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Timothy J. Aspinwall
Nossaman, Guthner, Knox & Elliott

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*Timothy J. Aspinwall**

INTRODUCTION

The anti-kickback statute is one of the laws the federal government utilizes in its effort to prevent fraud and abuse against publicly funded health care programs.[1] The primary purpose of this statute is to eliminate unnecessary health care costs and compromises in quality that can result when providers are given financial inducements to make referrals.[2] With certain narrow exceptions, the anti-kickback statute makes it illegal to knowingly and willfully solicit, receive, offer or pay any remuneration, in cash or in kind, in exchange for referrals for items or services for which payment may be made under a federal health care program.[3] Federal courts interpret the statute primarily by determining whether, in a given case, there was a knowing and willful intent to induce referrals.[4] If there is some remuneration in connection with referrals, illegal intent can be inferred. Given this method of interpretation, the legal prohibitions can apply to a broad spectrum of compensation arrangements, rang-

* Timothy J. Aspinwall is an associate in the Sacramento office of Nossaman, Guthner, Knox & Elliott. He received his Juris Doctor from Vanderbilt University, a Masters in Religious Ethics from the University of Chicago, and a Master of Laws from Loyola University Chicago, Institute for Health Law. The Author would like to thank Professor Joan Krause of Loyola University Chicago for her many helpful suggestions and for frequently displaying her commitment to teaching. The author would also like to thank the firm of Epstein, Becker & Green for sponsoring the 1999-2000 Health Law Writing Competition, in which this article was awarded first place.

1. *See* 42 U.S.C. § 1320a-7b(b) (1994 & Supp. 1997). Other significant federal statutes include the Civil False Claims Act, 31 U.S.C. § 3729 (1994 & Supp. 1997), and the Stark prohibition against physician self-referrals, 42 U.S.C. § 1395nn (1994 & Supp. 1997).

2. *See* discussion *infra* Part I.

3. *See* 42 U.S.C. § 1320a-7b(b) (1994 & Supp. 1997). Violations are punishable by a fine of up to $25,000 and/or imprisonment for up to five years. Violators may also be subject to civil monetary penalties of $50,000 for each violation and three times the remuneration involved. *See* 42 U.S.C.A. § 1320a-7a (West Supp. 1998). They may also face exclusion from participation in all federal health care programs. *See* 42 U.S.C. § 1320a-7 (1994 & Supp. 1997).

4. *See* discussion *infra* Part II.A-C.

ing from obviously corrupt bribe and kickback schemes, to potentially beneficial patient management agreements between health care providers.[5]

A significant legal concern among health care providers is that the anti-kickback statute inadequately distinguishes between compensation arrangements that should be prohibited because they encourage inappropriate utilization of health care resources, and arrangements that should be permitted because they are likely to improve the quality of care or reduce costs without unacceptably compromising quality.[6] This concern about the broad reach of the anti-kickback statute was recently expressed in a colloquium report published by the American Health Lawyers Association ["AHLA"], a trade association with a membership of attorneys from both the private and public sectors.[7] One significant question that is asked but not answered in the report is whether the anti-kickback statute appropriately focuses on the intent of the parties as expressed in their conduct, rather than on the likely effects of a given compensation arrangement on cost and quality.[8]

The focus on intent is conceptually problematic for two reasons. First, the statute's standard of intent is unclear. This is evident in the division between federal appellate courts on the issue.[9] To the extent there is clarity, it exists primarily in circuits that give a very broad reading to the prohibitions.[10] The standard of intent is less clear in circuits that take a more nuanced approach.[11] Second, as can be inferred from the question asked in the AHLA colloquium report, a focus on party intent is a poor method by which to prevent inappropriate utilization of health care resources.[12] A legal standard that focuses on the likely outcome of the arrangement rather than the perceived in-

5. *See* discussion *infra* Part II.D.

6. *See* discussion *infra* Part III.

7. *See* AMERICAN HEALTH LAWYERS ASS'N, FRAUD AND ABUSE: DO CURRENT LAWS PROTECT THE PUBLIC INTEREST? 33 (1999) [hereinafter AHLA].

8. *See id.* at 22.

9. *Compare* United States v. Starks, 157 F.3d 833, 839 (11th Cir. 1998) (approving the trial court's jury instruction requiring the prosecution to show the defendants had a general bad intent to disobey or disregard the law) *with* Hanlester Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995) (requiring proof the defendants specifically intended to violate the anti-kickback statute) *and* United States v. Greber, 760 F.2d 68, 71 (3d Cir. 1985) (holding a violation of the anti-kickback statute occurs if any one purpose of a compensation arrangement is to induce referrals).

10. *See Greber,* 760 F.2d at 71.

11. *See Hanlester*, 51 F.3d at 1400.

12. *See* AHLA, *supra* note 7 at 22.

tent of the parties would be a clearer, more effective way to prevent inappropriate utilization.

A very practical problem with the anti-kickback statute as currently conceived is that it results in significant social costs. First, health care payers and providers expend substantial legal fees developing strategies to navigate the statutory ambiguities surrounding the issue of intent.[13] In addition to these expenses, the uncertainty surrounding the standard of intent leads to significant foregone opportunities to the extent that potentially beneficial health care arrangements are never implemented because of possible anti-kickback liability.[14] These costs indicate unnecessary tensions between the government's need to prevent inappropriate utilization and the desire among health care providers to implement compensation arrangements that optimize quality and efficiency.[15]

There has not been enough discussion of a possible legal standard that would take cost and quality into account in anti-kickback cases.[16] The objective of this article is to make the case for a standard of reasonableness under which compensation arrangements would be judged substantially on the basis of whether they increase cost-effectiveness as measured by a cost/

13. *See* AHLA, *supra* note 7 at 24.

14. *See* James F. Blumstein, *Rationalizing the Fraud and Abuse Statute*, 15 HEALTH AFF. 118, 118-19 (1996) (suggesting that current fraud and abuse laws discourage forms of integration that enhance both quality and efficiency); *see also* Timothy Stoltzfus Jost & Sharon Davies, *The Fraud and Abuse Statute: Rationalizing or Rationalization?*, 15 HEALTH AFF. 129-31 (1996) (agreeing with Blumstein that the anti-kickback statute discourages some efficient business arrangements).

15. *Cf.* Martha C. Nussbaum, *Flawed Foundations: The Philosophical Critique of (a Particular Type of) Economics*, 64 U. CHI. L. REV. 1197, 1203 (1997) (stating irrationality in social institutions can lead to conflicts between competing concerns that are not, in principle, incompatible).

16. *See* Tamsen Douglass Love, Note, *Toward a Fair and Practical Definition of "Willfully" in the Medicare/Medicaid Anti-Kickback Statute*, 50 VAND. L. REV. 1029, 1057 (1997) (arguing the word "willfully" in the anti-kickback statute should be construed to require that the defendant acted with corrupt intent).

Some critics propose safe harbors that specify:

> (1) that inducing future referrals must be a 'significant' (and not just any) purpose in the financial arrangements among providers; (2) that reducing Medicare or Medicaid costs is a defense to a prospective fraud and abuse violation in the absence of significant, unacceptable decreases in the level of quality; and (3) that a defense to a prospective fraud and abuse violation is established when improved quality or choice is provided to program beneficiaries at no increased costs.

See Blumstein, *supra* note 14, at 126; *but see* Jost & Davies, *supra* note 14, at 131 (asserting that Blumstein's proposed quality or efficiency defenses would increase uncertainty about the applicability of the anti-kickback statute).

quality ratio.[17] The term "cost-effectiveness," as used here, takes into account both costs and quality of clinical outcomes. As such, an improvement in cost-effectiveness indicates a more optimal balance between cost and quality.[18]

The claim underlying this proposal is that the current formulation of the anti-kickback statute, with the emphasis on intent, is unclear and unnecessarily broad as a means to prevent inappropriate utilization. A more useful approach would take into account the broadest possible set of costs and benefits associated with a given compensation arrangement. Ideally, the anti-kickback statute would prevent compensation arrangements that needlessly increase costs or threaten to degrade the quality of care, but permit innovative arrangements that improve cost-effectiveness.

Under the standard of reasonableness proposed here, the parties to certain categories of compensation arrangements would be able to defend an anti-kickback claim by asserting that the arrangement in question will increase cost-effectiveness in health care. This defense would not be available to parties engaged in blatantly unethical payment schemes.[19] But under most circumstances, compensation arrangements that improve cost-effectiveness would be permitted; those that do not would be condemned under the anti-kickback statute.

A cost-effectiveness approach to the anti-kickback statute is appropriate because in a world of finite resources, legislative restrictions that discourage or prevent cost-effective arrangements will, other things being equal, drive up costs and reduce demand for health care. Health care is not exempt from the economic forces of supply and demand.[20] The reality is that increased costs reduce the availability of health care, which will ultimately take its toll on individual lives.[21] Given these consequences, a

17. *See* discussion *infra* Part IV.A.

18. *See* discussion *infra* Part IV.A.

19. *See* discussion *infra* Part II.A-C.

20. *Cf.* Troyen A. Brennan, *Moral Imperatives Versus Market Solutions: Is Health Care a Right?* 65 U. CHI. L. REV. 345 (reviewing RICHARD A. EPSTEIN, MORTAL PERIL: OUR INALIENABLE RIGHT TO HEALTH CARE? (1997)). Brennan argues that managed care brings economic incentives to bear upon the patient-physician relationship. *See id.* at 346 (citing ALAIN C. ENTHOVEN, THEORY AND PRACTICE OF MANAGED COMPETITION IN HEALTH CARE FINANCE 9 (1988). *See also* CLARK C. HAVIGHURST, DEREGULATING THE HEALTH CARE INDUSTRY: PLANNING FOR COMPETITION 14 (1982).

21. *See* CASS R. SUNSTEIN, FREE MARKETS AND SOCIAL JUSTICE 298 (1997). Sunstein suggests regulations that increase the cost of health care will produce a health-

rational approach to health care legislation must include an understanding of the costs and benefits associated with a given law or regulation.

Part I of this article begins with an overview of the history and purpose of the anti-kickback statute. There are two primary objectives in this section. The first is to show through legislative history that Congress enacted the anti-kickback statute to prevent inappropriate utilization, thereby preventing unnecessary costs and protecting quality. The second point is to show that Congress attempted to reduce the ambiguity of the anti-kickback prohibitions by adding a knowing and willful requirement to the standard of intent. This section also discusses whether safe harbors and advisory opinions issued by the Office of the Inspector General ["OIG"] of the Department of Health and Human Services ["HHS"] provide sufficient protection and clarity. One clear limitation of safe harbors is that all elements of a compensation arrangement must fall within a safe harbor for the arrangement to be protected. The utility of advisory opinions is limited by the fact that the OIG will not opine on the requester's intent, and that advisory opinions refer to the broadest possible construction of intent.[22]

Part II examines three different lines of circuit court cases on the anti-kickback standard of intent, one of which is endorsed by the OIG. This discussion looks closely at the case law favored by the OIG, and how the other circuits interpret the willfulness requirement to develop different standards of intent for the anti-kickback statute. There is also a brief discussion of two types of arrangements that implicate the anti-kickback statute: gainsharing and disease management programs. Though the OIG recently issued a statement declaring gainsharing arrangements illegal,[23] both types of arrangements have been selected

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health trade-off, whereby the increased costs will make health care less widely available. *See id.* (citing ADA v. Martin, 984 F.2d 823, 826 (7th Cir. 1993).

