OPINION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following opinion was presented by H. Rex Greene, MD, Chair:

1. AMENDMENT TO E-9.011, "CONTINUING MEDICAL EDUCATION"

CEJA Opinion filed; see Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: FILED

INTRODUCTION

At the 2012 Interim Meeting, the American Medical Association House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 1-I-12, "Amendment to Opinion E-9.011, 'Continuing Medical Education.'" The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the *Code of Medical Ethics*.

E-9.011 Continuing Medical Education

Physicians should strive to further their medical education throughout their careers, to ensure that they serve patients to the best of their abilities and live up to professional standards of excellence.

Participating in certified continuing medical education (CME) activities is critical to fulfilling this professional commitment to lifelong learning. As attendees of CME activities, physicians should:

(a) Select activities that are of high quality and are appropriate for the physician's educational needs.

(b) Choose activities that are carried out in keeping with ethical guidelines and applicable professional standards.

(c) Claim only the credit commensurate with the extent of participation in the CME activity.

(d) Decline any subsidy offered by a commercial entity other than the physician's employer to compensate the physician for time spent or expenses of participating in a CME activity. (I, V)

REPORTS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1–6, were presented by H. Rex Greene, MD, Chair:

1. PHYSICIAN EXERCISE OF CONSCIENCE

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: REFERRED

The practice of medicine is inherently a moral activity, founded in a "covenant of trust" between patient and physician.[1,2,3] The respect and autonomy that medicine enjoys rest on the profession's commitment to fidelity and service in the patient-physician relationship, and on individual physicians' recognition that in becoming members of the profession they commit themselves to upholding its core ethical values and obligations.

Yet physicians are not defined solely by their profession. As individuals, physicians are moral agents in their own right and, like their patients, are informed by and committed to diverse cultural, religious, and philosophical traditions and beliefs, as well as the expectations of their profession. In some situations, the expectation that as healers physicians will put patients' needs and preferences first may be in tension with the physician's own need to sustain the sense of moral integrity and continuity that grounds his or her personal and professional life. In such situations, physicians must decide whether and how personal conscience should guide their professional conduct.

Preserving opportunity for physicians to act in accordance with the dictates of conscience is important for preserving the integrity of the medical profession as well as the integrity of the individual physician. Ethically sound patient-physician relationships and the practice of medicine as a moral activity rest on trust in physicians' personal and professional integrity. Thus physicians should have considerable latitude to practice in accord with well-considered, deeply held beliefs that are central to their self-identities. Nonetheless, both as individual moral agents and as members of a profession dedicated to promoting the welfare of patients, physicians have a responsibility to be thoughtful and deliberative in making such decisions.

CONSCIENCE, INTEGRITY & DEEPLY HELD BELIEFS

When individuals speak of "acting in good conscience" or of acting in a way that preserves their "integrity," they are saying that they seek to align their decisions and actions with the deeply held beliefs that shape their self-identity as moral agents. To have integrity requires that "one's words and deeds generally be true to a substantive, coherent, and relatively stable set of values and principles to which one is genuinely and freely committed."[4] Those values and principles—which encompass not only religious beliefs, but also moral, social, and political values[5]—are central to an individual's understanding of who he or she is,[6,7,8] as an individual and, for some, as a professional.

Having integrity provides a sense of personal identity, along with satisfaction and self-respect in knowing that one lives in accord with one's beliefs.[4] Acting against one's conscience can create a sense of self-betrayal, loss of self-respect, and a feeling that one undermines one's integrity.[5,6,7,8] Having integrity "provides the basis for reliance, trust, friendship, and love."[4] When an individual's integrity is called into question, the trust others extend to him or her is undermined.

A claim to exercise conscience is underpinned by a claim that an act supports or violates one's deeply held beliefs. It does not rest on intuition or emotion, but requires that the individual carefully consider what is at stake for the patient, the profession, and the physician and be able to articulate how the "substantive, coherent, and reasonably stable" values and principles that constitute those beliefs justify acting one way or another. A claim to exercise conscience also requires willingness to accept the consequences of that action.[7,9]

PHYSICIANS' PROFESSIONAL RESPONSIBILITIES

As a profession, medicine is dedicated to "a certain degree of altruism, or suppression of self-interest when the welfare of those [it serves] requires it."[10] In becoming members of the profession of medicine, physicians commit

themselves to upholding its ethical standards and expectations. Physicians' freedom to practice medicine within the bounds of their conscience must be considered in light of their professional responsibilities to their patients.

With certain exceptions, physicians are free to choose whether and with whom to establish a patient-physician relationship.[11,12] A physician must provide emergency care unless another qualified health professional is available, but a physician may decline to provide care for any individual patient so long as the decision is not based on characteristics that would constitute "invidious discrimination," such as race, religion, national origin, sexual orientation, or disease status.[13,14,15,16,17]

Prior to forming a patient-physician relationship, physicians have considerable latitude to establish expectations in accord with their well-considered, deeply held beliefs. Certain specialties or geographic locations may incur increased responsibilities on the part of physicians to establish these expectations. However, once a physician has agreed to enter into a patient-physician relationship, his or her first responsibility is to the patient.[11,18] Physicians' fiduciary obligations to patients include putting patient interests and well-being ahead of the physician's personal considerations [11] and respecting the patient as an autonomous decision maker.[18,19,20] To be able to participate meaningfully in decisions about their health care, patients must be confident that their physician will present medical facts accurately and make recommendations in accordance with good medical practice,[21] and that the physician will not withhold information without the patient's agreement.[22]

Having once taken on the care of a patient, physicians have a further duty not to abandon the patient, encompassing obligations not to neglect the patient and to "support continuity of care."[14,23] While a physician may ethically withdraw from a case, he or she must notify the patient of the intent to withdraw sufficiently in advance to allow transfer of care to another physician.[23]

CONSCIENCE & PROFESSIONAL PRACTICE

In some circumstances, a physician may find that the dictates of his or her conscience do not align with the professional ethical expectation that a physician will provide care in keeping not only with a patient's medical needs, but also with the patient's values, preferences, and goals for care. Resolving—or at least reducing—the moral tension this creates requires that the physician exercise discernment and thoughtful judgment.

Perhaps most commonly, this tension arises when a physician is asked to provide an intervention that the individual believes is inconsistent with or would outright violate his or her deeply held beliefs and, thus, compromise his or her integrity. Such situations would include, for example, those in which the physician objects to providing "a legally and professionally permitted service, such as abortion, sterilization, prescribing or dispensing emergency contraception, and organ retrieval pursuant to donation after cardiac death."[8] These situations should be distinguished from cases in which a physician refuses to provide care in keeping with his or her clinical judgment and consistent with recognized professional standards. Physicians are not expected to provide care that, in their professional judgment, is unlikely to achieve the patient's clinical goals. Indeed, they should not do so.[24]

Moral tension can also arise when conscience dictates that the physician provides an intervention or service that is medically permitted "when doing so is prohibited by law, institutional rules, employer policies, and so forth."[25] Examples include when a physician feels morally obligated to prescribe emergency contraception or to care for patients regardless of their immigration status, in violation of hospital policy, law, or professional ethics.[25] Importantly, health care professionals may hold very different core beliefs and thus reach very different decisions based on those core beliefs, yet equally act according to the dictates of conscience. For example, a physician who chooses to provide abortions on the basis of a deeply held belief in protecting women's autonomy makes the same kind of moral claim to conscience as does a physician who refuses to provide abortion on the basis of respect for the sanctity of life of the fetus.[26] It must be remembered that a physician may never impose medical care against the wishes of a patient who has decision-making capacity.[27,28]

In resolving situations of moral tension, a physician must balance preserving his or her integrity with the interests of the patient, future patients, and the medical profession. Yet, "being a conscientious medical professional may well mean at times acting in ways contrary to one's personal ideals in order to adhere to a general professional obligation to serve patients' interests first."[29] These obligations may arise more frequently when a physician works in an area in which access to care and referral options are limited. Or it may mean structuring one's practice to avoid, to the

greatest extent possible, situations in which one would be asked or expected to provide care that creates significant challenges to one's moral integrity.

Patients, the public, and fellow professionals must be reasonably able to expect that physicians will uphold the fiduciary responsibilities of the profession and will, in general, provide legally available, medically permitted interventions or services in keeping with patients' medical needs and values, preferences, and goals for care. Physicians should use great restraint in deciding to act contrary to that general expectation.

