

**MEDICAL RESEARCH AND EDUCATION: HIGHER
LEARNING OR HIGHER EARNING?**

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BEFORE THE
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MEDICAL RESEARCH AND EDUCATION: HIGHER LEARNING OR HIGHER EARNING?

WEDNESDAY, JULY 29, 2009

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 2:03 p.m. in room SD-562, Dirksen Senate Office Building, Hon. Herb Kohl (chairman of the committee) presiding.

Present: Senators Kohl [presiding], Franken, and Martinez.

OPENING STATEMENT OF SENATOR HERB KOHL, CHAIRMAN

The CHAIRMAN. Good afternoon to everybody. We are going to call this hearing to order at this time. We thank you all for being here with us today.

Today's hearing is the fourth in a series of hearings we've held on the financial relationship between drug and device industries and America's physicians. To provide patients with the best possible care, the practice of medicine requires medical students to absorb vast amounts of unbiased information over a number of years. Further, it demands that doctors continue their training long after they have finished school.

Officially, doctors are required to participate in continuing medical education, or CME, to retain their license to practice, but many other opportunities for ongoing medical education exist in the form of medical journals, conferences, and speakers' bureaus, as well as professional societies.

In recent years, the drug and device industries have become increasingly involved in the funding of education for doctors. Academic medical centers and medical schools are increasingly reliant on industry funding for their educational and research programs. Industry funding of CME has quadrupled in the past decade, and now totals over \$1 billion a year. As both Congressional and media scrutiny of the financial relationships between physicians and these industries has heightened, this type of indirect funding is considered to be the last frontier.

Providing ongoing training and access to the latest medical innovations is costly, to say nothing of the resources necessary to produce the research in the first place. Teaching hospitals and medical schools face rising costs, as well. From that perspective, industry funding is fulfilled a real need. But, as we now know, large corporations do not typically spend these sums unless they think that they will get something out of it. That's not an indictment of the drug and device industry, it's simply how business works.

This brings us to the crux of today's hearings, as the drug and device industries—Are the drug and device industries getting a return on their annual billion dollar investment in medical education? Do the programs funded by industry stay true to their mission of providing unbiased education and research, or do they instead market the industries' latest products? We are not suggesting that these financial relationships are rife with corruption, but it's clear to us that greater transparency, and perhaps stronger firewalls, need to be considered.

We will hear from respected physicians and a medical student association who will say that industry funding does have an influence on the information and material presented to doctors; and we'll hear from the Department of Health and Human Services Office of the Inspector General and a member of the Institute of Medicine committee investigating these issues, who contend that most medical schools, as well as professors' societies, are far from implementing the policies necessary to combat conflicts of interest.

We'll also hear from a new organization of respected medical professionals who believe that industry funding of medical research and education has been a positive development, and that restricting such industry funding would be counterproductive. We'll hear from the organization that grants approval to official CME programs about the recent regulations they've put in place to ensure the integrity of CME content.

Finally, though they will not be testifying today, we've been corresponding with the American Medical Association. In spite of the fact that these conflicts of interest have been on their radar screen for quite some time now, I'm disappointed that they have not yet updated their ethical guidelines on the topic, as other trade groups such as PhRMA and AdvaMed have, and I hope this is remedied soon.

Before we begin, I'd like to make mention of Senator Chuck Grassley's work and leadership in this area. He and I have collaborated on several investigations, and most recently have been working to bring transparency to the Federal funding of biomedical researchers. Together we are the cosponsors of the Physician Payments Sunshine Act, a bill to require drug and device companies to disclose payments to doctors. We're hopeful that provisions of our bill will be included in the Finance Committee's healthcare reform proposal.

I'd also like to thank Chairman Waxman and Chairman Stark, in the House, for including provisions of our bill in their healthcare reform proposal, and for broadening the language to include payments by drug and device companies to medical schools, sponsors of continuing medical education programs, and organizations of healthcare professionals.

We'd like to salute those drug and device companies, such as Merck, Eli Lilly, and Pfizer, who have voluntarily begun to change their policies in this area. Notably a professional medical society, the American Psychiatric Association, has also taken steps in this direction, and we will hear from them today.

I think we all agree that conflicts of interest in this area, whether real or apparent, are not worth losing the public's trust.

So, we're happy that you're all here with us today. I'd like to call on Senator Martinez, who's the ranking member, and then on Senator Franken, from Minnesota, our newest member.

Senator Martinez.

OPENING STATEMENT OF SENATOR MEL MARTINEZ, RANKING MEMBER

Senator MARTINEZ. Thank you, Mr. Chairman, very much, and thank you for calling this very timely hearing.

I'd like to just add my word of welcome to our newest member, Senator Franken. We welcome you to the committee.

Senator FRANKEN. Thank you, Senator.

Senator MARTINEZ. I think you'll find our work interesting and worthwhile, and we're glad you're here.

The subject of transparency in the medical profession is timely, given the current debate over the high cost associated with healthcare. We know that doctors, in pursuit of their profession, spend many, many years of preparation and study, very costly years, before they begin their practice of medicine. Then, to stay current in the medical field, and to maintain a medical license, doctors devote substantial time to develop their medical knowledge and skills through continuing medical education. For these reasons, doctors are rightfully held in high esteem by the general public and their patients. This is why accounts of ethical and legal lapses by some doctors and pharmaceutical companies are especially troubling. These ethical lapses raise questions about patient well-being and stewardship of taxpayer dollars.

One arrangement we'll hear about today involves off-label promotion of a prescription drug that purports to be independent in continuing medical education. Today, doctors and patients enjoy access to an abundance of information from numerous sources. Patients rely on doctors to sift through this information and use it to make sound judgments about the benefits and risks of certain medical procedures, drugs, and devices. While off-label prescribing by doctors is legal and, in many instances, appropriate, promoting a drug for off-label purposes by a drugmaker is not. Continuing medical education is essential for disseminating information that helps doctors make decisions about appropriate off-label use of a drug. Sometimes the line between promotion and education can be blurred. This is why transparency and appropriate commonsense safeguards are absolutely necessary.

While industry support of continuing medical education is an important source of funding for medical education, transparency and appropriate safeguards are crucial to maintaining the integrity of medical decisionmaking. Disclosing payments to doctors, be they for Medicaid or from pharmaceutical companies, allows the public to reach their own conclusions about the appropriateness of such payment agreements.

Transparency is the bedrock of the legislation that was introduced earlier this year, by me and others, the Medicaid Accountability Through Transparency Act, or MAT Act. It's consistent with Chairman Kohl's and Senator Grassley's bill, the Physicians Payment Sunshine Act.

I look forward to hearing from our witnesses about this important matter. Mr. Chairman, I thank you, once again, for calling another very interesting topic to our attention.

The CHAIRMAN. Thank you, Senator Martinez.
Senator Franken.

OPENING STATEMENT OF SENATOR AL FRANKEN

Senator FRANKEN. Thank you, Chairman Kohl. I'm very pleased to be a member of this committee. Thank you, Ranking Member. I'm looking forward to working with both of you and all the other—well, with both of you— [Laughter.]

The rest of the committee, as we make progress on the issues that affect Americans' quality of life as we all age.

I thank Chairman Kohl and Senator Grassley for shedding light, in recent years, on the influence of the pharmaceutical industry on healthcare, and for leading Federal efforts to reduce industry influence with the Physicians Payment Sunshine Act, which I am now, by the way, a cosponsor of, and proudly so.

When I think about conflicts of interest in healthcare, I come back to the most important question, How are patients affected? As we know from past hearings in this committee, the status quo allows almost unlimited, and far from impartial, interactions between physicians and industry. To me, what is most disturbing about the current situation is that these relationships between industry and providers don't often benefit patient care. In fact, research has shown that they often have a negative influence on patient outcomes. They drive up healthcare costs because providers make treatment decisions based upon materials generated by industry, not based upon unbiased, evidence-based scientific information.

I'm proud that my State of Minnesota was the first State to enact legislation, in 1993, requiring public reporting of drug-company marketing payments to doctors. However, based on our experience in Minnesota, we know that transparency isn't enough. Even under Minnesota's progressive State law, the influence of industry on healthcare is rampant.

I believe you're all familiar with the 2007 New York Times article about a 12-year-old Minnesota girl who was, tragically, treated with inappropriate medication prescribed by a psychiatrist, and she has had lifelong health problems as a result. It turned out that the psychiatrist had received more than \$7,000 from the maker of the drug.

The same year, a study of the Journal of the American Medical Association showed that between 2002 and 2004 more than 7,000 payments to physicians, totaling almost \$31 million were reported in Minnesota. All of this took place under the State's exemplary public reporting laws, which goes to show that, while transparency is a necessary first step, it is not sufficient.

Since we know that the influence of pharmaceutical companies begins in medical school, it's crucial that we get to the root of this issue. Today's hearing gives us a chance to learn more about this, and my goal is to understand what steps the Congress can take to ensure that we're doing all that we can to educate healthcare pro-

viders to make decisions based on the scientific evidence, and not on biased information.

Previously discussed in past hearings is the Institute of Medicine report, which describes the medical schools' over-reliance on industry funds. The same can be said for continuing medical education programs, as we've talked about today.

I'm proud that, in Minnesota, we have an institution that can be held up as an example of how to effectively reduce conflict of interest in medical education. Mayo Medical School was one of nine medical schools across the country which received an "A" on the American Medical Student Association Assessment of Academic Medical Center Policies. I believe we have a gentleman testifying today from that association.

It's my understanding that Mayo has strong policies governing gifts, consulting relationships, and pharmaceutical samples. Medical students also receive a specific curriculum developed to create a culture of providers who make independent decisions based on the best interest of the patient. But, I'd like to hear more from our witnesses on how we can move toward making the rest of the country more like Mayo.

Finally, I commend Chairman Kohl and Ranking Member Martinez on the timing of the hearing. It couldn't be better, as the Ranking Member said, because it's enormously relevant to the broader discussion of national healthcare reform. It's counter-productive to be discussing reforming the healthcare system while allowing industry to maintain its hold on physicians' decisions.

Nationwide, prescription-drug spending rose 500 percent between 2000 and 2005—500 percent—from 40.3 billion to 200.7 billion per year. But, while these costs to consumers grow exponentially, the pharmaceutical industry is spending an astonishing \$30 billion annually on marketing. We have created a culture in which physicians receive far too much information about drugs from pharmaceutical reps, who have a vested interest in selling the newest, highest-cost products. To ensure high-quality care and to control soaring drug costs, we must provide medical students and physicians with information that is based on the best science, and not the most expensive marketing tactics. As lawmakers, I believe it is our job to remove barriers that create unnecessary costs and unethical influence in the healthcare system.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Franken.

Now to our first panel. Our first witness on the panel will be Lewis Morris, who is Chief Counsel for the Office of the Inspector General in the Department of Health and Human Services. In this role, Mr. Morris oversees a staff of 70 individuals who provide legal guidance to the inspector general. He's also working on an ongoing assessment of conflicts on interest in medical education with his research partner, Dr. Julie Taitsman, the OIG's Chief Medical Officer.

Next witness today will be Dr. Steven Nissen, who is Chairman of the Department of Cardiovascular Medicine at the Cleveland Clinic. Previously, Dr. Nissen served as President of the American College of Cardiology, the professional society representing Amer-

ican cardiologists. In addition to these positions, Dr. Nissen has written extensively on drug safety matters.

Next we'll be hearing from Dr. Eric Campbell, the Associate Professor at the Institute for Health Policy, and the Department of Medicine at Massachusetts General Hospital and the Harvard Medical School. Dr. Campbell has conducted extensive research in understanding the effects of academic-industry relationships on biomedical research, and he serves on the Institute of Medicine's Committee on Conflict of Interest in Medical Research, Education, and Practice.

Finally, we'll be hearing today from Jack Rusley. Mr. Rusley is a fourth-year medical student at the Alpert Medical School of Brown University. He is the Chair of the Culture of Medicine Action Committee for the American Medical Student Association, and is a Doris Duke Clinical Research Fellow at Yale Medical School. Currently, he is the Director of the AMSA PharmFree Scorecard.

We welcome you all, and we hope you will limit your comments to 5 minutes, if you can, please. Mr. Morris, let's hear from you first.

STATEMENT OF LEWIS MORRIS, CHIEF COUNSEL TO THE INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Mr. MORRIS. Good afternoon. On behalf of the Office of Inspector General for the U.S. Department of Health and Human Services, thank you for the opportunity to discuss commercial sponsorship of continuing medical education, or CME.

Physicians must be kept abreast of advances in medicine, and access to objective, unbiased CME is essential to the quality of medicine practiced in this country. A productive collaboration between medicine and commercial interests can expand knowledge, drive innovation, and improve quality of care.

However, the relationship also contains a potential divergence of interest. Physicians must make the welfare of the patient their first priority. On the other hand, healthcare companies strive to increase market share. Industry-sponsored medical education can be an effective means to accomplish that business objective.

In 2007, drug companies spent more than a billion dollars to cover more than half of the cost of CME activities in that year. Researchers have found that commercially sponsored CME gives more favorable treatment to the sponsor's product than do programs that are not commercially funded. Given the mixed motivations of industry-sponsored education, it is essential that effective safeguards be in place to ensure that CME is free from commercial bias.

The Accreditation Council for Continuing Medical Education, or ACCME, plays a pivotal role in ensuring the integrity of CME. However, the current environment tolerates industry sponsors' preferential funding of programs that serve their business needs. Developing curricula biased in favor of the funder's economic interest is a logical outgrowth of CME providers seeking commercial financial support.

As a result, research has shown that industry-sponsored CME almost exclusively covers topics related to commercial products, instead of broader discussions of patient care.

Various Federal laws may also be implicated by industry sponsorship of CME. As my written testimony explains in detail, when a manufacturer misuses CME for the purpose of an off-label promotion of a drug or medical device, the Food, Drug, and Cosmetic Act may be implicated. A violation of the False Claims Act may also be triggered when a manufacturer's illegal, off-label promotion of a drug or device results in the submission of claims to the Federal healthcare programs.

Industry sponsorship of CME can also create liability under the criminal anti-kickback statute. Offering doctors money or other benefits to induce them to prescribe the manufacturer's product is illegal if the product is reimbursed by the Federal healthcare programs. When pharmaceutical manufacturer rewards a high-prescribing physician by directing a CME provider to pay, or overpay, that physician to be a CME faculty, that payment may be a kickback.

In light of the risks posed by commercial sponsorship of medical education, the question becomes how to best ensure the CME programs are not co-opted as marketing tools, and industry support does not conflict with relevant Federal law. The surest way to eliminate commercial bias in CME is to prohibit industry sponsorship. Eliminating industry sponsorship has an—appealing for its purity and simplicity. As Shakespeare observed, “An honest tale speeds best being plainly told.” However, CME providers would need alternative funding to maintain the availability of continuing medical education.

In the interim, the following measures would limit industry's ability to influence the content of CME while allowing industry support of physician education. We suggest that pharmaceutical and medical device companies: (1) separate grantmaking functions from sales and marketing; (2) establish objective criteria for making educational grants to CME providers; and (3) eliminate any control over speakers or content of the educational activities. These measures would help ensure that funded activities are for legitimate educational purposes, and would reduce the risk that CME is used illegally to promote the sponsor's products.

Another way to limit the influence of commercial sponsors is through independent CME grant organizations. These entities could accept donations from industry and use an independent board of experts to distribute funds to CME providers. In effect, the organization would build a firewall between commercial donors and CME sponsors, while allowing industry to contribute to physician education.

While the use of independent grant organizations has appeal, companies may not be willing to fund CME under its terms. If this proves to be the case, physicians—as do lawyers, accountants, and other professionals—would have to pay for their own continuing education. It is possible the quality of CME would improve if physicians, acting as prudent consumers, demanded more meaningful education for their training dollar. Ideally, the CME providers would respond to this change by offering higher-quality programs at lower cost.

In conclusion, there is a growing concern about the integrity of CME and the financial relationship between commercial sponsors

and CME providers. Although restricting commercial sponsorship could shift the cost of CME onto physicians, such a shift could have a positive impact on the quality and value of CME. To preserve the independence of CME while allowing commercial sponsorship requires that industry donors and CME sponsors implement appropriate integrity safeguards. Whether the medical profession, healthcare industry, and CME providers are willing to embrace these measure remains to be seen.

Thank you.

[The prepared statement of Mr. Morris follows.]

**Statement of Lewis Morris
Chief Counsel
Office of Inspector General
Department of Health and Human Services**

**July 29, 2009
Before the Senate Special Committee on Aging**

On behalf of Inspector General Levinson and the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS), I thank you for the opportunity to discuss commercial sponsorship of continuing medical education (CME). Physicians must keep abreast of advances in medicine, and access to objective, unbiased CME is essential to the quality of medicine practiced in this country. However, the integrity of medical practice and the quality of patient care may be compromised if biased or inaccurate CME influences the physician's clinical practice, including the prescription of drugs, biologics, and medical devices. Preserving the independence and integrity of continuing medical education requires enhanced safeguards to preserve the boundaries separating education from marketing.

Background

Graduation from medical school and completion of residency training are the first steps in a career-long educational process for physicians. To take advantage of the growing array of diagnostic and treatment options, physicians must continually update their technical knowledge and practice skills. CME is a mainstay for such learning. Most State licensing authorities require physicians to complete a certain number of hours of accredited CME within prescribed timeframes to maintain their medical licenses. Hospitals and other institutions may impose additional CME requirements upon physicians who practice at their facilities.

Although some physicians pay the full expense of this additional education, more often the programs are either fully or partially subsidized by sponsors that provide educational grants and other funding to CME providers. Frequently, these sponsors are manufacturers of drugs, biologics, or medical devices related to the topic of the CME program. According to the Accreditation Council for Continuing Medical Education (ACCME), in 2007, the pharmaceutical industry spent more than a billion dollars to cover more than half the costs for CME activities conducted in the United States that year. Moreover, industry funding of accredited CME increased by more than 300 percent between 1998 and 2007.¹

¹ ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION, ACCME ANNUAL REPORT DATA 2007 (2008). Available online at http://www.accme.org/dir_docs/doc_upload/207fa8e2-bdbe-47f8-9b65-52477f9faade_uploaddocument.pdf. Accessed July 15, 2009.

A productive collaboration between medicine and commercial interests can expand knowledge, drive innovation, and improve quality of care. However, the relationship also contains a potential divergence of interests. Physicians should make the welfare of the patient their first priority and pursue continuing education as a means to assist them to provide the best care possible. However, commercial sponsors, including pharmaceutical and medical device companies, strive to increase market share and maximize the shareholders' return on investment. Industry-sponsored medical education can be an effective means to accomplish those business objectives.

One study of the return on investment for pharmaceutical promotional strategies indicates that spending \$1 on physician events and meetings, including CME, generated an average of \$3.56 in increased revenue.² According to a report by the American Medical Association Council on Ethical and Judicial Affairs, industry-supported CME programs tend to focus on drug therapies and give more favorable treatment to sponsors' products than do programs that are not funded by commercial sponsors.³ Given the mixed motivations of industry-sponsored education, it is essential that effective safeguards be in place to ensure that CME is free from commercial bias.

The Oversight of CME

ACCME, the principal CME accrediting authority in the United States, plays a pivotal role in ensuring the integrity of CME by determining whether providers qualify to offer accredited CME programs and by providing ongoing oversight of the CME industry. Once a CME provider gains ACCME accreditation, the provider may offer programs as accredited CME activities without seeking ACCME review or approval of the topic, content, faculty, or format of the individual activity. Generally, physicians can use only accredited CME to satisfy licensure and hospital privileging requirements. ACCME has accredited 736 CME providers, 150 of which are for-profit medical education and communication companies (MECCs).⁴

ACCME allows accredited CME providers to offer CME activities that are directly funded by commercial interests in the health care industry. The Institute of Medicine has reported that funding from industry provides almost three-quarters of the total income for MECCs.⁵ In its "Standards for Commercial Support," ACCME imposes some requirements designed

² SCOTT NESLIN, ROI ANALYSIS OF PHARMACEUTICAL PROMOTION (RAPP): AN INDEPENDENT STUDY (May 22, 2001). Available online at http://www.rxpromoroi.org/rapp/media/slides_speakersnotes.pdf. Accessed on July 27, 2009.

³ AMERICAN MEDICAL ASSOCIATION, COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, CEJA REPORT 1-A-09 FINANCIAL RELATIONSHIPS WITH INDUSTRY IN CONTINUING MEDICAL EDUCATION (June 5, 2009). Available online at http://www.cohealthcom.org/content/library/cc/CEJA/CEJA_Recommendation_Jun09.pdf. Accessed on July 18, 2009.

⁴ ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION, ACCME ANNUAL REPORT DATA 2007 (2008). Available online at http://www.accme.org/dir_docs/doc_upload/207fa8e2-bdbe-47f8-9b65-52477f9faade_uploaddocument.pdf. Accessed July 15, 2009.

⁵ INSTITUTE OF MEDICINE. CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 5-17 (Bernard Lo & Marilyn J. Field eds., Nat'l Academies Press 2009).

to temper the potential influence of the industry sponsor on the content of the CME program. For example, CME content must not promote a specific proprietary interest of a commercial interest and decisions regarding identification of CME needs and content must be made “free of the control of a commercial interest.”⁶ Notwithstanding these standards, ACCME’s role in mitigating commercial bias is limited because it does not pre-approve CME content and does not routinely monitor CME programs. Furthermore, oversight is complaint-driven and occurs after the fact, and in practice, up to 9 years may elapse between the identification of a noncompliant CME activity and ACCME’s revocation of that provider’s accreditation.⁷

The current environment tolerates industry sponsors’ preferential funding of programs that serve the business needs of the funders. As the Senate Finance Committee observed in its study of industry-sponsored medical education, developing CME curricula biased to favor the funders’ economic interests is a logical outgrowth of CME providers seeking commercial financial support. Industry’s influence on CME content can be overt or more subtle. Some manufacturers publicize general topics they are willing to fund and invite CME providers to submit grant applications that propose programs in topic areas or disease states. CME providers are aware of the therapeutic areas and product lines of the potential industry sponsor. Many grant applications identify proposed faculty and other course details that indicate whether the program will favor the sponsor’s products. CME providers can easily pitch topics designed to attract commercial sponsors, who in turn award grants to programs that complement the manufacturers’ marketing strategies.⁸ As a result, industry sponsored CME almost exclusively covers topics related to commercial products, instead of broader discussions of patient care.⁹

The Role of Federal Law Enforcement in CME

Various Federal laws may be implicated by industry sponsorship of CME. Under the provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), a company is prohibited from introducing a new drug, biologic, or medical device into interstate commerce unless that product and its label have been approved, licensed, or cleared by the Food and Drug Administration (FDA). FDA restricts the promotion of the product to only the approved indications and prohibits marketing or promoting an unapproved or so-called “off-label” use. Although pharmaceutical and device manufacturers may not advertise or promote their products for unapproved uses, physicians may prescribe drugs, biologics, and devices

⁶ ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION, ACCME STANDARDS FOR COMMERCIAL SUPPORT: STANDARDS TO ENSURE THE INDEPENDENCE OF CME ACTIVITIES (2007). Available online at http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf. Accessed on July 14, 2009.

⁷ STAFF OF S. FINANCE COMM., 110TH CONG., USE OF EDUCATIONAL GRANTS BY PHARMACEUTICAL MANUFACTURERS. (Comm. Print 2007). Available online at <http://www.senate.gov/~finance/press/Bpress/2007press/prb042507a.pdf>. Accessed on July 27, 2009.

⁸ *Id.*

⁹ Harvey P. Katz, Stephen E. Goldfinger, & Suzanne W. Fletcher, *Academia-Industry Collaboration in Continuing Medical Education: Description of Two Approaches*, 22 J. CONTINUING EDUC. HEALTH PROF’L 43-54 (2002).

for unapproved uses and manufacturers can reap substantial profits from resulting off-label sales. It is not known exactly how much revenue is attributable to off-label uses, but at least one researcher has estimated that off-label uses account for about 21 percent of prescription drug sales.¹⁰ Simply put, increased off-label use of a product benefits its manufacturer financially.

Although it is illegal for a manufacturer to promote a product for an off-label use, there is no express prohibition against a manufacturer sponsoring a CME program that discusses an off-label use of the product. Thus, a CME forum funded by a pharmaceutical company can deliver messages about a drug that the law forbids the drug's manufacturer from delivering directly. When a manufacturer misuses CME for the purpose of off-label promotion, the FDCA may be implicated. A violation of the FDCA is inherently a fact-based determination, but the greater the manufacturer's involvement in the delivery of the off-label message, the greater the risk.

