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AMA rejects therapeutic privilege, advises giving patients full story

Physicians shouldn't decide what information patients can bear learning

Perhaps for as long as there have been physicians, there has been the notion that sometimes what a patient knows could hurt him. "Therapeutic privilege," the decision by a physician to withhold information from a patient for his or her own good, is a concept of the past, the American Medical Association (AMA) has determined.

"I don't know how long [therapeutic privilege] has been around — maybe since Hippocrates," says **John D. Banja**, PhD, assistant director for health sciences and clinical ethics at the Emory University Center for Ethics in Atlanta. "I find this change [away from the practice] refreshing and realistic and totally congruent to the consumer sovereignty and autonomy that has been going on in the U.S. for the last 20 or 30 years."

At the AMA's annual meeting in June, the AMA Council on Ethical and Judicial Affairs (CEJA) introduced a change in ethics policy, saying, "Withholding pertinent medical information from patients under the belief that disclosure is medically contraindicated, a practice known as 'therapeutic privilege,' creates a conflict between the physician's obligations to promote patients' welfare and respect for their autonomy by communicating truthfully."

Physician should not decide what patient should know

In changing its ethical policy, the AMA council said, point blank: To withhold medical information from patients without their consent, even if the physician is concerned that the patient can't withstand hearing bad news, "is ethically unacceptable."

That's not to say that there aren't cases in which it *is* ethical to withhold information, but only when the patient has made it clear to the physician that that is his or her wish. Physicians "should honor patient requests not to be informed of certain medical information or to convey the information to a designated proxy, provided these requests appear to genuinely represent the patient's own wishes," the council wrote.

Banja says that's an important point.

"What we need to teach physicians to do is, very early on in their relationship with patients — especially in physicians who deal with high-risk patients, such as oncologists and surgeons — to teach them to say in their first interview, before any interventions have been made, something like, 'Mrs. Jones, I am wondering how you'd like me to deliver information to you, especially if the news is not going to be good. Would you like to know about it, or would you want me to tell your spouse or your child and let them decide whether or how you are told?'

"And then the physician should stop talking and let the patient talk," he suggests.

Banja, who has written extensively on the effect that the demand for perfection has on physicians (*Medical Errors and Medical Narcissism,* Jones and Bartlett Publishers, 2005), says he often finds it is the physician, not the patient, who can't deal with bad news.

"We need to teach physicians how to control their own feelings, especially the feelings of inadequacy and helplessness, when they encounter these difficult situations," says Banja. "That's the fundamental reason they do badly in these conversations; these conversations contradict their psychological need to feel adequate, to feel knowledgeable, to feel helpful, to feel in control, and to feel they can do something to make the situation better."

When a physician can't live up to that standard, Banja explains, the encounter becomes painful to confront, so the physician might transfer his or her own feelings onto the patient, and make the decision that the patient won't be able to handle hearing the bad news.

Cultural considerations must be considered

The new AMA opinion prompted some questions about whether it conflicts with strides in cultural awareness among physicians, specifically that some cultures tend to protect patients from bad news in the belief that it could make them sicker.

Banja says the two aren't necessarily mutually exclusive.

"Asking 'how would you like your news?' is very interesting, culturally," he explains. "Some cultures think it is disrespectful, and even harmful, for a physician to actually say 'you have a very, very serious disease' to a patient. They believe that if a doctor says it, that makes it real.

"If physicians would just ask the patient how they would like the news delivered, they could get around that. If a patient is from Asia, China, the Mediterranean, a place we know the culture wants to shield the patient, and the patient says, 'I want to know,' then that's the way it ought to go."

Banja says that in the vast majority of cases, patients don't want to be shielded from the truth. Even bad news, when delivered frankly, candidly, and with compassion, is greeted with relief in that it puts speculations to rest.

"Without a full story, patients and their families will ask what happened or what will happen, and whose fault it is," he points out. "They want to develop a plan and manage what's going on, and they can't manage it if they have a vague, ambiguous idea of what's going on."

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Editorial Questions

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Teach doctors what to say, and when to say it

While the new AMA policy urges full disclosure, it concedes that not all bad news need be delivered in one blow.