> OSHA also exaggerates the number of lives likely to be saved by the rule [designed to control the spread of AIDS and hepatitis among health care workers] by ignoring the lives likely to be lost by it. Since the increased cost of medical care, to the extent passed on to consumers, will reduce demand for medical care, and some people may lose their lives as a result.

Id.

22. *See, e.g.,* Advisory Opinion No. 98-19 <http://www.dhhs.gov/progorg/oig/advopn> (citing United States v. Greber, 760 F.2d 68 (3d Cir. 1985)).

23. *See* Publication of the OIG Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 Fed. Reg. 37985 (1999).

for discussion here to illustrate the limitations of an intent-based statute in accommodating innovative compensation plans.

Part III proposes adopting a standard of reasonableness, using cost-effectiveness as the primary criterion. Such a standard can be modeled after the rule of reason as developed in antitrust law. Two lines of argument are presented to support this proposal. First, not all compensation arrangements that provide some incentive to make referrals are so obviously and inherently lacking in social value that they should be viewed as objectionable per se. Second, a legal standard that requires a balancing of costs and benefits is more likely to serve the public interest and to give the health care industry a reasonable point of reference in navigating the ambiguities of the anti-kickback statute.

Part IV examines some of the practical issues involved in a cost-benefit analysis of compensation arrangements within the terms of the anti-kickback statute. Some attention is given here to the cost/quality variables that must be addressed in any adequate cost-benefit analysis in health care. The discussion then returns briefly to gainsharing and disease management programs to assess how these compensation arrangements might fare under a cost-benefit approach to the anti-kickback statute.

This paper concludes by reasserting the claim that a cost-benefit outcomes-based approach to the anti-kickback statute would better serve the public interest by reducing tensions between the needs in private industry to maximize efficiency and the governmental imperative to prevent fraud and abuse. This tension can be addressed with a law that gives adequate attention to outcomes, rather than focusing primarily on the intent of the parties.

I. Legislative History and Purpose of the Anti-Kickback Statute

The anti-kickback statute was originally enacted in 1972 to reduce unnecessary governmental health care expenditures and control inappropriate utilization.[24] The original statute made it

24. *See* H.R. Rep. No. 92-231 (1972), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5093 (directing attention to "certain 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."). *See also* H.R. Rep. No. 95-393 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3055.

According to the OIG, the anti-kickback statute is intended to protect federal funds, to guard against the over-utilization of medical services and supplies, and to prevent anticompetetive conduct in the health care market. *See* 56 Fed. Reg. 35,952,

a misdemeanor for anyone to solicit, receive, offer, or pay a kickback, bribe, or rebate in connection with the provision of items or services for which payment may be made under Medicare or Medicaid. Defendants convicted of the crime could be punished by a fine of up to $10,000, one year imprisonment, or both.[25] If subsequent amendments are any indication, the 1972 statute was deficient in at least three respects: (1) the statute did not provide adequate deterrence, in that violations were punishable as misdemeanors rather than as felonies; (2) the statute did not have a scienter requirement, thus possibly including both intentional and inadvertent violations; and (3) the prohibitions focused exclusively on kickbacks, bribes, and rebates without specifically including other remunerations intended to induce referrals, such as office space or administrative services at below-market prices.[26] In these last two respects, the statute was both too broad and too narrow.

In 1977, amendments were enacted to increase the level of deterrence and to remove ambiguities regarding the types of remunerations prohibited.[27] The amendments upgraded the crime to a felony, punishable by $25,000, five years imprisonment, or both.[28] Moreover, ambiguities about the reach of the statute were addressed by expanding the prohibition to include "any remuneration."[29] However, concern emerged that the expanded

35,954 (1991) (citing United States v. Ruttenberg, 625 F.2d 173, 177 n.9 (7th Cir. 1980)). *But see* James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy,* 22 AM. J.L. & MED. 205, 207 n.15 (1996) (arguing disclosure rules and informed consent requirements would be better suited than the anti-kickback statute to regulate a physician's fiduciary duty to a patient, as physicians may be motivated by financial incentives to over utilize).

25. *See* Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972) (codified as amended in scattered sections of 42 U.S.C. § 1395 (1994)).

26. *See id.*

27. *See* Medicare and Medicaid - Antifraud and Abuse Amendments, H.R. REP. No. 95-393 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3055 (recommending penalties for anti-kickback violations be increased from misdemeanor to felony status to provide an adequate deterrent).

28. *See* Pub. L. No. 95-142, § 4(b)(1), 91 Stat. 1175, 1180 (1977) (codified as amended at 42 U.S.C. § 1396(h)(1994)).

29. *See id.* The use of the term "any remuneration" resolved a split among circuit courts over the issue of what constitutes a kickback, bribe or rebate. *See* Love, *supra* note 16, at 1035 (comparing United States v. Porter, 591 F.2d 1048 (5th Cir. 1979) and United States v. Zacher, 586 F.2d 912 (2d Cir. 1978), which defined bribe or kickback narrowly under the 1972 statute, with United States v. Tapert, 625 F.2d 111 (6th Cir. 1980) and United States v. Hancock, 604 F.2d 999 (7th Cir. 1979), which defined bribe or kickback broadly under the 1972 statute.

statute might ensnare individuals for "inadvertent conduct,"[30] and in 1980 the statute was again amended to prevent this occurrence.[31] The amended statute specified that persons can be prosecuted only if they "knowingly and willfully" engage in unlawful conduct.[32] This *mens rea* requirement is a legislative effort to provide some protection to the unwary. However, the courts have not reached agreement on the meaning of the term "willfully"–a fact that makes it difficult to develop a clear standard of intent.[33]

Ambiguity about the meaning of the anti-kickback statute was addressed again in 1987. Congress, in conjunction with the Attorney General, sought to develop "safe harbor" regulations that would not subject the parties to penalties under the law.[34] Within HHS, the OIG is responsible for developing and inter-

30. *See* Omnibus Reconciliation Act of 1980, H.R. REP. No. 96-1167, at 59 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526, 5572.

31. *See* Pub. L. No. 96-499, § 917, 94 Stat. 2599, 2625 (1980) (codified as amended at 42 U.S.C. §§ 1395nn, 1396(h)(1994)).

32. *See id.*

In relevant part, the anti-kickback statute now reads as follows:

> (b) Illegal remunerations.
>
> (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring 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 whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, 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.
>
> (2) whoever knowingly and willfully 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 whole or in part under a Federal health care program, 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 a Federal health care program, 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.

42 U.S.C. § 1320a-7b(b) (1994 & Supp. 1997).

33. *See* discussion *infra* Part II.

34. *See* Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93, § 14, 101 Stat. 680, 697-98 (codified as amended in 42 U.S.C. § 1320a-7b (1994 & Supp. 1997)).

preting the safe harbors. There are presently twenty-one safe harbors that have been finalized.[35] Payment arrangements that meet the criteria of one or more of the finalized safe harbors are protected from prosecution. But, the safe harbors are narrowly drawn and strictly construed.[36] As a consequence, very few arrangements will be completely protected.

Though the Department of Justice and the OIG will not prosecute all arrangements that fail to qualify for safe harbor protection, the uncertainty is a significant source of concern for the health care industry.[37] The decision whether or not to prosecute depends substantially upon a case-by-case evaluation of whether the requisite intent to induce referrals exists.[38] Because the OIG continues to refer back to the question of intent, this ambiguity in safe practices persists. The OIG concedes this problem in its published comments and responses to proposed safe harbors, where it states that there is "no way to predict the degree of risk" for arrangements that fall outside of a safe harbor.[39]

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35. Safe harbors cover the following types of arrangements: (1) Investment interests, (2) Space rental, (3) Equipment rental, (4) Personal services and management contracts, (5) Sale of practice, (6) Referral services, (7) Warranties, (8) Discounts, (9) Employees, (10) Group purchasing organizations, (11) Waiver of beneficiary coinsurance and deductible amounts, (12) Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans, (13) Price reductions offered to health plans, (14) Practitioner recruitment, (15) Obstetrical malpractice insurance subsidies, (16) Investments in group practices, (17) Cooperative hospital service organizations, (18) Ambulatory surgical centers, (19) Referral arrangements for specialty services, (20) Price reductions offered to eligible managed care organizations, (21) Price reductions offered by contractors with substantial financial risk to managed care organizations. *See* 42 C.F.R. § 1001.952 (1999).

36. *See* Scott J. Kelly, Comment, *The Health Insurance Portability and Accountability Act of 1996: A Medicare Advisory Opinion Mandate Sends the Inspector General "Shopping for Hats,"* 59 OHIO ST. L. J. 303, 313 (1998) (citing Hugh E. Aaron, *Application of the Medicare and Medicaid Anti-Kickback Statute to Business Arrangements Between Hospitals and Hospital-Based Physicians,* 1 ANNALS HEALTH L. 53, 63 (1992)).

37. *See* 56 Fed. Reg. 35,952, 35,954 (1991).

38. *See* 63 Fed. Reg. 38,311, 38317 (1998). *See also* United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 29 (1st Cir. 1989). While intent to induce referrals remains key to the OIG's evaluation of a given compensation arrangement, the OIG will also consider the impact that a given arrangement has on quality, cost and overutilization. *See generally* 56 Fed. Reg. 35,952 (1991).

39. 56 Fed. Reg. 35,952, 35,958 (1991). Another issue, not addressed in this essay, is whether the safe harbor legislation is fundamentally flawed because the OIG serves as both the promulgator and interpreter of safe harbors. *See* Pub. L. No. 100-93, § 14, 101 Stat. 680, 697-98 ("The Secretary of Health and Human Services, . . . in consultation with the Attorney General, . . . shall promulgate final regulations, specifying payment practices that shall not be treated as a criminal offense . . . .").

This lack of predictability gave force to the view that additional guidance from the OIG should be available.[40] In 1996, Congress enacted the Health Insurance Portability and Accountability Act ["HIPAA"], which required HHS to issue advisory opinions under the anti-kickback statute upon request by a party to a payment arrangement.[41] The OIG must provide advisory opinions on arrangements involving, but not limited to, the following types of issues: (1) what constitutes a prohibited remuneration; (2) whether an arrangement fits within a statutory exception; and (3) whether an arrangement falls within a safe harbor.[42] According to the legislative history, the purpose of the advisory opinion requirement is to remove some of the "chilling effect" the statutory ambiguity imposed upon provider development of new and innovative health care delivery systems.[43]

To provide some insight into the OIG's institutional perspective, it is worth setting forth a brief background of the advisory opinion process. As early as 1980, the OIG experimented with advisory letters by issuing some on its own volition without a legislative mandate. However, by 1991 the OIG stopped providing these advisory letters on the basis that HHS was not authorized to approve an illegal arrangement, and that the Department of Justice had exclusive authority to enforce federal criminal statutes.[44] As early as 1988, the OIG showed signs of fundamental opposition to the use of advisory opinions, arguing it could not make an adequate determination about a proposed arrangement on the basis of only written information, and that an advisory opinion in one situation could hinder prosecution in another.[45] The inherent difficulty of making a prospective determination about the application of an intent-based statute may explain the OIG's reluctance.[46]

Although advisory opinions allow payers and providers to obtain an opinion from the OIG before entering into an arrangement, there is a substantial limitation: advisory opinions will not

40. *See* H.R. REP. NO. 104-496, at 84-85 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1865, 1884-85.

