

# the Reporter

## TMB Action?

# Alert TMLT's Mededense



*by Anna Tauzin*

With medical liability reforms in place, the number of lawsuits filed against physicians has fallen dramatically. In exchange for this reduction in non-meritorious litigation, Texas physicians have been tasked to do a better job of policing themselves. This task falls squarely on the shoulders of the Texas Medical Board (TMB).

According to the TMB web site, between 2000 and 2005 there was a 169% increase in disciplinary decisions and a 53% increase in the number of investigations opened. According to a press release dated August 31, 2006, the Board disciplined a record 99 physicians for violations ranging from failure to meet the standard of care to maintaining inadequate medical records.

Patients have the ability to air grievances against physicians by taking their cases to the TMB. In addition, the TMB will initiate its own investigation of the "medical competency" of a physician if three or more separate lawsuits and/or settlements were reported to them within a five-year period. This general statutory violation is known as the "Recurring Healthcare Liability Claims" violation and the Board will approach their review in the same manner as it evaluates a third-party complaint against the physician.

TMLT policies covering individual physicians include a Mededense Endorsement that provides legal and audit expense reimbursement for disciplinary proceedings, including actions by the TMB, and tax audits.

Introduced in 1998, the endorsement covers insured events such as proceedings instituted by the TMB, peer review proceedings by hospitals and other specified credentialing bodies, proceedings alleging fraud or non compliance with Medicare or Medicaid

regulations, and measures taken by the state department of health or federal department of health and human services.

Once a TMLT policyholder is notified of a disciplinary action, he or she should follow the following steps to take advantage of Medefense coverage:

**Step One:** Notify TMLT as soon as you receive the initial letter from the TMB or other disciplinary authority. The policy states that a policyholder has 60 days in which to report an event or letter in order to receive reimbursement for covered expenses.

**Step Two:** Consider retaining an attorney to help draft a narrative and to respond to the TMB. John Southrey, a senior claims representative who handles many Medefense claims for TMLT policyholders advises that "retaining an experienced attorney as early as possible in this process can help to shape the case. It provides the attorney with the opportunity for an early interface with the Board's investigator, hopefully before the investigator has formed their impressions, and it can facilitate a clear, concise, and objective response to the Board's complaint without subjective or emotional overtones." Working with an attorney who is knowledgeable of TMB proceedings can be advantageous because sometimes this can result in an early dismissal of the complaint. Upon request, TMLT can provide policyholders with a list of attorneys who have experience with the TMB and in handling disciplinary proceedings.

## According to Southrey, "In order to preserve coverage it's very important that policyholders pay attention to that 60-day window in which to report knowledge of a proceeding."

"I do not think that you can overemphasize the need to timely and thoroughly respond to the initial investigation letter from the Board. I have seen too many examples of cases where the physician responds on his own, or forwards a copy of the medical records without a response. Often the physician's response does not contain what it should and can actually make matters worse. I have also seen responses, prepared by counsel with no prior Board experience, that do not adequately address the allegations at issue, and bring other issues to light which are then made part of the investigation," said

Gregory Myers, an attorney with Kroger, Myers, Frisby & Hirsch in Houston.

If the written response does not result in dismissal of the complaint, the Board will initiate an investigation and assign the case to an investigator. After the investigator obtains all the pertinent information, the file will be referred to the Board for its decision. If the results of the investigation show there was a possible violation(s), the file will be transferred to the Board's Litigation Section for further action. When a case is referred to the Litigation Section, the first proceeding, held at the Board's office in Austin, is an Informal Settlement Conference (ISC). It is strongly recommended that the physician retain legal representation well before the ISC, to give the attorney ample time to be fully prepared for that very important event.

The physician should keep track of all itemized attorney invoices and payment records. Southrey advises sending those invoices and payment records to TMLT periodically during the process. For reasonable legal expenses resulting from disciplinary proceedings, TMLT will reimburse policyholders up to \$25,000 per policy period. The deductible for all policyholders is \$1,000, with a 10% coinsurance for each insured event.

To receive timely reimbursement for Medefense coverage, policyholders should follow the guidelines outlined in the policy. According to the policy

endorsement, "As a condition precedent to payment of any benefit hereunder, the Named Insured shall notify the Trust within sixty (60) days from the date of a disciplinary proceeding or tax audit being instituted."

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Southrey also advises that any appeals stemming from the original disciplinary proceedings will be covered as a part of the same incident, and are reimbursable up to the maximum aggregate limit of \$25,000. For example, if the physician chooses to contest a

Board's decision and the investigation is prolonged or additional attorney hours are billed, TMLT will continue to reimburse the physician up to the \$25,000 annual aggregate limit, for all covered matters arising during the policy year. Physicians can use their Medefense coverage as many times as needed during the policy period, but the benefits paid for all actions combined cannot exceed the aggregate limit. Up to \$5,000 of the annual aggregate may be used for covered audit expenses.

To speed the reimbursement process under Medefense, promptly send the following information to TMLT:

- A copy of the initial notification letter informing the recipient that a disciplinary proceeding has begun.
- Copies of legal expense invoices pertaining to the defense of the claim. The legal or audit expenses should be documented thoroughly, itemized on an hourly basis showing the service provided, the time incurred, and the hourly rate.
- Copies of all payments made to the attorney or law firm representing the policyholder in the claim.
- A copy of a final letter describing the outcome so the claim can be closed.

Facing a disciplinary proceeding can be a stressful and humbling experience. Not only is the physician's license at risk, but TMB disciplinary actions are public information. Physicians are advised to work with an attorney who has experience with the TMB, and to report their Medefense claims within 60 days of notification. The Medefense endorsement assists our insured physicians by enabling them to get needed legal advice early in the process without having to bear the expense burden themselves. According to Bob Fields, Acting President and CEO of TMLT, "Our experi-

ence is that legal expenses required during TMB disciplinary proceedings rarely exceed \$25,000". This coverage affords the doctor some peace of mind during a distressing process.

To learn more about Medefense, please contact John Southrey or Aaron Trejo at 800-580-8658 or (512) 425-5800.

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# Conflicts of interest

## Course author

Jay Henderson, JD is a partner in the law firm of Cruse, Scott, Henderson and Allen in Houston.

## Disclosure

Jay Henderson, JD has no commercial affiliations/ interests to disclose related to this activity.

## Target audience

This three-hour activity is intended for physicians of all specialties who are interested in practical ways to reduce the potential for malpractice liability.

## CME credit statement

Texas Medical Liability Trust is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. TMLT designates this educational activity for a maximum of 3 *AMA PRA Category 1 Credits*.<sup>TM</sup> Physicians should only claim credit commensurate with the extent of their participation in the activity.

## Ethics statement

This course has been designated by TMLT for 3 hours of education in medical ethics and/or professional responsibility.

## Discount

TMLT policyholders who complete this course will earn a 3% discount (maximum \$1,000) that will be applied to their next eligible policy period.

## Directions

Please read the entire article and answer the CME test questions. To receive credit, submit the completed test and evaluation form to TMLT. All test questions must be completed. Please print your name and address clearly. Allow four to six weeks from receipt of test and evaluation form for delivery of certificate.

## Estimated time to complete activity

It should take approximately 3 hours to read this article and complete the questions.

## Release/review date

This activity is released on December 4, 2006 and expires on December 4, 2008.

## Introduction

"A physician shall uphold the standards of professionalism, be honest in all professional interactions..."<sup>1</sup> Thus begins the second principle of the Principles of Medical Ethics of the American Medical Association.

## Objectives

At the conclusion of this educational activity, the reader should be able to:

1. Define "conflict of interest" as it relates to the practice of medicine;
2. Identify how conflicts of interest develop and how they can affect patient care;
3. List the conflicts of interest related to pharmaceutical products;
4. Discuss the potential conflicts of interest associated with physician-owned health care facilities;
5. Explain how conflicts of interest arise in the conduct of biomedical research and clinical trials; and
6. Describe strategies to minimize the potential for conflicts of interest.

The subject of conflicts of interest, at one time of importance mainly to academicians, has today become the center of attention in the health care profession. Physicians no longer have the luxury of oversight conducted solely by their colleagues. Today, physicians, hospitals, and allied health care professionals suffer the scrutiny of not only the public, but of governmental agencies and law enforcement personnel. Thus, it is essential for physicians to understand the nature of conflicts of interest and their professional obligations to patients and the public.

"Conflicts of interest" are not defined in the AMA Code of Ethics; however, there is a "guideline" that provides parameters by which physician conduct may be judged.