"Physicians should assess the amount of information a patient is capable of receiving at a given time, delaying the remainder to a later, more suitable time, and should tailor disclosure to meet patients' needs and expectations in light of their preferences," the AMA opinion states.

Disclosure should be delayed only if early communication is contraindicated, the opinion continues, "according to a definite plan, so that disclosure is not permanently delayed."

Consultation with patients' families, colleagues, or an ethics committee may help in assessing the balance of benefits and harms associated with delayed disclosure, the opinion states.

Banja says while medical schools and residency programs are doing a fairly good job at educating doctors about the importance of delivering full information to their patients, physicians who have been practicing with a more paternalistic approach for two or three decades could probably use help in knowing what to say and how.

Discarding therapeutic privilege marks a "paradigm change," Banja says, from doctors controlling the conversation to allowing patients and families to be in charge.

"They have a hard time being frank and candid with patients sometimes," he says.

Knowing what to say is one part of the equation, Banja says; the other part is knowing when to listen.

"Stopping talking is one of the most difficult things to do, especially when you are anxious and things are tense," he explains. "When you say 'cancer' or 'death,' you have to stop talking and let the patient engage his or her reception of that word. If they stare blankly, you have to say, 'I wonder what you're feeling right now.'

"You have to take your cues from the patient, and a lot of doctors don't know how to do that. They come in with their script, and they impose that on the patient rather than taking conversational cues from patient." ■

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Study says: Prayer doesn't benefit heart patients

Critics say prayer can't be studied

Research studies on the effects of prayer on healing have yielded contrasting findings, but can — and should — medicine try to quantify and qualify religious faith as a healing modality?

"It seems to me that it is ethically suspect to subject prayer and medical outcomes to scientific study," suggests **J. Vincent Guss Jr.**, MDiv, director of pastoral care at Virginia Hospital Center, Arlington, and a member of the Association of Professional Chaplains advocacy commission. "[That's because] the implication is that prayer is characterized as something that it is not — a medical modality, or some sort of complementary/alternative medical technique that if used properly and frequently enough can have a specific positive outcome."

Study examined effects of prayer

A 10-year, $2.4 million study funded by the Templeton Foundation and reported by the *American Heart Journal* in June showed that about 1,800 heart bypass patients at six medical centers showed no measurable benefit from having their recovery prayed for. Although the long-awaited Study of the Therapeutic Effects of Intercessory Prayer (STEP) is considered the most scientific look at the effects of intercessory prayer (prayer offered for patients by others) to date, one of the leaders of the study says it is not definitive.

The authors — affiliated with the Mind/Body Medical Institute, Department of Medicine at Beth Israel Deaconess Medical Center, and Harvard Medical School, all in Boston — sought to address whether anecdotal claims of the benefits of intercessory prayer are the result of the prayers themselves or the knowledge or certainty that prayer is being offered. The authors evaluated whether receiving prayer (without patients'

knowledge) or certainty of receiving prayer led to uncomplicated recovery after coronary artery bypass graft (CABG) surgery.

Patients either received intercessory prayer after being told they might or might not receive prayer; did not receive prayer after being told they may or may not receive prayer; or received prayer after being told they would receive prayer.

Three groups — Silent Unity, a prayer ministry near St. Louis; St. Paul (MN) Monastery; and Teresian Carmelite in Worcester, MA — were asked to pray for the patients individually. They were given the patients' first names and last initials, and were told they could pray however they chose, so long as the prayers were offered at a set time and for a set length of time, and included the words, "for successful surgery with a quick, healthy recovery and no complications."

Intercessory prayer was provided for 14 days, starting the night before CABG, and the primary outcome was presence of any complication within 30 days of CABG.

In the two groups uncertain about receiving intercessory prayer, complications occurred in 52% of patients who received intercessory prayer and 51% of those who did not. To the admitted surprise of some of the study authors, complications occurred in 59% of patients certain of receiving intercessory prayer. One of the possible reasons some patients who were aware of prayers on their behalf suffered more complications, the authors theorize, is because of the expectations they had about the effects of the prayers.

Charles Bethea, MD, a cardiologist at Oklahoma City's Integris Baptist Medical Center and a co-author of the STEP study, says one conclusion that can be drawn from the study's findings "is that the role of awareness of prayer should be studied further."