41. *See* Pub. L. No. 104-191 § 205(b), 110 Stat. 1936, 2001 (1996).

42. *See* 42 U.S.C.A. § 1320a-7d(b)(2) (19xx).

43. *See* H.R. REP. NO. 104-496, at 84-85 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1865, 1884-5.

44. *See* 56 Fed. Reg. 35,952, 35,959 (1991).

45. *See* 53 Fed. Reg. 51,856, 51,857 (1988).

46. *See* Jost & Davies, *supra* note 14, at 131 (suggesting the advisory opinion process may be difficult to implement because it requires the OIG to evaluate criminal intent through an administrative process).

be provided on the issue of fair market value for goods or services.[47] Consequently, it is impossible to get a binding determination on a question that goes straight to the issue of intent. If the compensation in any given arrangement is at fair market value, it is less likely that the payments are intended to induce referrals.

The 1980 amendments adding a willfulness element to the anti-kickback statute, the 1987 safe harbor requirements, and the 1996 advisory opinion mandate all attempted to enhance the utility of the statute by making it fairer and more understandable. While these measures may have accomplished some of their objectives, the core of the problem persists: there is no clearly defined standard of intent.

II. The Standard(s) of Intent

The federal appellate courts disagree on the standard of intent required by the anti-kickback statute. There are essentially three views among the circuits. The broadest interpretation of the anti-kickback prohibitions is held by the Third Circuit and favored by the OIG. In *United States v. Greber*, the Third Circuit held that if any one purpose of a compensation arrangement is to induce referrals, the arrangement violates the anti-kickback statute.[48] However, such a statement raises the question: what level of intent is necessary to establish knowing and willful participation in a prohibited compensation arrangement?

The other two views more carefully examine the willfulness requirement, but come to different conclusions about the precise meaning of the term as applied in the anti-kickback statute. In *Hanlester Network v. Shalala*, the Ninth Circuit interpreted the term "willfully" to mean that the prosecution must show that the defendants both knew of the anti-kickback prohibitions and acted with the specific intent to violate that law.[49]

Another line of circuit court cases interpreting the willfulness requirement holds that the anti-kickback statute calls for a less stringent standard of intent. This set of cases is well-represented by the Eleventh Circuit in *United States v. Starks*,[50] which holds that the prosecution must show the defendant acted with the general bad intent to knowingly disobey or intentionally disre-

47. *See* 42 U.S.C. § 1320a-7d(b)(3) (Supp. 1997).
48. *See* 760 F.2d 68, 71 (3d Cir. 1985).
49. 51 F.3d 1390, 1400 (9th Cir. 1995).
50. 157 F.3d 833 (11th Cir. 1998)

gard the law.[51] This standard of intent is distinct from *Hanlester* in that it does not require proof that the defendant knew of or intended to violate the anti-kickback statute itself.

The purpose of the following discussion is to examine whether *Greber*, *Hanlester* or *Starks* provide a standard of intent that adequately accounts for the different types of arrangements prohibited by the anti-kickback statute, and that reasonably balances law enforcement and private imperatives. A significant point here is that the anti-kickback statute applies to a variety of arrangements, some of which are obviously corrupt and others of which are not. Arguably, fairness requires a high level of intent in cases where the compensation arrangement does not appear to be corrupt. On the other hand, predictability demands a uniform and consistent standard. A more fundamental point of inquiry is whether any of these standards offers the most effective way to achieve the congressional intent of protecting quality while preventing inappropriate utilization.[52]

A. Greber and Kats

The *Greber* opinion is known most for its holding that if even one purpose of a payment is to induce referrals, the compensation arrangement violates the anti-kickback statute.[53] Given the particular facts, the holding is unsurprising. First, the kickback scheme was blatant. Greber was an osteopathic physician and president of Cardio-Med, an organization he formed to provide diagnostic services for physicians. Physicians would refer patients to Cardio-Med for diagnostic monitoring services, including the use of a Holter-monitor, a device which produces a tape of a patient's cardiac activity. Cardio-Med billed Medicare for the diagnostic services and forwarded a portion of the payment to the referring physician for interpretation and patient consultation fees. In most instances, Cardio-Med, not the referring physician, performed the interpretation. Moreover, Cardio-Med paid the referring physicians regardless of whether they performed any interpretation or consultation services. On this point, the government introduced testimony given by Greber in an earlier civil proceeding that "'if the doctor didn't get his con-

51. *See also* United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Jain, 93 F.3d 436 (8th Cir. 1996); United States v. Neufeld, 908 F. Supp. 491 (S.D. Ohio 1995).

52. *See supra* text accompanying note 24.

53. *See Greber*, 760 F.2d at 69.

sulting fee, he wouldn't be using our service. So the doctor got a consulting fee."'[54]

Faced with his own admission that one purpose of the payments was to induce referrals from physicians, Greber argued the prosecution must show that the *only* purpose of the payments was to induce referrals.[55] Not surprisingly, this argument failed to persuade the court. Rather than attempt to discern Greber's mixed motives, the court focused on the simple question of whether Greber intended to induce referrals with these obvious kickbacks. The court held that an intent by Greber to induce referrals would not be excused simply because some of the payments were also intended as compensation for diagnostic interpretations.

In *Kats v. United States*, the Ninth Circuit followed the lead of *Greber* on an equally egregious kickback scheme.[56] The appellant Kats was a 25 percent owner of a medical clinic that referred blood and urine samples to a certain diagnostic laboratory on the condition the laboratory kick back to the clinic 50 percent of the Medicare payments attributable to the referrals.[57] As part owner, Kats directly benefited from the scheme, and on this basis was convicted of violating the anti-kickback statute.[58]

On the facts presented, the *Greber* and *Kats* holdings do not necessarily impose an undue burden on innovative compensation arrangements. However, the OIG gives a very broad reading to the "one purpose" rule, which includes many arrangements that are quite common and not obviously corrupt.[59] The OIG's very broad interpretation of these cases is significant because the OIG serves as the promulgator of safe harbors, the issuer of advisory opinions, and the prosecutor of civil violations.[60] In these combined multiple roles, the OIG can

54. *Id.* at 70.

55. *See id.* at 71.

56. 871 F.2d 105 (9th Cir. 1989).

57. *See id.* at 106-07.

58. *See id.* at 107.

59. *See* Alice G. Gosfield, *The New Playing Field*, 41 ST. LOUIS U. L.J. 869, 881 (1997). The OIG Comment and Response section preceding 56 Fed. Reg. 35,952 (1991), frequently cites *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, 874 F.2d 20 (1st Cir. 1989), for that decision's focus on the intent of the parties, rather than the impact of a given compensation arrangement. *Id.*

60. *See* Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93, § 14, 101 Stat. 680, 697-98 (1987) (codified as amended in 42 U.S.C. § 1320a-7b (1994 & Supp. 1997)).

essentially determine the terms of debate on what constitutes a violation. And given the severity of penalties, including possible exclusion from government-funded health care programs, health care providers are more likely to settle than to challenge the OIG position.

B. Hanlester and Ratzlaf

The Ninth Circuit's *Hanlester* decision is important because the court interpreted the anti-kickback statute to require a showing of specific intent to prove a violation.[61] The facts and procedural history of this case are convoluted, but can be summarized as follows: Hanlester Network ["Hanlester"] was a joint venture partnership that offered shares in its clinical laboratories to physicians who were in a position to refer business to its labs. Hanlester contracted with SmithKline BioScience Laboratories ["SKBL"], for SKBL to provide laboratory management services to all labs in which the Hanlester partnership had an ownership interest. SKBL also entered into separate agreements with Hanlester-owned laboratories under which the labs paid a monthly fee to SKBL for its services. The net effect of these agreements was that SKBL ran the Hanlester labs and returned approximately twenty-four percent of the profit to Hanlester.[62] From the government's perspective, this looked like a cleverly disguised kickback arrangement, providing the Hanlester appellants with a share of the net profits in exchange for test referrals to SKBL.[63]

After an investigation of the joint venture, the OIG notified Hanlester of its intention to recommend that the parties to these agreements be excluded from Medicare and state Medicaid programs for varying periods of time.[64] The Hanlester appellants requested an administrative hearing on the proposed exclusions, after which the Administrative Law Judge ["ALJ"] declined to impose permissive exclusions.[65] The government appealed to the Departmental Appeals Board, which, after remanding the matter for further proceedings, vacated the ALJ's decision not to exclude all of the appellants.[66] The Hanlester appellants then

61. *See* Hanlester Network v. Shalala, 51 F.3d 1390, 1405 (9th Cir. 1995).
62. *See id.* at 1400.
63. *See id.*
64. *See id.* at 1395.
65. *See id.*
66. *See id.*

appealed to the district court, which granted summary judgment for the government, thus allowing for exclusion.[67]

On appeal to the Ninth Circuit, the *Hanlester* appellants argued that the anti-kickback statute is inherently vague in that it fails to clearly describe the prohibited conduct.[68] The *Hanlester* court analyzed this argument in light of four criteria established by the Supreme Court: (1) whether the anti-kickback statute involves only economic regulation; (2) whether the statute involves only civil and not criminal penalties; (3) whether the statute includes a heightened scienter requirement; and (4) whether the statute implicates any constitutionally protected rights.[69] The court observed that the anti-kickback statute involves only economic conduct, and does not chill any constitutional rights.[70] The court also noted that the prohibitions had been significantly clarified by the 1977 amendment, which broadened the statute to include "any remuneration."[71] Most significantly, while the statute involves possible criminal penalties, the court found the requirement that violations be committed "knowingly and willfully" mitigates any statutory vagueness.[72]

The *Hanlester* court held that the "knowingly and willfully" language required the prosecution to show: (1) the defendants knew that the anti-kickback statute prohibits offering or paying remuneration to induce referrals, and (2) the defendants engaged in the alleged conduct with the specific intent to violate the law.[73] One is left to infer that even if the statute is vague, the specific intent requirement prevents an unfair result.

The court interpreted the terms "knowingly and willfully" by examining Supreme Court cases on the issue, paying particular attention to *Ratzlaf v. United States*.[74] In this case, Ratzlaf paid $100,000 to partially satisfy a gambling debt to a casino in Reno, Nevada, by purchasing a series of cashiers checks, each for less than $10,000, from different banks. The government argued

67. *See id.* at 1396.

68. *See id.* at 1397.

69. *See id.* at 1398 *citing* Village of Hoffman Estates v. The Flipside, 455 U.S. 489, 498-500 (1982). *See also* United States v. Neufeld, 908 F. Supp. 491, 494-95 (S.D. Ohio 1995) (using the same analysis).

70. *See id.* at 1398.

71. *See id.* (citing H.R. REP. NO. 95-393 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056).

72. *See id.* at 1398 (citing United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 32-33 (1st Cir. 1989)).

73. *See id.* at 1400.

