Nos. 01-806, 01-7087 and 01-7152

IN THE

Supreme Court of the United States

DAN H. ANDERSON, ROBERT C. LAHUE
AND RONALD H. LAHUE

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Tenth Circuit

BRIEF OF *AMICI CURIAE*
AMERICAN HOSPITAL ASSOCIATION
FEDERATION OF AMERICAN HOSPITALS
ASSOCIATION OF AMERICAN MEDICAL COLLEGES
AMERICAN OSTEOPATHIC ASSOCIATION
MISSOURI HOSPITAL ASSOCIATION
IN SUPPORT OF PETITIONERS

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INTEREST OF THE *AMICI CURIAE*[1/]

The *Amici* are the nation's leading representatives of hospitals, allopathic medical schools and their faculty physicians, and osteopathic physicians. We urge the Court to review an issue of deep concern raised by these Petitions: Whether 42 U.S.C. § 1320a-7b(b) (the "Anti-kickback Statute") criminalizes health care financial arrangements that inherently involve referrals.

Referrals are typically an intrinsic and necessary part of contemporary arrangements between hospitals and physicians. Although the Tenth Circuit seemed to acknowledge this reality in its opinion, it created a conflicting standard that appears to require that lawful financial arrangements be devoid of any such inherent referrals. The practical effect of this standard is that jurors will likely find innocent conduct criminal. *Amici* seek review because this decision casts a cloud over a wide array of heretofore acceptable hospital-physician arrangements that inherently involve referrals.

Amici are five hospital and medical organizations, representing approximately 5,000 hospitals, 125 U.S. medical schools, and 30,000 osteopathic physicians. *Amici* are dedicated to the delivery of quality, cost-effective health care and constantly seek to improve the nation's health care system. *Amici* share the government's concern with fraud and abuse, and they support efforts directed at prevention and punishment of

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[1/] No party or party's counsel in this matter has authored any part of this brief in whole or in part, nor has any person or entity other than the *Amici*, their members, and their counsel made any monetary contribution to the preparation or submission of this brief. *See* Sup. Ct. R. 37.6. The parties' written consents to the filing of this brief have been lodged with the Clerk.

providers who commit fraud.[2/] But well-intentioned efforts to eradicate fraud could jeopardize standard health care practices that are not within the Anti-kickback Statute's plain meaning and do not raise concerns that the fraud and abuse statutes were meant to prevent.

Each of the *Amici* is a long-standing leader among organizations of hospital and medical providers and educators. The American Hospital Association ("AHA"), a nonprofit association founded in 1898, is the primary national membership organization for hospitals and health systems in the United States. Its membership includes nearly 5,000 hospitals, health systems, networks, and other health care providers. The AHA's mission is to advance the health of individuals and communities; the AHA leads, represents, and serves health care provider organizations that are accountable to the community and committed to health improvement.

The Federation of American Hospitals is the national representative of 1,700 privately owned or managed community hospitals and health systems throughout the United States. Its members range from small rural hospitals to large urban medical centers and offer a variety of services including acute hospital care, outpatient services, skilled nursing care, rehabilitation, and psychiatric care.

The Association of American Medical Colleges ("AAMC") is a nonprofit association comprised of 125 accredited U.S. medical schools; 16 accredited Canadian medical schools; more than 400 major teaching hospitals and health systems, including 70 Department of Veterans Affairs medical centers; over 90 academic and

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[2/] *Amici* express no view as to the application of the properly interpreted law to the facts of this case.

professional societies representing 75,000 faculty members; and the nation's medical students and residents. The AAMC seeks to strengthen the quality of medical education and training, to enhance the search for biomedical knowledge, to advance research in health services, and to integrate education into the provision of effective health care.

