

Health Law Litigation

Committee on
Health Law Litigation
American Bar Association
Section of Litigation

HEALTH LAW LITIGATION NEWSLETTER

8th Edition, Volume 1

Spring 2005

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MESSAGE FROM CO-CHAIRS JAMES REEDER AND KATHERINE LAUER

We would like to extend a very warm welcome to you as members of the Health Law Litigation Committee. The Committee has over 700 members active in all areas of healthcare litigation, and we have a number of substantive Subcommittees focused in the following areas:

Antitrust and Consumer Protection
Fraud and Abuse and *Qui Tam*
Licensing and Peer Review
Managed Care

Medical Ethics
Medical Malpractice
Nursing Home

We also have Subcommittees dedicated to the development and publication of this Newsletter and E-communications, as well as our Website. We encourage you to visit our Website, which we have redesigned to make it more user-friendly, to provide links to other helpful sites and to increase our substantive content. Our goal is to make this a real practice resource.

As you are no doubt aware, few areas of the law are as fluid as Health Law, and one of our goals for the coming year is to expand our resource base and provide new and exciting materials to our members. To that end, we hope to add not only periodic E-alerts, but other methods of communication and education such as Teleconferences to help keep our members on the cutting edge of the ever-changing landscape of Health Law. We welcome not only your ideas for program topics, but also the contribution of articles or alerts of interest to our members. We are also looking for members interesting in serving on the Editorial Board of our Newsletter.

In addition to the written materials provided to members, we have scheduled a breakfast meeting for Friday, April 22, 2005 during the Litigation Section's Annual Meeting at the Waldorf Astoria in New York. We invite you to join us at that meeting and look forward to hearing your thoughts on how our Committee can best meet your practice needs.

The ABA Annual Meeting will be in Chicago from August 4, 2005 and we will be providing you more information about that meeting as plans are finalized.

We are looking forward to an exciting year, and hope you can join us. We welcome your participation and ask that you contact any of the Subcommittee chairs or us if you would like to participate in the work of the Committee. We are always grateful for volunteers and look forward to seeing people become involved in identifying and addressing the issues related to the practice of Health Law. Please contact us if you have any questions or are interested in participating in any of our Subcommittees, publications, website or programs.

EDITOR'S COLUMN¹

I ask that you consider contributing articles for this Newsletter. The articles can be long or short, and can address nearly any area relating to the healthcare field that might be of interest to litigators.

Please pass this invitation along to anyone else you think might be interested in contributing to the Newsletter and call or e-mail me with your ideas (or to volunteer). Thanks.

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¹ The Health Law Litigation Newsletter is published at irregular intervals by the Health Law Litigation Committee of the Section of Litigation, American Bar Association, 321 N. Clark St., Chicago, IL 60610. The views contained within do not necessarily reflect the views of the American Bar Association, the Section of Litigation, or the Health Law Litigation Committee. Issue: 8th Edition – Volume 1 ©2005 American Bar Association.

Editor's Note: Recent civil enforcement activity by the government under the False Claims Act should be of interest to healthcare providers. In this article, the authors discuss the new approach being taken by the government and some of its possible impacts.

Federalizing Quality of Care: New Frontiers In Enforcement

**By Katherine A. Lauer and
Jennifer Alonso¹**

INTRODUCTION

Quality of care issues in the health care arena have historically been regulated on the health provider side through the peer review process, and on the legal side through malpractice claims. The federal government, and regulators bringing suit on their behalf, has recently revealed a willingness to supplement this regulatory framework by bringing civil fraud claims under the False Claims Act² ("FCA") against health care providers who they believe have rendered substandard care. With its threat of significant fines, treble damages, and costly litigation fees, the FCA has the potential to become a powerful weapon for the Government to punish providers for poor quality care. Moreover, the Government's recent novel criminal fraud charges against a hospital for the actions of one of its staff physicians and against a nursing home owner suggests they may soon begin pursuing quality regulation through criminal actions. Courts will likely be frequently asked to consider the appropriate role of these alternative means of regulating health care quality in the near future.

FALSE CLAIMS ACT CLAIMS

The Government has advanced claims regarding allegations of substandard care under three theories of FCA liability: express false certification; implied false certification; and worthless services. These three theories were explained by the Second Circuit in *U.S. ex rel. Mikes v. Straus*.³ An expressly false certification claim is "a claim that falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment."⁴ "An implied false certification claim is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment."⁵ A worthless services claim, however, is not predicated upon any false certification of statutory or regulatory compliance;⁶ rather, "in a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all."⁷

Although the implied false certification theory has not yet been affirmed by any federal circuit court, it has successfully survived dismissal at the pleading stage in at least two federal district courts. In *U.S. ex rel. Aranda v. Community Psychiatric Centers of Oklahoma, Inc.*, the Government alleged Community Psychiatric Centers ("CPC") violated the FCA by submitting bills for Medicaid patients while knowingly failing to provide those patients with a reasonably safe environment.⁸ Providing poor quality care in this way violated the FCA under the Government's theory because CPC "implicitly certif[ied] that it was abiding by applicable statutes, rules and regulations requiring provision to patients of appropriate quality of care and a safe and secure environment."⁹ The applicable statutes and regulations the Government

relied upon were: 42 U.S.C. § 1320a-7(b)(6)(B); *id.* § 1320c-5; *id.* § 1396a(a)(30)(A); 42 C.F.R. § 455.2; which all relate to the exclusion of providers from federal health care programs who fail to meet unexplicit standards such as “professionally recognized standards of health care,” or “quality of care.” None of these statutes or regulations, however, states that compliance is in any way a prerequisite for being paid for services already provided. Nonetheless, the court “decline[d] to hold” that CPC’s alleged failure to provide government insured patients with a safe environment during inpatient treatment could not “form the basis of an FCA claim.”¹⁰

In *U.S. v. NHC Healthcare Corp.*, the Government similarly alleged that a nursing home’s patients were “not given care up to the standards required under the Medicare and Medicaid programs” in violation the FCA.¹¹ The court allowed this charge to survive a motion to dismiss, seemingly through a blending of an implicit certification theory with a worthless services theory. It held that by accepting per diem payments from Medicare and Medicaid, NHC Healthcare Corp. (“NHC”) “agree[d] in principle to ‘care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life,’” under 42 U.S.C. § 1396r(b),¹² despite the fact that 42 U.S.C. § 1396r(b) does not state that compliance is a prerequisite to payment, but does provide for penalties for violations, including denial of payments for new admissions, termination from federal insurance programs, and civil monetary penalties.¹³ The *NHC* court concluded that because of this implicit certification, the Government could prove NHC fraudulently billed government insurance agencies by

demonstrating it provided substandard care to the patients on whose behalf it billed.¹⁴