74. 510 U.S. 135 (1994).

that Ratzlaf intentionally structured these financial transactions to avoid triggering currency reporting requirements mandating that banks and other financial institutions (including casinos) report cash transactions in excess of $10,000.[75] Ratzlaf clearly knew of these currency reporting requirements because casino personnel had told him how to avoid them.[76] However, there was no evidence that Ratzlaf knew of a related law making it illegal for a person to structure financial transactions with the purpose of evading a financial institution's reporting requirements–the law under which he was convicted.[77]

At trial, the judge instructed the jury of the prosecution's burden to prove Ratzlaf knew of the currency reporting requirement and he structured his transactions to avoid triggering that requirement. However, the prosecution was not required to prove Ratzlaf knew that his conduct was unlawful.[78] Based on the judge's instructions and the facts presented at trial, the jury convicted Ratzlaf of "willfully violating" the antistructuring laws.[79] The conviction was upheld on appeal by the Ninth Circuit.[80]

The Supreme Court reversed, holding that the jury could not convict Ratzlaf of the crimes charged unless it found that he knew his conduct was unlawful.[81] The Court focused substantially on the meaning of the word "willfully," observing that the word has many different meanings which are influenced by context.[82] This is an unsettling point.[83] Given that guilt or innocence in complex cases often hinges upon establishing the requisite *mens rea*, one could reasonably hope the essential term "willfully" would be clearly defined within the context of a given

75. *See id.* at 136 (describing Bank Secrecy Act, 31 U.S.C. § 5313 (1994)).

76. *See id.* at 137.

77. *See* Money Laundering Control Act of 1986, 31 U.S.C. § 5324 (1994).

78. *See United States v. Ratzlaf*, 976 F.2d 1280, 1282 (9th Cir. 1992) (quoting the district court judge's jury instructions).

79. *See id.* at 1280 (applying 31 U.S.C. § 5322(a) (1994)).

80. *See id.*

81. *See Ratzlaf*, 510 U.S. at 149 (citing Cheek v. United States, 498 U.S. 192, 199 (1991)). The Court compared the statutory proof requirements in a case of criminal tax evasion with the antistructuring laws, and upheld the assertion that a statutory provision requiring knowledge of illegality does not dishonor the general principle that ignorance of the law is not a defense against a criminal charge. *See id.*

82. *See id.* at 141.

83. *Cf.* MODEL PENAL CODE § 2.02(8) note on definition of "willfully" (Proposed Official Draft 1962) (stating the term "willful" is "unusually ambiguous standing alone").

statute.[84] With this apparent objective, the Court examined interpretations of the word "willfully" within the context of the antistructuring laws. The Court noted that the federal circuits have consistently applied the term in other provisions within the same subchapter as requiring "'knowledge of the reporting requirement' *and* a 'specific intent to commit the crime,' *i.e.*, 'a purpose to disobey the law.'"[85] The majority adopted this definition. The Court here was clearly concerned that there should be only one interpretation of the term "willfully" as applied to the various provisions of the antistructuring statute.[86] The dissent, however, was careful to cite opinions from nine different circuits in which the prosecution in antistructuring cases was not required to show that the defendant knew his conduct was illegal.[87] This division among circuits supports the observation by the *Ratzlaf* majority that the word "willful" has different meanings.

Though the Supreme Court in *Ratzlaf* was obviously concerned that a uniform interpretation of the willfulness requirement apply to the antistructuring provisions, the Court also seemed persuaded primarily by principles of fairness. A person should not be prosecuted for apparently innocent conduct without fair warning of the legal prohibitions.[88] The Court pointed out that structuring financial transactions to avoid reporting requirements is not so obviously or inherently corrupt that an unlawful intent can be presumed.[89] There are any number of legitimate reasons why a person might intentionally avoid cash

84. *See* Rachael Simonoff, Ratzlaf v. United States: *The Meaning of "Willful" and the Demands of Due Process,* 28 COLUM. J. L. & SOC. PROBS. 397, 400-01 (1995) (discussing three standards of willfullness that have been developed by the courts with respect to the antistructuring laws).

85. *See Ratzlaf*, 510 U.S. at 141 (citations omitted).

86. *See id.* at 143.

87. *See id.* at 152 (Blackmun, J., dissenting) (citing United States v. Baydoun, 984 F.2d 175, 180 (6th Cir. 1993); United States v. Jackson, 983 F.2d 757, 767 (7th Cir. 1993); United States v. Shirk, 981 F.2d 1382, 1389-92 (3d Cir. 1992), *vacated*, 114 S. Ct. 873 (1994); United States v. Rogers, 962 F.2d 342, 343-45 (4th Cir. 1992); United States v. Beaumont, 972 F.2d 91, 93-95 (5th Cir. 1992); United States v. Gibbons, 968 F.2d 639, 643-45 (8th Cir. 1992); United States v. Brown, 954 F.2d 1563, 1567-69 (11th Cir.1992), *cert. denied*, 506 U.S. 900 (1992); United States v. Dashney, 937 F.2d 532, 537-40 (10th Cir.), *cert. denied*, 502 U.S. 951 (1991); United States v. Scanio, 900 F.2d 485, 489-92 (2d Cir. 1990), *appeal dismissed*, 37 F.3d 858 (2d Cir. 1994)).

88. *See id.* at 146-49.

89. *See id.* at 146.

transactions in excess of $10,000.[90] The implication here is that it would be unfair to criminalize apparently innocent conduct without requiring a showing of a bad intent.[91] This is consistent with the Court's interpretation that the willfulness language requires the prosecution to show that the defendant actually knew his conduct was unlawful.[92]

The fact that *Hanlester* cites *Ratzlaf* to interpret the statutory willfulness requirement is significant because it places the anti-kickback statute in a particular category of highly technical statutes, like tax regulations and antistructuring laws, for which the Court requires a heightened level of intent. The reasoning is persuasive enough, considering the facts in *Hanlester*. Laboratory management agreements of the type between Hanlester and SKBL were common at the time the appellants entered into the agreement. Although not unlawful per se, evidence of these agreements suggests the appellants believed their conduct was entirely legal.[93] On these facts, there is a strong argument that the heightened intent requirement is appropriate to prevent people from being prosecuted for conduct that is not obviously unlawful.

C. *Starks and Bryan*

In the context of less sympathetic facts, the Eleventh Circuit in *United States v. Starks*[94] held that the anti-kickback statute is not analogous to the highly complex antistructuring statute, and that a less stringent standard of intent is appropriate.[95] In upholding the guilty verdicts, the court of appeals held that the trial court did not err when it instructed the jury that the term "willfully" means that the act was committed with the specific intent to either "disobey or disregard the law."[96] This is distinctly different from the *Hanlester* standard of willfulness which requires the prosecution to show the defendant knew of, and intended to violate, a specific law.[97]

90. *See id.* at 144, 146 (citing examples of business persons who intentionally structure bank deposits in order to reduce the risk of an IRS audit, and taxpayers who structure cash gifts not to exceed $10,000 in a given tax year).
91. *See id.* at 145-46.
92. *See id.* at 149 (citing Cheek v. United States, 498 U.S. 192, 199 (1991)).
93. *See* Hanlester Network v. Shalala, 51 F.3d 1390, 1399, 1401 (9th Cir. 1995).
94. 157 F.3d 833 (11th Cir. 1998).
95. *See id.* at 838-39.
96. *See id.* at 837-38.
97. *See Hanlester*, 51 F.3d at 1400.

The payment arrangement in *Starks*, as in *Greber* and *Kats*, was blatantly corrupt. The scheme involved a private drug rehabilitation program known as Future Steps, Inc., owned and operated by Andrew Siegal, which paid public employees Angela Starks and Barbara Henry to refer patients to Future Steps programs at a local hospital. Starks and Henry were well positioned to provide referrals; they worked for the Florida Department of Health and Reproductive Services in a federally-funded project where they counseled pregnant women about treatment for drug abuse.[98] The supervisor of Starks and Henry advised them that they were required to report any outside employment, and that they were not permitted to accept any employment that could pose a conflict of interest with their work as state employees.[99] But apparently, cut-backs to federal program funds, along with a reduction in work hours, generated a sense of competing imperatives for the two. The admonition from their supervisor notwithstanding, both Starks and Henry agreed with a representative of Future Steps to accept payments of $250 for each patient referral.[100] Future Steps would pay $125 at the time a referred patient began inpatient treatment, and an additional $125 after the patient remained with the program for two weeks.[101] Under the approval of Siegel, Future Steps paid $3,750 and $3,175 to Starks and Henry, respectively, in cash and checks.[102]

Aside from the apparent conflicts of interest, the corrupt nature of this arrangement was clearly revealed in two ways. First, Starks and Henry insisted on concealing the transactions by taking payment at locations away from their office, such as in a parking lot or restaurant.[103] Such facts alone make it fairly obvious that Starks and Henry knew that they were behaving inappropriately, if not illegally.[104] A second more disturbing aspect of this arrangement is that it corrupted the way in which Starks and Henry treated pregnant women at the counseling center. There was clear evidence at trial that both Starks and Henry

98. *See Starks*, 157 F.3d at 836.
99. *See id.*
100. *See id.*
101. *See id.*
102. *See id.* at 836-37.
103. *See id.*
104. A logically consistent, if not persuasive, factual argument could be made that Starks and Henry were concealing their misdeeds not because they knew their conduct was illegal, but to avoid punishment from their employer. If such a defense was advanced at trial, the guilty verdicts suggest that the jury was not persuaded.

threatened that women would lose their babies if they did not obtain counseling from Future Steps.[105] As a result of economic incentives, Starks and Henry substantially and unjustifiably increased their referrals to Future Steps.[106]

Starks and Siegel[107] argued on appeal that the trial court erred by refusing to instruct the jury according to the standard of intent set forth in *Ratzlaf*.[108] The Eleventh Circuit Court of Appeals rejected the appellants' contention that the anti-kickback statute is analogous to the complex financial statutes that require a heightened level of intent. After comparing the anti-kickback statute to both the antistructuring laws in *Ratzlaf* and firearms licensure requirements in *Bryan v. United States*, the court found that giving or taking kickbacks or bribes is more clearly *malum in se* than *malum prohibitum*.[109]

In *Bryan v. United States*, the defendant was convicted of dealing firearms without a federal license.[110] Bryan used "straw purchasers" to obtain pistols under false pretenses, assured the straw purchasers that he would file the serial numbers off the guns, and sold the guns in Brooklyn on street corners frequented by drug dealers.[111] At trial and during appeal, Bryan contended the jury should have been instructed that the prosecution was required to show that he knew of the relevant legal prohibitions, and that he specifically intended to violate them.[112] On this point, Bryan relied primarily upon the Supreme Court's discussion in *Ratzlaf* of the term "willfully" to interpret the term

105. *See Starks*, 157 F.3d at 837.

106. *See id.*

107. Barbara Henry died during the course of the appeal and was dismissed from the case. *See id.* at 836 n.2.

108. *See id.* at 838. Starks and Siegel also argued that the statute was unconstitutionally vague because people of ordinary intelligence could not have ascertained from a reading of the Safe Harbors whether Starks and Henry were "bona fide employees" and, thus, exempt from the anti-kickback prohibitions. *See id.* at 839.

109. *See id.* (analyzing Ratzlaf v. United States, 510 U.S. 135 (1994), and Bryan v. United States, 524 U.S. 184 (1998)).

110. *See Bryan*, 524 U.S. at 187. The relevant statutory prohibition reads:

> (a) It shall be unlawful —
>
> (1) for any person —
>
> (A) except a licensed importer, licensed manufacturer, or licensed dealer, to engage in the business of importing, manufacturing, or dealing in firearms, or in the course of such business to ship, transport, or receive any firearm in interstate or foreign commerce.

18 U.S.C. § 922(a)(1)(A) (1994).

111. *See* Bryan, 524 U.S. at 189.

