states. *Id.* at 3077. *See infra* n. 9 at 25-26.

through their legislative development or history, were *ever* intended to federalize state medical malpractice law. That is, Congress has never established a federal venue for the protection of health care plan beneficiaries, or enrollees, as patients from acts or omissions, resulting in harm, made by those schooled and trained in the practice of medicine, i.e., made through medical decision-making. Rather, this area, better known as being accountable for harm arising from failing to follow state established medical standards, comes within rights afforded consumers traditionally and historically left to states to create.

Further, while redress for medical decision-making has been made more complex due to the insertion of managed care entities into the medical decision-making process, medical decisions and those who make them fall outside of ERISA's preemptive reach.

Third, anyone who makes a medical decision prospectively in the care and treatment of plan beneficiaries is subject to the application of remedial relief provided by state and territorial law.

Fourth, and most importantly, the hallmark of a medical decision by a managed care plan is the application of discretionary judgment[3] based upon the personal characteristics of a patient. This judgment is guided by personal experience

[3] "A power or right conferred upon them by law of acting officially in certain circumstances according to their own judgment and conscience, uncontrolled by the judgment or conscience of others. " *Black's Law Dictionary* at 466 (6th ed. 1990) (as cited in McLean and Richards, *Managed Care Liability for Breach of Fiduciary Duty After Pegram v. Herdrich*: *The End of ERISA Preemption for State Liability for Medical Care Decision Making*, 53 FLA. L. REV. 1, 21 (2001)).

and accumulated medical knowledge.[4] Medical decision-making based upon discretion is what occurs before a determination of whether a certain course of care or treatment is deemed "medically necessary" within a health care plan.

Finally, a prospective decision about what is or is not a medically necessary treatment – for example, the use of a pharmaceutical or the length of stay within a hospital – as in the cases before the Court here, is a discretionary judgment about medical necessity rather than a determination incidental to a finding of whether a plan beneficiary is entitled to a benefit under the plan.

———————♦———————

Culpae adnumerantur; veluti fi medicus curationem dereliquerit, male quempiam fecuerit aut perperam ei medicamentum dederit.[5]

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[4] *Id.*

[5] "Again, if a surgeon operates on your slave, and then neglects altogether to attend to his cure, so that the slave dies in consequence, he is liable for his carelessness. Sometimes, too, unskillfulness is undistinguishable from carelessness – as where a surgeon kills your slave by operating upon him unskillfully, or by giving home wrong medicines." Institutes of Justinian (Book IV, Title III (Of the lex Aquila)) [*see* http://members.aol.com/hsauertieg/institutes/book4.htm], quoted in Sir William Blackstone, COMMENTARIES ON THE LAWS OF ENGLAND (1765-1769) (Book III: "Private Wrongs" (Chapter 8, n. 24-26) (matters found actionable as injuries affecting a man's health; cited in Buckner, F., OVERVIEW OF THE HISTORY OF MEDICAL MALPRACTICE at 50 (The Graduate Group-pub. (ISBN 0-938609-70-X (2002)).

ARGUMENT

I.

Introduction

The ACLM leaves it to the parties to advocate the merits of existing federal and state appellate cases that have defined what is considered a benefits decision or a medical treatment decision (*see* Zaremski, *Liability of Managed Care Organizations* (ch. 36) LEGAL MEDICINE (Sixth Edition) (Reed-Elsevier (2004)), and *Liability Exposure Facing Managed Care Organizations*, LEGAL MEDICINE (Fifth Edition) (ch. 46) 541-546 (Mosby (2001)); what is "quality" versus "quantity" of medical benefits (*see, e.g., Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350 (3d Cir. 1995))[6]; what in the abstract is a pure administrative decision as opposed to identifying what is a pure treatment decision; and, most problematical, how to define what Justice Souter states in *Pegram* as a "mixed eligibility – treatment decision." *Pegram v. Herdrich*, 530 U.S. 211, 228 (2000). The ACLM also leaves it to the parties to explain the preemptive reach of ERISA in the area where medical decision-making interfaces with granting or denying a benefit under a health plan, specifically the Court's treatment of complete, and ERISA, or defensive, preemption (*see e.g.*, *Jass v. Prudential Health Care Plan, Inc.*, 88 F.3d 1482, 1487 (7th Cir. 1996)).

[6] This decision has quickly established broad acceptance. See *Morreim, E.H.*, *Special Issues in ERISA* at 268, n. 46 (listing some 33 federal and state cases), HOLDING HEALTH CARE ACCOUNTABLE (Oxford Univ. Press (2001)).

There is one necessary and critical predicate for answering whether, and when, ERISA preempts decisions made by health plan personnel. This "foundation," put simply, is, what does it mean to make a medical decision? The ACLM will provide this predicate as a springboard to the issues it addresses in this brief.

II.

