

*Compensation to Health Care Professionals
from the
Pharmaceutical Industry*

*A Report by the National Ethics Committee
of the Veterans Health Administration*

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Founded in 1986, the National Ethics Committee (NEC) of the Veterans Health Administration (VHA) is an interdisciplinary group authorized by the Under Secretary for Health through the National Center for Ethics in Health Care. The NEC produces reports on timely topics that are of significant concern to practicing health care professionals. Each report describes an ethical issue, summarizes its historical context, discusses its relevance to VHA, reviews current controversies, and outlines practical recommendations. Previous reports have been useful to VHA professionals as resources for educational programs, guides for patient care practices, and catalysts for health policy reform. Scholarly yet practical, these reports are intended to heighten awareness of ethical issues and to improve the quality of health care, both within and beyond VHA.

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Executive Summary

In its recent report, *Gifts to Health Care Professionals from the Pharmaceutical Industry*, the National Ethics Committee (NEC) of the Veterans Health Administration (VHA) noted that types of interactions between health care professionals and the pharmaceutical industry other than gifts, such as consulting or speaking fees, could also present ethical concerns. Serious ethical concerns have been raised that such arrangements risk compromising health care providers' professional objectivity and integrity and/or undermining their fundamental ethical commitment to putting the interests of patients first.

This report discusses the special nature of these compensated relationships, examines why such compensated relationships between health care professionals and the pharmaceutical industry may be ethically problematic, and reviews professional ethical guidelines and legal standards regarding health care professionals receiving compensation from the pharmaceutical industry. The report recommends that facilities develop policies to:

1. VHA develop national policy with respect to compensated, conflict-creating relationships between VA health care professionals and industry.
2. The Under Secretary for Health appoint a national task force to develop such a policy with representation from key stakeholders, including the Office of Patient Care Services (including representation from the Office of Pharmacy Benefits Management), Office of Nursing Services, Office of Human Resource Management, Office of General Counsel, Office of Research and Development, Office of Quality and Performance, National Center for Ethics in Health Care, and other program and field-based offices the Under Secretary for Health identifies as appropriate participants.

The report recommends that health care professionals in VA involved in activities that can have a significant effect on available range of treatments be required to report compensated relationships with industry. National policy governing such relationships with industry must provide guidance for assessing and managing potential conflicts of interest. An ethically appropriate policy will:

1. Establish fair, effective, administratively manageable mechanism(s) for reporting compensated relationships with industry.
2. Set out clear criteria for identifying which conflict-creating compensated professional relationships (if any) will be: prohibited entirely; permitted subject to ongoing oversight; or, permitted without oversight
3. Provide guidance regarding appropriate strategies for managing conflict in permitted relationships.
4. Define clearly in what situations a particular strategy/combination of strategies should be employed to manage conflict, and/or how a management plan is to be developed; and, who is responsible for assuring that an identified conflict is appropriately managed.
5. Establishing ongoing education about conflicts of interest.

Introduction

In its recent report *Gifts to Health Care Professionals from the Pharmaceutical Industry*,¹ the National Ethics Committee (NEC) of the Veterans Health Administration (VHA) examined the ethical implications of gifts to individual health care professionals from pharmaceutical companies. In preparing that report, the Committee noted that other kinds of interactions between health care professionals and the pharmaceutical industry are also potentially ethically troubling, particularly relationships in which providers receive compensation from pharmaceutical companies for services they perform on the company's behalf, such as consulting or speaking. There is concern that like gift relationships, compensated relationships with the pharmaceutical industry risk "compromising health care providers' professional objectivity and integrity, and undermining their ethical commitment to putting the interests of patients first."¹ Moreover, accepting compensation may carry implications for health care professionals' relationships with peers and colleagues and for the health care institutions in which they practice.

In this companion to its earlier work, the NEC examines the ethical values at stake when health care professionals enter into compensated relationships with the pharmaceutical industry.* These complex arrangements pose significant conceptual and practical challenges, especially for institutions like VA in which care is provided by an array of full-time, part-time, and contract professionals. This report discusses the ethically salient features of compensated relationships, examines how accepting compensation may be ethically problematic, explores various strategies for managing compensated relationships, and recommends practical steps for VA to develop policy to address these ethical challenges.