The American Osteopathic Association ("AOA"), an Illinois nonprofit corporation with approximately 30,000 osteopathic physicians as members, is the national professional association for osteopathic physicians and osteopathic medicine. Organized in 1897 to advance the philosophy and practice of osteopathic medicine, the AOA accredits colleges of osteopathic medicine, approves osteopathic postdoctoral training programs (i.e., internships, residencies and fellowships), inspects and accredits hospitals throughout the United States, and offers a program of board certification for osteopathic physicians in 18 medical specialties.

The Missouri Hospital Association ("MHA"), a nonprofit membership corporation, represents approximately 140 hospitals throughout Missouri. MHA members include most of the nonprofit and for-profit hospitals, children's hospitals, federal and state hospitals, rehabilitation and psychiatric care facilities, and specialty hospitals in Missouri.[3/]

[3/] When the relationships at issue in this case were formed, Baptist Medical Center ("Baptist") was not part of an integrated health care delivery system. However, in 1991 Baptist joined such a system with Health Midwest as its sole corporate member. Richard Brown is the Chief Executive Officer of Health Midwest and is a member of MHA's Board of Trustees, currently serving as Treasurer. The Petitioner, Dan Anderson, served as the Chief Executive Officer of Baptist at the time of the transactions that are at issue in the case below, and for a

ARGUMENT

MOST ARRANGEMENTS BETWEEN HOSPITALS AND PHYSICIANS INHERENTLY INVOLVE REFERRALS AND ARE JEOPARDIZED BY THE STANDARD APPLIED IN THIS CASE BY THE TENTH CIRCUIT

Petitioners validly challenge the jury instruction that the Tenth Circuit approved in the decision below in *United States v. LaHue*, 261 F.3d 993, 1008 (10th Cir. 2001), and previously in *United States v. McClatchey*, 217 F.3d 823, 834-35 (10th Cir.), *cert. denied*, 531 U.S. 1015 (2000).[4/] Although the Tenth Circuit considered the implications for the health care community of its broad interpretation, its decision wrongly puts most arrangements between hospitals and physicians at risk by permitting the jury to convict unless it finds that the reason for the financial arrangement is "entirely distinct" from any "hope for" referrals. *LaHue*, 261 F.3d at 1008; citing, *McClatchey*, 217 F.3d at 834 & n. 7. The many benign financial arrangements between hospitals and physicians that intrinsically involve referrals can rarely survive this standard. In today's health care system, inherent referrals are an inseparable part of the lawful motivation for hospital-physician arrangements.

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period of time during the 1990s served as Chief Operating Officer of Health Midwest. He also was a member of the Board of Trustees of MHA for most of the 1980s, serving as chairman of the Board in 1985.

4/ The jury instructions adopted by the Tenth Circuit has its origins in the "one purpose" test applied by the Third Circuit in *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985). In *Greber*, the Third Circuit held that the Anti-kickback Statute was violated where "one purpose" of the remuneration was to induce referrals, regardless of whether that purpose was the primary or motivating purpose of the transactions. 760 F.2d at 69.

It is therefore essential that the Court, at the earliest opportunity, restore the plain meaning of the Anti-kickback Statute and prohibit financial arrangements between referral sources only where the parties have criminal intent to pay remuneration to induce referrals.

A. Congress Did Not Intend to Condemn All Arrangements That Have "Referrals" as an Inherent Component.

Congress understood that referrals are a natural and perfectly appropriate part of most hospital-physician interactions. Congress's intent was only to deter practices "which have long been regarded by professional organizations as unethical as well as unlawful in some jurisdictions, and which contribute appreciably to the cost of the Medicare and Medicaid programs." S. Rep. No. 92-1230, at 208 (1972) (legislation authorizing the original Anti-kickback Statute). Congress consequently made financial arrangements between referral sources a crime only where the parties paid or received remuneration to induce referrals with criminal intent, i.e. to do something with knowledge their conduct is illegal. *See Bryan v. United States*, 524 U.S. 184, 193 (1998) (interpreting willfulness *scienter* element of Firearms Owners' Protection Act); *United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (applying *Bryan* to the Anti-kickback Statute).[5] Where a jury cannot find a criminal-inducement nexus

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[5/] Paragraphs (1) and (2) of 42 U.S.C. § 1320a-7b(b) make it an offense to receive or pay illegal remuneration in return for, or to induce, (a) the purchasing, leasing or ordering, (b) arranging for, or (c) recommending the purchasing, leasing, ordering; of any good, facility, service or item paid in whole or in part under a Federal health care program.

between the payments and referrals, it should be authorized to acquit.