RESOLVING OR REDUCING MORAL TENSION

As moral agents in their own right, physicians must have some scope to act so as to honor the beliefs that ground their sense of self and preserve integrity. As noted above, certain actions are beyond physicians' discretion: declining to provide care in emergency situations when no other qualified professional is available, discriminating against patients, imposing care against a competent patient's informed refusal. In other situations, when the foreseeable burdens for the patient are minimal, physicians have greater discretion to act in conscience. Between these endpoints, for physicians facing situations of moral tension, determining how best to preserve their integrity in discharging their professional ethical obligations to patients calls for thoughtful deliberation that takes into account a variety of factors. These include considerations of medical need, whether there is an established patient-physician relationship, and the burdens a decision to act in conscience will pose for the patient, the physician, and others. A physician's decision to act in conscience has ramifications at all levels of patient care: providing interventions or services, informing the patient about treatment options, and referring the patient elsewhere for care.

Patient-Physician Relationships

Entering into a patient-physician relationship establishes the physician's fiduciary obligations to this particular individual.[30] Until such a relationship is established, physicians may decline to accept prospective patients (with the caveats noted above) and have considerable latitude in their exercise of conscience. Once a relationship is established, physicians must fulfill their responsibilities to promote patient welfare, respect patient autonomy, and adhere to standards of professionalism or formally terminate the relationship.[23]

In some instances, of course, patient and physician will share deeply held beliefs, and situations are unlikely to arise in which a physician would feel compelled to act in conscience contrary to the patient's values and preferences. But physicians cannot predict that they will share deeply held beliefs with all of their patients, or all of the time. A physician who knows that there are specific interventions or services he or she cannot "in good conscience" provide has a responsibility to make that clear to prospective patients before entering into a patient-physician relationship with them,[31,32] for example, by posting a notice in the waiting room. During this time, before the onset of the patient-physician relationship, the physician's discretion to exercise conscience is at its greatest. If the physician does not make this clear prior to establishing a relationship, his or her obligation to refrain from acting in conscience, or temper his or her action, is stronger than it would otherwise be. Yet disclosure alone is not always sufficient; how clearly the physician states his or her position, how well the patient understands the disclosure (and its implications for future care), and the nature of the patient's needs (e.g., emergency care), are also important factors to consider. Further, prospective efforts to inform patients are limited to the extent that physicians cannot always predict the types of care patients might request, or how advances in medical science or technology may alter the course of their practices over time.

Having discretion to follow conscience with respect to specific interventions or services does not relieve the physician of the obligation to not abandon a patient. This includes a responsibility to facilitate transfer of the patient to another physician willing to provide an intervention or service the treating physician finds morally objectionable.[20] It also includes responsibility to provide ongoing care for a patient, even if the need for that care stems from an objected-to intervention, until the patient can be transferred to another physician.[14,23,33]

Medical Need, Timeliness & Alternatives

Medical need constrains physicians' freedom to act according to conscience. All patients are vulnerable to some degree—they must rely on physicians' professional knowledge and skill and must trust that physicians will be dedicated to promoting their welfare.[30] The greater a patient's medical need, the more he or she must trust the physician and the greater the physician's fiduciary obligation to fulfill that trust. Thus physicians have least latitude

to decline to provide care that is morally objectionable to them when that care is medically needed, unless the needed care is available to the patient elsewhere in a timely fashion.[23,33] The greater the medical need, the stronger the obligation to treat.[16] Conversely, physicians have greatest latitude to decline to provide care when that care is elective, particularly when the desired care is available elsewhere and delay in obtaining it will not unduly compromise the patient's well-being. Physicians should not act so as to create a significant barrier to the patient receiving care that is medically needed.

In some cases, delay in receiving treatment may alter the patient's outcome—for example, timely access to emergency contraception. In exercising conscience, physicians must consider whether their actions by delaying care would effectively deny the patient access to desired care and what harms the patient would experience as a result including financial, medical, psychological, or other harms.

Physician exercise of conscience often has a scalar effect where a physician might justify certain acts because the alternative would be less acceptable. For example, a physician who would decline to provide abortion may feel comfortable providing contraception to prevent an unwanted pregnancy the patient might choose to abort, or may morally oppose gender reassignment operations but justify it in the case of an otherwise self-destructive patient.

Harms & Burdens for Patients

The likelihood of harm to the patient and the degree of harm also constrain physicians' freedom to act on grounds of conscience. The fiduciary nature of patient-physician relationships carries with it the obligation for physicians to minimize harms, and to a lesser extent burdens, to patients. Harms to patients can come in a variety of forms and may include physical harms, dignitary harms (as when the physician fails to respect the patient and disregards the patient's values and preferences), and psychosocial harms.[34-38] As with medical need, the greater the likelihood that acting in conscience will harm the patient, the less discretion the physician has, particularly when the harm in question is serious and imminent (e.g., significant pain, disability). Some harm to the patient may be so significant and foreseeable that a physician's exercise of conscience is not justifiable—for example, death or permanent injury in contrast to minor bleeding or discomfort.

Beyond harms as such, physicians should consider other burdens that acting according to the dictates of their conscience may impose on patients. Burdens can range from the inconvenience of having to go elsewhere for care that is readily available when a physician declines to provide an intervention, to more significant challenges when the patient's access to care is limited by constraints on services in the local health care system or such patient-specific factors as health literacy or access to transportation. Time, distance to care, cost, or other logistic burdens might be so severe as to outright bar the patient from obtaining necessary care. Again, the more significant the burden, the more physicians should temper their exercise of conscience in the interests of patient welfare. Likewise a minor inconvenience to a patient should not force a physician to act outside the dictates of conscience. Yet, physicians must be aware that what may initially seem to the physician to be a minor harm or burden could act as a significant barrier to care for the patient, depending on the patient's individual situation.

Harms and Burdens to Physicians & Others

For an individual physician, not being able to conduct his or her life in keeping with deeply held beliefs can lead to moral distress,[39] the sense that one has fundamentally compromised one's integrity,[4] and loss of self-respect.[4] The moral and psychological harm for the individual physician can be compounded if it adversely affects his or her ability to provide high quality care.[40,41] Unaddressed moral distress can lead to dissatisfaction among health care workers, [6,40] which raises concerns that disaffected providers will be unable to provide high quality care, possibly resulting in harm to their individual patients and to patients as a class.

Moreover, prohibiting physicians from exercising conscience may deter some individuals from becoming physicians or from becoming certain types of specialists or it may lead physicians to become callous, disrespectful toward patients with diverging beliefs, or cavalier in upholding both their personal and their professional commitments, thus potentially compromising patient care and putting strain on the patient and public trust in personal and professional integrity of physicians.[40]

Patient care can also be affected at the institutional level. When a physician declines to provide an intervention or service on grounds of conscience, the burden falls to others to ensure that that exercise of conscience does not

disrupt practice or compromise patient care, including care of the patient whom the dissenting physician has declined to treat, or the functioning of the institution.[6,41,42] Permitting individual physicians to exercise conscience without constraint can also damage professional relationships with colleagues who either do not share a physician's deeply held beliefs, or who find other ways to resolve moral tensions between their beliefs and the expectations of their profession. Finally, while patients and the public must trust the moral integrity of physicians, permitting physicians to exercise conscience freely may paradoxically, put at risk the trust that physicians will uphold the commitments asked of them by their profession.

THE PROBLEM OF MORAL COMPLICITY

When a physician participates in an action that is in tension with his or her deeply held beliefs he or she may feel complicit, in some measure, in moral wrongdoing. Complicity involves "[sharing] in the guilt of an ethically improper act" by virtue of one's level of involvement with that act.[43] It is concerned with how participating in another party's immoral action (or inaction) violates one's own moral integrity.[32]

The degree to which an individual's action (or inaction) implicates him or her in a moral wrong depends on the individual's "moral distance" from the wrongdoer and/or the act, including the degree to which one shares the wrongful intent.[32,43] If one facilitates a moral wrong, but intended a morally licit purpose in doing so, then one is not morally complicit in the wrong. Moral distance also involves the extent to which one's action can be predicted to facilitate a moral wrong.[7,44] Loaning one's car to a friend who subsequently becomes drunk and kills someone while driving is morally more distant from the death than loaning one's car to a friend when one knows the friend plans to drink or has already been drinking.[32]

Other factors that influence moral complicity include the severity of the immoral act,[32] whether one was under duress in participating in the immoral act,[45] the likelihood that one's conduct will induce others to act immorally,[44] and the extent to which one's participation is needed to facilitate the wrongdoing.[32, 45]

For physicians, the question of moral complicity arises when they facilitate in some manner the accomplishment of an end they believe to be morally wrong. For example, a physician who declines to provide an intervention or service, such as abortion, on grounds of conscience must still grapple with whether to inform a patient about the objected-to option and whether to refer the patient to another physician who will provide the intervention or service. (A physician who is unwilling to forgo life-sustaining treatment may similarly worry that he or she is complicit in wrongdoing with respect to informing the patient about the option to forgo care or transferring the patient to another physician willing to withhold or withdraw such care.) Physicians must grapple with the degree to which their actions will compromise their feelings of moral integrity—some physicians may be able to justify some provisions of care but not others based on their level of complicity, even if the care implicates similar moral questions (for example, sanctity of life). It may be the case, as one example, that a physician can reconcile choosing not to participate in abortions with still providing emergency or other contraception. Yet in all circumstances, whatever the dictates of conscience, physicians must recognize and fulfill their other, continuing professional ethical obligations to the patient.