Compensated Relationships & Health Care Professionals

By "compensated relationships" with industry, we mean those arrangements between individual health care professionals and pharmaceutical companies, medical manufacturers, or other health-related entities that involve the exchange of professional services for money. Unlike gift relationships, in which expectations for reciprocation by health care professionals remain tacit, compensated relationships rest on an explicit *quid pro quo*. The arrangements of specific concern include compensation for participating in speakers bureaus on behalf of industry, serving on industry advisory boards or as an expert witness, or consulting for industry. The present analysis does not address activities sponsored by the professional's institution that may be funded by the pharmaceutical industry, such as education or research.†

This report focuses on relationships involving financial compensation from industry to health care professionals who are involved in making treatment recommendations for individual patients, in making formulary decisions for health care organizations, in developing clinical practice guidelines

* Although this report focuses on compensated relationships between practitioners and the pharmaceutical industry, this ethical analysis is germane both to relationships with other parties and to other types of financial interests. The analysis offered here will also apply to relationships with medical technology companies, industry-supported patient/disease advocacy groups, or other entities that have an interest in specific products whose use is controlled by health care professionals, whether the relationship involves cash payments, equity interest, or other financial benefits.

†VHA's Office of Research and Development is separately developing guidance relating to participation by VHA health care professionals in industry-sponsored clinical trials.

or institutional policies on care, or in other activities within the health care system that can have a significant effect on the range of treatment options available to patients. These may include physicians, advanced practice nurses, clinical psychologists, pharmacists, and certain administrators.

Why Are Compensated Relationships Ethically Problematic?

Compensated relationships between health care professionals and pharmaceutical companies raise ethical concerns in several ways. Such relationships may create conflicts of interest and/or conflicts of commitment that threaten to erode the professional's relationships with both patients and professional peers, compromise professional integrity, and undermine patient and public trust.

Conflicts of Interest & Bias. A conflict of interest “is a set of conditions in which professional judgment concerning a primary interest (such as a patient’s welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain).”² In a conflict of interest situation, the concern is not that the secondary interest is illegitimate, but that it unduly influences the primary concern. (This asymmetry distinguishes conflicts of interest from ethical dilemmas, in which by definition competing values have equal claim to priority.²

Recent inquiry into conflicts of interest, notably among NIH scientists who also serve as paid consultants for outside entities, has focused particularly on the amount of outside income received.^{3,4} The implication is that it is the magnitude of compensation that is problematic, rather than the existence of an explicit relationship. However, research indicates that the fact of participating in such relationships can undermine professionals’ objectivity and bias their judgments, no matter how much or how little money may be involved.

Social science research shows that in situations of conflict of interest “even when individuals try to be objective, their judgments are subject to an unconscious and unintentional self-serving bias” (emphasis added).^{5,6} Self-interest changes how individuals “seek out and weigh the information on which they later base their choices when they have a stake in the outcome.”^{5,7} These effects occur even among individuals who are motivated to be impartial and who have been explicitly instructed about bias.^{5,6}

Bias may have consequences for the health care system as well as for individual practitioners and patients, for example, when health care professionals with ties to industry participate in developing clinical practice guidelines. One study found that 59% of authors of clinical practice guidelines had financial relationships with companies whose products were considered in those guidelines. Seven percent “thought that their own relationships with the pharmaceutical industry influenced the recommendations and 19% thought that their coauthors’ recommendations were influenced by their relationships.”⁸ In this context financial conflicts of interest are particularly troubling “since they may not only influence the specific practice of these authors but also those of the physicians following the recommendations contained within the guidelines.”⁸

Not all conflicts of interest are equally problematic—some raise more serious concerns than others. Generally, the severity of a conflict of interest “depends on (1) the likelihood that professional judgment will be influenced, or appear to be influenced, by the secondary interest, and (2) the seriousness of the harm or wrong that is likely to result from such influence or its appearance.”² Widely accepted criteria for assessing the likelihood that a relationship with industry will create a conflict of interest include: (1) the value of the secondary interest (for example, the amount of compensation received by the professional, or the prestige associated with the position); (2) the nature of the relationship that creates the conflict or “scope” of conflict (how close or long

standing the relationship is); and (3) the extent of the professional's discretion in practice (e.g., how freely the professional may exercise his or her professional judgment in determining the treatments offered to patients).²