"Private or family prayer is widely believed to influence recovery from illness, and the results of this study do not challenge this belief," the STEP authors wrote. "Our study focused only on intercessory prayer as provided in this trial and was never intended to and cannot address a large number of religious questions, such as whether God exists, whether God answers intercessory prayers, or whether prayers from one religious group work in the same way as prayers from other groups."

Can prayer be studied scientifically?

Guss shares doubts expressed by other experts who say the study highlights the question of whether prayer is an appropriate subject for scientific study.

"I believe in the power of prayer and that healing and prayer are related," he explains. "There is a relationship between restoration of the human body/mind/soul and humanity's expressions of the soul known as 'prayer.'

"However, the wrong questions in the wrong framework of inquiry are being raised when trying to look for scientific, medical outcomes resulting from prayer."

There is a strong body of literature reflecting the value many Americans place on prayer, and the effect they believe their prayers have on themselves or loved ones when they are ill. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has recognized the necessity of providing for patients' spiritual care in its accredited organizations, and requires health care organizations to provide appropriate professionals, such as clinically trained and certified hospital chaplains, to identify patients' spiritual needs and provide for their care.

However, several studies that have attempted to establish a connection between prayers for another person and actual beneficial results have been questioned as poorly constructed. The authors of the STEP study point out that it is narrowly focused and does not attempt to address the effects of all types of prayer.

Bethea pointed out that such questions as the benefit of a particular type of prayer, whether God exists, if God answers prayers, or whether there was a difference among religions in terms of the results of intercessory prayers were not

SOURCES/REFERENCE

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addressed by the STEP study.

"I find studies indicating that there are success rates from intercessory prayer — whether those offering prayer are known or unknown by the patient — to be interesting but not conclusive, and I also find studies indicating no relationship, or even indicating a lower success rate, to be unsurprising, but again not conclusive, and in both cases, these studies are hopelessly flawed," Guss says. "They reduce prayer to magic instead of mystery. The scientific method cannot be applied to matters of faith. The communication between a human being or a group of human beings and God, or a 'Higher Power' or, in Paul Tillich's words, 'the Ground of All Being, the Ultimate Concern' can never be fully understood nor appreciated by the cognitive mind and by studies that are designed by such a mind, but can only be experienced in the spirit of one's own soul."

Guss says the reason prayer or religious faith cannot be studied boils down to a difference between healing and curing.

"Healing and curing are not the same thing," he explains. "These studies look to 'curing,' i.e., the relief of symptoms, the restoration of bodily functions, the elimination of disease, etc. Certainly, curing can be a sign of healing; however, healing is far more basic. It is the restoration of the body/mind/soul in relationship within oneself, with one's community, with whomever or whatever one identifies as 'God,' or one's 'ultimate concern.'"

Healing, on the other hand, involves one's values, vocation, sense of grace, and providence, in addition to physical and mental health, Guss points out; therefore, a patient may be healed without being cured of the medical condition; likewise, the same person might be cured of disease without being healed.

"One set of studies that I believe is unchallenged has to do with the generally 'better health' people enjoy who have an active spiritual life," he continues. "These studies are not very surprising, since the lifestyles of people active in faith groups generally are healthier because of being in a community, sharing specific values that contribute to a sense of well-being. [STEP study leader] Herbert Benson documented this fact in his studies of the 'relaxation factor' involving spiritual disciplines. When one senses and celebrates the meaning of life, through a religious expression of spirituality or some other spiritual expression, health is improved."

What prayer can't do, Guss concludes, is orchestrate desired results.

"Prayers cannot be used as a manipulation of God to affect a certain kind of healing in the precise way for which the person praying intends," he suggests. "Rather, prayer, as communication, has it greatest power in the communication one receives in prayer." ■

Concierge care: Does it benefit everyone or a few?

How will retainer medicine affect access to care?

In 2000, literally a handful of physicians were practicing what has become known as concierge medicine — they had slashed their patient load to a fraction of the number of patients seen in a traditional practice, and were charging their remaining 300 to 400 patients a retainer fee that gave them access to the doctors' services around-the-clock and for as much time as they needed.

By 2004, the U.S. Governmental Accountability Office (GAO) reported there were 146 concierge practices in the United States — a fraction of the total of more than 470,000 physicians who filed Medicare claims that year, but enough that Congress asked the GAO in 2005 to examine whether the springing up of concierge practices might be somehow hurting Medicare patients or Medicare itself.

