UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 06-5133

RENAL PHYSICIANS ASSOCIATION,

Plaintiff/Appellant,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants/Appellees.

On Appeal from the United States
District Court for the District of Columbia
in Case No. 05-CV-0067 (Honorable Reggie B. Walton, Judge)

BRIEF *AMICI CURIAE* FOR AMERICAN MEDICAL ASSOCIATION, AMERICAN SOCIETY OF ANESTHESIOLOGISTS, INFECTIOUS DISEASES SOCIETY OF AMERICA, AMERICAN COLLEGE OF PHYSICIANS, AND AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS IN SUPPORT OF PLAINTIFF/APPELLANT AND REVERSAL

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28, the undersigned counsel of record certifies as follows:

A. Parties and *Amici*

1. The parties and *amici* in the district court and in this Court are as follows:

Renal Physicians Association, plaintiff/appellant

United States Department of Health and Human Services, defendant/appellee

Secretary of Department of Health and Human Services, defendant/appellee

Administrator of Centers for Medicare and Medicaid Services, defendant/appellee

American Medical Association, *amicus curiae*

American Society of Anesthesiologists, Inc., *amicus curiae*

Infectious Diseases Society of America, *amicus curiae*

American College of Physicians, *amicus curiae*

American Association of Clinical Endocrinologists, Inc., *amicus curiae*

2. Pursuant to Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1, *amici* state the following:

American Medical Association, *amicus curiae*, is an Illinois non-profit corporation and association of physicians. It has no parent companies, and there are no publicly-held companies which have a 10% or greater ownership interest in it.

American Society of Anesthesiologists, *amicus curiae*, is a non-profit association of physicians. It has no parent companies, and there are no publicly-held companies which have a 10% or greater ownership interest in it.

Infectious Diseases Society of America, *amicus curiae*, is a non-profit association of physicians. It has no parent companies, and there are no publicly-held companies which have a 10% or greater ownership interest in it.

American College of Physicians, *amicus curiae*, is a non-profit association of physicians. It has no parent companies, and there are no publicly-held companies which have a 10% or greater ownership interest in it.

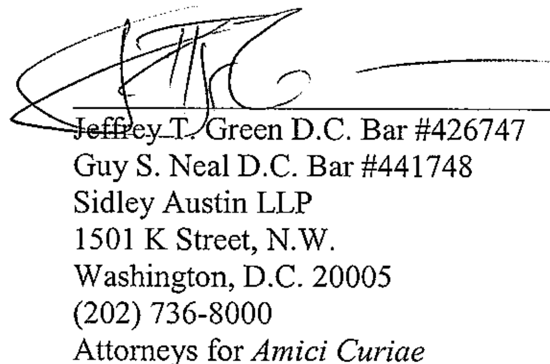
American Association of Clinical Endocrinologists, Inc., *amicus curiae*, is a non-profit association of physicians. It has no parent companies, and there are no publicly-held companies which have a 10% or greater ownership interest in it.

B. Rulings under Review

A reference to the ruling at issue, *Renal Physicians Association v. Department of Health and Human Services*, 422 F. Supp.2d 75 (D.D.C. 2006), appears in the Brief for Renal Physicians Association, Plaintiff/Appellant, at p.ii.

C. Related Cases

Amici curiae are unaware of any related cases.



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GLOSSARY

AACE	American Association of Clinical Endocrinologists
ACP	American College of Physicians
AMA	American Medical Association
ASA	American Society of Anesthesiologists
CMS	Centers for Medicare & Medicaid Services
ESRD	End-Stage Renal Disease
HHS	United States Department of Health and Human Services
IDSA	Infectious Diseases Society of America
RPA	Renal Physicians Association

INTERESTS OF *AMICI CURIAE*

The American Medical Association ("AMA") is a private, voluntary, not-for-profit corporation, whose members are approximately 240,000 physicians, residents, and medical students. Its members practice in all fields of medical specialization and in every state. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health. The AMA submits this brief on its own behalf and as a member of the Litigation Center of the AMA and the State Medical Societies.[1]

The American Association of Clinical Endocrinologists ("AACE") is a national, nonprofit association of approximately 5,300 physicians engaged in the medical subspecialty of endocrinology. Since it was founded in 1990, AACE has functioned as a research, scientific, and educational resource to advance its primary goals of raising and maintaining the standards of medical practice of endocrinology and improving patient care.

