CCH Healthcare Compliance LETTER

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Letters to the Editor

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AMA says FTC "has gone too far"

by Gordon R. Shea, J.D.

The incoming president of the American Medical Association (AMA), Dr. Donald J. Palmisano, has told the Federal Trade Commission (FTC) that he believes that "[s]omething is amiss" in the agency's healthcare antitrust focus.

Putting it bluntly. That "something," said Palmisano in testimony he presented to a recent FTC Workshop on Health Care Competition Law and Policy, is an untoward investigatory concentration on physician practices, and concurrent lax oversight of Health Maintenance Organizations (HMOs) and other health plans.

"To put it bluntly," Palmisano told the FTC working group, "we believe that federal antitrust agencies have placed physicians under a far higher level of scrutiny than is warranted by our comparative economic strength in today's health care system." Later in his testimony, Palmisano candidly stated his view that the FTC "has gone too far in policing physician conduct that poses little or no threat of harm to competition."

Palmisano suggested that consolidation in managed healthcare organizations during the 1990s — and not a spate of greed by physicians — was responsible for "double-digit increases in health premiums and in health plan profits," and is therefore now the most appropriate area for FTC antitrust inquiries.

Picking on doctors? Twice in the early part of his testimony, Palmisano said that according to his information, the FTC "*has never brought a single enforcement action against a health insurance company, HMO, health plan, or other third party payer*" [emphasis in original]. Palmisano said that "typical" recent FTC antitrust actions center on independent physician practices that have only "a handful of employees or fewer, and limited revenues."

According to Palmisano, the fact that the FTC is bringing its considerable powers to bear on such practices has resulted in a situation in which, over the last two decades, "every one of" the investigated physician practices "has settled with the Commission rather than commit to a time-consuming struggle which likely would have depleted the organization's resources before reaching decision."

The "time is ripe," Palmisano continued, for the FTC "to consider a fundamental shift in how it deploys its resources within the health care field."

A copy of Palmisano's September 9, 2002, testimony before the Federal Trade Commission's Workshop on Health Care Competition Law and Policy, titled "Taking the Payer Side Seriously: Why the Federal Trade Commission Should Redirect its Efforts in Health Care Antitrust Enforcement," is available at http://www.ftc.gov/ogc/healthcare/palmisano.pdf. ■

CCH Chicago Bureau, Nov. 25, 2002

No drug rep liability — no code in existence

by Geraldine S. Stroka, J. D., RN

Sales representatives may be susceptible to a wide array of liability issues. A recent case, *Dacosta v. Novartis AG*, demonstrated multiple state level claims that can be alleged against a sales representative and possible outcomes. However, in light of the recent Office of Inspector General (OIG) Draft Compliance Program Guidance for Pharmaceutical Manufacturers, sales representatives, and by association healthcare professionals, may become targets of federal liability, as well.

Multiple liability theories. The plaintiffs in this case were Mrs. Dacosta, a female patient who took two prescription medications manufactured by the defendant drug company, and her husband. They alleged that she suffered severe cardiac damage due to the failure of the sales representative, Weaver, and his employer, Novartis AG and Novartis Pharmaceuticals, to warn her physician, Dr. Leonard, about certain health risks associated with two drugs, DHE-45 and Migranal.

Allegations against Weaver were that he: 1) committed fraud because he knew that the advertising was false and misleading, 2) failed to warn, 3) was strictly liable because he sold these drugs without adequate warnings, and 4) failed to use the degree of care ordinarily used by sales representatives when he did not warn her physician of cardiac problems associated with these drugs. These claims are based on the fact that the active ingredient, DHE, found in DHE-45, which was prescribed by Dr. Leonard and taken by Mrs. Dacosta was also found in Migranal, the drug promoted by Weaver.

It is important to note that Weaver never promoted the specific drugs consumed by Mrs. Dacosta and did not consider them to be the same drug because both drugs underwent a full and completely separate Food & Drug Administration (FDA) approval process, as opposed to an abbreviated procedure for generic versions of the same drug.

Weaver's response. Ultimately, Weaver was dismissed from the case, but a review of his successful arguments is important. Weaver responded to the allegations by submitting an affidavit. The unrefuted affidavit stated that he was hired several years after Dr. Leonard first prescribed the medications. The affidavit implied that Mrs. Dacosta's cardiac problems occurred prior to any contact Weaver had with her physician. In addition, he stated that he merely provided information to physicians and never promoted these drugs to Dr. Leonard or any other physician. The goal of Weaver's affidavit was to deny any connection between Mrs. Dacosta's cardiac problems and his sales activities with her physician.

