01-9248

IN THE

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

BONNI CICIO,

Appellant,

v.

VYTRA HEALTHCARE, BRENT SPEARS, M.D., AND JOHN DOES, 1-8,

Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

BRIEF OF AMICI CURIAE AMERICAN MEDICAL ASSOCIATION
AND MEDICAL SOCIETY OF THE STATE OF NEW YORK
IN SUPPORT OF APPELLANT BONNI CICIO

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TABLE OF CONTENTS

TABLE OF AUTHORITIES……ii

CORPORATE DISCLOSURE STATEMENT……iv

INTEREST OF AMICI CURIAE…….1

SUMMARY OF RELEVANT FACTS……3

ARGUMENT……5

I. VYTRA AND DR. SPEARS MADE "MIXED ELIGIBILITY AND TREATMENT" DECISIONS REGARDING MR. CICIO, FOR WHICH VYTRA AND DR. SPEARS SHOULD BE HELD ACCOUNTABLE UNDER STATE TORT LAW…….……5

II. VYTRA AND DR. SPEARS CANNOT AVOID LIABILITY ON GROUNDS THAT THEY WERE MERELY ENGAGED IN UTILIZATION REVIEW ACTIVITIES, AS SUCH ACTIVITIES CONSTITUTE MIXED ELIGIBILITY AND TREATMENT DECISIONS…….……..9

CONCLUSION……18

TABLE OF AUTHORITIES

PAGE

CASES

DeBuono v. NYSA-ILSA Medical & Clinical Servs. Fund, 520 U.S. 806 (1997).....5

In re Unlicensed Practice of Med.: Roger H. Strube, No. 9420668 (filed Feb. 24, 1995) 14

N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 653-655 (1995) 5

Pappas v. Asbel, 768 A.2d 1089 (Pa. 2001), petition for cert. filed, 70 U.S.L.W. 3092 (Aug. 1, 2001) 8, 17

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

State Board v. Fallon, 41 S.W.3d 474 (2001).....11, 12, 15

STATUTES

Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1141, et seq. .....passim

2001 Minn. Laws 147.091, Subd. 1b.....14

OTHER AUTHORITIES

Tanya Albert, *Higher Accountability for HMO Medical Directors*, amednews.com (May 14, 2001), available at www.ama-assn.org/sci-pubs/amnews/ pick_01/prl120514.htm.....16

AMA Policy H-285.939, Managed Care Medical Director Liability. Available at http://www.ama-assn.org/apps/pf_online/pf_online?f_n=browse&doc=policyfiles/HOD/H-285.939.HTM&&s_t=&st_p=&nth=1&prev_pol=policyfiles/HOD/H-280.999.HTM&nxt_pol=policyfiles/HOD/H-285.922.HTM& 11

Phyllis C. Borzoi, *Erisa and Managed Care Plans: Key Preemption and Fiduciary Issues*, SF28 ALI-ABA 371 (Oct. 2000) at 423 n.2 17

Employer Health Plan Accountability: Do Plan Participants Have Adequate Protections?: Hearing Before the House Subcomm. on Employer-Employee Relations, House Comm. on Educ. and the Workforce, 106th Cong. 127 (1999) (Statement of Timothy T. Flaherty, M.D., American Medical Association). Available at http://commdocs.house.gov/committees/edu/hedcew6-24.000/hedcew6-24.htm.....10

Barry Gold, *Vulnerability of HMO Physicians Who Make Medical Necessity Decisions to Professional Misconduct Proceedings by State Licensing Agencies*, Presentation at New York State Bar Ass'n. Annual Convention (Jan. 26, 2000). 14

La. Op. Att'y Gen. No. 98-491, 1999 WL 288869 (Apr. 27, 1999).....12

MSSNY Position Statement § 165.969, available at http://www.mssny.org/position/managed.htm (Jan. 14, 2002) 17

MSSNY, News of New York, Oct. 1998.....13

National Conference of State Legislatures, *Major Health Care Policies*: *50 State Profiles, 2000* (Jan. 2001) 17

Policy Statement approved at February 5-7, 2001 Board Meeting, available at www.llr.state.sc.us/POL/Medical/Medical%20 Necessity.htm.....12

San Jose Business Journal, June 5, 1998 12

Texas State Board of Medical Examiners, Medical Board Report, Vol. 18, No. 2 (Spring 1997), available at http://www.tsbme.state.tx.us/news/Spring97/ spring97.htm. 11

The Changing World of HMO Liability Under ERISA, 22 J. LEGAL MED. 77, 86 (March 2001) 6

CORPORATE DISCLOSURE STATEMENT

American Medical Association and Medical Society of the State of New York, both not-for-profit corporations, state as follows:

1. Neither the American Medical Association nor the Medical Society of the State of New York has a parent corporation.

2. No publicly held company owns more than 10 % or more of the stock of either American Medical Association nor the Medical Society of the State of New York.