The American College of Physicians ("ACP") is the nation's largest medical specialty organization, representing 120,000 general internists, internal medicine sub-specialists, and medical students. Its mission is to enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine.

The American Society of Anesthesiologists ("ASA") is a national, nonprofit association of approximately 41,000 physicians and other scientists from around the world engaged or especially interested in the medical specialty of anesthesiology. More

[1] The Litigation Center is a coalition of the AMA and the medical societies of every state and the District of Columbia. The mission of the Litigation Center is to be an effective legal advocate in representing the interests of the medical profession in the courts by bringing or participating in cases of broad impact.

than ninety percent of all practicing anesthesiologists in the United States belong to the ASA, making it the preeminent voice of the specialty. Since it was founded in 1905, the ASA has functioned as a research, scientific, and educational resource to advance its primary goals of maintaining the standards of the medical practice of anesthesiology and improving patient care.

The Infectious Diseases Society of America ("IDSA") represents over 8,000 physicians, scientists, and other health care professionals who specialize in infectious diseases. Its purpose is to improve the health of individuals, communities, and society by promoting excellence in patient care, education, research, public health, and prevention relating to infectious diseases.

Amici are concerned about the methodologies for determining "fair market value" set forth within 42 C.F.R. § 411.351. Although this case focuses on the compensation paid to medical directors of outpatient kidney dialysis facilities, this Court's ruling will affect numerous other physicians. *Amici* believe that their expertise and knowledge in the area of health care give them a distinct and insightful perspective on certain key issues in this case and that this brief will assist this Court in better understanding these issues.

STATEMENT OF THE CASE

A section of the Social Security Act commonly known as the Stark Law, 42 U.S.C. § 1395nn, generally prohibits physicians from referring Medicare patients to health care facilities with which the physicians have a "compensation arrangement." This statute, intended to prevent conflicts of interest, has numerous exceptions. One such exception allows referrals to physicians' employers if the physicians are paid the fair market value of their services, without considering the volume or value of any referrals. 42 U.S.C. § 1395nn(e)(2).

The regulation at issue in this case, 42 C.F.R. § 411.351, establishes two methods for determining fair market value of physician services. These methodologies are seen as "safe harbors" for determining fair market value under the Stark Law.

The members of plaintiff, Renal Physicians Association ("RPA"), are commonly retained, on an independent contractor basis, as medical directors at outpatient kidney dialysis facilities. RPA's members are also commonly in a position to refer Medicare patients to dialysis facilities for treatment. Because the dialysis facilities naturally wish to allow referrals from their medical directors, the facilities have a strong incentive to set the medical directors' compensation within the safe harbor methodologies.

RPA's complaint, brought against the United States Department of Health and Human Services ("HHS"), the Secretary of HHS and the Administrator of the Centers for Medicare & Medicaid Services ("CMS"), a division of HHS, maintained that the regulation's methodologies for determining fair market value are defective as applied to its members. In fact, according to RPA, fair market value compensation for medical directors of outpatient dialysis facilities should be substantially more than the safe harbor

which results from application of the regulation's methodologies. As a practical matter, though, the dialysis facilities are likely to adopt a salary that falls within the regulatorily determined safe harbor, even if that salary falls beneath the fair market value of the medical directors' services. There is little the medical directors can do to negotiate additional compensation outside the safe harbor. Thus, due to the allegedly defective methodologies of the regulation, outpatient dialysis facilities are paying their medical directors less than fair market value rates.

This result is at odds with the statutory intent. The complaint sought a declaratory judgment invalidating the safe harbor provision.

The defendants moved to dismiss the complaint under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction. The motion asserted that RPA lacked standing to challenge the regulation and that, in any event, the regulation was a purely discretionary action of the defendants and not judicially reviewable.