The fraud claim, based on the company's written literature on Migranal, the drug that Weaver promoted, and his failure to supplement that information upon learning of DHE's link with severe cardiovascular disease, was defeated. The plaintiffs failed to prove fraud because Dr. Leonard testified that he performed his own research and no link was established between Dr. Leonard's prescription of DHE-45 to Mrs. Dacosta and the pharmaceutical information provided by Weaver.

Of particular interest for healthcare workers was Weaver's argument against the professional negligence claim. Weaver stated that as a sales representative he must adhere to FDA regulations and his own personal ethical standards but that no professional code of conduct existed for professional sales representatives. That argument could no longer be made today, for guidance now exists for pharmaceutical manufacturers and their sales representatives.

Decision's importance. Two new directives, one by private industry and one by the government, have established guidelines for pharmaceutical manufacturers and their sales representatives. These voluntary guidances are the Pharmaceutical Research and Manufacturers of America (PhRMA's) Code on Interactions with Healthcare Professionals (See CCH Healthcare Compliance Reporter ¶180,069 (July 1, 2002)) and OIG's Draft Guidance Program for Pharmaceutical Manufacturers (See CCH Healthcare Compliance letter, Vol. 5, Issue 20, Oct. 14, 2002, and CCH Healthcare Compliance Reporter, ¶151,018 (Oct. 3, 2002)).

These Guidances are important because they could be utilized as industry standards in state civil suits. In addition, they might be utilized in civil, criminal and administrative litigation under federal statutes for antikickback activities, as well as False Claims Act violations. None of the earlier compliance guidelines operated in a vacuum and neither will this one. Therefore, healthcare professionals need to review these new compliance measures to determine if any of their activities would subject them to possible liability under these guidances.

Dacosta v. Novartis AG, CV 01-800-BR, D. Ore., Mar. 1, 2002, ¶305,262

CCH Healthcare Compliance Letter

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Foghorns, buoys and compasses required for navigating health law waters

by Judith A. Tichenor, J.D., L.C.S.W.

The healthcare industry has faced major changes in the past twenty or more years, and as a result so has the face of health law, according to Douglas J. Hammer, Vice President and General Counsel of Intermountain Health Care in Salt Lake City, Utah. Hammer spoke on the "Legal Issues Facing Hospitals and Health Systems," at the American Health Lawyers Association Conference held in Chicago, Illinois, on November 13 - 15, 2002.

As a result of these changes, Hammer observed that the healthcare industry is now one of the most regulated in history. Medicare/Medicaid laws, the False Claims Act, anti-kickback statutes, STARK, and EMTALA, along with antitrust issues, HIPAA, tax law, and JCAHO have left the industry breathless.

In his presentation, Hammer noted several questions now facing the healthcare industry. Among the most significant were:

State revenue collectors: more proof. On the state level, nonprofit entities have to prove their value to state taxing bodies more than ever before. Some states are beginning to question whether the nonprofit exemption is worth the loss of tax revenue when compared to the value offered by these entities.

Conflicts of interest. Another area of legal concern relates to conflicts of interest, especially when it comes to hospital/healthcare systems board and committee memberships. For example, many organizations ask whether a physician who owns shares in a competing service should be allowed to serve on the hospital's governing board. Hammer's answer is an emphatic "no," stating that it would be a significant conflict of interest. What about board committees? Generally, he still says "no," unless the board committee is not one involving fiscal concerns such as a quality of care committee. Hammer would also recommend against medical staff sitting on any hospital boards where they have medical privileges.

Sarbanes-Oxley. Healthcare entities should also be concerned with the Sarbanes-Oxley Act of 2002, especially those who are for-profit and publicly traded. Now, not only can the Department of Health and Human Services pursue a false Medicare/Medicaid claim investigation, but under Sarbanes-Oxley, so can the Securities and Exchange Commission, if there is reason to believe that the outcome could affect corporate profits. Even nonprofit organizations should evaluate the independence of the majority of their boards of directors, their auditing committees, and their nominating committee.