112. *See id.* at 190.

as it appears in the penalty provision of the firearm statute.[113] The trial court did not give the requested instruction. Instead, the court instructed the jury that a person acts "willfully" if he intends to "disobey or to disregard the law," but he "need not be aware of the specific law or rule."[114]

The *Bryan* Court began its analysis of the term "willfully" by again observing that it has many meanings, depending on the context in which it is used.[115] The Court compared the application of the term as used in the firearms statute, the financial transaction statute from *Ratzlaf,* and the tax provisions from *Cheek v. United States.*[116] The *Bryan* Court makes the distinction that the federal firearms legislation is unlikely to ensnare unwary citizens, whereas tax and antistructuring laws often will.[117] A central point here is that the Court has read a heightened scienter requirement into the term "willfully" in cases where a highly technical law prohibits conduct that does not ordinarily appear to be illegal.[118] This was not the case with the firearms law: it is difficult to argue that dealing firearms without a license, particularly on street corners and after removing the serial numbers, would seem lawful to anyone.

Given its assertion that the anti-kickback statute is unlikely to ensnare individuals engaged in apparently innocent activity, the *Starks* court relied on *Bryan* rather than *Ratzlaf* to support a less stringent standard of intent.[119] However, *Starks'* characteriza-

113. *See id.* at 189. The relevant penalty provision reads: "whoever . . . willfully violates any other provision of this chapter . . . shall be fined under this title, imprisoned not more than five years, or both." 18 U.S.C. § 924(a)(1)(D) (1994).

114. *See id.* at 190.

115. *See id.*

116. *See id.* at 194 (citing Cheek v. United States, 498 U.S. 192, 199-200 (1991), and Ratzlaf v. United States, 510 U.S. 135, 149 (1994)).

117. By recognizing the danger that otherwise innocent persons might be trapped by complex statutes, the Court touches upon what is an essential point in Supreme Court opinions on the issue of willfulness. In the context of a highly technical statute, it would be fundamentally unfair to follow the common law presumption that each person knows the law. *See Cheek*, 498 U.S. at 199-200.

118. This analysis is most clearly set forth by then Chief Judge Breyer in a discussion of currency and tax law violations:

> Both sets of laws are technical; and both sets of laws sometimes criminalize conduct that would not strike an ordinary citizen as immoral or likely unlawful. Thus, both sets of laws may lead to the unfair result of criminally prosecuting individuals who subjectively and honestly believe that they have not acted criminally.

Bryan, 529 U.S. at 195 (citations omitted).

119. *See* United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998) (citing *Bryan*, 524 U.S. at 193).

tion of the anti-kickback statute appears to depend substantially upon its interpretation of the prohibited activities in that case.[120] Such logic is unconvincing. The fact that a given statute is employed in a given case against blatantly corrupt activity does not make a highly technical statute less technical. The possible applications of a statute bear no necessary relation to its inherent complexity. Instead, they relate more to the question of whether there is a danger of ensnaring apparently innocent activity, which is the relevant inquiry on the issue of intent.[121] Given the *Starks* Court's reasoning, one might question how it would have characterized the anti-kickback statute in a case with facts more akin to those in *Hanlester*, where the arrangement in question was common practice.[122] None of this should be taken to suggest that a fraudulent arrangement should be excused if and because it is common practice. But, as in *Hanlester*, a heightened level of intent may be necessary in order to ensure fairness to unwary defendants.

The foregoing discussion of *Greber*, *Hanlester*, and *Starks* provides a view of the different standards of intent that may apply to any given compensation arrangement, and shows that none of these standards focus adequately on the effects of a given compensation arrangement on cost and quality. The following discussion of gainsharing arrangements and disease management programs offers two examples of how the anti-kickback statute impacts two popular types of compensation arrangements.

D. Gainsharing Arrangements and Disease Management Programs

Gainsharing and disease management programs ("DMP") represent the very complex types of arrangements that have been developed in response to market pressures to reduce costs without compromising quality. While both types of arrangements involve the moral hazard of inappropriate utilization, compensation incentives are typically contingent upon clinical outcomes. An essential problem is that an intent-based statute is poorly suited to segregate arrangements that compromise cost-effectiveness from those that promote it. For this reason,

120. *See id.* at 838 (making the point that the kickback arrangement in *Starks* was clearly *malum in se* rather than *malum prohibitum*).

121. *See id.*; *see also Bryan*, 524 U.S. at 194 (stating it was "[t]he danger of convicting individuals engaged in apparently innocent activity that motivated our decisions in the tax cases and *Ratzlaf* . . . .").

122. *See* Hanlester Network v. Shalala, 51 F.3d 1390, 1399, 1401 (9th Cir. 1995).

the anti-kickback statute is so inclusive as to be self-defeating in that it prohibits or discourages arrangements that would otherwise advance the legislative intent of promoting cost-effective health care.[123]

Gainsharing, in its most basic form, is a compensation arrangement in which a hospital shares with a physician a portion of the savings in patient care costs that are attributable, at least in part, to the physician's efforts.[124] Gainsharing arrangements have become a popular strategy to align physician incentives with hospitals' need to control costs under prospective payment systems. These arrangements are based on the assumption that physicians have significant control over treatment costs, and are more likely to develop cost-effective methods if given financial incentives to do so. As a precaution, many gainsharing arrangements limit compensation to the fair market value of the physician's services and include a requirement that cost reduction measures not diminish the quality of patient care.[125]

Notwithstanding such protective measures, gainsharing arrangements are uniformly condemned by the OIG.[126] The OIG's primary legal contention is that gainsharing arrangements violate the civil money penalty provisions of the Social Security Act, which prohibit a hospital from directly or indirectly paying a physician to reduce or limit services to a Medicare or Medicaid patient under that physician's care.[127] In this analysis, however, the OIG also notes that gainsharing arrangements may violate the anti-kickback statute.[128] The apparent rationale is that under gainsharing, physicians are compensated as an inducement to make referrals to the hospital. It appears to be immaterial that the intent is to induce less costly referrals; again, the

123. *Cf.* SUNSTEIN, *supra* note 21, at 271 (suggesting a regulation is self-defeating if the unintended consequences negate the intended ones).

124. *See* Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 Fed. Reg. 37,985, 37,986 (1999).

125. *See id.*

126. It is worth noting that the Internal Revenue Service has taken a different view. In a private letter ruling, the IRS approved a gainsharing arrangement in which a hospital agreed to compensate physicians who improve services and save money with a portion of the cost savings. *See IRS OKs Gainsharing Arrangement in Unreleased Letter Ruling*, TAX NOTES TODAY, July 6, 1999, at 128.

127. *See* Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 Fed. Reg. 37,985, 37,986 (1999) (citing Social Security Act § 1128A(b)(1), 42 U.S.C. § 1320a-7a(b)(1) (1994 & Supp. 1997)).

128. *See id.* at 37,986 n.1.

gravamen of the offense is inducement. The anti-kickback prohibitions do not require that the arrangement in question increase costs.[129] Clearly, an outcomes-based standard would more readily accommodate gainsharing arrangements that enhance cost-effectiveness.

Similarly, disease management programs have recently become popular among pharmaceutical companies as a way to compete with other manufacturers for market share and to make their products more attractive to managed care organizations.[130] This is due in large part to pressures from managed care organizations to share some of the financial risk of pharmacotherapy. In essence, managed care organizations are challenging pharmaceutical companies to make good on their claims that certain chronic disorders, such as arthritis, asthma, diabetes, and hypertension, can be treated more cost-effectively with carefully managed treatment protocols.[131]

Though there is not uniformity among DMPs, typical arrangements include an agreement by a drug manufacturer to provide services to a managed care organization, such as developing clinical information systems, conducting education programs for physicians and patients, or providing case managers for a given condition or set of conditions.[132] The DMP will usually bear some of the financial risk of treatment. One method of risk-sharing is simply to work on a capitated basis. Another makes payment for disease management services contingent upon improved clinical outcomes, with the manufacturer agreeing to share in any financial losses if the program reduces cost-effectiveness. This outcomes-driven method of compensation places the financial risk on the parties providing the services, which encourages DMPs to develop cost-effective innovations.[133]

Disease management programs are problematic under the anti-kickback statute to the extent that a pharmaceutical company, through a DMP, offers remuneration in the form of management services, specialty physician services, or price discounts

129. *See* United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 32 n.21 (1st Cir. 1989).

130. *See* Arnold J. Rosoff, *The Changing Face of Pharmacy Benefits Management: Information Technology Pursues a Grand Mission*, 42 ST. LOUIS U. L. J. 1, 16 (1998); *see also* Mark Learn, Comment, *Applying Medicare and Medicaid Anti-Kickback Laws to Disease Management Programs: Ramifications for the Pharmaceutical Industry and a Regulatory Proposal*, 69 TEMP. L. REV. 245, 248 (1996).

131. *See* Learn, *supra* note 130, at 250; *see also* Rosoff, *supra* note 130, at 16.

132. *See* Learn, *supra* note 130, at 250.

133. *See* Rosoff, *supra* note 130, at 16.

in order to induce increased prescriptions of its drugs. The business objectives of pharmaceutical manufacturers are fairly obvious. The fact that some of the largest pharmaceutical companies have paid billions of dollars to acquire pharmacy benefit management companies, the leaders in developing DMPs, suggests that pharmaceutical companies see great market potential in DMPs.[134] However, it is also clear that a successful DMP may reduce costs and improve clinical outcomes.[135] These outcomes notwithstanding, DMPs rest on uncertain ground.

In order to reduce the risk of prosecution under the anti-kickback statute, the DMP must fit as closely as possible within the terms of at least one of four safe harbors: personal services agreements, referral services, and price reductions to two subsets of managed care plans.[136] While a detailed discussion of the applicable safe harbors goes beyond the scope of this discussion, it is worth summarizing. The safe harbor for personal service contracts protects payments to a DMP in exchange for services, as long as seven conditions are met.[137] Given that DMPs will often charge according to patient volume, some changes in billing practices may be necessary in order to comply with the fifth condition: that aggregate compensation be set in advance in an amount that reflects fair market value, and does not take into account the value or volume of referrals.[138]

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134. *See* Learn, *supra* note 130, at 247 & n.11 (citations omitted).

135. *See* Rosoff, *supra* note 130, at 16-17.

136. *See* 42 C.F.R. §1001.952(d) (1999), *as amended by* 64 Fed. Reg. 63,504, 63,551 (1999) (safe harbor for personal services and managment contracts); 42 C.F.R. §1001.952(f) (1999), *as amended by* 64 Fed. Reg. 63,504, 63,551 (1999) (safe harbor for referral services); 64 Fed. Reg. 63,504, 63,515 (1999) (codified at 42 C.F.R. §1001.952(t)) (safe harbor for price reductions offered to eligible managed care organizations); 64 Fed. Reg. 63,504, 63,515 (1999) (codified at 42 C.F.R. §1001.952(u)) (safe harbor for price reductions offered by contractors with substantial financial risk to managed care organizations). *Cf.* Learn, *supra* note 130, at 262-67 (discussing safe harbors for personal service contracts, warranties, and referral services).

137. The seven standards for the personal services and managment contracts safe harbor are: (1) the agreement must be in writing and signed by the parties; (2) the agreement must specify the services to be rendered; (3) the agreement must specify the schedule, precise length, and exact charge for any part-time or periodic services; (4) the agreement must be for a term of no less than one year; (5) the compensation to be paid must be set in advance, reflect fair market value, and not take into account the value of referrals payable under Medicare or Medicaid; (6) the agreement must not involve the counseling or promotion of any activity that violates State or Federal law; (7) the aggregate services do not exceed those which are reasonably necessary to accomplish their purpose. 42 C.F.R. §1001.952(d) (1999), *as amended by* 64 Fed. Reg. 63,504, 63,551 (1999).

