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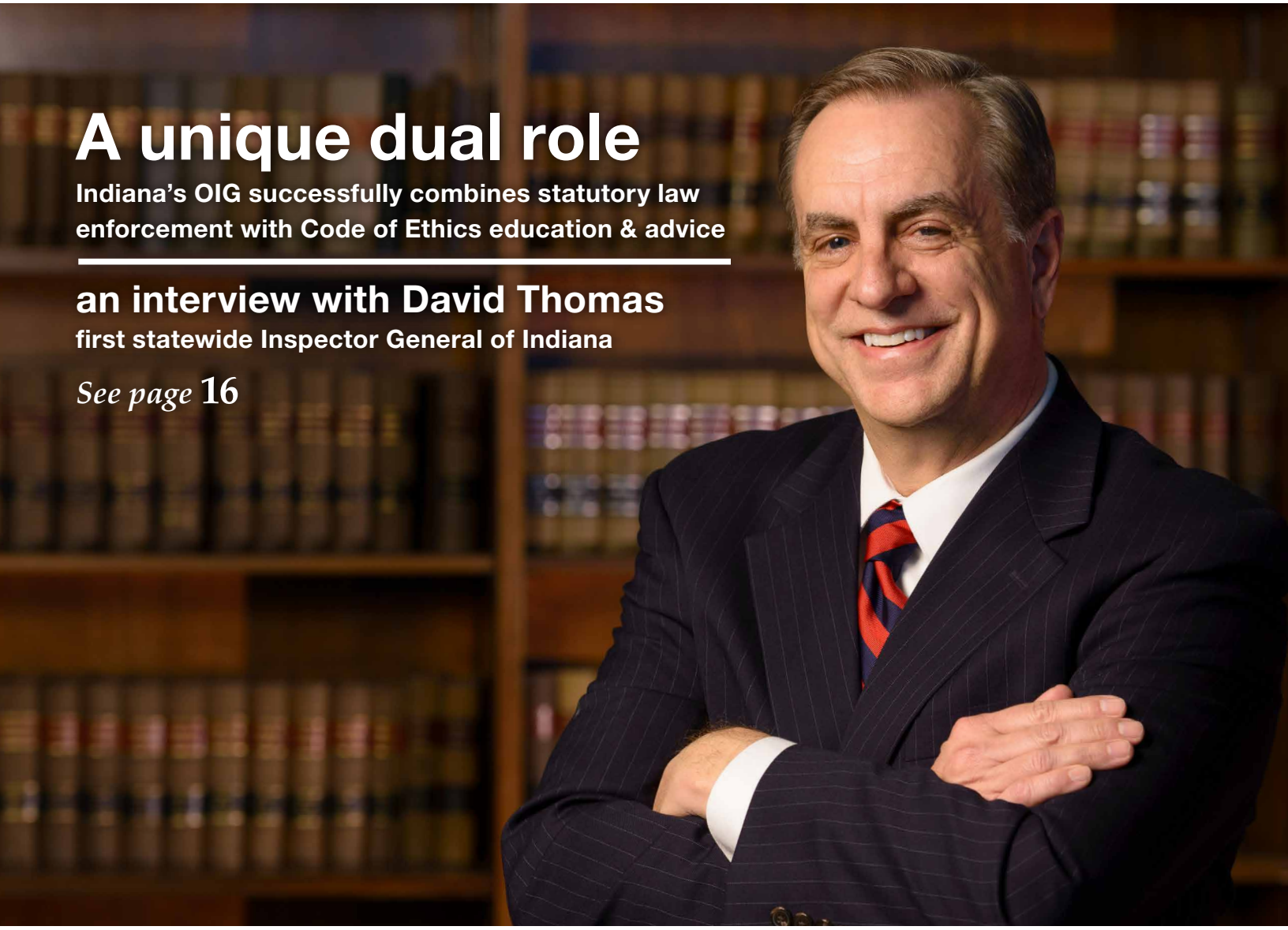

A unique dual role

Indiana's OIG successfully combines statutory law enforcement with Code of Ethics education & advice

an interview with David Thomas

first statewide Inspector General of Indiana

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by William Sacks, MBA

Implementing "best practice" conflict-of-interest policies: Observations on the current state

» Recently enacted NIH regulations, and the pending implementation of the "Physician Payment Sunshine" database are forcing academic medical centers (AMCs) to revisit their conflict-of-interest policies.