Arguably, the salient ethical consideration is not so much the existence of a conflict as the harm that may occur as the result of the financial relationship. Criteria for assessing the seriousness of the harm likely to result from a conflict of interest include: (1) the risk to the professional's primary obligation (such as the effects on patients' welfare); (2) the scope of the consequences (e.g., whether the conflict affects only the individual patient, a class of patients, or the medical profession as a whole); and (3) the level of accountability of the individual involved in the conflict (the more independently a professional operates, the more serious the conflict).² Taken together, these two sets of criteria help identify which relationships are ethically problematic.

Federal regulations, including the Standards of Conduct for Employees of the Executive Branch (5 CFR Part 2635), also known as "government ethics rules," prohibit a VA employee from using his or her public office for private gain or engaging in relationships that otherwise involve conflict of interest or might give the appearance of conflict of interest. However, the regulations also set out conditions under which an individual might be permitted to engage in otherwise prohibited activities. These exemptions (5 CFR 2640.301(b)(1)–(6)) suggest some additional criteria for thinking about the propriety of relationships with industry: (1) the type of financial interest involved (e.g., stock or cash payment); (2) the dollar value of the financial interest; (3) the importance of the health care professional's role in the matter that gives rise to conflict; (4) the sensitivity of the matter and need for the professional's services; and (5) whether or how the professional's duties might be adjusted to reduce or eliminate the likelihood that his or her integrity would be questioned.*

Conflicts of Commitment & Divided Loyalties. A conflict of commitment is a situation in which "outside activities . . . distract the employee from one or more of his or her employer's primary interests."⁹ Conflicts of commitment may arise out of time constraints or competing loyalties or responsibilities.^{9,10,11,12} A conflict of commitment can exist independently of a financial conflict of interest, although conflicts of commitment often accompany relationships that give rise to financial conflicts. Such situations of overlapping conflict deepen overall ethical concern about the relationships in question.

A practicing health care professional who enters into paid relationships with pharmaceutical companies "agrees to use his or her professional capabilities to further the agenda of a third party, in return for an immediate or prospective gain."¹³ Having multiple obligations is not necessarily problematic, until and unless an individual's competing obligations give rise to ambiguous, or, at the extreme, divided loyalties that place irreconcilable demands on him or her.¹⁴ The ethical significance of conflicts of commitment may be most readily apparent when a professional must serve competing obligations at one and the same time—for example, the specific needs of an individual patient and the overall goals of a managed care organization.¹⁴ But conflicts of commitment may also be ethically problematic when competing obligations do not overlap in time, a situation recognized in many university policies governing faculty conflicts of interest and outside activities,^{10,11,12,13} as well as federal regulations (5 CFR 2635.705(a)).

* We draw on these exemption categories here only for illustration. VA practitioners should be aware that formal review by Regional Counsel or the Office of General Counsel is required to determine whether an exemption is necessary in any specific case in which a practitioner engages in outside activities with industry.

There are no clear, specific, objective standards for determining when multiple loyalties create ethically problematic conflicts of commitment. But we can characterize in a very general way the kind of moral intuitions at work. For example, we might assess the relative similarity or “closeness in kind” of the competing activities and obligations: The more consonant with core professional activities, the less problematic a competing activity or obligation is likely to be judged. Many people would find it less problematic if a health care professional devoted time to caring for indigent patients, even if that sometimes adversely affected the individual’s relationships with other patients and colleagues, than if the professional devoted time to lecturing on behalf of a pharmaceutical company (especially if that adversely affected primary professional relationships). Such activities are likely to be the more troubling the more closely they are linked to the sponsor’s marketing efforts.*

We might also employ a broad principle of “proportionality” in thinking about how time commitments in multiple relationships may be ethically problematic. Generally speaking, if the time a health care professional spends on secondary activities (in the example above, caring for indigent patients) becomes “too great” relative to the amount of time he or she devotes to his or her primary activity (caring for patients in his or her usual practice), our moral judgment about the appropriateness of the ongoing multiple obligations might change. We might not be able to state the reasons behind those judgments in the form of clear, specific thresholds, but we may be able to agree broadly that at some point a clinician’s relative time commitment to secondary activities would lead most of us to question where his or her loyalties really lie. Thus some university policies explicitly restrict the amount of time a (full-time) faculty member may devote to outside activities.¹³