What does this mean? First, Hammer noted that counsel and CCOs must identify what issues are the top priorities for the CEO and the board Chairman. As those fluctuate, creative lawyering will be even more critical to the success of the compliance program and the healthcare organization. However, due to budget constraints, Hammer observed, the "art of underlawyering" will remain a critical talent in which both attorneys and CCOs will have to devote resources to the issues that impact the organization the most. When outside counsel is brought in they will have to be up-to-speed and will have to understand those priorities as well. Finally, keeping the CEO and COO current on issues as they emerge will prevent ugly surprises, something corporate officers never want, let alone need.

CCH Chicago Bureau, Nov. 25, 2002

Corporate compliance program critical to success of hospital compliance

by Judith A. Tichenor, J.D., L.C.S.W.

The benefits of a general corporate compliance program cannot be overstressed, according to David Matyas, a partner at the law firm of Epstein, Becker and Green, P.C. Matyas made his comments in his address to the American Health Lawyers Association's

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Reflections and trends — thoughts from HCCA's CEO, Roy Snell

by Geraldine S. Stroka, J.D., RN

The Health Care Compliance Association, co-founded by its present Chief Executive Officer, Roy Snell, in 1996, has assumed a leadership role in promoting compliance in the healthcare field. Recently, CCH had the opportunity to interview Roy Snell about HCCA's plans for the development of its Web site, the recently released 2002 HCCA Compliance Officer Survey, and his opinion on the challenges and future of Compliance Officers. Mr. Snell received a degree in Health and Human Service Administration and was a Compliance Officer at the University of Wisconsin as well as an administrator at Mayo Clinic. His complete biography is available on the HCCA Web site at http://www.hcca-info.org.

HCCA has certainly come a long way from its start in a Chinese restaurant and the proverbial napkin!

Yes it has. I was a Compliance Officer (CO) at the University of Wisconsin when I co-founded the organization. As an organization we have grown tremendously. Right now we are excited about our Web site and our future plans for it. Improvements to the present Web site would: 1) allow our members to order products right off the Web site, 2) establish "chat rooms" enabling members to post messages and receive responses from their colleagues, and 3) allow CO's to insert documents.

HCCA has had a rapid rise as an association. Has the mission of this organization changed since its inception?

The mission of the organization has remained almost the same. HCCA, unlike other associations, does not lobby. It does not lobby because it does not pick sides between the government and hospitals; its goal is to help people to meet regulations. If 50 percent of the money used for lobbying for healthcare was spent on compliance there would be a more effective use in terms of reducing risk.

Each fall, the healthcare compliance community eagerly anticipates HCCA's annual survey of healthcare compliance professionals. The 2002 survey was distributed to 3500 healthcare compliance professionals, both members and non-members of HCCA, with 700 individuals responding, a 20% response rate. Since 27% of healthcare systems and 27% of hospitals were respondents, this survey really gives an accurate picture of that segment of the healthcare system. It was impressive to read that of the respondents, 87% have active compliance programs, as opposed to 55% in 1999. Are you surprised at this statistic?

I am not surprised because this reflects HCCA's experience. Compliance is an entirely new department in healthcare; it was built within a time span of six years. Six years ago people were not ready for compliance; they either had not seen the need or were reluctant to spend the money. Now they realize that it needs to get done. All segments of healthcare now have compliance programs. It is difficult to find another healthcare field where six years ago no formal program existed and in 2002 there was an 87% compliance rate. Pressure and strong motivation have gotten it done.

The survey indicates that compliance officers are not leaving their positions. It stated that 44% of respondents have three or more years of experience, as opposed to 1999 when there were 8% at this experience level. Do you see this as a trend? If not, do you view the role of the compliance officer expanding into other areas of hospital management or remaining in purely the regulatory side of healthcare institutions?

Being a CO is a challenging job. One of the reasons for the seemingly reduced mobility of compliance officers is that they do the job well and know the rules and politics in that organization. Other reasons for this lack of movement might be the desire of the chief executive officer to retain them in that position or the CO may not desire another position. The numbers speak for themselves. There appears to be a change in CO's when either it is not working out for either the individual or the organization. This is one of the toughest jobs to get right; if you are too aggressive and make waves unnecessarily, the organization cannot keep you in that position. However, if you cannot facilitate change, you are not going to last too long.

This year the survey asked, for the first time, a question concerning the position of Chief Compliance Officer. Do you see this new senior position as a trend in the field?