The guideline states "Under no circumstances may physicians place their own financial interests above the welfare of their patients. The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. For a physician to unnecessarily hospitalize a patient, prescribe a drug, or conduct diagnostic tests for the physician's financial benefit is unethical. If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit."<sup>2</sup>

Another definition of "conflicts of interest" often quoted in journal articles states that "A conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary influence (such as financial gain)... The secondary interest is usually not illegitimate in itself, and indeed it may even be a necessary and desirable part of professional practice. Only its relative weight in professional decisions is problematic. The aim is not to eliminate or necessarily to reduce financial gain or other secondary interests (such as preference for family and friends or the desire for prestige and power). It is rather to prevent these secondary factors from dominating or appearing to dominate the relevant primary interest in the making of professional decisions."<sup>3</sup>

A more concise definition is "a set of conditions in which professional judgment concerning a primary interest (such as patients' welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)."<sup>4</sup>

Perhaps other readers would favor the Texas definition, known as the "smell test." "If it don't smell right it probably ain't right. So don't do it." Physicians, being persons of integrity by nature and training, can identify traditional conflicts of interest in all but the most subtle of situations. Today, however, a new breed of conflicts has arisen. These conflicts are not only more difficult to identify, but also subject to dispute regarding their very parameters.

The best approach to understanding the reach of the medical conflict of interest guidelines is by studying the AMA Code of Ethics and its provisions on conflicts, found in section E-8.0. The overall prohibition of the Code is that physicians should not place their own financial interest above that of their patients.

### Do conflicts affect physician judgment?

Before addressing specific conflicts in detail, it is helpful to explore the overall effects of conflicts of interest on physicians' actions. One activity that has received a great deal of attention both in the medical literature and in the media involves interactions between physicians and the pharmaceutical industry. A recent issue of *Forbes* magazine included the article, "Review Details Drug Companies' Reach."<sup>5</sup> The article begins with this ominous observation: "Drug companies often influence physicians' prescribing practices without the doctors even knowing it, a new report contends." The story discusses an article from *Annals of Internal Medicine* that describes one potentially troublesome scenario between physicians and a major pharmaceutical company.<sup>6</sup>

" 'A lot of strategies are quite subtle, but because they are so pervasive, they really add up,' said Dr. Michael Steinman, a staff physician with the San Francisco Veterans Affairs Medical Center and lead author of a paper that details the marketing activities of Pfizer Inc. on behalf of its drug gabapentin (Neurontin)."

In 1993, gabapentin was approved by the Food and Drug Administration (FDA) for the treatment of epileptic seizures. However, by late 1990s, it was widely used off-label to treat psychiatric conditions and pain. Although gabapentin was eventually approved for one pain indication, Warner-Lambert settled litigation in 2004, admitting it had violated federal regulations by promoting the drug for pain, psychiatric conditions, migraine, and other off-label uses.

Through the court case, researchers gained the opportunity to review Warner-Lambert's internal documents that covered the period when gabapentin was only approved for treating epilepsy. Their review was published in the August 15, 2006 issue of the *Annals of Internal Medicine*.

" 'A lot of the marketing was related to off-label use, but the issue we were trying to frame wasn't so much on-label versus off-label but the sorts of marketing strategies used to promote drugs regardless of what the labeling was,' Steinman explained."

According to Steinman, the marketing was often designed to influence physicians to write more prescriptions for the drug without realizing they were being influenced.

" 'A lot of the strategies that were used to promote this drug were activities that doctors might not recognize as promotional at all,' Steinman said. 'The real danger is that doctors are being marketed to without their even knowing it. You don't know that the material should be taken with a grain of salt, and this might adversely impact the way you prescribe.'"<sup>5</sup> The gabapentin story is one of several pharmaceutical "conflict" stories to draw the attention of the media and federal regulatory authorities.

Related to the gabapentin episode is the potential for conflicts in how drugs and devices are selected by physicians and health care professionals. This subject implicates ethical considerations as well as potential civil and criminal liability. A recent story in *Modern Healthcare* reported "The [Justice Department] investigations focus

on at least three issues: alleged price-fixing and collusion by one or more device makers in prices charged to at least one hospital; billing Medicare for the alleged off-label promotion and use of devices; and, most worrisome to hospitals, whether the judgment of physicians and even hospital executives charged with buying or recommending medical-device purchases is clouded by gifts, consulting arrangements or other financial considerations from the device makers.<sup>77</sup>

While an allegation of “price-fixing” may sound like an obvious departure from appropriate behavior, the government’s definition of this term may not necessarily mirror that of mainstream physicians.

Yet another fertile ground for potential conflicts of interest involves physician ownership of health care facilities. U.S. Senator Chuck Grassley explained the conflict in a recent article. “The growth in physician-owned specialty hospitals is of great concern to me. A clear conflict of interest exists among physician owners because clinical decision making can be driven by financial interest rather than medical appropriateness. Physician-owned specialty hospitals also treat significantly fewer uninsured and Medicaid patients than community hospitals, and they divert the better-insured and more profitable patients whom community hospitals count on to subsidize higher cost patients.”<sup>78</sup>

Finally, there has been an ongoing media blitz on potential conflicts of interest between researchers and authors and the companies whose drugs and products are under investigation.<sup>9</sup> This topic has drawn the attention of the *Journal of the American Medical Association*, which itself received unfavorable publicity.<sup>10</sup>

The FDA has even been implicated in conflict of interest violations. As reported in the *Los Angeles Times*, “the FDA has about 50 advisory panels that are supposed to provide impartial technical advice on issues such as over-the-counter allergy medicines, silicone breast implants and chemotherapy drugs with toxic side effects. A study published this year found that 28% of panel members disclosed financial conflicts, but only 1% recused themselves.”<sup>11</sup> In response, the FDA pledged to clarify its conflict of interest rules and provide greater public disclosure.

“Legislation pending in Congress would bar the FDA from employing outside experts with any financial ties to companies with a stake in a panel’s recommendation — whether the companies sponsored the drug in question or manufactured a competing product.

Defenders of the current system, on the other hand, argue that tightening the rules too much would force the FDA to rely on scientists who lacked expertise in a particular area.

FDA Deputy Commissioner Scott Gottlieb acknowledged that there were ‘clearly things we can improve on,’ but insisted that the agency must retain the flexibility to grant waivers from conflict-of-interest rules to get the highest quality scientific advice. Drug development has become so specialized that a relatively small number of scientists have the detailed knowledge needed to evaluate a new medication, he said, and most have worked as consultants or advisors to pharmaceutical companies at one time or another.”<sup>11</sup>

The *Times* article pointed out that the FDA budget for drug regulation relies extensively on user fees, the money drug companies pay for review of new drug applications. “As a consequence, the FDA is financially indebted to the companies it must regulate. This is a fundamental conflict of interest.”<sup>11</sup>

No one can doubt that the subject of conflicts of interest is as pervasive as it is troubling. Likewise, only a cynic would question the integrity of the vast majority of health care professionals. Physicians most frequently run afoul of conflict guidelines because of ignorance of emerging issues, inattention, or poor advice. This article will discuss common medical conflicts of interest, including:

- conflicts of interest in biomedical research;
- conflicts of interest in clinical trials;
- conflicts of interest in health facility ownership by physicians;
- conflicts of interest in home health care;
- economic incentives and level of care;
- direct-to-consumer advertising of prescription drugs;
- physician interaction with pharmaceutical companies;
- contingent physician fees;
- fee splitting and referrals;
- fees for medical services, federal programs, and co-payments;
- sale of non-health related goods from the physician’s office; and
- non-medical services.

### Conflicts of interest: biomedical research

All physicians rely upon medical research and literature to gain knowledge about disease, physical ailments, and the treatment of these conditions. Hence, the scientific validity of medical research is of the utmost importance to the effective delivery of medical care.

The summer of 2006 saw a number of news stories on this topic. In July, the Associated Press reported that a study in the February issue of *JAMA* was written by researchers who had financial relationships with manufacturers of the antidepressant drugs that were the subject of the study. “In total, the authors failed to disclose more than 60 different financial relationships with drug companies,” stated the article.<sup>12</sup>

On July 18, a report was published concerning yet another *JAMA* article that discussed a possible link between severe migraines and heart attacks in women. According to the report, “[a]ll six of the study’s authors have done consulting work or received research funding from makers of treatments for migraines or heart-related problems.” Although one of the authors stated in an interview that the alleged conflicts did not represent a true conflict of interest, *JAMA* Editor Catherine DeAngelis stated that the issue was one of perception. “Let me decide what’s pertinent or not,” she was quoted.<sup>13</sup>

Following these reports, *JAMA*’s editor announced that new disclosure requirements for authors would be implemented in January 2007. The current *JAMA* conflicts of interest policy will be supplemented with a “declaration of no conflicts of interest.”

A similar “conflict” issue arose recently following the publication of an article in the July issue of *Neuropsychopharmacology*. The article was a positive review of a vagus nerve stimulation (VNS) device made by Cyberonics, Inc. of Houston. The article described the device as a “promising and well-tolerated intervention that is effective in a subset of patients with treatment-resistant depression.”<sup>14</sup>

While the article acknowledged funding from Cyberonics, and listed co-author Stephen Brannan as an employee of Cyberonics, it did not reveal that eight of the nine academic co-authors were consultants for Cyberonics. Charles B. Nemeroff — lead author of the paper and editor-in-chief of *Neuropsychopharmacology* — was among those with financial ties to the company.