Duty to Inform

The duty to provide patients with the information they need to make well-considered decisions about their care is the embodiment of respect for patients' autonomy and is one of a physician's most fundamental professional obligations. As previously noted, physicians have a duty to present medical facts accurately,[17] including the risks, benefits, and costs of treatment alternatives,[13] and not to withhold information from patients.[33]

Providing information about treatment options the physician sincerely believes are morally objectionable or about how the patient might obtain objected-to treatment elsewhere is morally distant from what the physician's deeply held beliefs tell him or her is wrong. Providing information is sufficiently distant that the risk to physician integrity is outweighed by the professional obligation to inform, given the strong ethical import of informed consent.[5,29,32,46] Physicians can avoid any taint of complicity by notifying prospective patients prior to initiating a patient-physician relationship about interventions or services that conscience prohibits the physician from offering.[33]

Duty to Refer

The matter of referring a patient to a physician who will provide an objected-to intervention or service is more challenging. Physicians have a duty not to abandon their patients and to provide for continuity of care.[14,23] While these ground an obligation to refer when one cannot or will not provide needed care oneself, referring a patient for care that violates the physician's deeply held beliefs is clearly less morally distant from the objectionable act than is providing information.

As in making a determination whether to exercise conscience with respect to providing care, determining whether or how to refer requires that the physician consider medical need, risks and burdens to the patient of referring or not referring, and the likely impact of the physician's decision on colleagues and others. The greater the likelihood or severity of harm, the stronger the physician's duty to facilitate in some way the patient's access to needed care, even in the face of becoming in some measure complicit in what the physician believes is wrong. Conversely, when there is little risk of harm, the weaker the duty to facilitate access to the objected-to intervention or service. Physicians may have a heightened duty to refer in the context of an established patient-physician relationship.[47,48]

Physicians have a number of options for discharging the duty to refer, ranging from something as simple—and morally distant from wrongdoing—as providing a toll-free number or local hospital number for the patient to inquire about services, to formally referring the patient to a specific physician or institution.[32]

Physicians may also avoid (or at least minimize) moral complicity by terminating the patient-physician relationship and encouraging the patient to find another physician better able to meet the patient's needs.[46] However, terminating the relationship is ethically permissible only when timeliness of care is not a factor and the physician adheres to ethical guidelines for terminating the relationship, including providing needed care until the patient is transferred to another physician and ensuring that the patient's records are made available to his or her new physician.[23]

PROTECTING PATIENTS, PRESERVING INTEGRITY

The freedom to maintain moral views and act on them is central to a pluralist, democratic society.[6,7] Physicians, no less than patients, should be able to expect that they will be respected as moral agents. There is reason to think that preserving opportunity for physicians to act according to the dictates of conscience may "yield better overall medical quality by fostering a diverse workforce that possess integrity, sensitivity to patients' needs, and respect for diversity."[40] In determining whether and how to exercise conscience physicians have a responsibility—rooted in their own status as moral agents and their commitments as medical professionals—to deliberate thoughtfully about the implications for the well-being of patients and others and to seek ways to resolve or reduce moral tension that will neither unduly compromise the physician's moral integrity nor disproportionately burden the patient.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

> As practicing clinicians, physicians are expected to uphold the ethical norms of their profession, including fidelity to patients and respect for patient self-determination. As individuals, physicians are moral agents in their own right and, like their patients, are informed by and committed to diverse cultural, religious, and philosophical traditions and beliefs. For some physicians, their professional calling is imbued with their foundational beliefs as persons, yet the expectation that physicians will put patients' needs and preferences first may be in tension with the need to sustain the sense of moral integrity and continuity that grounds a physician's personal and professional life.
>
> Preserving opportunity for physicians to act (or to refrain from acting) in accordance with the dictates of conscience in their professional practice is important for preserving the integrity of the medical profession as well as the integrity of the individual physician. Ethically sound patient-physician relationships and the practice of medicine as a moral activity rest on trust in physicians' personal and professional integrity. Thus physicians should have considerable latitude to practice in accord with well-considered, deeply held beliefs that are central to their self-identities. Nonetheless, both as individual moral agents and as members of a profession dedicated to

promoting the welfare of patients, physicians have a responsibility to deliberate carefully about how best to preserve personal integrity. They should always uphold professional commitments and must not abandon a patient.

In some circumstances, physicians' professional obligations to patients outweigh considerations of personal moral belief:

(a) In emergency situations. The physician must provide care unless or until another qualified physician is readily available to provide the care needed;

(b) When declining to provide care would constitute discrimination. Physicians must not decline care for reasons such as race, color, religion, national origin, sexual orientation, gender identity, or the patient's disease status;

(c) When a patient who has decision-making capacity has made an informed decision to refuse life-sustaining care. If such situations create moral distress for the physician, the physician should facilitate transfer of care in keeping with ethical guidelines;

(d) When a patient may experience significant foreseeable morbidity or mortality as a direct result of the physician's exercise of conscience.

In other circumstances, physicians may be able to act (or refrain from acting) in accordance with the dictates of their conscience without violating their professional obligations so long as their actions do not disproportionately burden patients or the profession. Physicians should consider:

(e) Whether the physician has an existing patient-physician relationship with the individual and the nature and status of that relationship;

(f) The degree to which a legal, indicated non-emergency intervention/service is medically needed to avoid imminent risk of foreseeable harm to the patient;

(g) Whether or to what degree delay in access to care would adversely affect patient well-being;

(h) The likely burdens that would be imposed on the patient by the decision, including emotional, psychosocial, and dignitary harms as well as physical harm(s) and burdens;

(i) The availability of another qualified physician to provide the intervention/service and/or the degree to which the patient is able to access care elsewhere;

(j) Whether and how significantly a decision to act (or refrain from acting) will undermine the physician's personal integrity, create emotional or moral distress for the physician, or compromise his or her ability to provide care for this and other patients;

(k) Whether acting (or refraining from acting) will create undue burdens for patients in general, colleagues, and/or the profession of medicine, including whether the decision will adversely affect patient trust overall.

In all circumstances, physicians must recognize and fulfill their continuing professional ethical obligations to:

(l) inform the patient about all relevant options for care, including options to which the physician morally objects;

(m) inform the patient in some manner about how to obtain the desired care elsewhere, at a minimum directing the patient to sources of relevant information, up to referring the patient to a specific physician or institution willing to provide the care;

(n) facilitate transfer of care in keeping with ethical guidelines;

(o) either continue to provide other ongoing care for the patient or formally terminate the patient-physician relationship in keeping with ethical guidelines.

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2. AMENDMENT TO E-8.061, "GIFTS TO PHYSICIANS FROM INDUSTRY"

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: REFERRED

Opinion E-8.061, "Gifts to Physicians from Industry," was originally issued in 1992 to provide guidance for physicians in their relationships with industry in clinical practice. The American Medical Association (AMA) was a pioneer in turning physicians' attention to the ethical concerns posed by gifts from industry. However, medicine-industry relationships have evolved significantly since E-8.061 was last updated in 1998 and so has public and professional unease about the possibility that gift relationships between physicians and pharmaceutical, medical device and equipment, and biotechnology companies will have inappropriate effects. Over the intervening years empirical research has explored the question of gift relationships and other organizations have reflected on the ethical implications and issued policies in this area, many of which have built on the foundations of E-8.061. As it stands, E-8.061 no longer represents best thinking with respect to gifts to physicians from industry. The Council on Ethical and Judicial Affairs (CEJA) has thus concluded that this opinion should be updated.