I see a trend to move CO's into a stronger leadership position because they are always assisting top management to understand regulations. Also, there is a trend in healthcare to concentrate responsibility in one person. "Compliance with regulations" applies to many departments—auditing, risk management, and quality improvement. Many of these departments are reporting to compliance officers; this trend is good for healthcare. The word compliance means, "meeting the expectation of others," be it a regulation, state law, internal policy or procedure; this is exactly the role of compliance officers.

The 2002 survey states that the Health Insurance Portability and Accountability Act (HIPAA) is the #1 priority of 89% of the Compliance officers and that more than 50% of the CO's are charged with responsibility for HIPAA. How do you see HIPAA responsibility and the role of the CO evolving?

HIPAA should be under the CO from a budgetary, operational, and educational perspective. Healthcare organizations must realize that HIPAA is just another regulation ultimately under the compliance officer and not create a separate position. HIPAA compliance must be coordinated with all the other regulations in a healthcare institution; otherwise there could be conflicts. Compliance officers are routinely involved with implementing regulations; efficiencies can be achieved by utilizing the CO's expertise in this area.

Do you foresee any changes in CO responsibility for monitoring or auditing?

Monitoring and auditing are critical in ensuring compliance with regulations. HCCA has been working on an auditing and monitoring book edited by John Steiner, CO from The Cleveland Clinic. HCCA continues to refine education to address specific needs. CO's need documents to assist them in the performance of their responsibilities; HCCA has 1500 pages of compliance documents that are distributed to its members.

L. Stephan Vincze heads the Coalition to study Compliance Program Effectiveness. At the HCCA meeting in April 2002 the mission for this program shifted to the development of "generally accepted performance measurement standards" (GAPMS) for healthcare compliance programs, which were acceptable to the public and private sectors, independent, verifiable, and recognized by the government. The HCCA Compliance Program Measurement Task Force was established and chose hospitals as the first area for GAPMS development. According to L. Stephan Vincze, the Task Force would be releasing draft hospital measurement checklists for public review and comment in September and October 2002. What is the status of this project?

They are just about to get Board approval of the first phase—a document that lists all the elements typically found in a compliance program. By the end of the year it will be available for public comment.

In your opinion, what do you think is the most difficult task for CO's?

Convincing people to do things differently on matters of great importance. Determining what needs to change right away and how to do it. Millions have been spent on total quality management; most people never noticed or cared. However with compliance the risk of failure is enormous. If you fail at compliance there is a potential for millions of dollars in fines, loss of jobs, and possible incarceration.

With all the changes brought on by the terrorist attacks on September 11, do you envision any decrease in governmental concern with fraud and abuse in the future?

I believe that there is a point of confusion here. There is an assumption that all enforcement comes out of Washington, D.C. and Health and Human Services (HHS). The answer is what are people doing locally not nationally. There is a decrease in the national activity but a significant increase in the local activity.

On your website, in the HCCA forum section, HCCA lists pharmaceutical manufacturers as a segment of the industry that you serve. In the survey, 1% of the respondents were pharmaceutical manufacturers. The most recent OIG guidance targeted pharmaceutical manufacturers. Do you envision HCCA expanding into that segment of the compliance world?

HCCA has requested that L. Stephan Vincze from TAP Pharmaceuticals develop a pharmaceutical industry immersion session for the HCCA Compliance Institute in April 2003 to assist pharmaceutical manufacturers and their compliance officers. We are also planning to have an audioconference that would assist pharmaceutical manufacturers in explaining the OIG Draft Guidance for their industry to physicians.

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Anatomy of an anti-kickback case

by Raio G. Krishnayya, J.D.

In the law, arguments made in the past are studied to determine future cases and their outcomes. One area of law where precedence has significant impact on the corporate healthcare compliance officer is the law prohibiting kickbacks.

The history of one particular anti-kickback case, *United States v. Mittal,* raises several unique defenses to anti-kickback charges. In the latest development of this case, the appellant-defendant, Dr. Brij Mittal, has requested review (by filing a *Petition for a Writ of Certiorari*) before the U.S. Supreme Court. If the Supreme Court grants *cert.* (agrees to review the case), then the Court's opinion in the case will, hopefully, further define the knowledge element and the procedural requirements with regard to anti-kickback cases. In addition, the case is an interesting look at the evolution from trial to final appeal of the types of defenses that can be asserted in an anti-kickback case.