The journal printed a correction stating that the authors had submitted disclosures in accordance with journal policy, but that information had not been included in the acknowledgement section of the published paper. Nemeroff will not serve another term as editor of the journal.<sup>15</sup>

Regarding conflicts of interest in biomedical research, the AMA Code of Medical Ethics provides:

“Avoidance of real or perceived conflicts of interest in clinical research is imperative if the medical community is to ensure objectivity and maintain individual and institutional integrity. All medical centers should develop specific guidelines for their clinical staff on conflicts of interest. These guidelines should include the following rules: 1) once a clinical investigator becomes involved in a research project for a company or knows that he or she might become involved, she or he, as an individual, cannot ethically buy or sell the company’s stock until the involvement ends and the results of the research are published or otherwise disseminated to the public; 2) any remuneration received by the researcher from the company whose product is being studied must be commensurate with the efforts of the researcher on behalf of the company; and 3) clinical investigators should disclose any material ties to companies whose products they are investigating, including financial ties, participation in educational activities supported by the companies, participation in other research projects funded by the companies, consulting arrangements, and any other ties.

The disclosures should be made in writing to the medical center where the research is conducted, to organizations that are funding the research, and journals that publish the results of the research. An explanatory statement that discloses conflicts of interest should accompany all published research. Other types of publications, such as letters to the editor, should also include an explanatory statement that discloses any potential conflict of interest. In addition, medical centers should form review committees to examine disclosures by clinical staff about financial associations with commercial corporations.”<sup>16</sup>

It is beyond the scope of this article to suggest a cure for the ills that plague the conduct of medical research and the delivery of research findings to the medical community. However, an editorial in the *British Medical Journal* from 1998 strikes a chord of optimism in announc-

ing that all researchers and authors should disclose any “competing interest,” rather than permitting these individuals to subjectively define whether or not they have a “conflict of interest.”<sup>4</sup> Thereafter, if it becomes known that a competing interest was not disclosed, the *Journal* will advise its readers of the known facts.

An editorial in *The New York Times* states: “It seems imperative that more muscle be put into forcing disclosure and publication of conflicts of interest. If all leading journals agreed to punish authors who fail to reveal their conflicts by refusing to accept further manuscripts from them, a lot more authors would be inclined to fess up. Better yet, journals should try much harder to find authors free of conflicts. That is the best hope for retaining credibility with doctors and the public.”<sup>17</sup>

Is it practical to ban authors from future publication if a “conflict” is not revealed? Probably not. However, common sense would dictate that authors should err on the side of disclosure. Reveal all and let the presumably objective editors and readers determine the impact of any relationships. A *JAMA* article recently commented:

“How do editors preserve the integrity of their journals while ensuring that they serve as vehicles for dissemination of scientific information that could help clinicians provide better care for their patients? First and foremost is to ensure that all published articles are scientifically sound and as objective and unbiased as possible by using rigorous peer review and careful editorial evaluation. Another important aspect is to ensure that readers are aware of the authors’ financial relationships and potential conflicts of interest so that these readers can interpret the article in light of that information.”<sup>10</sup>

Medical research is only as good as the integrity of the researchers who carry it out. It is hoped that the basic tenets of honesty and full disclosure will become the mainstay of medical research and scientific literature.

### Conflicts of interest: clinical trials

Many physicians participate in clinical trials either directly or by contributing patient data to such endeavors. More importantly, all physicians and health care professionals rely on the outcomes of clinical trials in making treatment decisions.

The AMA Code of Ethics addresses clinical trials in a lengthy provision that outlines the conduct expected of clinical researchers. These ethical guidelines are similar to those for biomedical research, with the added factor that research subjects must be treated with respect and their health and well being given foremost attention. The AMA Code of Ethics states:

“As the biotechnology and pharmaceutical industries continue to expand research activities and funding of clinical trials, and as increasing numbers of physicians both within and outside academic health centers become involved in partnerships with industry to perform these activities, greater safeguards against conflicts of interest are needed to ensure the integrity of the research and to protect the welfare of human subjects.”<sup>18</sup>

There follows seven individual guidelines that provide a roadmap for physicians and researchers in the conduct of clinical trials. “Physicians should be mindful of the conflicting roles of investigator and clinician and of the financial conflicts of interest that arise from

incentives to conduct trials and to recruit subjects. In particular, physicians involved in clinical research should heed the following guidelines: (1) Physicians should agree to participate as investigators in clinical trials only when it relates to their scope of practice and area of medical expertise. They should have adequate training in the conduct of research and should participate only in protocols which they are satisfied are scientifically sound. (2) Physicians should be familiar with the ethics of research and should agree to participate in trials only if they are satisfied that an Institutional Review Board has reviewed the protocol, that the research does not impose undue risks upon research subjects, and that the research conforms to government regulations. (3) When a physician has treated or continues to treat a patient who is eligible to enroll as a subject in a clinical trial that the physician is conducting, the informed consent process must differentiate between the physician's roles as clinician and investigator. This is best achieved when someone other than the treating physician obtains the participant's informed consent to participate in the trial. This individual should be protected from the pressures of financial incentives, as described in the following section. (4) Any financial compensation received from trial sponsors must be commensurate with the efforts of the physician performing the research. Financial compensation should be at fair market value and the rate of compensation per patient should not vary according to the volume of subjects enrolled by the physician, and should meet other existing legal requirements. Furthermore, according to Opinion 6.03, "Fee Splitting: Referral to Health Care Facilities," it is unethical for physicians to accept payment solely for referring patients to research studies. (5) Physicians should ensure that protocols include provisions for the funding of subjects' medical care in the event of complications associated with the research. Also, a physician should not bill a third party payer when he or she has received funds from a sponsor to cover the additional expenses related to conducting the trial. (6) The nature and source of funding and financial incentives offered to the investigators must be disclosed to a potential participant as part of the informed consent process. Disclosure to participants also should include information on uncertainties that may exist regarding funding of treatment for possible complications that may arise during the course of the trial. Physicians should ensure that such disclosure is included in any written informed consent. (7) When entering into a contract to perform research, physicians should ensure themselves that the presentation or publication of results will not be unduly delayed or otherwise obstructed by the sponsoring company.<sup>18</sup>

Those physicians who engage in clinical trials should consult these guidelines and work to preserve the sanctity of clinical research. Fortunately, clinical trials are generally conducted through research management groups and academic institutions that provide oversight for the participating researchers. Internal review boards also play a key role in the conduct of clinical trials. Physicians can avoid conflicts of interest

if they scrutinize the trial in which they are invited to participate, and demand that the foregoing guidelines be respected.

#### Conflicts of interest: health facility ownership

This is a troublesome topic for many health care professionals, particularly those who practice in rural areas and seek to provide specialized health care facilities for their patients that might not otherwise be available.

The AMA Code of Ethics recognizes that physician ownership of health facilities can provide important benefits in patient care. Thus, physicians are free to establish and maintain an ownership interest in such facilities. The code also clarifies the inherent problem with this qualification:

"However, when physicians refer patients to facilities in which they have an ownership interest, a potential conflict of interest exists. In general, physicians should not refer patients to a health care facility which is outside their office practice and at which they do not directly provide care or services when they have an investment interest in that facility. The requirement that the physician directly provide the care or services should be interpreted as commonly understood. The physician needs to have personal involvement with the provision of care on site."<sup>19</sup>

In addition, the code also states "physicians may invest in and refer to an outside facility, whether or not they provide direct care or services at the facility, if there is a demonstrated need in the community for the facility and alternative financing is not available."<sup>19</sup> Such is the case in many communities in which physicians invest in health care facilities. Were it not for the willingness of physicians to invest in such facilities, they likely would not be available. Thus, physicians should be applauded for investing in worthwhile projects that deliver high quality, necessary medical services to patients.

Physician ownership of health care facilities was the subject of an article in *The Wall Street Journal* on August 30, 2006. The article commented on a recent surge of interest in these facilities following the Bush administration's decision in August not to extend a ban on such hospitals. "Such facilities, which tend to focus on medicine's most lucrative procedures, often provide high-quality care, but critics charge they drive up health-care costs and undercut nonprofit community hospitals, which must offer a wider array of services like emergency rooms and maternity wards that are costly to provide. Already doctor-owned hospitals are being developed in California, Pennsylvania and Indiana, and several more are planned in Texas, home to about a third of the 130 that are already operating in the U.S."<sup>20</sup>

The article discussed several potential problems with physician ownership of hospitals and similar facilities. "Supporters say the new breed of hospitals are more efficient and provide equal or better care to patients, but detractors, including mainstream hospital groups, accuse the specialty hospitals of 'cream skimming,' or choosing to perform only those procedures that bring the most profitable returns under federal Medicare and private-insurance schedules, leaving

nonprofit competitors with the most costly businesses and sickest patients. Critics also say doctor-owned hospitals drive up health-care costs, pointing to studies that have shown that when the facilities open in a community, they increase the number of procedures that are performed in their specialty areas.<sup>20</sup>

In response to concerns about conflicts of interest, Congress imposed an 18-month ban on physician-owned facilities in 2003. The ban expired in June 2005, but the Centers for Medicare and Medicaid Services (CMS) effectively extended the ban by refusing to certify new specialty hospitals to receive federal funds until it could study the matter further. The CMS ban was set to expire in February 2006, but Congress extended the ban until August 2006. On August 8, 2006 CMS said it would resume certification. The agency says it has devised a plan to address the concerns of Congress, including reforming the payment system and making it more difficult for the facilities to “cherry-pick” patients for more profitable procedures.