138. *See id.* § 1001.952(d)(5).

Under the safe harbor for referral services, remuneration does not include any payment or exchange of anything of value between the referring entity and the participant in the referral service, if four conditions are met.[139] The second condition demands that payments to a referral service be assessed equally among participants, and be based on the cost of operating the referral service, not on the value or volume of service.[140] This requirement becomes a problem when a participating physician prescribes pharmaceuticals sold or manufactured by a corporation with an interest in the DMP. Each prescription ordered by a participating physician may be interpreted as a form of remuneration to the referring DMP. Such remuneration bears no relation to the cost of operating the DMP, and lacks uniformity among participating physicians.

Two new safe harbors cover price reductions to "eligible managed care organizations"[141] and "qualified managed care plans,"[142] on the condition that certain standards are met. Safe

139. The requirements for the safe harbor for referral services are: (1) the referral service does not exclude as a participant in the referral service any person or entity (such as a physician or group practice) who meets the requirements for participation; (2) payments made by participants to the referral service must be assessed and collected equally from all participants, and be based upon the cost of operating the referral service, and not on the volume or value of referrals; (3) the referral service may not impose any requirements on the manner in which the participant provides services to a referred person, except that the referral service may require that the participant charges referred persons no more than it charges other persons; (4) the referral service discloses to each person seeking a referral certain information about how the referral service selects or excludes participants from the referrals service, and the nature of any relationship between the referral service and the participant. *See id.* § 1001.952(f).

140. *See id.* § 1001.952(f)(2).

141. *See* 64 Fed. Reg. 63,504, 63,515 (1999) (codified at 42 C.F.R. §1001.952(t)). The three standards for the safe harbor for price reductions to eligible managed care organizations are: (1) the managed care organization and the contractor offering discounts must have a written agreement that specifies the items and services covered, is for a period of at least one year, and places specific limits on when the contractor can directly bill a federal health care program for services under the contract; (2) neither party to the agreement shall give or receive remuneration to induce referrals not covered by the agreement for which payment may be made by a federal health care program; (3) neither party to the agreement shall shift the financial burden of the agreement to a federal health care program. *See id.* at 71,317 (codified at 42 C.F.R. § 1001.952(t)(1)(i)).

142. *See id.* at 53,515 (codified at 42 C.F.R. § 1001.952(u)). The five standards for qualified managed care plans are: (1) the agreement must be in writing and signed by the parties, specify the items and services covered, be for a period of at least one year, include participation in a quality assurance program, and specify a method of determining what is commercially reasonable; (2) any investment interest that the contractor has in the managed care plan must meet certain complex criteria; (3) the contractor must have a substantial financial risk in the cost or utilization of services it

harbors for price reductions are potentially significant because a central purpose of DMPs is to develop cost-effective treatments that may also be accompanied by price reductions.[143] A moderately inclusive safe harbor could eliminate substantial anti-kickback problems. The new safe harbors do not provide such wide relief.

The applicability of the price reduction safe harbors is limited to a narrow subset of managed care providers. The definitions of "eligible managed care organization"[144] and "qualified managed care plan"[145] are sufficiently restrictive to exclude many providers that might logically participate in a DMP. For example, a managed care organization is not "qualified" for the safe harbor for contractors with a substantial financial risk if it serves a patient base where more than 50 percent are Medicare beneficiaries.[146] This would likely exclude a managed care organization that serves a retired population. However, the same managed care program would likely qualify for the safe harbor for "eligible" managed care organizations if it served the elderly under the Programs For All Inclusive Care For The Elderly.[147] These complex distinctions may serve some purpose, but they

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provides; (4) for items and services reimbursable by a federal health care program, a qualified managed care plan must, with some exceptions, submit claims directly to the federal health care program, pursuant to a reassignment agreement, and payments to contractors for items and services reimbursed by a federal health care program must be identical to the payment arrangements for the same items or services provided when not reimbursable by a federal health care program; (5) neither party gives or receives remuneration to induce referrals, other than for items and services covered by the arrangement, for which payment may be made by a federal health care program, and neither party shall shift the financial burden to increase the payments claimed from a federal health care program. *See id.* (codified at 42 C.F.R. § 1001.952(u)(1)(i)).

143. *See* Rosoff, *supra* note 130, 16-17.

144. An "eligible managed care organization" is defined as: (1) a HMO or CMP with a risk or cost-based contract; (2) any Medicare Part C health plan that receives a capitated payment from Medicare, and has its cost sharing approved by HCFA; (3) Medicaid managed care organizations; (4) health plans that provide services to Medicaid enrollees under a risk-based contract with a state agency; (5) Programs For All Inclusive Care For The Elderly (PACE); (6) a federally qualified HMO. *See* 64 Fed. Reg. 63,504, 63,515 (1999) (codified at 42 C.F.R. §1001.952(t)(2)(ii)).

145. A "qualified managed care plan" is defined as one that: (1) offers a comprehensive range of services; (2) provides a utilization and quality assurance program that promotes the coordination of care and prevents inappropriate utilization, and includes grievance procedures and protections against patient financial liability beyond copayments and deductibles; and (3) covers a beneficiary population of which no more than 10 percent, or up to 50 percent under specific circumstances, are Medicare beneficiaries. *See id.* (codified at 42 C.F.R. §1001.952(u)(2)(vi)).

146. *See id.* (codified at 42 C.F.R. §1001.952(u)(2)(vi)(C)(2)).

147. *See id.* (codified at 42 C.F.R. §1001.952(t)(2)(ii)(E)).

have no apparent connection to the issue of whether a given DMP increases or decreases cost-effectiveness.

From this brief discussion, it is clear that DMPs do not fit neatly within any safe harbor. The result is that there will often be some risk of prosecution, despite the complexity of efforts to comply. The unfortunate irony is that many of these legally questionable arrangements help to reduce costs and improve health outcomes.

III. The Case for a Rule of Reason Analysis

The preceding review of the most significant cases on the issue of intent, and the examples of gainsharing and disease management programs, provides a clear indication that the anti-kickback statute, as currently written and interpreted, creates unnecessary tension between governmental and private objectives. The government's stated intent in enacting the anti-kickback statute is to save costs and prevent inappropriate utilization.[148] On the other hand, providers and payers in the private market are under serious pressure to develop cost-effective health care delivery systems. In pursuing its own objectives, the government insists that the laws and regulations must leave room for broad prosecutorial discretion.[149] And, not surprisingly, commentators argue that current regulations unduly restrict the implementation of innovative delivery systems that may be more cost-effective.[150]

148. *See supra* text accompanying notes 24-26.

149. This tendency is apparent in OIG statements regarding both advisory opinions and safe harbors. Regarding the risk of prosecution for compensation arrangements that do not fit completely within a safe harbor, the OIG states:

> [T]he degree of risk depends on an evaluation of the many factors which are part of the decision-making process regarding case selection for investigation and prosecution. . . . We do not believe the Medicare and Medicaid programs would be properly served if we assured protection in all instances of 'substantial compliance,' 'technical violations,' or 'de minimis' payments. Unfortunately, these are vague concepts, subject to differing interpretations. . . . The OIG therefore declines to adopt these concepts.

56 Fed. Reg. 35,952 (1991).

In declining to issue model advisory opinions the OIG states:

> [I]t is unlikely that a party could precisely duplicate an approved arrangement; invariably, there would be differences, some of which might be significant. Sanction authorities impose liability based on acts by specific people in particular factual circumstances. Thus, a particular arrangement may be legal with respect to one party, but not with respect to another.

Issuance of Advisory Opinions by the OIG, 63 Fed. Reg. 38,311, 38,314 (1998) (to be codified at 42 C.F.R. pt. 1008).

150. *See supra* note 14 and accompanying text.

While the government's campaign against inappropriate utilization and unnecessary costs is often in tension with the goal of private organizations to enhance revenue, these objectives are not necessarily incompatible. The friction between governmental and private imperatives has little to do with any fundamental differences between governmental interests and mainstream private interests.[151] There will always be a temptation for some health care organizations to seek profits through inappropriate utilization, and the government has a clear and unassailable interest in eliminating such abuses. But most organizations, both for-profit and nonprofit, recognize that, in the long-term, the most effective way to enhance revenue is to satisfy consumer demand for cost-effective care.[152] And, unintended consequences aside, the government has expressed no interest in preventing cost-effective care.

The tension between the government and private health care lies more at the margins, where the innovations fall into the gray zone of legal uncertainty. Two factors contribute to this tension. First, the lack of consensus among the courts makes it difficult to anticipate how government agencies or the courts will treat a given business arrangement, particularly in jurisdictions that have not recently ruled on the issue of willfulness. Second, and more fundamentally, the anti-kickback statute does not distinguish between compensation arrangements that increase costs or compromise patient care and arrangements that have no pernicious effects.[153] The anti-kickback statute flatly prohibits all arrangements involving remuneration in connection with an intent to induce referrals, regardless of the arrangement's actual ethical and economic effects.[154]

As the statute is currently written and interpreted, the only real distinction by the courts between different types of compensation arrangements relates to proof requirements, not the substance of the prohibited conduct. Under the law, an arrangement that enhances patient care and reduces costs is as

151. *See supra* note 15 and accompanying text.

152. This assumes a functioning market where consumers have ready access to information regarding cost and quality. When consumers lack such information, market failure may result, and government intervention may be necessary to correct an information imbalance. *See* Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 102-03 (1995).

153. *See* United States v. Bay State Ambulance and Hosp. Rental Serv., Inc., 874 F.2d 20, 32 n.21 (1st Cir. 1989).

154. *See id.*

illegal as an arrangement that grossly compromises the physician's professional relationship with patients. The main difference between the two is that it is far easier to prove unlawful intent in one instance than it is in the other. Cases like *Starks* exemplify this point, making it difficult to argue that the defendants did not know the conduct in question was wrong even under a more exacting standard of intent (as in *Hanlester*).

The fact that there is no formal legal distinction between potentially beneficial and obviously corrupt arrangements is mitigated to some degree by the government's assurance that it is likely to prosecute anti-kickback violations only if they involve a serious breach of a physician's obligations to patients.[155] That is, there must be a statutory violation *plus* some indication that the physician's fiduciary duties are likely to be compromised.[156] But this unwritten assurance does nothing to define precisely what this "plus" factor must be; nor does it offer any legal certainty for those who wish to remain within the letter of the law rather than merely avoid prosecution.

It is clear that the price for the simplicity of an all-inclusive prohibition is that the statute discourages or prevents many potentially beneficial compensation arrangements.[157] This sacrifice is not necessary. The tension between private and governmental interests could be greatly reduced, and public well-being correspondingly enhanced, if the applicable legal standard explicitly accounted for the distinction between those compensation arrangements that are obviously corrupt and those that are more defensible.

Such a distinction can be drawn by borrowing from antitrust law, where there is a conceptual difference between conduct treated as a per se violation and conduct that is subject to a rule of reason. Under the latter analysis, courts and regulators balance the anticompetitive impact of a given arrangement or practice against the procompetitive efficiencies.

