



THE ABA HEALTH LAW SECTION

THE HEALTH LAWYER

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THE GOVERNMENT UNLEASHES THE STARK LAW TO ENFORCE THE FALSE CLAIMS ACT: THE IMPLICATIONS OF THE GOVERNMENT'S THEORY FOR THE FUTURE OF FALSE CLAIMS ACT ENFORCEMENT

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Introduction

In the pantheon of healthcare fraud and abuse laws – based upon dollars recovered – stand the False Claims Act (“FCA”)¹ and the Anti-Kickback Statute.² Besides criminal prosecutions under the Anti-Kickback statute, essentially all substantial FCA settlements have included an allegation of and a release for a governmental claim that the defendant had breached the Anti-Kickback statute.³

Long ignored by the government in its law enforcement efforts under the FCA has been the Ethics in Patient Referrals Act, which is better known as the Stark Law.⁴ The Stark Law was initially passed in 1989 and applied to referrals of Medicare patients for clinical laboratory services made on or after

January 1, 1992 by physicians with a prohibited financial relationship with a clinical lab provider (known as Stark I).⁵ In 1993, Congress extended the Stark Law to referrals for ten additional designated health services (known as Stark II).⁶ The Stark legislation has triggered several rounds of rulemaking as the Health Care Financing Administration, now known as the Centers for Medicare and Medicaid Services (“CMS”), has sought to define several of the statute’s ambiguous terms.⁷ The rulemaking process is not yet complete.⁸

Most defense counsel had reasonably assumed that the basis for the government’s reluctance to invoke the Stark Law in FCA actions was the fact that the government has not issued final regulations interpreting the full scope of the Stark Law. The logic underlying the assumption is that if a statute is so vague that it requires several rounds of rulemaking spanning more than a half dozen years and yet the government still has not

A Note From Our Director

This year the Section celebrates its fifth anniversary as a full-fledged Section of the American Bar Association. First developed in 1976 as an ABA forum, the Health Law Section is the only forum to attain Section status. As we enter the beginning of the new ABA year, it seems like a good time to reflect on where the Section has been, and more importantly, where it is headed.

Five years ago under the leadership of E. Paul Herrington, III, the Forum on Health Law lobbied for and won Section status. Why was this important? Section status gave the Section a voice in the legislative activities of the ABA and allowed us to have two Delegates to the ABA House of Delegates. Without this move, the Section would not have as much opportunity to influence ABA policy on health law related matters as we do now.

Four years ago the Section recognized the need to fully support its important works and went from a part-time director to a full time director with two additional staff members. We have built a strong team with the help of a committed, talented leadership. This team is essential as we move forward on a number of Section projects and legislative initiatives.

Three years ago the Section began developing its ten Interest Groups. It is through these entities that the Section's major work is done. They develop CLE programs, review and comment on legislative activities, provide material for *The Health Lawyer*, and address important Section issues. The Interest Groups are evolving entities. For example, the *Clinical Ethical Issues Interest Group* broadened its focus this year to encompass the field's changing emphasis on technology and the important questions arising from it, changing its name to the *Medical Research, Biotechnology & Clinical Ethical Issues Interest Group*. The *Transactional & Business Healthcare Interest Group* will focus on complex health care transactions in the upcoming year. Look for all of the Interest Groups to make significant headway in developing their agendas to meet their constituents' interests and needs.

Two years ago the Section initiated its first Midyear meeting, centered around the *Emerging Issues* program. We looked at how legislation in both the Clinton and Bush administrations affected health law, how we dealt with transitions in the changing business of healthcare, and what impact technology was having on the delivery of healthcare and on the various reporting requirements. We also looked at the newly released Stark II, HIPAA, and Intermediate Sanctions regulations. The calendar year ahead will mark the Section's Third Annual Midyear meeting. The *Emerging Issues* program will take place at the end of February in Scottsdale, AZ. Section leaders and our membership will

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arrived at a definitive conclusion regarding the proper scope and interpretation of the statute, how could defendants rightfully be charged with knowing and understanding the full scope of the statute such that they are subjected to treble damages and civil penalties for breaching the Act's undefined terms?

Notwithstanding the government's failure to issue final rules interpreting the Stark Law in its entirety, the government has recently intervened in several *qui tam* actions alleging that various defendants have violated the FCA because they knowingly violated the Stark Law. The government's shift in enforcement strategy will trigger the development of important, new case law under the FCA regarding the scope of that statute.

Set forth below is a description of the government's theories in its complaints alleging a violation of the Stark Law based upon a violation of the FCA and a discussion of its strategy for invoking the Stark Law rather than the Anti-Kickback Statute in recent litigation. Further, various defenses that are likely to arise in the short term to challenge the government's theory are addressed.

The Government's Recent Actions Employing the Stark Law to Enforce the FCA

Recently, the government has intervened in high profile *qui tam* actions asserting that defendants breached the FCA because they allegedly breached the Stark Law. These cases are noteworthy both because the government asserted its view in court that a violation of the Stark Law can result in a violation of the FCA and because, in some of these actions, the government expressly disavowed any claim that the defen-

dants' conduct resulted in a violation of the Anti-Kickback Law and instead asserted that the allegedly improper conduct only violated the Stark Law, thereby indicating its intent in the future to employ the Stark Law, rather than the Anti-Kickback Law, as its enforcement vehicle of choice in FCA cases involving physician referrals.

On February 15, 2001, the United States intervened in a whistleblower action filed against Tenet Healthcare Corporation contending that it violated the FCA because it knowingly paid an inflated price to acquire physician practices in South Florida to induce those physicians to refer to Tenet owned facilities in violation of the Stark Law and the Anti-Kickback Act.⁹ The relator in that action was formerly a Chief Executive Officer of Tenet's Physician Services for the Florida Region from January to July 1996.¹⁰ He claimed that Tenet paid more than fair market value for physician practices to induce the physicians to make referrals to Tenet facilities.¹¹ Specifically, the relator contended that the amounts paid to physicians exceeded "the annual compensation received by virtually all similar health care professionals across the country" and that the physician practice appraisals, productivity studies, and "comparisons of physician compensation to practice net revenue" all demonstrated that the physician compensation "was not financially justified."¹² The United States intervened in the relator's action and stated in its Notice of Intervention that Tenet's alleged conduct violated the Stark Law.¹³ Interestingly, however, the United States expressly declined to intervene in the relator's assertion that the same conduct violated the Anti-Kickback Act.¹⁴

The government's position in the Tenet case was a harbinger of the position the United States would take one month later in the HCA – The Healthcare Company ("HCA") cases. In

United States ex. rel. King v. HCA – the Healthcare Company, et al.; *United States ex rel. Mroz v. HCA – the Healthcare Company, et al.*; *United States ex rel. Thompson v. HCA – the Healthcare Company*,¹⁵ the government contended that the defendants had breached the Stark Law and the Anti-Kickback Act because defendants had offered remuneration to physicians in various forms, including but not limited to (1) payments enabling the physicians to purchase partnership interests in defendants' local hospitals; (2) loans offered to physicians with the understanding that no interest and/or repayment would be required; (3) various lease benefits, including free and reduced rent and free remodeling; (4) directorship contracts that provided for payments to physicians not required to perform any duties; (5) lavish trips for physicians and their spouses; (6) free pharmaceuticals; (7) salary payments to physicians' employees; and (8) excessive payments for businesses owned by physicians.¹⁶

As specific examples of violations, the government alleged that the defendants engaged in some of the following conduct:

- "Preferential Investment Opportunities" – The government alleged that the defendants, in selling subscriptions for a partnership it would forge with local physicians, had targeted and solicited only those physicians who maintained the types of practices that routinely refer patients to hospitals and other health care facilities for inpatient and/or outpatient care. Further, defendants allegedly informed physicians that projected distributions would be directly linked to patient referrals such that "if they referred X number of patients, their expected distribution would be Y, and that as their referrals increased, so would their distributions."¹⁷

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- “Sham Equity Investments” – The government alleged that the defendants had offered and provided investments to physicians at minimal or no out of pocket cost to the physicians for the express purpose of inducing referrals. According to the government when the defendants loaned funds to physicians, pursuant to the issuance of a promissory note, the defendants’ officials “assured physicians that the promissory note investment vehicles were ‘risk free’ and that ‘no personal money’ would be involved” and that the physicians’ belief was “evidenced by one physician’s failure to list the note on a loan application, despite listing other debts.”¹⁸
 - “Sham Loans Not Related to Partnership Units” – The government alleged that the defendants at times made personal and business loans to physicians “to garner their patient referrals.” The government further contended that the defendants made minimal or no collection efforts on such loans and took no efforts to enforce the terms of the promissory note if a physician was delinquent or in default.¹⁹
 - “Sham Medical Office Building (MOB) Leases” – The government contended that the defendants had entered into “certain ‘side letter’ agreements with the physicians with additional remuneration including free rent, free parking spaces, reduced rent, and free remodeling among other things.”²⁰ Further, the government alleged that defendants would provide below market rent to physicians so that they would locate their office on the campus of the hospital and refer their patients to the hospital and paid “generous cash moving expenses” to offset relocation expenses as well as advertising and announcement support.²¹
 - “Sham Property Transactions” – The government alleged that the defendants evaluated the construction of an MOB based upon the combination of rental revenue and “Hospital Impact From Recruitment” and not simply the rental revenue the market could generate for the space and that on one occasion they approved construction of a MOB “purely on the basis of the value and volume of referrals the new building’s primary tenant could generate.” The government further alleged that the defendants “frequently overpaid and/or had no legitimate purpose for the space acquired or leased” from referring physicians and that defendants would incur “unnecessary expense to relieve physicians of lease or ownership burdens to enable them to move their practices, and their referrals, to [defendants] facilities.”²²
 - “Sham Personal Service Agreements (PSAs)” – The government alleged that the defendants had entered into certain medical directorship and/or consulting agreements with physicians. For example, the United States referred to one 80 bed psychiatric hospital that had an average patient occupancy rate of approximately 54 percent and yet had “in existence twenty-two directorships with physicians, at least seventeen of whom performed no work as directors.” Further, the government contended that at one point the “sham directorships included, among others: medical directors of ‘Bicultural,’ ‘Advertising,’ ‘P.R.,” ‘Spiritual Programming,’ and ‘Adjunctive.’”²³
 - “Improper Gratuities” – The government asserted that the defendants had provided illegal remuneration in the form of lavish out of town trips for physicians, their spouses and their families as a reward for reaching specific referral goals. These trips, according to the government, included various fishing trips to Alaska, the Amazon, Venezuela, Costa Rica, and dove hunting in Mexico.²⁴
 - “Free Pharmaceuticals” – The government contended that the defendants provided illegal remuneration to certain physicians in the form of free pharmaceuticals at the pharmacies at their facilities as an inducement for patient referrals and that at least one physician would in turn sell “the medication he acquired for free ... to his patients, and kept the proceeds for himself.”²⁵
- In the government’s complaints in the HCA case, as in the Tenet case, the government distinguished between alleged violations of the Stark Law and alleged violations of the Anti-Kickback Act. For example, in the HCA case, the government set forth specific unlawful remuneration paid from the hospitals to physicians that the government alleged breached the Stark Law, but not the Anti-Kickback Act, and concerned remuneration paid “to physicians with whom the hospital had no written PSA or other document memorializing the purpose or consideration the hospital received for the payment.”²⁶
- In describing how the PSA can violate the Stark Law, the government noted in the complaint that the Stark Law would necessarily be breached when the compensation paid to the physician exceeded fair market value:
- For example, compensation paid to a referring physician serving as a consultant to a hospital will fall

within an exception to the statute if the contract (1) is in writing and signed by the parties; (2) is for a term of a least one year; (3) specifies the services covered, covers all the services to be provided by the physician, and the aggregate of such services is reasonable and necessary for the legitimate business purposes of the hospital; and (4) sets the payment for contract services in advance, consistent with fair market value for services actually rendered, not talking into account the volume or value of the referrals or other business generated between the parties. 42 U.S.C. § 1395nn(e)(3). Thus, compensation paid to a physician (directly or indirectly) under a medical directorship that exceeds fair market value, or for which no actual services are required, triggers the referral and payment prohibitions of Stark II with respect to designated health services referred by that physician.²⁷

Similarly, the government asserted that hospital leases with physicians would necessarily be breached when payment under those leases were not set at fair market value:

[O]ffice space leased to a referring physician falls within such an exception if (1) the lease is in writing signed by the parties; (2) the lease is for a term of at least a year; (3) the space does not exceed that which is reasonable and necessary for the legitimate business purposes of the hospital; (4) the rent for that space is set in advance; (5) the total payment over the term of the lease is consistent with fair market value and is not determined in a way that takes into account the volume or value of referrals or other business generated between the parties; and (6) the lease would be commercially reasonable even if no referrals were made between the parties. 42 U.S.C. § 1395nn(e)(1)(A). Thus, rents paid (directly or indirectly) by a physician to a hospital that are

below fair market value trigger the referral and payment prohibitions of Stark II with respect to designated health services ordered, referred or arranged for by that physician.²⁸

The Government's Apparent Strategy To Invoke The Stark Law Rather Than The Anti-Kickback Law In Cases Where Both Statutes May Otherwise Apply

Historically, in FCA actions, the United States had alleged a violation of the Anti-Kickback Act created FCA liability but has not, until very recently, alleged that a violation of the Stark Law creates FCA liability. As noted, the perception was that, because of the uncertainty regarding the government's shifting interpretation of the Stark Law, the Stark Law could not operate as a vehicle to enforce the FCA – at least not until the government issued final regulations construing the Stark Law provisions.