Concierge practices are concentrated in urban areas, the largest numbers found in the Miami, Washington, Philadelphia, Seattle, and Boston metropolitan areas. Three-fourths of concierge practices participate in Medicare.

The GAO and Department of Health and Human Services concluded in the 2005 report that the impact of concierge care on patient access to services thus far has been "minimal," with there being "widespread availability of physicians to treat [Medicare patients]."

But the medical community continues to cast a wary eye at the growing field of concierge medicine, whether because of the appeal of a small, intimate practice reminiscent of the personal care doctors gave patients two generations ago, or because of the concern that it creates a "haves" vs. "have-nots" tier of health care.

"I believe if the utilization savings hold, and hospitalizations and emergency room visits decrease, the savings we effectuate could make

this a national model," says **Edward Goldman**, MD, president and CEO of MDVIP Inc., a Boca Raton, FL-based national network of physicians practicing concierge care.

A national model for health care?

MDVIP practitioners — the "VIP" stands for "value in prevention" — account for about 120 of the fewer than 200 doctors currently practicing concierge medicine in America. MDVIP helps physicians get their concierge practices up and running, and receives a percentage of the annual fee generated by the new practice.

Contrary to what some critics say, Goldman insists, concierge care is not about better care for the rich, or making doctors richer — though both are side effects of this type of medical practice.

The doctors affiliated with MDVIP are primary care physicians, as are almost all concierge practices in the United States, and they are, Goldman says, filling a need in health care.

"There's no question we have to change primary care practice as it is today. It's not patient-friendly or doctor-friendly, and it costs us more every year," he suggests. "If preventive care really works, and it's been well established that it does, then we can take the savings [created by the healthier patients he says concierge care results in] and use the savings to construct smaller traditional practices, where those patients will get better preventive care."

Concierge practitioners emphasize that they are all about having the time to give each patient what he or she needs to keep that patient healthy. An average patient load of 2,500 in a traditional practice means the doctor does well to devote a few minutes per office visit, as opposed to hour-long visits typical in a concierge practice.

"What our doctors are interested in is being able to do prevention and early detection in their practices, and that gives them a professional satisfaction they don't ordinarily get," Goldman says. "We do the same comprehensive exam that Mayo [Clinic] or the Cleveland Clinic does, under a fee, and we also do extensive risk assessments for habits and risk factors; then we educate patients, provide them with tutorials addressing those risk factors, and use extensive applications to track those risks."

Each MDVIP patient has his or her own web site, where the patient and doctor can monitor risk assessments and wellness programs.

Concierge patients are roughly divided into two camps. The first is the upper middle-class and wealthier person, 55 years old and up, who might have a chronic health condition such as hypertension or elevated cholesterol, who is interested in preventing those conditions from getting worse and affecting their health in other ways.

The other cohort, which Goldman says is the fastest growing, is corporate executives, age 40 and older, who along with their employers have a vested interest in staying healthy. These patients want an array of prevention and wellness programs available to them on demand, on their schedules, to keep from getting sick and negatively affecting their careers and businesses.

The result of this high-level preventive care is patients who require fewer hospitalizations and who stay healthier longer, which Goldman says benefits everyone by keeping national health care costs down.

But when a physician elects to convert his traditional practice to a concierge practice, it comes at a cost — patients who cannot or will not pay the average $2,000 annual fee to join a concierge care practice have no choice but to switch to another physician, perhaps leaving behind the doctor they have used for years.

MDVIP physicians, as with any physician who migrates to a concierge practice, are required to help patients leaving the practice to transition to appropriate providers. Goldman says about 10%

SOURCES/RESOURCES

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of the typical MDVIP patient population are "scholarship" patients who can't afford the annual fee but who the physicians do not want to lose.

"For those who don't join [the new practice], we don't go forward until we have a continuity-of-care plan for those patients, and until we identify other physicians who have openings in their practice who we can recommend to those patients based on their expertise and personality," Goldman says.

Ethical issues abound

Critics point out ethical dilemmas related to concierge care, starting with eliminating some patients who might not want to leave the physician's practice.