INTEREST OF *AMICI CURIAE*

The American Medical Association ("AMA") and the Medical Society of the State of New York ("MSSNY") (collectively "*Amici*") submit this brief in support of Appellant, Bonni Cicio, individually and as administratrix of the Estate of Carmine Cicio. *Amici* respectfully submit that the lower court erred in holding that the Employee Retirement Income Security Act of 1974 ("ERISA") preempted state law under Section 514(a), 29 U.S.C. § 1144(a), as well as state jurisdiction under Section 502(a), 28 U.S.C. § 1441. *Amici* accordingly submit that this Court should reverse the erroneous dismissal of the state law causes of action, and should remand this action to state court.

Founded in 1847, the AMA, an Illinois not-for-profit corporation, is the largest medical society in the United States. It has approximately 275,000 member physicians who practice in all fields of medical specialization and in every state. MSSNY, a New York not-for-profit corporation founded in 1807, has approximately 27,000 physicians, residents and medical students who reside or practice in the State of New York. *Amici* share a joint mission: to promote the science and art of medicine and the betterment of public health.[1]

In executing their mission, *Amici* often are required to take positions about what actions constitute medical decision-making (which, in *Amici*'s opinion,

[1] The AMA and MSSNY submit this brief on their own behalf and as representatives of the Litigation Center of the AMA and the State Medical Societies ("Litigation Center"). The Litigation Center, a coalition of the AMA and 50 state medical societies, including MSSNY, was established to present the views of the medical profession to the courts.

is part of the practice of medicine), what regulations should be imposed upon those who make medical decisions and thereby practice medicine, and what sanctions and consequences are appropriate for those who do so negligently. This case raises all of these issues. Accordingly, *Amici* submit that they are uniquely qualified to offer their opinions to this Court.[2]

In this action, the lower court failed to recognize that certain decisions of a managed care organization and its medical director constituted "mixed eligibility and treatment decisions" within the meaning of Pegram v. Herdrich, 530 U.S. 211 (2000). The decisions involved the refusal to authorize treatment that was recommended by the treating physician and the approval, after a medically significant delay, of different treatment.

Reversal and remand is essential because the U.S. Supreme Court made clear in Pegram that such decisions are not preempted by ERISA, and those responsible for such decisions are subject to liability under state law. Implicit in Pegram is the presumption that courts correctly will distinguish between decisions that involve medical treatment (identified in Pegram as "pure treatment decisions" and "mixed eligibility and treatment decisions," 530 U.S. at 229-30) and decisions that involve coverage alone (identified in Pegram as "'pure eligibility' decisions," 530 U.S. at 228-29). When courts fail to do so – as the lower court did in this case

[2] Courts throughout the country – including the United States Supreme Court and this Court – have accepted *amicus curiae* briefs filed by the AMA and the MSSNY. See, e.g., Brief of the AMA, et al.,

– their holdings must be reversed. Otherwise, an incorrect body of law will develop about what decisions are subject to traditional state remedies and fall outside of ERISA. As a result, this already complex area of law will be confused even further, and the essence of Pegram will be destroyed.

SUMMARY OF RELEVANT FACTS

1. As shown in greater detail in the Appellant's brief, Bonni Cicio was employed by North Fork Bank, and received health care coverage for herself and her husband, Carmine, through a health plan purchased by North Fork Bank. Vytra Healthcare ("Vytra") administered the plan (A. 11).