Because the Stark regulations have not been finalized, it is surprising on one level that the government has determined to invoke it in lieu of the Anti-Kickback Law. However, on another level, the government's decision, in hindsight, was predictable. The government's aim in enforcing the FCA is to maximize its recoveries under the Act while minimizing its costs. Because of differences between the Anti-Kickback Law and the Stark Law, the Stark Law, at first blush, appears to be a superior enforcement vehicle than the Anti-Kickback Law.

Using the Anti-Kickback Act as a predicate offense to establish FCA liability is fraught with risk and uncertainty. This is because the Anti-Kickback Act is a criminal statute. Presumably, to establish a violation of the FCA because the defendant breached the Anti-Kickback statute, the United States would need to establish that the defendant “knowingly and

willfully” paid remuneration to a person to induce the referral of federally funded health care business beyond a reasonable doubt.²⁹ This is a specific intent standard.³⁰ Only if the United States discharged this burden could it satisfy its claim that the defendant's breach of the Anti-Kickback Law resulted in a breach of the FCA. Because of this enhanced intent standard and the criminal burden of proof – proof beyond a reasonable doubt – the government would confront substantial difficulty in prevailing in its cause of action at trial.³¹

To avoid the quagmire of attempting to prove a violation of criminal law in the context of an FCA action, the United States has now chosen to invoke the Stark Law rather than the Anti-Kickback statute. Unlike the Anti-Kickback statute, the Stark Law is a civil statute. Moreover, unlike the Anti-Kickback statute, the United States need not demonstrate that the defendant had any intent to violate the Stark Law and presumably would need only prove the defendant's violation by a preponderance of evidence rather than beyond reasonable doubt.

Indeed, the government's allegations in the HCA case stand as “Exhibit A” regarding how easily the government can invoke the Stark Law as its enforcement mechanism of choice. There, with respect to the hospital's consulting arrangements and leases with physicians, the government reasons as follows:

- There was a violation of the Stark Law because a statutory element to the personal services and leases exception to the Stark Law require that the arrangements be at fair market value and be in writing and the various HCA arrangements with physicians were not at fair market value and/or were not in writing. (No specific intent to violate the Stark Law needs to be proven.)
- HCA had knowledge (as defined under the FCA) that it failed to

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adhere to the Stark Law because the whole industry was aware of the prohibitions contained in the Stark Law.³²

- Therefore, the government concludes, given HCA's alleged (a) awareness of the Stark Law and its prohibitions (through training programs and trade associations) and (b) its failure to heed that Law, it knowingly filed false cost reports and interim claims to the United States by certifying on its cost report that it was in compliance with all rules and regulations governing the Medicare program when in fact it was not in compliance with the Stark Law.

Because of the relaxed intent standard under the FCA – several courts have ruled that mere constructive knowledge is sufficient to satisfy the statutory intent element³³ – the government, under its theory, can easily transform almost all violations of the Stark Law into an FCA violation. The government would assert that the provider's underlying claims and certificates are false because of the Stark Law violation and that the providers "knew" that the claims and certifications were false because of information disseminated in "outside training programs" and by "trade associations and the government."³⁴ Such a broad interpretation places several segments of the industry at risk of getting embroiled in FCA actions.

The Future Implications of the Government's Theory

At this time, it is impossible to predict the extent to which the government will proceed with this far reaching theory regarding the applicability of the Stark Law to FCA proceedings. However, a few future events can now be reasonably predicted. First, in the short term, the government's position that a violation of the Stark Law can

result in a violation of the FCA will be whole-heartedly embraced by whistleblowers and they will in turn, even more readily than before, file actions asserting this theory. Second, important defenses to the FCA will be tested as defendants move to dismiss the plaintiff's action. Third, assuming that courts find defendants liable, courts will have to develop new tests to determine how to apply the FCA's treble damages and civil penalty provisions in the context of violations of the Stark Law. Fourth, and finally, if courts permit plaintiffs to advance their theory that a violation of the Stark Law can result in a violation of the FCA and award plaintiffs treble damages and civil penalties, there will be renewed calls to reform and amend the FCA. Each of these likely future events is discussed below.

First, in terms of defenses that will be tested, courts will have to grapple with whether the hospitals' cost report certification or the HCFA Form 1500 certification encompasses violations of the Stark law such that the certification, can be, as the government claims, a predicate to the violation. One recent unpublished court decision sheds light on this issue. Specifically, in *United States ex rel. Scott v. Dr. Eugene*,³⁵ the relator alleged that a defendant hospital had submitted false cost report certifications because, contrary to its representation that it had adhered to all program rules and regulations, it had in fact breached the Anti-Kickback Law. The court rejected the relator's contention and questioned whether, because of its breadth, a cost report certification could serve as a predicate to an FCA action. Specifically, the court reasoned:

[I]t is not clear that the cost reports are relied on by the government to the extent required for a FCA allegation. The compliance certification is quite broad, requiring the signer to state that the report is in compliance with all the many and complex laws and regulations

governing Medicare. This compliance certification may be so broad that it cannot stand as a basis for a false claim act allegation. Without reliance, the Cost-Report cannot serve as a basis for an FCA claim, even if false.³⁶

The court's reasoning appears persuasive and should be equally applicable in the context of the Stark Law.

A second defense likely to emerge in these prosecutions is whether any defendant, at this time, could be said to have the requisite "knowledge" to breach the FCA when the law it allegedly breached, the Stark Law, has not been fully interpreted by the agency charged with the responsibility of construing its provisions. The FCA does not apply when the governing regulatory guidance is vague or ambiguous.³⁷ As to the Stark Law, leaving aside the agency's shifting interpretations of key provisions in the statute – and its open acknowledgement that its final regulations have "substantially changed" from the proposed regulations – the statute would still be inherently ambiguous because it authorizes, in subsection (b)(4), that the agency create other permissible exceptions that it "determines, and specifies in regulations, do[] not pose a risk of program or patient abuse." The agency's final interpretation of subsection (b) was not published until January of this year and will not be effective until next year. Hence, until the effective date of the agency interpretation of this provision, it is debatable whether any court could find that the duty defined in the Stark Law is sufficiently precise such that any provider would have "knowledge," as defined in the FCA, of a violation of the Stark Law because those within the industry simply did not know, and reasonably could not be expected to know, in many contexts which activities the agency would ultimately determine did "not pose a risk of program or patient abuse."

Moreover, even in those instances in which a court were to find a party liable, a court, in light of the latest case law developments, would need to decide how to apply the FCA's treble damage and civil penalty provisions. In light of the Supreme Court's characterization of FCA damages as being "essentially punitive in nature,"³⁸ courts have declined to automatically apply the FCA's treble damage provisions and civil penalty provisions when the government's recovery would be substantially disproportionate to its damages.³⁹ Under the Stark Law the government arguably suffers no damages if, in fact, the services furnished to the patient were medically indicated and necessary and otherwise covered by the program. Hence there would be no damages to treble and, under these circumstances, the civil penalty provision would need to be limited so that it bears a fair relationship to the damages the government incurred. Under these circumstances, the government may win the battle (a court finding a violation of the FCA) but lose the war because the court declines to grant any measurable recovery to the government.⁴⁰

Finally, if the government and whistleblowers continue to institute FCA actions predicated upon a violation of the Stark Law and achieve success, there, no doubt, would be a strong impetus to amend and reform the FCA. The last time in which the government adopted an expansive interpretation of the FCA that resulted in potentially widespread liability for healthcare providers was when it initiated several "national projects," such as the 72-hour window project and the so-called lab unbundling project. As a result of these national projects, Congress seriously considered substantially amending the FCA to eliminate the government's ability to apply the FCA in circumstances in which defendant's conduct constituted little more than an honest mistake or was immaterial to the government's decision to pay.⁴¹ Similarly, if the government's latest enforcement actions result in the widespread application of

the FCA in cases involving nothing more than a technical violation of the Stark Law, the government's conduct could easily rekindle Congress' interest in amending the statute to ensure that it is applied equitably.

Conclusion

The government's latest application of the Stark Law transforms the statute from being a potential paper tiger to being a live animal with very sharp teeth. This is especially true because by virtue of the FCA's whistleblower provisions, the Stark Law may potentially be enforced by private individuals even though the Stark Law itself does not permit any private right to action. As a result of the important issues raised by the government asserting a violation of the FCA based upon a violation of the Stark Law, substantial and significant case law will develop over the next couple years defining a provider's duties both under the FCA and the Stark Law. These court decisions, in turn, will shape the precise manner in which health care is provided in the future.

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Endnotes

- ¹ 31 U.S.C. § 3729 *et seq.* The FCA, among other things, imposes liability upon those who submit or causes the submission of false or fraudulent claims with "reckless disregard" or in "deliberate ignorance" of the truth or falsity of the claim. *Id.* § 3729(b). The FCA also authorizes private persons (known as relators) to file actions (known as *qui tam* actions) on behalf of the United States to enforce the FCA and to obtain, if successful, a substantial bounty. Those held liable under the FCA must pay treble damages and civil penalties ranging from \$5,000 to \$10,000 per claim. For all violations committed on or after Sept. 29, 1999, the defendant is liable for treble damages plus penalties ranging from \$5,500 to \$11,000 per claim (*see* Civil Monetary Penalties Inflation Adjustment, 64 Fed. Reg. 47,103-04 [1999][to be codified at 28 C.F.R. pt.85]). For a discussion of the case law, *see* Robert Salcido, *FALSE CLAIMS ACT & THE HEALTHCARE INDUSTRY: COUNSELING & LITIGATION* (American Health Lawyers Ass'n 1999) [hereinafter Salcido, *FALSE CLAIMS ACT COUNSELING*]; *see also* Robert Salcido, *FALSE CLAIMS ACT & THE HEALTHCARE INDUSTRY: COUNSELING & LITIGATION: NOVEMBER 2000 SUPPLEMENT* (American Health Lawyers Ass'n. 2000) [hereinafter Salcido, *FALSE CLAIMS ACT COUNSELING: NOVEMBER 2000 SUPPLEMENT*].
- ² 42 U.S.C. § 1320a-7b(b). The Anti-Kickback Act, among other things, prohibits any person from knowingly and willfully making or accepting payment to induce or reward any person for referring, recommending or arranging for federally funded medical services. The violation of the statute constitutes a felony and subjects the person to a fine of up to \$25,000 and imprisonment of up to 5 years. Violation of the statute can also subject a person to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of \$50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. §§ 1320a-7(b)(7), 1320a-7a(a)(7).
- ³ *See, e.g.,* Settlement Agreement between Fresenius Medical Care, *et al.*, and the United States for \$385 million in recoveries under the FCA, ¶ X, p. 9 ("the United States alleges that at various times ... [the companies] violated federal statutes ... in connection with their willful, knowing and deliberate payment of illegal remuneration to dialysis facilities and their owners, officers, directors, employees, representatives, or agents, in the form of lavish entertainment; hunting trips; payment for full time employees; grants; up-front rebate checks; discounts and special pricing on products; free or low cost laboratory testing for indigent patients, facility staff, and HMO patients; free or low cost environmental and machine testing; profit sharing with medical directors ...; composite rate tests below fair market value; and computer hardware and software, all to obtain unlawful referrals of laboratory business...") (agreement dated Jan. 18, 2000); Settlement Agreement between SmithKline Beecham Clinical Laboratories, Inc. and the United States for \$325 million, ¶ N, p. 6 ("the United States contends that SBCL violated federal statutes ..., including the Medicare Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b),