DECISIONS

A. What is a Medical Decision?

The most cogent explanation to defining, pragmatically, medical decision-making is found in McLean and Richards at 35, *supra* n. 3 at 3. Therein, these authors state the following:

> The medical decision is the end result of a reiterative five-step intellectual process. The steps are:
>
> (1) evaluation of patient's complaints and history,
>
> (2) gathering physical and laboratory information,
>
> (3) making a medical decision,
>
> (4) reevaluation of the outcomes of those decisions, and
>
> (5) the collection of new information about the patient's altered condition.
>
> A treating physician gathers information by taking a history from a patient, the patient's family, or speaking with a fellow health care provider (Step 1). Alternatively, information can be

> extracted from the patient's medical record. This oral and written information is supplemented through the "laying of hands" on a patient (that is, physical examination) and through obtaining confirmatory laboratory studies (Step 2). Medical decision-making results from the physician's mental thought process as the first two steps are reviewed under the aegis of the physician's training and experience (Step 3). Such decisions are two-fold, encompassing a diagnosis and a treatment recommendation. While diagnosis is often seen as the key operational decision by physicians, from the patient's perspective, the treatment recommendation, or lack of one, is more critical. It is the remaking of these medical decisions that is the practice of medicine. Step 4, the evaluation of the outcome of the medical intervention, is the most critical because it closes the loop. If the outcome of treatment is not effective (that is, the patient does not improve), the medical decision must be re-evaluated. If the treatment is effective, the patient must be monitored to assure that the condition stays controlled. Step 5 begins the process again. Outcome evaluation may be based on follow-up lab tests, patient reports, and subsequent physical exams. These last two steps are most likely to be compromised in managed care, because they require the evaluation of what should be a "well" patient.

This translates into making discretionary judgments affecting a patient's care and treatment. In other words, a medical decision is a treatment, or, in the arena of an HMO, a decision of what care is medically necessary. This type of judgment in the medical field has been similarly defined as " . . . the formulation of observations and opinions based on . . . a highly technical knowledge base that is

distinctive to medicine as a profession. Two kinds of judging typically are involved . . . empirical judgments about what is going on . . . gathering diagnostic information about the patient and then combining these individualized observations with broader, scientific knowledge. . . . Second, . . . normative judgments about what ought to be done. Morreim, E.H., *Expertise and Tort Liability for Health Plans* at 107, 108, HOLDING HEALTH CARE ACCOUNTABLE (Oxford Univ. Press (2001)). A medical judgment is thus a choice about how to go about diagnosing and providing treatment for a patient's condition: given a patient's constellation of symptoms, what is the most appropriate medical response? *Pegram,* 530 U.S. at 228; *see Lancaster v. Kaiser Foundation Health Plan of Mid-Atlantic States, Inc., et al.,* 958 F. Supp. 1137, 1145 (E.D. Virginia (1997)) (the focus is on the soundness of a medical decision to grant or deny treatment made during the course of treatment).

Moreover, this decision-making paradigm does not constitute, as stated, for example, by Aetna (Br. at 34) the inclusion of "medical criteria" stated in a benefits plan, or incorporating certain "medical concepts" as eligibility criteria in a plan document, or even an interpretation of a health care contract (*see* U.S. Cham. Comm. Br. at 28). And, the "medical evidence," referred to in Aetna's brief (at 15) as arising from the *Black & Decker Disability Plan v. Nord*, 123 S. Ct. 1965 (2003) decision, is similarly misplaced. With the latter, this Court chose not to invite into ERISA the 'treating physician rule' used to deliver Social Security disability benefits; the cases at bar do not seek to install the opinions of others *outside* the administration of ERISA plans as a basis for state-based remedial relief – rather, relief outside ERISA is sought based

upon discretionary judgments used to base medical decisions by those made *within* ERISA plan administration.

III.

DECISION-MAKERS

A. Who Makes a Medical Decision?

After arriving at a proper definition of what defines a medical, or treatment, decision, the next question to answer is*, who makes these decisions*? Clearly, a medical doctor is the ultimate decision-maker. The query is then raised whether these individuals as affiliated with an HMO, notably as medical directors, or those whose ultimate responsibility is to make medical decisions by approving or disapproving proposed care and treatment (what is medically necessary or not), is akin to those who may have more of a direct patient-physician relationship – like patients' treating caregivers. The answer is reasonably certain: yes.

A decision made by an HMO medical director is based upon medical judgment, arising from background, expertise and training in medicine. This judgment as to what is medically necessary in care or treatment by that personnel is no different than if it is made in a doctor's office or in a hospital corridor. *See e.g., State Board of Regulation for the Healing Arts v. Fallon*, 41 S.W. 3d 474, 476 (Mo. 2001), *cert. denied*, 2001 U.S. LEXIS 9987; *Murphy v. Board of Medical Examiners of the State of Arizona*, 190 Ariz. 441, 949 P.2d 530 (1980) (ERISA does not preempt disciplining medical directors of a third party administrator who makes medically necessary decisions); *Corporate Health Insurance, Inc., et. al., v. The Texas Department of Insurance*, 220 F.3d 641, 644-645 (2000) (" . . . Congress never intended to

preempt a state's power to regulate the quality of medicine;" (*id*. at 645)); *Isaac v. Seabury & Smith*, 2002 WL 1461710, *8 (S.D. Ind. 2002) [*Pegram*] focused on *decisions* . . . Regardless of who makes these decisions, they are all decisions which affect beneficiaries . . . we fail to see how . . . the nature of the enterprise – HMO or third party administrator – is a pertinent factor in determining whether ERISA completely occupies the field"). (emphasis in original); *see also* Zaremski, *HMOs, Accountability and the Death of ERISA Preemption*, 23 J. LEG. MED. 547, 557, 562 (2002). Consequently, treating physicians of plan beneficiaries are not the only ones who make decisions and identify care and treatment they may receive.