The *NHC* court recognized that allowing the Government to bring a FCA claim in this way was in tension with the holding of the Southern District Court for the District of New York in *U.S. ex rel. Mikes v. Straus*, which held that “implied false certification is to be found only in those exceptional circumstances where . . . the Government would have refused to pay had it been aware of the claimant’s non-compliance.”¹⁵ *NHC* distinguished itself from *Mikes* by finding that the Government was alleging that “it paid the Defendant for complete care of these elderly patients . . . and the Defendant failed to meet this standard by knowingly failing to perform all necessary acts.” Thus, the court found the question at issue was not “how” the nursing home treated it’s patients, but “whether” it treated them at all,¹⁶ despite the fact the Government was not alleging that NHC’s patients received no care, or even practically no care, but rather that they received an amount of care that failed to reach the standards required under the Medicaid and Medicare programs.¹⁷

A relator’s attempt to expand FCA liability to quality of care allegations reached the Second Circuit in the afore mentioned *U.S. ex rel. Mikes v. Straus*.¹⁸ The court expressed significant reluctance to allowing such expansion, raising concerns against federalizing medical malpractice and substituting judicial oversight of the standard of care over better suited agencies such as state, local or private medical agencies, boards and societies.¹⁹ Specifically, the court held that that the FCA was “not designed for use as a blunt instrument to enforce compliance with all medical regulations – but rather only those regulations that are a precondition to payment.”²⁰ Therefore, plaintiffs may only

appropriately bring an FCA claim under an express certification theory when “a party certifies compliance with a statute or regulation as a condition to governmental payment;”²¹ or under an implied false certification theory when the “underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid.”²² Furthermore, an allegation based on substandard quality of care as a result of the failure to comply with a statutory standard is a separate and distinct issue from both “medical necessity”²³ and “reasonable and necessary” treatment.²⁴ Therefore a statute like 42 U.S.C. 1395y(a)(1)(A) which conditions Medicare payments on the fact that the care given is “reasonable and necessary” does not implicate the failure of a health care provider to conform to a particular standard of care.²⁵ Conversely, a statute such as 42 U.S.C. § 1320c-5(a)(2), which does not expressly state the provider must comply in order to be paid, but simply states that “[i]t shall be the obligation of [a] health care practitioner . . . who provides health care services for which payment may be made [under Medicare or Medicaid] . . . to assure . . . services . . . provided . . . will be of a quality which meets professionally recognized standards of health care,” only implicates a standard of care as a condition of *participation* in the Medicare program, but not a condition of *payment*.²⁶ As a result, the *Mikes* court declined to apply the False Claims Act to complaints that the care provided failed to comply with the statutory standards.

The *Mikes* court also concurred with the Ninth Circuit’s decision in *U.S. ex rel. Lee v. SmithKline Beecham, Inc.*²⁷ that an independent theory a plaintiff may use in bringing a False Claims Act charge against a health care provider is that the provider submitted a claim for “worthless services.”²⁸

In *Lee*, the relator alleged that the operator of clinical laboratories had falsified lab test data when test results for controls fell outside the acceptable standard of error.²⁹ The Court of Appeals found that the District Court had erred when dismissing the Complaint, because “in an appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under [the FCA], regardless of any false certification conduct.”³⁰ Neither the *Lee* nor the *Mikes* court, however, reached the question of whether the relevant tests billed for in those cases should be considered worthless services (the *Mikes* court concluded instead that, as a matter of law, the defendant lacked the necessary scientor to uphold a False Claims Act charge on a worthless services theory).³¹

However in *U.S. ex rel. Swan v. Covenant Care*, a case with a fact pattern similar to NHC, a California district court rejected the notion that substandard quality could form the basis for an FCA claim under a worthless services theory.³² In *Covenant Care*, the relator challenged the level of care and amount of services the patients received as a result of under-staffing at a nursing home.³³ As opposed to the implication of NHC, the court held that a plaintiff may not challenge the *amount* of care provided to nursing home patients under a worthless services theory of the FCA. “The False Claims Act only attaches liability to false claims for payment, not to underlying activity that allegedly violates federal law.”³⁴ Only treatment billed to the government that is so inadequate that, for all practical purposes, the patient receives no care at all may serve as the basis of a FCA claim under the worthless services theory.³⁵

The *Covenant Care* court also rejected the holdings of *NHC Healthcare* and *Aranda* in

dismissing the FCA claim under an implied false certification theory,³⁶ holding, similarly to *Mikes*, “[t]he prevailing law is that regulatory violations do not give rise to a viable FCA action unless government payment is expressly conditioned on a false certification of regulatory compliance.”³⁷ The court supported this conclusion by referring to the remedies that could be imposed under the Social Security Act, as amended by the Federal Nursing Home Reform Act, (which also provided the statutes relied upon in *NHC*) for the failure to meet quality of care guidelines – including the *discretionary* denial of payment – reasoning, “To allow FCA suits to proceed where government payment of Medicare claims is not conditioned on perfect regulatory compliance – and where HHS may choose to waive administrative remedies, or impose a less drastic sanction than full denial of payment – would improperly permit *qui tam* plaintiffs to supplant the regulatory discretion granted to HHS under the Social Security Act, essentially turning a discretionary denial of payment remedy into a mandatory penalty for failure to meet Medicare requirements.”³⁸

CRIMINAL FRAUD CHARGES

In an even more aggressive use of a fraud statute, the U.S. Attorney’s Office for the Western District of Michigan (“Michigan USAO”) brought criminal mail and wire fraud charges against United Memorial Hospital for its role in billing the patients of Dr. Jeffery Askanazi, who was convicted in December, 1998 of 33 counts of mail fraud for billing Medicare, Medicaid and private insurers for unnecessary surgeries.³⁹ Additionally, the Michigan USAO brought conspiracy charges against the hospital and two physicians who served on the hospital’s Medical Executive Staff.⁴⁰ The government

pursued these charges under a theory that these defendants failed to properly evaluate Dr. Askanazi in credentialing and peer review capacities, and that they failed to properly investigate when nurses and physicians criticized Dr. Askanazi’s frequent use of pain-management procedures of questionable medical benefit.⁴¹ The hospital eventually pleaded guilty to a single count of wire fraud, admitting as part of that agreement that many of the procedures performed by Dr. Askanazi were medically unnecessary and that they nevertheless billed for these procedures.⁴² The criminal charges against the two physicians were dismissed.⁴³

Recently, the U.S. Attorney for the Eastern District of Louisiana (“Louisiana USAO”) was successful in convicting a former owner of three nursing homes for defrauding the Medicare program by providing inadequate care and insufficient services to nursing home residents.⁴⁴ The federal judge sentenced the owner to serve 37 months in prison, the maximum allowed under federal sentencing guidelines.