Integrity & Professionalism. Compensated relationships with industry also carry implications for practitioners’ integrity and professionalism. When health care professionals provide services to pharmaceutical companies in exchange for payment, they lend not only their technical expertise but also their professional reputations and integrity to the activities in which they participate as “key opinion leaders” (KOLs). Whether or not health care professionals fully appreciate the point, the pharmaceutical industry is quite clear about the goals of engaging them in these relationships. As one speakers’ agency puts it, “A top-flight speakers bureau generates important grassroots support for a marketer’s educational initiatives.”¹⁵

Of course, it is just those professionals who are most highly regarded by their peers—individuals who have outstanding reputations as knowledgeable practitioners and researchers—who are most sought after as speakers and advisors. Their value to pharmaceutical companies ultimately rests on professional (and public) belief in their objectivity and integrity: “KOLs must maintain their credibility and integrity in order to have maximum market impact.”¹⁶ Given the ways in which relationships with industry can bias clinicians’ judgment, maintaining that objectivity may be extremely difficult.

Speaking or consulting on behalf of one or several companies carries implications for peer relationships and the perceived professionalism and integrity of medicine overall as well. As we have seen, compensated relationships risk compromising health care professionals’ adherence to professional norms of objectivity and faithfulness to patient care, even without their awareness, and

* Admittedly, it can be difficult to draw a bright line between ethically problematic conflicts of commitment and failure to meet performance standards expected of an employee. For example, a clinician who worked full time for a health care organization and who repeatedly missed or rescheduled patient appointments in order to accommodate the demands of a pharmaceutical consulting agreement would likely be subject to disciplinary action as well as ethical criticism.

thus threaten individual integrity.¹⁷ When practitioners accept the existence of such arrangements uncritically, the integrity of medicine as a profession is threatened.

Undermining Patient & Public Trust. Because health care professionals' relationships with patients are fiduciary relationships, practitioners' primary commitments must be to their patients. Health care professionals must put patients' interests ahead of their own, explain the reasoning behind the treatment recommendations they make, and be candid with patients about influences on their decision making, including relationships with third parties.¹ Conflicts of interest and/or commitment threaten the trust on which these fiduciary relationships are based. Evidence indicates that patients are troubled to learn that health care professionals accept gifts from the pharmaceutical industry.^{18, 19, 20} Although the question has not been studied empirically, we might expect that patients would also be distressed to learn that health care professionals participated in marketing drug company products.

Concerns about sustaining patient and public trust take on additional importance for VA practitioners. As public servants, health care professionals in the VA system have compelling obligations to uphold the public trust. Also, VA practitioners serve a special patient population—not only have those who come to VA for health care served their country as members of the armed forces, often they are more vulnerable and more disadvantaged than are patients who seek treatment in the private sector.²¹ From the standpoint of the public's perspective, avoiding the appearance of conflict of interest or commitment is as important as avoiding actual conflict.

What Potential Benefits Can Compensated Relationships Offer?

Many argue that despite such ethical challenges, compensated relationships with industry can offer benefits to practitioners, patients, and health care organizations. Outside professional activities such as consulting, some argue, can enable health care professionals to broaden their perspectives and bring new insights to their own work, potentially benefiting patients and health care institutions. Outside activities can also enhance professionals' satisfaction, enable them to stay competitive in their fields, and, of course, enhance their incomes when they receive compensation for work beyond their primary employment.^{9, 13} For health care organizations, permitting staff to accept compensation from industry for outside professional activities may help to promote a positive atmosphere of innovation and collaboration. Being able to interact with diverse colleagues may encourage creative exchanges that enhance the professional workplace and practice. The NIH panel, for example, considered that relationships with industry help NIH fulfill its public mission by increasing the quality and productivity of its research programs.^{9*} In the realm of patient care, clinicians who serve as consultants with industry, for example, will be exposed to leading-edge technologies, perspectives, and skills that may translate into enhanced care for their own patients and potentially diffuse into colleagues' practice as well.