The American Medical Association has weighed in that concierge, or retainer practices, "are consistent with pluralism in the delivery and financing of health care," but cautions that physicians who engage in this kind of practice should be vigilant about not compromising patients' insurance coverage and should make special efforts to seek out ways to provide indigent care.

"Ethics come up all the time" when people ask him about concierge medicine, Goldman says. "And I ask, is it ethical to give a person an eight-minute office visit, where you're not able to spend time to find out the background history, genetics, and emotional history that went into that illness? What about the ethics of not giving patients the proper time to treat the illness they have? That's an ethical issue that's not written about."

Goldman says doctors who consider concierge practices already feel ethically conflicted because they don't think they are giving their patients adequate care under their current practice setup.

"They see patients coming in with illnesses they could have stopped but didn't have time to devote to prevention," he points out.

What about the argument that concierge care creates a two-tiered system of health care? Goldman says we already have a multi-tiered system.

"HMO patients are restricted. They don't have the same care that a PPO patient has, so they pay more money and become PPO patients," he offers as an example.

Because concierge medicine on a large scale is still very new, evidence is still being collected as to its impact on access to care. The *Journal of the American Osteopathic Association* in 2005 published a study, "Impact of concierge care on healthcare and clinical practice," that sought to establish what effect, if any, concierge practices have had on access to care thus far.

"[E]vidence suggests that concierge care satisfies consumer criteria for value, based on an individual patient's willingness to pay extra for some measure of health care and status," the authors wrote. "Concierge care's effectiveness, defined as a measure of the ability of an intervention to bring about a desired outcome [such as an increase in patient-physician satisfaction], is also suggested by evidence."

Further, the authors conclude, "Affluent consumers who choose concierge care do not represent a large portion of the overall health care consumer population. Thus, they should not be expected to disrupt society's economic equilibrium as it relates to providing health care services."

Hospitals get into concierge care

While primary care makes up the lion's share of concierge medicine, hospitals — Virginia Mason Medical Center in Seattle and the Tufts-New England Medical Center in Boston — have also added concierge components to their roster of services.

Virginia Mason advertising for the concierge care at its Lewis and John Dare Center touts it as "old-time medicine," appealing to patients who might recall days when doctors made house calls.

The 2005 study published in the *Journal of the American Osteopathic Association* points out that in the case of practices like those at Virginia Mason and Tufts-New England Medical Center, there is a greater good served by concierge arrangements.

"Concierge care programs have shown success in providing needed financial support for some primary care services, such as those at Tufts-New England Medical Center and the Virginia Mason Medical Center," the authors report. "Thus, it is reasonable to conclude that concierge care offers a mechanism to maintain a limited number of programs that are necessary for health care access for all citizens — programs that might face elimination without some form of economic subsidization."

Tufts cites that aspect of its program in its public information, reporting that the annual fee paid by patients of its Pratt Diagnostic Center concierge practice provides funding for low-income and uninsured patients seen at the medical center, as well as underwriting medical school and hospital residency programs. ■

Critics charge physician peer review misused

Calls growing for revisions

Physician peer review has been a galvanizing topic since the mid-1980s, when federal law imposed protections for those lodging charges against physicians; protections that, depending on your opinion, either protect the peer review process or allow it to serve as a weapon for hospitals and dishonest physicians to rid themselves of whistleblowers and competitors.

The goal of peer review, as set by the Health Care Quality Improvement Act (HCQIA) of 1986, is to improve health care by impartial review of complaints against physicians. Critics say the focus has shifted from improving health care to punishing errant — or simply troublesome — doctors.

"I don't think any reasonable person could argue that peer review, done correctly, is a necessary process," according to **C. William Hinnant Jr.**, MD, JD, president of Medicolegal Consultants LLC in Anderson, SC. "But what we've seen occur since HCQIA was enacted is basically a clear distortion of peer review from being a process that should be aimed at quality improvement to a process that is a punitive mechanism where immunity provisions of HCQIA can be used as a sword to dismiss physicians for reasons having nothing to do with health care quality."

Guilty until proved innocent

According to the Massachusetts Medical Society (MMS), it was estimated in the 1990s that one in 20 physicians will undergo an incident-based peer review process and one in five will serve on a peer review committee to evaluate an alleged quality problem.