These first-of-its-kind criminal prosecutions of a hospital and a nursing home owner for fraud originating from the medically unnecessary surgeries of one of its staff physicians and inadequate care, respectively, has obvious parallels to a civil FCA action for worthless services. As such, it is predictable that federal prosecutors will begin to use this theory to charge providers which the Government believes is offering substandard care, as it did *NHC*, *Mikes*, and (through a relator in) *Covenant Care*. Courts will then be asked to determine if such use of a statute goes beyond the intended purpose of the Legislature in passing it.

CONCLUSION

Attempts by the federal government to expand the regulation of quality of care concerns in health care beyond the malpractice and peer review realms through civil and potentially criminal fraud actions raises a number of issues. Most significantly, courts will need to decide if using fraud statutes in this way is consistent with the legislative intent behind these statutes. Additionally, there are federalism issues involved with the federal government attempting to regulate an area traditionally left to the states, and reason to doubt the ability of federal courts to answer these questions better than expert local regulatory agencies. The Department of Justice is no doubt motivated to pursue this kind of expansion both because of a desire to improve the quality of health care delivered and to stem the growing expenditures of programs such as Medicare and Medicaid. But considering current public debates concerning the regulation of health care quality, especially: (i) how to balance deterring poor quality health care delivery without exploding the cost of malpractice premiums, leading to higher health care costs and decreased access to patients; and (ii) whether lay juries are equipped to answer questions of malpractice, it may be unwise for the government to attempt to regulate health care quality through new these means, divorced from the precedents and procedures of those means that have had the opportunity to respond to these concerns for decades.

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² 31 U.S.C. § 3729.

³ 274 F. 3d 687 (2d Cir. 2001).

⁴ *Id.* at 698.

⁵ *Id.* at 699.

⁶ *See Id.* at 702.

⁷ *Id.* at 703.

⁸ 945 F. Supp. 1485, 1487 (W.D. Okla. 1996).

⁹ *Id.*

¹⁰ *Id.* at 1489.

¹¹ 115 F. Supp. 2d 1149, 1151 (W.D. Mo. 2000).

¹² *Id.* at 1153.

¹³ *See* 42 U.S.C. § 1396r(h).

¹⁴ 115 F. Supp. 2d 1153.

¹⁵ 84 F. Supp. 2d 427, 435 (S.D.N.Y. 1999).

¹⁶ 115 F. Supp. 2d at 1155.

¹⁷ *Id.* at 1151.

¹⁸ 274 F.3d 687 (2d Cir. 2001).

¹⁹ *See Id.* at 700.

²⁰ *Id.* at 699.

²¹ *Id.* at 697.

²² *Id.* at 700 (emphasis in original).

²³ *See Id.* at 698.

²⁴ *See Id.* at 700.

²⁵ *See Id.* at 701.

²⁶ *See Id.* at 702.

²⁷ 245 F.3d 1048 (9th Cir. 2001).

²⁸ *See* 274 F.3d at 702-03.

²⁹ 245 F.3d at 1050.

³⁰ *Id.* at 1052.

³¹ *See* 274 F.3d at 703.

³² 279 F. Supp. 1212, 1221 (E.D. Cal. 2002).

³³ *See Id.*

³⁴ *Id.*

³⁵ *See Id.*

³⁶ See *Id.* (“these questionable holdings have not been adopted by the Ninth Circuit or any other appellate court”).

³⁷ *Id.* (internal quotations removed).

³⁸ *Id.*

³⁹ See Grand Jury in Michigan Indicts Physicians, Hospital for Conspiracy, Health Care Fraud, BNA’s Health Care Fraud Report, Dec. 12, 2001, at 917.


⁴⁰ See *Id.*

⁴¹ See Francis J. Serbaroli, *Feds Snag Hospital in Physician Fraud Case*, New York Law Journal, January 28, 2003, at 3.


⁴² See *Id.*

⁴³ See *Id.*

⁴⁴ See *Louisiana Nursing Home Owner Sentenced to Prison in Medicare Inadequate Care Case*, BNA’s Health Care Fraud Report, Nov. 5, 2004, at 1354. The Louisiana USAO also charged the owner with bilking employee retirement funds.



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LITIGATION UPDATE

We know: The daily deluge of e-mails can make it difficult to separate the “wheat from the chaff.” So, we wanted to make certain you did not miss *Litigation Update*, the Section’s monthly e-newsletter. In a quick, easy-to-read format, *Update* features information on benefits and services to help you get the most from your Section of Litigation membership. Areas covered include:

<p>Online Specialty Columns:</p> <ul style="list-style-type: none">• Tips from the Trenches—Practical insight from seasoned litigators• Second Chair—Fundamental information targeted toward newer lawyers• Sidebar—Practical new advice column offers good counsel for new litigators.	<p>Member Benefits:</p> <ul style="list-style-type: none">• Upcoming CLE programs & conferences• New Section video & audio programs, books, and monographs• Your Section Works—how the Section is giving back to the legal community
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Watch your e-mail inbox for *Litigation Update*, published the first week of each month.

Editor's Note: New procedures used by the Joint Commission on Accreditation of Healthcare Organizations impact healthcare compliance matters. In this article, the author explains JCAHO's new standards.

Legal Consequences of JCAHO'S Periodic Performance Review

By Tiffany L. Roepsch¹

Effective January 2004, the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") commenced implementation of its new accreditation and survey process, "Shared Visions – New Pathways." This new process requires each accredited ambulatory care, behavioral health care, home care, hospital, and long term care organization to conduct a Periodic Performance Review ("PPR") to assess compliance with applicable standards at the mid-point of its three year accreditation cycle. JCAHO has indicated that it considers the PPR an integral component to facilitating continuous compliance with standards and allowing surveyors to devote more time to concentrate on accredited organizations' critical focus areas and educational support during on-site triennial surveys.²

Overview of the Periodic Performance Review

The PPR requires each accredited organization to complete a self-assessment of its compliance with applicable JCAHO standards at the 18-month mid-point of its triennial accreditation cycle. During the self-assessment, if an organization finds that it is not fully compliant with any applicable standard(s), it must develop a plan of action specifying the corrective action it will take to address such non-compliance and identifying measures of success that will be

used to confirm that all problems identified during the self-assessment have been resolved at the time of the subsequent triennial on-site survey. Upon completion of the PPR, an organization shares the results of the PPR and the plan of action it has developed to address those results with JCAHO for review and approval; measures of success are shared with JCAHO during the subsequent triennial on-site survey. As long as an organization completes the PPR and undertakes the appropriate corrective action, the PPR will not change the organization's accreditation status.