A number of recent cases highlight the nexus between industry-sponsored CME and the enforcement of FDCA. In 2004, Pfizer/Warner-Lambert paid \$430 million to resolve charges relating to the off-label promotion of Neurontin, an anti-seizure drug used by epilepsy patients. The government alleged in part that the company engaged in an illegal promotion scheme that corrupted the physician education process by fraudulently sponsoring "independent medical education" events on off-label Neurontin uses with extensive input from Warner-Lambert regarding topics, speakers, content, and participants.

In 2007, Jazz Pharmaceuticals' subsidiary, Orphan Medical Inc., agreed to pay \$20 million to settle charges that it had illegally marketed the prescription drug Xyrem 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. 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.

In both of these cases, the companies entered into corporate integrity agreements (CIA) with the OIG as a condition of their continued participation in the 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 Government requirements. Those policies must also address the disclosure of financial support of CME and financial relationships

¹⁰ David C. Radley, Stan N. Finkelstein & Randall S. Stafford, *Off-Label Prescribing Among Office-Based Physicians*, 166 ARCHIVES OF INTERNAL MED. 1021-1026 (2006).

with faculty and speakers and ensure sponsored CME programs are independent and balanced.

Other laws may be implicated when commercial sponsors use CME to market drugs or devices for which reimbursement is sought from the Federal health care programs. Generally, Federal law and regulations governing Medicare and Medicaid do not provide for reimbursement for off-label prescriptions where the use is not medically accepted. The False Claims Act (FCA) imposes civil penalties (in the amount of treble damages plus \$5,500 to \$11,000 per claim filed) on any person who “knowingly presents, or causes to be presented ... a false or fraudulent claim for payment or approval” to the United States government.¹¹ The FCA may be implicated when a pharmaceutical manufacturer engages in a scheme to promote the off-label use of its drugs and the illegal marketing campaign results in the submission of claims for payment from Federal health care programs. In addition, the FCA sanctions a conspiracy to submit false claims.¹² If a manufacturer and a CME provider knowingly collaborate in the promotion of an off-label use, the resulting submission of claims for that drug to the Federal health care programs could establish a cause of action against both co-conspirators.

Industry-sponsored CME can also implicate the criminal anti-kickback statute.¹³ In general, the anti-kickback statute prohibits the knowing and willful offer or payment of anything of value to induce referrals to the Federal health care programs. Offering doctors or others money or other benefits to induce them to change a current prescription to the manufacturer’s product is illegal if the drugs are reimbursable by Federal health care programs. When the reward is a cash payment, the kickback is blatant. Sometimes, however, the kickback is more cleverly disguised. For example, when a pharmaceutical manufacturer rewards a high-prescribing physician by directing a CME provider to pay (or overpay) that physician to be CME faculty, that payment may be a kickback.

A number of significant cases have involved allegations that funding for “educational support” was a pretext for the payment of kickbacks. The following cases are illustrative.

- As part of the illegal promotion of Neurontin, Pfizer/Warner-Lambert allegedly made kickbacks to doctors in the form of payments to doctors to “author” medical journal articles that were actually written by a medical marketing firm.
- In a case against TAP Pharmaceuticals, sales representatives allegedly offered kickbacks disguised as “educational grants” that were intended to be used for everything from office Christmas parties to influencing placement on a health plan’s drug formulary. To settle these and other charges, in 2001 TAP pled guilty to criminal charges, paid \$875 million in fines and penalties, and entered into a CIA.

¹¹ 31 U.S.C. § 3729.

¹² 31 U.S.C. § 3729(a)(3).

¹³ 42 U.S.C. § 1320a-7b(b).

In 2006, Medtronic paid \$40 million and entered into a CIA to settle a range of allegations that it illegally paid physicians to promote and use its spinal devices. The improper payments allegedly included free travel and lodging of physicians and their families at lavish locations, such as Hawaii, Cancun, and Malaysia, for “discussion groups” of no or limited substance.

Preserving the Integrity of Continuing Medical Education

In light of the risks posed by commercial sponsorship of medical education, the question becomes how best to ensure that CME serves a *bona fide* educational purpose, the programs are not co-opted as marketing tools, and industry support does not conflict with relevant Federal law. The surest way to eliminate commercial bias in CME is to eliminate industry sponsorship by funders who have a significant financial interest in physicians’ clinical decisions. As the American Medical Association’s Council on Ethical and Judicial Affairs recently concluded, “it is ethically preferable that CME providers accept funds only from sources that have no direct financial interest in a physician’s clinical recommendations....”¹⁴ Commercial interests can deliver promotional messages to physicians through advertising and marketing.

Eliminating industry sponsorship is appealing for its purity and simplicity. However, CME providers would need to identify alternative sources of funds to maintain the availability of CME. In the interim, the following approaches would allow continued access to industry funding for CME, but limit industry’s ability to influence how that money is used and what messages physicians receive.

In our Compliance Program Guidance for Pharmaceutical Manufacturers (CPG)¹⁵, we recommended that pharmaceutical manufacturers should take steps to ensure that neither they, nor their representatives, are using CME to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence or control the content of the program. OIG identified several measures that manufacturers can take to enhance the integrity of industry-sponsored educational grants. Comparable safeguards would also promote the integrity of grants to CME providers.

We suggest that companies:

- (1) Separate grant making functions from sales and marketing. Effective separation of these functions helps insure that grant funding is not influenced by sales or marketing motivations and that the grant is for legitimate educational purposes.

¹⁴ AMERICAN MEDICAL ASSOCIATION, COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, CEJA REPORT 1-A-09 FINANCIAL RELATIONSHIPS WITH INDUSTRY IN CONTINUING MEDICAL EDUCATION (June 5, 2009). Available online at http://www.cohealthcom.org/content/library/cc/CEJA/CEJA_Recommendation_Jun09.pdf. Accessed on July 18, 2009.

¹⁵ OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).

(2) Establish objective criteria for making educational grants to the CME provider. This also would help ensure that funded activities are for legitimate educational programs.

(3) Eliminate any control over the speakers or content of the educational activity. This would help reduce the risk that the payment is for the speaker's referrals or to promote "off-label" uses.

When OIG issued the CPG in 2003, several pharmaceutical companies asserted that our suggestions were impractical and it would be difficult to separate educational grants from sales and marketing. However, since that time, we have been pleased to hear that many companies have adopted some of our recommendations. In addition, the Pharmaceutical Research and Manufacturers of America (PhRMA) recently updated its voluntary "Code on Interactions with Healthcare Professionals" to address industry support for CME.¹⁶ Among its recommendations are the separation of CME grant-making functions for sales and marketing departments, the adoption of objective criteria for making grants, and adherence to the ACCME standards for commercial support. The Advanced Medical Technology Association ("AdvaMed") has also recently updated its code of ethics. In contrast to the PhRMA code and OIG's CPG, the AdvaMed code provides that sales personnel may provide input about the suitability of a grant or donation recipient or program, but should not "control or unduly influence" the decision whether a health care provider will receive a grant.¹⁷ The AdvaMed code also permits a company to make recommendations for CME faculty, although suggests that the ultimate selection should be made by the CME sponsor.

Another way to limit the influence of commercial sponsors is the creation of independent CME grant organizations. These entities could accept donations from industry and use an independent board of experts to distribute the funds to CME providers. Such a pooled funding mechanism could limit the influence of commercial support by establishing a firewall between sponsors and CME providers. For example, in 2008, the American Academy of Orthopaedic Surgeons (AAOS) established a separate grant organization to receive and distribute funds to support orthopaedic education.¹⁸ The Center for Orthopaedic Advancement ("the Center") is structured to receive donations from industry and make grants based on objective criteria. The Center's board members may not have any personal or institutional relationships with an orthopaedic device or pharmaceutical manufacturer for the previous 3 years. OIG recently learned that five of the major

¹⁶ PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (effective Jan. 2009). Available online at <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>. Accessed on Jul. 17, 2009.

¹⁷ ADVANCED MEDICAL TECHNOLOGY ASSOCIATION, CODE OF ETHICS ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (effective July 1, 2009). Available online at <http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf>. Accessed on July 27, 2009.

¹⁸ Mark Wieting, *AAOS Announces Center for Orthopaedic Advancement*, AAOS Now, Sept. 2008. Available online at <http://aaos.org/news/aaosnow/sep08/youraaos4.asp>. Accessed on July 27, 2009.

manufacturers of artificial joints declined the Center's funding requests in favor of making grants directly to organizations. The future of the Center is uncertain.

Additional safeguards could include establishing broad educational categories for the allocation of industry donations. For example, an organization awarding grants for general topics, such as "orthopaedic education" or "oncology education," would operate with less influence from commercial interests than an organization awarding grants for education on specific topics, such as "injectable therapies for osteoarthritis of the knee" or "treating small cell lung cancer." Ensuring that the intermediary is not a potential customer of the commercial sponsors also reduces the risk of conflicts of interest. For example, if a hospital or group practice were to become a CME grant organization, there would be a risk that the organization might wield its purchasing power inappropriately. The integrity of the grant organization model would be impaired by efforts to make purchasing decisions dependent on a commercial entity's willingness to sponsor CME. An industry-sponsored CME pool might still favor CME activities that generally promote drug therapies or surgical intervention, but the risk of inappropriate influence would be lower than allowing sponsorship of individual programs.

While the use of independent grant organizations could limit the ability of industry sponsors to slant the content of the CME, companies may not be willing to fund CME under these terms. If this proves to be the case, physicians would have to pay for their own continuing education, as do lawyers, accountants, and other professionals. It is possible that the quality of CME would improve if physicians, acting as prudent consumers, demand more meaningful education for their training dollar. CME providers would no longer view industry sponsors as their customers and instead would address the needs of physician learners. Ideally, the CME providers would respond to this change by offering higher quality programs at lower cost.

Conclusion

There is growing concern about the integrity of medical education and the financial relationships between commercial sponsors and CME providers. Although restricting commercial sponsorship could shift some costs of CME onto physicians, such a shift could have positive impacts on the quality and value of CME. Commercial sponsorship could be maintained if the appropriate safeguards are implemented to prevent undue commercial influence and preserve the integrity and independence of CME. Whether the medical profession and health care industry are willing to embrace these measures remains to be seen.

The CHAIRMAN. Thank you, Mr. Morris.
Dr. Nissen.

STATEMENT OF STEVEN NISSEN, M.D., CHAIRMAN, DEPARTMENT OF CARDIOVASCULAR MEDICINE, CLEVELAND CLINIC, CLEVELAND, OH

Dr. NISSEN. Thank you. I really appreciate the opportunity to participate in these hearings, Senators.

My name is Steven E. Nissen, M.D. I am Chairman of the Department of Cardiovascular Medicine at the Cleveland Clinic, and a past President of the American College of Cardiology. My testimony does not reflect the views of either Cleveland Clinic or the ACC.

Continuing medical education, or CME, was originally intended to allow physicians to maintain professional competence and acquire new medical knowledge. In fact, most States require a minimum number of CME credits as a condition for continued licensure.

In recent years, CME has grown into an enormous industry with an extraordinary influence over the practice of medicine. In 1998, the total income for CME was \$888 million. By 2007, this had grown to more than \$2.5 billion. Ideally, CME should provide balanced and scientifically based education designed to improve the quality of healthcare. Instead, CME has become an insidious vehicle for the aggressive promotion of drugs and medical devices.

Amazingly, 50 percent of CME funding, about \$1.2 billion, comes from companies who market medical products. Essentially, the marketing divisions of drug and device companies now dominate the education of physicians.

CME has largely evolved into marketing cleverly disguised as education. Medical communications companies, often located in close proximity to the headquarters of major pharmaceutical and device companies, solicit funds from industry to conduct a wide variety of, quote, "educational," end quote, offerings. Often, the brochures state that the program was funded via a unrestricted educational grant from the sponsoring company. However, with a wink and a nod, the communications company selects speakers and topics they know will please the sponsors.

When I get these brochures, I often engage in interesting sport. I try to guess the sponsoring company by examining the list of speakers and topics. My guesses are nearly always correct.

The lucrative CME process is also undermining the independence of professional medical societies, which may derive more than 50 percent of their income from industry. Industry-sponsored CME offered through medical societies carries the risk that the imprimatur of a prestigious medical organization will be misused for promotional purposes. Recently, a group of current and former professional society leaders issued a statement in the Journal of the American Medical Association recommending that these societies adopt a policy of zero industry funding over the next several years.

With billions of dollars of industry money flowing into CME, who is guarding the integrity of the process? Current oversight by the Accreditation Council for Continuing Medical Education, or ACCME, is ineffective. The ACCME has strict rules governing edu-

cational activities, but appears uninterested or incapable of enforcing them. To my knowledge, few, if any, communications companies have lost their accreditation for biased CME. In fact, I have written to ACCME to complain about inappropriate CME-accredited activities. My letters were never even acknowledged.

As a nation, we spend on healthcare at nearly double the rate of other industrialized countries. We use more expensive drugs and medical devices, even when adjusted for our national wealth. I am convinced that the multibillion-dollar marketing machine known as CME directly contributes to this excess in healthcare expenditures. In my written testimony, I've provided more details and proposed several congressional initiatives to reform CME.

Thank you very much for the opportunity to speak to you.
[The prepared statement of Dr. Nissen follows:]

Testimony to the Senate Committee on Aging

My name is Steven E. Nissen, M.D. I am Chairman of the Department of Cardiovascular Medicine at Cleveland Clinic and a Past President of the American College of Cardiology (ACC). My testimony does not reflect the views of either Cleveland Clinic or the American College of Cardiology.

Continuing Medical Education, commonly known as or CME, was originally intended to serve as the principal means by which physicians maintain professional competence and acquire new medical knowledge. In fact, most states require a minimum number of CME credits as a condition for continued medical or nursing licensure. In recent years, CME has grown into an enormous industry with extraordinary influence over the practice of medicine. In 1998, the total income for CME was \$888 million. By 2007, this expenditure had grown to more than \$2.5 billion annually.

Ideally, CME should provide balanced and scientifically based education designed to improve the quality of health care. Instead, CME has become an insidious vehicle for the aggressive promotion of drugs and medical devices. Amazingly, 50% of CME funding, about \$1.2 billion, comes from companies who market pharmaceuticals and medical devices. Essentially, the marketing divisions of drug and device manufacturers now dominate a substantial proportion of physician education. CME has largely evolved into marketing, cleverly disguised as education.

An entirely new industry has been created, medical communications companies, often located in close proximity to the headquarters of major pharmaceutical and device companies. These communications companies solicit funds from industry to conduct a wide variety of "educational" offerings, providing a veneer of independence that camouflages the promotional nature of educational programs. Often the brochures state that the program was funded via an "unrestricted educational grant" from the sponsoring company. However, with a "wink and a nod", the communications companies select speakers and topics that they know will please the sponsors. When I get these brochures, I often engage in an interesting sport. I try to guess the sponsoring company by examining the list of speakers and topics. My guesses are nearly always correct.

At major scientific meetings, there are often dozens of "satellite" symposia sponsored by industry, advertised via slick, multi-color, glossy promotional brochures. These meetings offer a sit-down dinner, followed by a series of lectures by high profile and well-paid academic physicians. The content is artfully organized by the communications company to subtly and not so subtly promote the sponsoring company's products. If you don't attend national meetings, you can obtain the same content via web-based education, which is professionally produced and skillfully displayed. The communications companies that produce these materials often charge industry hundreds of thousands of dollars for a single event or webcast.

Companies readily pay hundreds of millions of dollars annually to support CME for one very simple reason - it sells their products. Industry-funded CME is not philanthropy, it is marketing. In fact, the funds for CME are derived from marketing budgets of companies. The flow of money is so enticing that large academic medical centers now commonly administer CME organizations that compete with communications companies for management of industry-funded educational programs.

Not to be left out, many scientific journals accept reimbursement to publish the proceedings of industry-funded CME via “special editions” of the journal.

The lucrative CME process also has undermined the independence of professional medical societies, which may derive more than 50% of their income from the pharmaceutical and device industry. Industry-sponsored CME offered through medical societies carries the risk that the imprimatur of a prestigious medical organization will be misused for promotional purposes. In one of the worst examples, a very prominent heart organization has created a “pharmaceutical roundtable” where companies that provide huge donations to the organization are afforded special private access to medical leaders.

Professional societies play critical roles in the practice of medicine. They author the guidelines and practice standards used by physicians to select the most appropriate therapies for our patients. The co-mingling of industry funding with professional society dues potentially jeopardizes the integrity and independence of these professional organizations and raises major questions about the objectivity of the guidelines they produce. Recently, a group of current and former professional society leaders published the attached statement in the Journal of the American Medical Association, recommending that medical societies adopt a policy of zero industry funding over the next several years.

There remain a few examples where industry funding of CME appears to meet a somewhat higher standard of independence, but they are relatively rare. In these cases, a major medical center or professional society conducts a CME program sponsored by several commercial entities, each of whom provide a modest amount of funding.

With the billions of dollars of industry money flowing into CME, who is guarding the integrity of the CME process? Current oversight by the Accreditation Council for Continuing Medical Education (ACCME) is largely ineffective. The ACCME has strict rules governing educational activities, but appears uninterested or incapable of enforcing them. I am unaware of any communications companies that have lost their accreditation because of biased CME.

In fact, on several occasions I have written to ACCME to complain about inappropriate CME-accredited activities. My letters were never even acknowledged. In the worst of these cases, I received a document via mail that was titled “Cardiology Consensus Report” and formatted to mimic a professional society guideline. In fact, it was designed to promote a specific product and the authors were paid by the communications company to “write” the “consensus report.” The ACCME never acknowledged my complaint.

In recent years, CME has been increasingly used to conceal payments to physicians that would otherwise be disclosed by transparency rules at hospitals and medical schools. Since the honorarium comes from a third party and is used to support CME, recipients are shielded from disclosure. Essentially, communications companies are used to “launder” money to avoid disclosure.

As a nation, we spend nearly double the expenditures of other industrialized country on health care. We use more expensive drugs and medical devices than other countries, even when adjusted for our national wealth. I am convinced that the multi-billion marketing machine known as CME directly contributes to this excess in healthcare expenditures.

How can the Congress help?

- 1) Congress should pass the Physician Sunshine Act, introduced by Senators Grassley and Kohl, that requires pharmaceutical and device companies to disclose all payments to physicians. This law should require disclosure of payments routed through CME providers, not just direct payments.
- 2) Congress should consider legislation requiring the drug and device companies paying for CME to assume legal responsibility for content. If false and misleading statements are offered during a funded CME presentation, the funding organization should be held liable by the FDA for misbranding.
- 3) The medical profession needs an independent oversight board to replace ACCME, perhaps established by the Institute of Medicine. The current fees charged for CME accreditation are more than adequate to fund such an effort. No taxpayer dollars are needed.
- 4) For non-profit professional societies, Congress should consider designating industry funding of CME as taxable income rather than a charitable contribution.

The CHAIRMAN. Thank you very much, Dr. Nissen.
Dr. Campbell.

STATEMENT OF ERIC CAMPBELL, PH.D., ASSOCIATE PROFESSOR, DIRECTOR OF RESEARCH, INSTITUTE FOR HEALTH POLICY, MASSACHUSETTS GENERAL HOSPITAL, HARVARD MEDICAL SCHOOL, BOSTON, MA

Dr. CAMPBELL. Chairman Kohl, Ranking Member Martinez, and members of the committee, I'm honored to testify before you today.

Recently, I served on the Conflict of Interest Committee in Medical Research, Education, and Practice at the Institute of Medicine. The Conflict of Interest Committee was convened by the IOM to examine conflicts of interest in medicine, medical research, and medical education, to develop recommendations to identify, limit, and manage such conflicts without affecting constructive collaborations.

My comments today will focus on the overall frequency of industry relationships and the disclosure of these relationships. I will also describe a set of recommendations specific to continuing medical education, that are contained in the full report of our committee.

In terms of the frequency of industry relationships, the IOM committee carefully considered the evidence and found that industry relationships, and the conflicts of interest that these relationships create, are ubiquitous in all aspects of biomedical research, clinical practice, and medical education. While I will not recite the data, the bottom line is that it is very difficult, if not impossible, to find a single aspect of medical education, medical practice, or biomedical research, in which pharmaceutical and device companies do not create a significant risk of undue influence through the provision of capital, goods, and services.

Because it is impossible for institutions and individuals to manage and evaluate what they are not aware of, well-functioning systems for disclosing conflicts of interest are essential. Our committee carefully considered the data regarding the various disclosure mechanisms that exist today, and concluded that they are inadequate. Our committee recommended that Congress create a national program requiring pharmaceutical, medical device, and biotech companies to publicly report payments to physicians, researchers, healthcare institutions, professional societies, patient advocacy groups, disease-specific groups, and the providers of continuing medical education.

Through CME, physicians commit to lifelong learning to maintain their current skills and to develop new skills and knowledge. Most state licensing boards, specialty boards, and hospitals require accredited continuing medical education for re-licensure, recertification, and staff privileges. As we've heard today, presently about half of all funding for accredited continuing medical education comes from commercial sources. This substantial industry support—indirectly subsidizes physicians, who pay less for these programs than they otherwise would. The members of the IOM committee generally agreed that the accredited continuing medical education system has become far too reliant on industry funding, and that such support tends to promote a narrow focus on medical products, and neglect a broader education on alternative strategies

for preventing disease and managing health conditions, and other important issues, such as communication with patients and coordination of healthcare services.

Further, given the lack of validated and efficient tools for preventing or detecting bias in educational presentations and programs, our committee concluded that industry funding creates a substantial risk of bias as education providers seek to maintain or attract industry support for future programs. Although the committee did not reach agreement on a new funding mechanism, it concluded that the current system of funding is unacceptable, and should not continue.

As noted in recommendation 5.3, of the report—the report calls on representatives from key groups, including educators, certification boards, accrediting organizations, and—the public and others, to convene a consensus process to develop a new system of funding accredited continuing medical education that is free of industry influence, that provides high-quality education, and that enhances the public trust.

In general, our committee believed that such a consensus process was likely to result in a new funding system that was feasible and that did not create unnecessary administrative burdens or have unintended adverse consequences. The committee left open the possibility that industry funding might be determined to be acceptable, under certain circumstances, with appropriate safeguards.

In conclusion, society traditionally has placed great trust in physicians and researchers, granting them considerable leeway to regulate themselves. However, there is growing concern among lawmakers, government agencies, and the public that the extensive conflicts of interest in medicine require stronger measures. Our committee clearly believes that more transparency is necessary. Our committee also believes that the current levels of industry funding of accredited CME is unacceptable and is in need of reform.

Thank you very much.

[The prepared statement of Dr. Campbell follows:]

CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND
PRACTICE

Statement of

Eric G. Campbell, Ph.D.
Associate Professor
Director of Research
Institute for Health Policy
Massachusetts General Hospital
Harvard Medical School
and

Member, Committee on Conflict of Interest in Medical Research, Education, and Practice
Board on Health Sciences Policy
Institute of Medicine
The National Academies

before the

Special Committee on Aging
United States Senate

July 29, 2009

Good afternoon, Mr. Chairman and members of the Committee. Thank you for the opportunity to speak to you today. My name is Eric Campbell, Associate Professor at the Institute for Health Policy and the Department of Medicine at Massachusetts General Hospital and Harvard Medical School. Recently, I served as a member of the Institute of Medicine (IOM) committee that produced the report, *Conflict of Interest in Medical Research, Education, and Practice*. Established in 1970 under the charter of the National Academy of Sciences, the IOM provides independent, objective, evidence-based advice to policymakers, health professionals, the private sector, and the public.

The committee was convened by the IOM to examine conflict of interest in medicine and to develop recommendations to identify, limit, and manage such conflicts without affecting constructive collaborations with industry. The committee held six meetings between November 2007 and October 2008, four of which included public sessions. The committee received oral and written statements from stakeholders such as academic leaders, biomedical researchers, professional societies, consumer groups, accreditors, and federal agencies. The committee also reviewed relevant literature and commissioned two papers to inform their analyses and recommendations.

The study focused on financial conflicts involving pharmaceutical, medical device, and biotechnology companies. The committee's final report, which includes 16 recommendations, describes an important goal of conflict of interest policies: to prevent bias rather than try to remedy the harm caused by compromised judgments in research, education, or practice. The study was sponsored by the National Institutes of Health, Robert Wood Johnson Foundation, Greenwall Foundation, ABIM Foundation, Burroughs Wellcome Fund, and Josiah Macy Jr. Foundation.