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in connection with the provision to physicians and/or referral sources of free or discounted tests; free or discounted tests to certain patients affiliated with managed care organizations; the provision in client facilities of computers and computer-related equipment, fax machines, refrigerators, or other laboratory-related equipment; the placement of phlebotomists in clients' offices; or the payment of rent to referring clients") (agreement dated Sept. 27, 1996). In cases involving cost reports, the government's theory is that the defendant's certification on the cost report is "false" because on the certification the defendant had represented that it had adhered to the rules and regulations governing the Medicare program when in fact, according to the government, the defendant was not in compliance by virtue of its breach of the Anti-Kickback statute. See, e.g., Complaint of the United States filed in *United States ex rel. Thompson v. HCA – the Healthcare Company*, No. 99-3302 ¶ 61 (D.D.C. March 15, 2001) ("Under all versions of the HCFA Form 2552 [cost report] certification, the provider certified that the services provided in the cost report were not infected by a kickback") (hereinafter "Thompson Complaint"). In cases involving Part B claims, under which physicians and suppliers do not make a broad certification representing compliance with all rules and regulations, the government claims that the alleged breach of the Anti-Kickback Act taints the claim for payment rendering it false or fraudulent. See, e.g., Memorandum of the United States in Opposition to Apria Healthcare Group, Inc., Georgia Lung Associates, P.C. and Edward I. Swartz's Motions to Dismiss in *United States ex rel. Parker v. Apria Healthcare Group, Inc.*, No. 1:95-CV-2142-FMH at 14-16 (filed Aug. 22, 1996).

4 42 U.S.C. § 1395nn. The Stark Law prohibits physicians from referring to entities in which they have a financial relationship unless a statutory exception applies. Violation of the law may subject the perpetrator to exclusion from participation in federal health care programs and various financial penalties, including (a) a civil money penalty of \$15,000 for each service included in a claim for which the entity knew or should have known that payment should not be made under section 1395nn(g)(1); and (b) an assessment of three times the amount claimed for a service rendered pursuant to a referral the entity knew or should have known was prohibited. See 42 U.S.C. §§ 1395nn(g)(3); 1320a-7a(a). Ironically, to the extent the Stark Law has been invoked in FCA actions, it has been done, until recently, only by relators. See, e.g., *United States ex rel. Obert-Hong v. Advocate Health Care*, No. 99 C 5806, 2001 U.S. Dist. LEXIS 3767 (N.D. Ill. Mar. 27, 2001); *Gublo v. Novacare, Inc.*, 62 F.Supp.2d 347, 355 (D.Mass. 1999); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F.Supp.2d 1017, 1047-48 (S.D. Tex. 1998); *United States ex rel. Pogue v. American Healthcorp., Inc.*, 914 F.Supp. 1507, 1513 (M.D. Tenn. 1996). Thus far courts have found that a breach of the Stark Law can result in a violation of the FCA. See

United States ex rel. Goodstein v. McLaren, No. 97-CV-72992-DT, 2001 U.S. Dist. LEXIS 2917 at 14-15 (E.D. Mich. Jan. 3, 2001) ("Under Stark, if a physician has a specified financial relationship with an entity, the physician may not make referrals to the entity for the furnishing of designated health services 42 U.S.C. § 1395nn(a)(1). The Government's complaint alleges that Defendants [which included a professional limited liability company that employed nine physicians who provide orthopedic services and a reality company that the physicians controlled] have a financial relationship with McLaren [Regional Medical Center] in violation of Stark, and that Defendants referred to McLaren for physical therapy and occupational therapy in violation of Stark. As it is conceivable that a set of facts could be proven in support of the Government's allegations, dismissal under 12(b)(6) is not warranted"); *Novacare*, 62 F.Supp.2d at 355 ("A number of courts ... have recognized that the submission of a false certification of compliance with the Stark Law in order to qualify for Medicare reimbursement can constitute a false claim under the FCA") (citations omitted).

5 See Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, § 6204, 103 Stat. 2137, 2236.

6 See Omnibus Reconciliation Act of 1993, P.L. 103-66, § 13562, 107 Stat. 596; Social Security Amendments of 1994, P.L. 103-432, § 152, 108 Stat. 4436, 4444. As of January 1, 1995, Stark II applied to patient referrals by physicians with a prohibited financial relationship for the following ten additional "designated health services": (1) inpatient and outpatient hospital services; (2) physical therapy; (3) occupational therapy; (4) radiology; (5) radiation therapy (services and supplies); (6) durable medical equipment and supplies; (7) parenteral and enteral nutrients, equipment, and supplies; (8) prosthetics, orthotics, and prosthetic devices and supplies; (9) outpatient prescription drugs; and (10) home health services. See 42 U.S.C. § 1395nn(h)(6).

7 See, e.g., 57 Fed. Reg. 8588 (March 11, 1992) (Stark I Proposed Rule); 60 Fed. Reg. 41914 (Aug. 14, 1995) (Stark I Final Rule with Comment Period – "Physician Financial Relationships With, and Referrals to, Health Care Entities that Furnish Clinical Laboratory Services and financial Relationship Reporting Requirements"); 63 Fed. Reg. 1659 (Jan. 9, 1998) (Stark II Proposed Rule with Comment Period – "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships"); 66 Fed. Reg. 856 (Jan. 4, 2001) (Stark II (Phase I) Final Rule with Comment Period).

8 CMS announced that it would complete its Final Rulemaking on the Stark Law in two phases. Phase I was issued on January 4, 2001 and implemented subsections (a) and (b) of the Act, and related definitions. See 66 Fed. Reg. at 859. The agency issued its final regulations in this piecemeal fashion because of "the importance of subsections (a) and (b)" and because of the "substantial changes" it had made to the January 1998 proposed rule.

Id. CMS requested comment on its Phase I rules and delayed implementation of the provision "to allow individuals and entities engaged in business arrangements affected by Phase I time to restructure those arrangements to comply with the provisions of Phase I..." *Id.* CMS stated that it "intend[s] to issue Phase II of this rulemaking to cover the remainder of section 1877 of the Act, including its application to the Medicaid program, shortly." *Id.*

9 See The Government's Notice of Election to Intervene in Part and to Decline to Intervene in Part filed in *United States ex rel Barbera v. Tenet Healthcare Corp.*, No. 97-6590 (Feb. 16, 2001) (hereinafter Notice of Intervention).

10 See Relator's Complaint filed in *United States ex rel Barbera v. Tenet Healthcare Corp.*, No. 97-6590, ¶ 9 (May 13, 1997).

11 *Id.* ¶ 13.

12 *Id.* ¶ 18.

13 See Notice of Intervention at 1.

14 *Id.* Cf. Complaint of the United States in *United States ex rel. Goodstein v. McLaren Regional Med. Center*, No. 97-CV-72992-DT (E.D. Mich. Filed Sept. 26, 2000). There the government alleged defendants Family Orthopedic Associates ("FOA"), the sole shareholders of which are medical doctors who provide orthopedic services to patients, Family Orthopedic Realty ("FOR"), whose shareholders included FOA's physicians, and McLaren Regional Medical Center ("McLaren"), a 476-bed health care facility, violated both the Stark Law and the Anti-Kickback Law because FOA referred physical and occupational therapy services to McLaren while FOR received above fair market rent for space used by McLaren. As proof of the violation, the government asserted that FOR had previously contested the assessed value of the building for tax purposes because it claimed that the lease price on FOR's lease to McLaren was above fair market value for comparable lease space. *Id.* at ¶ 48. The government contended that the state tax tribunal agreed, holding that the lease price at comparable properties was \$12.50, not the \$17.00 amount the hospital paid to lease the space. *Id.* at ¶ 50. Because of the excess amount of rent paid by the hospital, the government contended that the arrangement breached the Stark Law and the Anti-Kickback Law, which resulted in a violation of the FCA.

15 These complaints are available on the Department of Justice's ("DOJ's") website, http://www.usdoj.gov/civil/cases/alderman/mar ch15_2001/index.htm.

16 See, e.g., Thompson Complaint ¶ 5.

17 *Id.* ¶¶ 93-103.

18 *Id.* ¶¶ 104-116.

19 *Id.* ¶¶ 122-125.

20 *Id.* ¶¶ 126-129.

21 *Id.* ¶¶ 186-199.

22 *Id.* ¶¶ 200-208.