Health lawyers, risk managers, hospital associations, and others are concerned that the disclosure of PPR materials by an accredited organization to JCAHO may result in legal liability. Of specific concern is whether: (a) PPR materials fall outside of applicable state peer review/quality assurance statutes, protecting the confidentiality of peer review and/or quality assurance information and deeming such information nondiscoverable; (b) disclosure to JCAHO would result in a waiver of the peer review privilege, and (c) regulatory agencies would have access to PPR materials, use these materials against the organization in a regulatory action and subsequently disclose this information to the public through the state freedom of information law. In response to these concerns, JCAHO has developed three options to the full PPR process described in the preceding paragraph and completion of any one of these options will also satisfy the PPR requirement.³

Option one requires an organization to complete the self-assessment survey and, if necessary, develop a plan of action and identify measures of success. The organization must then affirm that it has completed these activities, but that it has

been advised by legal counsel not to submit to JCAHO the results of the PPR, or other materials developed during the PPR. The organization may, however, discuss standards-related issues with JCAHO staff, without regard to the organization's specific level of compliance, and must make the measures of success it identifies available to JCAHO during the subsequent triennial on-site survey.

Under the second option, an organization may complete the PPR by means of an abbreviated on-site survey, lasting approximately one-third of the length of the triennial survey, which JCAHO will conduct for an additional fee. The organization must address non-compliance with applicable standards identified during this survey in a plan of action, and must submit such plan of action to JCAHO for approval. The organization must also develop measures of success and provide these to JCAHO during the subsequent triennial on-site survey.

Finally, the third option similarly allows an organization to complete the PPR process through an abbreviated on-site survey conducted by JCAHO for an additional fee. However, under this third option, the JCAHO surveyor conveys the PPR results to the organization orally rather than through a written report. During the subsequent triennial on-site survey, JCAHO surveyors will have the PPR results, but will not address non-compliance identified during the PPR unless requested by the organization.

Legal Consequences of the Periodic Performance Review

While the three options are intended to alleviate the legal risks associated with an accredited organization's completion of the PPR process, none of the options fully address these risks. As a preliminary matter,

most states have enacted laws establishing some form of peer review privilege to protect the confidentiality and discoverability of peer review materials. State law, however, varies greatly with regard to protected entities and activities. For example, some states afford protection from discovery only to limited types of peer review information and/or quality assurance information.⁴ Accordingly, it is important for an organization to determine whether it is an entity that is afforded protection by the state statute and, if so, whether PPR information is deemed confidential and nondiscoverable under applicable state law. Another concern is that some state peer review statutes do not treat documents produced in connection with the PPR as confidential peer review/quality assurance records, but rather as general business records produced in the ordinary course of business. Business records are not typically afforded protection from disclosure under state peer review statutes.⁵ In some states, the peer review privilege extends only to information that is gathered through a process conducted or initiated by a quality assurance committee.⁶ In those states, PPR materials may be deemed to be confidential peer review/quality assurance material if the organization's peer review/quality assurance committee authorizes the performance of the PPR. However, whether such material is protected by peer review/quality assurance statutes depends upon the laws of the applicable state. For this reason, it is important for organizations to consider the laws of their state in determining whether documents developed in connection with the PPR process must be initiated, generated or created by its peer review/quality assurance committee to be eligible for protection under applicable law. It should also be noted that any information developed or maintained independently by JCAHO in connection with the PPR process (e.g., during an

abbreviated on-site survey) may not be protected by peer review statutes and may be discoverable.

Even if PPR materials are protected by the peer review privilege under the laws of the applicable state, disclosure of this material to JCAHO may result in a waiver of the privilege. In many states, peer review statutes protect only those documents and information in possession of a peer review/quality assurance committee. Thus, the disclosure of peer review information to a person or entity outside of this may constitute waiver of the peer review privilege and result in a loss of the confidentiality protections.⁷ In other states, however, peer review statutes have been interpreted as providing more far-reaching protections, and disclosure to third parties will not result in a waiver of the peer review privilege.⁸

As a final matter, even when PPR materials are protected from discovery, accredited organizations may be required to disclose materials created during the PPR process to state regulatory agencies. Such disclosure is required in a number of states that deem organizations accredited by JCAHO as compliant with applicable Medicare Conditions of Participation and, in some states, applicable state licensure requirements. An organization that enjoys this “deemed status” is often required by state law to submit all materials related to its JCAHO accreditation to the state licensing authorities.⁹ This information could potentially be used by state licensing authorities in a regulatory enforcement action against the accredited organization. Moreover, this information may become available to the public through the state freedom of information act. Such a result presents a compelling reason for accredited organizations to consider the laws of their

state and limit their disclosures of PPR materials to JCAHO.

Conclusion

State law largely determines the impact that the creation and disclosure to JCAHO of PPR materials may have on an accredited organization. While JCAHO has attempted to address legal concerns in connection with the disclosure of this information, none of the options available for completing the PPR process fully protect an accredited organization. To limit potential exposure to civil and regulatory liability, organizations are well advised to seek legal counsel in determining which one of the four methods for completing the PPR process best protects the organization.

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² See *Shared Visions-New Pathways*, JOINT COMMISSION PERSPECTIVES, October 2002, at 6.

³ See *The Launch of Shared Visions-New Pathways*, JOINT COMMISSION PERSPECTIVES, January 2004, at 7-9 (explaining the four methods an organization may use to complete the PPR). It should be noted that JCAHO provides accredited organizations with the tool for completing the PPR approximately three months prior to the 18-month point in their accreditation cycle. Before an accredited organization may access the PPR tool, the organization must use the PPR tool to notify JCAHO whether it will be completing the full PPR process or utilizing one of the three options to complete the PPR process. Prior to making this notification, JCAHO has advised organizations that any data entered into the PPR tool will be available to JCAHO, but will not be accessed or used by JCAHO in the organization’s accreditation process. *Id.* at 7.

⁴ See, e.g., VA. CODE ANN. § 8.01-581.17 (2002) (extending the privilege to only limited information).

⁵ See, e.g., TEX. HEALTH AND SAFETY CODE ANN. § 161.032 (2003).

⁶ See *Doe v. Illinois Masonic Medical Center*, 696 N.E.2d 707, 709 (Ill. App. 1998).