A. Rule of Reason

The statutory framework of federal antitrust law consists of the Sherman Act, the Clayton Act, and the Federal Trade Com-

155. *See* AHLA, *supra* note 7, at 17.

156. *See id.* at 24.

157. *See supra* note 14 and accompanying text.

mission Act.[158] The rule of reason is the product of common law interpretations of section 1 of the Sherman Act. Taken literally, the Sherman Act would prohibit every contract, combination, or conspiracy in restraint of interstate or foreign trade.[159] Early Supreme Court decisions interpreted the word "every" literally, and imposed broad prohibitions. In *United States v. Trans-Missouri Freight Ass'n,*[160] the Court held that a price fixing agreement between railroad companies violated the Sherman Act, notwithstanding the argument that prices as set were not excessive and that the arrangement was necessary to ensure business stability. The Court stated the "plain and ordinary meaning" of the statute does not confine the prohibitions to only those restraints of trade that are unreasonable.[161]

However, in *Standard Oil Co. v. United States,*[162] the Court developed a more nuanced interpretation of the statute that distinguished reasonable and unreasonable restraints of trade. Standard Oil Company developed and exercised monopolistic power over a substantial portion of the production, transportation and sale of petroleum products in the United States.[163] It achieved this power largely by conspiring with and acquiring competing companies to limit competition.[164]

In examining Standard Oil's conduct under the Sherman Act, the Court set forth its first articulation of what is now known as the rule of reason. Although the Court ordered Standard Oil to

158. Section 1 of the Sherman Act prohibits all contracts, combinations, and conspiracies in restraint of interstate or foreign trade. 15 U.S.C. § 1 (1994 & Supp. 1997).

Section 2 of the Sherman Act prohibits monopolies, attempts to monopolize, and conspiracies to monopolize. 15 U.S.C. § 2 (1994).

Section 2 of the Clayton Act, commonly known as the Robinson-Patman Act, prohibits price discrimination for goods sold in interstate commerce. 15 U.S.C. § 13 (1994).

Section 7 of the Clayton Act prohibits mergers and acquisitions that may substantially reduce competition or tend to create a monopoly. 15 U.S.C. § 18 (1994 & Supp. 1998).

Section 5 of The Federal Trade Commission Act gives authority to the Federal Trade Commission to challenge unfair or deceptive trade practices. 15 U.S.C. § 45 (1994).

159. Section 1 of the Sherman Act reads: "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal." 15 U.S.C. § 1 (1994).

160. 166 U.S. 290, 330-31 (1897).

161. *Id.* at 328.

162. 221 U.S. 1 (1911).

163. *See id.* at 71.

164. *See id.* at 56-60

spin off its various subsidiaries, the Court determined that it would be unreasonable and against the presumed legislative intent to adopt a literal understanding of the word "every" as found in section 1 of the Sherman Act. The Court, thus, examined the Sherman Act within the context of the preceding common law on restraint. The Court inferred that the law was written broadly in order to include the different types of contracts and combinations that would emerge in an evolving economy, but that the legislative intent was to prohibit only those arrangements which imposed an undue restraint on trade.[165] In order to distinguish between permissible and impermissible restraints, the Court adopted a "rule of reason" to examine the direct and indirect effects of a particular arrangement.[166]

In *Chicago Board of Trade v. United States,*[167] the Court further developed the doctrine of the rule of reason. In this case, the Court approved an agreement between members of the Chicago Board of Trade which limited trading during off-market hours. The agreement prohibited members from purchasing or offering to purchase grain "to arrive" between the time of the closing bids on one day and opening bids the next day at a price other than the last closing bid.[168] In approving this arrangement, the Court distinguished between restraints that suppress and those that promote competition.[169] In order to determine the actual or probable effect of a given restraint, the Court emphasized that it would look to the particular facts and the intent of the parties. The Court noted that, while good intent will not save an anticompetitive trade restraint, knowledge of the parties' intent may help the Court predict the likely consequences of the arrangement.[170]

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165. *See id.*

166. *See id.* at 66.

167. 246 U.S. 231 (1918).

168. *See id.* at 237.

169. The Court set forth a concise formulation of the rule of reason: "The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition." *Id.* at 238.

170. The Court stated:

> [T]he court must ordinarily consider the facts peculiar to the business to which the restraint is applied; . . . The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because good intention will save an otherwise objectionable regulation or the reverse; but . . . knowledge of intent may help the court to interpret facts and to predict consequences.

This formulation of the rule of reason accommodates the common purpose of all commercial agreements–to regulate trade between parties and, thereby, to restrain trade to some degree.[171] By acknowledging this fact and applying the rule of reason, the Court in *Chicago Board of Trade* avoided an unreasonable result that a strict reading of the Sherman Act would create. Because the trading restrictions were on balance procompetitive, the Court held the restraints to be reasonable and permissible.[172] This method weighs the benefits of a given practice, in contrast to the per se rule.

B. Per Se Rule

Under the per se rule, certain categories of business conduct are judged by the courts to be so consistently anticompetitive that they are categorically prohibited without close examination of the precise harms or business.[173] This generalization reflects a judgment by the courts that the anticompetitive effects of certain types of business arrangements consistently outweigh any procompetitive benefits and should, therefore, be prohibited.[174] The per se rule permits a degree of business certainty and litigation efficiency that would not be possible if the courts had to evaluate each individual business arrangement. The price for this efficiency is that some arrangements are summarily invalidated, though closer examination might show that they are reasonable in a particular case.[175] The per se rule also reflects a judgment that this does not occur frequently enough to justify the time and expense necessary to individually evaluate each business arrangement.[176] Several types of practices are judged

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Id. at 238.

171. *See id.* at 237.

172. *See id.* at 240.

173. *See* Continental T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36, 50 (1997) (citing Northern Pac. R. Co. v. United States, 356 U.S. 1, 5 (1958)).

174. *See* Arizona v. Maricopa County Med. Soc'y, 457 U.S. 332, 351 n.23 (1982) (citing United States v. Socony-Vacum Oil Co., 310 U.S. 150, 226 n.59 (1940) ("Whatever economic justification particular price-fixing agreements may be thought to have, the law does not permit an inquiry into their reasonableness. They are all banned because of their actual or potential threat to the central nervous system of the economy.").

175. *See Maricopa County*, 457 U.S. at 344 & n.16 (citing United States v. Topco Assocs., Inc., 405 U.S. 596, 609 (1972)).

176. *See Continental T.V.*, 433 U.S. at 50 n.16.

under the per se rule, including tying arrangements,[177] boycotts,[178] and horizontal price fixing.[179]

The per se rule was set forth in *United States v. Trenton Potteries Co.*,[180] which involved a group of individuals and corporations that together controlled over eighty percent of the manufacture and distribution of sanitary pottery for use in bathrooms and lavatories in the United States. The defendants were convicted in district court of agreeing to (1) fix prices and (2) limit sales to "legitimate jobbers." The trial court instructed the jury that such agreements were, in and of themselves, unreasonable restraints on trade, and that if the jury found that the parties participated in such agreements, it could return guilty verdicts without considering whether prices were fixed at reasonable levels or whether sales were actually restricted to "legitimate jobbers." The Second Circuit reversed their convictions. One of the issues before the Supreme Court was whether the trial court should have allowed the jury to determine whether the agreements constituted an unreasonable restraint of trade.[181]

The Supreme Court held that the trial court correctly withdrew from the jury the question of whether the alleged restraints were unreasonable.[182] In finding the agreements per se unlawful, the Court stated that the purpose of every price-fixing agreement is to eliminate competition, and that agreements which create such power, whether reasonably exercised or not, are unlawful per se.[183]

177. The per se rule against tying arrangements was first announced in *International Salt Co. v. United States*, 332 U.S. 392, 396 (1947). The Court has since limited the rule to circumstances where a purchaser of the tying product is effectively forced to purchase a tied product. *See* Jefferson Parish Hosp. Dist. v. Hyde, 466 U.S. 2 (1984) (approving an exclusive services contract between an anesthesiologist group and a hospital because there was no evidence that any patient expressed a desire to use any other anesthesiologist).

178. *See* FTC v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411 (1990) (disapproving an agreement among independent trial lawyers to withhold services until the compensation for appointed cases was increased).

179. *See Maricopa County*, 457 U.S. at 348-55 (disapproving an agreement setting price caps for certain procedures); United States v. Trenton Potteries Co., 273 U.S. 392 (1927).

180. 273 U.S. 392 (1927).

181. *See id.* at 394-95.

182. *See id.* at 401.

183. *See id.* at 371.

> The power to fix prices, whether reasonably exercised or not, involves power to control the market and to fix arbitrary and unreasonable prices. . . . Agreements which create such potential power may well be held to be in themselves unreasonable or unlawful restraints, without the necessity of

This application of the per se rule is fairly representative in that it reflects that a category of practices lacks any positive net social utility. Consequently, such practices are prohibited.

Notwithstanding the differences between the rule of reason and the per se rule, the objective of both is to prevent anticompetitive business practices while permitting those that are on balance procompetitive. Under both rules, courts will examine a given arrangement to the extent necessary to determine with reasonable certainty whether the competitive efficiencies outweigh the anticompetitive effects. The primary difference between these rules lies in how far the courts must look to make the necessary determination.[184] Under the per se rule, courts must look only far enough to determine whether the practice in question falls into one of the prohibited categories. In contrast, under the rule of reason, courts must examine the particular competitive efficiencies. But the common objective of both is to maximize market efficiencies and, thereby, advance net social utility.[185]

The rule of reason/per se distinction allows courts to reasonably interpret and apply the very broad prohibitions of the Sherman Act. Similar conceptual distinctions should be employed under the anti-kickback statute in order to achieve the original legislative intent of preventing inappropriate utilization and the consequent increases in cost and compromises in quality.

C. *An Anti-Kickback Rule of Reason*

The anti-kickback statute and the Sherman Act contain similarities in that they both impose very broad prohibitions and apply to a wide range of business practices, some of which appear on their face corrupt and others which are more defensible on the basis of social utility. For example, the Chicago Board of Trade's decision to limit trading during off-market hours was held to be reasonable,[186] even though it was a restraint of trade,

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minute inquiry whether a particular price is reasonable or unreasonable as fixed . . . .

See id. at 397.

184. Craig D. Bachman, *Legal Analysis of Health Care Antitrust Issues: What Rules Apply?- Per Se Offenses*, *in* ANTITRUST HEALTH CARE ENFORCEMENT & ANALYSIS, at 3, 7 (M. Elizabeth Gee ed., 1992).

185. "[T]he per se rules . . . are . . . directed to the protection of the public welfare; they are complementary to, and in no way inconsistent with, the rule of reason." United States v. Topco Assocs., Inc., 405 U.S. 596, 621 (1972) (Burger, J., dissenting).

186. Chicago Bd. of Trade v. United States, 246 U.S. 231, 240 (1918).

but the exclusionary practices in *Standard Oil* were impermissible.[187] Similarly, the anti-kickback statute reaches both potentially beneficial disease management programs, as well as obviously corrupt bribery and kickback schemes. From a cost-benefit perspective, arrangements likely to produce some net social utility should be treated differently than those that will not. A rule of reason in the anti-kickback context would permit clear legal distinctions between such practices that are not now explicit in the statute or judicial interpretations.