Society relies upon research to advance scientific discoveries and develop new medications and medical devices to benefit both individuals and public health. Research partnerships among industry, academia, and government are essential to the discovery process. In recent decades, corporate funding for research has expanded substantially; industry now funds more than half of all biomedical research in the United States.

Although patients and the public benefit from constructive collaborations between academic medicine and industry, particularly in moving discoveries from basic science into improved patient care, financial ties between medicine and industry can create significant risks that these relationships will inappropriately influence doctors' judgments and actions. Conflicts of interest jeopardize the integrity of scientific research and also threaten the objectivity of medical professionals' education, affect the quality of patient care, and erode the public's confidence in medicine. The IOM report spells out a reasonable strategy to protect against financial conflicts while at the same time allowing productive relationships between the medical community and industry.

DISCLOSURE

Lack of disclosure of financial relationships is a problem that has been highlighted in several media reports about physicians' and researchers' conflicts of interest. To support research institutions, professional societies, medical journals, and others who rely on

disclosures by individuals and institutions, the report calls on Congress to create a national public reporting program for the industry. This program should require pharmaceutical, medical device, and biotechnology companies to report, through a public Web site, payments they make to physicians, researchers, health care institutions, professional societies, patient advocacy and disease-specific groups, and providers of continuing medical education. A public record like this could serve as a deterrent to inappropriate relationships and undue industry influence. It also would provide medical institutions with a way to verify the accuracy of information that physicians, researchers, and senior officials have disclosed to them. The report also calls for the development of standardized categories for disclosure of relationships with industry.

INSTITUTIONAL CONFLICTS OF INTEREST

In medical research, conflicts may exist at both the institutional and the individual level. Thus, conflict of interest policies must address both. Institutional conflicts typically arise when research conducted within an institution could affect an investment holding by an institution or a patent the institution licenses to a company. Conflicts can also be caused by the financial relationships senior institutional officials have with industry.

The Public Health Service (PHS) requires institutions that receive PHS research grants to adopt policies on individual conflict of interest. The report suggests that the National Institutes of Health (NIH) continue its recent efforts to provide guidance to grantee institutions and to make public information about research institutions whose policies are not in full compliance with PHS regulations. The report also recommends that governing boards of medical institutions establish standing committees to oversee conflicts of interest at the institutional level and that NIH require its research grantees to adopt such policies.

CLINICAL RESEARCH

It is critical for public trust that research institutions protect the integrity of the medical research that is the foundation of clinical practice and education. Bias in the design and conduct of clinical trials may expose research participants to risks without the prospect that the trials will generate valid, generalizable knowledge. Moreover, such bias and also bias in the reporting of research may result in compromised findings being submitted to the Food and Drug Administration for approval of drugs or devices. Further, it may also expose much larger numbers of patients to ineffective or unsafe clinical care.

The committee recommends, as described in Recommendation 4.1 of the report, that, in general, researchers with a significant conflict of interest not participate in research with human participants. For example, if a researcher holds the patent on an intervention being tested in a trial, she generally should not conduct the study. Exceptions may be made if an investigator's participation is vital to the safe and rigorous conduct of research and if mechanisms are in place to manage the conflict, safeguard research participants, and protect the integrity of the research. This recommendation is similar to the AAMC "rebuttable presumption" described earlier in this chapter.

RECOMMENDATION 4.1 of the IOM's report, *Conflict of Interest in Medical Research, Education, and Practice*, reads, "**Academic medical centers and other research institutions should establish a policy that individuals generally may not conduct research with human participants if they have a significant financial interest in an existing or potential product or a company that could be affected by the outcome of the research. Exceptions to the policy should be made public and should be permitted only if the conflict of interest committee (a) determines that an individual's participation is essential for the conduct of the research and (b) establishes an effective mechanism for managing the conflict and protecting the integrity of the research.**"

Compared to clinical research, conflicts of interest involving nonclinical research have received much less attention. The IOM committee found differing opinions of the risk involved when nonclinical investigators have a financial stake in the outcome of a research project. This area warrants further discussion and investigation, and the committee suggests that the NIH play a role in promoting and organizing this discussion. At a minimum, research institutions should evaluate individual and institutional financial relationships in nonclinical research to assess the risk they pose to scientific judgment and then respond as appropriate to protect the integrity of the research.

CONTINUING MEDICAL EDUCATION

Physicians commit to lifelong learning to keep pace with new knowledge and skills and to maintain their current skills. Most state licensing boards, specialty boards, and hospitals require accredited continuing medical education for relicensure, recertification, or staff privileges.

According to the Accreditation Council for Continuing Medical Education, about half of all funding for accredited continuing medical education programs now comes from commercial sources; the proportion is even higher for some categories of providers. The fees paid by program attendees once provided the majority of provider income, but today industry-supported programs are often provided free or at reduced cost to physicians. This substantial industry support indirectly subsidizes physicians who pay less for many programs than they otherwise would.

The members of the IOM committee generally agreed that accredited continuing medical education has become far too reliant on industry funding and that such support tends to promote a narrow focus on medical products and a neglect of broader education on alternative strategies for preventing and managing health conditions and other important issues, such as communication with patients. Given the lack of validated and efficient tools for preventing or detecting bias in educational presentations and programs, industry funding creates a substantial risk of bias as education providers seek to maintain or attract industry support for future programs.

Although the committee did not reach agreement on a specific path to reform of continuing medical education, it concluded that the current system of funding is unacceptable and should not continue. As noted in Recommendation 5.3, the report calls

on representatives from key groups—education providers, certification boards, accreditation organizations, and the public among others—to convene a consensus process to develop a new system of funding for accredited continuing medical education that is free of industry influence, provides high-quality education, and enhances public trust.

RECOMMENDATION 5.3 of the IOM’s report, *Conflict of Interest in Medical Research, Education, and Practice*, states, “**A new system of funding accredited continuing medical education should be developed that is free of industry influence, enhances public trust in the integrity of the system, and provides high-quality education. A consensus development process that includes representatives of the member organizations that created the accrediting body for continuing medical education, members of the public, and representatives of organizations such as certification boards that rely on continuing medical education should be convened to propose within 24 months of the publication of this report a funding system that will meet these goals.**”

In general, the committee believed that such a consensus process was likely to result in a funding system that was feasible and that did not create unnecessary administrative burdens or have unintended adverse consequences. The committee left open the possibility that industry funding might be determined to be acceptable under certain circumstance and with appropriate safeguards.

CONCLUSION

Society traditionally has placed great trust in physicians and researchers, granting them the considerable leeway to regulate themselves. However, lawmakers and others are increasingly asking whether conflicts of interest in medicine require stronger measures. Taken together, the changes recommended in this report should reduce the risk that financial ties with industry will unduly influence the judgments of researchers and research institutions. The changes should not burden socially valuable collaborations between industry and academic researchers and research institutions. Rather, they should help justify and maintain public trust in the integrity of these collaborations.

Thank you for the opportunity to testify. I would be happy to address any questions the Committee might have.

BIOGRAPHICAL SKETCH

Eric G. Campbell, Ph.D., is an Associate Professor at the Institute for Health Policy (IHP) and the Department of Medicine at Massachusetts General Hospital and Harvard Medical School. His main research interests lie in understanding the effects of academic-industry relationships on the process and outcomes of biomedical research, investigating the effects of local health care market competition on the activities and attitudes of medical school faculty and understanding the impact of data-sharing and withholding on academic science. In addition, he is researching the role of organizational culture in

promoting patient safety and he is participating in a national evaluation of the use of health information technology for the Office of the National Coordinator of Health Information Technology. Dr. Campbell has published numerous articles in professional journals and has delivered numerous presentations at local, national and international conferences on health care policy, medical education and science policy. He served on the IOM Committee on Alternative Funding Strategies for DOD's Biomedical Research Program and the IOM Committee on Conflict of Interest in Medical Research, Education, and Practice.

The CHAIRMAN. Thank you, Dr. Campbell.
Mr. Rusley.

STATEMENT OF JACK RUSLEY, CHAIRMAN, CULTURE OF MEDICINE ACTION COMMITTEE, AMERICAN MEDICAL STUDENT ASSOCIATION; STUDENT, BROWN UNIVERSITY, ALPERT SCHOOL OF MEDICINE, PROVIDENCE, RI

Mr. RUSLEY. Thank you, Senators, for the opportunity to speak here today.

My name is Jack Rusley, and I'm a 4th-year medical student at Alpert Medical School of Brown University. I'm also a national leader of the American Medical Student Association, or AMSA, where I'm the current Director of the PharmFree Scorecard, which is a rigorous, comprehensive assessment of industry-medicine interaction and conflict-of-interest policies at academic medical centers.

I'm here today to tell you why my organization, and a growing number of physicians-in-training, believes the following: first, that disclosure is a first—is an important first step in bringing about transparency to industry-medicine interactions; next, that CME must be free from industry funding; and finally, that medical research must directly serve the public good over industry profits and physician lifestyles. Therefore, we need more high-quality, unbiased research and less marketing and freebies.

So, with 62,000 members, AMSA is the oldest and largest independent group of physicians in training in the United States, and we have a long history of activism around issues in healthcare that affect our current and future patients. In fact, AMSA was the first national organization of healthcare professionals to end industry advertising in, or sponsorship of, all meetings and publications in 2001. AMSA began its PharmFree campaign in 2002 to educate ourselves and others about the impacts of conflicts of interest.

The first scorecard was introduced in 2007. Because of its immense success, the Pew Prescription Project has invested in this effort to help us broaden its scope. Throughout this entire time, AMSA has been a leader in the movement to promote evidence-based prescribing and access to medicines while preserving true pharmaceutical innovation.

So, right now you may be wondering, Why do students care so much about these issues, and what do they have to contribute to the debate? As long as there have been students, there have been energetic young people, not yet tinged with the streak of cynicism, who will challenge the status quo. Most importantly, students are not as tangled in the financial and administrative webs as are many physicians, and are therefore more able to be powerful and passionate advocates for patients and the healthcare system we want to inherit, while also being free from conflicts of interest.

A generation ago, these qualities of student activists were less present, and medical students were known for their docility and acceptance of authority. I've had the privilege to work with students from all over the country who have flipped this model on its head. Now it's students who bring these issues to administrators, as I've done with my colleagues at Brown.

My computer's shutting down. Sorry about that. So, I will continue speaking off-the-cuff.

The CHAIRMAN. Thank you very much.

Mr. RUSLEY. You're welcome.

I just want to recount the events that occurred at Harvard Medical School, where a group of students, similar to the ones that I'm speaking about, sat in class one day last spring listening to one of their faculty members lecture to them about a treatment for cancer. When this faculty member advocated for the use of a new, less researched, more expensive medication as a first-line treatment for this cancer, over the well-studied, effective, and cheaper alternatives, the students were a little disturbed by this, and wondered why. So, they actually went and Googled this faculty member, and found that he was actually a paid consultant of the drug company that produced this medication. They were concerned about this development, and approached their administration, which—and Harvard Medical School, like many medical schools, does not require faculty members to disclose conflicts of interest to students during lectures. So, after some negotiations, and with little progress, the students rallied for a call for increased transparency of industry-medicine interactions and an end to conflicts of interest at their—in their medical education. As you can imagine, this is no small request. Harvard is one of the most complex industry-medicine interactions in the Nation and its medical school—Harvard received a failing grade on the 2008 AMSA Scorecard because they had submitted no policy.

To make a long story short, after pressure from Senator Grassley, the press, and students, Harvard has reviewed its policies, and now, this year, received a "B" on the AMSA Scorecard.

So, I just want to reiterate that AMSA endorses the Physician Payment Sunshine Act, that we look for the end for industry-sponsored CME, and I just want to leave you with a pledge that Harvard students took on the steps of Memorial Hall, and that students across the country take to show our commitment to this issue, and it goes, "That I am committed to the practice of medicine and the best interest of patients, and to the pursuit of an education that is based on the best available evidence, rather than on advertising or promotions, I therefore pledge to accept no money, gifts, or hospitality from the pharmaceutical industry, to seek unbiased sources of information, and not rely on information disseminated by drug companies, and to avoid conflicts of interest in my medical education and practice." Thank you very much.

[The prepared statement of Mr. Rusley follows:]

TESTIMONY OF JACK RUSLEY
TO
SENATE SELECT COMMITTEE ON AGING
HERB KOHL, CHAIR
MEL MARTINEZ, RANKING MEMBER
JULY 29, 2009
WASHINGTON DC

My name is Jack Rusley and I am a fourth year medical student at the Alpert Medical School of Brown University, in Providence, Rhode Island. I am also a national leader in the American Medical Student Organization, or AMSA, where I am the current director of the PharmFree Scorecard, a rigorous, comprehensive assessment of industry-medicine interaction and conflict of interest policies at academic medical centers across the United States.¹

I am here today to provide a perspective from a large and growing group of physicians-in-training regarding the relationship between the pharmaceutical and device industries and the medical profession. My organization and I believe the following:

- 1) Disclosure is an important *first step* in bringing transparency to industry-medicine relations
- 2) Continuing medical education, or CME, must be *free from industry funding*
- 3) Medical research must *directly serve the public good over industry profits*

With 62,000 members, AMSA is the oldest and largest independent association of physicians-in-training in the US, and has a long history of activism around health care issues that affect our current and future patients. In fact, AMSA was the first national organization of health care professionals to end industry advertising in or sponsorship of all meetings and publications in 2001. AMSA began its PharmFree Campaign in 2002 to educate ourselves and others about the impacts of conflicts of interest. The first Scorecard was launched in 2007, and throughout this time, AMSA has been a leader in the movement to promote evidence-based prescribing and access to medicines while preserving true pharmaceutical innovation.²

Right about now, you may be wondering, “why do students care about these issues, and what do they have to contribute to this debate?” As long as there have been students, there have been young people not yet tinged with the streak of cynicism who will challenge the status quo. Students are not as tangled in the financial and administrative webs as are our physician mentors, and are therefore more able to be passionate and powerful advocates for our patients and the health care system we want to inherit.

A generation ago, these qualities of student activists were less present, and medical students were known for their docility and acceptance of authority. I’ve had the privilege to work with students from all over the country that have flipped this model on its head. Instead of accepting and repeating the questionable ethical practice of their elders, they take the lead to create a new conversation about industry-medicine interaction, often at the risk to their academic record.

A group of such students in their first year at Harvard sat in class one day last spring, listening to a faculty member lecture about treatment options for a rare and deadly form of cancer. When this faculty member advocated for the use of a new, less-researched, and expensive drug to be the first-line treatment for this cancer over well-studied, effective, and cheaper alternatives, the students wondered why. They googled him and discovered he was a paid consultant for the drug company that makes the expensive new drug, yet had not disclosed this fact during his presentation. After negotiations with the

administration, a large group of students rallied to call for increased transparency of industry-medicine interactions and an end to conflicts-of-interest in their medical education. This is no small request – Harvard and its affiliated hospitals represent one of the largest and most complex industry-medicine interactions in the nation, and the medical school received a failing grade on the 2008 Scorecard because they had submitted no policy. The students asked national AMSA leaders for help, and I was one of those who helped them organize this protest. I was also present to see a group Pfizer employees nearby. What I did not know until the story was published in the New York Times,³ was that one of whom had taken a picture of us with his phone, apparently for “personal use” according to a company spokesperson.⁴ Under increasing scrutiny by students, the press, and your colleague Senator Grassley, Harvard agreed to require faculty disclosure and is now reviewing its policies. This year, Harvard received a grade of B on the Scorecard.⁵

This story became a symbol of a larger movement among students across the country, one that has been growing for years and is only now receiving due attention. It is a movement rooted in the desire to learn the best, most scientifically sound, evidence-based treatments for our future patients.

I would like to directly address some of the arguments and misconceptions from the other side of this debate. The first is that AMSA and our partners in this movement are anti-pharma, anti-research, or anti-innovation. Quite the opposite. Industry-medicine interaction has in the past and can in the future result in innovative and life-saving therapies. We want more, well-designed, unbiased research to create truly innovative drugs and devices.

Second, some think disclosure policies and conflict of interest regulations, such as the “Sunshine Act” (S.301, introduced by Chairman Kohl and Senator Grassley) are “red light restrictions” that would stifle research, limit continuing medical educational opportunities, and demean physicians. In fact, the Sunshine Act would do none of these things. If this “chilling effect” does occur and faculty stop interacting with industry out of embarrassment, perhaps these relationships were not appropriate in the first place. There are many examples of academic medical centers ending industry sponsorship without the world ending, and even with positive results.⁶ What about the classic “bad apples” argument, that there are a few rouge physicians out there taking all the gifts and advising 18 different companies? There is no evidence to support this claim, whereas the evidence for a system of widespread influence peddling is extensive.⁷ Social science research clearly shows that influence is an unconscious, powerful force that is most effective in those who think they cannot be influenced.⁸ Disclosure, like that provided by the Sunshine Act, is a first-step toward bringing transparency to industry-medicine interactions.

Third, the pro-industry side argues that industry-sponsored CME and speakers bureaus provide an important source of information for physicians who may not otherwise receive it. According to the Accreditation Council of Continuing Medical Education, in 2005, industry spent \$1.1 billion on sponsoring CME, which accounted for 50% of all CME

funding.⁹ Multiple studies in peer-reviewed journals make it clear that industry-sponsored CME is biased in favor of the sponsors' products.^{10,11} Far from preserving and building the reputations of faculty members, speakers bureaus (where industry pays key opinion leaders who are physician experts are paid by industry to speak to their peers) can effectively turn them into salespeople.¹² Unlike lawyers, physicians are one of the few groups of professionals that does not pay for their own continuing education. It is time we did, ended industry-sponsored CME, and stopped relying on industry to tell us what to think.

Finally, a common refrain from the other side is that there is no evidence that industry-medicine interaction does harm to patients, yet there are many examples of the positive results of this relationship (i.e. vaccine development). Again, we do not dispute that incredibly useful and lifesaving products have been created by industry with the support of physicians and researchers in academia. However, this narrow view ignores the larger picture: that the goal of medical research should be the service of the public good not industry profits.

The pharmaceutical industry alone, even without the device industry, is still one of the most profitable industries in the world: their profits are \$26.2 billion annually and they rank number one among all industries on all measures, including return on revenues, equity, and assets.¹³ However, all of the top five companies allocate a higher proportion of their revenue to net profit than to research and development.¹⁴ It is no surprise that there are fewer and fewer truly innovative products, meaning for every new miracle drug there are a much larger number of new drugs with similar profiles and effects as their alternatives, also called "me-too" drugs. Only 2% of new drugs developed in the past 25 years constituted an important therapeutic innovation – meaning they were significantly different from and better than what we already had – while 90% offered no real benefit over existing drugs.¹⁵ Much of the new drug research (and all the expenses involved) occurs in academic medical centers funded by taxpayers through the National Institutes of Health.¹⁶ In the meantime, diseases like tuberculosis with the greatest burden occur in developing nations where we continue to use 20 year old drugs because there is "insufficient market share" to justify research and development of new therapies.¹⁷ Only when drugs and devices are designed, sold, and distributed in such a way to maximize benefit to people, not return to shareholders, will the industry-medicine interaction thrive.

Despite its occasional successes, the profit-driven model of research, development, and marketing is broken and we need a new model of industry-medicine interface. Fortunately, there are many alternative models for this interaction. From Equitable Access Licensing,¹⁸ to promotion of neglected disease research, to public-private partnerships such as those forged by the Clinton Foundation to lower the prices of antiretroviral therapy,¹⁹ individuals and organizations are finding ways to bridge the industry-medicine divide that are beneficial for both and conflicting for neither. Until we find a model that works, we need more oversight and transparency, not more secrecy and opportunities for abuse. We believe that strong, regulated collaboration between industry and academic medical centers is necessary for the development of innovated drugs and devices, but it is not sufficient. We need novel sources of drug research funding, a

stronger FDA with a more efficient drug approval process, and increased funding for the National Institutes for Health.

For all these reasons, hundreds of medical students across the country have taken this simple pledge:

I am committed to the practice of medicine in the best interests of patients and to the pursuit of an education that is based on the best available evidence, rather than on advertising or promotion.

I, therefore, pledge to accept no money, gifts, or hospitality from the pharmaceutical industry; to seek unbiased sources of information and not rely on information disseminated by drug companies; and to avoid conflicts of interest in my medical education and practice.

Thank you very much for this opportunity to share this perspective.

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The CHAIRMAN. Thank you, Mr. Rusley.

One question, before I turn it over to Senator Martinez for the panel. The next panel will be—consist of witnesses who make the point that some of the things you're making—they may contend that some of the statements you're making, are overblown, and many of the conflicts of interest that you talk about are, by far, not the case, to the extent that you're talking about them, and that the reforms that many of you might advocate might actually do more damage than good, in terms of medical education. We'll be hearing from your next panel, so we'll give you a chance, in advance, to respond to them, because you won't have a chance to be back after they make their comments.

So I'll give you, Mr. Morris, Dr. Nissen, Dr. Campbell, and Mr. Rusley, just a minute to respond. Who wants to go first? Mr. Morris, you want to be first?

Mr. MORRIS. Certainly, I'd be pleased to be. I would note that, from our perspective, there is a distinction between education and marketing. For those who want to blur the line and suggest that the inspector general's office or this panel is against educating doctors, I think that mischaracterizes our concern.

Our concern, or at least the concern from which I speak, is that what is presented as education is disguised marketing, and is biased and misleads the physician. So, it would be a mischaracterization of our view that we are against educating doctors. We strongly favor that.

We also appreciate there's a role for marketing. But the audience should understand the difference. The physician should know that one is marketing, and they can bring a certain level of skepticism to it, and the other is education, and they should trust the educator.

The CHAIRMAN. Dr. Nissen.

Dr. NISSEN. I think the problems are really self-evident. If you did a Google search for CME, for all the CME programs that teach physicians on how to use generic drugs to save their patients money, I don't think you can find any.

So, the problem we have is that the people paying the bills are determining what the topics are that are actually being used in education. Those topics invariably involve expensive, either high-technology devices, imaging devices, drugs, whatever. So, when you think about the fact that more than half of the prescribing in America is actually for generic drugs, and yet there's no education around generic drugs, I think you get an idea of how those biases increase the cost of medical care and lead to the over-use of therapies that—probably should be using—

The CHAIRMAN. All right.

Dr. Campbell, you want to make a comment?

Dr. CAMPBELL. Our committee spent over a year reviewing the evidence—not anecdote, not allegation, but published evidence—regarding the frequency of industry relationships in all aspects of medicine, research, and medical education, and they are ubiquitous. They exist in almost every single aspect—as I said before, it's hard to find somewhere where they don't exist.

The committee also notes that these relationships have benefits, but these relationships also carry substantial risks, and it is under-

standing the nature of the balance of the risks and benefits that is important today. Our committee supports disclosure; disclosure, in and of itself, does not say relationships are good or bad, they simply say they should be made public, so that people can understand them and evaluate them. Our belief is the fact that, essentially, one can't manage or evaluate what one doesn't know about.

The CHAIRMAN. All right.

Mr. Rusley, you want to make a comment?

Mr. RUSLEY. Yes. I would just also advocate for education, starting in medical school, around these issues, and talking to students about how the industry and medicine interaction works, particularly when it comes to critical evaluation of research, so that when students become physicians and are out evaluating CME, and participating in it, that they can make informed choices and informed decisions about what to believe.

The CHAIRMAN. OK.

Senator Martinez.

Senator MARTINEZ. Thank you, Mr. Chairman.

Some of this comes as a real surprise to me, because, as a lawyer, which immediately makes me suspect to this kind of medical group, I went to continuing legal education. I had to do it in order to maintain my license. I also participated as a lecturer, many times, never got paid by anyone. I guess only maybe book salesmen would have been interested in promoting seminars. So, it comes as a real surprise, the level of underwriting that goes on by providers and suppliers of continuing medical education. It would seem to me—and perhaps this would be harmful to continuing education, if there's not another source of funding—but would it be a good idea to simply not have CME that was funded by anyone other than the participants or the AMA or whatever other subset of medical group might be interested in providing it?

Related to that, could there then be a separate type of event, where a pharmaceutical company says, "Come and enjoy a nice weekend, and I'll tell you about my product?" I mean, separate the two. What's education is education. Marketing can also be partially education, but wouldn't they be better if they were separate and apart? Seems simple.

Dr. NISSEN. I couldn't have said that any better myself. I mean, I think you make an extremely powerful point, that we need a firewall between marketing and education. Right now they're blended together, and the problem is, you never know quite where the boundary is.