Further, while the cases above indicate a medical director of an HMO is a licensed practitioner subject to licensure requirements and discipline within the state for which (s)he is so licensed, a more problematic notion is whether those who assist physicians in providing patients with care, like a nurse, technician or assistant, also can, and do, make medical decisions. Logic dictates an affirmative response since the foundation for medical decisions, identified *supra* n. 3 at 3, and accompanying text, consist of data and information gathering as well as evaluating a patient's complaints and history. It is thus not inconceivable, particularly in a managed care setting, for these steps of the medical decision process to be undertaken by persons other than a physician as a medical director. Consequently, it lacks credence to assert that only a physician makes a medical decision (as asserted, for example, by Cigna (Cigna Br. at 32)) but those who gather the information upon which the decision is based, or who make decisions on their own, do not share in a measurable

way in the input upon which the ultimate decision is carried out. *A fortiori*, all those involved in this intellectual process, as defined above, necessarily make medical decisions. Consequently, the reference made to the *Pegram* Court about physician employees (*Id*. and at 33) is taken out of context to the issues presented here and out of step with the realities of modern day delivery of medical care.

Concomitantly, whether or not a category of an individual is a fiduciary under ERISA misses the point of whether that person is part of the medical decision-making process. Stated otherwise, that person can be a medical decision-maker whether or not acting in a fiduciary capacity under ERISA. *See* Cigna Br. at 36, n. 6, and U.S. Br. at 22 (a wrongful denial of benefits is actionable whether undertaken by a fiduciary or not). To be certain, nonetheless, those who contribute data or information to the physician are part of the decision-making process; not, as Cigna asserts, a " . . . trigger for what the statutes and regulators explicitly contemplate will be a fiduciary benefit determination process." *Id. But see Pegram*, 530 U.S. at 237 ("We hold that mixed eligibility decisions by HMO physicians are not fiduciary decisions under ERISA.")

IV.

STRUCTURE OF ENTITY WHICH MAKES DECISIONS

A. Capacity

Next, in what capacity does the entity exist on whose behalf a decision is made which responds to whether a requested treatment regimen is medically necessary or

not? In its case, Aetna admits being a third party administrator, and which asserts does not provide medical services (Aetna Br. at 6). Aetna is not the plan at issue either. The plan defines the scope of benefits, but not its implementation. (*See* Aetna Br. at 8) (Aetna is given discretionary authority for the determination of whether and to what extent eligible individuals and beneficiaries are entitled to coverage). Moreover, the Plan there provided for anti-inflammation medication without qualification; thus, the request for Vioxx was not a request for a benefit that was not provided in the first instance by the plan. *Id*. (prescription drugs are covered only as "indicated . . . for a medical condition as determined by Aetna." Less expensive drugs are covered first before a prescription for a more expensive medication is approved and allowed). *See id*. at 8-9. ("Vioxx is a covered plan benefit only if the member has already tried – or cannot try, because of allergy or contraindication – at least two of the fifteen other, similar drugs. . . . "). *See also* Morreim at 103, 123, *supra* at 8. (A request for a costlier drug, [such as Vioxx in *Aetna*], requires evaluating side effects of drugs previously administered, contraindications the patient's condition presents, how likely the requested drug will be to avoid side effects, and so forth. This constitutes making a medical judgment. An HMO " . . . should be held to a medical standard of care for the adequacy of the factual and medical basis on which they make their medical judgments." "When HMOs undertake this type activity, they should be liable for traditional tort claims of medical malpractice.") Aetna does, indeed, therefore provide a medical service.

From its record (Cigna Br. at 2), Cigna also acted as a third party administrator in order to administer plan benefits. Acting in this capacity, Cigna was not the plan

either as it did not determine which benefits were provided to *Calad*, only whether pursuant to a discharge protocol, Calad could receive the additional hospital stay she sought. *Id*. In other words, Cigna was making a judgment based on discretion – using medical decision-making whether the additional hospital stay was necessary or not. (*See Ouellette v. Christ Hospital,* 942 F. Supp. 1160 (S.D. Ohio 1996); *Bauman v. U.S. Healthcare, Inc.,* 1 F. Supp. 2d 420 (D.N.J. 1998); *aff'd.* as *In Re U.S. Healthcare, Inc.,* 193 F.3d 151 (3d Cir. 1999), *cert. denied*, 120 S. Ct. 2687 (2000); and *Plocica v. NYLCare of Texas, Inc.,* 43 F. Supp. 2d 658 (N.D. Tex. 1999) (issue of length of hospital stay was deemed to be a quality of care matter not within the preemptive grasp of ERISA).