“A federal law bars doctors from referring patients to businesses they have a financial interest in, but that law contains loopholes. One of them allows for doctors to invest in hospitals where they practice. When the law was drafted in 1988, there were only a few hospitals owned by doctors.”<sup>20</sup>

The expansion of physician-owned and specialty hospitals is of concern to some federal lawmakers, including Senator Charles Grassley, a Republican from Iowa. Grassley, who chairs the Senate Finance Committee, failed to persuade the administration to extend the ban on physician-owned facilities. He is now asking Congress to enact a permanent ban, an approach that has the support of the American Hospital Association.

The dual problem begins with concerns over the reimbursement paid to physician-owned hospitals. As will be noted later in this article, physicians would be wise to carefully monitor the procedures that exist for reimbursement of medical and surgical care to patients in federally funded health care programs.

There is yet another, perhaps more insidious concern about physician-owned health care facilities. There is the perception, right or wrong, that specialty hospitals are for the select and privileged of the community. The *Journal* offers the following example of how divisive this topic may be.

“In Ruston, La., the local community hospital is up for sale, a situation the hospital’s chief executive blames on the opening of a doctor-owned hospital three years ago. Most of the doctors who backed the physician-owned Green Clinic Surgical Hospital were on the medical staff at the community hospital, Lincoln General. When they started their own hospital, surgical volume at Lincoln declined 35 percent and the patients who were being treated tended to be sicker and less profitable, says Lincoln’s chief executive, Tom Stone.

But Robert Goodwill, the chief executive of Green Clinic, says the leaders of Lincoln General are responsible for the financial problems. He says the community hospital spurned an offer to become a 49 percent investor in the doctor-owned hospital. (Lincoln

General says the terms weren’t acceptable.) He also says the community hospital erred by going on a doctor-hiring spree in an effort to challenge the specialty hospital.”<sup>20</sup>

In 2005, the Texas Legislature passed Senate Bill 872. The bill requires a physician to notify the Department of State Health Services of an ownership interest in a niche hospital, includes provisions relating to unprofessional conduct by a health care provider who refers a patient to niche hospitals, and requires the Department of State Health Services to conduct a study regarding the impact of niche hospitals on the financial viability of other general hospitals.<sup>21</sup>

SB 872 also contains details regarding the definition of key terms and defines a “niche” hospital. “ ‘Niche hospital’ means a hospital that:

(A) classifies at least two-thirds of the hospital’s Medicare patients or, if data is available, all patients:

- (i) in not more than two major diagnosis-related groups; or
- (ii) in surgical diagnosis-related groups;

(B) specializes in one or more of the following areas:

- (i) cardiac;
- (ii) orthopedics;
- (iii) surgery; or
- (iv) women’s health; and

(C) is not:

- (i) a public hospital;
- (ii) a hospital for which the majority of inpatient claims are for major diagnosis-related groups relating to rehabilitation, psychiatry, alcohol and drug treatment, or children or newborns; or
- (iii) a hospital with fewer than 10 claims per bed per year.”<sup>21</sup>

The Texas Medical Board has also modified its rules to require physicians to file a notification of ownership in a “niche” hospital. This rule does not apply to ownership in publicly traded funds, such as mutual funds. The form is available at <http://www.tmb.state.tx.us/rules/rules/Niche%20Hosp%20Form%20199.pdf>.<sup>22</sup>

Assuming physicians are not discouraged from health facility ownership by these requirements, there are additional ethical considerations. First, according to the AMA Ethics Code, there must be proof of the need for physician investment in the facility.

“Need might exist when there is no facility of reasonable quality in the community or when use of existing facilities is onerous for patients. Self-referral based on demonstrated need cannot be justified simply if the facility would offer some marginal improvement over the quality of services in the community. The potential benefits of the facility should be substantial. The use of existing facilities may be considered onerous when patients face undue delays in receiving services, delays that compromise the patient’s care or affect the curability or reversibility of the patient’s condition.”<sup>19</sup>

In addition, physician-investors are expected to seek alternative sources of funding for such facilities. “The requirement that alternative financing not be available carries a burden of proof. The builder would have to undertake efforts to secure funding from

banks, other financial institutions, and venture capitalists before turning to self-referring physicians.”<sup>19</sup>

Additional disclosure requirements include the following.

“Where there is a true demonstrated need in the community for the facility, the following requirements should also be met: (1) physicians should disclose their investment interest to their patients when making a referral, provide a list of effective alternative facilities if they are available, inform their patients that they have free choice to obtain the medical services elsewhere, and assure their patients that they will not be treated differently if they do not choose the physician-owned facility; (2) individuals not in a position to refer patients to the facility should be given a bona fide opportunity to invest in the facility on the same terms that are offered to referring physicians; (3) the opportunity to invest and the terms of investment should not be related to the past or expected volume of referrals or other business generated by the physician investor or owner; (4) there should be no requirement that a physician investor make referrals to the entity or otherwise generate business as a condition for remaining an investor; (5) the return on the physician’s investment should be tied to the physician’s equity in the facility rather than to the volume of referrals; (6) the entity should not loan funds or guarantee a loan for physicians in a position to refer to the entity; (7) investment contracts should not include ‘noncompetition clauses’ that prevent physicians from investing in other facilities; (8) the physician’s ownership interest should be disclosed to third party payers upon request; (9) an internal utilization review program should be established to ensure that investing physicians do not exploit their patients in any way, as by inappropriate or unnecessary utilization; (10) when a physician’s commercial interest conflicts to the detriment of the patient, the physician should make alternative arrangements for the care of the patient.”<sup>19</sup>

Concern also arises when a competing facility enters the market after the physician-owned facility has been established. One may ask — are physicians expected to divest themselves of ownership in the existing facility? According to the AMA “Opinions on Practice Matters,” the answer is yes.

“The risks inherent in self-referral require divestment when the need for self-referral no longer exists. However, physicians who invested in facilities to meet a demonstrated need in the community should not be damaged by the requirement to later divest. If the investor were able to recover his or her original investment, plus a reasonable rate of return, there would appear to be no loss or hardship. The Council expects that, generally, physicians can fully divest within three years after the entry of competitors into the market. In the meantime, there is still an obligation to comply with the Council’s guidelines in Opinion 8.032, ‘Conflicts of Interest: Health Facility Ownership by a Physician.’”<sup>23</sup>

Physicians face a potentially difficult dilemma when they invest in a health care facility, particularly when they refer patients to that facility. The guidelines set forth in the AMA Code of Ethics are intended to

maximize the delivery of optimal patient services while protecting both the professional and financial interest of philanthropic investor-physicians.

#### Closed Claim

*The following closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust and the plaintiff attorney argued that the defendant physician elected to perform surgery at an outpatient surgery center for financial reasons. The ultimate goal in presenting this case is to help physicians practice safe medicine. An attempt has been made to make the material more difficult to identify. If you recognize your own claim, please be assured it is presented solely to emphasize the issues of the case.*

An 18-year-old man came to an otolaryngologist complaining of increased right cheek swelling of six to 12 months duration. Initially, the physician suspected sinusitis. The patient’s history included right nasal airway obstruction and nasal congestion. A large mass was visible on a prior MRI ordered by the patient’s previous physician.

#### Physician action

The otolaryngologist estimated the size of the mass to be 3 by 4 cm, filling most of the sinus cavity. The prior MRI indicated that the mass was more consistent with a tumor than a mucocele. The physician ordered a CT scan of the sinuses. That study found significant total opacification of the right maxillary sinus and a large polypoid mucosal thickening in the left. Based on the results from the CT scan, the otolaryngologist decided that immediate surgical removal of the cyst was necessary. Surgery was scheduled two days later.

A major factual dispute in this case involved the patient’s preoperative PTT value, reported at 49.5 (normal range is 26.1-39.2). The otolaryngologist testified that he reviewed the patient’s PTT value before the surgery. However, the otolaryngologist signed and dated the PTT lab report four days after the surgery.

The surgery was performed at an outpatient surgical center. The otolaryngologist maintained a small financial interest in this center, and he estimated that he performed approximately 80 percent of his sinus surgeries at the center. The patient’s mother expressed concern about the surgery being performed at an outpatient center instead of a hospital.

The otolaryngologist performed the following procedures:

- image-guided sinus surgery;
- left maxillary antrostomy with removal of tissue;
- left anterior ethmoidectomy;
- right anterior ethmoidectomy;
- right maxillary antrostomy; and
- right Caldwell-Luc with removal of mucous retention cyst.