The case began when Mittal was indicted in November 1998 for one count of "unlawfully, willfully and knowingly conspiring to violate 42 U.S.C. §§1320a-7(b)(1) and three counts for receiving prohibited remuneration in violation of 1320a-7(b)(2)," — the Medicare anti-kickback provisions of the Social Security Act. The government alleged that from October 1990 through 1997, Mittal, a physician with a clinic in Brooklyn, New York, had "solicited and received illegal remuneration" by entering into a referral arrangement with Niranjan Patel. Mr. Patel was a co-owner of Ganesh Surgical Supplies, Inc., and American Open MRI. Ganesh Surgical is a medical supply company operating out of Westchester County, New York and American Open is a diagnostic center that operates in Queens County, New York. The locations of these two enterprises were important to Mittal's first attack on the government's case.

In April 2000, Mittal was convicted on all four counts and was sentenced to 30 months incarceration and three years of supervised release. Mittal and his attorney appealed their case before the U.S. Court of Appeals for the Second Circuit, which affirmed the judgment of the trial court. As part of the petition before the U.S. Supreme Court, Mittal challenges the jury instructions issued by the trial court, as well as the jurisdictional findings by that court.

Location, location, location. After the government filed its indictment against Mittal, Mittal made a preliminary attack at the indictment by asserting, in part, that the government had filed its case in the wrong venue. Venue is an issue that presumes that although the jurisdiction is correct (i.e. the case is properly in either state or federal court in the right geographic part of the country), the case is in the wrong district. To better understand this, consider Mittal's pretrial argument regarding venue.

Recall that Mittal operated a practice in Brooklyn, New York and that the co-conspirator (Patel) operated his organizations in Westchester and Queens counties. The case against Mittal was filed in the U.S. District Court for the Southern District of New York. Mittal, however, asserted that the case should have been filed (if at all) in the U.S. District for the Eastern District of New York, because any illegal activity that pertained to him occurred only out of his office in Brooklyn. Therefore the Eastern District of New York would have been the only proper venue.

The government countered that the calls and documents which evidenced Mittal's conspiracy and receipt of prohibited remuneration could not only be traced to his office in Brooklyn, but also to Patel's offices in Westchester and Queens. Therefore, the operative facts giving rise to the charges also occurred in the Southern District of New York, thus establishing proper venue. In other words, the illegal activity did not stop at the doorstep of Mittal's office.

The court agreed with the government, based on a federal statute stating that venue is proper in any district where a crime was "begun, continued, or completed." Furthermore, the law requires proper venue to be established for each count of an indictment. With regard to conspiracy laws, venue is proper in any district where any "overt act in furtherance of the conspiracy" would have been committed by any of the conspirators. See CCH ¶105,038.

After being convicted on all counts, Mittal appealed the issue before the Second Circuit. The Second Circuit agreed with the trial court that venue was proper as to all three counts under a "substantial contacts" test.

The substantial contacts test is an analog of the standard used by the trial court. It presumes that if a defendant is significantly involved in any aspect of an offense that carries over to another district, he or she has substantial contact in that district, enough to satisfy the venue requirement. Thus, relying on the documents and the records of telephone calls between Mittal and Patel, the Second Circuit quickly disposed of Mittal's venue argument.

Mittal's current petition for *cert.* challenges the lower courts' findings with regard to venue. In short, his argument against proper venue asserts that "[t]here was no evidence that Mittal received 'remuneration' in the Southern District." Furthermore, "[a]ssuming there was a criminal act — which is a stretch given the safe harbor provisions — the criminal act was the solicitation or acceptance of remuneration which took place in the Eastern District of New York."

Mittal's venue challenge to his conviction may not be his strongest argument, but it is important because it raises a broader question about the boundaries regarding transaction-based offenses. In the realm of conspiracy law, it is well known that the boundaries are vast. The government need not prove that each co-conspirator had knowledge of the other conspiring parties, nor would the government need to show that one co-conspirator had the same intent as the others. The only proof that is necessary is that the co-conspirator had the intent to commit an overt act to further the conspiracy. Therefore, Mittal's venue charge is in effect asking the Supreme Court to define

the transactional boundaries as related to conspiracy law.

Sting money a kickback? Prior to Mittal's indictment for his involvement in a prohibited kickback scheme, the government had conducted an in-depth investigation into Mittal's practices. The investigation resulted in a sting operation against Mittal, which involved a transfer of federal funds — earmarked for the sting — between investigators and Mittal.