⁷ See, e.g., *State ex rel. St. John's Reg'l Med. Ctr. v. Dally*, 90 S.W.3d 209, 216 (Mo. Ct. App. 2002) (holding that the peer review privilege can be waived by the entity generally responsible for overseeing the care provided at the hospital); *Plourde v. Hartford Hosp.* 2003 WL 22959086, at *6 (Conn. Super. 2003) (unreported) (finding that the peer review privilege was waived when a physician placed a document that he knew, or should have known, was protected by the peer review privilege in a patient's medical file).

⁸ See, e.g., *Ollman v. Wisconsin Health Care Liab. Ins.*, 505 N.W.2d 399, 407 (Wis. App. Ct. 1993) (holding that the disclosure of confidential peer review records to third parties does not constitute a waiver of the peer review privilege); *Mulder v. Vankersen*, 637 N.E.2d 1335, 1340 (Ind. Ct. App. 1994) (stating that absent a written waiver that complies with statutory requirements, the breach of confidentiality does not result in a waiver of the peer review privilege).

⁹ See generally 42 U.S.C. § 1395bb. See also WIS. STAT. § 50.36(3m) (2003).



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SECTION OF LITIGATION
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Editor's Note: Expert witness testimony often is a key to success in litigation. In this article, the author analyzes the issue of causation in medical malpractice litigation.

Treating Physicians' Opinions on Medical Causation: Subject to the Same Standards of Admission as All Other Expert Testimony

By Michelle Jerusalem Cole¹

In product liability and medical malpractice cases, treating physicians, given their involvement in a plaintiff's medical treatment, are regularly asked to testify as witnesses. All too often, however, courts overlook flaws in such witnesses' testimony and permit them to testify on critical issues such as causation without regard for the reliability of their opinions. But given the significance of causation testimony and the unique ability of physician witnesses to influence a jury, courts should not simply brush aside any challenges that may be made. The testimony of a treating physician on causation is no different than that of any other expert witness and, as such, it should be required to withstand a *Daubert* analysis before it is allowed to be heard by a jury.

I. Reliable Expert Testimony Is Essential to Determine Medical Causation.

The key question a jury must resolve in any complex product liability or medical malpractice action is whether the defendant's alleged negligence caused the plaintiff's injury. It is well-established that this question, by its very nature, is "beyond the ken" of laymen, and that its resolution, therefore, is dependent upon expert testimony.²

Using their specialized knowledge, experts – qualified by their experience, training, and/or education – convey to the jury a realistic appraisal of whether a particular defendant breached his or her duty of care and the chances that the alleged breach caused the plaintiff's injuries. Ideally, a jury uses this evidence to make an informed decision in a given case. This very nature of expert testimony makes it a powerful tool. With experts' impressive credentials and complex opinions, jurors are less likely to question their testimony and more likely to lend it additional weight than other types of evidence.³

Given that the resolution of product liability and medical malpractice cases requires expert testimony and that its impact is so significant, it is axiomatic that, to be admissible, the expert testimony provided must be *reliable*.⁴ Indeed, were it not, it would lead jurors – whom courts have already recognized as insufficiently knowledgeable to determine the soundness of medical evidence – to an unreliable verdict.

Recognizing the need for expert testimony to be reliable, the U.S. Supreme Court, starting in 1993, decided a trilogy of cases that require federal trial court judges, as "gatekeepers," to determine the reliability of expert testimony, and to exclude such testimony that does not meet certain standards.⁵ As stated by the Court in the first such case, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, "[i]n a case involving scientific evidence, evidentiary reliability will be based upon scientific validity."⁶ To help lower courts assess the reliability of scientific testimony, the *Daubert* decision identified four non-exclusive factors: (1) whether the theory or technique can be and has been tested, (2) whether it has been subjected to "peer review and publication,"

(3) whether the technique has a high known or potential rate of error or whether there are standards controlling the technique's operation, and (4) whether it enjoys "general acceptance."⁷

In its subsequent decisions, the Supreme Court clarified that the underlying gatekeeping principles and the need for assessments of expert reliability should apply to *all* expert testimony, not just scientific testimony. In addition, and partially because of that determination, the Court emphasized that a gatekeeper's analysis often involves the examination of factors in addition to or different from those identified in the earlier *Daubert* decision, depending on the particular type of expert and testimony at issue.⁸ Ultimately therefore, compliance with the *Daubert* doctrine requires that a gatekeeper scrutinize all aspects of an expert's testimony – "factual basis, data, principles, methods, [and] their application" – and determine whether the testimony "has 'a reliable basis in the knowledge and experience of [the relevant] discipline.'"⁹

II. As With Other Expert Testimony, the Opinion of a Treating Physician Testifying on Causation Must Not Only Be Clinically, But Also Scientifically, Reliable.

Product liability and medical malpractice plaintiffs commonly employ treating physicians as expert witnesses to testify regarding medical causation in their cases. While some courts maintain that treating physicians should be immune from *Daubert* scrutiny,¹⁰ such witnesses testifying on causation should be subject to the same reliability requirements as other types of experts. In other words, the causation testimony of a treating physician should not be deemed admissible simply by virtue of the fact that he or she is a treating physician

or that he or she employed the methodology of a treating physician.

The "art" of medicine used for diagnosing difficult cases is distinguishable from the "science" of medicine used to help a jury evaluate the soundness of a plaintiff's legal claim. The primary goal of every doctor is to diagnose and then treat his or her patients. This goal, however, sometimes proves elusive and a doctor must resort to a trial and error process to determine whether different factors impact this one particular patient's condition. Ultimately, the doctor hopes to uncover a treatment that will make the patient feel better, but in the complex world of medicine, he or she may not be able to explain precisely why or replicate the results with another patient. In this scenario, while the doctor may have successfully treated the patient, he or she has not produced a scientifically valid principle. The latter occurs only after the doctor's theory is validated through legitimate scientific testing or support from other sufficiently relevant studies. *See* "Introduction to Clinical Medicine," Harrison's Principles of Internal Medicine (11th ed. 1987) (noting that the practice of medicine combines both science and art).