Contrary to the Anti-kickback Statute's plain meaning, the court below authorized financial relationships between hospitals and physicians only "where the motivation to enter into the relationship is for legal reasons entirely distinct from the collateral hope for or decision to make referrals." *LaHue*, 261 F.3d at 1008.[6/] By stringing together the words "motivation," "entirely distinct from," and "collateral hope for . . . referrals," *id.*, the Tenth Circuit disregarded the realities of today's health care system in which hoped-for referrals cannot be separated from the financial relationship. Since referrals are intrinsically part of the customary relationship between hospitals and physicians, the jury should be free to consider this inherent referral component together with other evidence, including payments made at fair market value for legitimate, needed services, in determining whether the arrangement was motivated for legal reasons. The Tenth Circuit's standard equates financial arrangements that include inherent referrals with arrangements that are criminally intended to induce referrals. This is not the standard Congress contemplated, and the statutory language does not warrant such limitations on permissible conduct.

The "entirely distinct" or "wholly for other purposes" standard is likely to confuse jurors because it makes little sense in the real world. Jurors who understand that referrals are a routine and inherent part of

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[6/] The District Court instructed the jury that a finding of illegal intent to induce referrals "must, *at least in part*, have been the reason [for] the remuneration . . . ." *McClatchey*, 217 F.3d at 834. Jurors were also instructed that they could acquit only if they concluded that the payments in question were designed "*wholly for other purposes*." *Id.*

a physician's relationship with a hospital, are asked by the Tenth Circuit to impute a criminal purpose to otherwise legitimate relationships.

B. "Referrals" Are an Inherent Component of Relationships Between Hospitals and Physicians.

The Tenth Circuit's decision troubles *Amici* because it conflicts with the complexity of health care delivery. Hospitals can meet the health care needs of the communities they serve only with the assistance and coordination of physicians. Hospital care must be provided by and through arrangements with physicians. Physicians rely upon the assistance and support of the hospital's clinical staff and facilities to diagnose and treat patients.

The definition of the term "referral" includes most of the daily interactions that physicians have with hospitals. When a physician admits a patient with chest pain, it is a "referral." When a physician uses a hospital surgical suite to perform surgery in conjunction with a team of hospital nurses, it is a "referral." When a physician orders a blood test performed by the hospital's laboratory, it is also a "referral." And when a physician discharges a patient and orders post-hospital services in conjunction with hospital discharge planners, it is a "referral." Since physicians are licensed to make medical judgments and order services, a "referral" is a necessary yet intrinsic component of virtually every interaction between a hospital and a physician.

We offer below several examples of common, beneficial hospital-physician relationships that are threatened by the Tenth Circuit Court's mistakenly broad construction of the Anti-kickback Statute. These examples have two common, coexisting features: (1) an

economic relationship is formed that is necessary for patient care; and (2) patients receive needed services from the referrals the physicians have made. These examples, therefore, all involve "remuneration" and "referrals" as a natural part of the relationship, but without the required nexus of criminal inducement.

Clinical and Administrative Services. Hospitals have important medical reasons to contract with physicians to provide clinical services to patients. Similarly, hospitals often ask physicians to provide medical administrative services, such as serving as the medical director of a program or department. The hospital customarily pays the physician for these duties.