So, you know, I wandered into a CME program—often they're free, so you don't have to pay for it—and literally had to walk out because the bias was so terrible that it was just—you know, something that was unacceptable to me. So, at least if a physician goes to something that they know is marketing, that they know what they're getting in for—the problem now is that they—physicians will go to programs which are marketed as CME, and think that it's unbiased education, when, in fact, it's not unbiased at all. So, I do think a firewall is a very good idea.

Now, what it means is that some of these programs would be not as lavish. You know, they won't have these multicolor brochures and all the kind of extras that are there. Well, that's not really

what education's about. It's about content. I think you can offer very high content without spending the hundreds of millions of dollars that's spent for these very fancy programs.

Dr. CAMPBELL. Senator, it's my own opinion, not the opinion of the committee, but I want—I just want to point out to you that the primary rationale that we use for paying resident physicians almost poverty wages in America when they work in hospitals during their training is that they are accruing human capital, and it's that investment in their education for which they will financially benefit later on. In other words, they work for low wages because they're learning something, and they will ultimately benefit from those when they go out and practice medicine. We don't—

Senator MARTINEZ. Maybe not in the future. That's been the case in the past.

Dr. CAMPBELL. Right.

Senator MARTINEZ. I'm not so sure about the future.

Dr. CAMPBELL. Right. But, we don't actually apply that rationale to continuing medical education, where it could—you could make the same argument that physicians need to invest in their own education, because they are accruing the capital.

Mr. MORRIS. One last point. There certainly are physicians, particularly those just coming out of medical school, saddled with enormous debt; and there are those who—perhaps serving in rural communities—who are struggling to make ends meet. It is possible to set up independent grant organizations that could take money from industry and appropriately allocate it to those who need subsidy for their education. But, have educational grants controlled by those who don't have skin in the marketing game, have it run by people whose interest is advocating for the interest of the patient and the physician, and have it removed from the marketing side of the house.

The CHAIRMAN. Senator Franken.

Senator FRANKEN. Thank you, gentlemen.

Dr. NISSEN, you were talking about the ACCME, which is the accreditation organization and basically you were saying that they can't seem to monitor this properly. Why is that?

Dr. NISSEN. You know, I really don't understand. I think that perhaps they don't have the resources, perhaps they don't have the will. You know, historically this was not an area that got a lot of scrutiny. I will look forward to hearing their testimony, but I can assure you that a considerable amount of CME that any objective observer—I mean, anyone objective—would look at and say, "This is marketing"—it goes on, it is not restricted in any way; you know, these companies continue to do this. Frankly, even some of the CME produced by academic organizations and professional societies is highly biased. So, whatever the ACCME is doing, it has really been ineffective. That's why, in my written statement, I propose that we need a new system. We need the ACCME to go away, and we need to replace it with something else. Now, what that is, I think we've got to think about. But, it needs to be able to have the authority, but also the will, to police this.

I think a better and easier solution is Mr. Martinez's solution, which is to have a firewall, and say, "We're going to separate marketing from education. We're not going to mingle the two," and

then you don't need an ACCME, because marketing is unrestricted, you can do whatever you want; but CME is never going to be industry-funded.

Senator FRANKEN. You and Dr. Campbell and—is it Mr. Morris, or Doctor?

Mr. MORRIS. Mr. Morris.

Senator FRANKEN. Mr. Morris—all used the word “firewall.” Let me see if I understand that. Mr. Morris, you were talking about the drug companies actually funding this, but putting into a pool of money, and then someone else would organize the CME. Is that correct?

Mr. MORRIS. Yes.

Senator FRANKEN. I think you also said you don't know if that would work— [Laughter.]

Because you don't know if the drug companies would do it, then, right?

Mr. MORRIS. There is—I mention this in my written testimony there have been some attempts to create these independent grant organizations. One was founded by the American Academy of Orthopaedic Surgeons, and it has not received any grants from industry. So, the question is, if you build it, would they come?

Senator FRANKEN. Is there any benefit from the situation, anything good that can be said of the way CME is funded by the drug companies—other than a nicer hotel and shrimp? Is there some kind of synergy between doctors and these drug companies or medical device companies, or anything that can be said, positive, about this?

Dr. NISSEN. There is good CME, and—you know, 100 percent of the industry-sponsored CME is not bad. Let me give you at least one example that I mention in my written testimony. Sometimes, academic medical centers will put on a course, and they'll go to a dozen different companies and ask for small contributions from each of them to fund this educational program. Very good firewalls in place. It's often not about specific drugs or specific uses. Frankly, I've been to some of those programs, and I thought they were really pretty good. But, what they did is, they avoided this one-to-one relationship, where a company, from its marketing budget, funds somebody to do CME about their product. The minute that happens, you lose the objectivity. It becomes biased. Most of the time, if you go to those programs, what you hear is subtly, or not so subtly, organized to try to get people to use the product.

But, I think there are some examples where it's done well. Unfortunately, it's not the majority.

Senator FRANKEN. But, the conclusion of all of you is that this practice, of industry-funded and specific industry-funded CME drives up the cost of medicine in this country?

Dr. NISSEN. I think it's a huge driver. Let me tell you what the—what the data is. We spend \$90 billion a year, on drugs and nondurables, above what would be expected for our per-capita national wealth. Much of that is due to two things. One is, drugs cost more in America, as I think you all know—about 50 percent more—but, we use a different mix of drugs. We use much more branded, expensive drugs than other countries do.

Now, the Senate and House are looking for \$600 billion over the next 10 years to take care of healthcare reform. I'm telling you that we're spending \$90 billion a year more on drugs and nondurables than we should be spending. That's \$900 billion over the next 10 years. So, if we're right—and I believe that we are—that this machine for getting physicians to prescribe the most expensive medicines, or use the most expensive devices, is skyrocketing healthcare costs, that's one of the ways we can pay for healthcare reform. That is why this is such a critical issue.

Senator FRANKEN. So, when the healthcare reform debate takes place, and there are some Senators, like myself, who think that the money to pay for this is actually there in the system, that if we do this right, we can save enough money to cover everybody, that that seems to conform with what you think.

Dr. NISSEN. Specifically, if you look at our national expenditure on healthcare, adjusted for our per-capita GDP, overall—not just for drugs and nondurables, but overall—it's \$650 billion a year more that we're spending than we should compared to, say, Canada, Germany, France, and other countries with relatively similar national wealth. So, that's \$6 trillion over the next 10 years.

It drives me crazy to hear all this talk about, "We can't pay for healthcare reform." We can pay for healthcare reform, but we've got to get on top of the overuse of expensive therapies in place of therapies that actually may work better and cost a whole lot less.

Senator FRANKEN. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator Franken.

We thank you so much, gentlemen on the first panel, you've been very forthcoming, very honest, very frank, and shed a lot of light on the topic. So, your being here today is well worth your time and effort, and certainly does help us in our deliberations.

Thank you.

We'll now go to the second panel. We have three doctors on the second panel. The first witness will be Dr. Thomas Stossel. Dr. Stossel is currently the Director of the Division of Translational Medicine and a Senior Physician at Brigham & Women's Hospital, as well as an American Cancer Society professor of medicine at the Harvard Medical School.

The next witness will be Dr. James Scully, who is the Medical Director and CEO of the American Psychiatric Association, a medical specialty organization representing over 38,000 members.

Finally, we'll be hearing from Dr. Murray Kopelow. He is the Chief Executive and Secretary of the Accreditation Council for Continuing Medical Education, where he leads the organization's efforts to certify standards for continuing medical education.

We thank you, gentlemen, for being here today, and, Dr. Stossel, we'll take your testimony.

STATEMENT OF THOMAS STOSSEL, M.D., TRANSLATION MEDICINE DIVISION AND SENIOR PHYSICIAN, HEMATOLOGY DIVISION, BRIGHAM & WOMAN'S HOSPITAL, HARVARD MEDICAL SCHOOL, BOSTON, MA

Dr. STOSSEL. Thank you, Mr. Chairman, and I'm honored to participate in this important hearing.

Since I'm pushing 68 years of age, I know I'm before the right committee. I've been in medicine for a long time, over 40 years. From that experience, I can say that medicine is incomparably better than when I got into it.

It's hard to imagine that when I was an intern, in 1967, heart-attack patients languished on my ward, in bed for a month—imagine what that would cost—and left hospital with damaged, poorly functioning hearts. Now, when my father had a heart attack, 15 years ago, he was in and out of the hospital in a few days, and he did just fine. Today it would even be better, and faster; and because of continuing education, more patients so benefit.

Now, statistics bear out this personal perspective. Deaths from cardiovascular disease are down by 50 percent. Since the death rate remains one per person, if the number-one killer—heart disease—doesn't get you, you sign up for the number-two—cancer. But, cancer death rates are at an all-time low. We have done something right in American medicine. What is right is not that doctors became more altruistic, ascetic, ethical, or better regulated; it's because of the tools provided by the private medical-products industry.

Knowledge flows back and forth between the bedside and the laboratory. This flow promotes innovation and its proper application to patient care. For this reason, physician-industry collaboration is essential in all aspects of medical innovation and education. The synergy, Senator Franken, is huge.

Given this fact and the track record of value creation, the energy we are expending on financial conflicts of interest has been incomprehensible to me. How could we have made so much progress if business simply promotes salesmanship over substance and corrupts greedy, gullible physicians?

But, such accusations are rampant and are imposing damaging barriers to constructive physician-industry collaboration in innovation and education. We'd better have pretty good evidence to tamper with a system of innovation and education that's done so much good.

But, the evidence justifying this tampering is extraordinarily weak, and I didn't hear anything today that changes me from that opinion. What passes for evidence is the relentless reiteration of inevitable, sometimes, egregious, but vanishingly uncommon, adverse events, without reference to the tens of thousands of actions that lead to valuable products and much better patient outcomes.

The plural of anecdote is never data. Lacking substantive data, the case for tampering is based on speculation, inference, and moral bullying. We heard a lot of that from the first panel. To focus on who pays whom how much, rather than on the quality of the work product, is not evidence. There is no conflict between learning and earning. I heard very definite statements about, "I know this

is not objective, this is biased.” I’ve never seen a study that has actually demonstrated such conclusions formally.

The tampering has produced no documented benefits. It causes harm. Commercial support for continuing medical education’s fallen 20 percent since last year. This decline hurts physician education, especially out in the countryside. Postgraduate medical training slots—something Mr. Chairman, I believe you’ve expressed concern about—are down, too, because of rules against commercial funding of such positions. Prohibitions against researchers owning equity in startup companies, where innovation begins, chases investment away.

All said and done, what matters is, Do patients benefit from physician-industry collaboration, as we’ve seen it? History absolutely attests that the answer is in the affirmative.

Now, medicine’s come a long way in my lifetime, but it has a long way to go. After surviving his heart attack, my father went on to develop Alzheimer’s disease. Since I’m genetically signed up for that fate, I want to see innovation and education progress as rapidly as possible. I want to recognize my children and grandchildren when I die. My father could not.

I thank you for your attention, and I hope you will accept my written testimony into the record.

Thank you.

[The prepared statement of Dr. Stossel follows:]

**WRITTEN TESTIMONY SUBMITTED BY THOMAS P. STOSSEL, MD TO THE
UNITED STATES SENATE SPECIAL COMMITTEE ON AGING, JULY 28, 2009**

Facts: Medicine Then and Now

Forty-two years ago, when I was an intern in internal medicine, we practiced (by today's standards) terrible and unsafe medicine. I cite a few examples.

Heart attack patients languished on our wards for a month. We simply observed them and hoped that they would not suffer cardiac arrests as they gradually advanced from lying in bed to sitting, to limited walking and finally discharge. We also routinely confronted patients in great pain with crippling rheumatoid arthritis, barely able to move from deformed joints. Primitive surgical procedures to repair degenerated hips required long convalescence times, and knee replacements did not exist. Most patients hobbling about with degenerative arthritis were therefore forced to live a life of limited physical activity, which predisposed them to obesity and its many complications. A diagnosis of leukemia was an automatic death sentence. Blood sugar monitoring of patients with diabetes was difficult, rendering its control nearly impossible, and complications arose with certainty.

Today, treatments for all of these ailments – heart disease, arthritis, leukemia, diabetes - are radically different, not because physicians are more "ethical" or better regulated, but because of the tools (drugs, diagnostics and devices) they have at their disposal.

Heart disease mortality has declined by over 50% in the last 50 years, thanks to interventions like drugs that dissolve clots in obstructed arteries and stents that prop them open. Most of these procedures, done safely thanks to technologies that constantly monitor the patient's status, do not require more than a few days of hospitalization. Other drugs (like statins) are available to lower "bad" cholesterol safely and with excellent tolerability or reduce blood pressure with few minimal side effects – preventing heart attacks and strokes for millions of patients worldwide. Still others prevent blood clotting responsible for heart attacks and strokes.

Table 1 partial list, in no particular order, of valuable medical products industry has provided since I completed my medical internship in 1967.

<i>Product</i>	<i>Conditions Addressed</i>
Hepatitis B vaccine	Prevention of liver failure and liver cancer
Interferons	Treatment of hepatitis, multiple sclerosis, cancers
Erythropoietin	Anemias
Proton pump inhibitors	Stomach ulcers, reflux esophagitis
ACE inhibitors	High blood pressure, heart & kidney failure
Azole drugs	Fungus infections
Anti-TNF	Rheumatoid arthritis, other autoimmune diseases
Anti-CD20	Lymphomas, autoimmune diseases
Bisphosphonates	Osteoporosis, bone fractures
Clotting factors	Hemophilia, other bleeding disorders
Anti-CD4	Diagnosis of AIDS
Anti-hepatitis B,C, -HIV	Diagnostics to prevent transfusion-transmission
Rotavirus vaccine	Infantile diarrhea

Coronary stents	Heart attacks
Fluoroquinolones	Severe bacterial infections
MRI and CT scanning	Imaging of internal organs
Anti-HIV retrovirals	Treatment of AIDS
Anti-Gp2b/3a	Heart attacks
Statins	High LDL cholesterol, heart attacks, strokes
ADP receptor blockers	Heart attacks, strokes
Factor 10a inhibitors	Prevent and treat blood clots
HPV vaccine	Cervical cancer
Femoral head implants	Hip degeneration
Aromatase inhibitors	Breast cancer
Porcine valves	Heart valve degeneration
PDE5 blockers	Erectile dysfunction
Knee & other implants	Joint degeneration
Imitinab	Chronic myelogenous leukemia, GI stromal tumors
Enzymes	Inborn metabolic deficiencies
SSRIs	Depression and other mental disorders
5HT3 blockers	Chemotherapy-induced nausea & vomiting
CMV antivirals	Cytomegalovirus infection
H. flu vaccine	Haemophilus influenza infection
Inhaled corticosteroids	Asthma
Calcium channel blockers	High blood pressure
Cyclosporine/Tacrolimus	Organ transplant rejection
Cisplatin	Cancers
Anti-Veg F	Macular degeneration
Colonoscopes	Colonic polyps, cancer diagnosis
Endoscopes	Minimally invasive surgery
Portable defibrillators	Cardiac arrest
Long-acting bronchodilators	Asthma
Leukotriene receptor blockers	Asthma
Biguanides, insulin analogs	Diabetes

The tools listed above came from private industry, informed and assisted by entrepreneurial physicians and scientists in academic health centers.

Private investment in product development by companies reflects the worldwide exponential run up in health care costs (1). This growth rate, and corporate research expenditures began to exceed public (mainly National Institutes of Health-NIH) support of research in the late 1980s, and the gap between them has risen to almost two-fold (2).

The 1970s saw the establishment of the biotechnology industry driven by leading scientists, including Nobel Laureates, who had ushered in the watershed use of genetics to discover rare but potent components of body function, to make these components in quantities suitable for therapeutic use. Some, like erythropoietin that stimulates red blood cell production enabled patients with kidney failure and severe anemia to avoid needing blood transfusions. Others block toxins such as inflammation-causing substances responsible for rheumatoid arthritis.

The expansion of medical product development also created opportunities for physicians to participate in clinical trials testing product efficacy and safety. Because of their proximity to daily patient care, the physicians involved were in the best position to advise

companies developing the products as they navigated the risks and unknowns inherent in complex biology. The same physicians were also well suited to familiarizing practicing physicians with new products as they emerged on the market.

Opposition to Profit in Medicine and Regulatory Reactions.

The substantive benefits of corporate money in medicine are almost too well documented to ignore – but they are ignored. At face value, a profound animus against such money is difficult to understand.

Prior to the late 1980s physician and researcher interaction with industry was almost completely unregulated. Suddenly, however, a rising tide of criticism poured out of the medical journals attacking physicians and academic scientists for consorting with corporations. The outburst included articles and editorials in medical journals and books. The code word for the animus against companies and those who associate with them was "conflict of interest (3-12)."

"Conflict of interest" is only a meaningful term in terms of regulatory implications in the context of self-dealing by persons in positions of political or judicial power – and physicians and researchers do not come even close to having such influence. Therefore, the intent of the phrase in the context of medicine is a ploy, used since the beginning of recorded history, of adversaries to invoke allegedly evil motives of an opponent – such as greed -- as a weapon in an argument they cannot win on substance (13).

The assault on money in medicine has been two-pronged, claiming, on the one hand that conflict of interest is detrimental to medical innovation and medical care in practical ways, and, on the other, that it is fundamentally inimical to accepted canons of medical ethics. Both attacks hinge on the fundamental assumption that money – profit, especially profit above some arbitrarily defined limit – is obligatorily corrupting and inconsistent with medical professionalism.

The practical arguments against industry encroachment into medicine vary in stridency. At the extreme, they claim that most medical innovation derives from publicly funded academic research (through the National Institutes of Health or other mechanisms), and that after appropriating it, companies rig the evaluation of subsequent developed products in their favor. They exaggerate the difficulties of product development to inflate prices. Every adverse outcome is the result of malign intentions rather than inadvertent error. The extreme critics aver that if industry simply diverted resources from marketing to research, breakthrough products would automatically appear.

Even those with seemingly more moderate attitudes that pay some tribute to the contribution of industry to medical innovation and to the difficulties of translational product development, however, ally with the extremists by advancing the proposition that in their ruthless pursuit of profit corporations obligatorily deviate from accepted standards of scientific rigor in the execution of studies to evaluate their products, in the reporting of those studies and in the marketing of approved products to physicians.

The crescendo of attacks on conflict of interest have elicited waves of regulatory actions. Initially focused on research, academic health centers enacted rules inhibiting researchers from receiving corporate sponsorship for their work, in some cases even laboratory research, if they had above a defined minimal amount of equity or fees from

the sponsoring company. The institutions required faculty to disclose their financial relationships with companies to university authorities empowered to "manage" or prohibit such relationships.

After newspaper reports alleged extensive irregularities in disclosure of corporate relationships by researchers at the NIH intramural program, the NIH banned all paid consulting to industry by such researchers. This action took place despite the number of violations analyzed by subsequent investigation being few and no damages having occurred. Just as profit supposedly causes corporations to misbehave, the underlying assumption enabling these academic rules is that arbitrarily definable profits or prospects of profits determine an unacceptable risk of corruption of faculty in their research work.

The next tier of regulatory escalation directed itself against overt product marketing and what it interpreted as marketing in the guise of corporate subsidies for CME activities. To eliminate what was presented as, yet again, the damaging influence of profit-motivated corporate misrepresentation of scientific evidence on patient care, recommendations, enacted in some academic health centers, have emerged, with great fanfare, to curtail the provision of product samples to physicians by company sales representatives and, and, especially, the conferral of small gifts and meals to compensate physicians for their time devoted to learning about new products. Corporations and their trade groups embraced these measures, somewhat disingenuously, since they all save marketing costs (14, 15).

Another regulatory thrust has been to exact extensive public disclosure of payments from private companies to physicians and researchers. Laws mandating such public information in the interests of "transparency" have passed in several states and are under consideration nationally. In anticipation of such legislation, pharmaceutical companies have begun to disclose such payments on their websites.

A central battleground concerning eliminating conflict of interest is corporate support for CME, presently over half of a \$ billion enterprise encompassing a diverse range of educational activities. Some academic health centers have started down the elimination pathway by prohibiting physicians from giving educational talks to other physicians when corporations pay the lecturers. The slogan categorizing such lecturing is "speakers' bureaus."

Once again, the central assumption justifying purging CME of corporate funding is that such subsidy must on balance result in biased educational content. An additional presumption is that commissioning a cadre of educators with no interests in particular products will provide better education because it is more "objective."

Where's the Evidence of Corruption?

Examining the data on which the anti-commercial critics base their allegations, analyses by the NIH and by the Congressional Research Office, and, especially, an in-depth review of the development history of the 35 most widely prescribed drugs or drug classes uniformly attest that pharmaceutical companies have made major contributions to innovation and that they markedly increase the value of academic research results (16-18).

Almost every reason put forward for how conflict of interest supposedly compromises medical research, especially that it promotes research misconduct, is, when subject to factual analysis, untrue (19). Similarly, scholarly assessments of the amount of research that moves into product development or of the risks of failure and the costs of that process are inconsistent with critics' claims of exaggerated risks or of price gouging (20-23).

The *New York Times* editorialized that "none of the steps yet contemplated by industry or professional groups would completely sever the medical profession and many individual doctors from their far more disturbing ties to the drug industry," and that "the medical profession needs to wean itself entirely from its pervasive dependence on industry money (24)."

What are these "disturbing ties" and "pervasive dependence?" According to statistics compiled by The Association of University Technology Managers, American universities, hospitals and research institutions receive over five times more research support from the NIH than from industry sources – hardly "pervasive dependence (25)." And while surveys reveal that nearly all American physicians have received something of monetary value from industry, in most cases it is in the form of the small sums associated with marketing activities (26). A minority of physicians and academic researchers receive larger and even very large monies for participation in clinical trials or for research and development consulting. The fundamentally important question bearing on whether or not these ties are "disturbing" is their *value*.

Do the allegations concerning the parasitic and devious aspects of the medical products industry survive analytical scrutiny to justify concluding that conflict of interest degrades medical integrity? They do not. Their principal flaws are that they only address *risk*, not benefit, generalize by extrapolating from anecdotes, confuse value and merit and, most importantly, they lack rigorous empiric support.

One striking fact is the relative paucity of adverse outcomes blamed on financial conflict of interest. Table II lists a compilation of such events taken from the large number of journal articles, books and newspaper accounts that have covered this area over the past 20 years.

Table II. Specific Adverse Outcomes Ascribed to Financial Conflicts Since 1967

<i>Case</i>	<i>Allegations or Events</i>
Tseng (Mass. Eye and Ear Infirmary) case	Insider trading, IRB violations
Dong (UCSF) case	Publication suppression by sponsor
Kahn (UCSF) case	Suppression of data access
Olivieri (University of Toronto) case	Researcher intimidation
Gelsinger (University of Pennsylvania) case	Death of research subject & lack of financial disclosure
Zimmer settlement	Payments for device use
CLASS publication	Publication of incomplete results
Neurontin settlement & guilty plea	Off-label promotion
TAP settlement	Kickbacks to physicians
Paxil settlement	Non-reporting of efficacy lack & possible side effects

Cephalon settlement	Off-label promotion
Lilly Zyprexa settlement & plea	Off-label promotion
Pfizer Bextra settlement	Off-label promotion
23 drug recalls & device recalls	

The events listed in Table II, some not necessarily ascribable to venal financial motivation, pale before the amount of benefit summarized in Table I. Indeed, the literature output exceeds the substance that it describes; the same stories are simply retold over and over again.

The foregoing is not to argue that the occurrences of Table II, some unearthed by numerous legal monitoring mechanisms, are not undesirable or even reprehensible. Rather it is to ask whether, in the context of total events, they warrant piling more vigilante activity on top of current oversight mechanisms that include the FDA, The Office of the Inspector General, and whistleblower lawsuits or a justify a radical restructuring of financial relationships between the medical products industry, physicians and medical researchers.

Many of the events in Table II are examples of inferior value – apparently intentional devious behavior that could have promoted inappropriate patient care outcomes, although some are only allegations. Nevertheless, the clear-cut instances in the Table contrast with actions critics subjectively deem lacking in merit in the absence of knowledge concerning their ultimate value. Table III lists such cases gleaned from the voluminous conflict of interest literature. Again of note is that the number of examples is not large, especially compared to the volume of pages devoted to describing them.