- 23 *Id.* ¶¶ 130-140.
- 24 *Id.* ¶¶ 140-142, 224-230.
- 25 *Id.* ¶ 144.
- 26 *Id.* ¶¶ 258-259.
- 27 *Id.* ¶ 39.
- 28 *Id.* ¶ 40.
- 29 *See, e.g., United States ex rel. Scott v. Dr. Eugene*, No. 99-117 DOC (Eex) (C.D. Cal. Dec. 19, 2000). There, in an FCA case alleging a violation of the Anti-Kickback Law, the court noted that it would have to apply the criminal standard of the Anti-Kickback Law even though the FCA is a civil statute. *Id.* at 7 (“The anti-kickback provision also requires the violation be ‘willfully and knowingly’.” The Court cannot determine as a matter of law whether [the hospital] acted willfully and knowingly. In a criminal case, scienter is an issue for a finder of fact.... It is true that this is a civil matter. However, § 1320a-7b(b)(2) is a criminal statute, violation of which is a felony punishable by prison and/or fine. Therefore, it is entirely appropriate that the standard for a criminal matter be applicable here”).
- 30 Courts have split regarding the type of proof the government would need to advance to satisfy the intent element of the Anti-Kickback Law. Specifically, courts have disagreed on whether it is sufficient to prove the defendant generally intended to do something wrongful, or whether the government must prove that the defendant specifically intended to violate the Anti-Kickback Law. The Ninth Circuit, in *Hanlester Network v. Shalala*, developed the most stringent test, holding that the government could only satisfy the Anti-Kickback Statute’s intent standard of “knowingly and willfully” by demonstrating that the persons “(1) know that [the Anti-Kickback Law] prohibits offering or paying remuneration to induce referrals, and (2) engage in prohibited conduct with the specific intent to disobey the law.” 51 F.3d 1390, 1400 (9th Cir. 1995); *see also United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989) (upholding jury instruction explaining that “[w]illfully means to do something purposely, with the intent to violate the law, to do something purposely that law forbids”); *Feldstein v. Nash Community Health Servs.*, 51 F. Supp. 2d 673, 681 (E.D.N.C. 1999) (adopting Hanlester standard); *see generally* Michael Tichon, Charles Oppenheim, and Brad Tully, *Compliance Issues Under The New Fraud and Abuse Rules*, 16 WHITTIER L. REV. 1085, 1094 (1995) (noting that under the Hanlester decision, “unless someone subjectively believes that at the time of his or her conduct it was illegal, he or she did not violate the statute . . .”). Other courts have developed less demanding tests that require the government prove that the defendant knew that his or her conduct is wrongful, rather than that he or she necessarily intended to violate the law. *See United States v. Starks*, 157 F.3d 833, 837-38 (11th Cir. 1998) (upholding jury instruction that “[t]he word willfully . . . means the act was committed voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law” and not requiring proof that defendants were aware of the specific law violated); *United States v. Jain*, 93 F.3d 436 (8th Cir. 1996) (affirming jury instruction that “the word ‘willfully’ means unjustifiably and wrongfully, known to be such by the defendant”); *United States v. Anderson*, 85 F.Supp.2d 1047, 1077 (D. Kan.1999) (stating that “to convict [under the Anti-Kickback Statute] the jury was required to find that the defendants knew that their conduct was unlawful,” not that defendants were aware of the specific provision violated), *rev’d. on other grounds sub nom., United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000); *Zimmer, Inc. v. Nu Tech Med., Inc.*, 54 F. Supp. 2d 850, 862 (N.D. Ind. 1999) (holding that “[t]he statute requires that the prohibited acts (soliciting, receiving, offering, or paying) be done ‘knowingly and willfully’, not that the actor ‘knowingly and willfully’ intends to violate the statute”); *United States v. Neufeld*, 908 F. Supp. 491, 496 (S.D. Ohio 1995) (stating that “a concern for prosecuting those acting inadvertently, however, does not equate ‘willfulness’ with knowledge of illegality”); *Medical Dev. Network, Inc. v. Professional Respiratory Care/Home Med. Equip. Servs.*, 673 So. 2d 565, 567 (Fla. Dist. Ct. App. 1996) (holding that the Anti-Kickback Statute “is directed at punishment of those who perform specific acts and does not require that one engage in the prohibited conduct with the specific intent to violate the statute”). Regardless of the competing formulations of the intent standard under the Anti-Kickback Law, the bottom line, as the district court explained in the Scott case, is that the defendant must, at a minimum, have “the specific intent to do something the law forbids.” *Id.*, No. CV 99-117 DOC(Eex), at 8, n.6.
- 31 For a discussion of the difficulty, and perhaps the impossibility, of proving a violation of the criminal Anti-Kickback Law in the context of a civil FCA proceeding, *see* Robert Salcido, *Mixing Oil and Water: The Government’s Mistaken Use of the Medicare Anti-Kickback Statute in False Claims Act Prosecutions*, 6 ANNALS H. LAW 105 (1997).
- 32 Specifically, the government alleged in its complaint:
- During the time period relevant hereto, HCA was aware of the prohibitions against kickbacks and the legal restrictions on financial relationships with physicians. This awareness was based on information obtained by HCA from various sources, including its counsel, outside training programs, trade associations, and the government. Despite this information, HCA embarked on a strategy of paying kickbacks to and engaging in unlawful financial relationships with physicians to induce patient referrals to HCA facilities. HCA in turn billed for and collected hundreds of millions of dollars in reimbursement from the United States based on patient referrals from these same physicians.
- Thompson Complaint ¶ 86.
- 33 For a discussion of courts’ historical interpretation and application of the FCA’s intent standard, *see* Salcido, FALSE CLAIMS ACT COUNSELING §§ 1:03, 1:04, 2:05; *see also* Salcido, FALSE CLAIMS ACT COUNSELING: NOVEMBER 2000 SUPPLEMENT § 2:05. Mere negligence has never been actionable under the FCA. *See id.* Hence if a company demonstrated that it was, at worst, only negligent in its violation of the Stark Law, the government’s FCA action would be subject to dismissal.
- 34 *See supra* n. 32.
- 35 No. 99-117 DOC (Eex) (C.D. Ca. Dec. 19, 2000).
- 36 *Id.* at 9; *but see United States ex rel. Thompson v. Columbia/HCA Healthcare*, 20 F.Supp.2d at 1046-47 (certification that Medicare services identified in the cost report complied with the laws and regulations dealing with the provision of healthcare services may trigger FCA liability because CMS relies on the certification in determining the issues of payment and retention of payment as well as continued eligibility for participation in the Medicare program).
- 37 *United States v. Krizek*, 859 F. Supp. 5, 9-10 (D.D.C. 1994) (because the relevant provision of the CPT itself, during the relevant time frame, was “ambiguous,” the government could not state an FCA cause of action), *aff’d., in part, rev’d. in part*, 111 F.3d 934 (D.C. Cir. 1997). *See also Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1477 (9th Cir. 1996) (when statute grants government discretion to allocate costs, contractor’s reliance on the government’s exercise of discretion in allocating costs does not render claim false because all that existed was proof of “a disputed legal issue,” which is not enough “to support a reasonable inference” that the claim “was false within the meaning of the False Claims Act”); *United States v. Data Translation, Inc.*, 984 F.2d 1256 (1st Cir. 1992) (when supplier’s actions conformed with industry practice and were otherwise reasonable, the government could not state a cause of action under the FCA); *United States ex rel. Swafford v. Borgess Medical Center*, 98 F. Supp. 2d 822, 831-32 (W.D. Mich. 2000) (where the relator had contended that in order to bill for an “interpretation or reading” of the “results of the test” of ultrasound studies the defendant physicians must do more than merely rely upon the findings of the technician and independently review the supporting data from which the technician arrived at her conclusions, the court rejected the relator’s claim because it found that those terms were undefined and ambiguous and that the relator’s position “devolves to a dispute over the meaning of the terms governing the delivery of the professional component of physicians services” and that such a “legal dispute is . . . insufficient” to establish FCA liability); *United States v. Napco Int’l, Inc.*, 835 F. Supp. 493, 498 (D. Minn. 1993) (because underlying regulation was ambiguous, the court would not permit the government to apply “an interpretative afterthought by the agency” against the contractor in an FCA action).
- 38 *United States ex rel. Stevens v. Vermont Agency of Natural Resources*, 120 S.Ct. 1858, 1869 (2000).
- 39 *See, e.g., United States v. Mackby*, 243 F.3d 1159 (9th Cir. 2001). There the Ninth Circuit concluded that “the civil sanctions provided by the False Claims Act are subject to analysis under the [Constitution’s] Excessive Fines Clause because sanctions represent a payment to the government, at least in part, as punishment. Inquiry must be made, therefore, to determine whether the payment required by

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the district court is so grossly disproportionate to the gravity of [the defendant's] violation as to violate the Eighth Amendment." *Id.* at 1167 (citation omitted). Additionally, the court concluded that the FCA's treble damages provision was similarly subject to scrutiny to determine whether it was unconstitutionally excessive. *Id.* at 1168 ("We conclude that the FCA's treble damages provision is, like the statutory penalty provision, not solely remedial and therefore subject to an Excessive Fines Clause analysis under the Eighth Amendment. Accordingly, we remand to the district court for its consideration of the question whether a treble damage award in this case would be unconstitutionally excessive") (citation omitted). See also *United States ex rel. Garibaldi v. Orleans Par. School Bd.*, 46 F.Supp.2d 546, 564-65 (E.D.La. 1999), vacated on other grounds 244 F.3d 486 (5th Cir. 2001). There, the district court noted that the Fifth Circuit, in *Peterson v. Weinberger*, 508 F.2d 45, 55 (5th Cir. 1975), had previously ruled that courts can exercise their discretion to ensure that the penalties assessed "reflect a fair ratio to damages" and that the "Government completely recoups its losses." The district court believed that, notwithstanding the 1986 legislative amendments to the FCA mandating civil penalties of \$5,000 to \$10,000 per violation, the *Peterson* ruling remained "good law" in the circuit. Applying that standard, the court found that, in a case in which the jury verdict was \$7.4 million (which would be trebled to \$22.8 million) and the civil penalties equaled

\$7,850,000, the judgment was "excessive;" thus, the court exercised its discretion to reduce the forfeiture from \$7,850,000 to \$100,000. The court noted that a "penalty of \$100,000 is an adequate forfeiture, as the automatic trebling of the verdict as prescribed in the statute has already resulted in a judgment for \$15.8 million more than was actually falsely claimed by the [defendant]." Cf. *United States v. Cabrera-Diaz*, 106 F.Supp.2d 234 (D.P.R. 2000). In *Cabrera-Diaz*, upon granting the United States' motion for a judgment of default, the district court applied the treble damage provision in computing the amount of the judgment but expressly refused to apply any civil penalties because the number of penalties would be "excessive." *Id.* at 242 ("If this Court was to imposed [sic] civil penalties of between \$5,000.00 to \$10,000.00 for each of the one of the 455 false claims, in addition to the treble damages, the same would range between \$2,275,000.00 and \$4,550,000. We deem this amount to be excessive and therefore no civil penalties are hereby imposed").

⁴⁰ Under these circumstances, however, the defendant's victory may be short-lived because if the court found a substantial violation of the law, the government would presumably exercise its discretion to exclude the provider from participation in federal health care programs.

⁴¹ Specifically, as a result of DOJ's use of the FCA in national projects, both chambers of Congress in 1998 promptly proposed

legislation to amend the FCA. The legislation, known as the Health Care Claims Guidance Act, S. 2007 and H.R. 3523, 105th Cong. (1998), was narrowly tailored and designed to address the practices that engendered criticism. For example, to make it more difficult for DOJ to assert that minor, technical regulatory breaches constituted FCA violations, Congress proposed amending the statute so that the government must prove a violation by "clear and convincing evidence" rather than a "preponderance of the evidence" and bar DOJ from obtaining a judgment when the amount of alleged damages was immaterial relative to a provider's annual claims. *Id.* The proposed legislation had over two hundred co-sponsors. Thus, to head-off passage of the legislation, DOJ issued the Holder Guidelines to Department attorneys regarding their use of the FCA. As a result of DOJ's issuance of the Holder Guidelines, Congress did not pass the Health Care Claims Guidance Act but instead, as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, § 118, 112 Stat. 2681, 2681-69, required the General Accounting Office to monitor DOJ's compliance with its guidelines. For a general history regarding the national projects, Congress' backlash, and DOJ's consequent promulgation of the Holder Guidelines, see Robert Salcido, *DOJ Must Reevaluate Use of False Claims Act in Medicare Disputes*, WASHINGTON LEGAL FOUNDATION (Jan. 7, 2000).

The Health Lawyer wishes to thank the members of The Health Lawyer Editorial Board. The Editorial Board was established to provide expertise in specialized areas covered by the Section. Individual Board members were appointed by the Interest Group Chairs and Editor Nina Novak. If you are interested in submitting an article to the newsletter, you may contact one of the Editorial Board members or Ms. Novak. With the establishment of the Editorial Board, the Section strengthens its commitment to provide the highest quality analysis of topics in a timely manner.

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ACTUAL EXPOSURE OR REASONABLENESS? POLICY ISSUES DRIVE THE ONGOING DEBATE OVER WHAT STANDARDS SHOULD GOVERN THE RECOVERY OF EMOTIONAL DISTRESS DAMAGES FOR FEAR OF CONTRACTING INFECTIOUS DISEASE

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Introduction

During a routine visit to your family doctor, your hand is stuck with a syringe protruding from a drawer full of magazines. As you attempt to report the incident, the syringe is removed and discarded. Apologetic, your doctor can provide no information about the prior use of the needle or the patient on which it was used. He does, however, recommend that you obtain a series of blood tests since he recently treated patients afflicted with infectious disease, including Acquired Immune Deficiency Syndrome.

Should you be fearful of contracting an infectious disease? Would such fear or anxiety be reasonable under these circumstances? Should you be able to recover damages for your emotional distress? Answers to these questions are the subject of a continuing debate over what standard should govern claims of emotional distress damages for fear of contracting infectious disease.

While early cases generally held that negligent exposure to an infectious or contagious disease was actionable provided that the feared disease actually developed,¹ today, a majority of jurisdictions adhere to the “actual exposure” test with or without proof of an accompanying physical injury.² The California rule, which requires that, absent physical injury, a plaintiff prove that it is “more likely than not” that he or she will contract the disease, falls within the purview of the actual exposure test.³

A minority of courts apply a general reasonableness standard with some variation.⁴ In these cases, actual exposure and physical injury are mere factors considered in determining whether a plaintiff’s claim for fear of contracting an infectious disease is reasonable under the circumstances. More recently, even courts which have adopted the minority view have begun to interject some greater indicia of reliability for determining whether these emotional distress claims are “reasonable” under the circumstances of each case.⁵

Now, more than ever, public policy considerations drive the debate over what standard is appropriate. Courts which require actual exposure to the feared disease rely upon traditional policy concerns, including protection against excessive litigation and speculative damages claims, as well as the preservation of resources to ensure the availability of funds to compensate those with valid emotional distress claims.⁶ These courts also have begun to express a desire to discourage claims based upon public misconceptions about infectious diseases, particularly AIDS, and to counteract the general ignorance and public hysteria about disease and the prejudice against those infected.⁷

Courts adopting the reasonableness approach cite the desire to avoid harsh, unfair results which may occur when a plaintiff lacks the requisite information and resources to prove actual exposure.⁸ In addition, these courts seek to deter unreasonable conduct which, according to at least one court, would decrease the number of exposure incidents, and thereby serve the goal of promoting public health.⁹

In sum, what a plaintiff is required to prove to recover emotional distress damages for fear of contracting infectious disease will vary by court and, more specifically, by those public policy considerations which prevail within a particular jurisdiction.