And the opportunity to participate in outside professional activities can be an important consideration for highly skilled individuals—i.e., just the individuals health care institutions most want to recruit and retain. Recruiting and retaining highly qualified professionals can be especially

* Participants in a recent qualitative study of the effects of relationships between academia and industry felt that such relationships offered broad benefits for their institutions, including interdisciplinary educational programs and learning experiences that would not otherwise have been available.²²

challenging for health care institutions in the public sector, where compensation may not be competitive with that available in the private sector—or even academic medicine, where salaries often lag well behind private practice. Disparities between VA practitioners and their academic counterparts prompted the Under Secretary for Health to recommend congressional approval to adjust pay rates for health care professionals employed by VHA.^{23*} While the annual salaries of general internists in VA are largely comparable to those of peers in academic medicine, the picture can be quite different for higher-paying specialties. For example, based on 2003 data, a full-time cardiologist in VA earned anywhere from \$20,000 to \$75,000 less in annual salary than his or her academic counterpart at the assistant professor level.[†]

Salary differences by themselves, of course, aren't evidence that practitioners in VA are any more likely to engage in compensated relationships with pharmaceutical companies than are practitioners elsewhere. And they don't tell us why health care professionals do or don't accept employment with VA. But they do describe the kind of environment in which the opportunity to supplement salary through compensated outside professional activities may be attractive, as, indeed, was noted by the NIH's Blue Ribbon Panel on Conflict of Interest Policies.⁹

Professional, Ethical & Legal Standards

Health care professionals look to several sources for ethical guidance in their relationships with industry, including the professional medical community, academia, and industry itself. In addition, practitioners should be aware of the legal implications of such relationships.

Ethical Standards in the Professional Community. To date in the professional medical community, concern about relationships between health care professionals and the pharmaceutical industry has focused on gift relationships and on financial conflicts of interest in research. The American Medical Association, for example, addresses gifts, but not consulting relationships,^{24,25} while the American Society of Hospital Pharmacists makes only passing reference to paid consulting or speaking arrangements.²⁶ The American College of Physicians notes only that “[l]ike gifts, financial relationships between physicians and industry can jeopardize professional objectivity,” and recommends that physicians “guard against conflicts of interest when invited to consult or speak on behalf of a company”; refuse to accept commissions for ghost-written articles, editorials, or reviews; and disclose their relationships to audiences and editors.²⁰

Ethical Standards in Academic Medicine. In the academic setting, the potential for financial conflict of interest is receiving considerable attention, and policies on faculty conflict of interest promulgated by academic medical institutions also offer standards of conduct for health care professionals. Conflict of interest management strategies, including disclosure, are prominent among university policies. The University of Southern California, for example, requires that faculty members disclose conflicts of interest to their department chairs or deans, who will then take

* Public Law 108-445, the Department of Veterans Affairs Health Care Personnel Enhancement Act of 2004, which will take effect in January 2006, gives the Secretary of Veterans Affairs authority to adjust salaries. It remains to be seen, however, whether the salary gap will narrow in the future.

† Comparisons based on data available in VA Office of Human Resource Management Workforce Information Systems Team, September 2003 Title 38 Reports, and Association of American Medical Colleges, Report on Medical School Faculty Salaries, 2002–2003.

appropriate action to manage or eliminate the conflict, including ongoing monitoring.¹² University of Southern California policy requires supervisors to distinguish activities that may be permitted “as is” (because they do not, in fact, involve a conflict of interest), permitted contingent on appropriate management of the apparent or actual conflict, or prohibited. With respect specifically to outside consulting, the policy prohibits full-time faculty from devoting more than 39 days per academic year to consulting activities.

Stanford University similarly requires that faculty disclose to university officials “significant financial interests,” defined as greater than 0.5 percent equity interest or \$100,000 (direct) ownership interest, and restricts the amount of time full-time faculty may devote to outside consulting activities to 13 days or 130 hours per academic quarter.¹⁰ Faculty must annually certify to their deans compliance with university policy regarding conflicts of commitment and interest. With respect to consulting arrangements, whenever there is uncertainty about the propriety of a relationship, Stanford’s policy mandates that “it is the faculty member’s obligation to obtain prior consent from the appropriate University officer.”¹³ Similar requirements are in place at Vanderbilt,¹¹ Michigan State,²⁷ and other academic medical institutions.