Table III. "Low-Merit Behavior" Ascribed to Financial Conflict of Interest

<i>Low-Merit Behavior</i>	<i>Reasons Given for Condemnation</i>
"Positive" research reports	Negative research results delayed or suppressed
"Speakers' bureaus"	Biased and/or misleading CME
"Seeding" trials	Designed for marketing, not research
"Ghostwriting"	"Honorary" academic authors lend credibility to research they did not do
Conflicted FDA panels & practice guidelines	Biased recommendations for product approval and disease treatment
NIH consulting violations	Rules not followed
Conflict disclosure failures	Erosion of public trust
Gifts to physicians	Inappropriate patient care, increased costs

Overbalancing anecdotes concerning industry's distortion of, delay in or failure to report unfavorable research results are studies documenting that corporate-sponsored clinical trials are of higher quality than most academic trials (27), and examples of the timely publication in high-profile journals of clinical trial results that have had enormous negative economic consequences for the companies that sponsored them (28, 29).

The topics of "speakers' bureaus" and "ghostwriting" exemplify the confusion between merit and value. "Speakers' bureau" is a euphemism for physicians giving educational talks to other physicians concerning specific medical products and for which they receive

payment from the product manufacturer or from some intermediary. The merit criticism is that for physicians to perform "promotional" talks for commercial entities is, by definition, unprofessional.

But the value proposition is whether information conveyed by promotional talks benefits patient care. Speakers and their audiences believe it does, and no evidence supports the opposite conclusion. Critics find distasteful that companies sometimes provide speakers with communication aids such as projection slides. However, companies do this to assure that the information presented complies with FDA regulations (and the speakers have final control of these materials). Advocates opposing promotional speaking have not come close to proving that such speaking lacks value.

If physicians or researchers allow themselves to be designated authors of papers written by professional writers without having participated in the research or contributed in some other way to the article – so-called – "honorary" authorship, low value is manifest, and this practice should be eliminated. Nevertheless, professional writers appropriately acknowledged can help render publications more timely and readable.

If "seeding" trials get published in peer-reviewed journals, as they are, they arguably provide value; a scientifically valid trial is useful irrespective of the motives behind it (30). Internal and external analyses of FDA panel decisions have revealed no effect of financial conflicts (31).

By far the most aggressive criticism that money devalues medicine is in the context of product marketing. The centerpieces of the case against medical product marketing are two articles published in *JAMA*, *The Journal of the American Medical Association*. The first, entitled "Physicians and the pharmaceutical industry. Is a gift ever just a gift?" appeared in 2000 and is a summary of 29 studies surveying the relationship between practicing physicians and medical product company sales representatives (32). Although, as revealed by the subtitle, the article's author took a dim view of trinkets and meals provided by the salespeople, she compiled a list of outcomes that arguably balanced out in favor of marketing, despite the admission of only one "positive" outcome: "improved ability to identify the treatment for complicated illnesses."

Against this powerful benefit was pitted non-rational prescribing behavior, a conclusion based on a single Dutch study (33). Strangely identified as a "negative" was that physicians acquired a "positive attitude" toward sales representatives. The other "negative" outcomes were rapid and increased prescribing of promoted medications and requests to have them added to formularies – exactly what one might expect new information to cause. The author squarely acknowledged the absence of outcome information to inform whether these prescriptions were inappropriate for patients, and, in fact, evidence exists that undertreatment, such as failure to address high blood pressure, is overall a worse problem than overtreatment (34).

The stated absence of patient outcome data in the Wazana article did not deter the authors of the second *JAMA* paper that came out six years later from exaggerating the actual outcomes by stating,

The systematic review of the medical literature on gifting by Wazana found that an overwhelming majority of interactions had negative results on clinical care (35).

In the same spirit of quantitative declarations based on no evidence they also claimed:

Physicians' commitment of altruism, putting the interests of patients first, scientific integrity, and an absence of bias in medical decision making now regularly come up against financial conflicts of interest.

Despite its errors, most institutional policy preambles cite this paper to justify the need for severe conflict of interest regulation.

Cost savings is a reason frequently given to justify such regulation. However, sales of medical products -- drugs and devices -- have contributed relatively little to the relentless increases in medical expenditures over time. Currently this contribution is less than 15%. Despite this fact, physicians, hospitals, health insurers, the news media and politicians have disproportionately blamed the industries producing those products for medical costs. This distortion conveniently deflects blames away from the major cost drivers.

Real Costs.

Proving what does not happen is difficult, but venture capitalists, making risky investments in technologies at early development stages, state that they would much prefer to invest when physicians and scientists have financial incentives to devote time and energy to such projects. Anecdotally, academic researchers have been unable to attract investment for startup companies to translate research into products or to license technologies to existing companies.

The ban on paid consulting inflicted on researchers in the NIH intramural program has caused morale, recruitment and retention problems (36). By definition, companies are not obtaining the advice of these researchers.

Burgeoning disclosure regulations divert company resources from research and development to reporting payments, and taxpayers foot the bill for state and national repositories that house the reports. What good these databases will bring is unclear, because surveys reveal that the public in general and patients in particular have almost no concerns about who pays physicians or researchers how much (37-39).

Allegations of financial disclosure failures have received much media attention. Since consultants only disclose fees, equity and royalties, and the companies tend to report all payments such as expense reimbursements, the inconsistencies are most probably unintentional, so that few of these investigations unearth serious disclosure violations, and none have revealed consequential damages. As the volume of public disclosure increases, any theoretical benefits must be weighed against whether it will be used for industrial espionage, or for plaintiffs' attorneys to troll for "failure to warn" litigation opportunities.

Complexity and rapid changes in the medical product environment mean that physicians, especially physicians outside of academic health centers, are hard pressed to familiarize themselves with new developments. Statutory requirements mandate continuing medical education (CME), and CME is a large enterprise substantially subsidized by the medical products industry.

Attacks on the validity of commercial sponsorship of CME have ratcheted up the difficulty community hospitals have in obtaining corporate support for CME events (40). Heeding the call to purge all such support can only eventuate in drastically reduced education, an outcome hardly in the interests of patient care.

Why Criticism and Regulation Succeed.

Why, despite the weakness of the evidence and the opportunity costs, does policy intended to purge conflict of interest from medicine and separate physicians and researchers from their productive partnerships with private industry flourish?

One major cause of physicians' unwillingness to resist may reside in medicine's unique history, the vast majority of which is a chronicle of bad ideas and ignominious failure. For thousands of years medicine was mired in superstition and reasoning by analogy.

Until the birth of the modern era and the modern corporation, doctors could do little to help their patients – and much to hurt them. Bleeding and purging were favored techniques, as was a cornucopia of herbs and potions that were – at best - placebos. Even early in the last century, science had not yet impacted importantly on medical care. Medical research (such as it was) was the pastime of the leisured aristocrat with disdain for craftsmen and merchants and their pursuit of lucre.

The understandable need for traditional medical practitioners to cloak their practical inadequacies with aristocratic and priestly trappings disappeared when science and industry afforded them the ability to provide legitimate and desired services and ever more opportunities to improve those services. Nevertheless, the opprobrium against "business values" persists, cloaked in a one-sided view of "professionalism" that views profit with contempt (41).

The arguments made against commercialism in medicine invoke a dualism epitomized by an oft-repeated mantra that "companies have a fiduciary responsibility to shareholders whereas physicians' fiduciary responsibility is to patients." This opaque platitude implies that business has no social responsibility and that physicians only behave in a venal manner when contaminated by business. In addition to the fundamentally disrespectful position of this binary stance is its prejudicial demonization defining what is to dislike: it is all well and good for industry to interact with physicians and academic institutions – as long as it does not behave like industry – interested in profits.

Infected by medical school ethics instruction with guilt, physicians suffer embarrassment over profiting from failure. Hence, a low profile seems the best course for avoiding attention from critics and the news media.

Conclusion.

Modern medicine extends our lifespan and improves our life quality because of its grounding in rigorous science, its minute specialization and its ability to attract market entrepreneurship. Unfortunately, these very attributes of success have divided and distracted the medical workforce from the ground of their own success – the modern for-profit firm. This consequence has empowered simplistic linear thinking and

unsubstantiated and archaic beliefs to inflict with little accountability or feedback coercive limits on the freedom of medical practitioners and innovators.

History has repeatedly demonstrated that top-down, central planning impedes innovation. Unless we resist the zealots driving conflict of interest regulations, progress will slow – and patients will suffer.

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The CHAIRMAN. We will do that, sir, and thank you so much for what you just said.

Dr. Scully.

STATEMENT OF JAMES SCULLY, M.D., MEDICAL DIRECTOR AND CEO, AMERICAN PSYCHIATRIC ASSOCIATION, ARLINGTON, VA

Dr. SCULLY. Mr. Chairman and members of the committee, thank you for inviting me here today. I am James Scully, Jr. I'm the Medical Director of—

Senator MARTINEZ. Would you turn on your mike, please?

Dr. SCULLY. Now it's on, sorry.

Thank you, Mr. Chairman. I'm James Scully, Jr., M.D. I'm the Medical Director and Chief Executive Officer of the American Psychiatric Association, the medical specialty representing over 38,000 psychiatric physicians. Thank you for inviting me today.

By our board's direction, our highest priority is advocating for our patients and our profession, and I wanted to take the time, just for a second, to thank you, in this past year, for passage of the parity legislation, ending a 12-year struggle to end discrimination against patients suffering from mental illness in our insurance programs. Thank you, Mr. Chairman, and all of Congress. I'm sure you would have helped too, Senator Franken, if you'd been there.

So, we, at APA, promote the highest standards of care for our patients and families, and strive to have those same standards of excellence in psychiatric research, and in the education and training of our workforce.

Many of the most dramatic improvements in the effective treatment of mental illness have come as a result of newer and better medications. They've meant remarkably positive changes in the lives of tens of millions of Americans, and would not have been possible without the commitment of the pharmaceutical industry, to research and development. We need to support continuing innovation so that these improvements can continue. The challenge is, we need to do this in a way that protects the integrity of our association, our members while we continue to support innovation.

Over the past years, the relationship between medicine and industry, including pharmaceutical and device manufacturers, has been under increased scrutiny, and appropriately so. Patients need to be able to rely on the objective recommendations of their physicians. In turn, physicians need to be able to rely on the objectivity of research as it pertains to how they're going to safely and effectively use the medications and devices.

Recognizing the necessity of managing potential conflicts of interest, we've been looking—proactively—in examining our relationships with the pharmaceutical industry. We've taken considerable pains to implement safeguards to reduce the risk of these conflicts of interest between industry and the provision of continuing medical education. We, in fact, received a commendation and a 6-year accreditation from the Accreditation Council for Continuing Medical Education for our efforts, and we've continued those too—but, the key is, as you've been saying, separating promotion and commercial activities from educational activities. They are seen in the symposia, they don't end there. We've also set some rules to create

a buffer between promotional materials, commercial materials, product advertisements, and educational activities.

In March of 2008, our board voted to establish a work group to take an even more in-depth look at our relationship with the pharmaceutical industry and, if necessary, to recommend additional changes in our policies. The working group submitted its recommendations last December, and among those recommendations for the board to review was to phaseout all industry-supported educational symposia industry-supported meals, which are a big part of this, at our scientific meetings. In March of 2009, the board voted to accept that recommendation. As far as we know, we're the first professional medical society to do this, and we've already begun—we actually began a little earlier—to implement this policy.

For example, in 2006, we had 46 industry symposia that were presented, out of 500 or so total programs; in 2008, the industry symposia went to 28; and this year, 11 such sessions. This action is not without real cost to us short-term, for sure. For example, this year we'll lose a million and a half dollars in revenue that we would have otherwise had. So, there is real short-term cost that we've decided to pay. But, in the long run, we believe that the elimination of even the perception of undue influence and maintaining, or regaining, public trust, is well worth the cost.

The fact that the relationships between the pharmaceutical industry and the medical profession is facing increasing scrutiny is not a bad thing. To the contrary, patients need to know about their physicians' potential conflicts of interest, where they truly exist, and only then can we have confidence in the decisions about medical decisionmaking.

As our awareness of conflicts of interest evolves, and we need greater clarity, doctors, and we in the professional societies, need to continue to re-examine the pros and cons of our relationships with the industry. What are the real and what are the perceived, not-real, conflicts? How can we manage them, eliminate them? This is a process that's underway, not just with us, but, I know, with many, if not most, of our sister medical organizations. We are all currently struggling with this, how to improve. We're pleased to be in the forefront of this process.

Thank you for the opportunity to testify this afternoon.

[The prepared statement of Dr. Scully follows:]



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**Testimony of the
American Psychiatric Association**

**Regarding
"Medical Research and Education: Higher Learning
or Higher Earning?"**

**Presented to the
Senate Special Committee on Aging**

**By James H. Scully Jr., M.D.
Medical Director and C.E.O.
American Psychiatric Association**

July 29, 2009

Mr. Chairman and members of the Committee, I am James H. Scully Jr., M.D. I am the Medical Director and CEO of the American Psychiatric Association, which is the medical specialty representing more than 38,000 psychiatric physicians across the country. Prior to my present position at the APA, I was the Alexander Donald Professor and Chair of the Department of Neuropsychiatry and Behavioral Science at the University of South Carolina School of Medicine in Columbia, S.C., and President of the Education Trust of the University of South Carolina School of Medicine. I have also served as an interim director of the South Carolina Department of Mental Health, on the boards of a variety of medical organizations, and presently as the president of the Council on Medical Specialty Societies.

By direction of our Board of Trustees, our highest priority is to advocate for our patients and profession, as most recently evidenced by our twelve year effort to secure enactment of last year's landmark law requiring "parity" in the coverage of treatment for mental illness, including substance use disorders. I thank you, Mr. Chairman, along with your Committee members and the entire Congress for your efforts to make parity a reality.

APA also promotes the highest standards of care for our patients and their families, and to that end we strive for standards of excellence in psychiatric research and in the education and training of our psychiatrist workforce. Critical goals and activities of the American Psychiatric Association include:

- Advocating for patients and for the profession, and fighting discrimination against people suffering from mental illnesses, including substance use disorders.
- Supporting education, training and career development of psychiatrists and other physicians.
- Enhancing the scientific basis of psychiatric care.
- Defining and supporting professional values and ethics.

I note that many of the most dramatic improvements in the effective treatment of mental illness have come as a result of newer and better medications. These have meant remarkably positive changes in the lives of tens of millions of Americans and would not have been possible without the commitment of the pharmaceutical industry to research and development.

Nevertheless, we need to support continued innovation so that improvements in treatment will continue. Since most of the research on new medicines is funded by pharmaceutical companies, we need to be able to access the information developed and academic researchers need to be able to interact with industry. The challenge is to do this in a way that protects integrity while supporting innovation and the better treatment and outcomes for our patients.

Over the past decade, the relationship between medicine and industry, including pharmaceutical manufacturers and medical device companies, has been under increased public scrutiny, and appropriately so. Patients need to be able to rely on the objective recommendations of their physicians. In turn, physicians must be able to rely on the objectivity of research as it pertains to the safe and effective use of medications and medical devices.

Recognizing the necessity of managing potential conflicts of interest, the APA has been proactive in examining the pros and cons of our relationships with the pharmaceutical industry. We have, for example, taken considerable pains to implement safeguards to reduce the risk of a conflict of interest between the industry and the provision of Continuing Medical Education. In fact, the APA received a commendation and a six year accreditation for outstanding compliance with accreditations rules and regulations-2004-2010 from the Accreditation Council for Continuing Medical Education.

APA's efforts to avoid bias in CME-related activities includes careful monitoring by our Committee on Commercial Support, which is charged with the oversight of all industry supported symposia (ISS) at the APA Annual Meeting, including evaluation, program revisions and the process for responding to infractions of the APA and ACCME guidelines. The Committee formulates policy and guidelines for commercial support of CME activities consistent with ACCME guidelines. Each of the past several years we have increased our oversight of the ISS's. This includes previewing slides and other materials used in ISS, and requiring changes where needed. Monitors attend all sessions to watch for commercial bias and compliance with APA commercial support procedures. If there is a report of alleged commercial bias or other non-compliance with standards, the CSS reviews audiotapes of the sessions and will take corrective action as needed.

The APA also has a Scientific Program Committee (SPC) which is responsible for all decisions concerning the content and format of the APA Annual Meeting, including editorial responsibility for the peer review, selection and presentation of the scientific and clinical content of the Annual Meeting. The Committee reviews all submissions for scientific and clinical merit, including those symposia seeking industry support. Members of this committee must also submit disclosure forms and recuse themselves from discussions that might involve a perceived conflict. Every aspect of the meeting must be approved by the SPC. The ISS at our Annual Meeting have been valued by our members and have received very positive evaluations by participants, yet other members continued to raise concerns about appearance of bias and conflict.

Our efforts to ensure appropriate separation of commercial and educational activities do not begin and end with the symposia. We also set rules to create a buffer, such that:

- No commercial materials, promotional materials or product advertisements may be displayed outside of the exhibit hall.
- No commercial materials, promotional materials or product advertisements may be displayed or distributed in the same room or adjacent areas immediately before, during, or immediately after an educational activity certified for CME credit.
- No commercial materials, promotional materials or product advertisements may be distributed to guest rooms or space otherwise shared with attendees at the Annual Meeting.
- No promotional activities are permitted in the same area as the educational activities.
- Representatives of commercial supporters of the Annual Meeting may register for and attend an educational activity, but may not engage in sales or marketing activities inside educational activities or adjoining areas.

Our efforts do not begin and end with these protections. In March, 2008, the APA's Board of Trustees voted to establish a working group to assess our relationship with the pharmaceutical industry, and if necessary to recommend additional changes in policy. The working group submitted its report to the Board in December, 2008.

Among the recommendations submitted for Board review was that the APA phase out industry-supported education programs and industry-supported meals served at the APA scientific meetings. The Board voted in March, 2009 to accept the recommendation.

As far as we know, the APA is the first professional medical specialty to end industry-sponsored symposia. Implementation began at our 2009 Annual Meeting in San Francisco. In 2006 the industry-supported programs comprised 46 of the over 549 educational programs at the scientific meetings. In 2008, the industry-supported programs constituted about 5 percent or 28 of the over 549 educational programs at the scientific meetings. As a result of the Board action, in 2009 this was reduced to 11 programs. I do want the Committee to note that the overwhelming majority of our educational activities at our annual meetings are not developed by the pharmaceutical industry but by APA members including the NIH.

Mr. Chairman, this action is not without considerable short-term costs. For example, APA's decision to phase out the ISS will result in a loss of revenues totaling some \$1.5 million. In the long run, however, we believe that the elimination of even the perception of possible undue influence is worth the cost.

The American Psychiatric Association has long understood the need for a comprehensive disclosure policy based on clarity and transparency, particularly in the areas of publishing, research and education. APA recognizes that the ultimate success of its education enterprise rests on the public's (and its members') trust and confidence that the educational content is based on accepted scientific information free of any perceived marketing bias. Similarly, the success of our research enterprise rests on the public's trust and confidence that the research is conducted and presented in an unbiased manner.

These basic principles inform all of our work. All members (and staff) participating in any activities (including policy development, governance, as well as education and research) must submit a disclosure statement, which includes a listing of current or potential competing interests, and members must recuse themselves from any activity or decision making that may have a perceived or actual competing personal or professional interest. Our credibility as

psychiatrists and the credibility of our products and programs require this transparency and complete disclosure of any current or potential conflicts of interest such as affiliation and sources of income from the biomedical and pharmaceutical industry. We currently have a Board of Trustees workgroup revising our disclosure forms and policies in order to continue to improve our management of potential conflicts.

Ultimately, a close examination of current practices coupled with the appropriate disclosures will further enhance patient trust and, therefore, patient care. Disclosure, however, is not a panacea; physicians and medical societies should frequently examine their relationships with all third parties and ensure that they are not unwittingly placing themselves in the very situations that tend to promote undue influence.

We are working with our sister societies in CMSS (Council of Medical Specialty Societies) to respond to the call by the Institute of Medicine to develop standards for managing potential COI's (Conflicts of Interests).

The fact that the relationship between the pharmaceutical industry and the medical profession is facing increasing scrutiny is not a bad thing. To the contrary, patients should know about their physicians' potential conflicts of interest where they truly exist. Only then can they have confidence in decisions made about their medical care. As our awareness of conflicts of interest evolves into greater degrees of clarity, doctors and their professional societies should re-examine the pros and cons of their relationships with the pharmaceutical industry. Where are the real and perceived conflicts? How can they be eliminated? This is the process that many medical societies are currently undertaking. The American Psychiatric Association is proud to be at the forefront of that process.

Thank you for the opportunity to testify. I would be pleased to answer your questions.

The CHAIRMAN. Thank you very much, Dr. Scully.
Dr. Kopelow.

STATEMENT OF MURRAY KOPELOW, M.D., MS, FRCPC, CHIEF EXECUTIVE, ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION, CHICAGO, IL

Dr. KOPELOW. Good afternoon, Chairman Kohl, Ranking Member Martinez, and members of the committee.

I'm Murray Kopelow, Chief Executive of the Accreditation Council for Continuing Medical Education. I also serve as a Special Advisor to the White House Office of National Drug Control Policy.

Senator Kohl, in full disclosure, my daughter, Miriam, is a proud student at the University of Wisconsin at Madison.

Mr. Chairman, my colleagues and I have prepared written testimony that I request be included in the hearing record.

The CHAIRMAN. It will be done.

Dr. KOPELOW. Senators, ACCME is the firewall between promotion and education. ACCME administers a voluntary self-regulated system for accrediting providers of continuing medical education. These regulations include the standards of commercial support, standards for independence of continuing medical education.

As all the panelists have pointed out, continuing medical education is important to physicians and to patients. As everyone here has said, ACCME is committed to ensuring that accredited CME contributes to the quality and safety of healthcare, contains valid content, and is developed without the influence of commercial interests.

Accredited CME is independent from the influence of commercial interests. At your request, our testimony will focus on commercial support, our enforcement of our standards, and how the ACCME is becoming more transparent and responsive to its external constituencies.

As said, the total revenues of CME providers are about \$2 billion. About half comes from the learners; the rest comes from commercial interests. During 2008 this commercial support has fallen by \$200 million. Eighty percent of the providers accept commercial support in amounts that range from thousands of dollars to tens of millions of dollars. But, 15 percent of the providers receive 80 percent of the commercial support. It's not distributed equally across the continuing medical education enterprise.

ACCME has taken steps to enhance its requirements concerning independence from commercial interests, and enhanced its enforcement of these requirements. Next month, new policy becomes effective that excludes from accreditation any entity that markets, sells, or distributes healthcare products or services. In 2008 and 2009, we offered several policy proposals regarding the funding structure of CME and restricting CME's interactions with commercial interests. These included possibly restricting commercial support to when educational need is verified by an organization free of commercial support, and when the CME addresses a gap in professional practice, and when CME content was from a specified curriculum, and when that CME is verified as free of commercial bias, much as proposed by Mr. Morris.

We proposed excluding persons that have been paid to create or present promotional materials from controlling the content of accredited CME. We have proposed the use of designations like “Promotional Teacher and Author-Free” and “Commercial Support-Free” to help learners and the public. We proposed the creation of a new entity to pool unrestricted educational donations from commercial interests. We have not yet acted on these proposals, and they remain on the table while a nationwide discussion about the impact of industry relationships continues within many organizations, including the ACCME’s member organizations.

In the meantime, ACCME has gone on to enhance its enforcement of policy. Since 2008, our complaints and inquiries process closed 17 inquiries; 12 of them remain open and will be completed this year. We began a process to more closely scrutinize providers who receive a large amount of commercial support. We now have a Web-based system for collecting educational activity information, ready to be deployed. We will now implement a surveillance and monitoring system that will include our direct observation of activities in the field. We now require all providers found not in compliance with our standards to receive—to submit an improvement plan within weeks of the findings, and to demonstrate—to submit a demonstration of compliance and practice within 6 or 12 months.

This process is effective in bringing about compliance with our standards. The number of providers being put on probation has increased to about 10 percent of accreditation decisions.

We have 725 providers that we accredit directly, and about 1600 providers that are accredited by 47 ACCME-approved State-based medical societies, including Minnesota, Wisconsin, and Florida. Because of new ACCME policy, now all these accreditors will be enforcing the same ACCME standards the same way, creating equivalency of enforcement across the nation. This enforcement is carrying over to other professions—pharmacy, nursing, and optometry—each of whom intend to enforce the same ACCME standards.

We continue to require disclosure of relevant financial relationships of teachers, authors, and planners, and to require disclosure of all commercial support to learners. We have enhanced our own disclosure of ACCME information. This month, we began making public the accreditation status of providers, if a provider takes commercial support, and the accreditation findings on which we base our accreditation decisions. All of this is to continue to ensure independence, and to ensure that CME matters to patient care.