As Aetna and Cigna are not health plans, they do exercise judgment in determining whether medically necessary treatment is warranted, as this is synonymous with providing a medical service. Contrary to support they receive from one of their *amici*, there are no health plans here making medical necessity determinations. (*See* Assoc. Fed. Health Org. Br. at 3.)

B. Managed Care Entities are Unlike Indemnity Insurers in the "Fee for Service" Era

A final point here is a needed response to petitioners' assertions that they essentially provide coverage and merely pay claims, nothing more, and that coverage decisions referencing medical customs and standards constitute an interpretation of a contract (*see* U.S. Cham. Comm. Br. at 27-28). In this way, so HMOs assert, they are like indemnity insurers of days past (which HMOs supposedly replaced) and therefore they make the same

decisions whether or not to pay, through utilization review procedures, as did indemnity insurance companies that were never subject to state based relief in tort. *Id.* at 23. The difference, however, between now and then is striking. **HMOs make decisions on a *prospective* basis through their utilization review programs; indemnity insurers made decisions on a *retrospective* basis, i.e., whether or not to pay for treatment already provided.** If decisions are made on a prospective basis, then these types of decisions are the very same ones made countless times a day, every day, 365 days a year, by physicians and other healthcare providers nationwide. *See Long v. Great West Life & Annuity Ins. Co.,* 957 P.2d 823, 826-828 (Wyo. 1998); *Wickline v. California,* 192 Cal. App. 3d 1630, 1633-34 (Cal. Ct. App. 1986); *Fulton-DeKalb Hosp. Auth. v. Dawson,* 270 Ga. 376, 380 n. 5 (Ga. 1998); and Frankel, *Medical Malpractice Law and Health Care Cost Containment: Lessons for Reformers from the Clash of Cultures,* 103 YALE L.J. 1297, 1303 (1994). Moreover, another difference between the modern delivery and payment for health care treatment and the way it was done years ago is that if a traditional insurer denied or balked at payment, it did not deny access to care (the care, to reiterate, had already been given); if an HMO denies payment or erroneously denies a benefit, it does so before the care is rendered and before payment ever becomes an issue. In this regard too, causes of action, as here, that result from harm said to have occurred are not proximately caused from payment not forthcoming, but because the medical decision made did not meet accepted medical standards of care.

V.

APPLICATION OF DECISIONS TO THE CASES AT BAR

A. Applying "Discretionary Judgment" Standard

From respondent Davila's petition in the record, then, Aetna, not the language of the ERISA plan itself, determined which drugs were included in its formulary, or what would have to be done medically before receiving them. (*See* U.S. Br. at 1) (The agreement [between Aetna and Davila's employer] gave Aetna 'complete authority to review all claims for Covered Benefits', including '**discretionary authority**' to determine whether and to what extent eligible individuals and beneficiaries are entitled to coverage and construe any disputed or doubtful terms under th(e) Group Agreement. Pet. App. at 102a." (emphasis supplied)). This included Aetna's "step program" as a predicate for additional pharmaceuticals if required for the failure of ones initially provided by it. This constitutes what this *Amicus* puts forth as the five steps to the intellectual process composing a medical decision-making, *supra* at 6-7: determining what drugs to initially provide and after which only then determining whether a different drug should be provided is no different than if the same intellectual process is carried out in a doctor's office or in a corridor of a hospital.

What about Ruby Calad? A decision was initially made, as part of the precertification process, to provide her a one-day hospital stay, given her type surgery (from the record it was a complex one – hysterectomy with rectal, bladder and vaginal repair). However, once the surgery was completed, her surgeon believed additional hospitalization

was required. The Cigna discharge nurse insisted upon the pre-certified one day of stay. Again, as with Davila, a *decision* was made, after considering and reevaluating the patient needs, completed surgery and what the physician requested, to not deviate from the one day stay. (*See* U.S. Br. at 4) (Under the Cigna plan, stays determined by pre-admission certification or c**ontinued stay review**. (Cigna Opp. Mot. Remand App. 22) (emphasis supplied).

Additionally, from their respective petitions filed in the lower courts, neither claimant sought relief directly for *payment* of the benefit denied or for denial of a covered benefit (*see* U.S. Br. at 14 and AAHP-HIAA Br. at 12, 25); again, the predicate upon which the causes of action are seemingly based are decisions medically-based, resulting in *care and treatment* that should have been provided. To reiterate a point earlier made, the relief sought was not for payment for care already provided, but for care yet to have been rendered which resulted in claimed harm. As with Davis in the *Aetna* case not requesting Vioxx as a benefit of the plan, so, too, was Calad in *Cigna* not requesting an additional hospital stay as it was a defined benefit in her employer's plan. Neither Aetna nor Cigna made a decision to enforce the plan's prescribed algorithm for granting benefits; the decisions made and judgments used were not only ones a patient's treating physician could very well make, but were also predicated upon facts (choice of pharmaceutical/length of hospital stay) either not contemplated by plan benefits or not contemplated by the plan's prescribed algorithm.