Ethical Standards in the Pharmaceutical Industry. The pharmaceutical industry, for its part, has addressed compensated relationships in some detail. The voluntary code of ethics promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA) permits member companies to engage physicians in consulting arrangements under the following conditions: (1) the services to be provided are clearly identified in advance and specified in a written contract; (2) selection of consultants is based on criteria directly related to the identified purpose and made by persons qualified to assess consultants’ expertise; (3) arrangements are made with only as many consultants as are “reasonably necessary” to achieve the purpose; (4) appropriate records are kept; and (5) the venue and circumstances of meetings are “conducive to consulting services.”²⁸ A substantially similar code to govern compensated relationships between health care professionals and manufacturers of medical technologies was adopted by the Advanced Medical Technology Association (AdvaMed) in September 2003.²⁹

Legal Standards. In addition to ethical concerns about compensated relationships between health care professionals and industry, there are legal considerations. Health care professionals in situations of conflict of interest face both possible criminal and administrative sanctions. Conflict of interest law (18 U.S.C. 208) prohibits VA employees, including practitioners, from participating in government matters that affect the interests of their outside employers or their equity interests in pharmaceutical companies or medical manufacturers. Professionals must seek legal advice to determine whether any particular relationship in fact meets regulatory criteria for exemption (5 CFR 2640.301(b)(1)–(6)).

VA practitioners must also adhere to the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR Part 2635). They have legal obligations not to engage in financial transactions that conflict with the conscientious performance of their duties; not to use their public office for private gain; not to give preferential treatment to any private individual or organization; and to refrain from “outside employment or activities, including seeking or negotiating for employment, that conflict with official government duties and responsibilities.”^{9, 30, 31} Government ethics rules effectively prohibit practitioners who serve on formulary committees, for example, from participating in decisions regarding products of manufacturers with whom they have financial ties.

We strongly urge individuals who engage in outside activities and compensated relationships with pharmaceutical companies and/or medical manufacturers to seek guidance from their local Regional Counsel or the Office of General Counsel. We remind VA health care professionals that the appearance of conflict of interest or inappropriate behavior can be highly problematic even when there has been no clear violation of law or regulation.

Managing Conflict-Creating Compensated Relationships

Obviously, health care professionals should avoid conflicts of interest or compensated relationships that violate legal prohibitions. But law and regulation don't fully address our central concern. They establish a floor of acceptable conduct for any federal employee, but they are silent about the unique tensions that compensated relationships with industry can create for health care professionals. And they offer no guidance for how practitioners and health care organizations respond when a relationship that is legally permissible is nonetheless ethically problematic.

Responses range from prohibiting compensated relationships with industry entirely through a variety of strategies for monitoring and managing the conflicts these relationships create. Prohibiting such compensated relationships across the board offers a certain ethical clarity and has the virtue of administrative simplicity. But blanket prohibition is a blunt instrument that fails to distinguish appropriately between individuals who have decision-making authority over what treatments are offered to patients (e.g., physicians or advanced practice nurses) and those who do not have such authority (e.g., intake clerks). Moreover, the clarity and simplicity of prohibiting all conflict-creating relationships would come at the cost of forgoing the potential benefits of such relationships.*

Short of blanket prohibition, health care institutions could require formal reporting, evaluation, and approval of conflict-creating relationships, and impose strategies of varying stringency for managing relationships that are permitted to go forward. To be effective, such approaches must provide clear guidance about which potentially conflict-creating relationships must be reported and to whom, and how relationships should be managed to mitigate conflicts. The conceptual and administrative challenges can be considerable.

Which conflict-creating relationships should be reported? Institutions might choose to require that certain categories of staff report all compensated relationships with industry, for example, all employees who recommend or prescribe medication. Within VA, senior leaders are, of course, already required to disclose financial holdings annually. But these general disclosures are not specifically directed toward identifying the particular relationships that concern us here. Nor do these disclosures necessarily trigger specific strategies for managing potential conflicts in the arena of clinical care, though they may. For example, if a medical center director had a position with an affiliated medical school, he or she would have to recuse from any matters having a direct and predictable effect on the affiliate, such as sharing agreements for clinical services.