THE CURRENT CONSENSUS

Since CEJA's original report, concerns about physicians' relationships with industry, including the acceptance of gifts, have continued to grow as evidence has accumulated about the influence of such relationships on physician practice.[1-5] A consensus has emerged over the past decade or so that recognizes the enormous value of maintaining strong relationships between medicine and industry, notably in research and innovation, but equally recognizes the need for circumspection where gifts to individual physicians are concerned. This is the case whether gifts are large or small, financial or in kind, office supplies or patient educational materials or sample medications or devices.[6-8]

Gifts

Calls for physicians to decline industry gifts of any size or nature have become prominent among many scholars of medicine-industry relationships,[2,3,9] in reports by distinguished national bodies,[4,5] and among national professional organizations and in advocacy campaigns.[10-12] In 2007, the American Medical Student Association began surveying the conflict of interest policies of all allopathic medical schools in the US to create its "PharmFree Scorecard," scoring medical schools with respect to their policies on gifts and pharmaceutical samples, among other domains.[13] In 2008 the Association of American Medical Colleges urged academic medical centers to "establish and implement policies that prohibit the acceptance of any gifts from industry by physicians and other faculty, staff, students, and trainees."[4] The following year, in its report on conflicts of interest in medicine, the Institute of Medicine similarly recommended that all physicians decline "items of material value" from industry and urged professional societies to amend their policies to support its recommendations.

The Pharmaceutical Research & Manufacturers Association (PhRMA) 2008 *Code on Interactions with Healthcare Professionals* bans noneducational and practice-related gifts (other than samples), items intended for the physician's personal benefit, and cash or cash-equivalents other than compensation for bona fide services, though it permits "items designed primarily for the education of patients or healthcare professionals" valued at under $100.[14] The 2009 *Code of Ethics* of the Advanced Medical Technology Association (AdvaMed) similarly restricts gifts to physicians.[15]

According to data collected for AMSA's most recent "PharmFree Scorecard," 73 of 149 US medical schools responding to the survey now prohibit gifts from industry entirely, while another 36 have policies restricting acceptance of gifts in various ways.[13]

Samples

Providing free drug samples has long been a prominent marketing practice of the pharmaceutical industry,[16,17] about the relative advantages and disadvantages of which there is ongoing debate.[3,18,6] In its 2007 report *Preventing Medication Errors,*, the Institute of Medicine recommended that the Agency for Healthcare Research and Quality fund studies "to evaluate the impact of free samples on overall patient safety, provider prescribing practices, and consumer behavior (e.g., adherence to medication regimen), as well as alternative methods of distribution that can improve safety, quality, and effectiveness.[19]

On the pro side, it is argued that drug samples improve quality of care and help provide needed medications for patients who might otherwise not have access to them.[16] Medication cost can be a significant barrier to adherence. Dispensing drug samples is one strategy physicians use to address this problem with individual patients.[20-23] On the con side, studies suggest that access to free samples can inappropriately influence physician prescribing, pose risks to patient safety when patients do not receive appropriate counseling about medications or samples are not appropriately managed, and can ultimately result in higher medication costs overall.[16,21,24-27]

Although published studies are relatively few, they indicate that the availability of free samples does influence prescribing practices.[24,18,20,28,22,16] Studies have indicated that physicians who have access to samples may prescribe brand name drugs in preference to alternatives, even when the branded sample is not their preferred drug choice,[20,24] and that removing samples from the practice setting may increase rates of prescribing for generic alternatives.[29]

The relationship between provision of samples and cost is complex, but there is evidence that associates prescribing samples with increased costs,[20,24] including for those patients who received samples.[18] Moreover, as Westfall and colleagues noted in 1997, in training settings, having access to free samples "prevents physicians and staff from appreciating the costs of medications, removing an important motivator in changing prescribing behavior."[26]

Whether samples primarily reach the neediest patients is open to question,[28,16,18] although access to samples is at least in part conditioned on access to care.[28,30,31,23]. Among Medicare beneficiaries, access to samples was greatest for patients who reported cost-related nonadherence to medications, but even among this population, access to samples was greater among beneficiaries with higher annual incomes and/or some form of drug benefits than among beneficiaries with lower incomes or no drug coverage.[23]

Evolving policy favors centralized mechanisms for acceptance and distribution of drug samples over management by individual physicians. In 2008 the AAMC recommended that academic medical centers that accepted samples at all should manage them centrally or, if central management was not feasible, explore alternatives that would not "carry the risks to professionalism with which current practices are associated."[4] In 2009 the IOM similarly recommended that individual physicians "not accept drug samples except in specified situations for patients who lack financial access to medications" and that professional associations and health care organizations adopt policy consistent with this recommendation.[5]

This is increasingly the case. For example, policy adopted in 2001 by Detroit's Henry Ford Health System prohibits use of sample drugs (including OTC medications) unless the drugs are approved by the Ambulatory Pharmacy and Therapeutics Committee and dispensed through clinics.[32] In 2009 the report of the Partners' Commission on Interactions with Industry urged Boston-based Partners HealthCare to "develop a mechanism for distributing free drug samples to patients only through the pharmacy or some other centralized system" and to prohibit individual physicians from distributing samples once that system was in place.[33] New regulations governing industry relationships with Veterans Health Administration personnel published in March 2012 require that samples be presented only to the individual designated by each medical facility to receive them and that all samples be stored and dispensed by pharmacy services.[34]

Some specialty societies are likewise re-examining guidance for their members. Policy of the American Congress of Obstetricians and Gynecologists adopted in 2008 provides that "[u]ntil a means is found to ensure that all patients

have access to medications, physicians may choose to provide samples or vouchers," but urges them to be aware of potential industry influence and to distribute samples "preferentially to those patients with a true need" and to dispense "a supply sufficient for a full course of therapy."[35]

A growing number of academic medical centers similarly restrict industry representatives' access to physicians and trainees and either prohibit samples or provide for central management. According to AMSA's 2011-2012 data, of 112 medical schools that have policies regarding drug samples, 10 prohibit them entirely and 86 manage samples in some way—e.g., centralized collection (20 schools), case-by-case approval (19 schools), or voucher programs (five schools).[13] Some academic medical centers prohibit samples entirely, including Emory University's Woodruff Health Sciences Center,[36] Johns Hopkins;[37] University of Michigan;[38] and the University of Pennsylvania.[39] Others, such as Stanford University;[40] University of California—Los Angles,[41] San Francisco,[42]and Davis;[43] the University of Pittsburgh;[44] and Vanderbilt University,[45] have established centralized mechanisms for collection, management, and dispensing of samples.

Patient assistance programs & other alternatives

Patient-assistance programs sponsored by pharmaceutical companies are another mechanism to provide free or low-cost access to prescription drugs. Most such programs base eligibility at least partly on income, but many also accept beneficiaries who also have some coverage for prescription drugs.[16,22,30-31] One study that evaluated 165 company-sponsored programs found that the majority of programs cover only one or two specific drugs, often have complex application processes, and generally provide drugs to patients' physicians rather than directly to patients themselves, leading the authors to conclude that "the extent to which these programs provide a safety net to patients is poorly understood."[31]

PROTECTING PATIENTS' INTERESTS & PUBLIC TRUST

Patients must be able to trust that their physicians have based treatment recommendations on the physician's independent professional judgment and knowledge of the patient's unique circumstances. Gifts from industry can undermine physicians' objectivity and put at risk physicians' ability to fulfill their primary professional commitment to serve patients' interests.

Medication samples, as a form of gift, are double-edged. Cost-related non-adherence to medication is a problem for many patients and to the extent that samples can help alleviate this situation they provide benefit to patients. However, the bias that access to samples can introduce into physician judgment, as well as concerns patient safety when individual physicians take on the administrative burden of managing sample medications argue against physicians accepting the gift of samples from industry representatives. Collecting, managing, and dispensing samples through a centralized mechanism can preserve the benefits for patients of access to needed medication and at the same time, reduce the risks.