The operative report noted that the patient experienced postoperative bleeding as a complication. When the physician entered the sinus cavity through the front of the patient’s dental cavity, he found that the tumor filled nearly the entire sinus cavity, reaching back as far as the pterygoids muscles. After removing the mass,

the patient immediately experienced bleeding in the sinuses, which the doctor packed with gauze. The patient's eyes began to swell, and the physician removed the gauze packing and placed manual pressure on the wound. The bleeding subsided.

After controlling the bleeding, the physician estimated that the patient had lost 700 ccs of blood. Keeping in mind the need for a possible blood transfusion, the physician had the patient reintubated and transported to a nearby hospital.

The patient was quickly brought into the operating room and the hemorrhage was controlled, but not before the patient lost approximately 200 more ccs of blood.

Postoperatively, the patient was extubated and transferred to the recovery room. His hemoglobin in the recovery room was 11.2. Two hours later his hemoglobin was at 11.3. He was transferred to the intermediate monitoring care unit. The patient complained of shortness of breath, and the otolaryngologist asked for a pulmonary consultation. Based on chest x-rays, it was confirmed that the patient had atelectasis. He was started on Levaquin. Although there was no evidence of hematemesis or hemoptysis, the patient's hemoglobin was 8.0 one day after the surgery. CT scans of his chest, abdomen, and pelvis showed no evidence of hemotoma, bleeding, or retroperitoneal blood.

Two days after the surgery, the patient's hemoglobin was at 7.9 and dropped to 7.3. The otolaryngologist decided to transfuse the patient with two units of packed red blood cells. The following day the patient's hemoglobin had risen to 9.7 with no evidence of bleeding.

At the family's request, the patient was transferred to another hospital. An internal medicine physician assumed his care. A gastroenterologist was consulted, and he ruled out gastrointestinal blood loss. A hematologist evaluated the patient to rule out an inherited bleeding disorder. After reviewing the family history, past surgical history, and coagulation labwork, he assessed that the bleeding was most likely secondary to the high vascularity of the maxillary lesion. The hematologist repeated coagulation studies, and his final diagnosis was "no evidence of bleeding disorder; normal coagulation/clotting studies."

The patient underwent carotid arteriography with embolization of the right internal maxillary artery. Another otolaryngologist removed the nasal packing and performed a nasal endoscopy without complications. The patient was discharged the following day.

### Allegations

A lawsuit was filed against the otolaryngologist. The plaintiffs alleged that the defendant should have investigated the reason for the abnormal PTT value and cancelled or delayed surgery until such time that it had been adequately addressed. The plaintiff's attorney also argued that the defendant elected to perform surgery at the outpatient surgery center for financial reasons.

### Legal implications

The plaintiff's case focused on the preoperative report that indicated an abnormal PTT value. Their expert testified that the otolaryngologist should have repeated the PTT test, and if it was still elevated, seek a

hematology consult. He did not criticize the choice of procedure, technique, setting (outpatient center), or any of the defendant's postoperative care. He conceded that hemorrhage is a known risk and complication of surgery.

The plaintiff's hematology expert testified that the patient's elevated PTT revealed an increased risk for an intraoperative bleed. As he could not rule out a mechanical cause for the bleeding, he testified that the amount of bleeding was aggravated by the presence of mild von Willebrand's disease in the patient. The expert described this as a variable disease that can be active or inactive in an attempt to explain why, if the patient always had the disease, he never experienced any bleeding problems with prior surgeries.

Consultants who reviewed this case for the defense concluded that the otolaryngologist properly performed the surgery and treated the postoperative bleeding appropriately.

One criticism they had of the defendant was that the abnormal preoperative lab work was not addressed. However, the otolaryngologist who testified at the trial stated that he does not routinely order PTT or other lab studies before procedures. Since those lab studies are not necessarily predictive of bleeding, he did not think they needed repeating. He stated that patient history is a more predictive indicator, and the patient had nothing in his history to indicate concern for a bleeding complication. The patient's bleeding was a surgical/mechanical bleed rather than a systemic bleed from a blood disorder.

The hematologist who reviewed the case for the defense stated preoperative coagulation studies are not necessary unless there is a history of bleeding or a reported blood problem. She testified that the otolaryngologist did not need to re-order the studies.

Regarding the defendant otolaryngologist's review of the lab results before the surgery, he testified that he reviewed the study at the fax machine on the morning of the surgery. He dated and initialed the report four days later while reviewing the entire chart.

A possible weakness for the defense involved the otolaryngologist's decision to perform the surgery in the outpatient setting rather than a hospital that had transfusing abilities. There was also concern that adequate informed consent had not been obtained with regard to the possible complication of bleeding.

### Disposition

This case was taken to trial and the jury returned a verdict in favor of the plaintiffs. The jury believed that given the size of the patient's tumor, the surgery should have been performed at the hospital so the defendant would be better equipped to handle complications. They reported they were not influenced by the physician's financial interest in the outpatient facility.

### Risk management considerations

In the AMA Code of Ethics a guideline states "if a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit."<sup>2</sup> It is incumbent for all physicians to judi-

ciously evaluate the risks relevant to performing procedures in the outpatient setting. Policy regarding patient transfer to an inpatient hospital in the event of a medical emergency needs to be clearly defined and implemented rapidly when necessary.

The plaintiff's preoperative PTT and the defendant's decision to proceed in the ambulatory surgery center became a point for debate and questions. The timely review of labs that may impact a decision to proceed with surgery and the physician's documentation of that review with supportive reasons for the decision are expected as part of the medical record. Retrospectively, it becomes easy to criticize this decision.

Although the defendant and jury acknowledged that the physician's interest in the ambulatory surgery center did not influence each of their decisions regarding care and liability, one may opine it seems difficult to exclude this fact.

### Conflicts of interest: home health care

The AMA Code of Ethics contains a rather straightforward provision regarding referral of patients to home health care. This provision provides, in part:

"Physicians who refer patients to home care providers or any other outside facility should avoid possible conflicts of interest by not accepting payment from those providers or facilities for referrals or as compensation for their cognitive services in prescribing, monitoring, or revising a patient's course of treatment. Payment for these cognitive services is acceptable when it comes from patients who are the beneficiaries of the physician's services, or from the patients' designated third party payers."<sup>24</sup>

Thus, the Code recognizes that physicians may use the customary reimbursement mechanisms for the delivery of home health care, while avoiding any practice that might give rise to an allegation of a "kick back" from the facility.<sup>24</sup>

The provision also states "physicians may refer patients to home care facilities in which they have an ownership interest if they actively participate on-site in the care provided to patients. Since the appropriate frequency and duration of home visits is a medical decision that should be made on a case-by-case basis, there is no specific minimum number of home visits that may be identified as a conclusive test of the physician's involvement in the patient's home care regimen. Although different patients will have different needs, physicians who directly provide care in the patient's home on at least every fourth visit may presumptively be considered to have made home care a true extension of practice."<sup>24</sup>

### Economic incentives and levels of care

It is inherently a matter of professional judgment to determine the level and extent of care warranted by a particular medical condition. Hence, physicians are often confronted with the dilemma of deciding whether a patient should be admitted to a hospital versus treated as an outpatient. Does a patient require surgery or will conservative treatment suffice? Does the

patient's condition justify an extra day in the hospital or can the patient be discharged?

AMA Code of Ethics provision E-4.04 states "Physicians are responsible for the timely delivery of necessary medical care to their patients." No one would question that patient care is the first priority of all health care professionals. With this understanding, the Code advises:

"The primary obligation of the hospital medical staff is to safeguard the quality of care provided within the institution. The medical staff has the responsibility to perform essential functions on behalf of the hospital in accordance with licensing laws and accreditation requirements. Treatment or hospitalization that is willfully excessive or inadequate constitutes unethical practice. The organized medical staff has an obligation to avoid wasteful practices and unnecessary treatment that may cause the hospital needless expense. In a situation where the economic interests of the hospital are in conflict with patient welfare, patient welfare takes priority."<sup>25</sup>

The overriding principle should always be to place the interests of the patient first, and the physician's financial interest should not be a factor in the delivery of patient care.

### Direct-to-consumer advertising of prescription drugs

Direct-to-consumer (DTC) advertising of prescription drugs has survived a tumultuous history of regulation, finally evolving to guidance under the auspices of the Federal Trade Commission (non-prescription products) and the Food and Drug Administration (prescription drugs and devices).

Prior to the Pure Food and Drug Act of 1906, advertising of medicines and other "cures" was virtually unregulated. As explained by a story that aired on the Public Broadcasting System, "The list of diseases that one patent medicine could 'cure' was amazing."<sup>26</sup> The cited act, however, prohibited "cures" from being advertised to the public as "medicines" or as having the ability to combat disease, illness, or injury. Since the formation of the FDA in 1927, that agency has overseen advertising and marketing of prescription drugs.

