



Remarks as Prepared for Keynote Address Given by Daniel R. Levinson, Inspector General of the Department of Health & Human Services, to a Conference of the American Healthcare Lawyers Association  
January 21, 2010  
Washington, DC

Conflicts of Interest: Trust, but Verify

## I. Introduction

This conference, “Legal Issues Affecting Academic Medical Centers and Other Related Institutions,” is timely in that it focuses on a wide range of important issues currently undergoing debate that impacts researchers, teaching hospitals, academic medical centers (AMCs), and the Federal Government. In fact, just this week I read with interest the article on conflicts of interest (COI) published in American Healthcare Lawyers Association’s (AHLA) *Connections* by Dawn Crumel and Heidi Sorenson (an OIG alumna). I also had the pleasure of speaking with Professor Goldner of St. Louis University School of Law about his journal article on regulating COIs in research. I appreciate the opportunity to speak with you today about the work of the Office of Inspector General (OIG) regarding conflicts of interest.

My remarks today will focus on OIG work regarding COIs and the challenging aspect of managing, reducing, and eliminating conflicts under the current regulatory framework and system where reliance is placed primarily on individuals, researchers, and institutions.

The nature and amount of information that should be reported and disclosed, and where responsibility should be placed for reviewing and verifying the information, remains a constant subject of debate within the life-sciences community and the Federal Government.

Before I address the substance of OIG work in the area of COIs, I would like to provide some brief background about our office. The OIG is an independent unit within the Department of Health & Human Services (HHS) that is responsible for providing oversight to all agencies and programs within HHS and for reporting to the Secretary and to the Congress. Our nationwide workforce of approximately 1300 auditors, investigators, evaluators, and attorneys oversees the approximately 300 HHS programs with a total budget in excess of \$700 billion. Because of our funding mandate, our principal focus is the oversight of HHS’s two largest programs, Medicare and Medicaid.

However, we also devote many resources to conducting oversight activities in other vitally important public health programs, including those at the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC). We also respond to requests for investigations and reviews from members of Congress. Based on our reviews and investigations, we make recommendations to improve efficiency and to prevent fraud, waste, and abuse. In our role, we do not make policy, but rather provide

information to decisionmakers as to the operation of programs and how they can be improved or changed to maximize effectiveness.

## II. Background on Conflicts of Interest

First, I want to acknowledge that the vast majority of physicians and scientists are ethical and honest and committed to the welfare of their patients. AMCs play a special role in health care that is very different than other providers. First, AMCs are responsible for educating and training the next generation of physicians, nurses, and other types of health care workers. Second, AMCs serve their communities by providing uncompensated care to uninsured populations. Third, AMCs advance clinical care for the sickest patients. Fourth, AMCs advance basic science in pre-clinical research and participate in clinical trials to develop new technology. Additionally, and of great importance, AMCs are considered to be leaders in the sense that community hospitals follow the lead of AMCs.

These important roles and responsibilities bring challenges to institutions and researchers regarding potential COIs. Conflicts can arise in a variety of contexts: profit incentives to commercialize products that had successful clinical trials; questionable clinical trial results; corrupt data; purchase of drugs and devices based on commercial influence; and industry support for school, residency and continuing medical education (CME) programs. COIs can be subtle and often hard to detect. For instance, what may appear to be an appropriate arrangement between a researcher and a drug manufacturer may actually raise potential COI issues that could taint the results of a clinical trial.

The crux of the debate regarding systems for detecting and reporting potential COIs has centered on whether physicians, researchers, and institutions should be primarily responsible for reporting and managing COIs and the extent to which government regulation should place oversight and verification responsibility on Federal agencies.

If COIs are undetected or are disclosed and not appropriately dealt with, the result can be serious enough to damage reputations and raise public concern about the integrity of research and patient care. If undetected, the public may suffer numerous potential harms: people who volunteer in trials may be subjected to unnecessary risk or deprived of beneficial therapies, unsafe or ineffective drugs or devices may enter the US market, patients may receive inferior therapies when safer or more effective therapies are available, and the public may waste limited Medicare and Medicaid dollars to pay for this inappropriate treatment. As a result, it is important that systems be in place to ensure that the independence and integrity of health care providers and medical researchers are maintained.