RECOMMENDATION

In light of these considerations, the Council on Ethical and Judicial Affairs recommends that Opinion E-8.061, "Gifts to Physicians from Industry," be amended by substitution as follows, its accompanying clarification be rescinded, and the remainder of this report filed:

> Relationships among physicians and professional medical organizations and pharmaceutical, biotechnology, and medical device companies help drive innovation in patient care and contribute to the economic well-being of the community to the ultimate benefit of patients and the public. However, an increasingly urgent challenge for both medicine and industry is to devise ways to preserve strong, productive collaborations at the same time that they take clear effective action to prevent relationships that damage public trust and tarnish the reputation of both parties.
>
> Gifts to physicians from industry create conditions that carry the risk of subtly biasing—or being perceived to bias—professional judgment in the care of patients.
>
> To preserve the trust that is fundamental to the patient-physician relationship and public confidence in the profession, physicians should:

(a) Decline cash gifts in any amount from an entity that has a direct interest in physicians' treatment recommendations.

(b) Decline any gifts for which reciprocity is expected or implied.

(c) Accept an in-kind gift for the physician's practice only when the gift:

(i) will directly benefit patients, including patient education; and

(ii) is of minimal value.

(d) Whenever possible, access sample medications or medical devices through a central distribution mechanism. Physicians who do not have access to such a mechanism should exercise great discretion in accepting samples from industry representatives and must adhere to relevant law and best practices for management of samples.

(e) Physicians who provide samples to patients should:

(i) ensure that samples are made available preferentially to patients who lack financial resources to purchase the prescribed medication or device. Samples should not be used by staff, the physician, or family members; and

(ii) provide branded sample medications/devices when in the physician's independent professional judgment, the branded medication/device is an appropriate treatment option for the patient and not primarily for convenience.

(f) Academic institutions and residency and fellowship programs may accept special funding on behalf of trainees to support medical students', residents', and fellows' participation in professional meetings, including educational meetings, provided:

(i) the program identifies recipients based on independent institutional criteria; and

(ii) funds are distributed anonymously to recipients.

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APPENDIX I – "E-8.061, Gifts to Physicians from Industry" *Issued June 1992; updated June 1996, June 1998.*

Many gifts given to physicians by companies in the pharmaceutical, device, and medical equipment industries serve an important and socially beneficial function. For example, companies have long provided funds for educational seminars and conferences. However, there has been growing concern about certain gifts from industry to physicians. Some gifts that reflect customary practices of industry may not be consistent with the Principles of Medical Ethics. To avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

(1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members.

(2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (eg, pens and notepads).

(3) The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.

(4) Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

(5) Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

(6) Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policy-making meetings of national, regional, or specialty medical associations.

(7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures. (II)

APPENDIX II – E-8.061 Gifts to Physicians from Industry
Clarification of Opinion 8.061, Issued 1992; updated December 2000, June 2002, June 2004.

Scope
Opinion 8.061, "Gifts to Physicians from Industry," is intended to provide ethical guidance to physicians. Other parties involved in the health care sector, including the pharmaceutical, devices, and medical equipment industries and related entities or business partners, should view the guidelines as indicative of standards of conduct for the medical profession. Ultimately, it is the responsibility of individual physicians to minimize conflicts of interest that may be at odds with the best interest of patients and to access the necessary information to inform medical recommendations.

The guidelines apply to all forms of gifts, whether they are offered in person, through intermediaries, or through the Internet. Similarly, limitations on subsidies for educational activities should apply regardless of the setting in which, or the medium through which, the educational activity is offered.

General Questions
(a) Do the guidelines apply only to pharmaceutical, device, and equipment manufacturers?
"Industry" includes all "proprietary health-related entities that might create a conflict of interest."

Guideline 1
Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or for use by family members.

(a) May physicians accept gram stain test kits, stethoscopes, or other diagnostic equipment?
Diagnostic equipment primarily benefits the patient. Hence, such gifts are permissible as long as they are not of substantial value. In considering the value of the gift, the relevant measure is not the cost to the company of providing the gift. Rather, the relevant measure is the cost to the physician if the physician purchased the gift on the open market.
(b) May companies invite physicians to a dinner with a speaker and donate $100 to a charity or medical school on behalf of the physician?
There are positive aspects to the proposal. The donations would be used for a worthy cause, and the physicians would receive important information about patient care. There is a direct personal benefit to the physician as well, however. An organization that is important to the physician-and one that the physician might have ordinarily felt obligated to make a contribution to-receives financial support as a result of the physician's decision to attend the meeting. On balance, physicians should make their own judgment about these inducements. If the charity is predetermined without the physician's input, there would seem to be little problem with the arrangement.

(c) May contributions to a professional society's general fund be accepted from industry?
The guidelines are designed to deal with gifts from industry which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

(d) When companies invite physicians to a dinner with a speaker, what are the relevant guidelines?
First, the dinner must be a modest meal. Second, the guideline does allow gifts that primarily benefit patients and that are not of substantial value. Accordingly, textbooks and other gifts that primarily benefit patient care and that have a value to the physician in the general range of $100 are permissible. When educational meetings occur in conjunction with a social event such as a meal, the educational component must have independent value, such as a presentation by an authoritative speaker other than a sales representative of the company. Also, the meal should be a modest one similar to what a physician routinely might have when dining at his or her own expense. In an office or hospital encounter with a company representative, it is permissible to accept a meal of nominal value, such as a sandwich or snack.

(e) May physicians accept vouchers that reimburse them for uncompensated care they have provided?
No. Such a voucher would result directly in increased income for the physician.

(f) May physicians accumulate "points" by attending several educational or promotional meetings and then choose a gift from a catalogue of education options?
This guideline permits gifts only if they are not of substantial value. If accumulation of points would result in physicians receiving a substantial gift by combining insubstantial gifts over a relatively short period of time, it would be inappropriate.

(g) May physicians accept gift certificates for educational materials when attending promotional or educational events?
The Council views gift certificates as a grey area which is not per se prohibited by the guidelines. Medical textbooks are explicitly approved as gifts under the guidelines. A gift certificate for educational materials, ie, for the selection by the physician from an exclusively medical textbook catalogue, would not seem to be materially different. The issue is whether

the gift certificate gives the recipient such control as to make the certificate similar to cash. As with charitable donations, preselection by the sponsor removes any question. It is up to the individual physician to make the final judgment.

(h) May physicians accept drug samples or other free pharmaceuticals for personal use or use by family members?
The Council's guidelines permit personal or family use of free pharmaceuticals (i) in emergencies and other cases where the immediate use of a drug is indicated, (ii) on a trial basis to assess tolerance, and (iii) for the treatment of acute conditions requiring short courses of inexpensive therapy, as permitted by Opinion 8.19, "Self-Treatment or Treatment of Immediate Family Members." It would not be acceptable for physicians to accept free pharmaceuticals for the long-term treatment of chronic conditions.

(i) May companies invite physicians to a dinner with a speaker and offer them a large number of gifts from which to choose one?
In general, the greater the freedom of choice given to the physician, the more the offer seems like cash. A large number of gifts presented to physicians who attend a dinner would therefore be inappropriate.

There is no precise way of deciding an appropriate upper limit on the amount of choice that is acceptable. However, it is important that a specific limit be chosen to ensure clarity in the guidelines. A limit of eight has been chosen because it permits flexibility but prevents undue freedom of choice. Each of the choices must have a value to the physicians of no more than $100.

(j) May physicians charge for their time with industry representatives or otherwise receive material compensation for participation in a detail visit?
Guideline 1 states that gifts in the form of cash payments should not be accepted. Also, Guideline 6 makes clear that, in the context of the industry-physician relationship, only physicians who provide genuine services may receive reasonable compensation. When considering the time a physician spends with an industry representative, it is the representative who offers a service, namely the presentation of information. The physician is a beneficiary of the service. Overall, these guidelines do not view that physicians should be compensated for the time spent participating in educational activities, nor for time spent receiving detail information from an industry representative.

Guideline 2
Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (eg, pens and notepads).

(a) May physicians, individually or through their practice group, accept electronic equipment, such as hand held devices or computers, intended to facilitate their ability to receive detail information electronically?
Although Guideline 2 recognizes that gifts related to a physician' s practice may be appropriate, it also makes clear that these gifts must remain of minimal value. It is not appropriate for physicians to accept expensive hardware or software equipment even though one purpose only may pertain to industry-related activities of a modest value.

Guideline 3
The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.

Guideline 4
Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's sales representative may create a relationship which could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

(a) Are conference subsidies from the educational division of a company covered by the guidelines?
Yes. When the Council says "any subsidy," it would not matter whether the subsidy comes from the sales division, the educational division, or some other section of the company.