The past 20 years have seen various modifications of the rules designed to provide consumers with accurate information while recognizing the importance of commercial free speech. Beginning in 1985, the FDA ruled that prescription drug ads must advise consumers of specified, important, and potential side effects. However, pharmaceutical companies soon began using "reminder" ads that promoted the product but not the condition it was approved to treat. Critics contend that such ads were a thinly-veiled attempt to escape the review process applicable to DTC advertising.

The debate between "big pharma" and public interest groups will undoubtedly continue. The PBS story reported that 29% of television advertising dollars (\$110 million) expended during the network nightly news was spent by pharmaceutical companies. The same story reported that Merck spent \$78 million advertising Vioxx in 2004. Millions of dollars are spent on advertising each year for a very simple reason - it works.<sup>27-28</sup> The question remains: does DTC advertising assist in the delivery of quality health care?

The medical community continues to engage in this debate. Most recently, on June 14, the AMA announced a new policy on DTC advertising. "The new policy includes imposing a temporary moratorium on the advertising of newly approved drugs and guidelines for pharmaceutical companies to follow when preparing DTC advertising."<sup>29</sup>

In addition to the moratorium (the time interval for this moratorium will be determined by the FDA), the AMA adopted additional guidelines for DTC ads. The ads

- should provide objective information about drug benefits that reflect the true efficacy of the drug, as determined by clinical trials;

- should show fair balance between the benefits and risks of the advertised drugs by providing comparable time or space and cognitive accessibility, and by presenting warnings, precautions and potential adverse reactions in a clear and understandable way without distraction of content;

- should clearly indicate that the ad is for a prescription drug and refer patients to their physician for more information and appropriate treatment;

- should be targeted for age-appropriate audiences; and

- should receive pre-approval from the FDA."<sup>29</sup>

The AMA announcement correlates with the existing ethical provision relevant to DTC advertising. Under the current Code of Medical Ethics:

"Physicians must maintain professional standards of informed consent when prescribing. When a patient comes to a physician with a request for a drug he or she has seen advertised, the physician and the patient should engage in a dialogue that would assess and enhance the patient's understanding of the treatment. Although physicians should not be biased against drugs that are advertised, physicians should resist commercially induced pressure to prescribe drugs that may not be indicated. Physicians should deny requests for inappropriate prescriptions and educate patients as to why certain advertised drugs may not be suitable treatment options, providing, when available, information on the cost effectiveness of different options. Physicians must remain vigilant to assure that direct-to-consumer advertising does not promote false expectations. Physicians should be concerned about advertisements that do not enhance consumer education; do not convey a clear, accurate, and responsible health education message; do not refer patients to their physicians for more information; do not identify the target population at risk; and fail to discourage consumer self-diagnosis and self-treatment."<sup>30</sup>

The pharmaceutical industry steadfastly defends the integrity and usefulness of DTC advertising. These ads provide information to consumers who might otherwise go untreated. Besides, say industry officials, there must be a consensus between the patient and physician before a prescription drug is available to a consumer. The pharmaceutical industry group, PhRMA (Pharmaceutical Research and Manufacturers of America), states: "PhRMA member companies understand that accurate information about disease and treatment options makes patients and doctors bet-

ter partners. And getting that information to doctors and patients is the goal of Direct-to-Consumer (DTC) prescription medicine advertising. DTC advertising increases people's awareness of diseases and available treatments. Studies show DTC advertising brings patients into their doctor's office and starts important doctor-patient conversations about health that might otherwise not have happened."<sup>31</sup>

The PhRMA web site also includes "Guiding Principles for Direct to Consumer Advertising," which the group states "are a balanced approach to advertising that empowers patients and their doctors with information. Because knowledge is the best medicine of all."<sup>31</sup>

A contrary point of view was set forth in a recent article in *The Christian Science Monitor*. "But advertising is the most pervasive and aggressive way of selling sickness. It also is the hardest to justify. Medicine is supposed to be about science, not huckstering; about healing people, not persuading more of them that they are sick. There are far better ways to inform the public about health issues than to spend billions of dollars a year pushing pills."<sup>32</sup>

Once again physicians are faced with a situation that has no simple solution. Patients frequently visit their physicians with ready diagnoses and self-selected treatment options. Sometimes their preferred treatment is the result of conversations with friends or relatives. Other times they arrive with a coupon clipped from a magazine. Still other times they request prescription drugs they have seen advertised as the cure to their ailment.

Physicians must serve as both counselors and healers. They must exercise independent judgment in the selection of treatment options. In some instances, a popular, advertised drug may provide the patient needed relief. In other cases, the patient's urgent request must be declined. The ultimate selection of an appropriate treatment must be based on an informed decision by the patient in consensus with the best judgment of the physician.

#### Physician interaction with pharmaceutical companies

A more prevalent and equally contentious area of interest is the interaction between pharmaceutical company representatives and physicians. This topic could rightfully occupy a lengthy treatise in and of itself. The issue of potentially inappropriate physician influence by pharmaceutical and medical device manufacturers is one of the hot button medical news topics of the decade.

An article in the January 2006 issue of *JAMA* found that 90% of the \$21 billion dollars pharmaceutical companies spend on marketing goes directly to physicians. Medical journals and editors have suggested potential reforms to alleviate the harmful and undesirable effects of medical drug and device promotion.<sup>10, 33</sup>

"A conflict of interest exists when a primary ethical or professional interest clashes with financial self-interest, a situation that arises commonly in medical practice. When physicians are remunerated for performing specific tests and procedures, they face a conflict of interest when they also recommend those same tests and procedures. When they are paid for referrals to clinical trials, physicians are in the conflicted position of deciding whether their patients are appropriate for the

studies. Performing industry-supported research, physicians face an implicit demand for a positive finding to obtain further financial support. And, when pharmaceutical companies court high-volume prescribers, writing prescriptions becomes an act not only with financial and health consequences for patients, but also with financial consequences for the physician.<sup>34</sup>

Industry responds to such statistics by stating that complaints of physicians being influenced by gifts “is old news, and this has really been dealt with. There was a 2002 Pharmacode which stopped a lot of this behavior.”<sup>35</sup> Thus, industry maintains that the majority of the negative influence arising from industry gifts or “perks” has been reined in by the rules instituted by the AMA and PhRMA regarding gifts.

An opposing view was recently highlighted in a *New York Times* article on lunches for physicians paid for by pharmaceutical companies. “Doing business over lunch is a common practice in many fields, but drug makers have honed it to perfection, particularly since 2002, when the drug industry adopted a new code banning many other free enticements — golf outings, athletic tickets, trips and lavish dinners for doctors. The code gives approval to modest meals in the course of business. And conventional wisdom in both the pharmaceutical industry and the medical profession is that a lunch is too small to pose an ethical problem. But a growing number of critics say that even those small lunches should be banned.”<sup>36</sup>

The article quoted Dr. John G. Scott, assistant professor of family medicine at the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School in New Brunswick, New Jersey. Dr. Scott is studying the interaction between medical practices and pharmaceutical representatives. In the article, he described several studies that illustrate how lunches, drug samples, and small gifts like pens and self-stick pads can lead physicians to prescribe brand name drugs when cheaper generic drugs would be as effective.

“We found that some offices get breakfast and lunch every day,” said Dr. Scott, who calls lunch the ‘currency’ that buys access to doctors’ offices for drug representatives. He also noted that some doctors were hard pressed to meet payrolls and that the lunches provided an added benefit for their employees. ‘Essentially, we feel that most of what the pharmaceutical reps do works at an unconscious level,’ Dr. Scott said. He said most doctors said they were not influenced by the food deliveries and other small gifts. But, he added, ‘They do influence prescribing.’<sup>36</sup>

The pharmaceutical company representatives who were interviewed for the article emphasized that the lunches they provide are appropriate and modest. “The \$258 Merck lunch, for example, cost the company only \$10.75 a person and fell clearly within industry guidelines allowing modest meals. But it could easily return thousands of dollars for the drug maker in prescriptions for the osteoporosis medication Fosamax and the asthma treatment Singulair, the two drugs discussed during lunch with two Merck representatives.”<sup>36</sup>

Who is to say the effect “gifts” have on the prescribing behavior of physicians? Some physicians may be

subconsciously influenced by gifts. Others may feel a sense of obligation, while others eschew any gratuity from industry. It ought to be fairly clear, however, that pharmaceutical companies usually will not spend money on programs that do not work. These programs appear to have a positive impact on drug sales.

Concern about the influence of drug companies on patient care and physician education has led several academic medical centers to prohibit its physicians from accepting any gifts from pharmaceutical companies, device manufacturers, and other companies. Yale University, the University of Pennsylvania, and Stanford University have all implemented such policies. Under the Stanford policy, physicians are prohibited from accepting small gifts like pens, free drug samples, and from publishing articles in medical journals that are ghost-written by industry contractors. Company representatives are banned from areas where patient treatment and physician education occur, with some exceptions.<sup>38</sup>

Related to the topic of gifts is the issue of the quality of information that comes from the pharmaceutical industry. Some argue that industry itself is perhaps the most important source of information about specific drugs. After all, the company that formulates, develops, manufactures, markets, and monitors a drug presumably knows more about the drug than any other individual or entity.