» The Pew Charitable Trust has proposed 15 best practices for management of conflicts of interest.

» Some recommendations have been widely accepted by AMCs, but others have met resistance by faculty and voluntary medical staff.

» AMCs face an evolving political and regulatory landscape as they refine their policies to eliminate bias from their research, teaching, and clinical enterprises.

» Numerous resources are available to support the development of new policies or the reevaluation of old policies in light of newly published research on conflict of interest.

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On December 10, 2013, the Pew Charitable Trusts released an important document titled "Conflicts-of-Interest Policies for Academic Medical Centers: Recommendations for Best Practices."[1] This document was developed by an expert task force convened by Pew in 2012 to assist academic medical centers (AMCs) in developing their conflict-of-interest (COI) policies.

Sacks

The task force reviewed literature and consulted experts with a goal of updating recommendations developed in 2008 by the American Association of Medical Colleges. The document presents recommendations in 15 areas that would "protect the integrity of education and training and the practice of medicine within the academic medical center while not standing as an impediment to research and scientific inquiry."

For each of its 15 recommendations, the authors provide case studies or sample policies from various medical centers that can act as models or, at least, as the basis for policy discussions. Some of these recommendations (e.g., prohibitions on the ghostwriting of journal articles or presentations) have already been adopted by most AMCs, but others (e.g., prohibitions on attending educational events sponsored by industry) are still the exception rather than the rule.

This article will discuss each of the 15 recommendations in turn. It will provide some insight on where that recommendation stands on the continuum of AMC acceptance, and why implementing some will be a long, hard slog. The "level of acceptance" rating is my own, based on my experience with dozens of medical

schools and hundreds of academic affiliated hospitals around the country. In some cases, I have also taken into account ratings compiled by the American Medical Student Association in their AMSA PharmFree Scorecard 2013.[2]

The best practice recommendations

The numbered recommendations below are taken from the Pew report's "Overview" section. The report itself provides more detail and a more nuanced discussion on each item.

1. **Acceptance of gifts and meals: No gifts or meals of any value should be accepted by clinical faculty members and staff, medical students, residents, clinical fellows, or other clinical trainees from the pharmaceutical, biotechnology, medical device, or medical diagnostics industries or their sales representatives.**

Over the last few years, more and more academic institutions and non-academic health systems have adopted the no-gift policy. While many still allow "nominal" gifts (e.g., gifts worth up to $10), there is a growing recognition that even small gifts have the potential to affect the behavior of physicians and other providers[3] and, on the non-clinical side, anyone with purchasing authority. Even more important, for some, is the recognition that accepting gifts *looks* bad. Patients are becoming more aware and have taken note of the office "tchotchkes" with pharmaceutical logos and the salesmen dispensing pizza to the office staff.

The availability of the Physician Payment Sunshine Act database in 2014 should serve as the death knell for the provision of outright gifts, at least at AMCs. ***(Level of acceptance: 8 out of 10)***

2. **Disclosing conflicts of interest: Faculty should be required to disclose to their institutions all industry relationships that relate to their academic activities in teaching, research, patient care, and institutional service.**

Virtually all academic medical centers, by definition, are involved in clinical research, and most (perhaps all) receive some level of funding from the Public Health Service and the National Institutes of Health (NIH). NIH conflict-of-interest rules, which were updated in 2012,[4] require any institution receiving such funding to have mechanisms and processes in place to enable researchers to disclose "significant financial interests" (SFI) related to their institutional activities. These institutions must then identify, manage, and report to the government on any researcher's "financial conflicts of interest" (FCOI) pertaining to any federally funded grant.