Accordingly, the provision of the requested medical care and its application were not an ERISA plan. " . . . the ERISA plan is the employer's designation of preferred benefits, not the medical administrative structure used to

deliver the preferred benefits." McLean and Richards at 30, *supra* n. 3 at 3. This is consistent with when the *Pegram* Court said the word, 'plan' referred " . . . to a scheme decided upon in advance." *Pegram v. Herdrich,* 530 U.S. 211, 231; *see also* Peter D. Jacobson & Scott D. Pomfret, *Form, Function and Managed Care Tort: Achieving Fairness and Equity in ERISA Jurisprudence*, 35 HOUSTON L. REV. 985, 1050 (1998). Thus, a plan beneficiary's benefits based on the exercise of judgment are *not* the contractual rules by which an entity administering the plan operates. *See Isaac v. Seabury & Smith*, 2002 WL 1461710, *8 (S.D. Ind. (2002)).

VI.

STATE VERSUS FEDERAL FORUMS

A. Relief From Medical Decisions Resulting in Harm Rests in State Courts, Not With ERISA Remedies Enforced in Federal Courts

Justice Frankfurter once observed, " . . . in law also, doctrine is illuminated by history." *Kovacs v. Cooper*, 336 U.S. 77, 95 (1949) (Frankfurter, J., concurring). Casting the lens of history upon American malpractice jurisprudence reveals that physicians, once hailed as "captains of the ship" regarding medical decision-making, have been joined on the captain's bridge by hospitals, health insurance companies and, now, HMOs. More importantly, history demonstrates that states have repeatedly responded to the sharing of physician control over decision-making by extending liability to those parties that have been the recipients of decisional authority.

Buckner, in his work, OVERVIEW OF THE HISTORY OF MEDICAL MALPRACTICE, *supra* n. 5 at 4, provides, too, an exhaustive treatment of the history of medical malpractice over literally recent centuries – even inclusive of Blackstone's reference to harm committed by physicians and surgeons during the era of the Roman empire referenced in Latin atop the "Argument" section of this brief (*supra also* at 4). However, the importance of his (Buckner's) work is a beacon to illuminate that of which Justice Frankfurter spoke: using history as a base, having the law craft solutions for acts or omissions that reflect the wrongs from practicing medicine or providing that care – in other words, applying ***accountability*** to settings in which medical decisions are made. As these settings change, or evolve, so, too, must the law's recognition and enforcement of those to be held accountable.

(This development of) "accountability" is the watchword that best suggests the focus for confronting the realities of how medical care is now provided. One scholar put it this way: " . . . the law addressing patients' adverse outcomes in the context of health care should be and reasonably can be better attuned to the profound changes in the ways health care is now . . . delivered." Morreim at 158, *supra* at 8. For example, and as opposed to Cigna's assertion (Cigna Br. at 39), modern medicine involves well-trained individuals who do not necessarily have direct contact with the patient and who are not the patient's treating physician. Buckner at 135; *see Darling v. Charleston Community Hospital*, 33 Ill. 2d 326 (1965) (hospitals liable for institutional negligence); *Jones v. Chicago HMO Ltd. of Illinois*, 191 Ill. 2d 278 (2000) (an HMO may be held liable for institutional negligence) (HMOs undertake an expansive role in arranging for and providing drugs

and health care services to its members); *Shannon v. McNulty*, 718 A. 2d 828, 835-36 (Pa. Super. Ct. (1998)) (HMOs consist of an amalgam of individuals who play various roles in order to provide comprehensive health care services to their members); *Petrovich v. Share Health Plan of Illinois, Inc.*, 188 Ill. 2d 17, 28 (1999) (HMOs act as health care providers); and *Official Lists Current Amicus Briefs of Labor Department on Medical Malpractice*, 68 U.S.L.W. 2249-50 (November 2, 1999) (HMOs wear "three different hats", one of which is "medical provider").

The period between *Darling* and *Jones* was 35 years, but the Illinois Supreme Court extended institutional accountability from hospitals to HMOs in its state courts over that time span. Now, this Court is given the opportunity to declare once and for all what has been menacing state and, particularly, lower federal courts for an equally imposing time, and that is, that ERISA's preemptive reach should not, and does not, extend to medical decisions based on discretionary judgment made on a prospective basis by those who provide or administer healthcare pursuant to, or on behalf of, ERISA health plans. The evolution of state-based remedies for such decisions, and, concurrently, ERISA preemption analysis now must lead as well to where such decisions envelop the province of state law in state courts; not remedial relief found in ERISA. *See Lancaster v. Kaiser Foundation Health Plan of Mid-Atlantic States, Inc*., 958 F. Supp. at 1149) (Common law medical malpractice is quintessentially the province of state authority. There is simply no reason to believe that Congress – by enacting a statement [ERISA] designed to protect the interests of workers in their benefit plans – intended to remove the long-standing protection against

medical negligence afforded by state malpractice law; *see also infra* n. 9, 11 at 25-28.)