Institutions might also set threshold criteria for when staff members must report such relationships, such as establishing a *de minimis* level of compensation above which reporting is

*Further, implementing a blanket prohibition could require that VA request the Office of Government Ethics to promulgate additional supplemental regulations authorizing the Department to take such action. Cp. "Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services" published in the February 3, 2005 Federal Register at pages 5543–65.

required, as many university conflict of interest policies do. Unfortunately, there isn't wide agreement as to what amount of compensation should trigger reporting. Northwestern University and Vanderbilt University, for example, require faculty to report relationships when the income or expected income exceeds \$10,000 per year;^{11,32} other institutions, like Johns Hopkins, place the de minimis at \$25,000.³³ Still others, such as Harvard, include level of ownership interest in the company with whom the faculty member has a conflict-creating relationship.³⁴ The NIH Blue Ribbon panel, meanwhile, proposed setting a reporting threshold at 50 percent of salary (25% for any single source of compensation).⁹ In comparison, federal regulation sets a \$200 reporting threshold, but only for employees who hold senior executive positions—i.e., above GS-15 or the equivalent (5 CFR 2634.302(a), 907(a)).

The amount of time spent on outside activities can also trigger a reporting requirement at a certain threshold. For example, the University of Texas requires faculty members to report outside commitments that exceed 15 percent of their total professional effort,³⁵ while Johns Hopkins requires faculty to report their outside activities whenever the aggregate time commitment for all such activities exceeds 26 days per year.³³

Ultimately, setting any specific threshold for reporting is essentially an arbitrary decision. Yet how reporting requirements are defined will have significant implications for how administratively burdensome those requirements are for the individuals affected and for the institution.

Defining clear, fair reporting requirements is only the first step in managing conflict-creating relationships, however. Health care organizations must also make clear to whom within the organization such relationships should be reported and how designated institutional conflict managers are to fulfill their responsibilities.

To whom should conflict-creating relationships be reported? Policies at academic institutions vary considerably with regard to the logistics of reporting compensated relationships/conflicts of interest. Some, such as Johns Hopkins University, require that all financial interests be reported annually to designated institutional officials.^{12, 32, 33} Some—for example, the University of Texas—direct faculty to report potential conflicts as they arise to their immediate supervisors, department heads, or deans.^{10, 11, 35} And some, like Harvard, establish standing committees to oversee the process of reporting, review specific cases conflicts of interest or commitment, and establish protocols for managing permitted relationships.³⁴

How should conflict-creating relationships be managed? Because each conflict-creating situation is different, managing conflicts of interest inevitably involves making determinations on a case-by-case basis. However, case-by-case determinations can be problematic, both because they are open to challenge for being arbitrary, and because they are time-consuming. For these reasons, it would be useful for institutions to establish consistent criteria to ensure fairness in the decision-making process and/or reduce the number of individualized determinations that need to be made. Thus they might provide guidance for determining when the terms of a conflict-creating relationship should be revised—for example, by reducing the level of allowable compensation or amount of time involved; or they might define conditions under which relationships should be subject to ongoing monitoring by a designated institutional officer or other third party.

Unfortunately, there are few models available of clear and effective criteria for managing conflict-creating relationships. This is not to say that it is impossible to develop such criteria. It is only to underscore the difficulties involved in doing so. For VA, the challenges of managing conflict-creating relationships are compounded by the particular regulatory environment in which

the Department operates as an agency of the federal government, such as constraints on its authority to restrict the outside activities of its employees.

Recommendations

Existing conflict of interest law and Executive Branch standards of conduct set basic parameters for VA practitioners' relationships with industry. However, as health care professionals VA practitioners have ethical obligations to patients above and beyond their duties as public employees. We find ethical arguments for limiting compensated relationships with the pharmaceutical industry to be compelling. Public outrage in the wake of discoveries of widespread financial conflict of interest and apparent violation of institutional policy within the National Institutes of Health^{3, 4, 36, 37} makes it all the more imperative that VA as a public entity take a firm stand regarding compensated relationships with pharmaceutical companies and provide clear guidance for its health care professionals and managers. The National Ethics Committee therefore recommends that:

(1) VHA develop national policy with respect to compensated, conflict-creating relationships between VA health care professionals and industry.