## III. Players in the Debate Over Management of Conflicts of Interest

### A. Congress / Media

As you are well aware, over the past decade the oversight of COIs has received increasing attention in Congress, the media, and oversight entities including my office. In the early 2000s, Congressional committees (the House Committee on Energy and Commerce especially) held a

series of hearings dealing with COIs. Most of this attention focused on NIH intramural researchers and, to a lesser degree, extramural researchers. In response to the increased attention, the NIH Director established a Blue Ribbon Panel on COI policies to look at whether or not the COI policies for intramural research were sufficient to uphold agency standards and maintain public trust in NIH and its activities, among other things. The Panel found an extremely complex set of rules governing COIs at NIH. The Panel made 18 recommendations with its guiding principle being that NIH employees must avoid COIs incompatible with the proper exercise of their authority and the proper performance of their duties.

OIG, as well, has devoted attention to COIs and ethics matters within HHS. For example, OIG issued a report on how NIH handles allegations about employee activities that might be criminal or improper, which resulted in NIH adding new guidance to the NIH policy manual.

More recently, Congress has focused increased attention on extramural COIs. For example, Senators Grassley and Kohl have conducted oversight hearings and promoted legislation on COI topics. COI hearings before the Senate Special Committee on Aging have focused on the relationships between physicians and pharmaceutical and device manufacturers. Last year, Senators Grassley, Kohl, and Klobuchar introduced S-301, the Physician Payments Sunshine Act of 2009. The bill provides for transparency in the relationship between physicians and manufacturers of drugs, devices, biologicals, or medical supplies for which payment is made under Medicare, Medicaid, or CHIP. A similar bill was introduced in the House of Representatives in July 2009.

Moreover, the 2010 Omnibus Appropriations Act requires that the Secretary of HHS amend Federal regulations to strengthen government and institutional oversight of financial conflicts of interest by May 1, 2010.

OIG's body of work focused on COI issues is also receiving Congressional and media attention. For example, Representative Rosa DeLauro, Member of the House Appropriations subcommittee that funds CDC and NIH, reviewed a recent OIG report identifying limitations in CDC's oversight of the financial interests of Special Government Employees (I will be talking to you in more detail about this report), and she stated that the findings were concerning and that "the work of the CDC is too important to be tainted in any way." Over 300 news outlets reported on the report when it was issued.

## B. External Organizations

Respected organizations in the academic community are also continuing to debate the appropriate roles and responsibilities of institutions and the Federal Government when it comes to monitoring and managing COIs.

A common theme among all of the players in this debate is what information should be disclosed and who—individual, government or institution—should bear the responsibility for monitoring and managing potential COIs.

In April 2009, the Institute of Medicine (IOM) published a comprehensive report on COIs with the goal to examine COIs in medicine and provide recommendations for policy and best practices. The committee that drafted the report came up with a number of conclusions that are relevant in thinking about roles and responsibilities with respect to COIs. These conclusions include that the goals of COI policies in medicine are primarily to protect the integrity of professional judgment and to preserve public trust rather than to try to remediate bias or mistrust after they occur.

The disclosure of individual and institutional financial relationships is a critical but limited first step in the process of identifying and responding to COIs. COI policies and procedures can be strengthened by engaging physicians, researchers, and medical institutions in developing conflict of interest policies and consensus standards.

A range of supporting organizations—public and private—can promote the adoption and implementation of COI policies and help create a culture of accountability that sustains professional norms and public confidence in professional judgments.

Research on COIs and COI policies can provide a stronger evidence base for policy design and implementation—extremely relevant to our discussion today. If medical institutions do not act voluntarily to strengthen their COI policies and procedures, the pressure for external regulations is likely to increase.

The AHLA *Connections* article I referred to earlier, *Be Careful What You Ask for: NIH Request for Comments on Conflicts of Interest in Research*, also discusses the appropriate role for Government and institutions in managing COIs. The article concludes that “It is critical for AMCs to recognize that institutional conflicts of interest exist, to establish an environment of vigilance against the appearance of institutional conflicts of interest, to identify such conflicts in a timely manner and to manage such conflicts to ensure the impartiality of the research.”