Majority Rule – Actual Exposure

Courts which have adopted the actual exposure test generally require both the presence of the disease-causing agent, whether a virus, carcinogen or other contamination source, and a scientifically accepted channel in mode of exposure or infection.¹⁰ Some courts consider allowing recovery without proof of exposure as “purely speculative.”¹¹

Actual Exposure With Physical Injury

Most courts which require actual exposure to the feared disease also require proof of an accompanying physical injury. For example, in *Poole v. Alpha Therapeutic Corp.*,¹² plaintiff’s husband, who suffered from hemophilia, contracted AIDS from the allegedly negligent manufacture of a blood factor, and died the following year. The plaintiff alleged that, in the course of ordinary and marital relations with her AIDS-infected husband, she had been directly exposed to the virus which causes AIDS. However, the district court noted that plaintiff failed to allege any physical injury or illness and, applying Illinois law, dismissed plaintiff’s claim for emotional distress damages for fear of contracting the disease.

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Actual Exposure or Reasonableness?

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Similarly, the Arizona Court of Appeal in *Burns v. Jaqueays Mining Corp.*,¹³ affirmed summary judgment in favor of defendants concluding that the presence of asbestos fibers in the plaintiffs' lungs alone was not proof of bodily injury or the manifestation of a bodily injury. The evidence established that plaintiffs, who resided in a mobile home park adjacent to an asbestos mill, were exposed to substantial quantities of airborne asbestos fiber. The court explained that allowing recovery for mere exposure to asbestos would result in highly speculative damages resulting in windfalls to healthy plaintiffs who will never manifest injury, and insufficient compensation for those who actually sustained such injuries: "There can be no claim for damages for fear of contracting asbestos-related diseases in the future without manifestation of a bodily injury."

The plaintiffs in *Bubash v. Philadelphia Elec. Co.*,¹⁴ sought to recover for emotional distress from fear of cancer resulting from exposure to radiation from a nuclear power plant. Defendant's undisputed expert testimony indicated that the risk of plaintiffs' contracting cancer was minimal in light of the rapid dissipation of the radiation. Defendant moved for summary judgment on the ground that plaintiff had sustained no physical injury. Applying Pennsylvania law, the district court granted defendant's summary judgment motion.

In *Burk v. Sage Products, Inc.*,¹⁵ a paramedic pricked his finger on a hypodermic needle protruding from a container used for disposal of used syringes. The paramedic, who alleged loss of sexual function, brought a product liability action against the container manufacturer seeking to recover emotional distress damages caused by his fear of contracting AIDS. Although the plaintiff's HIV tests were negative, he was able to show that several patients suffering from AIDS had been seen on the floor of the hospital on

which he had been working on the date he sustained the injury. After acknowledging that plaintiff satisfied the physical harm requirement, the district court granted summary judgment in favor of the defendant manufacturer on the ground that, under Pennsylvania law, plaintiff could not recover for emotional distress unless he could prove actual exposure, e.g., that the needle which had stuck his finger had actually been used on an AIDS patient.

By contrast, in *Johnson v. West Virginia University Hospitals*,¹⁶ the Supreme Court of Appeals of West Virginia applied the actual exposure test and upheld a jury award for emotional distress damages for fear of contracting AIDS. In *Johnson*, the plaintiff, a hospital security guard, was summoned to restrain an unruly patient. As the guard attempted to put the patient into his bed, the patient bit himself on the arm, thereby drawing blood into his mouth. Then, the patient bit the guard on the forearm. Shortly thereafter, as the guard washed his wound, a paramedic informed him that the patient had AIDS. Although the guard subsequently tested negative for AIDS, he brought an action against the defendant hospital for his emotional distress from the incident. The court opined that "recovery of such damages is limited to the situation where the plaintiff is actually exposed to the AIDS virus as a result of physical injury." Acknowledging evidence of both actual exposure and physical injury, the court upheld a jury award for the plaintiff.

In *Lubowitz v. Albert Einstein Medical Center*,¹⁷ the court stated that a patient's fear that she would develop AIDS as a result of the use of HIV-positive blood in an in-vitro fertilization process was not a legally recognizable injury. After being told that an embryo which had been placed in the donated placental, HIV-positive blood had been implanted, plaintiff allegedly experienced mental distress and various physical ailments, including recurrent

nausea, vomiting and diarrhea. Despite additional testing which yielded negative results as to HIV, plaintiffs sued for negligent infliction of emotional distress. The court upheld an order granting summary judgment on the ground that plaintiffs were unable to prove actual exposure to the HIV virus. The court stressed that the physical symptoms suffered by the wife were not caused by the HIV virus.

In *Nesom v. Tri Hawk, Int'l.*,¹⁸ plaintiff sought recovery for emotional distress damages premised upon the possibility that he might develop Creutzfeldt-Jakob Disease ("CJD"), which is fatal. The Fifth Circuit Court of Appeals affirmed summary judgment for the defendant on the grounds that plaintiff was not entitled to maintain a cause of action for alleged fear of contracting a disease in the future absent any proof that he was actually exposed to the disease which is the source of the fear. The court noted that some human *dura* in the batch used in plaintiff's surgery may have been contaminated with CJD. However, this was insufficient to provide a basis for an award of emotional distress damages for fear of developing the neurological disease absent proof that the *dura* used was, in fact, contaminated with CJD. The Court reasoned that allowing recovery for fear of possible exposure does not provide sufficient indicia of reliability and would open the door to thousands who claim fear without any proof of actual exposure to the dangerous substance.

In *Griffin v. American Red Cross*,¹⁹ the court concluded that a woman who was misdiagnosed as being positive with HIV could not bring a claim for negligent infliction of emotional distress absent an accompanying physical injury. The plaintiff had donated blood at the American Red Cross facility in Philadelphia on advice of her surgeon so that she could avoid the possibility of a transfusion-associated illness during her planned hysterectomy. Plaintiff

alleged that a Red Cross representative contacted plaintiff's surgeon a few weeks after the blood donation to inform him that the patient's blood had tested positive for HIV. Within approximately 24 hours, the plaintiff's surgeon took another blood sample from her, which showed that she was HIV negative. Plaintiff sued the Red Cross for negligent infliction of emotional distress, claiming emotional and physical problems as a result of the incident. The court stated that there could be no recovery on a claim that was based upon the fear of contracting an infectious disease with accompanying physical injury where the injury alleged did not arise out of the exposure to the disease itself.

The Supreme Court of Delaware adopted the actual exposure test in *Brzoska v. Olsen*,²⁰ and concluded that 38 patients of a dentist, who died of AIDS, could not recover damages for a fear of contracting HIV. The court affirmed summary judgment in favor of the dentist's estate on the grounds that, in the absence of showing a physical harm or injury, the plaintiffs could not recover emotional distress damages for fear of contracting AIDS.

In *RJ. v. Humana of Florida*,²¹ the Supreme Court of Florida concluded that a patient, who was misdiagnosed as having contracted HIV, did not state a claim for emotional distress damages. Plaintiff alleged that defendant hospital took a blood sample from him, sent it for testing and later informed him that he was HIV positive. Although a second test, taken 19 months later, revealed that plaintiff was not HIV positive, plaintiff sued the hospital, testing facility and the physician alleging that he was incorrectly lead to believe that he had contracted HIV, which caused him to suffer bodily injury, including hypertension, pain and suffering, and mental anguish. The court affirmed the dismissal of plaintiff's complaint based upon the "impact rule," which required that, before the plaintiff could recover damages for emotional distress caused by the negligence of another, the emotional distress suffered must flow

from physical injuries that the plaintiff had sustained in an impact. The court found that the intangible, mental injuries claimed by plaintiff in this case were not sufficient to meet the physical injury requirement.

The Texas Court of Appeals in *Drury v. Baptist Memorial Hospital System*,²² found that a patient, who received banked blood during surgery, could not recover against the hospital and doctor for emotional distress allegedly suffered because of fear of contracting AIDS. In upholding summary judgment for the defendant hospital, the court noted that Texas cases involving fear of cancer, and AIDS cases from other jurisdictions, mostly require that the plaintiff establish that he or she was actually exposed to the disease and that the fear be reasonable and based on the knowledge of exposure. In the absence of some proof of actual exposure to HIV or AIDS, the court concluded that any fear of contracting the disease was, as a matter of law, unreasonable.

Likewise, in *Pendergast v. Pendergrass*,²³ the Court of Appeals of Missouri held that a patient's fear of contracting AIDS after receiving human whole-blood factor VIII during a hernia operation was not a legally compensable injury absent proof of actual exposure to the HIV virus. The patient had requested a "synthetic" factor VIII blood-clotting agent for the hernia operation believing it to be safer than the human whole blood. After learning he received human whole blood, the patient sued the hospital for negligent infliction of emotional distress. The court held that, absent proof of actual exposure to the HIV virus as a result of defendant's conduct, *i.e.*, proof of both a scientifically accepted method, or channel, of transmission and the presence of the HIV virus, the fear of contracting AIDS is unreasonable as a matter of law. In support of its adoption of the actual exposure rule, the court cited a number of public policy concerns, including the prevention of claims premised on the public misconception about AIDS, the preservation

of defendant's resources to ensure that victims who were actually exposed were compensated for their emotional distress, and the protection of the justice system from the burden of frivolous litigation.

In *Majca v. Beekil*,²⁴ the Illinois Supreme Court upheld a lower court ruling that the complaint failed to state a cause of action for fear of contracting AIDS. Plaintiff, a dental patient, alleged that the dental student was infected with HIV at the time he provided dental treatment. The court held that, in the absence of an allegation that the patient was actually exposed to the HIV virus, that patient could not recover for emotional distress damages for fear of contracting HIV or AIDS.

Similarly in *O'Neill v. O'Neill*,²⁵ the Appellate Division of the Supreme Court of New York applied the actual exposure rule to determine the validity of plaintiff's claim of emotional distress damages for fear of contracting AIDS. Plaintiff claimed intentional negligence and infliction of emotional distress against his wife for failing to inform him that her first husband died of AIDS in 1990. The court found, based upon the undisputed evidence presented by defendant, that she consistently tested negative for the disease, and that plaintiff failed to prove actual exposure. Thus, the court upheld the lower court order granting summary judgment for the defendant.

The Court of Appeal of Louisiana upheld summary judgment in favor of a defendant hospital in *Falcon v. Our Lady of the Lake Hospital, Inc.*,²⁶ in which the plaintiff sought emotional distress damages for fear of contracting disease after having been given two units of blood from the general inventory of a blood bank, instead of the direct donor blood which had been earmarked for her prior to surgery. Plaintiff alleged physical pain and suffering, as well as mental anguish and distress as a result of the incident. The undisputed evidence established that plaintiff consistently tested negative for HIV and Hepatitis, and there was no

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evidence that the blood was contaminated. The court concluded that, although she demonstrated a channel of infection, plaintiff could not prove the presence of HIV and, therefore, her emotional distress claim failed as a matter of law.

The Court of Appeals of Oregon also applied the actual exposure rule in *Rustvoid v. Taylor*,²⁷ and focused on the need for an accompanying physical injury. In that case, plaintiff alleged emotional distress based upon her fear of contracting Hepatitis B or HIV following information that she had been administered anesthesia with a used syringe. Having concluded that the alleged physical injuries, which were limited to fatigue, anxiety and depression, did not satisfy the physical injury requirement, the court affirmed the order granting summary judgment for the defense on the emotional distress claim.

Actual Exposure Without Physical Injury

Within the jurisdictions which require actual exposure, some courts do not require proof of any physical injury. In these cases, actual exposure alone is sufficient to establish a claim for emotional distress damages for fear of infectious disease.