Furthermore, denying a request for care and treatment as not medically necessary can be viewed as a denial of a benefit but it *is* in essence making a medical decision *if* discretionary judgment resulting in the denial is used. These two notions [denying care and making a medical decision] are " . . . practically inextricable from one another." (*Pegram*, 530 U.S. at 229). This description also more accurately describes what occurs in administering a health plan.[7] To deny the clarity of what has just been stated is to deny (1) the need for medical directors and medically trained personnel in the employ of HMOs, and (2) to deny the purpose for which Congress sought creation of HMOs in the early 1970s. *See Holmes v. Pacific Mut. Life Ins. Co.,* 706 F. Supp. 733, 735 (C.D. Cal. (1989)). Thus, so long as discretionary judgment is embedded in decisions made prospectively resulting in a denial of requested medically necessary treatment, remedial relief for any harm arising therefrom must, as it has, remain with the states for adjudication.

Finally, this Court has spoken using by reference, the "mixed eligibility/treatment" decision (*Pegram*, 530 U.S. at 228). These words should no longer be the terminology used by this Court as they are misleading and their connotation inappropriate. More accurate verbiage is that medical decisions made prospectively based on discretionary judgment that conclude in a denial of requested care is

[7] Morreim describes it as combining resources and expertise. Morreim, *supra* n. 6, at 142, 148.

a denial of a request for medically necessary treatment. This translates to a blending of medical care and administrative functions which are neither related to a plan nor completely preempted by ERISA.[8]

VII.

HEALTH CARE COSTS

A. State Based Remedies for Medical Decision-Making Have Not Increased Health Care Costs or Costs To Provide Benefits.

A "footnote" to the positions advanced in this brief. To say, as put forth by petitioners, that imposing state medical malpractice remedies as a replacement for relief under ERISA for adverse benefit decisions would drive up costs of health care is totally disingenuous. To be sure, the debate has not concluded on what is the principal force behind the malpractice crises said to have existed since the late 1960s (*see* MEDICAL MALPRACTICE: THE PATIENT VERSUS THE PHYSICIAN, A study submitted by the Subcommittee on Executive Reorganization (Sen. A. Ribicoff, Chr.) to the Committee on Government Operations, United States Senate (91st Congress, 1st Session (November 20, 1969)), and MEDICAL MALPRACTICE: (Report of the Secretary's Commission on Medical Malpractice) (DHEW Publ. No. (0S) 73-88 (January 16, 1973)) and now found in the first decade of this century. However, the literature is rich with discussions that medical malpractice litigation has not been the genesis for huge spikes in malpractice insurance found to have occurred now and

[8] *See Id*.

in decades past. U.S. General Accounting Office, *Medical Malpractice Insurance: Multiple Factors Have Contributed to Increased Premium Rates, GAO-03-702* (Washington, D.C., June 27, 2003), and U.S. General Accounting Office, *Medical Malpractice*: *Implications of Rising Premiums on Access to Health Care*, GAO-03-836 (Washington, D.C., August 8, 2003). *See* Hunter and Doroshow, *Premium Deceit: The Failure of Tort Reform To Cut Insurance Prices*, Center for Justice and Democracy (New York, New York (2002)), and Statement of Richard J. Hillman and Kathryn G. Allen, *Medical Malpractice Insurance-Multiple Factors Have Contributed to Premium Rate Insurance*, Subcommittee on Wellness and Human Rights, Committee on Government Reform, U.S. House of Representatives (October 1, 2003 (GAO-04-128T)). Moreover, the asserted linkage between state medical malpractice litigation and the costs of health care is tenuous too. *Id. See Limiting Tort Liability for Medical Malpractice at 1, 6*, ECONOMIC AND BUDGET ISSUE BRIEF (Congressional Budget Office (January 8, 2004)) (malpractice costs represents less than 2 per cent of overall health care spending).

It is claimed as well (Cigna Br. 48) that the mere threat of costly medical malpractice litigation encourages "defensive medicine". In fact, the government's own study, *Medical Malpractice: Implications of Rising Premiums on Access to Health Care*, *id*. at 6, states, " . . . the overall prevalence and costs of such [defensive medicine] practices have not been reliably measured."

All of the above notwithstanding, petitioners' logic that importing state tort medical malpractice relief into employee health benefit plan administration would seriously affect employee benefits as it [allegedly] has the cost of medical care (Cigna Br. at 49, Aetna Br. at 17, 41, and

U.S. Cham. Comm. Br. at 24-25.) is also seriously flawed. Because the *sine qua non* of benefit plan administration in this day and age of HMOs is to make, where they are made, discretionary judgments prospectively about what care and treatment a plan beneficiary should be given or allowed.