Many, often diverging, interests are at stake in establishing institutional policy regarding conflict of interest. The policy development process must look to the complex practical and legal considerations of implementing the final product in an even-handed way that also minimizes institutional and individual burdens. Not least of these considerations is that implementing standards that go beyond those already in place for employees of the Executive Branch and that apply to practitioners who are not Title 38 employees will likely require VA, like NIH, to issue supplemental standards of conduct after consulting with the Office of Government Ethics. In light of its ethical analysis and the institutional challenges it has identified, the NEC further recommends that:

(2) The Under Secretary for Health appoint a national task force to develop such a policy with representation from key stakeholders, including the Office of Patient Care Services (including representation from the Office of Pharmacy Benefits Management), Office of Nursing Services, Office of Human Resource Management, Office of General Counsel, Office of Research and Development, Office of Quality and Performance, National Center for Ethics in Health Care, and other program and field-based offices the Under Secretary for Health identifies as appropriate participants.

In the NEC's view, prohibiting all compensated relationships between VA health care professionals and industry would be too draconian a response to potential harms. Prohibiting such relationships entirely would unduly restrict the activities of staff outside their VA tours of duty and deny the organization the benefits that may flow from such relationships—notably the ability to recruit and retain excellent staff and to preserve high staff morale.

Thus the Committee urges a more moderate course. We recommend that health care professionals in VA who are involved in activities that can have a significant effect on the range of treatments available to patients be required to report compensated relationships with industry. This would include practitioners who are involved in institutional activities, such as development of clinical guidelines, as well as those who are involved in treatment decisions for individual patients. National policy governing practitioners' compensated relationships with industry must provide guidance for assessing and managing potential conflicts of interest. Ethically appropriate policy will:

(3) Establish fair, effective, administratively manageable mechanism(s) for reporting compensated relationships with industry.

For example, by defining specific classes of health care professionals who must report such relationships (such as extending requirements for confidential financial disclosure currently applicable to chiefs of staff or members of VISN formulary committees to additional categories of staff) and/or establishing a de minimis monetary threshold for reporting.

(4) Set out clear criteria for identifying which conflict-creating compensated professional relationships (if any) will be:

- (a) prohibited entirely;
- (b) permitted subject to ongoing oversight;
- (c) permitted without oversight.

Examples of possible criteria include: the likelihood that the relationship will influence the professional's judgment, the likelihood and seriousness of potential harm to patients and/or the institution, the scope of the professional's discretionary authority, the nature of the proposed relationship or activity (e.g., marketing vs. education, or service as an executive with the entity in question), and/or the nature of the compensation (e.g., stock options or other equity interest).

(5) Provide guidance regarding appropriate strategies for managing conflict in permitted relationships.

For example, revising the terms of the relationship to reduce the conflict (less money, less time, providing a different service, etc.), having the professional withdraw from decisions implicating the secondary interest, and/or third-party monitoring of the relationship.

(6) Define clearly:

- (a) In what situations a particular strategy/combination of strategies should be employed to manage conflict, and/or how a management plan is to be developed;
- (b) Who is responsible for assuring that an identified conflict is appropriately managed.

(7) Establishing ongoing education about conflicts of interest.

Like any other policy, guidance regarding compensated relationships with industry must reinforce awareness of employees' duties to uphold applicable federal law and must apply consistently to all health care professionals and trainees who care for patients under VHA authority. Part-time employees should be held to proportionately rigorous standards of conduct.

Conclusion

Care for VA patients is provided by a diverse staff of full-time, part-time, and contract health care professionals, many of whom have concurrent professional affiliations with academic institutions. The National Ethics Committee recognizes that these complex arrangements pose significant conceptual and practical challenges. However, such difficulties do not absolve us of the

obligation to make every effort to define expectations for conduct that honor public trust and VA's mission. As a public entity, and as the training ground for a significant proportion of health care professionals in the United States, VA has strong obligations to uphold public trust and assure that its health care professionals put the interests of patients first and avoid conduct that creates actual or perceived conflicts of interest or commitment. We must act to assure that relationships between VA health care professionals and industry do not compromise, or appear to compromise, the welfare of VA patients; the objectivity, professionalism, or rights of VA practitioners; or the integrity and reputation of the Department.

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