As such, all AMC's have a process in place to manage COI disclosures. These processes range from paper-based surveys and Excel® spreadsheets, to comprehensive online relational database survey tools. A few AMCs require disclosures only as they relate to federally funded research, but many more require disclosures pertaining to any institutional responsibilities, including research, teaching, or clinical activities. ***(Level of acceptance: 8 out of 10)***

3. **Industry-funded speaking: Faculty should not accept industry funding for speaking engagements directed toward other faculty, medical students, trainees, patients, community physicians, health professionals, or the public.**

A relatively small number of AMCs have enacted stringent policies to limit industry funding of speaking engagements, particularly for non-employed faculty physicians. In the 2013 AMSA PharmFree scorecard, only 43 of more than 150 entities received the most favorable rating on the topic of speaking

fees. Many institutions are reviewing their policies in this area, but there are still powerful vested interests resisting changes that might curtail outside income to physicians. ***(Level of acceptance: 4 out of 10)***

4. **Continuing medical education: In general, continuing medical education should not be supported by industry.**

Although industry funding of CME has gradually declined from 46% of funding in 2007 to 27% in 2012 (according to the Pew report), studies indicate that industry funding of CME "tends to bias topic choices and content in favor of the sponsors' products and therapeutic areas." The task force recommends that AMCs go beyond the recommendations of the Accreditation Council for Continuing Medical Education (ACCME) "Standards for Commercial Support" to prohibit industry funding.

The ACCME disputes the Pew assertion that research definitively supports its conclusions, and believes that its published standards, which were implemented in 1992 and updated in 2004, provide the guidance needed to enable AMCs to eliminate the feared "bias" while allowing AMCs to take advantage of an important source of educational funding.[5] ***(Level of acceptance: 5 out of 10)***

5. **Attendance at industry-sponsored lectures and meetings: Faculty, students, and trainees should not attend promotional or educational events that are supported directly by industry.**

According to the 2013 AMSA PharmFree Scorecard, the large majority of medical schools have policies on the books to limit faculty or student attendance at events that are not primarily for education and are directly funded by industry. Many non-employed faculty and community physicians, however, still welcome paid industry representatives (often fellow physicians) into their offices and clinics to provide information on pharmaceutical or mechanical therapeutics. ***(Level of acceptance: full-time faculty: 7 out of 10; voluntary faculty and community physicians: 4 out of 10)***

6. **Pharmaceutical sales representative presence in academic medical centers: Pharmaceutical sales representatives should not be allowed access to any faculty, students, or trainees in academic medical centers or affiliated entities.**

Only three medical schools in the country received the top grade on the AMSA scorecard, by prohibiting virtually any contact with pharmaceutical industry sales representatives. Most schools allowed contact with some restrictions, such as requiring registration of sales reps, prohibiting sales rep access to patient care areas, and requiring that pharmaceutical reps only have access to faculty or others by appointment. Although the number of reps with their black sample cases has diminished over the last several years, they are still easy to find wandering the halls of most academic practices, and they are ubiquitous in the community setting. ***(Level of acceptance: 4 out of 10)***

7. **Medical device representative presence in academic medical centers: The access of medical device representatives to patient care areas should be limited to in-service training and technical assistance on devices and other equipment already purchased and then only by appointment and with disclosure to and consent from the patients who would be involved.**

There is recognition in the Pew report of the distinction between sales representatives

from pharmaceutical companies and those from medical device manufacturers, and of the fact that medical device representatives (or "industry-employed allied professionals," as they are referred to in one institution's policy) often provide valuable support during and after surgery. As such, this recommendation is easier for many institutions to accommodate. In spite of the fact that vendor access to patient care areas has been increasingly limited, medical device reps have maintained a special status by assisting in the delivery of quality patient care.
(Level of acceptance: 7 out of 10)

8. **Curriculum on conflict of interest: Conflict-of-interest education should be required for all medical students, residents, clinical fellows, and teaching faculty.**

In 2012, as part of the update to the NIH rules on conflicts of interest, training related to financial conflicts of interest (FCOI) was made mandatory for the first time. The rules require that FCOI training be provided to researchers at least once every four years. As such, most medical schools and AMCs that receive federal funding for research have mechanisms to provide some level of training on the topic.