A hospital, for example, may have a choice of hiring one of the leading surgeons in the field as a medical director or an accomplished, but lesser known, physician. The leading surgeon will likely bring to the institution prestigious research grants and superior education and training. This surgeon also will likely attract more referrals because of her name recognition. Moreover, when that surgeon agrees to become the medical director of that service, it should surprise no one that she will actually refer her patients to her service at the hospital. When she starts her work at that hospital, she will expect to be paid.

Under the approach of the Tenth Circuit, the simple fact of the surgeon's acceptance of payments coupled with her desire to treat patients for the service she has been chosen to run could be sufficient evidence for the jury to convict her of a crime. Specifically, in our example, the selection of the leading surgeon could be construed as a criminal offense under the Tenth Circuit's test unless the surgeon is selected for "legal reasons" that are "entirely distinct" from the prospect of referrals to the

hospital. *Id.* To avoid the danger of criminal prosecution, the hospital might not select the leading surgeon or that surgeon might tell her patients to go elsewhere. This is an obviously absurd and undesirable result.

Physician Recruitment. Hospitals often consider ways to recruit physicians to locate to the hospital's service area after the completion of residency training. This recruitment usually follows the completion of a community "needs analysis" by which the hospital has identified needs for various categories of physician-specialists in the service area, which may include necessary hospital services based on community demographics. As part of its efforts to recruit a physician, the hospital typically provides the physician with a moving allowance and an income guarantee to ease the financial burden while the physician establishes a private practice. In addition, the physician is asked to obtain and maintain medical staff privileges at the supporting hospital. Since the physician will likely admit patients to the hospital, both elements of the offense are present.[7/]

Flight Programs. As part of their community service, hospitals in urban areas often sponsor flight programs to provide needed specialty care to surrounding rural areas. Physicians on the hospital's medical staff are flown to rural areas to see patients at rural hospitals or clinics. These flights are provided without charge, and

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[7/] In 1978, the Department of Health and Education and Welfare, Office of Program Integrity ("OPI"), the predecessor to today's Department of Health and Human Services, Office of Inspector General ("OIG"), opined that such recruitment practices are permissible under the Anti-kickback Statute. *See* Letter by Director, Office of Program Integrity, dated October 30, 1978. Appendix at 1a.

therefore the physicians may be considered to have received remuneration. Even though the physicians earn fees for the care they provide, the amounts received rarely would justify the flights if they paid the full cost themselves. The primary purpose of the flight programs is to provide needed treatment to patients in a setting close to their home. If more needed services are not available locally, the physician will usually refer the patient to the sponsoring hospital at which she is on the medical staff.

None of the above practices has traditionally been viewed as unethical or as increasing the costs of medical programs or treatments. Absent other aggravating facts, these arrangements to provide needed services and many other everyday practices of hospitals and physicians should not be subjected to criminal investigation and prosecution. Yet in these examples referrals are an inherent, inevitable part of the legal relationship, but they are not "entirely distinct," as required by the Tenth's Circuit's standard.

C. The Court Should Grant Review to Remove the Cloud Cast Over a Wide Array of Benign Health Care Arrangements.

The Tenth Circuit's interpretation of the Anti-kickback Statute is troubling to the health care community because it treats in the same manner relationships that intrinsically involve referrals with those that are entered into unlawfully to induce referrals. As a result, it could criminalize arrangements described in the examples described above, as well as many other common beneficial practices of health care providers.

Congress recognized: "Providers want to comply with the fraud and abuse statute, but many are unsure of how the statute affects them." H.R. Rep. No. 104-496, at 84 (1996). When no meaningful line can be drawn between legal and illegal activity, hospital executives and physicians cannot know what is expected of them. Consequently, "a chilling effect is placed on legitimate arrangements, particularly where providers are attempting to structure new and innovative health care delivery systems to contain health care cost[s]." *Id.* There is no shelter for innovation or for the development of cost-effective programs if a jury may misunderstand these activities and convict under the Anti-kickback Statute.

The Court should therefore grant review because of this chilling effect on existing financial relationships and important new, beneficial programs.