As part of his pre-trial challenge, Mittal asserted that the sting money used in the operation against him could not be construed as prohibited remuneration because the government had only alleged that Mittal received a "kickback." Implied in Mittal's argument was that with regard to sting money, he would have received no value from the sting money therefore it could not have been construed as a prohibited kickback.

The government retorted that Mittal was improperly focused on the money rather than the anti-kickback's broader term, "remuneration." The government asserted that the term "remuneration" is not limited to monetary gain, which the court agreed as true.

Citing a 1981 case from the U.S. Court of Appeals for the Ninth Circuit, *United States v. Duz-Mor Diagnostic Lab, Inc.*, the trial court noted that even a bribe for a referral of patients for reimbursable services would still be construed as prohibited remuneration. Moreover, the trial court found that the framers of the anti-kickback provisions intended that any transaction that was not a "kickback" (i.e. no service had been provided but payment had still been made) still constituted prohibited remuneration. In short, Mittal's argument that sting money could not be construed as remuneration seemed to be treated as mere semantics by the court.

Knowledge. Often as part of the pre-trial hearings, a court considers possible jury instructions submitted by both parties. In many instances, the jury instructions can be hotly contested matters as they dictate the burdens that each side must bear. In almost all criminal cases, the government must prove that a defendant had the intent or knowledge to commit a criminal act as well as execution of the criminal act itself. In Mittal's case, a significant issue was how to define the knowledge element.

Mittal argued that in order for the jury to find him guilty, it had to determine that he knew of the existence of the specific statutes that he was alleged to have violated, as well as the intent to violate those laws. Contrary to Mittal's assertion, the court permitted the following instruction regarding the definition of knowledge:

> A person acts "knowingly" if he acts intentionally and voluntarily, and not because of ignorance, mistake, accident, or carelessness. Whether the defendant acted knowingly may be proven by the defendant's conduct....

Furthermore, the court instructed the jury that Mittal had to have known that his conduct was unlawful. This instruction, according to the trial court, was designed to prevent the jury from convicting Mittal for an innocent mistake.

On appeal, the Second Circuit found that even if the trial court's issuance of the above instruction was erroneous, any resulting prejudice toward Mittal would have been harmless. The Second Circuit continued by stating that the evidence at trial indicated that Mittal **knew** of the existence of the anti-kickback laws.

A former business partner of Mittal, Dr. Pritpal Kang, had testified that in 1993 that he along with Mittal and other business partners sought legal advice regarding the operation of a jointly owned diagnostic center. The advising attorney drafted a letter, which was sent to Mittal explaining the anti-kickback provisions in elaborate detail. Kang then recounted before the court that he spoke with Mittal about the letter and that he perceived Mittal to have full understanding of the contents of that letter. The Second Circuit noted that none of this evidence had been challenged by Mittal during trial.

Mittal's current petition to the Supreme Court challenges the Second Circuit's belief that the instruction would, at the worst, have resulted in harmless error. To substantiate the validity of his request for review, Mittal notes a discrepancy in the jurisdictions regarding this issue.

The petition cites a 1995 case, *Hanlester Network, et al. v. Shalala*, arising from the Ninth Circuit, which held that under the anti-kickback statute, a defendant had to: (1) know of the statute's existence, and (2) intend to have violated the statute. According to the petition, this is in contrast to a 1996 case, *Jain v. United States*, which was heard by the U.S. Court of Appeals for the Eighth Circuit. The *Jain* court held that the government only needed to show that a defendant knew that his or her conduct was wrongful rather than prove that the defendant knowingly violated a "known legal duty."

In essence, Mittal's petition seeks to have the Supreme Court interpret the anti-kickback statute to include a specific intent requirement — sometimes considered a double intent requirement — which would require the government to prove that someone like Mittal knew that a prohibiting statute existed and that despite its existence, he knowingly violated the law. The discrepancy cited by Mittal demonstrates a need to have this issue of intent, with regard to the anti-kickback statute, further defined.