Some institutions have taken a proactive approach with respect to COI policies and procedures in an effort to manage potential COIs and avoid or minimize additional government regulation. For instance, earlier this month it was announced that the owner of two research hospitals affiliated with the Harvard Medical School imposed restrictions on outside pay for two dozen senior officials who also sit on the board of pharmaceutical or biotechnology companies. And just last week, Stanford University announced plans to develop new CME programs for doctors that will be devoid of the drug industry influence that has often permeated such courses. Stanford received a \$3 million grant from Pfizer, and, according to the plan, Pfizer will have no say in how the grant dollars will be spent.

The goal of this new policy of transparency is to avoid activities such as pharmaceutical companies rewarding high-prescribing physicians by directing a CME provider to pay them as CME faculty, consultant, or members of a CME speakers bureau.

### C. The Department of Health & Human Services

Monitoring COIs continues to garner significant attention by HHS. In the 2009 HHS Agency Financial Report, my office continued to list Ethics Program Oversight and Enforcement,

including COI issues, as a Top Management Challenge. In response to all of the attention from Congress, the media, external organizations, and OIG work that I will discuss shortly, on May 8, 2009, HHS issued an Announcement of Proposed Rulemaking (APRM) to gather input from interested stakeholders regarding revisions to the Federal financial COI rules issued in 1995 (42 CFR Part 50, 45 CFR Part 94, “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors”).

The announcement recognized that relationships between the private sector and investigators have become more complex and that the collaborations “may generate an increased potential of investigators to hold financial interests in multiple sources which, if not reported and appropriately managed, reduced, or eliminated, could introduce bias into the conduct of their research.” NIH specifically requested comments regarding the expansion of the scope of the regulation and disclosure of interests; definition of “significant financial interest;” identification and management of COI by institutions; assurance of institutional compliance; provision of additional information to Federal officials by research institutions; and broadening of the regulations to address institutional COIs.

As most of you are likely aware, American Association of Medical Colleges responded to the APRM, noting, among other recommendations, that covered investigators should be required to report to institutions all of their external financial interests directly or indirectly related to their research responsibilities, regardless of amount, and institutions should be required to submit information on managed COIs that goes beyond current regulatory requirements; but it opposes routine disclosure to NIH of full management plans themselves, unless requested by NIH.

#### IV. OIG Reviews

Based on the work we have done, we believe that Federal rules pertaining to COI reporting by grantee institutions place significant reliance on grantees to self-disclose and self-verify that their actions comply with Federal laws. Current Federal regulations require grantees to report the existence of a conflicting interest—but not the details—and to assure that the interest has been managed. However, the same regulations require grantees to make information about all identified conflicts available to NIH, or HHS, upon request. This is why we have recommended that NIH use its current authority to request further information about reported COIs where basic information about the COI is missing and, at the same time, revise the current regulation to require grantees to report certain details to NIH about their reported COIs.

For example, we conducted two reviews of oversight and compliance with the COI regulation in 42 CFR Part 50, Subpart F, governing extramural research at NIH. In both reports, we found that COI reports received from grantees did not provide specific details about the nature or amount of the financial COIs. In our first report, we reviewed NIH’s monitoring of COI reports submitted by grantees. We found that 89 percent of the reports provided to NIH lacked information about the nature of the COI and how it was addressed. Based on our findings, we conducted a second study that examined the extent to which the grantees themselves handled COIs.

For the second study, we examined the nature of financial COIs reported by grantee institutions to NIH and the ways in which grantees addressed these COIs. We found that 90 percent of the grantee institutions we reviewed relied solely on the researchers' discretion to determine which of their significant financial interests are related to their research and are therefore required to be reported. When researchers submitted information regarding their financial interests, we found that grantee institutions did not routinely verify it. Additionally, because nearly half of the grantee institutions we reviewed do not require researchers to provide specific amounts of equity or compensation on their financial disclosure forms, the extent of financial interests of NIH-funded researchers is rarely known.