Misuse of HCQIA, commonly called "sham peer reviews," occur when a physician who is brought to peer review on a complaint that is either exaggerated or fabricated, Hinnant says. Frequently, the physician finds himself asked to prove his innocence; HCQIA gives peer reviewers immunity from monetary damages arising from peer review actions, provided that:

- The peer review arises from a belief that it furthers quality health care;
- Those bringing the action act in good faith to seek out the facts;
- The physician reviewed is given adequate notice and afforded due process;
- The hospital has a reasonable belief that the review action is warranted.

The trouble, as Hinnant and others see it, is that once a peer review is done and a finding of fault is returned, the appeals process affords the sanctioned physician little hope for reversal.

"Hospital attorneys can follow a cookbook easily," Hinnant says. "All [reviewers] have to do to walk away with immunity is create a pretext where something is related to health care, show that they investigated and obtained some facts, that they gave the guy a hearing commensurate with the bylaws, and show that it was reasonable."

The burden falls to the physician to demonstrate that the peer review was unreasonable, a struggle that can be protracted, expensive, and, ultimately, unsuccessful, Hinnant suggests. Making the battle more difficult is the likelihood that the physician has been suspended.

"The premise now is to simply exclude people, and there's a rampant abuse of summary suspension," he explains. "It has shifted from saying, 'Let's use peer review to get better without damaging doctors, to identify why some problems might be occurring often, to say let's figure out why and get beyond it.' Now you have doctors being suspended for events that occurred five, six, seven years earlier."

The good peer reviews, Hinnant says, are rarely heard of.

"The cases of true peer review, designed ethically and designed to improve quality of care, you don't hear about because they are being handled correctly," he says. "The problem has been confronted, remedial steps taken, with the goal being to help physician and patients. Those cases never result in litigation."

SOURCES/RESOURCES

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- **Semmelweis Society**, information on-line at www.semmelweis.org.
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But some recent cases that doctors claim are examples of peer review used maliciously have resulted in monetary damages awarded to the sanctioned physicians and national publicity about peer reviews. The attention drawn to the peer review process by those cases and by positions taken by some health care associations against misuse of the process has heightened calls for reform.

The Association of American Physicians and Surgeons has issued a statement condemning malicious use of peer review. In a March 2002 letter to state medical association directors, hospital medical presidents, and chiefs of staff, the American Medical Association said of compliance with HCQIA:

"The potential for abuse of peer review exists. Personal agendas, competition or other reasons unrelated to quality care must not be the motivation for peer review actions. Peer review that is not fair or objective can undermine patient care, patient access, as well as a physician's reputation. Failure to adhere to a fair peer review process can erode public confidence in the ability of the medical profession to adequately monitor itself."

Society urges 'clean hands' in peer review

The Semmelweis Society was founded by a physician who spent years fighting and appealing a peer review. The society seeks to reform peer reviews in the United States and make abuse less likely.

The society takes its name from Ignaz Semmelweis, a Hungarian obstetrician, who successfully showed that having staff wash their hands reduced mortality among women in childbirth. In the process Semmelweis infuriated his supervisors, who refused to reappoint him to the hospital staff, ruining his career.

"I have represented hundreds of doctors, and there is no scenario anywhere that surprises me," says Hinnant, who serves as president of the Semmelweis Society. "I have seen doctors peer reviewed because they demanded things of the hospital administration on behalf of patients, or complained of faulty equipment. And the next thing you know, the hospital has gone to the chief medical officer, had the complaint externally reviewed, and, now, the person is suspended from staff."

At that point, the physician is in a difficult position. Suspension from staff not only can be a crippling financial blow, but a suspension that lasts longer than 30 days must, by law, be reported to the National Practitioner Data Bank (NPDB), which was created along with HCQIA. From that point, any time the physician applies for licensure or a new job, a mandated search of the NPDB will reveal suspension, and that, Hinnant says, destroys careers.

"Scores of cases go through hearings, a year of discovery, and finally go to hearings, and the judge says, 'I am constrained by HCQIA,' and grants summary judgment to the hospital," he explains. "By that time, the doctor has lost his contracts, the medical board might have investigated, some lose their licenses, and their medical careers are pretty much over. It's a pretty sad process."