(b) May a company or its intermediary send physicians a check or voucher to offset the registration fee at a specific conference or a conference of the physician's choice?
Physicians should not directly accept checks or certificates which would be used to offset registration fees. The gift of a reduced registration should be made across the board and through the accredited sponsor.

Guideline 5
Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians'

time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

(a) If a company invites physicians to visit its facilities for a tour or to become educated about one of its products, may the company pay travel expenses and honoraria?
This question has come up in the context of a rehabilitation facility that wants physicians to know of its existence so that they may refer their patients to the facility. It has also come up in the context of surgical device or equipment manufacturers who want physicians to become familiar with their products.

In general, travel expenses should not be reimbursed, nor should honoraria be paid for the visiting physician's time since the presentations are analogous to a pharmaceutical company's educational or promotional meetings. The Council recognizes that medical devices, equipment, and other technologies may require, in some circumstances, special evaluation or training in proper usage which cannot practicably be provided except on site. Medical specialties are in a better position to advise physicians regarding the appropriateness of reimbursement with regard to these trips. In cases where the company insists on such visits as a means of protection from liability for improper usage, physicians and their specialties should make the judgment. In no case would honoraria be appropriate and any travel expenses should be only those strictly necessary.

(b) If the company invites physicians to visit its facilities for review and comment on a product, to discuss their independent research projects, or to explore the potential for collaborative research, may the company pay travel expenses and an honorarium?
If the physician is providing genuine services, reasonable compensation for time and travel expenses can be given. However, token advisory or consulting arrangements cannot be used to justify compensation.

(c) May a company hold a sweepstakes for physicians in which five entrants receive a trip to the Virgin Islands or airfare to the medical meeting of their choice?
No. The use of a sweepstakes or raffle to deliver a gift does not affect the permissibility of the gift. Since the sweepstakes is not open to the public, the guidelines apply in full force.

(d) If a company convenes a group of physicians to recruit clinical investigators or convenes a group of clinical investigators for a meeting to discuss their results, may the company pay for their travel expenses?
Expenses may be paid if the meetings serve a genuine research purpose. One guide to their propriety would be whether the National Institute of Health (NIH) conducts similar meetings when it sponsors multi-center clinical trials. When travel subsidies are acceptable, the guidelines emphasize that they be used to pay only for "reasonable" expenses. The reasonableness of expenses would depend on a number of considerations. For example, meetings are likely to be problematic if overseas locations are used for exclusively domestic investigators. It would be inappropriate to pay for recreation or entertainment beyond the kind of modest hospitality described in this guideline.

(e) How can a physician tell whether there is a "genuine research purpose?"
A number of factors can be considered. Signs that a genuine research purpose exists include the facts that there are (1) a valid study protocol, (2) recruitment of physicians with appropriate qualifications or expertise, and (3) recruitment of an appropriate number of physicians in light of the number of study participants needed for statistical evaluation.

(f) May a company compensate physicians for their time and travel expenses when they participate in focus groups?
Yes. As long as the focus groups serve a genuine and exclusive research purpose and are not used for promotional purposes, physicians may be compensated for time and travel expenses. The number of physicians used in a particular focus group or in multiple focus groups should be an appropriate size to accomplish the research purpose, but no larger.

(g) Do the restrictions on travel, lodging, and meals apply to educational programs run by medical schools, professional societies, or other accredited organizations which are funded by industry, or do they apply only to programs developed and run by industry?
The restrictions apply to all conferences or meetings which are funded by industry. The Council drew no distinction on the basis of the organizer of the conference or meeting. The Council felt that the gift of travel expenses is too substantial even when the conference is run by a non-industry sponsor. (Industry includes all "proprietary health-related entities that might create a conflict of interest.")

(h) May company funds be used for travel expenses and honoraria for bona fide faculty at educational meetings?
This guideline draws a distinction between attendees and faculty. As was stated, "[i]t is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses."

Companies need to be mindful of the guidelines of the Accreditation Council on Continuing Medical Education. According to those guidelines, "[f]unds from a commercial source should be in the form of an educational grant made payable to the CME sponsor for the support of programming."

(i) May travel expenses be reimbursed for physicians presenting a poster or a "free paper" at a scientific conference?
Reimbursement may be accepted only by bona fide faculty. The presentation of a poster or a free paper does not by itself qualify a person as a member of the conference faculty for purposes of these guidelines.

(j) When a professional association schedules a long-range planning meeting, is it appropriate for industry to subsidize the travel expenses of the meeting participants?
The guidelines are designed to deal with gifts from industry which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

(k) May continuing medical education conferences be held in the Bahamas, Europe, or South America?
There are no restrictions on the location of conferences as long as the attendees are paying their own travel expenses.

(l) May travel expenses be accepted by physicians who are being trained as speakers or faculty for educational conferences and meetings?
In general, no. If a physician is presenting as an independent expert at a CME event, both the training and its reimbursement raise questions about independence. In addition, the training is a gift because the physician's role is generally more analogous to that of an attendee than a participant. Speaker training sessions can be distinguished from meetings (See 5d) with leading researchers, sponsored by a company, designed primarily for an exchange of information about important developments or treatments, including the sponsor's own research, for which reimbursement for travel may be appropriate.

(m) What kinds of social events during conferences and meetings may be subsidized by industry?
Social events should satisfy three criteria. First, the value of the event to the physician should be modest. Second, the event should facilitate discussion among attendees and/or discussion between attendees and faculty. Third, the educational part of the conference should account for a substantial majority of the total time accounted for by the educational activities and social events together. Events that would be viewed (as in the succeeding question) as lavish or expensive should be avoided. But modest social activities that are not elaborate or unusual are permissible, eg, inexpensive boat rides, barbecues, entertainment that draws on the local performers. In general, any such events which are a part of the conference program should be open to all registrants.

(n) May a company rent an expensive entertainment complex for a evening during a medical conference and invite the physicians attending the conference?
No. The guidelines permit only modest hospitality.

(o) If physicians attending a conference engage in interactive exchange, may their travel expenses be paid by industry?
No. Mere interactive exchange would not constitute genuine consulting services.

(p) If a company schedules a conference and provides meals for the attendees that fall within the guidelines, may the company also pay for the costs of the meals for spouses?
If a meal falls within the guidelines, then the physician's spouse may be included.

(q) May companies donate funds to sponsor a professional society's charity golf tournament?
Yes. But it is sensible if physicians who play in the tournament make some contribution themselves to the event.

(r) If a company invites a group of consultants to a meeting and a consultant brings a spouse, may the company pay the costs of lodging or meals of the spouse? Does it matter if the meal is part of the program for the consultants?
Since the costs of having a spouse share a hotel room or join a modest meal are nominal, it is permissible for the company to subsidize those costs. However, if the total subsidies become substantial, then they become unacceptable.

Guideline 6
Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

(a) When a company subsidizes the travel expenses of residents to an appropriately selected conference, may the residents receive the subsidy directly from the company?
Funds for scholarships or other special funds should be given to the academic departments or the accredited sponsor of the conference. The disbursement of funds can then be made by the departments or the conference sponsor.

(b) What is meant by "carefully selected educational conferences?"
The intent of Guideline 6 is to ensure that financial hardship does not prevent students, residents, and fellows from attending major educational conferences. For example, we did not want to deny cardiology fellows the opportunity to attend the annual scientific meeting of the American College of Cardiology or orthopedic surgery residents the opportunity to attend the annual scientific meeting of the American Academy of Orthopedic Surgeons. However, it was not the intent of the guideline to permit reimbursement of travel expenses in other circumstances, such as when conferences or symposia are designed specifically for students, residents, or fellows. Funds are limited to travel and lodging expenses for attendance at major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

Guideline 7
No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

(a) May companies send their top prescribers, purchasers, or referrers on cruises?
No. There can be no link between prescribing or referring patterns and gifts. In addition, travel expenses, including cruises, are not permissible.

(b) May the funding company itself develop the complete educational program that is sponsored by an accredited continuing medical education sponsor?
No. The funding company may finance the development of the program through its grant to the sponsor, but the accredited sponsor must have responsibility and control over the content and faculty of conferences, meetings, or lectures. Neither the funding company nor an independent consulting firm should develop the complete educational program for approval by the accredited sponsor.

(c) How much input may a funding company have in the development of a conference, meeting, or lectures?
The guidelines of the Accreditation Council on Continuing Medical Education on commercial support of continuing medical education address this question.