For example, the plaintiff in *Bordelon v. St. Francis Cabrini Hospital*²⁸ was able to state a claim for negligent infliction of emotional distress stemming from a fear of contracting the HIV virus. The plaintiff, who was scheduled for a hysterectomy at defendant hospital, had provided her own blood in anticipation of surgery. During surgery, however, plaintiff was erroneously given someone else's blood. Plaintiff filed suit claiming severe mental anguish about the possibility of contracting AIDS. On appeal, the Louisiana Court of Appeal concluded that plaintiff's claim for negligent infliction of emotional distress *unaccompanied by physical injury* was

viable. The court found that plaintiff's fear is a foreseeable consequence of the alleged negligent act, since it was widely known that AIDS could be transmitted through blood transfusions, even with screening. The court noted that it was common knowledge that AIDS was both incurable and fatal, and opined that extraordinary measures should be taken to prevent its spread.

The Ohio Supreme Court in *Heiner v. Moretuzzo*²⁹ found that a patient who was misdiagnosed as HIV positive could not bring an action against health care providers for negligent infliction of emotional distress arising out of the anxiety suffered as a result of the misdiagnosis. Plaintiff, who was interested in conceiving a child through artificial insemination, had her blood drawn by the defendant medical center and tested by another defendant, the American Red Cross. She was informed that the blood sample was HIV positive, although subsequent tests were negative for HIV. Plaintiff brought an action against defendants alleging negligence, malpractice and negligent infliction of emotional distress. In upholding summary judgment for defendants, the court concluded that Ohio law did not recognize the right of a plaintiff to maintain a cause of action for negligent infliction of emotional distress where the defendant's negligence produced no actual threat of physical harm or injury to the plaintiff or any other person.

Similarly, in *John and Jane Roes, 1-100 v. F.H.P., Inc.*,³⁰ plaintiffs were allowed to recover emotional distress damages for fear of contracting AIDS based on evidence of actual exposure, but without the need for proving actual physical injury. The plaintiffs, baggage handlers employed by a flight service at Honolulu International Airport, were exposed to blood tainted with the HIV virus. Claiming that they were suffering from open wounds on their hands at the time they came into contact with the tainted blood, plaintiffs filed suit

alleging causes of action for negligence and sought emotional distress damages for fear of contracting HIV. The Hawaii Supreme Court held that, since "actual exposure to the HIV positive blood would in fact pose a direct, immediate and serious threat to an individual's personal safety, such exposure would foreseeably engender serious mental distress in a reasonable person." Thus, the court concluded that the plaintiffs stated a claim for negligent infliction of emotional distress for actual exposure to HIV-positive blood, whether or not there is a predicate physical harm.

California's "More Likely Than Not" Standard

In California, in the absence of actual physical injury, emotional distress damages for fear of cancer or other serious physical illness or injury following exposure to a carcinogen or other toxic substance is not compensable *unless* plaintiff pleads and proves "that the fear stems from a knowledge, corroborated by reliable medical and scientific opinion, that it is more likely than not that the fear of cancer will develop in the future due to the toxic exposure."³¹

In *Potter v. Firestone Tire & Rubber Co.*,³² plaintiffs were landowners living adjacent to a landfill where Firestone had disposed of toxic wastes. None of the landowners suffered from cancer or pre-cancerous conditions, but each faced "an enhanced but unqualified risk of developing cancer in the future due to exposure" because of toxic chemicals in their domestic water wells. In support of its "more likely than not" standard, the California Supreme Court cited numerous policy reasons, including the prevention of the "unduly detrimental impact that unrestricted fear of liability would have in the health care field" and the establishment of "a sufficiently definite and predictable threshold for recovery to permit consistent application from case to case."³³

California courts have applied the *Potter* “more likely than not” test in various cases involving emotional distress claims for fear of contracting an infectious disease. For example, in *San Diego Gas and Electric Co. v. Covalt*,³⁴ the California Supreme Court affirmed a Court of Appeal decision to follow *Potter* in disallowing emotional distress damages for fear of cancer due to exposure to electromagnetic fields (“EMFs”). Plaintiffs alleged that they were exposed to “unreasonably high” levels of EMFs and that they had been injured by the exposure since persons exposed to EMFs have an “elevated risk” of contracting cancer or similar diseases. However, the Court found that plaintiffs had failed to plead any facts to support the second prong of the *Potter* test requiring that the alleged fear stem “from a knowledge, corroborated by reliable medical or scientific opinion, that it is more likely than not that they will develop cancer in the future due to EMF exposure.”³⁵

In *Kerins v. Hartley*,³⁶ the First Appellate District of the California Court of Appeal applied the *Potter* “more likely than not” standard in the context of emotional distress damages for fear of AIDS. In that case, plaintiff sued a medical partnership and individual partners when, 17 months after surgery, she learned that her surgeon had tested positive for HIV at or about the time of the surgery. It was undisputed that the defendant physician suffered no cuts during surgery, and that plaintiff subsequently tested negative for HIV. After examining the policy concerns enumerated in *Potter* in support of the more likely than not standard, the Court of Appeal expressly concluded that all of the concerns applied with equal force to AIDS. Noting that the record provided “only the most speculative possibility that [plaintiff] would actually develop AIDS at some point in the future,” the *Kerins* court affirmed summary judgment for defendants.

Similarly, the California Court of Appeal in *Herbert v. Regents of University of California*³⁷ denied recovery of emotional distress damages to a

3 year-old boy who stuck himself with a needle he found on the floor of a medical center that had been used the previous day by an AIDS clinic. In affirming summary judgment for the defendant, the court noted that the undisputed evidence indicated that the risk the boy would contract HIV was about one-half of one percent, assuming the needle was contaminated with the feared virus at all. The court concluded that, as a matter of law, plaintiff could not prove that it was “more likely than not” that he would contract HIV or AIDS in the future.

In *Macy’s California, Inc. v. Superior Court*,³⁸ the court denied plaintiff’s claim for emotional distress damages for fear of contracting AIDS on similar grounds. In that case, plaintiff, a customer at Macy’s Department Store, pricked her finger on a dermic needle found in a jean jacket. Although she claimed severe emotional injury, including insomnia, panic attacks and depression, as well as physical injuries, including diarrhea, uncontrolled weight loss and tiredness, the court found that plaintiff could not prove that she sustained a physical injury, “meaning detrimental change to the body.” The court concluded that plaintiff, who tested negative for HIV, could not prove that it was “more likely than not” that she would contract the disease since, even assuming a contaminated needle, the chance of contracting HIV from a needle stick was one in approximately 200,000.

Minority Rule – Reasonableness

While most courts have defined *reasonableness* in the context of recovering emotional distress damages for fear of contracting an infectious disease in terms of actual exposure and accompanying physical injury, some courts have adhered to a traditional reasonableness standard relying on the totality of the circumstances presented in each case. In these cases, actual exposure and physical injury are mere factors to be considered in determining whether an

individual may recover emotional distress damages.

For example, in *Castro v. New York Life Ins. Co.*,³⁹ a janitorial employee was stuck by a discarded hypodermic needle and syringe as she was attempting to empty a trash can. Although the plaintiff refused to reveal the results of her HIV test to defendant, the court denied defendant’s motion for summary judgment. The court concluded that, because the “claim [could] be tied to a distinct event which could cause a reasonable person to develop a fear of contracting a disease like AIDS, there is genuineness of the [plaintiff’s] claim’.

Similarly, the Supreme Court of Virginia applied a reasonableness standard in *Howard v. Alexandria Hospital*,⁴⁰ a medical malpractice action in which the plaintiff sought recovery for emotional distress damages for injuries sustained during surgery performed at the hospital with instruments which allegedly were not adequately sterilized. Plaintiff was treated intravenously and given pain shots and frequent blood tests to determine whether she had contracted Hepatitis B, HIV, Staph virus and Tetanus, each of which plaintiff was told she could develop. Expert testimony during trial indicated that plaintiff’s “symptoms complex” was connected to the use of unsterile instruments, and that it was “reasonable” for plaintiff “to be in some fear of infection for 6 months.” The court found that plaintiff established a prima facie case of injury sufficient to support a claim of emotional distress based on fear of developing AIDS, even though there was no proof of exposure and no actual injuries as a result of the use of unsterile instruments. The court reversed the judgment in favor of defendant and remanded the case for a new trial.

More recently, courts which have adopted the minority, reasonableness standard, have begun to interject greater indicia of reliability into their analysis, thereby providing parameters as to what is reasonable for the recovery of emotional distress damages for fear of contracting infectious disease.

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For example, in *Faya v. Almaraz*,⁴¹ the Maryland Court of Appeals, applying a reasonableness standard, found that two women, who were unwittingly operated upon by an AIDS-infected surgeon, stated a claim for emotional distress damages. The surgeon's infection was unknown to the patients. The surgeon later died of AIDS, and the women learned of his death and the cause thereof from an article in the local newspaper. They sued the surgeon's estate and the hospital for emotional distress damages alleging that they were exposed to HIV by virtue of the operations. The trial court dismissed plaintiffs' claims on the grounds that they failed to establish actual exposure since they could not prove that the surgeon's blood had entered their bodies. However, the Court of Appeals reversed the judgment and expressly adopted a reasonableness standard for determining whether a plaintiff is entitled to emotional distress damages for fear of AIDS:

[W]e cannot say that appellants' alleged fear of acquiring AIDS was initially unreasonable as a matter of law, even though the averments of the complaints did not identify any actual channel of transmission of the AIDS virus.

In *Madrid v. Lincoln County Medical Center*,⁴² the Court of Appeals of New Mexico found that a woman who was exposed to bodily fluid through paper cuts on her hands while transporting medical samples stated a claim against a medical center for negligent infliction of emotional distress. Expressly rejecting the actual exposure requirement, the court held that the cause of action for negligent infliction of emotional distress based upon a fear of developing AIDS could be stated if there was a medically sound channel of transmission, and plaintiff was aware of the possibility of transmission, and had no reason to know that he or she was not exposed to a deadly disease. As a result, the court concluded that plaintiff stated

a cause of action based upon her allegation that she had unhealed paper cuts on her hands at the time her hands came in contact with the bodily fluid. In adopting a reasonableness standard, the court explained that the goal of deterring unreasonable conduct was of primary importance, and that imposition of liability for unreasonable conduct would decrease the number of exposure incidents and discourage the spread of disease ultimately serving the goal of promoting public health.

Similarly, in *Hartwig v. Oregon Trail Eye Clinic*,⁴³ the Nebraska Supreme Court found that a plaintiff, who was stuck by two used hypodermic needles placed in ordinary trash receptacle in a medical clinic she was cleaning, was able to recover emotional distress damages. Two days after the accident, plaintiff was informed by a nurse at the clinic that she was at risk for HIV and Hepatitis B infection and advised to submit to four blood tests to determine whether she had been infected. Although plaintiff never tested positive, the court expressly rejected the actual exposure rule, and held that she was able to state a claim for emotional distress damages since she was *potentially exposed* to tissue, blood, or bodily fluid through a medically sufficient channel of transmission of HIV. The court further noted that it was impossible or impracticable to determine whether the needles were in fact contaminated with HIV positive blood.

The New Jersey Supreme Court also applied a reasonableness standard in *Williamson v. Waldman*,⁴⁴ and concluded that a plaintiff, who was pricked with a lancet while cleaning a common trash can in a medical office, stated a claim against the physician owners of that medical office for negligent infliction of emotional distress. After the incident, plaintiff was advised to receive annual blood tests for HIV. Although she consistently tested negative for both HIV and hepatitis, plaintiff alleged severe emotional

distress and lifestyle changes, including a decision not to have another child. In adopting a "reasonableness" standard, the court considered competing public policy considerations offered in favor of the various tests and standards that had been adopted in these types of cases. The New Jersey Supreme Court ultimately settled upon a qualified reasonableness standard:

[A] person claiming damages for emotional distress based on the fear that she has contracted HIV must demonstrate that the defendant's negligence proximately caused her genuine and substantial emotional distress that would be experienced by a reasonable person of ordinary experience who has a level of knowledge that coincides with then-current, accurate, and general available public information about the causes and transmission of AIDS.

In formulating this test, the court expressly intended to deter unreasonable conduct, decrease the number of exposure incidents, and counteract general ignorance and public misconceptions about infectious disease.

Conclusion

Undoubtedly, competing public policy considerations will continue to drive the debate over what standards should apply to determine whether a plaintiff may recover emotional distress damages for fear of contracting an infectious disease. Courts will continue to grapple with the need to guard against speculative damages, excessive litigation, and harmful public misconceptions on the one hand, and the need to ensure fair treatment of legitimate claims and to deter unreasonable conduct in the name of promoting public health on the other. Even the prevailing policy considerations are likely to change as we learn more about various infectious diseases, the means by which they may be transmitted, as

well as how best to prevent their transmission and spread.