2. In March 1997, Carmine Cicio was diagnosed with multiple myeloma, a potentially fatal cancer (A. 12).

3. On January 28, 1998, Mr. Cicio's treating physician, Dr. Edward Samuel, made the determination that high dose chemotherapy, supported with peripheral blood stem-cell transplantation in a tandem double transplant, was medically necessary for Mr. Cicio, and possibly life saving. He wrote to Vytra to request approval for this treatment. In that letter, he stated that the "likelihood of maintaining [Mr. Cicio's] disease under control [through other means] . . . is low for any sustained period of time" and that the proposed treatment "demonstrated superiority in over-all survival and disease-free survival" (A. 15).

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filed in Rush Prudential HMO, Inc. v. Moran, 2001 WL 1480546 (U.S. Nov. 7, 2001); Brief of the AMA and the MSSNY, filed in Mikes v. Straus, 27 F.3d 687 (2d Cir. Mar. 16, 2001).

4. Vytra received the request on January 29, 1998 (A. 12). Vytra did not respond until February 23, 1998 – almost one month later. When Vytra did respond, through its Medical Director, Dr. Brent Spears, it denied the request as an "experimental/investigational" procedure (A. 13).

6. Mr. Cicio, through Dr. Samuel, appealed the denial in writing on March 4, 1998, stressing that the procedure was not "experimental/investigational" and citing numerous articles from major medical journals as support. (A. 14).

7. Vytra did not respond until March 25, 1998, three weeks later. At that time, Vytra reversed its decision, but only in part. It approved an alternative treatment: a single stem-cell transplant (A. 14-15).

8. Vytra's determination of the appropriate treatment for Mr. Cicio , however, came too late. By March 25, Mr. Cicio's condition had worsened such that he no longer was a candidate for any transplant (A. 15).

9. On May 11, 1998, Carmine Cicio died (A. 11).

ARGUMENT

I. VYTRA AND DR. SPEARS MADE "MIXED ELIGIBILITY AND TREATMENT" DECISIONS REGARDING MR. CICIO, FOR WHICH VYTRA AND DR. SPEARS SHOULD BE HELD ACCOUNTABLE UNDER STATE TORT LAW.

The U.S. Supreme Court made clear in Pegram that "treatment decisions" and "mixed eligibility and treatment decisions" are subject to state law, and are not preempted by ERISA. 530 U.S. at 235. This analysis comports with

prior holdings that the "historic police powers of the state include the regulation of matters of health and safety," see DeBuono v. NYSA-ILSA Medical & Clinical Services Fund, 520 U.S. 806 (1997), and that "the historic police powers of the states were not to be superseded by the federal act [ERISA] unless that was the clear and manifest purpose of Congress." N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 653-655 (1995).

ERISA does not show that Congress intended to preempt state law in the traditionally state-regulated area of health and safety.[3] Notably, in the text of the statute, "hospital" appears only once and "physician" not at all. Billie Elliott McAuliffe, *The Changing World of HMO Liability Under ERISA*, 22 J. LEGAL MED. 77, 86 (March 2001). The U.S. Supreme Court repeatedly has recognized in recent years that "[n]othing in the language of [ERISA] or in the context of its passage indicates that Congress chose to displace general health care regulation, which historically has been a matter of local concern."[4] Travelers, 514 U.S. at 661. See also Pegram, 530 U.S. at 235. Without such evidence, there is little choice but to conclude that Congress did not do so.

[3] ERISA provides only that it "shall supersede any and all state laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a).

[4] The AMA supports changes in federal law to prohibit, affirmatively, the exemption from liability of managed care organizations, including ERISA plans, for damages resulting from their policies, procedures, or administrative actions taken in relation to patient care. The AMA believes that such changes are appropriate to clarify the current confusion. AMA Policy H-285.945, available at http://www.ama-assn.org/apps/pf_online/ pf_online? f_n=browse&doc=policyfiles/HOD/H-285.945.HTM

Because ERISA does not preempt treatment decisions and mixed eligibility and treatment decisions, the simple issue here is whether the decisions made by Vytra and Dr. Spears fall into either category. The simple answer is that they do.

Treatment decisions answer the question: "given a patient's constellation of symptoms, what is the appropriate medical response?" Pegram, 530 U.S. at 228. Here, Vytra and Dr. Spears examined Mr. Cicio's "constellation of symptoms" and determined, ultimately, that the appropriate medical response was a single stem-cell transplant. This decision constituted, at the very least, a mixed eligibility and treatment decision within the meaning of Pegram. It necessarily required medical decision-making, as Vytra and Dr. Spears decided on, then approved, a treatment that the treating physician had not recommended in the first place: a single (as opposed to a double) stem-cell transplant.