A successful appeal doesn't always repair damage from an unfounded peer review, Hinnant points out. Besides the lost income and standing, there is still the matter of the NPDB listing, which doesn't go away once the charges are dropped. A physician entered into the databank stays there unless the person or institution that lodged the original complaint requests that the doctor's name be removed from the list.

A model for improvement?

Both critics and supporters of the peer review process point to the Massachusetts Medical Society (MMS) as a body that has evaluated the risks and benefits of peer review with immunity and designed a way to improve its function.

The MMS, through its committee on medical service led by **S. Jay Jayasankar**, MD, introduced and adopted 27 principles to adhere to in incidence-based peer review in hopes of ensuring patient safety and fair treatment of physicians.

Jayasankar is a proponent of bifurcating the peer review process into two channels. One would allow near-misses and other incidents that do not require penalty to the physician but could provide lessons to his or her peers that can improve patient safety. The second channel would be for physicians facing discipline.

In the first type of review, the process would remain confidential and the instigators of the complaint could remain anonymous. In the other, however, Jayasankar suggests the process remain confidential.

Among the 27 principles for unbiased peer review are:

- Patient safety and quality of care must be the goal;
- Relevant information should be obtained

promptly from the subject physician, and early discussion with the subject physician to evaluate the "incident" and explore alternate course of action before proceeding to the formal peer review process;

• Triggers that initiate a peer review within a health care facility should be valid, transparent, and available to all member physicians and should be uniformly applied to all cases and physicians;

• Any conclusion reached or action recommended or taken should be based upon the information presented to the peer review committee and made available to the subject physician. Indefensible and vague accusations, personal bias, and rumor should be given no credence and should be carefully excluded from consideration. Any conclusion reached should be defensible under a "reasonably prudent person" standard.

• Summary suspension or restriction of clinical privileges may only be used to prevent "imminent danger to the health of any individual." Such summary actions must be followed by adequate notice and hearing procedures prior to becoming final.

• Membership on the peer review committee must be open to all physicians on the medical staff and not be restricted to one or more groups, such as those practicing exclusively at a given institution, salaried physicians only, or faculty physicians only.

"Revocation should be the last alternative," says Hinnant. "We should have a system that places remediation first, not exclusion." ■

AMA creates guidelines for advertising new drugs

Rules seek FDA review of all ads

It's an ambush of sorts — a patient, armed with information on the latest prescription drug gleaned from television or print advertising, insists that his or her doctor prescribe the drug, even if the physician is unfamiliar with the drug or unsure of its safety and efficacy.

The American Medical Association (AMA) would like physicians to have the opportunity to learn about new drugs on the market and be sure of their safety before patients start asking for them. Toward that end, the AMA has called for a moratorium on direct-to-consumer (DTC) advertising of new drugs and medical devices until the products have been shown to work and to be safe.

In a new policy, the AMA urged the FDA to require manufacturers to wait for an unspecified period after a drug or device obtains regulatory approval before launching direct-to-consumer advertising.

RESOURCES

For more information:

- **American Medical Association**, Board of Trustees Report 9: Direct-to-consumer advertising of prescription drugs, House of Delegates 2006 Annual Meeting. Available at www.ama-assn.org.
- **Pharmaceutical Research and Manufacturers of America**, Guiding principles on direct-to-consumer advertising, July 2005. Available at: www.phrma.org/files/2005-11-29.1194.pdf.

Advertising a two-edge sword

According to the AMA's president-elect, **Ronald M. Davis**, MD, the AMA is not opposed to pharmaceutical companies advertising to consumers in all cases.

"There are some potential benefits to DTC advertising," Davis says. "The ads can educate patients about the availability of these drugs, can increase awareness about the drugs, and may also prompt communications about the medications between patients and physicians."

In general, Davis says, anything that promotes communication between doctor and patient is a good thing.

"On the other hand, the ads may not provide a full and balanced presentation of information on the benefits and risks among patients about whether this drug is appropriate for the patient and whether it will accomplish what the patient is hoping for," he adds.

Besides asking that the FDA set moratorium periods for new prescription drug or device advertising, the AMA adopted additional guidelines for DTC ads:

• Ads should provide objective information

CE/CME answers

5. B; 6. A; 7. B; 8. B.

about drug benefits that reflect the true efficacy of the drug, as determined by clinical trials;

• They 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;

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

• Ads should be targeted for age-appropriate audiences;

• Advertising should receive pre-approval from the FDA.