Much of what I have reported to you today is new. To provide the resources to meet these expectations, the CME system is paying new fees to support a 50-percent increase in ACCME staff and a 60-percent increase in ACCME expenditures over 2007 levels.

I would welcome your questions on these or any other issue of importance to the committee, and I thank you for this opportunity to testify.

[The prepared statement of Dr. Kopelow follows:]



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Testimony of

Murray Kopelow, MD, MS (Comm.), FRCPC
Chief Executive
Accreditation Council for Continuing Medical Education (ACCME)

on

*"Medical Research and Education: Higher Learning or Higher
Earning?"*

Before the
Special Committee on Aging
United States Senate

July 29, 2009

Testimony of
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INTRODUCTION

Good afternoon, Chairman Kohl, Ranking Member Martinez, and Members of the Committee. I am Dr. Murray Kopelow, the Chief Executive of the Accreditation Council for Continuing Medical Education, commonly known as the ACCME. In that role, I direct the executive and staff leadership functions of ACCME, including its relationships with medical education providers and other member organizations. I currently also serve as a special advisor to the White House Office of National Drug Control Policy.

By way of background, ACCME administers a voluntary self-regulated system for accrediting providers of continuing medical education (CME). This system of standards and credentialing is recognized, and often deferred to, by government entities including state medical licensing boards, the Food and Drug Administration and the Department of Health and Human Services Office of Inspector General.

At your invitation, we welcome the opportunity to address the current state of medical education including the quasi-regulatory standards of ACCME and extent of funding support by commercial interests. This written testimony is intended to supplement and update our Statement of June 2008 provided to the Committee in response to its continuing review of the relationship between drug and device manufacturers, and CME providers.

Specifically, at your request, our testimony will focus on: (1) the extent of industry support; (2) ACCME enforcement of its accreditation requirements and standards for commercial support; and (3) how the Council is implementing its commitment to become more transparent and responsive to its external constituencies.

A. Extent of Industry Support

1. Continuing Decrease in Commercial Support of CME

The relative proportion of CME supported by commercial entities continued a decline that began in 2003. For the first time in 2008, the absolute amount of commercial support also

decreased - by about \$200 Million. As indicated below, in 2008, total commercial support of CME in the U.S. approached the levels reported by ACCME in 2003 and 2004.

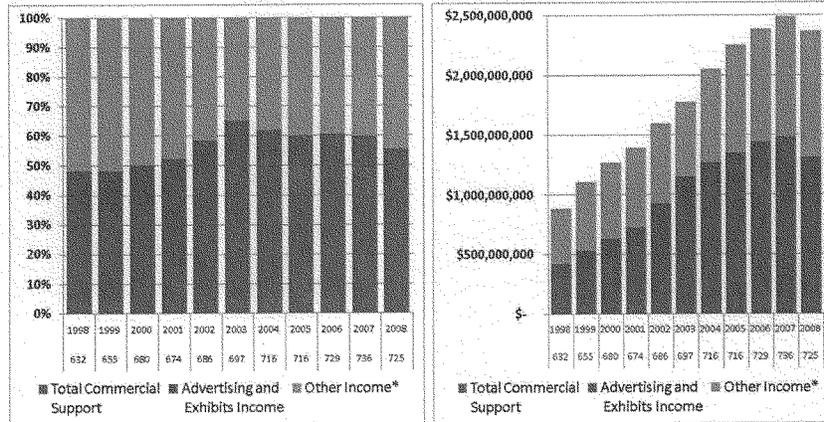


Figure 1: Percentage of Commercial Support of CME (1998-2008) and Amount of Commercial Support of CME (1998-2008)

		Total Commercial		Advertising and Exhibits		
	Count	Total Income	Support	Income	Other Income*	Total Expense
1998	632	\$ 866,544,752	\$ 301,949,112	\$ 125,901,179	\$ 467,694,461	\$ 842,061,037
1999	655	\$ 1,110,462,468	\$ 367,619,740	\$ 148,241,180	\$ 574,621,568	\$ 920,897,966
2000	680	\$ 1,271,189,580	\$ 466,971,749	\$ 168,864,400	\$ 635,353,431	\$ 1,053,684,130
2001	674	\$ 1,393,926,271	\$ 568,787,299	\$ 159,955,455	\$ 665,203,517	\$ 1,179,631,684
2002	686	\$ 1,586,198,685	\$ 749,015,426	\$ 187,327,758	\$ 662,855,883	\$ 1,327,042,030
2003	697	\$ 1,774,516,385	\$ 971,100,098	\$ 183,293,597	\$ 620,122,700	\$ 1,539,686,438
2004	716	\$ 2,052,577,784	\$ 1,071,064,979	\$ 197,032,732	\$ 794,460,073	\$ 1,612,476,355
2005	716	\$ 2,250,468,669	\$ 1,115,597,071	\$ 235,721,224	\$ 899,160,373	\$ 1,717,466,541
2006	729	\$ 2,394,581,430	\$ 1,199,405,519	\$ 244,913,694	\$ 840,262,229	\$ 1,820,708,534
2007	736	\$ 2,487,737,069	\$ 1,211,345,204	\$ 274,071,865	\$ 1,002,319,999	\$ 1,891,809,458
2008	725	\$ 2,365,097,746	\$ 1,035,942,134	\$ 277,295,124	\$ 1,051,860,486	\$ 1,976,030,151

Table 1: Total Income for all providers (by source) and total expenses, for the period 1998 to 2008

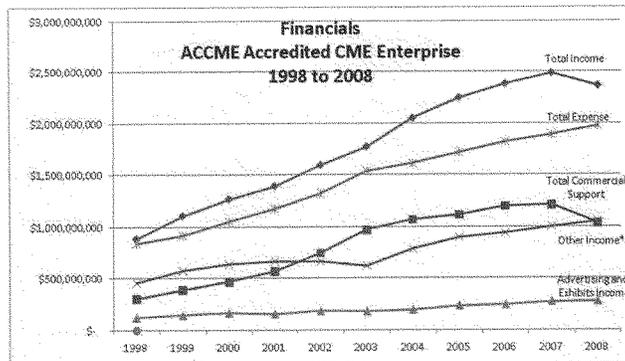


Figure 2: Total Income for all providers (by source) and total expenses, for the period 1998 to 2008 (same data as Table 1)

There was no associated contraction of CME made available to learners. (Note: most of the decrease in reported "activities" counts in 2008 was due to a change in reporting by Internet providers.)

Year	Activities	Hours of Instruction	Physician Participants	Non-Physician Participants
1998	48,092	574,069	3,662,701	1,544,664
1999	47,129	585,446	4,436,197	1,760,504
2000	49,451	551,739	5,093,595	1,883,811
2001	51,048	583,449	5,178,883	2,159,312
2002	55,967	624,824	5,415,945	2,692,971
2003	66,788	704,077	6,037,395	3,041,898
2004	71,564	692,673	6,516,564	3,235,562
2005	79,820	678,528	7,650,207	3,683,749
2006	93,582	712,163	8,255,017	4,577,078
2007	113,003	741,261	8,698,298	5,177,299
2008	100,898	769,439	10,665,514	6,559,564

Table 2: Size of the accredited CME enterprise.

Table 3 below, shows the impact of changes in amounts of commercial support across Provider groups. In addition to the absolute decrease in commercial support during this period, these changes can be attributed to attrition in providers as well as movement between provider groups.

Commercial Support			
Provider Type	2006	2008	% Change
Government or Military	\$4,191,416	\$128,790	-96.93%
Hospital / Health Care Delivery System	\$57,937,148	\$39,473,400	-31.87%
Insurance Company / Managed Care Company	\$262,200	\$376,833	43.72%
Non-profit (Other)	\$49,488,025	\$86,637,092	75.07%
Non-profit (Physician Membership Organization)	\$179,932,428	\$202,541,623	12.57%
Not Classified	\$27,878,144	\$17,677,761	-36.59%
Publishing / Education Company	\$620,657,409	\$463,382,987	-25.34%
School of Medicine	\$259,058,752	\$225,723,643	-12.87%
Total	\$1,199,405,522	\$1,035,942,126	-13.63%

Table 3: 2006 and 2008 Comparison: Total Commercial Support, by Provider Type

There continues to be a non-uniform distribution of commercial support across accredited providers. There has been a small increase in number (to 140) and proportion (to 20%) of Providers that do not accept commercial support.

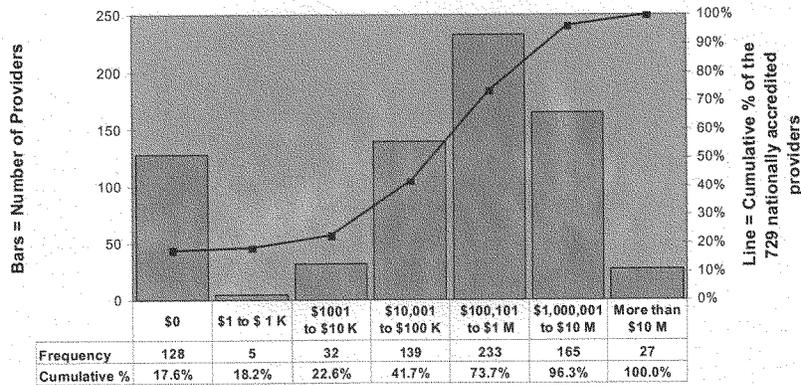


Figure 3; 2008 Distribution of Commercial Support by amount, across all accredited 725 providers

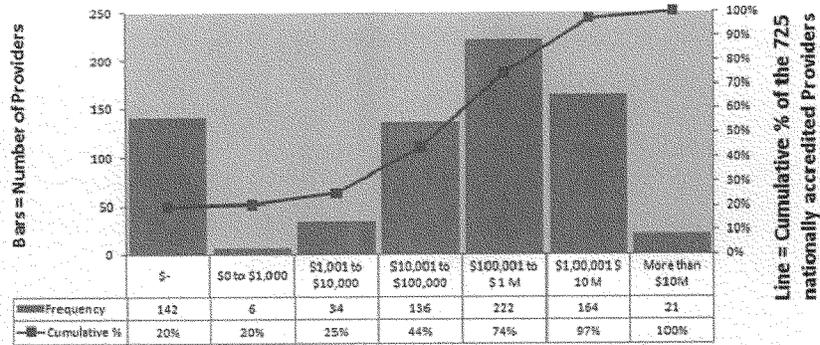


Figure 4: 2008 Distribution of Commercial Support by amount, across all accredited 725 providers

B. ACCME Enforcement of Accreditation Requirements

1. Initiation of Discussion over Policy Proposals

In January 2007, ACCME initiated a nation-wide discussion of whether commercial support of accredited CME should continue. We announced that we were considering taking action regarding the funding structure of continuing medical education. Ideas included in proposals for which comment was solicited included:

- a. The *status quo* with commercial support of CME remaining an acceptable funding mechanism;
- b. Complete elimination of commercial support;
- c. Allowing commercial support only where it is in the public interest based on criteria including: (1) when educational needs are identified and verified by an organization free of commercial support; (2) if the CME addresses a gap in professional practice corroborated by *bona fide* performance measurements; (3) when CME content is from a curriculum specified by a *bona fide* organization; and (4) when the CME is verified as free from commercial bias;
- d. Accredited providers must not receive communications from commercial interests related to specific content that would be preferred; including receiving internal criteria for providing commercial support;

- e. Persons paid to create, or present promotional materials on behalf of commercial interests cannot control the content of accredited CME on that same content;
- f. Use of designations like "Promotional Teacher and Author Free"™ where teachers or writers of any part of a CME program could not maintain financial relationships derived from marketing or promotional activities for commercial interests;
- g. Use of designations like "Commercial Support-Free"™ where providers would not accept any commercial support including the use of advertising and promotion funds to underwrite the costs; and
- h. Creation of a new entity independent of ACCME to pool unrestricted educational donations from commercial interests that would be available to ACCME accredited CME providers.

In March 2008, ACCME again expressed the belief that due consideration be given to the elimination of commercial support of CME. Many stakeholders inside and outside of CME enterprises responded with views on the subject. Based on that input, ACCME announced in its Executive Summary of the March 2009 Board Meeting that it "would not be taking any action to end the commercial support of accredited [CME]." In our June 2008 Statement to the Committee, we said that "...nothing would be worse than the deconstruction of a system without the identification of alternatives." The proposals remain "on the table" even though ACCME has chosen not to act on them at this time.

The profession has become fully engaged in a discussion of the future relationship between industry and medical education as follows:

- a. In July 2009, the Council on Ethical and Judicial Affairs of the American Medical Association (AMA) presented a report with recommendations for action on a new construct for classifying the ethics of the medical profession's relationship with industry in CME.
- b. In June 2009, the Committee on Conflict of Interest in Medical Research, Practice, and Education of the Institute of Medicine (IOM) identified the need for stakeholders to come together, in a consensus building process, to identify a future funding model for CME that ensures its independence from industry (IOM Recommendation 5.3).
- c. During 2009 the Council on Medical Specialty Societies convened a Task Force on Professionalism and Conflict of Interest to "*develop and recommend a 'Code of Conduct' for specialty societies, to enhance professionalism and to disclose, manage and resolve conflicts of interest in relationships with industry.*"
- d. Late in 2008, the Conjoint Committee for Continuing Medical Education, a group CME stakeholders convened by the Council of Medical Specialty Societies, identified a strategic imperative for itself to, "*convene a*

national conversation about a system of financing [CME] that responds to Recommendation 5.3...., to ensure that CME is free from the influence of commercial support."

- e. In 2009, the American Boards of Medical Specialties approved Standards for its Maintenance of Certification program that include requirements that continuing professional development activities to be free of commercial bias, as regulated by ACCME and its Standards for Commercial Support. Issues of commercial support and potential bias will be topics for future discussion by that organization's Ethics and Professionalism Task Force.
- f. In June 2009, the Association of American Medical Colleges convened a group to "Focus on Conflict of Interest in Academe" which included a half day discussion on the issues of conflict of interest in CME.

2. Definition of Commercial Interest

- (1) In 2007, ACCME announced an expanded definition of a "commercial interest" to exclude from accreditation those organizations that market, re-sell, or distribute health care products or services used by, or on, patients. Accredited CME providers could also lose their accreditation if they joint ventured with a "commercial interest."
- (2) ACCME has provided guidance concerning corporate models that would create independence between commonly owned commercial interests (e.g., marketing and advertising entities) and CME providers.
- (3) Eligibility for continuing accreditation ends on August 31, 2009.
- (4) Enforcement is being performed through enhanced screening for compliance within the accreditation eligibility process.
- (5) ACCME has been conducting specific organizational reviews.
- (6) Private CME providers have retained counsel to reorganize entities now designated as commercial interests under the new expanded definition, by separating affiliates seeking ACCME accreditation, or seeking to joint sponsor with accredited ACCME providers (e.g., creating "firewalls" to insure ACCME-defined independence).
- (7) Reorganized accredited CME providers have sought the opinion of ACCME concerning the sufficiency of their "firewalls."

3. Enforcing Existing Policy on Independence

In 2009, ACCME continued to issue many clarifications concerning independence criteria in response to provider questions. For example, ACCME provided the following descriptions of appropriate roles and contributions that staff persons of commercial interests may make to accredited CME.¹

¹ ACCME Standards for Commercial Support, Standard 1: Independence prohibits the circumstance that would allow the employee of the commercial interest to take the role of planner or teacher inside

NEW (03/2009)

PROVIDER QUESTION #8) Can employees of commercial interests serve as planners or speakers in our accredited CME activities?

ACCME RESPONSE: If the content of CME that the employee of the commercial interest controls relates to the business lines and products of its employer – **NO**. If the content of CME that the employee of the commercial interest controls DOES NOT relate to the business lines and products of its employer – **YES**.

NEW (03/2009)

PROVIDER QUESTION #9) Can we offer accredited CME activities on research that was controlled in some way by a commercial interest, either through funding, collaboration, or involvement of the commercial interests' staff in the research itself?

ACCME RESPONSE: Yes, as long as the CME activity complies with the ACCME's Accreditation Criteria, including the ACCME® Standards for Commercial SupportSM. It is understood and accepted that industry conducts its own research and that industry partners, as funder or collaborator, in research projects. An important step in the translation of discovery to practice is the dissemination of the results of this research. There are several layers of internal and external controls already in place to manage the conduct of research (e.g., Institutional Review Boards, Government agencies) and the dissemination of results (e.g., editors, peer review, international standards.) The ACCME does not intend to interfere with these carefully managed phases. However, when an organization chooses to base its CME content on research the organization assumes responsibilities related to CME, including compliance with the ACCME® Standards for Commercial SupportSM. The CME content (not the research that has already taken place or is taking place) cannot be controlled by a commercial interest. As an example, industry employees cannot deliver oral presentations and cannot author enduring materials that are accredited CME if the CME content relates to business lines or products of their employer.

NEW (03/2009)

PROVIDER QUESTION #10) One of our CME courses is an intensive hands-on course that trains physicians to perform vascular interventions in a laboratory setting. The training is primarily about newer medical devices

accredited CME if the content of the CME is related to the business lines or products of the commercial interest. Standard 1 states:

SCS1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a 'commercial interest' and some exemptions.)

- (a) Identification of CME needs;
- (b) Determination of educational objectives;
- (c) Selection and presentation of content;
- (d) Selection of all persons and organizations that will be in a position to control the content of the CME,
- (e) Selection of educational methods;
- (f) Evaluation of the activity.

SCS1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.

and equipment, their use, and practical training in how to perform the procedures. The course director has asked a couple of companies to provide both training equipment/devices to use and company personnel to operate the equipment. We will track this loaned equipment as in-kind commercial support. The course director has independently designed the activity, determined the procedures to be taught, instructs the technologists on their roles, and is present to oversee and participate in the instruction. The course director verifies that the training and comments provided by the device technologists are technical only about the use of the equipment, and do not favor a commercial product or compare products. Is this situation allowed under the ACCME® Standards for Commercial Support?

ACCME RESPONSE: Education on devices is a special use-case in accredited CME. Some equipment contains "labeling requirements" set by the FDA that include the requirement for instruction prior to use. Each set of circumstances needs to be taken on a case-by-case basis as the conflicts of interest of industry employees are irreconcilable in CME, so they can never take the usual role as teacher or author in accredited CME. Industry employees can demonstrate the operational aspects of the use of a device under the umbrella of a provider's ACCME accreditation - but they must only demonstrate the operational aspects. They can do this without contributing in any way to any decision-making about the elements of SCS 1 of the ACCME® Standards for Commercial SupportSM. It is also critical that the employees never expand their input into areas of clinical medicine while involved in accredited CME (e.g., never talk about indications for use, never talk about comparisons between competing products or comparisons between the device and/or invasive surgery and/or medical treatment). This special use-case, if it is going to remain compliant, requires careful supervision by the accredited provider's faculty and staff and proper professional behavior by industry staff.

4. Monitoring and Surveillance

ACCME maintains a ***Complaints and Inquiries Process*** (Attachment 1) whereby it can initiate formal inquiries into Providers' compliance with the ACCME requirements during their terms of accreditation.

Providers found in non-compliance with ACCME's requirements in the Complaints and Inquiries Process submit Notices of Correct Action where they describe, and provide verification of, their compliance with ACCME requirements.

In 2008 and 2009, ACCME completed and closed 17 Inquiries (see Attachment 2), 12 of which involved the Standards of Commercial Support (SCS). Five Inquiries ended with findings of non-compliance in at least one element of the SCS. Seven Inquiries ended with findings of compliance. Twelve Inquiries relating to the SCS are still open.

a. ACCME Inquiry of Providers Receiving Commercial Support for CME Programs

In the July 2008 Statement to the Committee, ACCME wrote, "The ACCME has begun a process for looking into the practices of the approximately one hundred ACCME Providers that receive most of the commercial support."

Each provider surveyed was able to submit information descriptive of a mechanism and procedures in place to implement the ACCME SCS. This project did not produce useful diagnostic information because of the design and execution of the evaluation by the ACCME.

The Providers submitted a considerable amount of description and documentation of their mechanisms for compliance with the ACCME Standards of Commercial Support, exactly as requested.

We asked experienced ACCME surveyors and/or review committee members to review the submitted information and draw conclusions on items included in the Survey Instrument in Attachment 3.

An analysis of the results of the reviewers' analysis showed ACCME that there was considerable inter-rater variability which could not be explained on the basis of the descriptions submitted by Providers.

We discovered, after the fact, that the wording of our request for information consistently produced the delivery of an information set that was exactly aligned with our SCS but did not produce information for our evaluators to reliably make inferences about these areas of interest. ACCME could not draw conclusions. Upon analysis of the information that we got back, it appears that all the variability between providers was due to inter-rater variability as opposed to true differences between Providers.

We now consider the process a 'pilot' within a larger project in which we are looking for reliable, sensitive and specific ways to measure the outcomes of the implementation of the ACCME SCS. ACCME will be undertaking further analysis of the data and information submitted.

b. Monitoring by Direct Observation

In the July 2008 Statement to the Committee, ACCME wrote, "An additional system is being developed to directly monitor educational activities so as to establish the prevalence of commercial bias and to determine if there is any subsequent over use, or inappropriate use, of commercial products as a result of continuing medical education."

ACCME developed a new activity database. CME Providers were required to provide information described in the announcement contained in Attachment 4. Creation and use of the new database was divided into three phases; (1) submission of additional information by CME Providers; (2) inclusion of monitoring information; and (3) inclusion of self-assessment data.

Phase 1 is just being completed. ACCME has developed a web-based database system to capture information descriptive of Providers' CME activities as they are being planned and presented. This ACCME "activity database" has been built incorporating national standards and definitions so as to promote interoperability and communication between systems.

An example of the web pages for the Activity and Program Reporting System is included in Attachment 5.

c. Potential for Monitoring through Reporting Educational Impact on Strategy, Practice or Patient Outcomes

Since November 2008, ACCME has been measuring accredited Providers' compliance with the 2006 Accreditation Criteria. In these Criteria, ACCME requires each Provider to measure the effectiveness of all educational activities in terms of changes in physician competence (strategy), performance-in-practice or patient outcomes.

It will now be possible for ACCME to ask Providers about the results of measurements of the changes in attitude, changes in strategies for use, changes in actual use and changes in patient outcomes with respect to outcomes of certain educational activities. Eventually, inferences will be able to be drawn about whether, or not, the direction of change is in a direction that will result in the learners' inclination towards, or actual, use of a product or service that is more than is necessary.

5. Enforcement at Reaccreditation

a. Compliance Results- Standards for Commercial Support (2008-2009)

ACCME data shows that the non-compliance rate for elements of the SCS varies from 5% to 49% for recent decisions (Figure 5) and varies from 2% to 38% over the entire time period covered by the Updated Standards for Commercial Support (Figure 6).

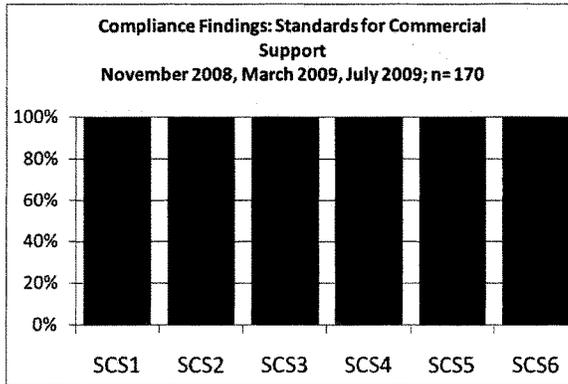


Figure 5: Recent Accreditation Decision

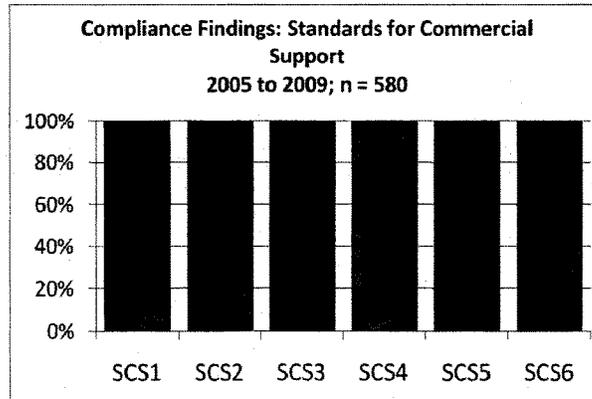


Figure 6: Accreditation findings since 2005

Figure 7 represents the "ACCME Compliance Grid" containing the accreditation findings for the 170 Providers evaluated under both the 2006 Accreditation Criteria and the 2004 SCS.

A row represents findings for an individual provider.