The phrase, "he who lives in glass houses should not throw stones", has considerable force in this regard. That is to say, HMOs have taken it upon themselves, as part of being in their business, to interject discretionary judgments prospectively made regarding the care and treatment to be provided a patient as part of administering, delivering and providing that care. This decision-making has consequences if it does not meet a standard of applicable care; the *quid pro quo* for such consequences is, to reiterate, accountability – again to reiterate, the very same accountability imposed upon physicians and others who deliver and provide healthcare by making or contributing to medical decisions. And to camouflage such decisions as simply a denial of a benefit or simply as nothing more than paying a claim, as petitioners and their *amici* have done, is to avoid the realities of how health care is provided in this country today.

If HMOs are the genesis for their own accountability due to the medical decisions their personnel make, it defies logic to then say that a state tort malpractice system will be the culprit for increasing the cost of providing a benefit under a health plan; or, perhaps, are the managed care entities in the cases at bar asserting that they agree to be held as accountable for the same decisions as other health care providers make, but only in a legal venue of their own liking which is not state-based and which provides them with limited exposure? The latter, if

true, would cause consumers and health care practitioners alike to align in dramatic revolt against this HMO position; this stance would also prove costly for the legal system since adjudicating accountability for medical decision-making of the same variety would have to be based in two forums: federal for HMOs and state for all others.

B. Accountability, Preemption and State Based Relief

Because ERISA was never intended to federalize medical malpractice law, accountability for harm resulting from medical decisions based on discretionary judgment on a prospective basis must continue to rest in state and territorial venues – as it has for over 200 years. Buckner at 54, 154, *supra* at 4, 18 (citing to 1794, Connecticut 2 Root 90. Jesse Root, *Reports of Cases Adjudged with the Superior Court and in the Supreme Court of Errors in the State of Connecticut*, 1793-1798 n. p., 1802, Vol. II, pp. 90-92 as contained in Burns, *Malpractice Suits in American Medicine Before the Civil War*, BULLETIN OF THE HISTORY OF MEDICINE, 43:41 at 54-56 (1969)).

Finally, there are assertions advanced in the cases at bar that ERISA's remedial provision is exclusive, and that exclusivity gives rise to preemption of any state tort cause of action based on medical decision-making, and certainly to ones Congress forgot to incorporate expressly. (Aetna Br. at 19, 20, and 40; *see also Mutual Life Ins. v. Russell*, 473 U.S. 134, 147 (1985)). Even one of petitioners' *amici* advocates that state negligence claims aimed at medical necessity decisions constitute a frontal attack on regulating ERISA plans. *See* Assoc. Fed. Health Orgs. Br. at 9.

If these assertions all were true, then no discretionary judgments prospectively rendered and by the persons in whose capacities are similarly described (in this brief) could ever give rise to a state cause of action for asserted breach of state established standards of medical care. These positions would fly in the face of much decades-old jurisprudence that standards for medical care and treatment are state – based (*see*, Epstein, MORTAL PERIL: OUR INALIENABLE RIGHT TO HEALTHCARE? 365 (1967)), which has been well recognized and acknowledged as such by Congress, certainly at least from before passage of the HMO Act of 1973.[9] It follows that state-based

[9] *See* Senate Committee on Labor and Public Welfare Report No. 93-129 on The Health Maintenance Organization and Resources Act of 1973 (S. 14) at 3077 (" . . . that states should be given the opportunity to develop health care standards . . . An added factor in the Committee's decision to encourage states to develop their own standards is the fact that experience in the medical care field has indicated that the closer the responsibility for standard development and health care regulation is to the actual provider of the care, the more likely the provider is to become involved in the development and setting of standards . . . The Committee also feels that states, through their agencies, should be given the opportunity to enforce such standards . . . The concept of permitting the state agencies to develop their own standards and to enforce them . . . is in keeping with the overall philosophy of the Committee." See *supra* n. 2 at 2.

This notion of states being the proper forum for standards and medical decision-making can also be seen in remedy sections of various patients' bills of right ("PBOR") crafted and passed by one Congressional chamber or another since October 1999, through bipartisan leadership of, among others, the Hon. Charlie Norwood (R.-Ga.) and Hon. John Dingell (D.-Mich.) in the House (Section 302 in HR 2723, succeeded by HR 2990, which passed overwhelmingly in the House in October 1999) (*see* Zaremski, *Liability Exposure Facing Managed Care Organizations,* LEGAL MEDICINE (Fifth Edition) at 545-549 (Mosby Inc. (2001)) and the Hon. Edward M. Kennedy (D.-Mass.), Hon. John Edwards (D.-N.C.) and Hon. John McCain (R.-Az.) in the Senate (*see*,

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remedies are the appropriate Damoclean swords to insure that plan participants receive appropriate levels of medical care. These remedies are certainly far from being "crude" (Aetna Br. at 44) or unnecessary to protect plan beneficiaries from harm that results from medical decisions made by HMOs. (AAHP-HIAA Br. at 5) ("There is no reason to believe that such [state tort litigation] suits are