Vytra and Dr. Spears made an entirely separate "mixed eligibility and treatment decision" when they decided that Mr. Cicio should not receive the double stem-cell transplant that was recommended. That decision clearly incorporated treatment issues. See Pegram, 530 U.S. at 230 (decisions regarding the experimental nature of a treatment are "mixed eligibility and treatment decisions"). Thus, the denial did not regard coverage alone.

These decisions about the treatment of Mr. Cicio are comparable to decisions that were made by U.S Healthcare in connection with the treatment of

Basile Pappas. See Pappas v. Asbel, 768 A.2d 1089 (Pa. 2001), petition for cert. filed, 70 U.S.L.W. 3092 (Aug. 1, 2001). There, U.S. Healthcare, as plan administrator of Mr. Pappas' health plan, initially rejected a treatment recommendation made by the treating physicians: transfer to, and surgery at, a hospital that specialized in spinal cord injuries. After some delay, a transfer to a different hospital was approved instead. The Pennsylvania Supreme Court held that U.S Healthcare's decisions constituted "mixed eligibility and treatment decisions."[5] 564 Pa. at 419.

Thus, the plain language of Pegram, combined with the similarities between the decision-making here and in Pappas, make clear that the lower court erred. The lower court should not have dismissed the state law counts and it should have remanded this action.

II. VYTRA AND DR. SPEARS CANNOT AVOID LIABILITY ON GROUNDS THAT THEY WERE MERELY ENGAGED IN UTILIZATION REVIEW ACTIVITIES, AS SUCH ACTIVITIES CONSTITUTE MIXED ELIGIBILITY AND TREATMENT DECISIONS.

Vytra and Dr. Spears argue that their decisions regarding Mr. Cicio's treatment involve coverage only, as they were made in the course of utilization review. In fact, the lower court's decision rests upon the acceptance of this

[5] "[The treating physician] did not, in the [United States] Supreme Court's words, only make a 'simple yes or no' decision as to whether Pappas' condition was covered; it clearly was. Rather [he] also determined where and, under the circumstances, when Pappas' epidural abscess would be treated. His was a mixed eligibility and treatment decision, the adverse consequences of which, if any, are properly redressed, as Pegram teaches, through state medical malpractice law." Pappas, 564 Pa. at 419-20.

argument (A. 215, 226). This argument, however, is completely wrong and fails to support the lower court's decision. In short, whenever physicians or managed care organizations make decisions about the treatment that patients should receive, they are making treatment-related decisions. Neither physicians nor managed care organizations should be able to evade responsibility for the consequences of such decisions by engaging in an exercise in semantics: i.e., by simply saying these decisions regard coverage rather than treatment. [6]

In recent years, policymakers have recognized that utilization review constitutes medical decision-making. For example, the AMA's current policy on the topic is "that utilization review decisions to deny payment for medically necessary care constitute the practice of medicine."[7]

State regulators are increasingly in accord. For example, in 1997, the Texas State Board of Medical Examiners decided that "the determination of medical necessity or appropriateness of proposed care so as to effect the diagnosis

[6] In a hearing before Congress in 1999, amicus AMA testified that "medical necessity decisions are ultimately medical decisions and should continue to be treated as such. [They] must always be made in accordance with those generally accepted standards of medical practice that a prudent physician would follow when treating a patient." Employer Health Plan Accountability: Do Plan Participants Have Adequate Protections?: Hearing Before the House Subcomm. on Employer-Employee Relations, House Comm. on Educ. and the Workforce, 106th Cong. 127 (1999) (Statement of Timothy T. Flaherty, M.D., American Medical Association), available at http://commdocs. house.gov/committees/edu/hedcew6-24.000/hedcew6-24.htm.