It is equally likely, however, that all courts will remain focused on the need for greater indicia of reliability in making the determination of whether an emotional distress claim for fear of contracting infectious disease is valid. Even the minority, reasonableness standard has been qualified by recent decisions to ensure that there is some evidence of a scientifically acceptable mode of transmission of the feared disease before a plaintiff will be allowed to recover emotional distress damages in this context. Without the common focus on the need for some greater indicia of reliability, litigants would be faced with highly speculative damage-claims and an increased potential for windfalls to healthy plaintiffs who will never manifest disease or injury at all.

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A Note From Our Director

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join together to explore cutting-edge issues in health law and to develop the Section's agenda. If you are interested in becoming more involved with the Section, please make time to attend this pivotal meeting.

One year ago, we celebrated the Section's commitment to our diverse membership by undertaking a number of initiatives to help assure that all members of the Section have the opportunity to speak on panels, write for the Section's publications, and contribute their talents to the Section's

Endnotes

- 1 *Duke v. Housen*, 589 P.2d 334, 340 (Wyo. 1979).
- 2 *Madrid v. Lincoln County Medical Center*, 121 N.M. 133, 138; 909 P.2d 14 (1995).
- 3 *See, Potter v. Firestone Tire & Rubber Co.*, 6 Cal.4th 965, 25 Cal.Rptr.2d 550 (1993).
- 4 *Madrid v. Lincoln County Medical Center*, *supra*, 121 N.M. at 138.
- 5 *See, e.g., Williamson v. Waldman*, 150 N.J. 232; 696 P.2d 14 (1997).
- 6 *See, Madrid v. Lincoln County Medical Center*, *supra*, 121 N.M. at 138.
- 7 *See, Pendergist v. Pendergrass*, 961 S.W.2d 919, 926 (1998).
- 8 *Williamson v. Waldman*, *supra*, 150 N.J. at 242.
- 9 *Madrid v. Lincoln County Medical Center*, *supra*, 121 N.M. at 143.
- 10 *See, e.g., John & Jane Roes v. FHD, Inc.*, 91 Haw. 470, 476, 985 P.2d 661 (1999); *Falcon v. Our Lady of the Lake Hospital, Inc.*, 729 So.2d 1169, 1173 (1999); *Babich v. Wankesha Memorial Hospital, Inc.*, 205 Wis.2d 698, 556 N.W.2d 144 (1996).
- 11 *See, Rothschild v. Tower Air, Inc.*, 1995 U.S. Dist. Lexis 2078, 1995 WL 71053 (E.D.Pa. 1995).
- 12 698 F.Supp. 1367 (N.D. Ill. 1988).
- 13 156 Ariz. 375, 752 P.2d 28 (1988).
- 14 717 F.Supp. 297 (N.D.Pa. 1989).
- 15 747 F.Supp. 285 (E.D.Pa. 1990).
- 16 186 W.Va. 648, 413 S.E.2d 889 (1991).
- 17 424 Pa. Super. 468, 623A.2d 3 (1993).
- 18 985 F.2d 208 (5th Cir. 1993).
- 19 1994 U.S. Dist. Lexis 16838, 1994 WL 675105 (E.D. Pa. 1994).
- 20 668 A.2d 1355 (Del. 1995).
- 21 652 So.2d 360 (Fla. 1995).
- 22 933 S.W.2d 668 (1996).
- 23 961 S.W.2d 919 (1998).
- 24 183 Ill.2d 407, 701 N.E.2d 1084 (1998).
- 25 694 N.Y.S.2d 772 (1999).
- 26 *Supra*, 729 So.2d 1169.
- 27 170 Ore.App. 128 (2000).
- 28 640 So.2d 476 (1994).
- 29 73 Ohio St.3d 801, 652 N.E.2d 664 (1995).
- 30 91 Haw. 470, 985 P.2d 661 (1999).
- 31 *Potter v. Firestone Tire & Rubber Co.*, *supra*, 6 Cal.4th 965.
- 32 *Ibid*.
- 33 The *Potter* court ultimately found that, since they alleged that defendant's conduct causing the toxic exposure amounted to "oppression, fraud or malice," under California Civil Code §3294, plaintiffs were excused from having to meet the "more likely than not" test. *Id.* at 997-1000.
- 34 13 Cal.4th 893, 55 Cal.Rptr.2d 724 (1996).
- 35 Plaintiffs ultimately conceded that they were no longer asserting that EMFs were harmful, but only that public fear of EMFs reduces the value of their property. Thus, the court denied plaintiffs' claim for emotional distress damages for fear of cancer. 13 Cal.4th at 913.
- 36 27 Cal.App.4th 1062, 33 Cal.Rptr.2d 172 (1994).
- 37 26 Cal.App.4th 782, 31 Cal.Rptr.2d 709 (1994).
- 38 41 Cal.App.4th 744, 48 Cal.Rptr.2d 496 (1995).
- 39 588 N.Y.S.2d. 695 (1991).
- 40 245 Va. 346, 429 S.E.2d 22 (1993).
- 41 329 Md. 435, 620 A.2d 327 (N.D. 1993).
- 42 *Supra*, 122 N.M. 269.
- 43 254 Neb. 777, 580 N.W.2d 86 (1998).
- 44 150 N.J. 232, 696 A.2d 14 (1997).

work. In addition, we committed financial support to the ABA Minority Opportunity Scholarship fund and developed stronger ties to law students. We brought more in-house counsel and government attorneys to the table, and more fully developed our list serve capabilities to enable broader input on issues. As a result, we are proud to report that the Section continues to tap more deeply into the experience and abilities of our members.

Where will the Section be one year from now? Five years down the road?

The answer to that question lies with you. You have the ability to help shape the Section's agenda through your participation in the Interest Groups, and by joining in Section activities. I'm looking forward to many more years of stimulating and challenging work with the Section. I hope you are too.

Jill Peña
Director
Health Law Section

ADVISORY OPINION ON “INSURANCE-ONLY BILLING” REQUIRES CAREFUL READING

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Introduction

The United States Department of Health and Human Services (DHHS) Office of Inspector General (OIG) recently released a new advisory opinion on “insurance-only” billing, OIG Advisory Opinion 01-7 (July 2, 2001).¹ As is often the case with OIG advisory opinions, the facts on which the opinion is based are unusual, such that the opinion may be easily misunderstood if taken out of context. This article attempts to identify the salient facts of the opinion from a health care provider standpoint, and to provide a context for its correct interpretation.

Background

The phrase “insurance-only” in billing for medical services is most commonly used to refer to waiver by the physician or other health care provider of the out-of-pocket, up-front payment the patient may be required to make to the provider at the time of each visit or service under the terms of his or her health benefit plan.² The term also may be commonly used to include a waiver of the uninsured portion of a charge for health services a patient may be required to pay, usually a percentage of the total charge billed and collected in arrears. An example of this would be traditional indemnity insurance coverage that pays 80 percent of the provider’s fee, with the remaining 20 percent to be collected in arrears from the patient.

The up-front payment is most commonly called a “copayment,” while the balance remaining to be paid by the patient after the health plan has paid its portion is usually referred to as “coinsurance.” These terms are sometimes used interchangeably and are not finely

distinguished in OIG Advisory Opinion 01-7, but the opinion clearly uses the term “coinsurance” to include both up-front and in-arrears patient payment responsibilities.

The Facts of OIG Advisory Opinion 01-7

OIG Advisory Opinion 01-7 addresses the insurance-only billing practices of an unnamed tertiary-care specialty hospital and its employed staff physicians.³ According to the opinion, the hospital has a long history of providing services without charge to patients or their families. Its services were funded entirely through private contributions until the 1960s, when the prevalence of health insurance and the implementation of Medicare and Medicaid caused it to begin seeking reimbursement from third-party payers, where available. Uninsured patients continue to receive care free of charge.

The same billing policies apply for hospital inpatient (Medicare Part A) services, other hospital (Medicare Part A) services, and for the (Medicare Part B) services of the hospital’s staff physicians who are employed full-time and exclusively by the hospital. Medical staff members who have outside, private practices independent of the hospital are dealt with separately in the opinion (see “Private Practice Physicians” below).

For its insured patients, the hospital waives all deductibles, copayments, and coinsurance, but accepts whatever available third-party reimbursement is available. Significantly, the hospital’s insurance-only billing policy applies to all of its patients, without regard to the patient’s financial need. It is not part of a bargained-for price reduction agreement between the hospital and the third parties, and no allocation of waived deductibles, copayments, or coinsurance is made to bad debt for Medicare cost-reporting purposes.

The OIG’s Analysis

The OIG begins its analysis with the observation that the hospital’s waiver of deductibles, copayments, and coinsurance charges for its inpatient hospital services fits squarely within the existing safe harbor for such waivers, found at 42 C.F.R. § 1001.952(k). Its waiver of charges for non-inpatient services and the services of its salaried physicians, on the other hand, are not protected by any existing safe harbor, and could potentially violate the anti-kickback statute. In this case, however, the OIG determined that it would not pursue sanctions.

In explaining its special treatment of this hospital’s billing practices, the OIG noted the long history of the hospital’s charitable service; the uniform application of the waiver to *all patients*, regardless of need or ability to pay; the salaried arrangements with staff physicians, reducing any personal incentive to provide or order unnecessary services; and the absence of any inducement to referral sources. Further distinguishing this case from the more typical arrangement, the OIG explained that its determination in this opinion —

rests in large measure on a recognition that . . . [the hospital’s] Insurance Only Billing Policy is a singular vestige of [the hospital’s] charitable origin and continuing mission. . . . This institutional history merits deference to the Insurance Only Billing Policy that would be inappropriate for an identical policy implemented today.

No Immunity For Private Practice Physicians

Like all OIG advisory opinions, Opinion 01-7 provides immunity from prosecution only for the hospital involved. It cannot be relied on by any other person in the defense of any enforcement action, and is limited in

scope to the precise facts presented. It expressly excludes from its protection the physicians who are on staff at the hospital, but who also maintain private practices outside of the hospital. With respect to those physicians and their patients, the opinion noted:

[The hospital] is one of several regional hospitals competing for lucrative cardiology business. [The hospital's] waiver of otherwise applicable patient coinsurance amounts potentially confers a competitive advantage both on [the hospital] and on the Private Practice Physicians In these circumstances and with respect to patients of the Private Practice Physicians, we see no distinction between [the hospital] and competing hospitals such that we should protect [the hospital's] waiving of patient coinsurance [in cases other than those based on financial need] when competing hospitals cannot.

Conclusion

OIG Advisory Opinion 01-7 applies narrowly to the facts and circumstances of a hospital whose historically and uniformly charitable mission distinguishes it sharply from the vast majority of medical institutions in the United States. It should not be read as a loosening of the legal standard generally prohibiting waiver of deductible, copayment, and coinsurance amounts other than in cases of financial need.⁴

Charles M. Key, Esq. is a member of The Bogatin Law Firm, PLC, Memphis, Tennessee. His practice focuses on representation of health care providers in business and regulatory matters such as service contracting, managed care systems, provider networks, faculty practice plans, Medicare reimbursement, antitrust, insurance, risk management, peer review, and licensing. Mr. Key is a

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Endnotes

- ¹ The opinion is available on the DHHS web site at <http://www.os.dhhs.gov/progorg/oig>.
- ² See Charles M. Key, "Professional Courtesy and the New Order: Recognizing Legal Constraints and Economic Realities," *The Health Lawyer*, Vol. 11, No. 6, pp. 13-17 (Aug. 1999).
- ³ The identities of the parties are routinely redacted from OIG advisory opinions prior to publication.
- ⁴ See Key, *supra* note 2 for a review of the legal issues raised by waiver of deductible, copayment, and coinsurance payments.

THE LAW OF UNINTENDED CONSEQUENCES: HOW WILL THE AFFORDABLE PRESCRIPTION DRUGS AND MEDICAL INVENTIONS ACT AFFECT AMERICAN HEALTH CARE?