The court below granted the motion and dismissed the case based on one narrow holding. Relying heavily on *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), and *National Wrestling Coaches Ass'n v. Dep't. of Education*, 366 F.3d 930 (D.C. Cir. 2004), it found that RPA lacked Article III standing, because the injury the medical directors suffered could not be redressed even if the safe harbor provision were to be held invalid. The court asserted that "the ultimate injury arises not from the safe harbor provision itself, but from regulated third parties [*viz.*, outpatient dialysis facilities] who 'insist on limiting medical director compensation to the safe-harbored levels.'" Further, the court concluded, the injury to the physicians' interests is now irrevocable, regardless of whether the regulation were to be invalidated:

> The safe harbor provision has put employers on notice that the CMS considers compensation rates matching those derived by the articulated methodologies to be within the fair market value for the purposes of the Stark Law exception. This notice, and employers' knowledge that use of the methodologies represents a regulatory safe harbor, will persist whether or not the Court grants the plaintiff's requested relief. In any event, even if the safe harbor is rescinded ... dialysis facilities would remain free to set compensation rates at safe-harbored levels, with or without the use of the challenged methodologies, and the CMS would remain free to determine that such rates 'are comparable to what is ordinarily paid ... by parties in arm's length transactions who are not in a position to refer to one another.
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> * * * *
>
> By approving the safe harbor methodologies, the defendants have informed employers that certain rate calculations yield fair market value, and the Court cannot 'unring the bell [now that] the information has been released' simply by invalidating the challenged provision.

Thus, the trial court concluded, dialysis facilities would continue to set medical directors' compensation at safe harbor levels even if that provision were to be invalidated. The injury caused by the safe harbor provision would, according to the court, be unredressable, no matter how it might rule.

SUMMARY OF ARGUMENT

The trial court's conclusion that the medical directors' injury is unredressable is at odds with everyday experience and logic. There is no reason to believe that the government, the renal dialysis facilities, or the medical directors themselves will continue to honor the safe harbor methodology if it is struck down, and there is every reason to think otherwise.

The trial court's conclusion is also wrong empirically. *Amici*'s experience is that the safe harbor provisions in the Stark Law are powerful considerations within the health care industry, which frequently overcome the ordinary supply and demand factors that would otherwise set prices in an unregulated market. Unlike the trial court's conjecture about the behavior of marketplace participants, the RPA claim is based on evidence.

This brief will so demonstrate.

ARGUMENT

I. Contrary to the Trial Court's Speculation, Medical Directors' Compensation Will Not Remain the Same if the Safe Harbor Provision is Invalidated: the Bell Can be Unrung.

No one, of course, can know how the market would react if the safe harbor provision were to be struck down. It seems reasonable, though, that the removal of an aberration will restore the condition that existed prior to the creation of that aberration, particularly when free market mechanisms are allowed to operate. Certainly, at the Rule 12(b) motion stage such inference should be indulged.

Based on pure speculation, the trial court saw the matter differently. The opinion held, even assuming the safe harbor provision were to be found invalid *ab initio*, that its effect will be permanent, not to be abated with time. For some reason, the dialysis

facilities would proceed as though the government were still bound to the safe harbor provision and would set their compensation levels accordingly, regardless of any judicial rulings.

This holding posits multiple, unfounded assumptions about human psychology, and it disregards marketplace dynamics. To begin with, if this Court were to find the safe harbor provision invalid, then there is no reason to expect the government to honor it and there is no reason to expect dialysis facilities or medical directors to rely upon it. The shift in the marketplace would be immediate.

Furthermore, even if the safe harbor provision could have some sort of lingering effect, that effect would erode with time. However government prosecutors may be presently disposed regarding proper compensation for medical directors, new health care attorneys will come to the bar and newly minted MBAs will succeed to the management of dialysis clinics. These attorneys and these managers will have their hands full to learn the law and the financial conditions as they exist at the moment; they will have little inclination or opportunity to study a regulatory provision that has been legally invalidated and to ponder whether or how that invalid regulation might shape law enforcement actions. The safe harbor provision would simply be forgotten or ignored, and the bell would then be unrung.[2]

Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992), provides no support for the trial court's holding. The issue there was whether the plaintiff organizations had standing to litigate the validity of a regulation that allowed federal agencies to fund projects