Looking beyond the researchers themselves, and into medical school curriculum, according to the AMSA survey data, some medical schools are training students to understand institutional conflict-of-interest policies and to recognize how industry promotion can influence clinical judgment. Many, however, are addressing conflicts of interest in a more limited way (e.g., by focusing on institutional policies rather than the effects of COI) and some schools provide no training in their curriculum at all.
(Level of acceptance: faculty: 9 out of 10; students: 5 out of 10)

9. **Extension of institutional conflict-of-interest policies to community educational settings: Conflict-of-interest policies established by academic medical centers should apply to all faculty members regardless of the nature of their relationship to the institution—paid or voluntary, full time or part time, on-site or off-site—and to affiliated institutions participating in the academic medical center's educational and training programs.**

The politics within and around AMCs are famously complex and fraught with sensitive issues, one being the relationship between full-time and voluntary faculty. Many AMCs, especially those in the top tier, have enough leverage with voluntary faculty (as a result of the prestige and social benefits they impart) to require compliance with all COI policies and procedures. Other AMCs, particularly those dependent on the clinical activities of busy surgeons and other heavy admitters, are hard pressed to impose what those physicians may consider onerous compliance requirements. Although it may not be difficult to require compliance with mandated COI regulations (such as NIH or Internal Revenue Service requirements), getting agreement from community-based physicians on other COI policies (such as limiting interactions with pharmaceutical sales reps or imposing limits on attending industry-sponsored events) can be problematic.
(Level of acceptance: 4 out of 10)

10. **Industry-supported clinical fellowships: In general, clinical fellows, residents, and medical students may not accept industry-sponsored fellowships earmarked specifically for clinical training but may compete for industry fellowships awarded for scientific training.**

The Pew report recommends that medical schools and AMCs not accept industry-sponsored fellowships for clinical training, but may accept funding for scientific training under certain circumstances.

According to the AMSA scorecard, a significant majority of medical schools have enacted policies that either prevent industry from earmarking or awarding funds to support the training of particular individuals, or mandate institutional review of the giving of funds. Although these policies do not coincide completely with the Pew recommendations, they are seen by many to be a reasonable accommodation to balance COI concerns with the desire to take advantage of a valuable source of educational funding. ***(Level of acceptance: 7 out of 10)***

11. Ghostwriting and honorary authorship: Academic medical faculty and trainees should follow the International Committee of Medical Journal Editors standards for authorship and contributorship. Ghostwriting and honorary authorship are strictly prohibited.

Senator Charles Grassley brought attention to the issue of ghostwriting (i.e., the practice of pharmaceutical and other companies drafting medical journal articles to be published in the names of prominent physicians) in public hearings in 2008, and he published a Staff Report on the topic in 2010.[6] Even at the time that report was published, there was wide recognition of the negative impact ghostwriting had on the real and perceived integrity of medical journals.

The International Committee of Medical Journal Editors published editorial guidelines pertaining to journal authors as early as 1997, and updated the sections related to potential conflicts of interest in 2001. The guidelines were further updated in 2003 and 2010,[7] and are now recognized as the authoritative guiding principles on the topic. This is perhaps the most well accepted recommendation of the 15 in the Pew report. Even so, there remains concern that companies funding research retain some degree of influence over which results get published, and which do not. ***(Level of acceptance: 9 out of 10)***

12. Consulting relationships for research and scientific activities: Faculty and trainees should be permitted to engage in consulting relationships with pharmaceutical and device companies about research and scientific matters.

This recommendation spells out something that is allowed, rather than prohibited, so acceptance is widespread. The collaboration between industry and academic medicine is important, and industry provides functions that are essential to the development of new drugs and other interventions.