In both of these reports, we recommended that NIH request grantee institutions to provide it with details regarding the nature of all reported financial COIs. NIH did not agree with this recommendation. In response to our second report, NIH stated that this recommendation was not within the current scope of Federal regulation but this issue was raised by NIH as a specific area for comment in the May 8, 2009, Advanced Notice of Proposed Rulemaking.

Like at NIH, vulnerabilities that we have identified in FDA's oversight of COIs provides further evidence that COIs might not be properly addressed. For instance, COI information submitted to FDA by clinical trial sponsors lacked specific details necessary to confirm that COIs were properly reported and addressed by clinical trial sponsors pursuant to various parts of 21 CFR. Currently, sponsors are required to submit financial information on clinical investigators to FDA when an application for drug approval is filed, often years after the research began. In our report on FDA's oversight of clinical investigators' financial interests, we found that 42 percent of marketing applications were missing financial information. Some of these applications were missing financial information because sponsors used the due diligence exemption to indicate that they were unable to provide financial information.

If sponsors use this exemption, regulations require them to explain why they were unable to obtain the information. However, we found that often sponsors did not explain why they were unable to obtain financial information from all clinical investigators, as required. Moreover, when sponsors did include an explanation, they most often reported that clinical investigators could not be located or failed to return the financial form.

The examples I have just mentioned highlight that although grantees and clinical trial sponsors might technically meet Federal mandates, there is evidence to suggest that not all COIs are managed and resolved properly. Additionally, we have found that HHS also faces challenges in managing, reducing, and eliminating COIs. In our review of CDC's ethics program for Special Government Employees, or SGEs, for example, we found a systemic lack of effective oversight of COI issues.

SGEs on Federal advisory committees provide expert advice to the Federal Government. At CDC, SGEs address important public health topics, such as breast and cervical cancer, immunization, smoking, tuberculosis, and clinical laboratory improvement. For example, in 2009, SGEs on one CDC committee made recommendations that led to the establishment of H1N1 influenza vaccination priority groups in the United States.

SGEs are temporary Federal employees who are typically involved in work outside of the Government in the same areas as their committees' work. Similar to regular Government employees, SGEs are subject to financial disclosure and COI regulations issued by the Office of Government Ethics. However, despite this fact, we found that CDC did not require SGEs to disclose their interests completely before participating in meetings, nor did it identify or resolve all SGE potential COIs, even when adequate information identifying a COI was provided.

In 2007, 64 percent of SGEs had potential COIs that CDC did not identify and/or resolve prior to certifying their OGE confidential financial disclosure forms. For example, one SGE was a member of a committee that reviewed CDC grant applications. The SGE listed a CDC-funded grant related to committee work on his curriculum vitae, which was provided to CDC for review. Yet, CDC did not notify the SGE that he was prohibited from participating in particular matters regarding his specific employer and/or grant.

These findings raise concerns regarding how COIs are handled in HHS.

## V. Enforcement Work

OIG employs a multi-pronged strategy for achieving our mission of promoting integrity and efficiency of HHS programs and protecting the health and welfare of program beneficiaries. The studies I just discussed exemplify how we identify program vulnerabilities and suggest ways to modify policies or improve how those policies are implemented. When we find potential vulnerabilities, we offer recommendations to eliminate the vulnerabilities or reduce their potential for exploitation to protect the programs going forward. We strive to ensure that the programs are structured to minimize the risk of fraud, waste, and abuse, and while we expend significant resources to educate program managers and recipients and promote compliance, there are always a few companies and individuals who operate in ways the laws do not allow.

Next I want to turn to our enforcement capabilities. While we would always prefer that no violation occur in the first place, working in conjunction with our law enforcement partners at the Department of Justice and the Federal Bureau of Investigation, we have developed extensive expertise in identifying fraud, waste, and abuse and taking swift enforcement action against transgressors.