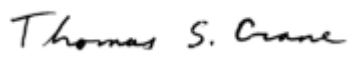
CONCLUSION

Our health care system must be free both from corrupt payment-for-referral scams *and* from the dangerous specter of criminal conviction for legitimate health care arrangements. Congress intended this in enacting the Anti-kickback Statute. *Amici* strongly support the vigorous and fair enforcement of this law. But this Court's prompt assistance is needed to achieve clarity in construing the Anti-kickback Statute to

maintain the legality of traditional financial arrangements between hospitals and physicians while prohibiting only what is unethical and corrupt.

December 14, 2001

Respectfully submitted,



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APPENDIX

DEPARTMENT OF HEALTH EDUCATION AND WELFARE

October 30, 1978

Dear _____:

Secretary Califano has asked me to respond to your October 10 letter to him requesting an opinion as to the legality of certain hospital practices under the Medicare-Medicaid Anti-Fraud and Abuse Amendments, P.L. 95-142.

In the correspondence attached to your letter, questions a situation wherein a remote, rural hospital in California in an effort to induce physicians to practice in the area, guarantees a portion of the physician's salary for one year. There is no explicit agreement with the hospital that the physician must refer his Medicare or Medi-Cal patients (or any of his patients) to that particular hospital. However, since this rural hospital is the nearest within 50 miles, it is most likely that the physician's patients who must be hospitalized would be referred to the local hospital. Specifically, inquiries whether such an arrangement would be a violation of Section 1877(b)(2) of the Social Security Act (42 U.S.C. 1395nn(b)(2)). Since Section 1877(b) is a penal provision, a conclusive determination to whether this or any other arrangement violates the section can only be rendered by the courts. We can, however, offer out thoughts on particular aspects of the arrangement we believe are important in making a determination whether it would be prohibited under the Act.

Since 1972, the Social Security Act has provided specific penalties for transgressions against the Medicare or

Medicaid programs for certain practices that have long been regarded by professional organizations as unethical, which are unlawful in some jurisdictions, and which contribute significantly to the cost of the programs. For example, kickbacks are illegal and improper no matter how a transaction might be construed to obscure the true purpose of a payment. The concern of both Congress and the health care programs administered by the Department of Health, Education, and Welfare is the unnecessary and illegal escalation of health care costs which result from the type of practices prescribed by the anti-Kickback or Rebates Provision (42 U.S.C. 1395nn and 1396h).

In the Medicare-Medicaid Anti-Fraud and Abuse Amendments (P.L. 95-142) Congress acted to clarify, restructure, and strengthen the penalty provisions included in the Social Security Act. Thus, Sections 1877(b)(2) and 1909(b)(2) of the Act were amended to provide:

> Whoever offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whose or in part under this title, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under this title,

> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

The intent of these provisions is not to penalize individuals or entities participating in legitimate business transactions. Rather it is to penalize those who engage in unethical and illegal financial arrangements (such as kickbacks, rebates, or bribes) that unnecessarily increase the costs of Federal health care programs. Many business offer financial inducements to attract competent personnel. The physician recruitment program acts to insure adequate and competent medical care in a remote, rural area. Moreover, the costs of the recruitment program are not reimbursable by either Medicare or Medicaid. This, based on description of the arrangement (a hospital guarantees a portion of physicians' salaries for one year in order to have them practice in the area serviced by the hospital), it would appear that neither the hospital nor the physicians would be in violation of these penal provisions of the Social Security Act.

You, of course, understand that our reply is predicated on an understanding of the arrangement as we interpret letter. If facts or conditions differ from those we understand or infer, there is a possibility that the arrangement might be in violation of the subject provisions of the Act. Should any questions arise to the propriety of an arrangement, or regional office will consult with the appropriate we trust that our comments will be helpful in responding to [_____] questions.

Sincerely yours,

Don Nicholson
Director
Office of Program Integrity