Interestingly, industry sources take diverse points of view on whether physicians and patients may rightfully rely on industry-produced information. In some instances, particularly in the context of litigation, some industry sources seem to imply that physicians know the information they receive from pharmaceutical industry representatives may be biased.

In a PBS interview, one industry spokesman said, “I think doctors are able to consider the sources of information that they get. And they are well aware that when the source of information is a drug company that there’s a pecuniary interest that the drug company has in providing the information. Again, I think doctors are able to consider the source of the information.”<sup>35</sup>

On the other hand, the “official” position of the drug industry is set forth in a lengthy set of DTC guidelines and Questions & Answers on the subject of interactions with physicians, both espoused by the PhRMA. The latter document includes the following:

“Q: Do pharmaceutical marketing and promotion provide any benefit to physicians and other health care providers?

A: Yes. Pharmaceutical marketing and promotion provide physicians and other health care providers with the latest information on new treatments and medical advances that give them another means of providing patients with the newest and highest quality of care.”<sup>37</sup>

Also of interest is the preamble to PhRMA’s Guiding Principles on Direct to Consumer Advertising, “Given the progress that continues to be made in society’s battle against disease, patients are seeking more information about medical problems and potential treatments so they can better understand their health care options and communicate effectively with their

physicians. An important benefit of direct-to-consumer (DTC) advertising is that it fosters an informed conversation about health, disease and treatments between patients and their health care practitioners."<sup>31</sup>

Empirical data from 20 plus years of interviewing and working with physicians lead the author to conclude that most busy physicians do consider information they obtain from drug industry sources to be reliable and accurate. It is often the case today that educational activities are sponsored or underwritten by pharmaceutical companies. While the presenters may be independent scientists and physicians, the environment in which the education is delivered is influenced by pharmaceutical companies. Doctors frequently are given abstracts, handouts, summaries, and brochures pertaining to disease conditions or alternative means of treatment. Physicians use drug-industry supplied diagrams to explain physical ailments and human anatomy. When new drugs are introduced to the market, it is the drug company representatives who frequently educate physicians about the product and provide them with samples. It would be a shame indeed if physicians were criticized for relying upon information they obtained merely because it came from or was supported by the pharmaceutical industry.

An article published in 2004 found that the pharmaceutical industry spends approximately \$12 billion annually on gifts and payments to physicians.<sup>39</sup> It is likely this statistic has changed since the new rules limiting such gifts took effect. However, physicians still accept drug samples every day. Drug samples are an essential part of the practice of many primary care physicians, especially those serving indigent or uninsured patients. Free seminars where industry-sponsored representatives present scientific evidence abound. Medical research is funded in large part by the pharmaceutical industry. It would be optimal if all vestiges of potentially harmful influence could be eliminated from our health care system. Until that is possible, physicians must serve as the gatekeepers of the integrity and independence of their own medical practices.

### Contingent physician fees

The AMA Code of Ethics contains several provisions that deal with fees and charges. Code provision E-6.01 addresses "Contingent Physician Fees." This section states:

"[A] physician's fee for medical services should be based on the value of the service provided by the physician to the patient and not on the uncertain outcome of a contingency that does not in any way relate to the value of the medical service. A physician's fee should not be made contingent on the successful outcome of medical treatment. Such arrangements are unethical because they imply that successful outcomes from treatment are guaranteed, thus creating unrealistic expectations of medicine and false promises to consumers."<sup>40</sup>

### Fee splitting and referrals

Fee splitting is addressed in the next section of the AMA Code of Ethics, E-6.02. According to this provision, "[p]ayment by or to a physician solely for the referral of a patient is fee splitting and is unethical. A

physician may not accept payment of any kind, in any form, from any source, such as a pharmaceutical company or pharmacist, an optical company, or the manufacturer of medical appliances and devices, for prescribing or referring a patient to said source."<sup>41</sup>

Physicians are prohibited from accepting financial remuneration from patients based on patient referrals. "Physicians should not offer financial incentives or other valuable considerations to patients in exchange for recruitment of other patients. Such incentives can distort the information that patients provide to potential patients, thus distorting the expectations of potential patients and compromising the trust that is the foundation of the patient-physician relationship."<sup>42</sup>

Similarly, referral to health care facilities may give rise to an unethical fee-splitting situation, as set forth in provision E-6.03. "Clinics, laboratories, hospitals, or other health care facilities that compensate physicians for referral of patients are engaged in fee splitting which is unethical."<sup>43</sup>

This provision also states, "Health care facilities should not compensate a physician who refers patients there for the physician's cognitive services in prescribing, monitoring, or revising the patient's course of treatment. Payment for these cognitive services is acceptable when it comes from patients, who are the beneficiaries of the physician's services, or from the patient's designated third party payer. Offering or accepting payment for referring patients to research studies (finder's fees) is also unethical."<sup>43</sup>

### Fees for medical services, federal programs, and co-payments

An extremely complex situation arises in the area of Medicare payments and insurance co-payments. The first issue concerns physician reimbursement under federal health care programs. In the AMA Code of Ethics, section 6.05 states "A physician should not charge or collect an illegal or excessive fee. For example, an illegal fee occurs when a physician accepts an assignment as full payment for services rendered to a Medicare patient and then bills the patient for an additional amount."<sup>44</sup>

The federal government has implemented its "Compliance Program Guidance for Pharmaceutical Manufacturers" (the Notice).<sup>45</sup> This rather lengthy and complex document sets forth rules intended to prevent and reduce fraud in the federal health care programs. The "program" is characterized as providing guidelines for pharmaceutical companies; however, many of the provisions apply when prescription drugs are delivered through physicians. Thus, physicians should be aware of the general tenor of this program.

The key area of interest to physicians is the "kickbacks and other illegal remuneration" provision. This section references the anti-kickback statute and its criminal prosecution provisions. Under this section, manufacturers are directed to "identify any remunerative relationship between itself (or its representatives) and persons or entities in a position to generate federal health care business for the manufacturer directly or indirectly."<sup>45</sup> Physicians are named as parties who may fall into the latter category. The Notice then states "the

next step is to determine whether any one purpose of the remuneration may be to induce or reward the referral or recommendation of business payable in whole or in part by a Federal health care program."<sup>45</sup> In laymen's terms, this can be interpreted to say that drug company payments to prescribing physicians will be examined carefully for any hint of impropriety.

Various "safe harbors" exist in which a relationship between a health care provider and a pharmaceutical company can minimize their risk of federal scrutiny, such as personal services and management contracts. If not in a "safe harbor," these relationships are examined for the "nature of the relationship between the parties;" the "manner in which the remuneration is determined;" the "value of the remuneration;" the "potential federal program impact of the remuneration;" and the "potential conflicts of interest."

The Notice remarks by example that "business courtesies and other gratuities" between pharmaceutical companies and parties in a position to influence referrals "potentially implicate the anti-kickback statute if any one purpose of the arrangement is to generate business for the pharmaceutical company." Such broad terminology is disquieting to say the least. Any physician may be in a position to "influence referrals," and "business courtesies" leaves much to the imagination. Fortunately, industry and AMA guidelines have the respect of most observers in this context.

A recent article in *The New York Times* discussed one situation that gained the attention of federal regulators. The article focused on a study conducted at the Midwest Heart Foundation that resulted in a favorable appraisal of a blood filtering device. The researcher did not disclose that, not only was she a paid consultant in the device manufacturing company, but the research institution itself was heavily funded by the product manufacturer.