3. AMENDMENT TO E-5.055, "CONFIDENTIAL CARE FOR MINORS" (RESOLUTION 1-A-12)

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: RECOMMENDATION ADOPTED IN LIEU OF RESOLUTION 1-A-12 AND REMAINDER OF REPORT FILED
See Opinion E-5.055

This report is submitted in response to Resolution 1-A-12, "HPV Vaccination for Minors," introduced by the Medical Student Section and referred by the House of Delegates, which asks that "our American Medical Association (AMA) develop and support model state legislation allowing unemancipated minors to consent to HPV vaccination" and was referred to the Council on Ethical and Judicial Affairs (CEJA) by the Board of Trustees for input on the relevant ethical considerations. Based on its review of the ethical analysis that informs current AMA policies, CEJA recommends that Resolution 1 be addressed by amending Opinion E-5.055, "Confidential Care for Minors" to allow minors to consent to measures that not only treat sexually transmitted disease, but also prevent it.

BACKGROUND

Human papillomavirus (HPV) is one the most common sexually transmitted infections (STI) in the world with a lifetime prevalence of 80%, and an estimated 6.2 million new infections occurring each year.[1,2] The Food and Drug Administration has approved several vaccines that are between 93%-100% effective in preventing the strains of HPV that are associated with cancers and genital warts in both males and females.[1] Vaccination can prevent 70% of all cervical cancers as well as vaginal and vulvar cancers in females, 90% of genital warts in both genders, and anal, penile, and oropharyngeal cancers.[1,3] Although HPV vaccines can be administered through age 26, the Center for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP) recommends HPV vaccinations in early adolescence, when the best antibody response occurs and before the adolescent becomes sexually active.[4,5] The vaccine can be administered as early as 9 years of age and ACIP recommends HPV

vaccination for both adolescent males and females, given the disease burden associated with HPV in both genders.[4,5]

An estimated 24% of parents may object to vaccinating their children against HPV [2]. Parents may not wish to consent to the vaccine on behalf of their children for a variety of reasons: they are conscientious objectors of vaccines generally; they do not feel their child is at risk for acquiring an STI, safety concerns, a lack of knowledge about the vaccine, or perceptions that the vaccine will promote sexual activity prematurely.[2,6,7] Recent data reveals that HPV vaccination of 11 and 12 year old girls is not associated with the clinical markers that suggest increased sexual activity like sexually transmitted disease or pregnancy.[8] The FDA has licensed HPV vaccines as safe and effective, and vaccination has shown only mild side effects like pain, fever, headache, or nausea.[9]

HPV vaccination has been at the center of state legislation over last several years, mainly considering whether states can and should mandate HPV vaccination for minors.[10] With respect to the question of consent, in January 2012, a California law went into effect that explicitly allows minors (ages 12 years and older) to consent not just to treatment and diagnosis of STIs (which the law already permitted), but also to prevention of STIs, including the HPV vaccine, Hepatitis B vaccine, and medications to prevent HIV exposure before or after sexual contact.[11,12]

CURRENT AMA POLICY

AMA Policy H-60.965, "Confidential Health Services for Adolescents," confirms that confidential care for adolescents is critical to improving patient health and that, while parental involvement in children's health should generally be encouraged, parental consent should not act as a barrier to needed medical care.[13] Moreover, H-60.958, "Rights of Minors to Consent for STD/HIV Prevention, Diagnosis, and Treatment," emphasizes the importance of minors being permitted to consent for prevention of STIs, as well as STI treatment and diagnosis.[14] While Opinion E-10.016, "Pediatric Decision-Making," acknowledges that generally parental consent should be sought in the treatment of pediatric patients, parental consent is not always mandatory.[15] For example, Opinion E-2.015, Mandatory Parental Consent to Abortion," ultimately allows minors to consent to abortion without parental involvement when, in the discretion of the minor, parental involvement is not appropriate.[16] Moreover, Opinion E-5.055, "Confidential Care for Minors," provides ethical guidance for physicians in the provision of other types of medical care to minors without parental consent.[17] According to Opinion E-5.055 and its related report, CEJA Report G-A-92, "Confidential Care for Minors," physicians should always permit competent minors to consent to medical care, only notifying parents with the patient's consent.[17,18] For incompetent minors physicians should ordinarily provide certain types of medical services without parental consent if, in the absence of confidentiality, the minor may otherwise fail to receive healthcare that is necessary to prevent serious harm. Such services include contraception, treatment of STI, pregnancy-related care, drug and alcohol abuse or mental health treatment.[17,18]

ETHICAL CONSIDERATIONS

Confidentiality is necessary in the medical encounter to ensure that patients are not reluctant to disclose all relevant health information or to visit the physician for certain sensitive health problems.[18] Confidentiality is of particular importance in minor care, or minors may avoid care that they do not want their parents to learn about.[18] Parents are generally seen as the authority in their children's health, including in making healthcare decisions on behalf of their children, however this relationship changes as the child matures and increasing need for confidentiality emerges.[18] In the vast majority of scenarios, minors will not object to their parents' involvement in their healthcare. Yet some care is private in nature and may be associated with behaviors that the parent would disapprove of, such as use of contraceptives or treatment for drug abuse. While minors should be encouraged to involve their parents in healthcare decisions and such involvement will usually be in line with the best interests of the minor, there are times where it is important to preserve confidentiality in order to ensure that the minor feels safe to seek care that can prevent serious harm.[6,7,18]

As AMA Policy H-60.958 already recognizes, preventing STIs in minors is equally as important as treating them—thus confidentiality is important in either case. Just like treatment for STIs, adolescents may be reluctant to seek care to prevent STIs and include their parents in these decisions for a variety of reasons: a desire to take ownership over their own health as they develop autonomy, or fear of embarrassment, parental disapproval, or parent refusal.[6] Without confidential care, some minors may avoid such preventive measures rather than have their parents find out. If parental consent is required, patients may fail to receive care which is necessary to promote patient health and prevent serious harm. For example, an HPV vaccine allows the prevention of a number of burdensome cancers

associated with the disease, and the morbidity and mortality associated with those cancers. Moreover, like treatment for STIs, prevention of STIs may also be time-sensitive (as in the case of the HPV vaccine which minors should ideally receive before reaching age of majority). Preventive measures (like treatment) involve sensitive, private health matters where parental consent may sometimes act as a barrier to important care and thus confidential care should be permitted in preventive STI treatment as it is in treatment and diagnosis. Such preventive measures may include vaccinations against STIs, as well as medicines that minimize exposure to STIs. Like treatment of STIs, physicians should generally provide preventive STI measures to minor patients without requiring parental consent.

Like other services, the physician who is uncomfortable administering the vaccine without parental involvement should inform the patient that care may be available elsewhere.

RECOMMENDATION

Given these considerations, the Council recommends that Opinion E-5.055, "Confidential Care for Minors," be amended by insertion as follows and that the remainder of this report be filed:

> Physicians who treat minors have an ethical duty to promote the autonomy of minor patients by involving them in the medical decision-making process to a degree commensurate with their abilities.
>
> When minors request confidential services, physicians should encourage them to involve their parents. This includes making efforts to obtain the minor's reasons for not involving their parents and correcting misconceptions that may be motivating their objections.
>
> Where the law does not require otherwise, physicians should permit a competent minor to consent to medical care and should not notify parents without the patient's consent. Depending on the seriousness of the decision, competence may be evaluated by physicians for most minors. When necessary, experts in adolescent medicine or child psychological development should be consulted. Use of the courts for competence determinations should be made only as a last resort.
>
> When an immature minor requests contraceptive services, pregnancy-related care (including pregnancy testing, prenatal and postnatal care, and delivery services), or treatment for sexually transmitted disease, measures to prevent sexually transmitted disease, drug and alcohol abuse, or mental illness, physicians must recognize that requiring parental involvement may be counterproductive to the health of the patient. Physicians should encourage parental involvement in these situations. However, if the minor continues to object, his or her wishes ordinarily should be respected. If the physician is uncomfortable with providing services without parental involvement, and alternative confidential services are available, the minor may be referred to those services. In cases when the physician believes that without parental involvement and guidance, the minor will face a serious health threat, and there is reason to believe that the parents will be helpful and understanding, disclosing the problem to the parents is ethically justified. When the physician does breach confidentiality to the parents, he or she must discuss the reasons for the breach with the minor prior to the disclosure.
>
> For minors who are mature enough to be unaccompanied by their parents for their examination, confidentiality of information disclosed during an exam, interview, or in counseling should be maintained. Such information may be disclosed to parents when the patient consents to disclosure. Confidentiality may be justifiably breached in situations for which confidentiality for adults may be breached, according to Opinion 5.05, "Confidentiality." In addition, confidentiality for immature minors may be ethically breached when necessary to enable the parent to make an informed decision about treatment for the minor or when such a breach is necessary to avert serious harm to the minor. (IV)

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4. CEJA'S SUNSET REVIEW OF 2003 HOUSE POLICIES

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

At its 1984 Interim Meeting, the House of Delegates (HOD) established a sunset mechanism for House policies (Policy G-600.110). Under this mechanism, a policy established by the House ceases to be viable after 10 years unless action is taken by the House to retain it.