Both the anti-kickback statute and the Sherman Act are intended to promote efficiency. Under the Sherman Act, the Court uses the rule of reason to balance competitive and anticompetitive effects.[188] The assumption here is that a competitive market will most efficiently advance the public welfare.[189] The legislative history of the anti-kickback statute lists cost and quality as significant concerns.[190] An underlying point of the anti-kickback statute is to prohibit compensation arrangements that contain economic incentives to inappropriately utilize health care resources. Legislative intent notwithstanding, neither the statute nor the courts recognize inappropriate utilization, and the accompanying cost increases or decreases in quality, as necessary elements of the offense.[191] Thus, a rule of reason focusing on cost and quality would be more consistent with the original legislative intent than current judicial interpretations of the statute.

An additional similarity between the business practices governed by the anti-kickback statute and the Sherman Act is that under either statute, the parties' intent provides an indication of the likely results of a given business arrangement. The observation here is simple: if the parties have a corrupt intent, then the effects are likely to be corrupt. However, the statutes also differ on the issue of intent. Under the Sherman Act, courts look to party intent as only one factor influencing procompetitive or anticompetitive results.[192] Intent itself is not controlling. On the other hand, under the anti-kickback statute, the parties' intent is

187. Standard Oil Co. v. United States, 221 U.S. 1, 55-60 (1911).

188. *See supra* note 170.

189. *See supra* note 186 and accompanying text.

190. *See supra* note 24-26 and accompanying text.

191. *See* United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 33 n.21 (1st Cir. 1989).

192. *See* Chicago Bd. of Trade v. United States, 246 U.S. 231, 238 (1918).

controlling, regardless of cost or quality.[193] Here, too, a rule of reason could be usefully employed to widen the focus of courts to include cost and quality.

If social utility is an objective of the anti-kickback statute, then there are persuasive arguments for the adoption of a rule of reason. As outlined above, a rule of reason would permit distinctions between different types of business activity. It would encourage an explicit examination of the efficiencies involved in a given arrangement, and it would force the courts and regulators to focus more carefully on issues of cost and quality. A rule of reason should be statutorily enacted in order to offer clarity to market participants and to facilitate the legislative intent. The OIG's promise not to challenge a compensation arrangement unless it is likely to produce increased costs and compromise care is insufficient.[194] OIG's adherence to the *Greber* "one purpose" rule speaks for more articulately than clearly any informal assurance of prosecutorial moderation. Without a legislatively enacted rule of reason, there is no assurance that reason will prevail in any given case.

Consistent with antitrust jurisprudence,[195] the rule of reason should be available as an affirmative defense if the arrangement fits within certain parameters. Compensation arrangements that unnecessarily compromise care or increase costs without corresponding improvements in clinical outcomes would be treated as illegal per se. However, it will often be a complex task to determine whether a given arrangement is appropriately judged under a rule of reason, and, if so, whether the arrangement passes muster. The following discussion examines some of the variables involved in a rule of reason, cost-benefit analysis, and then for an example, briefly considers how gainsharing arrangements and disease management programs would be evaluated under a rule of reason.

IV. Cost-Benefit Analysis and a Rule of Reason

The rule of reason presumes a cost-benefit analysis whereby the courts and government agencies try to ascertain whether a given business practice increases or decreases net social utility.

193. *See Bay State Ambulance*, 874 F.2d at 33 n.21.

194. *See* AHLA, *supra* note 7, at 17.

195. *See, e.g.*, National Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679 (1978) (rejecting the defense that a prohibition against competitive bidding was justified under the rule of reason).

In an antitrust case, this involves a comparison of competitive and anticompetitive effects. Although the measurement of market impact is neither simple nor precise, the direct comparison of competitive and anticompetitive effects is more straightforward than a cost-benefit analysis under an anti-kickback rule of reason.

A. Cost and Quality Variables

A cost-benefit analysis in health care typically requires the balancing of economic costs against the quality of clinical outcomes.[196] Two tasks present themselves in this comparison. First, the quality of health outcomes for a given type of treatment must be accurately measured. The ability of researchers to measure clinical outcomes and patient satisfaction is well developed and has advanced substantially since the 1970s.[197]

The second task is more complex and requires that health outcomes for a given treatment be measured against economic costs. There are two complicating factors involved in any attempt to balance the cost of treatment against the quality of clinical outcomes. First, marginal costs and quality of clinical outcomes will often vary with time and units of patient care delivered.[198] The result of this variability between cost and quality is that there will very rarely be a straight line ratio where costs or quality go up or down at a constant rate. Rather, the ratio may change over time and with volume. For instance, marginal costs may decrease and quality may improve to a certain level of productivity, beyond which marginal costs may begin to increase.[199] One reason for this is that economies of scale relating to fixed and variable costs will usually permit a higher quantity of patient care to be delivered at a lower cost per unit than a smaller quantity.[200] The practical implication of this is that no compensation arrangement can be judged out of context. Consideration must be given to the type and quantity of care delivered under any given compensation arrangement.

196. *See generally* Alice G. Gosfield, *Value Purchasing in Medicare Law: Precursor to Health Reform*, 20 AM. J.L. & MED. 169 (1994).

197. *See* Troyen A. Brennan, *The Role of Regulation in Quality Improvement*, 76 MILBANK QUARTERLY 709 (1998).

198. *See generally* Hal R. Varian, INTERMEDIATE MICROECONOMICS: A MODERN APPROACH 351-2 (4th ed. 1996) (discussing marginal and variable costs).

199. *See id.*

200. *See id.* at 352 (the average cost curve will initially fall with increased production because of a corresponding decrease in fixed costs per unit).

The second complicating factor in balancing health care costs and quality is that in many instances it will be necessary to directly compare a given amount or marginal change in one against a given amount or marginal change in the other. The difficulty with this task is that health and money have qualitatively different values.[201] A bundle of health care is not the same as a bundle of money. An essential difference between the valuations of money and health is that health is an intrinsic good with a value of its own, whereas money is an instrumental good, having value only insofar as it serves other ends.[202] For this reason, money and health outcomes cannot be easily or categorically measured one against the other as readily as, say, the monetary value of competitive and anticompetitive effects.

One practical manifestation of this difference is that people think differently about their health than they do about money. Losing or regaining your health is not the same as losing or acquiring money, and it would be an obvious over-simplification to treat them as representing just more or less of the same thing.[203] Health and money are not the same, and it is not possible to value both along a single metric without distorting or diminishing substantial characteristics of both.[204] In this sense, health and money are incommensurable goods.[205]

Much could be said about incommensurability, but for present purposes, the significant point is that without a common unit of measure, it is impossible to develop an algorithm to direct meaningful choices between health and money.[206] For this reason, rational choices between costs and quality will necessarily be practical, rather than theoretical or abstract.[207] The goal is to develop a balance that minimizes the adverse effects on both costs and quality. This raises the question about the relative weights cost and quality should be assigned. Though a discussion of this normative choice goes well beyond the scope of this

201. *See generally* SUNSTEIN, *supra* note 21, at 72-3 (1997) (discussing different types of valuation with a particular focus on money).

202. *See id.* at 72 (distinguishing between intrinsic and instrumental goods).

203. *See id.* (contrasting the loss of a friend, an intrinsic good, with the loss of money, an instrumental good).

204. *See id.* at 80 (naming money as an example of a single metric, where one amount can easily be measured against another).

205. *See id.* (incommensurability occurs when "relevant goods cannot be aligned along a single metric without doing violence to our considered judgments about how these goods are best characterized.") *Id.*

206. *See id.* at 101.

207. *See id.*

article, it is worth noting that some practical agreement already exists about the broad parameters. For example, most would agree that a substantial improvement in the prevention or treatment of strokes would be worth a substantial amount of money–even without taking into account improvements in patients' earning potential. And most would agree that a slight reduction in the rate of the common cold would not be worth substantial increases in health care expenditures–especially if those increases greatly exceed lost income from sick days. However, the balance of cost and quality rarely invovles such an obvious point of consensus. The immediate objective here is to develop a conceptual framework within which more typical (and common) cases can be examined. Thus, no effort will be taken to develop a set of relative values between cost and quality here.

The scenarios in which a cost-benefit analysis is appropriate can be categorized into four groups, two of which include cases that are difficult to resolve and two of which are relatively easy. The two types of more difficult cases include situations where increased expenditures produce a corresponding improvement in clinical outcomes, or where a decrease in expenditures results in a diminution in the quality of care. In instances where the compensation arrangement causes both costs and quality either to increase or decrease, it will be necessary to determine whether the increase or decrease in one is justified by the parallel increase or decrease in the other. These types of cases are difficult because health and money are valued differently and cannot be adequately compared using a single unit of measure.

Not all compensation arrangements are as difficult to evaluate. A compensation arrangement clearly fails a cost-benefit analysis if it drives up costs while the quality of clinical outcomes decreases. If such an arrangement involves compensation in exchange for referrals, it is and should be illegal under the anti-kickback statute. On the other hand, if a compensation arrangement improves clinical outcomes and either reduces or maintains costs, the arrangement should pass muster under a cost-benefit analysis.

Given the legislative intent of the anti-kickback statute, a compensation arrangement that improves clinical outcomes at no cost should be approved unless there is a compelling reason to prohibit it. Indeed, the anti-kickback statute is self-defeating

to the extent that it prohibits compensation arrangements that improve clinical outcomes without increasing costs.[208]

B. Gainsharing, Disease Management Programs, and Legal Defenses

Under an outcomes-based, cost-benefit approach, disease management programs, gainsharing and other compensation arrangements would be analyzed very differently than at present. The legal test of a given arrangement would be whether it improves cost-effectiveness. It would be unnecessary to fit an efficiency-enhancing compensation arrangement within safe harbors or to guess the OIG's interpretation of intent. Instead, providers could gain a clear indication of whether a given arrangement is permissible by developing the appropriate outcomes data. For example, a gainsharing plan that compensates physicians with a fair portion of the savings attributable to their innovations would pass muster if the arrangement improves cost-effectiveness. Likewise, a disease management program compensating a pharmaceutical manufacturer for patient management would be judged under the same principle.

The proposal here is that the parties to a compensation arrangement should be able to assert as an affirmative defense to an anti-kickback claim that the arrangement in question improves cost-effectiveness. To raise the defense, the parties would need to develop the necessary outcomes data to credibly demonstrate this point. This might require a neutral party to conduct the supporting outcomes research. In any event, placing the burden on the parties to the arrangement would accomplish two important objectives. First, it encourages the parties to conduct outcome studies before implementing any questionable compensation arrangements on a large scale. Second, it conserves governmental resources that would otherwise be used to collect the data necessary to show that any number of suspect arrangements did not enhance cost-effectiveness.

This proposal for an affirmative defense is not a perfect solution for private industry. An affirmative defense provides no assurance against costly prosecutions, although it reduces the likelihood. Second, the burden of producing outcomes data sufficient to show cost-effectiveness is significant. However, the burden is appropriately placed on the parties who have the

208. *See id.* at 276 (suggesting a statute or regulation that does not produce a net benefit is self-defeating if its purpose is to achieve a net improvement).

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greatest access to the data and the most control over the clinical outcomes.

Conclusion

The conclusion here, as stated in the introduction, is uncomplicated. The public interest is better served if outcomes are taken into account when enforcing a statute that was originally intended to protect patients and federal health care programs against inappropriate utilization. The almost exclusive focus on intent fails to achieve the desired result. For this reason, the anti-kickback statute has proven too confusing and has created unnecessary tensions between private objectives and law enforcement imperatives.