Conclusion. The facts of *Mittal* present a commonality that any healthcare provider could be faced with subsequent to being charged with an anti-kickback violation. This commonality has given rise to important issues that require clarification. The issue of venue provides a geographic element to conspiracy violations especially with regard to fraud cases and particularly anti-kickback cases. Supreme Court review can further define that geographic element. More importantly, the question of intent raises the question about whether the Medicare anti-kickback statute is a general or specific intent crime. The answer to this question could impact evidentiary requirements and change the way anti-kickback cases are investigated and tried. ■

U.S. v. Mittal, S.D.N.Y., No. 98 Cr. 1302(JGK), July 7, 1999, ¶105,038; U.S. v. Mittal, 2nd Cir., No. 01-1318, June 10, 2002, ¶102,040; Mittal v. U.S., Petition for a Writ of Cert., U.S.S.C., No. 02-713, Nov. 7, 2002, ¶190,000

"Fundamentals of Health Law Conference" in Chicago, Illinois on November 12-15, 2002. A basic corporate compliance program is based on two general themes: standards of conduct and a code of ethics.

Benefits of a compliance system. Matyas noted that the benefits of having such a program in place are manifold, and include:

- a proactive, rather than just a reactive, approach to compliance problem solving;
- The promotion of an ethical corporate culture from the top down that sends the message: "We want to do it the right way;"
- a reduction of risk of improper conduct;
- a process to address problems if they arise, *e.g.* overpayments;
- a reduction of the likelihood of a *qui tam* action;
- a reduction of the "criminal culpability score" under the federal sentencing guidelines should the organization be found to have committed a compliance violation; and
- a reduction of the likelihood that the corporate integrity agreement will be imposed.

Tips and recommendations for development. Matyas made the following recommendations about initiating a corporate compliance program.

1. Before undertaking the development process, review:

- the Federal Sentencing Guidelines. Within the Guidelines are the seven essential elements that the government evaluates when determining its course of action with a healthcare organization that has run into compliance problems.
- various Office of Inspector General (OIG) Guidances including those outside your industry. For example, hospital compliance officers and general counsel should review Guidances for pharmaceuticals and laboratories.
- Corporate Integrity Agreements, especially those designed for your own industry.

2. Establish written compliance standards and procedures

The program should be in plain English and include policies and procedure addressing specific risk areas, such as STARK, or Medicare fraud and abuse.

3. Assign someone to be in charge of the program.

A compliance program is only effective if someone is at the helm, making sure the provider is doing what it intends to accomplish. The best person for the job is a corporate compliance officer, and the position must have high-level authority. The OIG has recommended that the CFO, CEO or corporate counsel not hold the position. However, Matyas said that the healthcare organization must pick the right person for the job and then develop training, implementation and documentation standards that will overcome OIG concerns.

4. Hire people while keeping corporate compliance at the forefront of your mind.

"Be careful who you hire," remarked Matyas. Criminal background checks, reference checks, and employee licenses and certifications need to checked and verified before hiring occurs. He further recommended checking the OIG's Sanctions List and the GSA's List of Excluded Individuals prior to hiring a candidate.

5. Communicate your expectations through training.

Train employees on a mandatory, regular, and ongoing basis in various aspects of the laws relating to healthcare compliance. Training should be both general and specific to employee position, and should also be both formal and informal. The goal is to make compliance awareness second nature to each employee.

6. Evaluate the program regularly.

Make sure your program has a built-in, ongoing evaluation mechanism that requires periodic compliance audits by qualified personnel and focuses on specific areas of government enforcement. Use baselines and benchmarking to ascertain the effectiveness of training programs. For example, a 90 percent pass rate after training in the first year and a 60 percent pass rate after the same training in the second year means the program may need retooling.

7. Listen to your employees.

When it comes to compliance issues, an employer cannot hear enough. Let the concept of open communication between staff and management be a true and valid process. Utilize hotlines and other forms of communication to enhance problem identification. Establish confidentiality and non-retaliation policies to assure employees that you are not out to blame them.

8. Best practice.

Get documented and dated responses from employees. This point cannot be stressed enough, especially for the purposes of clarification and tracking of information.

9. Punish noncompliance.

No program is effective if its policies are not enforced. However, Matyas stressed the importance of making sure that the punishment fits the infraction and that employees are dealt with equally and fairly across the board. The program should contain written policies that set forth degrees of discipline that may be imposed for failure to comply.

"If the CFO is notorious for fondling employees at the annual Christmas party with impunity, don't expect your employees to take your compliance program seriously until you deal appropriately with that corporate officer's sexual harassment problem," Matyas noted.

10. Find it and fix it.

If a problem occurs, the program must have policies and procedures in place for a prompt investigation of alleged violations and for an equally prompt corrective action plan.

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