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e.g., S. 1052, which passed the Senate 59-36 on June 29, 2001 (107th Congress)). Contrary to the assertion put forth by Aetna (Br. at 42, n. 23), both the House *and* the Senate have thus passed versions of PBORs containing provisions to remove the ERISA shield and permit cases regarding medically reviewable issues to be brought in state court), not " . . . exclusively federal".) *Id*. Parenthetically, the amendment to H.R. 2563 on liability, as referenced by Aetna, passed the House by a 218-213 margin, so the passage of this amendment was anything but overwhelming. As amended, the bill would have permitted an injured patient to bring a cause of action against a health plan in state court but would impose certain standards, for example, if an independent medical reviewer upheld a determination by a health plan to deny a benefit, it would create a presumption, rebuttable only by clear and convincing evidence, that the health plan exercised ordinary care in making the determination. In this (108th) Congress, S. 1945 would amend ERISA to remove the ERISA shield and permit patients injured by decisions made by their employer-sponsored health maintenance organizations to bring cases regarding medically reviewable issues in state court under state tort laws. H.R. 596 would amend ERISA to exclude from preemption state causes of action to enforce determination under group health plans based on medical necessity. S. 1945 was referred to the Senate Health, Education, Labor and Services Committee. H.R. 596 was referred to the House Education and the Workforce Committee.

See also H.R. 5 ("Health Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2003) which passed the House in the current Congress. Section 13 of the bill, at 26, states as follows: "**It is the sense of Congress that a health insurer should be liable for damages for harm caused when it makes a decision as to what care is medically necessary and appropriate**." (emphasis supplied)

necessary to protect plan beneficiaries.")[10] What would be crude is, for example, the government's position that there are circumstances where harm could result from treatment being denied, but the beneficiary would be denied [state based] relief except for the loss of the benefit denied provided by ERISA. U.S. Br. at 25-26.

VIII.

CONCLUSION

While a denial of medically necessary treatment concludes in denying requested care and treatment, e.g., denying a benefit, the essential premise put forth by this *Amicus* is that determining medically necessary care on a prospective basis is not in any fashion incidental to denying a plan benefit. **Denying a benefit prospectively using discretion in the administration of a health plan care *is* requested care and treatment denied.** Consonant with this is that HMOs employ suitably trained personnel charged with making these decisions. And so long as these individuals exercise discretionary judgment, neither remedial relief provided plan beneficiaries by ERISA is implicated[11] nor are state remedies duplicative or supplemental of what Congress intended ERISA to provide.

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[10] Yet, apparently the government does not concede this position when recognizing the existence of decisional law allowing for HMOs to be vicariously liable for decisions made by their physicians. U.S. Br. at 29.

[11] This would be in line with commentators favoring a limited reach of ERISA's preemptive arm. *See* Jacobson and Pomfret at 985, 994, 1048, *supra* at 17; *see also Ceminara, Protecting Participants in and Beneficiaries of ERISA – Governed Managed Health Care Plans,* 29 UNIV. OF MEMPHIS LAW REV. 317-361 (1999); *Koutoulogenis, The*

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More importantly, the day has finally arrived for this Court to pronounce that medical decisions in the form of what is medically necessary made on a prospective basis to determine care and treatment for a plan beneficiary by HMO personnel are no different than if those decisions are made by the plan beneficiary's treating physician or by someone medically trained who provides care, through judgments made, to a patient indirectly, such as by a hospital based health care practitioner or hospital employee. Just as healthcare providers indisputably have been subject to accountability under state laws for making erroneous medical necessity decisions that deny patients access to a reasonable standard of care, so should HMOs be similarly accountable. By making such a declaration, this Court will recognize that state courts have historically extended malpractice liability to those parties who are involved in the medical decision-making process. As a matter of public policy, this Court should not thwart that course, which states have undertaken within the purview of their police powers over the medical profession. *See New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.*, 514 U.S. 645, 655 (1995) ("'. . . the historic police powers of the States were not to be superceded by the Federal Act unless there was the clear and manifest purpose of Congress'.") Furthermore, the deliberate footprints created by malpractice jurisprudence demonstrates

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Invisible Man: a Call to Empower Individual Participants and Beneficiaries against Fiduciary Breaches in ERISA Plans, 34 TORT & INS. LAW J. 131-166 (1998); and Wethly, *New York Conference of Blue Cross and Blue Shield Plans v. Travelers Insurance Co.*: *Vicarious Liability Malpractice Claims Against Managed Care Organizations Escaping ERISA's Grasp*, 37 BOSTON COLL. L. REV. 813-860 (1996).

that Congress, in passing ERISA, did not intend to stop the states in their paths simply by remaining silent on the issues. Only a clearly expressed congressional intent can impede state-adjustment of malpractice liability's scope when that adjustment is made in an effort to hold accountable those parties who steer the course of medical decision-making.

For the foregoing reasons, the judgments of the Fifth Circuit should be affirmed.[12]

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[12] By doing this, this Court will not need to deviate from its position that it is not in a position to differentiate one type HMO model from another (*Pegram*, 530 U.S. at 222; *see also* Aetna Br. at 33, n. 16). HMO structures, like network or group models, can remain separate *except* insofar as when personnel from each makes a medical decision prospectively as to what care and treatment is medically necessary based upon discretionary judgment – in such situations the structures become irrelevant.