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[2] The trial court quoted *Maness v. Meyers*, 419 U.S. 449, 460 (1975), for the statement that "the Court cannot 'unring the bell [now that] the information has been released.'" *Maness* considered the ethical and practical dilemmas faced by litigants and their attorneys who wish to challenge court orders that require disclosure of arguably privileged information. Neither the holding nor the reasoning of *Maness* has significant relevance to the issue at bar.

outside the United States without complying with the full requirements of the Endangered Species Act, 16 U.S.C. § 1536. The Court discussed the criteria for legal standing at length, and it mentioned several areas in which the plaintiffs' case fell short, with a particular focus on redressability. The Court pointed out that only the Secretary of the Interior was a defendant in the lawsuit, whereas the funding agencies whose actions had been challenged were not parties. Thus, even if the case were to be decided in favor of the plaintiffs, they would not have meaningful redress, as the other federal agencies would not be bound by the ruling. The Court noted:

> [When] standing depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict ... it becomes the burden of the plaintiff to adduce facts showing that those choices have been or will be made in such manner as to produce causation and permit redressability of injury.... Thus, when the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily substantially more difficult to establish.

504 U.S. at 562. (Internal citations and quotation marks omitted).

The differences between the *Lujan* situation and the case at bar are manifest. For one thing, the compensation levels likely to be set by the dialysis facilities are not "unfettered," they will be constrained by the rigors of the open market. For another, the compensation to be paid the medical directors will depend in part on the decisions of the medical directors themselves, persons who are an object of the safe harbor regulation and are before this Court, at least through the *persona* of their professional association. The safe harbor regulation acts directly upon the renal physicians and only indirectly on the dialysis facilities. Further, the language quoted above explicitly cautions that standing is not precluded merely because the government regulation in question will have some effect upon third parties.

National Wrestling Coaches Ass'n v. Dep't. of Education, 366 F.3d 930 (D.C. Cir. 2004), is also off point. Title IX of the Education Amendments of 1972, 20 U.S.C. §§ 1681, *et seq.*, as well as the implementing regulations of the Department of Health, Education, and Welfare (now HHS), 34 C.F.R. § 106.41, prohibited sexual discrimination in federally funded educational programs and activities. The Department of Health, Education, and Welfare had promulgated a "Policy Interpretation" and "clarification" to advise the public about the tests it used to measure compliance with certain aspects of Title IX and the implementing regulations. The plaintiffs, several membership organizations that purportedly represented the interests of collegiate men's wrestling coaches, athletes, and alumni, sued to have the Policy Interpretation and clarification declared invalid, claiming that those statements had led to the elimination of men's varsity wrestling programs at certain universities. The plaintiffs did not, however, challenge the validity of Title IX or the implementing regulations.

This Court held that the plaintiffs lacked standing, both because there was no reason to think that the Policy Interpretation and clarification had injured the plaintiffs and because there were independent causes at work which would not be redressed by a favorable ruling. There was thus no reasonable likelihood that invalidation of the Policy Interpretation and clarification would affect collegiate wrestling. Any curtailment of the wrestling programs was ultimately either a result of the statute and regulations, whose enforceability was not at issue, or of other independent forces. Accordingly, no judicial action could redress the plaintiffs' claimed injury.

An important distinction between *National Wrestling* and the case at bar is that here RPA has alleged that the safe harbor provision caused the dialysis facilities to lower

their compensation rates, whereas no such cause and effect relationship was discernable in *National Wrestling*. Moreover, a mechanism – the free market -- exists in this case to rectify the damage. Here, unlike in *National Wrestling*, there is every reason to think that invalidation of the offending regulation will effect a discernable change.

II. In Light of the Risks of Violating the Stark Law, the Safe Harbor Rule is Frequently the Practical Method of Choice to Determine the Fair Market Value of Physicians' Compensation.

RPA's brief, under the "Standard of Review" section, pp. 13-14, cites extensive case law for the proposition that a Rule 12(b)(1) motion contemplates acceptance of all material allegations of the complaint as true, including the drawing of all reasonable inferences in favor of the plaintiff. *Amici* will not repeat RPA's legal arguments on this issue, which are incontrovertible. In fact, the trial court itself conceded the validity of the point, although the decision then went on to transgress the applicable standard.