This distinction between medical diagnosis and scientifically valid – and thus legally admissible – principles has been recognized by courts. As one Georgia federal court recently stated in excluding the testimony of an expert witness who had based his opinion on the connection between strokes and Parlodel – a drug taken to suppress postpartum lactation – on a methodology applied by doctors in their clinical practices:

"Doctors every day seek to determine causes of injury and illness and make patients healthier. In their eternal quest for "the answer," however, doctors sometimes

believe that they have found a cause when they have not necessarily done so. Doctors in their day-to-day practices stumble upon coincidental occurrences and random events and often follow human nature, which is to confuse association and causation. They are programmed by human nature and the rigors and necessities of their clinical practices to conclude that temporal association equals causation, or at least that it provides an adequate proxy in the chaotic and sometimes inconclusive world of medicine.”¹¹

The court did not question the expert’s honest belief that Parlodel causes strokes or that his methodology serves him well in the clinical practice of medicine. This, however, was not enough in a court of law. “Unfortunately, [the expert’s] clinical impression is not the sort of scientific methodology that *Daubert* demands.”¹²

Based on similar reasoning, the court in *Wynacht v. Beckman Enterprises, Inc.*, 113 F. Supp.2d 1205 (E.D. Tenn. 2000), excluded a treating physician’s proposed testimony that plaintiff’s exposure to chemicals in a laboratory accident caused her fibromyalgia, chronic fatigue syndrome, and other health problems. At the outset, the court recognized the “fundamental distinction” between the physician’s ability to render a medical diagnosis and the ability to render a causation opinion: “The ability to diagnose medical conditions is not remotely the same ... as the ability to deduce, delineate, and describe, in a scientifically reliable manner, the causes of those medical conditions.”¹³ The court then concluded that because the physician’s causation opinion was based solely on the temporal relationship between the chemical spill and his subsequent diagnosis of plaintiff’s symptoms – without the support of any biochemical, medical, or toxicological principles or studies – it fell

“well short” of the *Daubert* reliability standard.¹⁴

Thus, treating physicians’ testimony should not be deemed reliable simply because they are treating physicians or because they applied the methodology of a treating physician. Rather, their testimony, and the underlying methodology on which that testimony is based, like that of all expert witnesses, should be evaluated for its reliability using the *Daubert* framework described above.¹⁵

Conclusion

In *Daubert*, the Supreme Court highlighted the “important differences” between the quest for truth in the courtroom and the quest for truth in the laboratory; while science is furthered by the consideration of hypotheses, law is promoted by the fair, prompt, final resolution of disputes.¹⁶ In science, theories that are ultimately proven wrong represent advancement, but in law, they are only obstacles to a just result. With this in mind, the Supreme Court emphasized the significance of its new rule requiring judges to act as gatekeepers of reliable scientific evidence even though the rule “inevitably on occasion will prevent the jury from learning of authentic insights and innovations.”¹⁷

Physicians seeking to determine the cause of their patients’ injuries in order to provide treatment are no different from *Daubert*’s scientists seeking breakthroughs in the laboratory. Their theories are only helpful to a jury trying to decide a legal dispute if they are valid. Thus, their testimony should be scrutinized and only admitted if it is deemed reliable under *Daubert*.

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² See, e.g., *Zwiren v. Thompson*, 578 S.E.2d 862, 865 (Ga. 2003) (expert testimony required to support plaintiff's contention that defendant doctor's allegedly negligent conduct proximately caused plaintiff's harm); *Miller v. Pfizer Inc. (Roerig Division)*, 196 F. Supp.2d 1095, 1125 (D. Kan. 2002) ("Plaintiffs ... cannot meet their burden of proving medical causation without expert testimony that Zolof caused [the decedent's] suicide.") (listing cases).

³ See *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 505 (1993) (recognizing the "power" of expert testimony).

⁴ See *Id.* at 590 ("In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability."); see also, e.g., *Swallow v. Emergency Med. of Idaho, P.A.*, 67 P.3d 68, 73 (Idaho 2003) (excluding plaintiff's expert's testimony in a medical malpractice action for prescribing antibiotic Ciproflaxin because expert's opinion lacked a reliable foundation, stating that "[a] jury does not need the 'assistance' of this type of 'expert' testimony to draw the same speculative conclusion that Cipro caused the myocardial infarction in this case").

⁵ See *Daubert*, 509 U.S. 579; *General Elec. Co. v. Joiner*, 522 U.S. 136 (1997); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999).

⁶ 509 U.S. at 590 n.9.

⁷ *Id.* at 593-94.

⁸ See *Kumho Tire*, 526 U.S. at 150-52 (noting that the factors listed in *Daubert* were meant to be helpful but may not be relevant in all cases and that therefore, trial courts must have leeway in deciding in a particular case how to go about determining whether the expert testimony at issue is reliable); *Joiner*, 522 U.S. at 146 (advising that courts should consider whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion); see, e.g., *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp.2d 434, 559 (W.D. Penn. 2003) (considering whether expert's theory generated

consistent results and was objective and reproducible).

⁹ *Kumho Tire*, 526 U.S. at 149 (quoting *Daubert*, 509 U.S. at 592); see, e.g., *Joiner*, 522 U.S. at 143-45 (examining, in a direct and thorough manner, proffering party's validity showing); *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1202 (11th Cir. 2002) (carefully examining plaintiffs' proffered testimony in alleged support of their claim that Parlodel caused hemorrhagic stroke and concluding that such testimony was inadmissible as it was based on "several scientifically unsupported 'leaps of faith' in the causal chain").

¹⁰ See, e.g., *Perkins v. Origin Medsystems, Inc.*, 299 F. Supp.2d 45, 55-56 (D. Conn. 2004) (permitting treating physician to testify that surgical fastening device is capable of causing unforeseen post-operative pain (*i.e.*, general causation) based solely on her clinical experience); see also *Id.* at 55 n.18 ("A treating physician can testify as a fact witness about the care and diagnosis rendered as part of plaintiff's treatment."); *Santoro v. Signature Construction, Inc.*, Case No. 00 Civ. 4595, 2002 WL 31059292, at *4 (S.D.N.Y. Sept. 16, 2002) ("[E]ven after *Daubert*, treating physicians have routinely been permitted to testify to determinations that they made in the course of providing treatment regarding the cause of an injury and its severity.") (listing cases).

¹¹ *Siharath v. Sandoz Pharmaceuticals Corp.*, 131 F. Supp.2d 1347, 1372 (N.D. Ga. 2001), *aff'd sub nom. Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194 (11th Cir. 2002).

¹² *Id.* In *Siharath*, the experts relied in part upon differential diagnosis, a methodology in which potential causes are "ruled in" and then systematically "ruled out" based on objective data and criteria, and causation is ultimately attributed to the last remaining cause on the list. 131 F. Supp.2d at 1362. Differential diagnosis is the methodology frequently used by physicians testifying on causation, and many courts have recognized that such a methodology, unless applied in a sufficiently reliable manner,

is insufficient to meet *Daubert*'s requirements. See *Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1210-11 (10th Cir. 2002) (excluding experts' testimony that was based, in part, on differential diagnosis); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999) (only a "reliable differential diagnosis provides a valid foundation for an expert opinion"); *Caraker v. Sandoz Pharmaceuticals Corp.*, 188 F. Supp.2d 1026, 1030 (S.D. Ill. 2001) (noting that differential diagnosis "in the abstract, has been considered sound ..., but when it is used in the practice of science (as opposed to its use by treating physicians in the practice of medicine out of necessity) it must reliably 'rule in' a potential cause").

