

**UNITED STATES COURT OF APPEALS  
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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No. 06-5133

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**RENAL PHYSICIANS ASSOCIATION,**

**Plaintiff/Appellant,**

**v.**

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

**Defendants/Appellees.**

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On Appeal from the United States  
District Court for the District of Columbia

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**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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Jon N. Ekdahl  
Leonard A. Nelson  
American Medical Association  
515 N. State St.  
Chicago, IL 60610  
(312) 464-5532

Guy S. Neal  
Sidley Austin, LLP  
1501 K. Street, N.W.  
Washington, D.C. 20005  
(202) 736-8000  
*Local Counsel*

Date: December 8, 2006

**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

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 appears in the Brief for Renal Physicians Association, Plaintiff/Appellant.

**C. Related Cases**

*Amici curiae* are unaware of any related cases.

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Guy S. Neal  
Sidley Austin, LLP  
1501 K. Street, N.W.  
Washington, D.C. 20005  
(202) 736-8000  
Attorneys for *Amici Curiae*

Date: December 8, 2006

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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 THE *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 *Amici Curiae* on its own behalf and as a member of the Litigation Center of the AMA and the State Medical Societies.<sup>1</sup>

The American Association of Clinical Endocrinologists (“AAACE”) is a national, nonprofit association of approximately 5,300 physicians engaged in the medical subspecialty of endocrinology. Since it was founded in 1990, AAACE 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 117,000 general internists, internal medicine subspecialists, 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 40,000 physicians and other scientists from around the world engaged or especially interested in the medical specialty of anesthesiology. More than ninety percent of all practicing anesthesiologists in the United States belong to the

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<sup>1</sup> 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.

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 deeply concerned about the likely impact the “fair market value” safe harbor regulation, included within 42 C.F.R. § 411.351, will have on the compensation rates of many physician specialties, not just those of the medical directors of outpatient dialysis centers. They believe that their expertise and knowledge in the area of health care give them a distinct and insightful perspective on many of the key issues in this case and that a brief from *amici curiae* would assist this Court in better understanding these issues.

## SUMMARY OF ARGUMENT

The court below dismissed the case based on one narrow ruling: Renal Physicians Association (“RPA”), a professional association of physicians, acting on behalf of its members, supposedly lacked Article III standing because the injury its members had suffered resulted from the actions of third parties, rather than from the regulation at issue. The injury, therefore, would not be redressable by judicial relief. This conclusion is at odds with everyday experience and logic. It is also wrong empirically. *Amici*’s brief will so demonstrate.

## ARGUMENT

The Stark Law, 42 U.S.C. § 1395nn, to prevent conflicts of interest, generally prohibits physicians from referring Medicare patients to health care facilities with which the physician has a “compensation arrangement.” This statute, however, has numerous exceptions. One such exception allows referrals to the physician’s employer if the physician is paid the fair market value of his or her 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.

RPA’s members are commonly employed 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 under one of the safe harbor methodologies.

RPA maintains 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 methodologies. As a practical matter, though, the dialysis facilities are likely to adopt a salary that falls within a 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 harbors. Thus, due to the allegedly defective regulation, outpatient dialysis facilities are paying their medical directors less than fair market value rates.

The court below, 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), found that RPA lacked Article III standing, because the injury the medical directors suffered would not be redressed by holding the regulation invalid.<sup>2</sup> 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 is 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

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<sup>2</sup> The defendants raised other threshold arguments as well, but the lower court made clear that its decision was premised solely on the redressability issue.

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.'

\* \* \* \*

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 the regulation were to be invalidated. The injury caused by the safe harbor regulation would therefore be unredressable, no matter how the court might rule. That conclusion, however, is based on pure speculation and simply does not withstand analysis.

**I. Contrary to the Trial Court's Speculation, Medical Directors' Compensation will not Remain the Same if the Regulation is Invalidated: the Bell Can be Unrung.**

To restate the issue -- the complaint has alleged, either directly or by inference, that prior to the contested regulation compensation rates for directors of outpatient dialysis facilities were determined by fair market valuations. Due to the new regulation and to market imperfections, compensation rates are now set at rates substantially below the fair market value of the services purchased, a result at odds with Congressional intent. If the regulation is invalidated, compensation rates will revert to their normal, fair market value levels. Thus, according to RPA (and to *amici*), judicial action will redress the injury suffered by RPA's members.

No one, of course, can know how the market will react if the safe harbor provision is stricken 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.

The trial court, however, saw the matter differently. The opinion holds, even assuming the safe harbor provision is found invalid *ab initio*, that its effect will be permanent, not to be abated with time. For some reason, the dialysis facilities will proceed as though the government is still bound to the safe harbor provision and will 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 will be immediate.

Furthermore, even if the safe harbor provision could have some sort of lingering effect, that effect will 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 regulation that has been legally invalidated and to ponder whether or how that invalid regulation is likely to shape law enforcement actions.

The safe harbor provision will simply be forgotten or ignored, and the bell will then be unrung.<sup>3</sup>

*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 outside the United States without complying with the full requirements of the Endangered Species Act, 16 U.S.C. § 1536. Standing was supported by testimony that one member of the plaintiff organizations had traveled to Egypt to observe the endangered Nile crocodile and hoped to do so again, and another member had traveled to Sri Lanka and also hoped to repeat that trip and observe the habitats of various endangered species. 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 that

“[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

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<sup>3</sup> 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.

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 *personum* 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, because there was no reason to think that the Policy Interpretation and clarification had injured the plaintiffs. 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 a result of the statute and regulations, whose enforceability was not at issue. Accordingly, no judicial action could redress the plaintiffs' claimed injury.

The principal 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, 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 violate 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* adds their voices to support 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 HealthCare Programs with Onerous Sanctions.**

The Stark Law applies to any individual or entity 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. *Id.* 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) and 42 U.S.C. § 1320a-7a(c)(1).

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 2002, the latest year for which data is publicly available, approximately 300,000 ESRD patients were receiving Medicare benefits. Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy* (March 2005), at p. 122. 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. *Id.*

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.

**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 more than quadrupled from \$296 million in 1998 to \$1.3 billion in 2003. 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 2003* (December 2004) 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 107 new civil cases, while in 2003 they filed 231 new civil cases. *Id.*

Moreover, in several states CMS has initiated a pilot program under which private auditors are hired to scour Medicare claims to ensure compliance and proper reimbursement rates. 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), at p. 5. This plan seeks to dig deeper into physician records than agency contractors typically do at the present.

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), at p. 5.

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*, 2 (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 Rule. 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**

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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Guy S. Neal  
Sidley Austin, LLP  
1501 K. Street, N.W.  
Washington, D.C. 20005  
(202) 736-8000  
Local Counsel for *Amici Curiae*

Jon N. Ekdahl  
Leonard A. Nelson  
American Medical Association  
515 N. State Street  
Chicago, Illinois 60610  
(312) 464-5532

Date: December 8, 2006

**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 \_\_\_\_\_ words.

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Guy S. Neal

**CERTIFICATE OF SERVICE**

I, Guy S. Neal, an attorney, certify that on December 8, 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:

Robert Plotkin  
McGuireWoods LLP  
1050 Connecticut Avenue, N.W., Suite 1200  
Washington, D.C. 20036

Thomas M. Bondy  
Room 7535  
United States Department of Justice  
950 Pennsylvania Avenue, N.W.  
Washington, D.C. 205300

---

Guy S. Neal  
Sidley Austin, LLP  
1501 K. Street, N.W.  
Washington, D.C. 20005  
(202) 736-8000