The columns represent the 22 Criterion, in groups. Criteria 7 to 10 (indicated with the blue box) are the SCS.

b. Accreditation Results Since November 2008

- Two Providers received **NON ACCREDITATION** for failure to come into compliance with Criteria through the Progress Report process.
- Fourteen of the 22 Initial Applicants for accreditation received decisions of **NON ACCREDITATION** for failure to demonstrate compliance in all ACCME accreditation elements. All, but one, was found in non compliance with the SCS.
- Fifteen Providers were placed on **PROBATION** for: **a)** a failure to demonstrate any implementation of the 2006 educational accreditation criteria; or **b)** recidivism with respect to compliance with the ACCME SCS. (This represents some providers that were found in non-compliance with the SCS four years previously, demonstrated correction with a Progress Report and then were found in non-compliance with the SCS during this re-accreditation review.); or **c)** failure to address some components of the ACCME Standards for Commercial Support.
- Eighty-eight providers were awarded **ACCREDITATION** with a Progress Report. These providers are being required to submit a Progress Report in order to demonstrate compliance in all elements of the ACCME requirements. Seventy one included non compliance findings in the SCS.
- Fifty Providers were found in compliance with all their required accreditation elements. Of these:
 - Eight received **PROVISIONAL (INITIAL) ACCREDITATION**.
 - Twenty six received **ACCREDITATION**.
 - Sixteen received **ACCREDITATION WITH COMMENDATION**.

The table is a large grid of data, organized into several distinct sections. Each section is headed by a bolded label: 'Non-Accreditation', 'Non-Accreditation from Initial Application', 'Probation with Progress Report', 'Accreditation with Progress Report', 'Provisional', 'Accreditation', and 'Accreditation with Commendation'. The data within these sections is presented in a dense, multi-column format, with many cells containing small, illegible text or numbers. The overall appearance is that of a complex data matrix or a detailed report table.

Figure 7

Figure 8 shows that for 170 Providers, 81% received **ACCREDITATION**, 9% received **PROBATION** and 10% received **NON ACCREDITATION**.

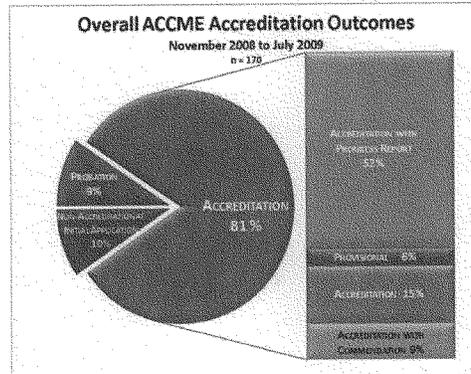


Figure 8: Combined Accreditation Outcomes November 2008, March 2009 and July 2009. n=170

In August 2008, ACCME contacted accredited Providers and informed them that information would be required more quickly when non-compliance findings were made and that ACCME verification would be more rigorous and timely. This new process requires Providers to establish improvement plans (immediately after receipt of the accreditation decision) followed by the submission of verification of improvements within one year. This two-step improvement process is intended as a mechanism for assisting and encouraging providers to identify solutions to deficiencies and remediate them more quickly. The process is designed to assist Providers by providing fair notice and opportunity to modify existing practices, as well as to ensure that learners are receiving the highest quality CME.

ACCME's accreditation system is a careful and deliberate process in which serious and systemic issues that place providers and their learners at risk can be identified. We have learned over the years that an accreditation status of "**Probation**" sends a clear message that significant changes need to be made. ACCME has also observed that the vast majority of providers make the necessary changes immediately, leading to sustained compliance, and in a number of instances, Accreditation with Commendation.

In order to increase Provider compliance with new and increasingly rigorous requirements, ACCME has placed more accredited Providers on **Probation** - especially those found in Non Compliance with the most important elements of the ACCME Standards for Commercial Support.SM The current rate of **Probation** has

increased to about 10% of Providers seeking Reaccreditation from about 1% prior to 2008.

c. Path to Compliance or Non Accreditation

The enforcement outcomes of a finding, or findings, of non compliance in the SCS are,

1. An alteration to the Provider's accreditation status to Probation; **and/or**
2. An ACCME Progress Report that requires the Provider to: a) submit an improvement plan (new in last year) descriptive of intended corrective action; and b) submit documentary evidence that verifies compliance.

Provider's accreditation status is changed to **PROBATION** at REACCREDITATION if the Provider demonstrates recurrence of non-compliance in the SCS between terms of accreditation (new in last year), failure to implement elements of the ACCME Standards for Commercial Support, or a general failure to meet ACCME requirements as demonstrated through multiple non-compliance findings. **PROBATION** will also occur in the presence of persistent non-compliance after submission of a first Progress Report that is submitted at 9 months; decision rendered at 12-15 months. (As of November 2009, Progress Reports will be considered by ACCME at 4, 8 or 12 months which will require submission at 2, 6 or 10 months (new in last year.)

Providers can remain on **PROBATION** for up to 24 months. If Providers cannot demonstrate compliance through adequate Progress Reports, their accreditation status will be changed to **NON ACCREDITATION**.

Providers also receive decisions of **NON ACCREDITATION** if, at Initial Accreditation, applicants are in non-compliance with any element of ACCME's standards. In the 3 cohorts evaluated using the 2006 Criteria, 59% of initial applicants received a decision of **NON ACCREDITATION**.

d. Enforcement of Requirements through Progress Report Process

It is rare that Providers fail to demonstrate improvement and compliance through the Progress Report process. In the period from 2007 to 2009, ACCME's enforcement policies and procedures are projected to produce an overall compliance rate of 96% with the SCS.

Figure 9, below, shows that for every 100 providers seeking reaccreditation, 52 will be found in compliance with all elements of the SCS at initial review. Eighty-nine will be in compliance after a single Progress Report, and 96 will be in compliance after a second Progress Report. This compliance rate equates to 96%. The 4 that remain in non-compliance will withdraw, go to non-accreditation, or come into compliance with a third Progress Report.

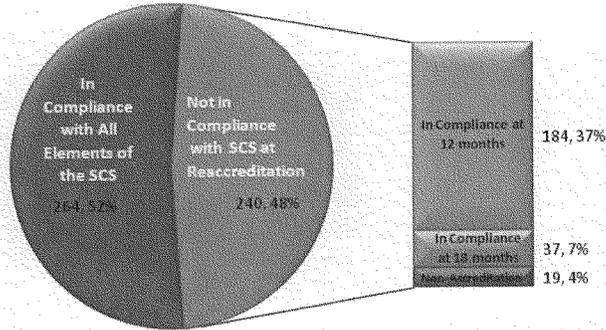
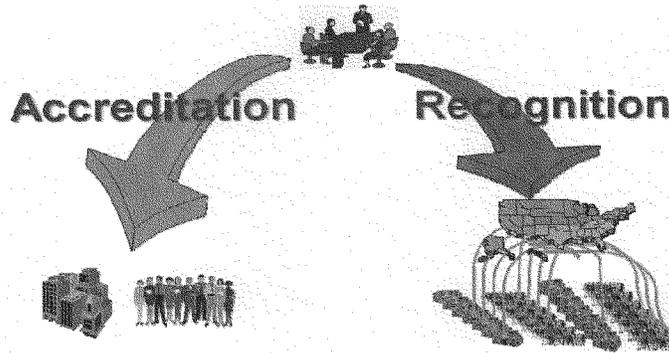


Figure 9: Outcomes as a Result of Compliance with the ACCME Standards for Commercial Support at Accreditation and on Progress Reports 2007 - 2009 (projected)

6. Enforcement by Equivalency between Accreditors

a. Equivalency within ACCME System

ACCME accredits 725 providers directly. In addition, there are about 1,600 state-based accredited providers that enjoy all the rights and privileges of an ACCME accredited Provider resulting from their accreditation by a state medical society, or equivalent. These Providers are not directly accountable to ACCME. The 46 organizations that accredit them, however, are accountable to ACCME through the ACCME process of RECOGNITION.



This process of RECOGNITION by ACCME has relevance to medical licensure, and CME in general. The policy of the Physician's Recognition Award of the AMA states that, "organizations accredited by the ACCME or a Recognized state medical society may designate CME activities for AMA PRA Category 1 Credit.TM"

Until 2009, ACCME RECOGNITION was achieved through the enforcement of a set of process-based requirements. ACCME required that a Recognized state medical society adopt and use the ACCME SCS as part of their own accreditation process. ACCME did not verify if the SMS applied the SCS in the same manner as ACCME.

Starting in 2009, the SMSs are now required to demonstrate that: **a)** each SMS' processes and accreditation rules and accreditation standards are the same as ACCME's decision-making rules and standards; **b)** that the SMS interprets provider practices with respect to compliance in the same manner as ACCME; and **c)** that their accreditation outcomes (e.g., accreditation status award) are appropriate to the accreditation findings and the same as the other ACCME-system accreditors.

Because of ACCME's new 2008 **ACCME Markers of Equivalency** (Attachment 6), starting in 2009, all accredited Providers within the ACCME system, regardless of where an accredited provider is reviewed, their performance will be interpreted the same, and their accreditation outcome will be the same -- and neither will be a manifestation of decision-making that is less than the national standard. These accreditation standards include the ACCME SCS.

RECOGNITION and the 2008 ACCME **Markers of Equivalency** require that the SMS's produce equivalent interpretations and accreditation outcomes – equivalent to ACCME, and equivalent to each of the other SMSs.

b. Enforcement by Equivalency between Continuing Professional Education Systems

The ACCME Standards for Commercial SupportSM, and associated ACCME definitions and interpretations, are moving closer to becoming a common national standard to manage the issues surrounding commercial interests and commercial support in continuing professional education (CPE).

Three accrediting bodies – all of which are currently incorporating accreditation standards concerning commercial support in their accreditation programs - have indicated their intent to voluntarily agree to adopt the ACCME Standards for Commercial SupportSM along with the ACCME definitions, interpretations and clarifications. They have committed to use these ACCME Standards for Commercial SupportSM in the same manner as ACCME does in making accreditation decisions. ACCME is drawing up documents currently for formal consideration and execution by three accreditors.

When agreeing to use the ACCME Standards for Commercial SupportSM in this manner, ACCME will ask each organization to agree to:

1. Adopt the ACCME SCS and all of the policies published on www.accme.org related to the ACCME Standards in their entirety;
-

2. Accredite continuing education using the ACCME SCS and the definitions, interpretations and clarifications that ACCME has established and has published on www.accme.org;
3. Maintain an accreditation system that determines compliance with the ACCME SCS;
4. Display and use the licensed service mark and copyrighted document in accordance with the format established by ACCME;
5. Share sufficient information with ACCME so that ACCME can make a fair determination about the colleague organization's fulfillment of 1 to 4, above; and
6. Indemnify ACCME against damages, claims and expenses incurred by ACCME by reason of a third party claim relating to the use of the licensed mark, or document, by the colleague organization.

ACCME will, in turn, offer to implement a simple, non-intrusive no-cost system, to determine that the colleague organization is, in fact, fulfilling these expectations.

ACCME will offer to attest publicly that the colleague organization does indeed use and apply the ACCME SCS to the level specified in the agreement.

Under these circumstances, continuing professional education accreditation will use the ACCME SCS as the national and inter-professional standard.

C. Transparency and Responsiveness to External Constituencies

1. Transparency Regarding Personal Financial Relationships with Commercial Interests of Teachers and Authors

Since 1992, ACCME has required teachers, authors and providers to disclose relevant financial relationships to learners before the start of a CME activity. Since 2005, ACCME has required teachers, authors and planners to disclose financial relationships that cause conflict of interest in CME to the CME provider during the process of activity planning so that Providers can implement mechanisms to identify and resolve any conflicts of interests prior to presentation of the activity to learners.

2. Transparency Regarding Commercial Support of CME

Since 1992, ACCME has required Providers to disclose to learners whether or not the CME Provider has received any funds, including in-kind support, from commercial interests. This disclosure must include the identity of the firm supplying the funds.

3. Transparency Regarding ACCME Accredited Providers

In 2009 ACCME announced:

"In the spirit of transparency, the ACCME believes that additional data and information about the accreditation system and the accredited CME enterprise will allow all stakeholders of our system – including physician learners, licensing and certification bodies, and the public – to assess the accredited continuing medical education in the United States for themselves."

ACCME now includes the following information in each Provider's record on our public list of accredited Providers contained on www.accme.org:

- The provider's current accreditation status;
- # of activities reported in the last year;
- # of contact hours reported in the last year;
- # of physician participants reported in the last year;
- # of non physician participants reported in the last year;
- Accepts commercial support (Y/N);
- Accepts advertising and exhibit revenue (Y/N);
- Reported participating in joint sponsorship (Y/N);
- Produces courses (Y/N);
- Produces performance-improvement CME (Y/N);
- Produces Internet live or enduring materials CME (Y/N);
- Produces other enduring materials (Y/N);
- Produces Internet searching and learning activities (Y/N); and
- Produces other types of activities (Y/N).

4. Transparency Regarding ACCME Decision-Making

Beginning with the results of the July 2009 ACCME meetings, ACCME is publishing the ACCME's Accreditation Grid depicting the compliance findings for each Provider and the array of findings associated with accreditation status decisions. In this way, ACCME will make public its compliance data by element and compliance data by Provider, and by accreditation outcome (see Figure 5, Figure 6: Accreditation findings since 2005, Figure 7).

5. Feasibility of Implementation

In June 2008, we announced the following expansion to operational elements of the ACCME in order to fulfill the strategic imperatives identified by the Board (e.g., monitoring, education communication, enforcement):

"Since its inception in 1981, the ACCME has always been run on a tight budget with little allowance for growth or development. For most of the last decade, a small staff has administered the ACCME oversight processes for close to 50 recognized state-accreditors and nearly 2,500 providers of CME. The ACCME has taken pride in its efficiencies and controlled growth. However, during the same period, ACCME's sister accrediting bodies have doubled or tripled their operations. The ACCME now finds that it requires greater support to meet the needs of the CME system.

For decades, the ACCME has emphasized value-based, professional self-monitoring to ensure propriety in continuing medical education. As called for by elements within and outside the ACCME, the system now needs more emphasis on monitoring and measuring. Some have called for more 'enforcement.'

The majority of Accredited Providers are accredited by ACCME Recognized State Medical Societies that voluntarily participate in this process, donating their operational and educational resources to ensure that there is regional access within the local communities of practice to high quality continuing medical education. These entities have asked for, and are receiving, additional educational, administrative and operational support from the ACCME.

The ACCME is willing to add additional layers of monitoring, surveillance, and support to the systems it oversees. The ACCME is acting quickly so that it will be ready and able to implement on its expanded mandate in the coming months. Taken together, the following substantive actions will ensure that the ACCME can contribute vibrantly to the impact of the CME system on US healthcare.

ACCME enhancements approved for implementation over 2008 and 2009:

- An enhanced monitoring and surveillance system.
- Expanded educational supports -especially for State Medical Society Accredited Providers and Accreditors.
- Expanded operational and educational supports for the accreditation decision-making processes within State Medical Societies.
- An Information Technology/Knowledge Management development plan that includes enhancements to web services and a restructuring of ACCME electronic systems.

- Updated online accreditation surveyor report tools
- Operational plans for development of a provider-maintained database of CME activities and learner participation
- Expansion of Chicago office space by 100% to improve services and resources provided to Providers, Recognized Accreditors, volunteers, leadership, and staff.
- Twenty percent increase in ACCME staff (2008 to 2010)."

The 2009 ACCME budget, and its new 2009 – 2012 fee schedule, supports a 50% increase in operational expenses and revenue (over 2006 levels). In this period ACCME will have gone from \$3.5 Million in annual expenses to \$5.26 Million with a growth in staff complement from 15 to 24.



ACCME's Process for Handling Complaints/Inquiries Regarding ACCME Accredited Providers

1. Complaints/inquires are written notifications to the ACCME by a third party which claim that an ACCME accredited provider is not in compliance with ACCME Essential Areas, their elements, or accreditation policies with regard to one or more of its activities.
2. To receive status as a complaint/inquiry the written complaint must confirm the name, USPS address and contact information of the person making the submission.
3. Complaints/inquires may a) refer to single activities / series or b) the provider's entire program of CME.
4. The statute of limitation of the length of time during which an accredited provider must be accountable for any complaints/inquiries received by the ACCME is twelve months from the date of a live activity, or in the case of a series, twelve months from the date of the session which is in question. Providers are accountable for an Enduring Material during the period of time it is being offered for CME.
5. The confidentiality of the complaining/inquiring party shall be protected, except as may be required by legal process.
6. ACCME may initiate a complaint or inquiry about an accredited provider.

Procedure for review, analysis, compliance determination and reporting regarding complaints and inquiries

7. ACCME will review the complaint/inquiry to determine whether it relates to the manner in which the provider complies with Essential Areas, their elements, or accreditation policies.
8. The person initiating the complaint will be notified of the planned course of action by the ACCME.
9. ACCME may or may not need to ask the provider for additional information. If, during the course of addressing the complaint inquiry, additional information is needed from the provider then the provider's response must be accompanied, where possible, by supporting documentation.
10. All responses from the provider to a Letter of Inquiry must be received by the ACCME within thirty days after the provider receives the request for information/response from the ACCME. If a provider fails to respond to any request for information, the ACCME may change the provider's accreditation status to **Probation** or **Non Accreditation**^{vi}.

When ACCME determines that the information submitted is adequate upon which to base a finding

11. The provider may be found in Compliance or Not in Compliance for that activityⁱⁱ.
12. The provider will be notified of the finding. If the finding is Not in Compliance, the non-compliance will be explained in a **Notice of Non-Compliance** to the providerⁱⁱⁱ.

Next steps

13. The ACCME may require the provider to submit **documentation of corrective action**^{iv} within thirty days of receipt of the Notice of Non-Compliance.
14. The ACCME may require the provider to submit a **Monitoring Progress Report**^v at a time determined by the ACCME.

Outcomes

15. If a provider fails to respond to a request for information, the ACCME will change the provider's accreditation status to **Probation** or **Non-Accreditation**^{vi}.
16. If a provider fails to convert **Non-Compliance** to **Compliance**, the ACCME reserves the right to change the provider's accreditation status to **Probation** or **Non-Accreditation**^{vi}.
17. At any point in the complaint/inquiry process the ACCME reserves the right to require an immediate full or focused accreditation survey, including a full or focused self-study report and interview^{vii}.
18. ACCME reserves the right to make public some information about the ACCME Complaints and Inquiries Process which may include but is not limited to the facts and circumstances involved in the complaint or inquiry, the name of the accredited provider involved, the names of commercial supporters, the names of non accredited joint sponsors and the ACCME's findings.

- i If, during the course of addressing the complaint inquiry, additional information is needed from the provider then ACCME will send a written communication (Letter of Inquiry) that confirms receipt (e.g., email, USPS certified mail, FEDEX-type courier) to the provider describing the nature of the complaint/inquiry. The Letter of Inquiry will request a response in which the provider can offer its interpretation of how it complies with ACCME Essential Areas, their elements, or accreditation policies. Upon receipt of the provider's response, the ACCME shall determine whether additional information is necessary and may request such information from the provider.
- ii If a finding of 'Not in Compliance' results from a complaint of inquiry then the ACCME Letter of Inquiry, the provider's response, any documentation of corrective action and any Monitoring Progress Report will be placed in the provider's file and will be made available to the survey team and the ARC reviewer at the next review. The activity will be included in the files reviewed by ACCME for re-accreditation.
- iii ACCME will send a Notice of Non-Compliance (that confirms receipt e.g., email, USPS certified mail, FEDEX-type courier) to the Provider describing the nature of the non compliance.
- iv When asked for 'documentation of corrective action' the provider will be asked to provide documentation of corrective action to the ACCME within thirty days of receipt of the Notice of Non-Compliance, and will be notified that failure to correct the deficiencies may result in an immediate resurvey which may affect the provider's accreditation status.
- v If the Monitoring Report adequately describes and documents Compliance it will be accepted. If the Monitoring Report does not adequately describe and/or document Compliance it will NOT be accepted.
- vi **Regarding Letters of Inquiry:** Change of status to **Probation** will automatically occur at 45 days from the time the provider receives a request for information/response from the ACCME, if the provider has failed to respond to a request for information. **Regarding Documentation of Corrective Action:** Change of status to **Probation** will automatically occur at 15 days after the due date for the notice set by the ACCME, if the provider has failed to submit the required documentation of corrective action. **Regarding Monitoring Progress Report:** Change of status to **Probation** will automatically occur at 15 days after the due date for the Monitoring Progress Report set by the ACCME, if the provider has failed to submit the required Monitoring Progress Report. Change of status to **Non-Accreditation** will occur at 15 days from the date a provider was placed on Probation for failure to submit information, documentation of corrective action or a monitoring Progress Report if the provider has still failed to submit the required information. Change of status to **Probation** or **Non-Accreditation** for 'failure to submit' does not require Board action.
- ACCME will send a notice to the provider of this change of status in a manner that confirms receipt (e.g., email, USPS certified mail, FEDEX-type courier). In the communication the provider will be informed that a change of status to Non Accreditation will occur if the provider has failed to respond to the request for information in the manner stipulated by ACCME.
- vii A provider's compliance must be reviewed by the ARC/DC in order to either a) change the provider's accreditation status to Probation or Non Accreditation or b) proceed with a full or focused accreditation survey, including a full or focused self-study report and interview.

History of Complaints and Inquiries Received and Processed (2008-June 2009)

1. The complainant was ACCME. The complained-against organization was a Publishing/Education Company. The activity was a Enduring Material. The finding was **not in compliance** with SCS 4.5 because the accredited provider used a commercial interest as the agent providing a CME activity to learners. The finding was **compliance** with SCS 1 (Independence); **compliance** with SCS 1 Conflict of Interest) and **compliance** with SCS 5 (Bias).
2. The complainant was the ACCME's Accreditation Review Committee. The complained-against organization was a Nonprofit (Physician Membership Organization). The activity was a Journal-based activity. The finding was **not in compliance** with SCS 2 in that the provider failed to identify a *relevant* financial relationship from the disclosure information provided by an author. In addition, the accredited provider's accreditation statement did not appear in the on-line version of the activity and the finding was also **not in compliance** with SCS 6 because although the conflict was disclosed to the provider, the provider failed to the relevant financial relationship to the learners.
3. The complainant was another accredited provider. The complained-against organization was a Publication/Education Company that was acting as a joint sponsor with a non-accredited provider. The activity was a live activity. The finding was **not in compliance** with SCS 1 (Independence) because five speakers were employees of commercial interests and the provider presented no documentation of who authored materials for the activity or who participated in the planning group so ACCME was unable to determine what role if any these five speakers played; **not in compliance** with SCS 2.3 (Resolution of Personal Conflicts of Interest) in allowing these five employees of commercial interest to speak during the activity but to resolve the conflict by not to awarding CME credit for their presentations; **not in compliance** with SCS 4.2 (Appropriate Management of Associated Commercial Promotion) because the provider allowed product promotion to occur in and during a CME activity.
4. The complainant was a non-accredited joint sponsor. The complained-against organization was a Publishing/Education Company. The activity was an online activity. The finding was **not in compliance** with ACCME's policy of requiring separation between education and promotion because email advertisements of commercial interests were sent from the domain and using the logo of the accredited provider.
5. The complainant was a newsletter. The complained-against organization was a Nonprofit (Physician Membership Organization). The activity was a Journal-based activity. The finding was **not in compliance** with SCS 2 in that the provider failed to identify a *relevant* financial relationship from the disclosure information provided by an author. In addition, the accredited provider's accreditation statement did not appear in the on-line version of the activity. The finding was also **not in compliance** with SCS 6 because although the conflict was disclosed to the provider, the provider failed to the relevant financial relationship to the learners.

Figure 1: Compliance findings for five inquiries with at least one element of the SCS in Non Compliance

Twelve Inquiries relating to the SCS are still open.

1. The complainant is the ACCME based on an article by an on-line media company. The complained-against organization is a School of Medicine. The activities were on line materials, enduring materials, and live programs. The issues raised are that the activities were not planned independent of commercial interests (C-7 (SCS 1.2.6)) the activities promoted a commercial interest (C-10)(SCS 5) and these activities violated ACCME Policy on Content Validation. The accredited provider's response in the form of a Notice of Corrective Action is under review.
2. The complainant is a learner. The complained-against organization is a Publishing/Educational Company. The issues raised are whether two activities that were part of a multi-year single subject initiative were planned independent of commercial interests (C-7) whether the activities promoted a commercial interest (C-10) and whether these activities violated ACCME Policy on Content Validation.
3. The complainant is a learner. The complained-against organization is a Publishing /Education Company. The activity was an enduring material. The issues raised are are that the activity violated SCS 1 relating to planning of activities free of commercial interests and SCS 5 relating to delivery of content and format free of commercial bias.