¹³ See *Id.* at 1209; see also *Adams v. Blue Cross/Blue Shield of Maryland, Inc.*, 757 F. Supp. 661, 668 (D. Md. 1991) ("[T]he objective scientific evaluation of a technique for purposes of determining the admissibility of expert testimony in a trial is far different from the practical evaluation of a medical treatment In the first case, scientists are asked to quantify a technique's reliability, predictability, and precision so that a jury can rely upon it to determine facts. In the second, physicians practicing the scientific art of medicine must strike a practical balance between the risks of a particular treatment, the effectiveness of the treatment, and the availability of other options.")

¹⁴ *Id.*; see also *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1207 (8th Cir. 2000) (excluding treating physician's causation testimony because it was based on an unreliable methodology and because "[h]e was clearly more concerned with identifying and treating [plaintiff's] condition than he was with identifying the specific substance that caused her condition"); *Munafu v. Metropolitan Transport. Auth.*, Case Nos. 98 CV-4572, 00-CV-0134, 2003 WL 21799913 at *19 (E.D.N.Y. Jan. 22, 2003) (excluding testimony of plaintiff's treating psychopharmacologist on the cause of plaintiff's depression because, as his treating physician, witness was concerned "primarily with identifying and treating [plaintiff's] condition, not determining its underlying cause").

¹⁵ See *Turner*, 229 F.3d at 1207 (rejecting plaintiffs' contention that *Daubert* did not apply because the witness' causation testimony was provided as a treating physician; stating that a "treating physician's expert opinion on causation is subject to the same standards of scientific reliability that govern the expert opinion of physicians hired solely for the purposes of litigation") (citing *Kumho Tire*, 526 U.S. at 151); see also *Amorgianos v. National RR Passenger Corp.*, 303 F.3d 256, 270 (2d Cir. 2002) (excluding testimony of treating physician because "the analytical gap between the studies on which she relied and her conclusions was simply too great"); *In re Breast Implant Litig.*, 11 F. Supp.2d 1217, 1234 (D. Col. 1998) ("A statement does not become scientific knowledge because it is uttered by a doctor.").

¹⁶ *Daubert*, 509 U.S. at 596-97.

¹⁷ *Id.* at 597.

Editor's Note: There has been much news about class action lawsuits filed against nonprofit hospitals. In this article, the author explains the lawsuits and offers some observations about them.

TAX-EXEMPT HOSPITALS UNDER FIRE

By Linda S. Moroney¹

It seems that, of late, it's become rather fashionable to bash nonprofit hospitals. Whether the setting is the mainstream media, Congressional hearings, or courtrooms across the country, hospitals are suffering one blow after another in a maelstrom of scrutiny.

CLASS ACTION LAWSUITS

Over the past months, over 30 class action lawsuits have been filed targeting the alleged failure of nonprofit hospitals to adequately care for the uninsured, focusing in particular upon such hospitals' fee structures and collection practices. Thus far, the defendants include approximately 340 hospitals and healthcare organizations across the country, along with the American Hospital Association as a "conspirator" in the defendants' purported tactics. Some of the suits have named additional "John Doe" defendants, presumably including officers, directors, attorneys and others who have participated in the decision-making regarding institutions' charges and billing and collection practices. The initiative is being led by Richard Scruggs, the Mississippi attorney who found fame and fortune in the context of the tobacco litigation of the 1990s.

The cases generally assert that the defendant hospitals have enjoyed tax-exempt status under Internal Revenue

Code Section 501(c)(3), and/or under applicable state law insofar as the facilities are exempt from state and local property taxation, on the grounds that they explicitly or implicitly promised to provide charity care for the uninsured and would not operate to benefit private interests. The cases allege that the hospitals have breached these promises by instead:

- (i) Charging uninsured patients significantly more than those covered by Medicare, Medicaid or insurance, and thus more than fair market value;
- (ii) Pursuing the poor or uninsured relentlessly by aggressive, abusive, harassing and humiliating collection techniques;
- (iii) Rampantly violating prohibitions against private benefit through arrangements with physicians, board members and insiders;
- (iv) Amassing and hoarding billions of dollars rather than spending these amounts to provide care to the uninsured; and
- (v) Misreporting financial results, including charity care, through Hollywood-type accounting schemes.

The plaintiffs seek damages, and have further asked for the courts to impose a constructive trust on the defendants' assets. The cases also seek injunctions prohibiting the defendant hospitals from (a) charging the uninsured the full undiscounted cost of care, (b) charging the uninsured more than they charge insured patients for the same services, and (c) using abusive collection practices against the uninsured.

CONGRESSIONAL SCRUTINY

Three separate Congressional committees are currently investigating tax-exempt hospitals (either specifically, or as part of a broader review of exempt organizations generally).

First, the House Ways and Means Committee has established an Oversight Subcommittee on Hospital Pricing Practices. The first of what has been described as a “very long series” of hearings was held on June 22, 2004. While the topics and testimony at the initial hearing were broad in scope, the central theme of the discussion was whether hospitals are sufficiently charitable to warrant continued tax-exempt status.

Second, the House Energy and Commerce Committee has established an Oversight Subcommittee on Hospital Billing and Collection Practices. This Subcommittee is an outgrowth of the effort undertaken by various Representatives in July 2003 to obtain greater information required billing practices in the healthcare industry, toward the end of assessing billing inequalities faced by the uninsured.

Finally, perhaps the most far-reaching inquiry is being undertaken by the Senate Finance Committee. That Committee is focusing more broadly on the tax-exempt organization community, both healthcare organizations and otherwise, in an effort to identify and curb a wide array of abusive practices, including without limitation executive compensation, charitable fundraising techniques, insider transactions, financial reporting, board governance, etc. The initial hearing was held on June 24, 2004. As a precursor to that hearing, the Senate Finance Committee released a draft white paper prepared by the Committee’s staff, which proposed a

broad array of possible legislative reforms for tax-exempt healthcare providers and other nonprofit organizations.