I would now like to discuss a few examples of recent enforcement actions related to COIs in medical education that are of special interest to AMCs. Although these cases did not involve AMCs, AMCs can learn important lessons from these examples in terms of ensuring the integrity of educational sessions they host, responsible partnerships with co-hosts or industry funding sources, and appropriate behaviors and industry relationships for medical staff serving as faculty or filling the audience for educational events.

In 2004, Pfizer paid \$430 million to resolve charges relating to the off-label promotion of Neurontin. Neurontin had FDA approval for use preventing seizures in epilepsy patients, but Pfizer enjoyed extensive revenue from Neurontin sales for various unapproved uses, including headaches and other pain treatment.

The Government alleged that the company engaged in an illegal promotion scheme that corrupted the physician education process by fraudulently sponsoring medical education events on off-label Neurontin uses. These educational events were purportedly independent, but in reality they were developed and produced with extensive input from Pfizer regarding topics, speakers, content, and participants, with the ultimate goal of promoting off-label sales.

For another example, in 2007, Jazz Pharmaceuticals' subsidiary, Orphan Medical Inc. (Orphan), agreed to pay \$20 million to settle charges that it had illegally marketed Xyrem, a prescription drug approved for use in narcolepsy, for off-label uses. Xyrem, also known as "GHB," has been subject to abuse as a recreational drug and is classified by the Federal Government as a "date rape" drug. The Government alleged that the company engaged in a scheme to expand the market for Xyrem by promoting the drug to physicians for off-label indications, including weight loss and chronic pain. As part of the scheme, the Government alleged that the company paid a psychiatrist tens of thousands of dollars for speaking engagements that promoted a wide range of off-label indications.

Some of these speaking engagements were characterized as independent CME programs, when in fact they were promotional events approved by Orphan's marketing department.

Individuals and health care companies that violate the fraud and abuse laws can be excluded from participation in Federal health care programs. This means that they cannot provide any items or services for reimbursement by the Medicare or Medicaid programs. In both of these cases, the companies entered into corporate integrity agreements, or CIAs, with OIG as a condition of avoiding exclusion and allowing their continued participation in Federal health care programs. The CIAs require, among other provisions, that the companies implement written policies and procedures designed to ensure that the funding of medical educational activities, including CME, conform to Federal requirements.

Industry-sponsored CME can also implicate the criminal anti-kickback statute when it is used to channel remuneration to physicians. OIG has pursued several cases where companies provided funding purportedly for "educational support," but that in reality constituted payment of kickbacks. For example, in 2006, Medtronic paid \$40 million to the Government and entered into a CIA to settle a range of allegations that it illegally paid spine surgeons to promote and use its spinal implant devices. The improper payments allegedly included free travel, lodging, and entertainment for physicians and their guests at lavish locations, such as Hawaii, Cancun, and Malaysia. The physicians participated in meetings the company called "discussion groups," but the sessions were actually of no or limited substance. The Government alleged that the company's true purpose was simply to induce the surgeons to use Medtronic's spinal implants instead of devices sold by competitors.

## VI. Conclusion

In conclusion, our work has identified vulnerabilities in the current process for identifying and remediating COIs.

Today, I have noted a few examples from our work that highlight the need for enhanced safeguards to reduce or possibly eliminate COI vulnerabilities. And, my office will continue to conduct work in this area. For instance, we are currently conducting an evaluation examining a number of grantee institutions that had financial interests related to NIH research grants in fiscal year 2008. We are also conducting an evaluation of COI waivers issued to Federal employees across HHS to resolve COIs. It is our hope that our work will continue to inform decisionmakers regarding specific changes that can improve the management of COI issues. Without a systematic infrastructure in place and clear roles for each stakeholder, the process for identifying and eliminating COIs will not be effective.

Recommendations from OIG reports, the IOM report and journal articles, and your own professional organizations highlight the need for engaging stakeholders in a discussion about best practices for strengthening COI policies and procedures. There have been informal discussions about convening a meeting of public and private stakeholders to discuss these issues.

OIG has successfully participated in such roundtables previously. If such a dialogue could advance understanding of these important issues, we would be pleased to participate.

Again, thank you for the opportunity to share some of the work my office has done related to COIs. I am happy to address any questions.