The detailed recommendations in the Pew report suggest that these legitimate consulting arrangements be spelled out in written contracts with clear deliverables, and that compensation is of fair market value for comparable services to ensure that inappropriate payments are not disguised as consulting contracts. Most AMC conflict-of-interest policies require research faculty to report any consulting payments they receive on their annual Conflict of Interest Disclosure Forms ***(Level of acceptance: 9 out of 10)***

13. Consulting relationships for marketing (excluding scientific research and speaking): Academic medical faculty and trainees should be prohibited from engaging in consulting relationships that are solely or primarily for commercial marketing purposes.

The Pew report acknowledges that there can be a fine line between scientific and marketing consultations, but it nonetheless recommends that AMCs develop policies that prevent faculty from participating in activities where they are "…explicitly engaged in the creation or review of promotional material or participating in the development of marketing strategies."

Some medical schools have developed such policies, but there is a long way to go (according to the AMSA scorecard) to clearly define prohibited consulting activities, to communicate those prohibitions, and to change the culture of many institutions (particularly among affiliated community physicians) to eliminate this practice. ***(Level of acceptance: 6 out of 10)***

14. Pharmaceutical samples: An academic medical center should not accept samples unless it determines that there are compelling circumstances to do so. In these cases, it should implement mechanisms for accepting samples that prevent their use as marketing tools.

The acceptance and distribution of free pharmaceutical samples has historically been viewed as a way to give indigent patients access to the latest medications, but the practice has also been recognized (and criticized) as a very effective marketing technique on the part of pharmaceutical companies.

In countering common perceptions on the subject, the Pew report cites several studies which demonstrate that (1) samples are more likely to be given to affluent than poor patients,[8] and (2) patients who receive samples ultimately have higher out-of-pocket prescription expenditures than their counterparts who do not receive samples.[9] In addition, the AMSA scorecard refers to published studies which show that a substantial proportion of the $18 billion of free samples distributed by pharmaceutical companies are used by physicians, staff, and their families, representing a clear financial conflict of interest.

Despite this evidence, only 41 of more than 150 medical schools listed in the AMSA survey had model policies in effect pertaining to the acceptance and distribution of pharmaceutical samples, although many AMCs have taken steps to mitigate the potential influence of this ubiquitous pharmaceutical industry marketing effort. ***(Level of acceptance: 5 out of 10)***

15. Pharmacy and therapeutics committee: Ideally, voting members of these committees should not have a financial relationship with industry. In circumstances when this standard cannot be achieved, members with such relationships should be recused from any discussion of, or voting on, a related product, whether the product is manufactured by the company, is a competitor of that product, or is in the same class as that product. All committee members should disclose financial relationships with pharmaceutical and medical device companies, as should practitioners requesting changes or additions to the institution's formulary.

Given the myriad issues and policies discussed in the first 14 Pew Trust recommendations, it should be obvious that the individuals most intimately involved with—and in a position to influence—these issues have a special responsibility to avoid real, potential, or even perceived conflicts of interest. The final Pew recommendation singles out members of the Pharmacy and Therapeutics (P&T) committee for special scrutiny.

For many years, AMCs have recognized the special role that the P&T committee holds in managing the institution's fiduciary responsibility and the clinical reputation.

As such, a significant proportion of the AMCs listed in the AMSA scorecard have strong policies in place to ensure that the decisions of the P&T committee are made based on the best interests of the institution and are not unduly influenced by the financial or other considerations of members. ***(Level of acceptance: 7 out of 10)***

Conclusion

Academic organizations and their constituent medical centers have contributed greatly to the evolution of thought on the topic of conflicts of interest in medicine. The American Association of Medical Colleges has published, and continues to update, its recommendations on the topic. The Institute of Medicine Committee on Conflict of Interest in Medical Research, Education and Practice has published a white paper on the topic, as have other highly regarded associations and societies. The American Medical Student Association has contributed to the discussion with its PharmFree Scorecard.

The Pew Charitable Trusts, a non-profit public interest organization, has developed its own set of recommendations, which it presents as best practices in its December 2013 report. AMCs face many challenges in moving toward the ideal of eliminating all conflicts of interest in the practice, teaching, and research associated activities of medicine.

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