OBSERVATIONS

Only the purest of heart might believe that the timing for the filing of the class action lawsuits, coming in the midst of the first major Congressional inquiry into hospitals’ tax-exempt status in decades, is merely coincidental. The class action lawsuits are sure to evolve in the court system in months and years to come. The initial reaction from the legal community is that the cases are largely meritless, in that they fail to state claims that are supportable under current federal and/or state law. Nonetheless, hospitals and healthcare leaders are appropriately recognizing that the cases have been designed to appeal to the emotion and untapped frustration of the general public regarding deficiencies in the American healthcare delivery system, including the means by which care is delivered, billed and paid for. As such, regardless of their legal merit, the cases are likely to consume millions of dollars of the already-stretched financial resources of hospitals and healthcare systems.

On the Congressional front, certain legislators have indicated that the current review is warranted simply given the sheer size of tax-exempt healthcare institutions in the U.S. today, in comparison to the overall tax-exempt nonprofit sector. More cynical observers, however, suggest that the scrutiny is a function of various scandals publicized in the media, and suspicion of healthcare systems as falling into the same “big business” and “corporate greed” modes that led to the fall of Enron and other major public companies. Perhaps not surprisingly, much of the initial Congressional

dialogue is of the general tone that “there’s a problem with healthcare in America, so presumably these hospitals are to blame.” That said, however, some legislators have correctly noted that the current inquiry is covering many issues, some of which may be entirely unrelated to each other. For example, transparency in hospital pricing may be a good thing, but it will not necessarily result in access to healthcare for the 44 million uninsured Americans, nor should it otherwise be assumed as the “fix” for the country’s healthcare crisis; moreover, the fact that hospitals have diverse and complicated pricing practices does not necessarily mean that hospitals should lose their tax-exempt status.

Notably, the governmental scrutiny and class action lawsuits likely will pose a substantial price for all tax-exempt healthcare institutions (not solely those that have been named as defendants in the various class action filings). In the short term, healthcare providers likely will need to exert greater effort in demonstrating the grounds upon which they deserve exemption from federal and state income taxation, as well as the multitude of other benefits that traditionally have accompanied IRC Section 501(c)(3) status.

On the longer term horizon, it is reasonable to anticipate that Congress will enact legislation of some sort, although the scope and substance of such legislation remains far from certain.

Some measures appear to be fairly obvious, such as extending the requirements imposed by the Sarbanes-Oxley Act on public corporations (or similar provisions) to the nonprofit community, and expanding the type of detailed financial and other information required by IRS Form 990 (annual information return). Others, however, are more controversial, including a possible mandatory reconsideration of tax-exempt status every five years, express limits on compensation, and standards for acquisition or conversion of exempt hospitals.

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Editor's Note: In our last issue, the author discussed recent changes to the federal criminal sentencing guidelines. In this issue, he gives us more information on them.

PROPOSED SENTENCING RULES FOR ORGANIZATIONS POSE A DILEMMA FOR EVERY ORGANIZATION

John C. Thomure, Jr.¹

The ABA voted last year to oppose the proposed changes to the federal sentencing guidelines governing organizations (the "New Organization Guidelines"). The new rules will go into effect in November, provided Congress does not intervene.

Recent case law may further impede the New Organization Guidelines from taking effect. The constitutionality of the federal sentencing guidelines was seriously called into question in June, with the Supreme Court's decision in *Blakely v. Washington*. The case held that no sentence in a criminal case could be enhanced beyond the statutory maximum for an offense unless a jury finds the fact or the defendant waives the jury or pleads guilty. Consequently, several federal district and appellate courts ruled that the federal sentencing guidelines are unconstitutional. Thereafter, the Supreme Court ruled in *United States v. Booker*, 125 S. Ct. 738, 160 L. Ed. 621 (2005), that the federal guidelines are merely advisory. Accordingly, federal judges are not bound by the guidelines. Nevertheless, observers believe that judges will utilize the federal guidelines when sentencing defendants in federal criminal cases. In fact, the *Wall Street Journal* collected sentencing data since the Supreme Court ruling and found that over 70% of the

sentences imposed post-*Booker* applied the federal sentencing guidelines.

The New Organization Guidelines reward wayward corporations that implement meaningful compliance programs, self-report and cooperate with investigative agencies to root out fraud.² This carrot and stick approach to corporate sentencing provides rich incentives for corporations that enact strong compliance programs and cooperate with government investigators.³ As strong as the incentives are in the New Organization Guidelines for corporations to have compliance programs and fully cooperate with government investigations, there are countervailing incentives for corporations to not implement effective compliance programs.⁴

For instance, an effective compliance program is dependent upon obtaining and communicating information. An organization will seek information from its employees and agents about the organization to design an effective compliance program. This means an organization will ask its employees and agents about known and potential problems so it can correct such problems. That information will likely be of tremendous value to those who are involved in litigation with the organization.

For example, a meaningful compliance program requires effective auditing, monitoring, training and internal reporting systems. Such programs will generate a multitude of non-privileged documents such as investigative reports and audits that investigators and claimants will use as a litigation road map to prove claims against the corporation. This is known as the "Litigation Dilemma."⁵

The committee that drafted the New Organization Guidelines cited the Litigation Dilemma as a primary reason why corporations may not implement such programs.⁶ Indeed, the committee's report advocating the adoption of the New Organization Guidelines discusses how existing privileges such as the attorney/client privilege are often insufficient to prohibit the disclosure of investigative and audit reports, which often describe or provide the map to where the bones are buried.⁷ Thus, the Litigation Dilemma affects an organization's incentive to implement training, auditing, monitoring, internal reporting, cooperation, and self-reporting customs because of the corresponding risk that claimants will use the information from such programs against the organization. Accordingly, a compliance system can be compromised by an organization more concerned about civil litigation than the less likely appearance of facing criminal investigation and/or indictment.

The advisory group that considered the draft of the New Organization Guidelines did not recommend a solution to the Litigation Dilemma for the United States Sentencing Commission to consider in approving the New Organization Guidelines for submission to Congress. Whether it is appropriate to broaden existing privileges or create new confidentiality rules for compliance programs is left, at this stage, for Congress to consider. If the New Organization Guidelines are approved in November, however, organizations should identify the potential problems associated with implementing a compliance program designed to maximize the benefits of the proposed rules.

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² REPORT OF THE AD HOC ADVISORY GROUP ON THE ORGANIZATIONAL SENTENCING GUIDELINES 3-4 (October 7, 2003).

³ *Id.* at 28-35.

⁴ *Id.* at 106-131.

⁵ *Id.* at 6.

⁶ *Id.* at 118-122.

⁷ *Id.*

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Oct. 2003 328 pages 6 x 9 hard cover w/dust jacket

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