The objective of the sunset mechanism is to help ensure that the AMA Policy Database is current, coherent, and relevant. By eliminating outmoded, duplicative, and inconsistent policies, the sunset mechanism contributes to the ability of the American Medical Association (AMA) to communicate and promote its policy positions. It also contributes to the efficiency and effectiveness of HOD deliberations.

At its 2012 Annual Meeting, the House modified Policy G-600.110 to change the process through which the policy sunset review is conducted. The process now includes the following steps:

- Each year the House policies that are subject to review under the policy sunset mechanism are identified.
- Policies are assigned to appropriate Councils for review.
- For the Annual Meeting of the House, each Council develops a separate policy sunset report that recommends how each policy assigned to it should be handled. For each policy it reviews, a Council may recommend one of the following actions: (a) retain the policy; (b) sunset the policy; (c) retain part of the policy; d) reconcile the policy with more recent and like policy. A justification must be provided for the recommended action to retain a policy.
- A policy will typically sunset after ten years unless action is taken by the House of Delegates to retain it. A reaffirmation or amendment to policy by the House of Delegates resets the sunset clock, making the reaffirmed or amended policy viable for another 10 years.

Although the policy sunset review mechanism may not be used to change the meaning of AMA policies, minor editorial changes can be accomplished through the sunset review process.

2003 POLICIES

In this report, the Council on Ethical and Judicial Affairs presents its recommendations regarding the disposition of 2003 House policies that were assigned to or originated from CEJA.

DUPLICATIVE POLICIES

On the model of the Council on Long Range Planning & Development (CLRPD)/CEJA Joint Report I-01 and of subsequent reports of CEJA's sunset review of House policies, this report recommends the rescission of House policies that originate from CEJA Reports and duplicate current opinions issued since June 2005. As noted previously, the intent of this process is the elimination of duplicative ethics policies from PolicyFinder. The process does not diminish the substance of AMA policy in any sense. Indeed, CEJA Opinions are a category of AMA policy.

MECHANISM TO ELIMINATE DUPLICATIVE ETHICS POLICIES

The Council continues to present reports to the HOD. If adopted, the recommendations of these reports continue to be recorded in PolicyFinder as House policy. After the corresponding CEJA Opinion is issued, CEJA utilizes its annual sunset report to rescind the duplicative House policy.

For example, at the 2007 Interim Meeting, the HOD adopted the recommendations of CEJA Report 8-I-07, "Pediatric Decision-Making." It was recorded in PolicyFinder as Policy H-140.865. At the 2008 Annual Meeting, CEJA filed the corresponding Opinion E-2.026, thereby generating a duplicative policy. Under the mechanism to eliminate duplicative ethics policies, CEJA recommended the rescission of Policy H-140.865 as part of the Council's 2009 sunset report.

The Appendix provides recommended actions and their rationale on House policies from 2003, as well as on duplicate policies.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the House of Delegates policies that are listed in the Appendix to this report be acted upon in the manner indicated and the remainder of this report be filed.

APPENDIX – Recommended Actions for 2003 House Policies

Policy No.	Title	Recommended Action & Rationale
D-140.979	Moratorium on the Imposition of the Death Penalty	Rescind: Policy no longer relevant
H-100.967	Patient Privacy and Pharmaceutical Sales Representatives	Rescind: Policy no longer relevant
H-210.984	Conflicts of Interest	Rescind: Policy no longer relevant
H-245.984	Treatment Decisions for Seriously Ill Newborns	Retain: Policy remains relevant
H-275.952	Reporting Impaired, Incompetent or Unethical Colleagues	Rescind: Policy no longer relevant
H-515.983	Physicians and Family Violence	Rescind: Policy no longer relevant

5. JUDICIAL FUNCTION OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS ANNUAL REPORT

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

At the 2003 Annual Meeting, the Council on Ethical and Judicial Affairs (CEJA) presented a detailed explanation of its judicial function. This undertaking was motivated in part by the considerable attention professionalism has received in many areas of medicine, including the concept of professional self-regulation.

CEJA has authority under the Bylaws of the American Medical Association (AMA) to disapprove a membership application or to take action against a member. The disciplinary process begins when a possible violation of the *Principles of Medical Ethics* or illegal or other unethical conduct by an applicant or member is reported to the AMA. This information most often comes from statements made in the membership application form, a report of disciplinary action taken by state licensing authorities or other membership organizations, or a report of action taken by a government tribunal.

The Council rarely re-examines determinations of liability or sanctions imposed by other entities. However, it also does not impose its own sanctions without first offering a hearing to the physician. CEJA can impose the following sanctions: applicants can be accepted into membership without any condition, placed under monitoring, or placed on probation. They also may be accepted but be the object of an admonishment, a reprimand, or censure. In some cases, their application can be rejected. Existing members similarly may be placed under monitoring or on probation, and can be admonished, reprimanded or censured. Additionally, their membership may be suspended or they may be expelled. Updated rules for review of membership can be found at *www.ama-assn.org/ama/pub/about-ama/our-people/ama-councils/council-ethical-judicial-affairs/governing-rules/rules-review-membership.page*.

Beginning with the 2003 report, the Council has provided an annual tabulation of its judicial activities to the House of Delegates. In the appendix to this report, a tabulation of CEJA's activities during the most recent reporting period is presented.

CEJA Judicial Function Statistics – April 1, 2012 ~ March 31, 2013	
Physicians Reviewed	Summary of CEJA Activities
7	Determination of no probable cause
33	Final determinations following a plenary hearing (including no action taken)
25	Final determinations without a plenary hearing (hearing affirmatively waived, offer of compromise accepted, non-compliance with probationary/monitoring requirements, resignation accepted, or non-response to the offer of a hearing)

Physicians Reviewed	Final Determination (by type of action taken)
9	No sanction or other type of action
7	Monitoring
14	Probation
11	Revocation
3	Suspension
0	Resignation accepted
0	Application denied
14	Censure/Admonishment/Reprimand

Physicians Reviewed	Probation / Monitoring Status
21	Members placed on probation/monitoring during reporting interval
11	Members placed on probation without reporting to the NPDB.
7	Probation/monitoring concluded satisfactorily during reporting interval
28	Number of physicians on probation/monitoring at any time during reporting interval

Physicians Reviewed	Reports to AMA Staff of Possible Ethical Violations
35	Physicians under consideration by AMA staff for possible notification at end of reporting interval
125	Approximate number of physicians reviewed who were not brought to CEJA's attention.

6. NOMINATION FOR AFFILIATE MEMBERSHIP – JOSEPH M. GOODMAN, DDS, DMD

No reference committee hearing; adopted during general session Sunday, June 16.

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

In keeping with Bylaw 1.12, Affiliate Members, the Council on Ethical and Judicial Affairs (CEJA) recommends the following individuals for affiliate membership in the American Medical Association (AMA):

Dentists who hold a DDS or DMD degree and are members of the ADA, state, and local dental societies

Joseph M. Goodman, DDS, DMD

Dr. Goodman performs a number of cosmetic dentistry procedures in Beverly Hills, California including lumineeres, veneers and whitening, as well as restorative, preventive, and implant dentistry. Dr. Goodman received his DMD (medicine) from the University of Aachen in Germany with honors. After working in Germany, Switzerland, and London, he began practicing in Los Angeles, where he attained a DDS (surgery) from UCLA with high grades. He then participated in the "Advanced Education in Prosthodontics" postgraduate program at USC and the "Advanced Education in General Dentistry (AEGD)" program at UCLA. He is currently a member of the American Dental Association, the California Dental Association, and the Los Angeles Dental Association. Dr. Goodman has several websites that detail his credentials and work: dentistinla.com/ and www.beverlyhillsveneerdentist.com/.