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Introduction

On May 3, 2001, Representative Sherrod Brown (D, OH) introduced a bill entitled Affordable Prescription Drugs and Medical Inventions Act (H.R. 1708) (the "Bill"). (Full text of the Bill can be found at <http://thomas.loc.gov>.) The Bill initially has been referred to the House Committee on the Judiciary and to the Committee on Energy and Commerce. The committees have referred the Bill to the Subcommittee on Courts, the Internet, and Intellectual Property and the Subcommittee on Health respectively. No further action has been taken as of the date of this publication. If enacted, the Bill will make one of the most significant changes in the U.S. patent law ever. Under the proposed law, the government would have the right to grant commercial patent licenses against patent owners' will.

The Proposed Law

The Bill is intended to amend Federal patent law (U.S.C. Title 35) by adding a new Section 158, entitled "Compulsory Licensing." The new law would grant unprecedented powers to the Secretary of Health and Human Services ("HHS") and to the Federal Trade Commission ("FTC") to grant *compulsory* patent licenses (without the authorization of the owner of the patent rights) for use of patented inventions relating to health care. The proposed law has a broad subject matter scope. It is designed to be applicable to virtually all medications, medical devices (whether or not regulated by the FDA), biological products, and all technologies

and processes applied or applicable to "health or health care." The Bill does not specify how the power to grant compulsory licenses would be divided between the HHS and FTC.

When A Compulsory License Would Be Granted

If enacted, Section 158 would allow the HHS and FTC to grant compulsory licenses if either of them determines the existence of at least one of the five conditions specified in the Bill.

The first condition under which a compulsory license would be granted is a determination that the patent holder (or its contractor, licensee, or assignee) has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in a field of use. The Bill is silent on what should constitute "reasonable time" and "effective steps," how a determination of what's expected should be made, and what "a field of use" is. This provision would therefore give the HHS and FTC the power to define these terms.

The second listed condition is a determination of the necessity to establish "other use of the subject patent to alleviate health or safety needs which are not adequately satisfied by the patent holder, contractor, licensee, or assignee." It is not clear how the requisite adequacy is to be analyzed. For example, will the cost of the subject drug or device be a factor in analyzing the adequacy issue?

The HHS and FTC would also be able to grant a compulsory license if either of them determines that "the patent holder has engaged in anti-competitive behavior." The Bill provides two examples of the requisite anti-competitive behavior that would trigger this provision: (a) the patented

invention is priced excessively in relation to the median price for developed countries (or by other "reasonable" standards) and such pricing contravenes the public interest, or (b) the patented invention is an essential component of a health care product that involves patents, and the licensing terms for the patent on the invention are not reasonable and deter innovation or product development, contrary to the public policy. As in the previous provisions, this part of the Bill appears to give the HHS and FTC significant discretion to grant compulsory licenses.

The fourth determination that would allow the HHS and FTC to grant a compulsory license is that the subject patent is a blocking patent for a later patented invention. In other words, if another entity cannot practice its junior patent without obtaining a license from the holder of a senior (blocking) patent, the HHS and FTC would be able to grant a compulsory license under the senior patent to the holder of the junior patent. The restriction provided in the Bill for this kind of compulsory licenses is that the junior patent must protect an "important technical advance." The bill does not specify who would make the determination as to what an "important technical advance" is, nor does it specify what criteria would be used.

The fifth and final condition that would serve as a basis for granting a compulsory license is a determination by the HHS or FTC that the invention of the subject patent "is needed for research purposes that would benefit the public health, and that the invention is not licensed on reasonable terms and conditions." Once again, the Bill is silent regarding the criteria for evaluating the requisite public health interest. In addition, the Bill is silent on how a

determination of reasonableness of the license terms and conditions should be made.

Reasonable Remuneration For Compulsory Licenses

Another provision of the proposed law outlines how the FTC and HHS would determine reasonable remuneration to be paid to the owner of the patent right for a compulsory license. The following factors would be considered in the analysis:

- (1) the risks and costs associated with the patented invention and the commercial development of patented products;
- (2) the efficacy and innovative nature and importance to the public health of the subject invention;
- (3) the degree to which the invention benefited from publicly funded research;
- (4) the need for adequate incentives for the creation and commercialization of new inventions; and
- (5) the public health benefits of expended access to the subject patented invention.

Again, this portion of the Bill provides a lot of discretion to the HHS and FTC in making the requisite judgments.

Reporting Requirements

The Bill does not stop with creating a legal framework for compulsory licenses. It goes on to devise a reporting system according to which manufacturers of patented drugs would have to provide comprehensive annual financial reports to the HHS. The reports would have to include “all financial information relevant to the pricing of [patented drugs] nationally and internationally, including, in formats specified by the Secretary [of HHS] an accounting of the costs allocated to research and development of [each patented drug], as well as costs allocated to other research and development activities.” The same

reports would also be made available to the Congress. Non-compliance with the reporting requirements would subject the violator to civil penalties. There are no protections built into the Bill to ascertain that the highly confidential information included in the required reports would be unavailable to competitors of the reporting business and the public at large.

Although the Bill provides a procedure for judicial review of the assessed penalties for a violation of the reporting requirement, the Bill is silent on any review procedures for decisions to grant compulsory licenses.

Is The Cure Worth The Potential Damage From Side Effects?

The Bill was introduced in response to consumer complaints regarding the high cost of prescription drugs and medical devices. While other countries grant compulsory licenses to competing drug companies, so that patented drugs may be introduced to the market at lower prices, the United States has not followed this practice. Rep. Brown, a longtime advocate of lowering drug prices, believes that this law, if enacted, will lower prices through competition, making it more effective than using price controls.

In the short term, the proposed law may bring some prices to lower levels. However, what would be the potential long-term effects of such a drastic change in the U.S. patent policy?

If business entities have no confidence that the legal framework allows them to recover substantial research and development expenditures, they will naturally want to limit their financial risk and reduce R&D budgets. The reduced budgets are likely to cause a reduction in the number of newly developed drugs, biomedical products, medical devices, and other health care related inventions. The Canadian experience confirms that this danger is real. At one time Canada allowed companies to market generic versions of patented

drugs for a minimal royalty fee. Eventually, the Canadian Parliament concluded that “compulsory licensing had encroached too far into the patentee’s sphere of exclusivity, resulting in a decrease in research and development of new medicines in Canada.” ICN Pharmaceuticals, 138 D.L.R. 4th at 76 (reviewing the circumstances around passage of Patent Act, R.S.C., ch. P-4, 39 (1985), as amended at S.C. 1987, ch. 41). Canada later repealed compulsory licensing.

In Canada, compulsory licensing drove down prices for patented drugs, so that Canada no longer had the highest-priced drugs in the world. The licensing also kept prices of drugs from increasing above the level of inflation. See Shawn McCarthy, *Drive On to Rein in Drugs Costs: Patent Protection for Brand Names Limits Cost Save of Low-Price Copies by Generic Firms*, *The Toronto Star*, January 23, 1993 at C1. Since generic manufacturers could produce the drugs at a much lower cost, they could in turn offer the drugs at lower prices that kept the overall market price for prescription drugs low. See Michael B. Moore, “*Open Wide (Your Pocketbook That Is!) – A Call For the Establishment in the United States of a Prescription Drug Price Regulatory Agency*,” 1 Sw. J. of L. & Trade Am. 149, 162 (1994).

Some observers believe that compulsory licensing would *not* discourage research and development, pointing out that federal funding provides almost one half of all R&D monies spent in the pharmaceutical industry. But the nature of the drug market suggests that there would still be substantial effects. High sunk costs and a large time lag for approval of drugs in the pharmaceutical industry means that the companies rely heavily on money raised for research and development. In 1993, the Office of Technology Assessment determined that the cost of bringing a new drug from laboratory to market was \$359 million in 1991, and less than one in ten approved compounds allowed the developer to recover the *related costs*. See Office of Technical Assessment,

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Pharmaceutical R&D Costs, Risks and Rewards, at 21 (Feb. 1993).

While half of the money may come from federal funding, the other half of the R&D budget relies heavily on the sale of products already in the marketplace, so that drug sales provide significant funding for future research. Consequently, the entrance of competing and lower priced products is likely to result in the patent-holder selling fewer of its own products. In turn, commercial R&D budgets would have to be reduced. Alternatively, the patent-holder could seek to maintain its level of sales, but at a reduced price. Both outcomes would result in lower profits realized by the entities who traditionally have been major investors in new research. Would they be able to continue to afford comparable R&D budgets?

In addition, investors may perceive the proposed change in the law as a precursor to lower industry profits. Hence, it may become more difficult for pharmaceutical, biomedical and medical device companies to attract private investments. Perhaps more importantly, the proposed law may have a powerful impact on the public markets. If enacted, the bill would place a significant constraint on the ability of pharmaceutical, technology, and medical device companies to go public and to follow on offerings.

When profits fall, research and development suffers, therefore limiting the money spent on, and the introduction of, new drugs and inventions. If the United States is to remain the world leader in the development of new and effective health care technologies, compulsory licensing is not the answer. See Jerry Stanton, Comment, *Lesson for the United States From Foreign Price Controls on Pharmaceuticals*, 16 Conn. J. Int'l L. 149, 154 (2000). A comparison between the United States and countries with various regulatory schemes, including compulsory licensing in Canada, reveals that an unregulated pharmaceutical industry leads to a huge

volume of new drugs and inventions. Indeed, it is estimated that all of the European countries combined will produce only five new breakthrough drugs by the year 2002. See William C. Steere, Jr., *Thoughts Toward a Medicare Drug Plan*, (February 14, 2000) <http://www.pfizer.com/pfizerinc/about/medicare.html>.

Some may argue that lower prices will only affect current drugs - not future drugs - because generic drug producers will eventually raise prices to a level near the one set by patent-holders in order to make more money. Obviously, this is not the result the proponents of the Bill have in mind. More importantly, the logic of this argument is faulty. One of the basic economic principle is that increased competition always brings lower prices. Indeed, the Canadian experience proves it right — compulsory licensing in Canada resulted in lower drug prices.

Is the Proposed Law Constitutional?

Compulsory licenses could be considered unconstitutional under two theories: (1) the constitutional power to grant a patent carries no power to limit the patent; and (2) compulsory licensing constitutes an unconstitutional taking.

Congress has the right to grant exclusive rights to promote the science and the useful arts. Such power is said not to carry with it the power to encroach on that right or to grant a right conditioned upon subsequent government interference. An argument can be made that if such limitations were meant to be included, they would have been explicitly written into the Constitution. This argument has not been addressed by United States courts because broad commercial compulsory licensing laws have never been enacted. Commentators believe that a limitation on the granting of patents might meet with disapproval by the courts.

The second potential constitutional attack regards compulsory licensing as a “taking.” A taking must be for “public use.” While the taking of a patent may, in the end, benefit the public, the initial beneficiary is the competitor who gets the patented invention without having to invest the time and money spent to develop the subject technology. This taking would, first and foremost, benefit competitors of research and development companies in the pharmaceutical, biomedical, and medical device industries.

Some have tried to justify the taking of a patent under the police power of the federal government. The exercise of police power by Congress must be for the public benefit and can be used only to protect the health, safety, and morals of the community and to prevent the spread of any evil or harm. Strong arguments could be made that the taking of a patent would not be necessarily for the public benefit. Moreover, one may argue that unless the patented technology is not exploited, it is benefiting the public at large and therefore, it is already promoting health and safety. Finally, an argument can be made that compulsory licensing should not fall within the scope of the federal police power, as this power is based on regulatory principles.

For the above reasons, the Bill may be challenged on constitutional grounds.

The Proposed Law May Violate Basic Patent Policy Principles

A grant of a patent by the government has always been viewed as a *quid pro quo*. In other words, the inventor agrees to lay open the invented technology, and, in exchange for the full disclosure, the government grants the inventor a monopoly to benefit from the disclosed technology during a limited time. This policy yields two major benefits. On the one hand, it provides a powerful incentive for research and

innovation. On the other hand, it encourages the disclosure of the innovative research and thereby allows the scientists, researchers and engineers to build upon each other's results. This policy has provided the framework for an unprecedented spurt in technological progress in this country.

The proposed law may very well upset this delicate time-honored

balance. How it will affect the pace of invention in the critically important health care field remains to be seen.

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