This basic rule for evaluating pleadings should obviate any need to examine the factual underpinnings behind the complaint. Such rule forbids the speculation about market dynamics that the trial court used to justify the dismissal. Nevertheless, because *amici* cannot know how this Court will view the market for dialysis facility medical directors, *amici* add their voices to RPA's allegations of economic harm.

The market is such that the improper methodologies used to develop the safe harbor provision can lead to payment distortions, even if, as here, the regulatory scheme does not make the safe harbor payment mandatory. It is reasonable to conclude that what can be distorted through regulation can be rectified through deregulation. The likelihood of redressability is based on more than conjecture.

A. The Stark Law's Strict Liability Scheme, with its Extreme Penalties, Threatens Physicians Who Participate in Federal Health Care Programs with Onerous Sanctions.

The Stark Law applies to any physician referring a patient enrolled in Medicare, Medicaid, or any other federally sponsored health care program. 42 U.S.C. § 1395nn. Liability under the statute is strict, so the intent of those who make referrals in violation of its prohibitions, even in an emergency situation, is irrelevant. Individuals or entities may face denial or mandatory refund of payments for improperly referred services, a civil penalty of up to $15,000 for each referral or claim found to be in violation of the law, a civil penalty of $100,000 for any attempt to circumvent the Stark Law, or possible exclusion from Medicare, Medicaid, or other federally sponsored health care programs. 42 U.S.C. §§ 1395nn(g) & 1320a-7.

Because of the strict liability nature of the Stark Law and the onerous penalties involved, violations of the statute may prove catastrophic for physicians who participate in federally sponsored health care programs. Dialysis center medical directors who treat patients with end-stage renal disease ("ESRD") and refer to dialysis facilities are examples of such physicians.

Approximately 90% of ESRD patients are covered by Medicare. United States General Accounting Office, *Medicare Dialysis Facilities: Beneficiary Access Stable and Problems in Payment System Being Addressed* (June 2004). As of 2004, the latest year for which data is publicly available, approximately 310,000 ESRD patients were receiving Medicare benefits. Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy* (March 2006), at p. 109. This number is expected to grow dramatically, due to the aging of the United States population as well as the

increasing number of people with diabetes, a disease that is both a risk factor for ESRD and its most frequent underlying cause.

The increasing volume of these ESRD patients enrolled in Medicare means that dialysis center medical directors frequently receive the majority of their income from the federal government. Thus, the pressure on these medical directors to comply with the Medicare regulations is even greater than it is for other physicians.

While this precise issue has not made its way to the Supreme Court, the Court has nevertheless recognized how powerfully an artificially determined price can impact marketplace behavior. Maximum pricing agreements are routinely deemed *per se* Sherman Act violations, in part because of the judicial recognition that a maximum price can easily become a minimum price. *See, e.g., Arizona v. Maricopa County Medical Society*, 457 U.S. 332 (1982). No serious argument can be made that the harm done by such a maximum pricing agreement is unredressable or that the courts lack subject matter jurisdiction to strike down such an arrangement.

B. Federal Regulators and Prosecutors Scrutinize Physicians Who Participate in Federally Sponsored Health Care Programs to Ensure Strict Compliance with Anti-Fraud Regulations.

In recent years, physicians have faced an increasingly onerous regulatory environment. The threat of health care fraud prosecutions impacts numerous business decisions made by hospitals and other medical facilities, such as decisions concerning physician compensation rates. Federal investigators have decidedly increased their efforts to prosecute health care fraud and to recoup overcharges and funding shortfalls. While such efforts are not solely confined to violations of the Stark Law, they indicate a larger trend under which federal regulators and prosecutors are asserting ever greater

regulatory pressure on physicians who participate in federally sponsored health care programs.

According to HHS and the United States Department of Justice, the funds collected by federal prosecutors as a result of enforcement actions, judgments, settlements, and administrative proceedings in health care fraud cases quintupled from $296 million in 1998 to $1.5 billion in Fiscal Year 2005. Over $310 million was paid to the United States solely as a result of claimed fraud in billing for dialysis treatments. U.S. Dep't of Health and Human Servs. and U.S. Dep't of Justice, *Health Care Fraud and Abuse Control Program: Annual Report for FY 2005* (August 2006) and U.S. Dep't of Health and Human Servs. and U.S. Dep't of Justice, *Health Care Fraud and Abuse Control Program: Annual Report for FY 1998* (February 1999). Other statistics further confirm this trend. For instance, in 1998 federal prosecutors filed or intervened in 107 new civil cases, while in 2005 they filed or intervened in 266 new civil cases.