The AMA also calls for additional research into the effects of DTC advertising on the patient-physician relationship, overall health outcomes, and health care costs.

Davis says the most significant request is that all DTC advertising be submitted to the FDA for preapproval before being aired or printed. This is similar to one of the "guiding principles" issued in 2005 by the Pharmaceutical Research and Manufacturers of America (PhRMA), which recommends — but does not require — that pharma companies: submit all new DTC television advertisements to the FDA before releasing them for broadcast; ensure ads provide balanced presentation of risks and benefits; and educate health professionals about new medicines or therapies before launching DTC advertising.

"These [guiding principles] go beyond existing regulatory requirements in many ways and help promote patient and physician discussions," according to PhRMA President and CEO Billy Tauzin. Twenty-six PhRMA member companies have adopted the guiding principles, which took effect in January 2006.

Davis says the AMA will work cooperatively with the pharmaceutical industry toward gaining universal acceptance of the DTC guidelines. ■

Placebo therapy without patient consent unethical

Employing placebo therapy without patients' knowledge or cooperation is unethical, the American Medical Association's Council on Ethical and Judicial Affairs states in a new report. The report was met with some disagreement by the association's House of Delegates when it was introduced, with delegates asking the ethics council to reconsider its stand against a practice that members say is part of standard practice. The report emphasizes that physicians "must maintain patients' trust by avoiding the use of deception and properly informing patients when a placebo may be used in their treatment."

According to the ethics council report, some physicians prescribe placebo rather than active drugs or medical devices after reports from placebo-controlled clinical trials indicate patients randomized to placebo showed some benefit. When the substitution is made without patient knowledge and consent, the council report states, an ethical line is crossed because patients believe they are receiving active therapy.

The House of Delegates referral committee that heard the report countered that it heard testimony citing many examples where patient knowledge of the use of placebo "would nullify the placebo effect." The report was referred back to the ethics council, which is expected to refine the report's language and resubmit it to the House of Delegates later in 2006 or at the 2007 annual meeting.

The report only addresses the use of placebo therapy in clinical practice; the recommendations do not apply to placebo in clinical trials. (A description of the Council for Ethical and Judicial Affairs report, "Placebo Use in Clinical Practice," is available in the action report of the AMA House of Delegates 2006 Annual Meeting, at www.ama-assn.org.) ■

COMING IN FUTURE MONTHS

- Physician-owned specialty hospitals
- Ethics training for older physicians
- Privacy issues and electronic records
- Neuroethics

CME instructions

Physicians participate in this continuing medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge.

To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity, you must complete the evaluation form provided at the end of each semester and return it in the reply envelope provided to receive a credit letter. When your evaluation is received, a credit letter will be mailed to you. ■

CE objectives

After reading each issue of *Medical Ethics Advisor*, you will be able to do the following:

- discuss new information about hospital-based approaches to bioethical issues and developments in the regulatory arena that apply to the hospital ethics committee;
- stay abreast of developments in bioethics and their implications on patient care, risk management, and liability;
- learn how bioethical issues specifically affect physicians, patients, and patients' families. ■

CME Questions

5. According to the American Medical Association, physicians should persist in giving patients all the information they can about the patient's condition, regardless of whether the patient has indicated he or she would rather not know.
   A. True
   B. False

6. The Templeton Foundation study on intercessory prayer sought to gauge the effect of:
   A. prayer for patients by strangers;
   B. prayer for patients by family and strangers;
   C. the existence of a higher power;
   D. none of the above.

7. A report on the impact of concierge medicine on overall health care in America, published in the *Journal of the American Osteopathic Association*, concludes that because of the size of the affluent consumer population relative to the entire health care consumer population:
   A. Affluent patients' participation in concierge medicine will disrupt society's economic equilibrium as it relates to the provision of health care services.
   B. Affluent patients' participation in concierge medicine is NOT expected to disrupt society's economic equilibrium as it relates to the provision of health care services.
   C. Affluent patients will not be able to support concierge practices.
   D. None of the above.

8. The goal of peer review was established in 1995, when the Health Care Quality Improvement Act (HCQIA) was passed.
   A. True
   B. False