[7] AMA Policy H-285.939, Managed Care Medical Director Liability, available at http://www.ama-assn.org/apps/pf_online/pf_online?f_n=browse&doc =policyfiles/HOD/H-285.939.HTM&&s_t=&st_p=&nth=1&prev_pol =policyfiles/HOD/H-280.999.HTM&nxt_pol=policyfiles/HOD/H-285.922.HTM&. Moreover, *Amici* view the concept of "the practice of medicine" as being analogous to the concept in Pegram of "treatment decisions" and "mixed treatment and eligibility decisions." See 530 U.S. at 235..

or treatment of a patient is the practice of medicine." [8] In 1998, the California State Medical Board passed a resolution that "the making of a decision regarding the medical necessity. . . of any treatment constitutes the practice of medicine." [9]

In 1999, the Louisiana State Board of Medical Examiners held that "the requirement that the act of determining medical necessity or appropriateness of proposed medical care so as to effect the diagnosis or treatment of a patient in Louisiana is the practice of medicine." [10] Also, in 2001, the South Carolina Board of Medical Examiners declared that "the act of determining medical necessity or appropriateness of proposed medical care, so as to affect the diagnosis or treatment of a patient located in South Carolina, is the practice of medicine." [11]

More regulation of this type is likely, as such regulation is expressly advocated by the Federation of State Medical Boards of the United States, Inc. In 1998, this entity advised its membership, which includes the medical boards of all states and the District of Columbia, that "[s]tate medical boards, through legislative or regulatory process, should amend their medical practice acts or appropriate

[8] Texas State Board of Medical Examiners, Medical Board Report, Vol. 18, No. 2 (Spring 1997), available at http://www.tsbme.state.tx.us/ news /Spring97/ spring97.htm.

[9] See Silicon Valley San Jose Business Journal, June 5, 1998.

[10] See La. Op. Att'y Gen. No. 98-491, 1999 WL 288869, p.2 (Apr. 27, 1999).

[11] See Policy Statement approved at February 5-7, 2001 Board Meeting, available at www.llr.state.sc.us/POL/Medical/Medical%20Necessity.htm.

statutes to include the determination of medical necessity or decisions affecting the diagnosis and/or treatment of a patient as the practice of medicine."[12]

New York has considered the passage of legislation that would increase the accountability of managed care organizations.[13] Its only affirmative action thus far, however, has been an announcement in 1998 that the Office of Professional Medical Conduct will investigate complaints regarding denials of care made by medical directors of managed care organizations.[14]

Other states have taken this approach. For example, last year, Minnesota passed a law establishing that its Board of Medical Practice has jurisdiction to take action against utilization review physicians whose judgments violate the standard of care.[15] And, in 1995, the Florida Agency for Health Care Administration issued a cease and desist order against Roger Strube, a medical director of a Florida-based managed care organization. It alleged that he practiced medicine without a license in Florida by making utilization review decisions.[16]

Some courts have addressed cases arising from such laws, and allowed them to proceed. For example, in Murphy v. Board of Medical

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[12] Report of the Special Committee on Managed Care, S III.C., (May 1998), available at www.fsmb.org/Policy%20Documents%20and%20White %20Papers/ managecare.htm.

[13] See 2001 NY Assembly Bill 8318 (Mar. 28, 2001).

[14] MSSNY, News of New York, Oct. 1998, p.5.

[15] 2001 Minn. Laws 147.091, Subd. 1b.

[16] See Agency for Health Care Administration, Notice to Cease and Desist, at 1, In re Unlicensed Practice of Med.: Roger H. Strube, No. 9420668 (filed Feb. 24, 1995). The Agency did so even though Dr. Strube was licensed in two other states.

Examiners, 949 P.2d 530 (Ariz. App. 1997), the Arizona Court of Appeals ruled that the State Board of Medical Examiners had jurisdiction over a state-licensed physician who denied precertification for gallbladder surgery, on behalf of a managed care organization. Similarly, in State Board v. Fallon, 41 S.W.3d 474 (2001), the Missouri Supreme Court cited Murphy with approval in evaluating the state medical board's jurisdiction over a medical director who propounded pre-certification decisions. That court expressly found that jurisdiction was proper because the medical director's decisions were not administrative but medical:

> The determinations at issue in this case fall outside the scope of plan administration. Dr. Fallon did not simply look to a predetermined list of covered procedures to arrive at his conclusions. He used medical training and judgment to make a decision about the "medical necessity" of surgical treatment for a particular patient.[17]

In addition, a majority of states, including New York, have passed legislation requiring medical directors of managed care organizations to be licensed as physicians.[18] Such legislation is significant because it puts the lie to the contention that utilization review regards coverage alone. If that were true, then there would be no need for the "utilization reviewers" to be licensed physicians. Thus, MSSNY and other organizations call for regulations that:

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[17] See 41 S.W.3d at 478.