Moreover, in 2005 CMS initiated a pilot program under which private auditors are hired to scour Medicare claims to ensure compliance and proper reimbursement rates. 42 U.S.C. § 1395kk-1. Although the participating auditing firms are theoretically responsible for finding both overpayments and underpayments, in practice the contractors are compensated based only on how much in overpayments they recoup from physicians. David Glendinning, *Doctors Wary of Medicare Audit Plan's Incentives*, AMNews (April 4, 2005).[3] On November, 2006, CMS reported that these audits had already identified $290 million in alleged overpayments. CMS, *RAC Status Document for FY 2006. See also*, David Glendinning, *Medicare Touts Audit Plan Success as Doctors Decry "Bounty*

[3] "AMNews" refers to American Medical News, a weekly publication of the American Medical Association. AMNews can be found at http://www.ama-assn.org/amednews/index.htm.

Hunters," AMNews (December 18, 2006).

State governments, too, are increasing their efforts to recoup money spent as part of their health care programs. In response to the growth in Medicaid spending, some states have hired private firms to audit physicians participating in their Medicaid programs. Joel B. Finkelstein, *States Trying to Recoup Medicaid Money*, AMNews (May 23, 2005).

Physicians are faced with innumerable complex regulations. Medicare regulations alone consist of over 110,000 pages of official rules and policies. AMA, *Rethinking Medicare: Solutions for Medicine's Short- and Long-Term Problems*, (2002), *at* http://www.ama-assn.org/ama/pub/category/3374.html. Moreover, CMS publishes thousands of Medicare intermediary letters and program memoranda for physicians to monitor. These intermediaries and carriers, in turn, issue their own bulletins, interpretations, and local medical review policies. The HHS Office of Inspector General issues fraud alerts, model compliance programs, and other pronouncements on behalf of various government enforcement agencies. *See* Linda A. Baumann, *Health Care Fraud and Abuse: Practical Perspectives* (BNA 2002), at p. 221.

Because of the enormous pressure to comply with the Stark Law, as well as the myriad other regulations, a bright line safe harbor rule, if available, becomes an almost compulsory standard. As a practical matter, many physicians, such as those who run dialysis facilities, will have their compensation largely determined by the safe harbor methodologies. The impact on these physicians of a flawed regulation is significant. Safe harbor regulations, not just a classically free market, often determine physician compensation rates.

CONCLUSION

In this case, at least, what can be done by enactment of an unlawful regulation can be undone by invalidation of that regulation.

WHEREFORE, *amici curiae* urge this Court to reverse the judgment of the lower Court and remand this case for adjudication on the merits.

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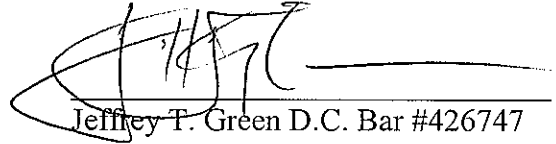
CERTIFICATE AS TO WORD COUNT

Pursuant to Fed. R. App. P. 32(a)(7)(C) and Circuit Rule 32(a), I certify that the foregoing Brief *Amici Curiae* in Support of Appellant Renal Physicians Association contains 5,107 words.



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I, Guy S. Neal, an attorney, certify that on December 18, 2006, two copies of the foregoing Brief *Amici Curiae* in Support of Appellant Renal Physicians Association were served by United States Mail on the following counsel:

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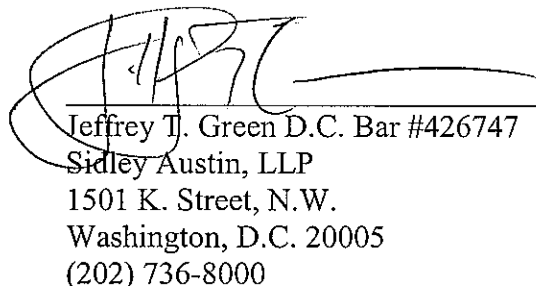

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