The article notes that the Justice Department has undertaken an investigation of "marketing activities" of one of the institution's primary contributors. Although the outcome of this particular case has yet to be seen, such payment "may lead to suspect research findings and at times may even risk running afoul of anti-kickback laws."<sup>46</sup>

The PhRMA has adopted a "Code on Interactions with Healthcare Professionals" which states: "In interacting with the medical community, we are committed to following the highest ethical standards as well as all legal requirements. We are also concerned that our interactions with health care professionals not be perceived as inappropriate by patients or the public at large. This Code is to reinforce our intention that our interactions with healthcare professionals are to benefit patients and to enhance the practice of medicine."<sup>47</sup>

The pharmaceutical industry takes seriously its exposure to criticism for entering relationships that may be questioned under federal guidelines. Physicians are well advised to do the same. This topic is addressed in more detail in an article found in the *New England Journal of Medicine*.<sup>39</sup>

A related topic concerns the manner in which physicians handle insurance co-payments. The AMA Code of Ethics contains the following guideline:

"Under the terms of many health insurance policies or programs, patients are made more conscious of the cost of their medical care through co-payments. By imposing co-payments for office visits and other medical services, insurers hope to discourage unnecessary health care. In some cases, financial hardship may deter patients from seeking necessary care if they would be responsible for a co-payment for the care. Physicians commonly forgive or waive co-payments to facilitate patient access to needed medical care. When a co-payment is a barrier to needed care because of financial hardship, physicians should forgive or waive the co-payment. A number of clinics have advertised their willingness to provide detailed medical evaluations and accept the insurer's payment but waive the co-payment for all patients. Cases have been reported in which some of these clinics have conducted excessive and unnecessary medical testing while certifying to insurers that the testing is medically necessary. Such fraudulent activity exacerbates the high cost of health care and violates Opinion 2.19, 'Unnecessary Services,' and is unethical. Physicians should be aware that forgiveness or waiver of co-payments may violate the policies of some insurers, both public and private; other insurers may permit forgiveness or waiver if they are aware of the reasons for the forgiveness or waiver. Routine forgiveness or waiver of co-payments may constitute fraud under state and federal law. Physicians should ensure that their policies on co-payments are consistent with applicable law and with the requirements of their agreements with insurers."<sup>48</sup>

As a malpractice defense attorney, the author is not qualified to offer advice on the mechanisms of insurance reimbursement and the propriety of non-standard co-payment practices. However, prudent risk management dictates that physicians should seek legal clarification before engaging in practices that fall outside the customary practices of their medical community. Insurance company representatives should be asked to clarify how to handle co-payments. It is unfortunate that physicians are faced with a complex health care reimbursement system that exposes them to allegations of potential wrongdoing.

### Sale of non-health related goods from the physician's office

It is a general rule that physicians should not sell non-health-care-related goods from their offices. The AMA Code of Ethics states:

"The sale of non-health-related goods by physicians presents a conflict of interest and threatens to erode the primary obligation of physicians to serve the interests of their patients before their own. Furthermore, this activity risks placing undue pressure on the patient and risks demeaning the practice of medicine. Physicians should not sell non-health-related goods from their offices or other treatment settings, with the exception noted below. Physicians may sell low-cost non-health-related goods from their offices for the benefit of community organizations, provided that (1) the goods in question are low-cost; (2) the physician takes no share in profit from their sale; (3) such sales are not a regular part of the physician's business; (4) sales are

conducted in a dignified manner; and (5) sales are conducted in such a way as to assure that patients are not pressured into making purchases.<sup>49</sup>

### Non-medical services

The subject of physicians engaged in providing services beyond the scope of a traditional medical practice is not directly addressed in the AMA Code of Ethics. This subject does receive the attention of the public and the press, however.

The prevalence of “medical spas” affiliated with physicians’ offices is growing in both the number of such facilities and the degree to which the practice is criticized. Many physicians begin offering such services — which are generally outside their area of expertise and training — often by the lure of patient demand and potential profit. While most physicians undergo adequate training before engaging in such practices, there are those who criticize the expansion of primary care providers into such fields as chemical peels, Botox® injections, and laser skin treatments. A recent article in the *Dallas Morning News* highlighted the debate.

“Plastic surgeons and dermatologists themselves say they are skeptical about the training of some of their fellow providers. Even with a medical degree, physicians are not adept at everything. ‘You have to know how the human face works,’ said Dr. Katz, who is president of the Medical Spa Society. The courses his society organizes are an effort to give non-core physicians additional expertise. ‘You have to understand the art of being a cosmetic physician.’

Dallas plastic surgeon Dr. Rod Rohrich, a former president of the American Society of Plastic Surgeons, agrees. ‘Just because they’re a physician doesn’t mean they know how to do Botox®,’ he said. ‘To do these things correctly, it’s not easy.’ He says that he doesn’t mind other specialties getting into the cosmetic business, as long as they have the skill.<sup>50</sup> The debate about the extent to which physicians should be permitted to engage in the delivery of “ancillary health care services” will continue as long as there are physicians willing to offer such services and consumers who seek them.

### Conclusion

The current medical and legal environment presents health care professionals with a multitude of impediments to the efficient and effective practice of medicine. Physicians are trained to educate, diagnose, and heal. Fortunately or unfortunately, medicine has become a profession that suffers from a degree of legal and ethical oversight not seen in previous generations.

Physicians are advised to bear in mind the oath that underlies their profession: “a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self.”<sup>51</sup> Physicians who maintain their medical practice with this principle in mind

should feel confident that they can avoid the potential conflicts of interest discussed in this article.

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continued on page 20

### CME test questions

Instructions: Using black ink, write your answers in the space provided and then clearly mark your answers. If you are unable to complete the test, please contact the risk management department at 800-368-6977. You can also mail the test to: Attention: Rebecca Henson, 1000 North 17th Street, Suite 1000, Dallas, TX 75201. A certificate of completion will be provided upon successful completion of the test.

1. "Conflict of interest" is a term which professional organizations use to describe situations in which professional judgment may be influenced by a secondary interest.  
 true
2. In the summer of 2005, the subject of unfavorable publicity and close financial ties to pharmaceutical companies was discussed in:  
a. *The New England Journal of Medicine*  
b. *The Journal of the American Medical Association*  
c. *Neuropsychopharmacology*  
d. a and b  
e. b and c
3. According to an advisory panel of the American Medical Association, which of the following is not an other tie to the conflict of interest that panel members seek to prevent themselves from panel members?  
 true
4. Some have suggested that a conflict of interest disclosure should:  
a. refuse to accept gifts from pharmaceutical companies  
b. only publish articles in peer-reviewed journals  
c. require authors to disclose any "competing interest" rather than permitting them to subjectively define whether or not they have a "conflict of interest."  
d. all of the above
5. The AMA Code of Medical Ethics provides that physicians who conduct clinical trials should be mindful of the conflicting roles of investigator and clinician and the financial conflicts that arise from incentives to conduct trials and recruit subjects.  
 true       false
6. Detractors of physician-own health facilities criticize these facilities because  
a. they drive up health care costs by increasing the number of procedures that are performed in their specialty areas  
b. they divert the better-insured and more profitable patients that community hospitals count on to subsidize their higher cost patient  
c. for physician investors, clinical decision-making can be driven by financial interest rather than medical appropriateness  
d. all of the above
7. In Texas, physicians with an ownership interest in a niche hospital must notify the Department of State Health Services of their interest.  
 true       false

8. According to the AMA Code of Medical Ethics, physicians who invest in health facilities are expected to  
a. disclose their investment in the facility  
b. disclose their investment in the facility when a competitor opens a facility  
c. disclose their investment in the facility when a competitor opens a facility  
d. disclose their investment in the facility when a competitor opens a facility
9. According to the AMA Code of Medical Ethics, physicians who invest in health facilities are expected to  
a. disclose their investment in the facility  
b. disclose their investment in the facility when a competitor opens a facility  
c. disclose their investment in the facility when a competitor opens a facility  
d. disclose their investment in the facility when a competitor opens a facility
10. According to the AMA Code of Medical Ethics, physicians who invest in health facilities are expected to  
a. disclose their investment in the facility  
b. disclose their investment in the facility when a competitor opens a facility  
c. disclose their investment in the facility when a competitor opens a facility  
d. disclose their investment in the facility when a competitor opens a facility
11. According to the AMA Code of Medical Ethics, physicians who invest in health facilities are expected to  
a. disclose their investment in the facility  
b. disclose their investment in the facility when a competitor opens a facility  
c. disclose their investment in the facility when a competitor opens a facility  
d. disclose their investment in the facility when a competitor opens a facility
12. According to the AMA Code of Medical Ethics, physicians who invest in health facilities are expected to  
a. disclose their investment in the facility  
b. disclose their investment in the facility when a competitor opens a facility  
c. disclose their investment in the facility when a competitor opens a facility  
d. disclose their investment in the facility when a competitor opens a facility
13. Which academic medical center recently implemented a policy that prohibits its physicians from accepting any gifts from pharmaceutical representatives?  
a. Harvard University  
b. Stanford University  
c. University of Colorado  
d. Johns Hopkins University
14. AMA Code of Medical Ethics states that routine forgiveness of co-payments may constitute fraud under state and federal law.  
 true       false
15. Regarding the sale of non-health-related goods from the physician's office, the AMA Code of Medical Ethics states the practice  
a. threatens to erode the primary obligation of physicians to serve the interests of their patients before their own  
b. is acceptable if the goods would benefit the patient  
c. places undue pressure on the patient  
d. a and c
16. Physicians who are considering offering services beyond the scope of a traditional medical practice, such as a "medical spa," should ensure that they have the appropriate experience and training beforehand.  
 true       false

Expired CME

**CME evaluation form**

Please complete the following regarding the article, "Conflicts of Interest."

Please fax the completed form to:

1. The objectives for this activity are:

2. The material will:

3. Did you perceive any conflict of interest in this activity? \_\_\_\_\_ in.

Yes  No

4. How long did it take you to complete this activity?

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5. On a scale of 1 to 5, how relevant is this activity to your practice? \_\_\_\_\_ it pertains to

1  2

6. What will you do as a result of this activity?

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--

8. Suggestions for future topics include:

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