[18] Tanya Albert, *Higher Accountability for HMO Medical Directors*, amednews.com (May 14, 2001), available at www.ama-assn.org/sci-pubs/amnews/pick_01/ prl120514.htm ("In the past several years, more than half of the nation's states have passed laws requiring HMO medical directors to be licensed physicians. And medical directors who are licensed physicians are increasingly being held responsible by state medical boards." In fact, the Federation of State Medical Boards mandates the passage of such legislation. See n.14, supra, at III.D

> . . . will declare that any person making decisions on the medical necessity or appropriateness of care affecting the diagnosis or treatment of a patient in New York must have a license to practice medicine in New York; and that a physician making decisions on the medical necessity or appropriateness of care affecting the diagnosis or treatment of a patient in New York without a valid New York license, as well as the company that employs him/her, will be subject to investigation, criminal prosecution and possible fines.[19]

Other than New York, states with such laws include Alabama, Arizona, Arkansas, California, Delaware, Florida, Hawaii, Illinois, Indiana, Kentucky, Louisiana, Maine, Maryland, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Oklahoma, Rhode Island, South Carolina, South Dakota, Texas, Vermont and Wisconsin.[20]

Finally, the U.S. Supreme Court made clear in Pegram that a number of states permit malpractice actions against HMOs, and that such actions are consistent with ERISA.[21] In recent years, five states - Texas, Georgia, California,

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("State medical boards must, through legislative or regulatory process, require that MCO medical directors hold current and unrestricted medical licenses in the states in which the patients of the plan reside").

[19] MSSNY Position Statement § 165.969, available at http://www.mssny.org/position/ managed.htm (Jan. 14, 2002).

[20] See National Conference of State Legislatures, *Major Health Care Policies*: *50 State Profiles, 2000* (Jan. 2001) at 26-29, Table 2, and passim in the state sections.

[21] 530 U.S. at 236. In fact, one reason the Court offered for failing to recognize a breach of fiduciary action under ERISA was that such an action could be seen as "a prescription for preemption of state malpractice law. . . ." As shown by Pappas, supra, and other cases discussed in Appellant's brief, such cases have proceeded under state common law in state and federal courts.

Arizona and Washington - have passed laws expressly giving consumers expanded rights to sue their HMOs. Other states actively are debating similar legislation.[22]

These policies, regulations, laws and decisions collectively illustrate that Vytra and Dr. Spears engaged in what *Amici* recognize as the practice of medicine, and what the U.S. Supreme Court described as "mixed eligibility and treatment decisions." Semantics aside, the outcome is clear. The decisions are subject to liability under state law and fall outside the scope of preemption.

CONCLUSION

For the reasons set forth above, *Amici* AMA and MSSNY respectfully request that this Court reverse the Eastern District of New York's decision to dismiss the state law claims against Vytra and Dr. Spears, and remand this case to state court.

Dated: January 29, 2002

Respectfully submitted,

AMICI CURIAE AMERICAN MEDICAL ASSOCIATION AND THE MEDICAL SOCIETY OF THE STATE OF NEW YORK

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[22] Phyllis C. Borzoi, *Erisa and Managed Care Plans: Key Preemption and Fiduciary Issues*, SF28 ALI-ABA 371 (Oct. 2000) at 423 n.2.

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CERTIFICATE OF COMPLIANCE

Rhonda D. Orin, attorney of record for *Amici Curiae* American Medical Society and the Medical Society of the State of New York certifies that the foregoing brief complies with the type volume limitation of F.R.A.P. Rule 32; that the number of words in the brief is 3,484, including footnotes, and that she relies on the word count of the word-processing system used to prepare the brief.

Dated: January 29, 2002

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Rhonda D. Orin (RO-0359)

CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on January 29, 2002, she caused the following documents:

1. Motion Information Form and Motion of American Medical Association and Medical Society of the State of New York for Leave to Appear as Amici Curiae, along with the Affidavit of Rhonda D. Orin in Support, and

2. American Medical Association's and Medical Society of the State of New York's Brief in Support of Appellant, Bonni Cicio, individually and as adminstratrix of the estate of Carmine Cicio,

to be served, via United States Mail, first-class, postage pre-paid, on:

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