4. The complainant is an author.
The complained-against organization is a Publishing/Education Company.
The activity was an enduring material.
The issues raised are that the accredited provider did not adhere to its own policies governing its business obligations and commitments namely the payment of honoraria.
5. The complainant is a commercial interest.
The complained-against organization is a Publishing/Educational Company.
The issues raised are whether three separate activities related a single medical condition were planned independent of commercial interests (C-7) whether the activities promoted a commercial interest (C-10) and whether these activities violated ACCME Policy on Content Validation because the medical writer for the joint sponsor had previously worked for the commercial supporter. The ACCME is currently looking at the additional question of whether these activities were planned in accordance with Criterion 7 and 10 relating to other planners and faculty.
6. The complainant is a publisher of a blog.
The complained-against organization is a Publishing/Education Company.
The activity was an on-line activity/enduring material.
The ACCME has found the activity violated SCS 5 relating to delivery of content and format free of commercial bias and that the accredited provider violated ACCME's Policy on Content Validation. The accredited provider's response in the form of a Notice of Corrective Action is under review.
7. The complainant is a physician.
The complained-against organization is a Publishing/Educational Company.
The issue raised is whether an on-line activity was planned independent of commercial interests (C-7) whether the activity promoted a commercial interest (C-10) and whether the activity violated ACCME Policy on Content Validation.
8. The complainant is The ACCME based on an article by an media publisher.
The complained-against organization is a School of Medicine.
The activities were an on line activity, and two live programs.
The issues raised are that the activities were not planned independent of commercial interests (C-7 (SCS 1,2,6)) the activities promoted a commercial interest (C-10)(SCS 5) and these activities violated ACCME Policy on Content Validation. The accredited provider's response in the form of a Notice of Corrective Action is under review.
9. The complainant is a physician.
The complained-against organization is a Publishing/Education Company.
The activities were two enduring materials.
The issues raised are that the activities were not planned independent of commercial interests (C-7 (SCS 1,2,6)) the activities promoted a commercial interest (C-10)(SCS 5) and these activities violated ACCME Policy on Content Validation. The accredited provider's response in the form of a Notice of Corrective Action is under review.
10. The complainant is ACCME based on a letter from a commercial interest.
The complained-against organization is a Publishing/Education Company.
The issue involves the commercial interest's decision to no longer fund any of the accredited provider's activities.
The issues are not known at this time because ACCME has not yet received the information that led to the commercial interest's decision.
11. The complainant is special interest group.
The complained-against organization is a Non-Profit (Physician Membership Organization).
The activity is an online enduring material.
The issues raised are that the accredited provider did not ensure the validity of the joint sponsor's content in violation of (C-10)(SCS 5) and ACCME's Policy on Content Validation.
12. The complainant is a learner.
The complained-against organization is a Non-Profit (Physician Membership Organization).
The activity was an enduring material.
The issues raised are that the activity violated SCS 1, 2, 6 relating to planning of activities free of commercial interests.

2008 SCS Inquiry Initial Review Tool

Reviewer Questions

1. The provider determines the content/scope of commercially-supported CME activities in the following way(s):
 - a) According to ACCME Criterion 2
 - b) According to educational needs/goals as stated by a commercial interest (e.g., within a Request for Proposal [RFP], posted on a grant submission website, communicated during a meeting)
 - c) According to a standing commitment or expectation of support for a legacy/continuing event, program, or initiative (e.g., annual conference, consortium)
 - d) As a result of an agreement stemming from personal relationships between persons that work with or for the accredited provider and commercial supporters (e.g., joint sponsor, consultant)
 - e) As a result of an ongoing relationship between a commercial supporter and a provider (e.g., trusted vendor)
 - f) Other Scenarios Described (optional):
2. The provider determines the format of commercially-supported CME activities in the following way(s):
 - a) According to the provider's mission, desired results of their CME program (e.g., changes in competence, performance, patient outcomes), practice-based needs and gaps, and environment of the learners
 - b) According to the interests of learners (e.g., via survey)
 - c) Because of the area of business expertise/experience of the provider
 - d) According to guidance or direction from a commercial supporter, as stated in a RFP, website announcement, or meeting
 - e) Because of a commitment to a legacy/continuing event, program, or initiative (e.g., live symposium at an annual meeting)
 - f) Other Scenarios Described (optional)
3. The provider uses the following safeguard(s) as processes to develop commercially-supported CME activities that are content-valid and free of bias:
 - a) A checklist or process tool that follows the ACCME Standards for Commercial Support
 - b) Internal review by planners and authors
 - c) External review with independent reviewers (e.g., committee, peers)
 - d) Self-attestation by planners and authors that content is valid and free of bias
 - e) External review by a joint sponsor or consultant
 - f) External review by agents of a commercial supporter(s)
 - g) Other Scenarios Described (optional):

4. The provider determines who will plan, author, present, and/or deliver a commercially-supported CME activity in the following way(s):
 - a) By determining what person(s) would have the best knowledge, skills, and insight to make the CME activity effective in reaching its desired results
 - b) By using internal staff and/or faculty that are broadly involved in content development for numerous activities within the providers program of CME (e.g., retained writers/teachers)
 - c) By recommendations or suggestions from partners and collaborators (e.g., joint sponsors, speaker's bureau)
 - d) By soliciting recommendations from commercial interests
 - e) Other Scenarios Described (optional)
5. The provider measures the effectiveness of its processes for ensuring validity and the absence of bias during the planning, execution, and evaluation of CME activities in the following way(s):
 - a) By screening or measuring for bias during the planning of a CME activity
 - b) By surveying activity participants (learners) on their perceptions of the validity and bias of the CME activity
 - c) Through external, independent review at an activity level (e.g., monitors)
 - d) Through measurement of validity/bias at a program level (e.g., annual review of activities)
 - e) By external review at an activity or program level by a joint sponsor or outside consultant
 - f) By external review at an activity or program level by the agent(s) of a commercial supporter
 - g) Other Scenarios Described (optional)
6. The provider evaluates the effectiveness of commercially-supported CME activities in the following way(s):
 - a) By the provider's own (internal) analysis in keeping with ACCME Criteria 11-12
 - b) Through provider-led collaboration with external resources (e.g., CME committee, peers)
 - c) By a third party vendor (e.g., joint sponsor, consultant, "outcomes" company)
 - d) By external review involving agents of a commercial supporter(s)

NEW ACTIVITY DATABASE, NEW SOURCES OF INFORMATION

The ACCME's maintenance of an accurate and complete database of CME activities and participants is critical to ACCME's ability to provide additional, direct oversight of activities in real-time.

Phase 1: All Accredited Providers will be required to transmit to the ACCME an enhanced data set of information descriptive of each of CME activity. Transmission of data to ACCME will be through a web-based portal or direct transmission of appropriately formatted spreadsheets. Maintenance of accreditation will depend on ACCME's receipt of complete information in a timely fashion.

Phase 2: The ACCME will expand the database of activity information to include data derived directly from ACCME 'monitors' present at activities. This will include information from learners and from other special ACCME observers. It may also be expanded to include lists of participants.

Phase 3: The ACCME database will be expanded to include self-assessment data that is reported to ACCME by Accredited Providers about their programs of CME. The ACCME will be requiring that Accredited Providers measure for commercial bias and content validity and report their results in real-time through a web portal. A Providers analysis of these data and their response to the findings will contribute to their compliance with Criteria 12 and 13. There will be transparency and disclosure of compliance information. **What the ACCME knows about provider compliance will be published publicly to www.accme.org.**

Detailed specifications will be announced shortly by ACCME and will be consistent with national data standards being developed.

Phase 1 Data Points	
• Activity Title	• Information on the prevalence of CME on products in the pipeline or use that is off-label
• Date and Location	• If designed to change Competence?
• Direct or Joint Sponsorship	• If changes in Competence measured?
• Type of Activity Format	• If designed to change Performance?
• # of Hours	• If changes in Performance measured?
• # of MD's	• If designed to change patient outcomes?
• # of non-MD's	
• The amount and source(s) of commercial support.	
• Content of CME	
• The nature, scope, and value of financial relationships of persons	

Activity and Program Reporting System

Homepage of Activity and Program Reporting System:

The screenshot shows the homepage of the ACCME Activity & Program Reporting System. At the top, there is a navigation bar with tabs for 'My Organization', 'Activities', 'Program Financials', and 'User Management'. A user is logged in as 'Jana Pirovski'. The main content area is titled 'Welcome to the ACCME Activity & Program Reporting System!' and features the logo of Karakase Community College. Below the logo, there is a table of organization details:

ACCME Organization ID: 0234567	Primary Contact: George Andrew Arnold Dr. Jana Pirovski CME Program Administrator 100 W. Main Street Kankakee, IL 62301 apirovski@kankakee.com Phone: 815-224-2007 Fax: 815-466-5450	Current Accreditation: Current Accreditation Decision: Accredited Progress Report Received? No Effective Date: 11/2/09 Expiration Date: 10/31/2011
Organization Type: School of Medicine		
Accredited By: ACCME		
Address: 1001 North La Sore Parkway Suite 1002 Kankakee, IL 62305		
Phone Number: 815-466-7000	Billing Contact: George Andrew Arnold Same as Primary Contact	
	CEO Contact: George Andrew Arnold Same as Primary Contact	

Below the table, there is a section titled 'Report Activities' with a sub-heading 'ACCME Policy For Reporting Activities'. The text states: 'Planned activities must be reported no later than 30 days prior to the planned activity date. Completed activities must be reported no later than 30 days after the activity completion date. Learn more about us at: cmeconnection.org, visit us at: cmeconnection.org'. There is a link 'Click here to learn more'.

At the bottom of the page, there is a copyright notice: '© Copyright 2009 ACCME® | 115 N. State Street, Suite 1801 | Chicago, IL 60604 | Phone: 312.921.9200'.

Figure 1

The presence of this database system will create an impact at several levels. It will streamline the accreditation process by making activity information available more easily for calculations of the Annual Report, activity lists at reaccreditation and sources of sampling information for documentation review and verification of performance in practice. It will also act as the platform from which ACCME will launch its monitoring and surveillance system (new this year).

A completed activity record will contain information about the amount of commercial support received, the name of the commercial supporter(s), the education content in standardized format¹ as well as an indication of how educational effectiveness is being measured (e.g., in terms of physician competence(strategy), performance-in-practice or patient outcomes).

¹ <http://www.nlm.nih.gov/mesh/MBrowser.html>

Figure 2

Figure 3

The intent is to monitor for commercial bias and content validity by the direct observation of qualified observers.

It is ACCME's intention to recruit observers from among the learner and expert community. (Experience in this type of monitoring reported by the American Academy of Family Physicians shows that in some case only content experts can detect commercial bias in CME activities.)

With the assistance of outside experts, ACCME data gathering instruments will be developed and observers will be recruited and trained so that direct monitoring can commence in 2010. The database development is virtually

completed and deployment is planned for the fourth quarter of 2009 to allow data entry beginning in 2010.



**ACCME'S NEW RECOGNITION REQUIREMENTS
MARKERS OF EQUIVALENCY**

1. **Equivalency of Rules**
2. **Equivalency of Process**
3. **Equivalency of Interpretation**
4. **Equivalency of Accreditation Outcome**
5. **Equivalency of Evolution/Process Improvement**

Critical Features have been identified for each Marker of Equivalency. In order for an Intrastate Accreditor to achieve and maintain Recognition by the ACCME, the Accreditor must demonstrate Equivalency with each Marker. Equivalency will be demonstrated by meeting the Critical Features associated with each Marker.

The ACCME has also identified and provided definitions and policies to make explicit its expectations for meeting the Critical Features and demonstrating Equivalency.

The Recognized Accreditor must:

1. Use the ACCME's Accreditation Requirements* that are applicable at the time ("accreditation requirements") as the basis for each accreditation decision.
2. Incorporate all the formats of CME activities into the accreditation review process consistent with national standards established by the ACCME*.

Regarding the development of accreditation decisions, the Recognized Accreditor must,

1. Implement a mechanism to communicate to its accredited providers and perspective applicants all applicable "accreditation requirements" and processes.
2. Implement an accreditation process that requires providers to describe and verify compliance in all applicable "accreditation requirements".
3. Implement an accreditation process that makes accreditation decisions using data and information,
 - a. descriptive of compliance in each applicable "accreditation requirement".
 - b. from a provider's self study report and a provider's performance in practice and an interview with representatives of the provider.
 - c. from all the types of CME activities offered by the provider.
 - d. from all years of a provider's term of accreditation.
4. Utilize its accreditation decision-making body to verify and adopt accreditation findings and outcomes before communicating findings and outcomes to the provider.

5. Report to the Provider in writing the Provider's compliance or non compliance,
 - a. with each applicable "accreditation requirement".
 - b. of an accreditation decision being made that is consistent with national standards established by the ACCME*.

Regarding the operations of an accreditation system the Recognized Accreditor must,

6. Implement procedures to resolve conflicts of interest within the accreditation decision making process consistent with national standards established by the ACCME*.
7. Maintain accurate accreditation records that are updated in a timely fashion by,
 - a. making an accreditation decision or granting an extension before a provider's term expires. If an extension is granted the extension must be consistent with national standards established by the ACCME*.
 - b. making all accreditation decisions by conducting a provider's survey interview consistent with national standards established by the ACCME*.
 - c. updating the provider's accreditation information through the ACCME Online System consistent with national standards established by the ACCME*.
8. Communicate in writing to the provider and the ACCME the new accreditation expiration date when an extension was granted.
9. Implement mechanism(s) to collect, store, and retrieve the following documents and information used in administering the accreditation process for each provider (Documents and information that must be maintained for each provider should be retained by the accreditor for its current term of ACCME Recognition).
 - a. Completed self study report/application from the provider that the accreditor reviewed in the process for making the most recent accreditation decision on the provider.
 - b. One ~~complete~~ activity file that was reviewed in the process for making the most recent accreditation decision on the provider.
 - c. All completed surveyor forms (e.g., surveyor report form, documentation review forms, activity review forms, etc) used in the process for making the most recent accreditation on the provider.
 - d. Correspondence between the accrediting body and the provider during the accreditation process (from notification to decision) and throughout the provider's term of accreditation.
 - e. Written actions taken by the accreditation body which outline the term and status awarded to the provider.
 - f. Follow-up reports (e.g., progress reports) generated by the CME provider, if required.
10. Ensure that Annual Report data from each accredited provider, consistent with national standards established by the ACCME, is submitted via the national reporting system in keeping with ACCME-designated expectations and deadlines*.
11. Have, and use when necessary, written policy and procedure on Reconsideration and Appeals on adverse accreditation decisions.
12. Have, and use when necessary, written policy and procedure on Complaints and Inquiries on its accredited providers.

3: EQUIVALENCY OF INTERPRETATION

The Recognized Accreditor must:

1. Must base its compliance findings and decisions solely on the integration of data collected from the three sources during the accreditation process.
2. Develop compliance findings for each accreditation requirement that are,
 - a. Supported by data and information from 3 sources.
 - b. Consistent with national standards established by the ACCME* and.
 - c. Appropriate to the performance of the provider.

4: EQUIVALENCY OF OUTCOMES

The Recognized Accreditor must:

1. Translate accreditation findings into accreditation outcomes (accreditation term; accreditation status, progress reports) that are
 - a. Appropriate for the accreditation findings and
 - b. Consistent with national standards established by the ACCME*.
2. Require the demonstration of improved performance (a Progress Report) for each finding of **NON COMPLIANCE** within a timeframe, consistent with national standards established by the ACCME*.
3. Require that a Progress Report contain both a review of a provider's performance in practice and descriptions of procedures and practices, in order to determine if the provider has improved.
4. Hold a provider accountable, through second Progress Reports or a change in accreditation status (Probation or Non Accreditation), when a provider fails to demonstrate improved performance within a timeframe and in a manner, consistent with national standards established by the ACCME*.

5: EQUIVALENCY OF EVOLUTION/PROCESS IMPROVEMENT

The Recognized Accreditor must:

1. Integrate new accreditation requirements and new national standards established by the ACCME into its accreditation processes and/or the CME programs of its providers.
2. Provide access to training for accreditation staff, surveyors and decision makers to ensure that these individuals attain and maintain adequate knowledge and competence in the accreditation of CME providers in a manner that supports equivalency in the national accreditation system.



ACCME Definitions and Policies that Support the New Recognition Requirements

Critical Feature of Markers of Equivalency	Link to current ACCME policy/practice
1.1 Use the ACCME's Accreditation Requirements that are applicable at the time ("accreditation requirements") as the basis for each accreditation decision.	ACCME's Essential Areas, Elements, Updated Accreditation Criteria and Policies (including 2004 Standards for Commercial Support) as noted on website: http://accme.org
1.2 Incorporate all the formats of CME activities into the accreditation review process consistent with <u>national standards established by the ACCME</u> .	Formats of CME as defined on website under Annual Report Definitions: http://accme.org/annualreports
2.5b. Report to the Provider in writing the Provider's compliance or non compliance...of an accreditation decision being made that is consistent with <u>*national standards established by the ACCME</u> .	Accreditor must inform provider of accreditation decision within 4 weeks of decision.
2.6 Implement procedures to resolve conflicts of interest within the accreditation decision making process consistent with <u>national standards established by the ACCME</u> .	Individuals with conflicts of interest must recuse themselves from the decision making process.
2.7 Maintain accurate accreditation records that are updated in a timely fashion by...	
a. ...making an accreditation decision or granting an extension before a provider's term expires. If an extension is granted the extension must be consistent with <u>national standards established by the ACCME</u> .	Extensions may not exceed 8 months.
b. ...making all accreditation decisions by conducting a provider's survey interview consistent with <u>national standards established by the ACCME</u> .	Accreditation decision must be made within 6 months of conducting a provider's survey interview.
c. ...updating the provider's accreditation information through the ACCME Online System consistent with <u>national standards established by the ACCME</u> .	Accreditor must update provider's accreditation information within 4 weeks of making an accreditation decision.
2.10 Ensure that Annual Report data from each accredited provider, consistent with <u>national standards established by the ACCME</u> , is submitted via the national reporting system in keeping with ACCME-designated expectations and deadlines.	Accreditors are required to facilitate the annual report data collection of its providers within the designated deadlines. Failure to meet ACCME administrative deadlines by providers or recognized entities could result in (a) an immediate change of status to Probation, and (b) a subsequent change of status to Nonaccreditation or Nonrecognition.

<p>3.2b</p> <p>Develop compliance findings for each accreditation requirement that are...consistent with <u>national standards established by the ACCME</u>.</p>	<p>ACCME's Decision Making Pathways as described on website: http://accme.org</p>
<p>4.1b</p> <p>Translate accreditation findings into accreditation outcomes (accreditation term; accreditation status, progress reports) that are...consistent with <u>national standards established by the ACCME</u>.</p>	<p>Accreditation Status and Terms must allow for: Accreditation with Commendation with 6 years; Accreditation; Provisional Accreditation; Probation with 2 year maximum.</p>
<p>4.2</p> <p>Require the demonstration of improved performance (a Progress Report) for each finding of NON COMPLIANCE within a timeframe, consistent with <u>national standards established by the ACCME</u>.</p>	<p>Providers seeking re-accreditation that receive Non-Compliance in one or more of the ACCME's Criteria including the Standards for Commercial Support will be required to submit a Progress Report.</p> <p><i>Applicants seeking provisional accreditation that receive one or more Non-Compliance findings in the ACCME's Criteria automatically receive a decision of Non-Accreditation.</i></p> <p>The usual due date for a Progress Report is one year from the date of the original finding.</p>
<p>4.4</p> <p>Hold a provider accountable, through second Progress Reports or a change in accreditation status (Probation or Non Accreditation), when a provider fails to demonstrate improved performance within a timeframe and in a manner, consistent with <u>national standards established by the ACCME</u>.</p>	<p>Progress reports rejected when performance doesn't meet criteria.</p> <p>Repeated failure to demonstrate compliance through progress reports = change in status.</p> <p>Providers on probation must demonstrate all NC findings converted to compliance within 2 years or status change to non-accreditation.</p>

The CHAIRMAN. Thank you very much.

One question for the panel, then I'll turn it over again to Senator Martinez.

Is it a fair statement, or would you agree, that continuing medical education is critical in the medical profession? It's not cheap; it's expensive. To the extent that commercial interests are providing a great deal of the funding, that's, on the face, a good thing—in the sense that they're providing all that money, as well as all that knowledge and experience—but we need to be sure that we separate all of that from any possible conflicts of interest, in terms of their activities. Is that—and that's our job, and that's what we're here to talk about—is that a fair statement?

Dr. Stossel.

Dr. STOSSEL. I'm so glad I'm not in politics—

Senator MARTINEZ. Hit your mike, if you don't mind. Yeah. Then we can hear your unpopular things. [Laughter.]

Dr. STOSSEL. OK.

Continuing education's absolutely essential. I think the problem is—I come back to, What's the quality of the product? Not, What's the motive of the producer? Of course companies want to sell stuff, but there has been an implicit assumption that if they're trying to sell, it's bad, or it's not the right information that patients need.

I recently heard a young woman, who had gotten multiple sclerosis, tell her story. She explained how new products have come on line rapidly over the last few years to manage what previously was practically untreatable, nothing could be done, and now the prognosis is much better. She explained how the only way she heard about the most up-to-date products, which are the most effective, was through commercially sponsored continuing education. The nonprofit societies just can't get up to speed fast enough, because it's at that interface where the physicians, working with industry, are actually doing this innovation, know what's going on, and can get that information to patients. I've heard it from juvenile-diabetic parents. It's a very consistent message.

The CHAIRMAN. Thank you.

Yes, Dr. Scully?

Dr. SCULLY. Marketing and education need to be separated. That's what we're trying to do. Senator Martinez, your comment about legal education hits home. I actually have more lawyers on my staff than I do doctors, and they point out to me all the time, they pay for their own CLE, why don't doctors do that?

I think we're in transition now. What you're seeing is things changing, as they do. We get new knowledge, we look at things, we say, "Geez, we need to take a look at this, maybe we're not doing it the best way we can."

CME long term, in professional development, is critical for physicians. We have new knowledge all the time. It has to be part of doctors' learning. There's—no question about it. We need to do it as well as we can. I think doctors are going to have—and we've gotten acculturated to having free CME and having a good meal, free. That's going to change.

I'll stop there.

Dr. STOSSEL. Lawyers and doctors are completely separate, different business models. I'm sure the doctors are going to love to

hear that if—as you’re debating healthcare reform, and that their reimbursement may go down, that they’re going to have to pay for their own CME.

The CHAIRMAN. Dr. Kopelow.

Dr. KOPELOW. Senator, I agree with you that continuing medical education is critical. The literature says that it’s effective in improving practice and changing practice. Our goals are to address overuse, underuse, and misuse, all three of them, and to incorporate, and to assist, and promote change.

Two weeks ago, in the Journal of the American Medical Association, there was a news story on the issues of the use of nonsteroidal anti-inflammatories in the elderly. The story was about the fact that the use of the nonsteroidal anti-inflammatories needs to go away, because they’re dangerous, and the physicians need to start to use narcotics to manage the pain in the elderly, instead of the other drugs.

That is a complex professional change that needs to take place; and it needs to take place urgently, needs to take place now; it needs to have the interests of the patients at heart.

The participation of the producers of the nonsteroidal anti-inflammatories, and the participation of the industry that produces the narcotics, is reasonable and rational in—from a funding source, because it’s in their interests, both of their interests, for those products to be used properly in the aged.

What we believe is that that education needs to be developed independently of those kinds of industries, from the perspective of content, direction, advice, and recommendations.

We have policy about that, we have principles; the profession shares these ethics and values, and this is what we promulgate. We’re going to be able to monitor the system in order to ensure that the outcome of those educational activities is in the best interests of the elderly and the aged who are in pain.

The CHAIRMAN. Thank you.

Senator Martinez.

Senator MARTINEZ. Dr. Stossel, I want to tell you, first of all, I appreciate you being here with a bit of a contrarian point of view from what is the prevalent point of view at the hearing, but I think it’s important to hear your point of view, and I think you make excellent points.

I just wonder if there would not be a better way to continue to educate doctors, and understanding that, perhaps culturally or because of constraints on how doctors are compensated, perhaps doctors also paying for CME would be kind of a novel thought. Would you conceive that it might be better if CME was then done at medical—I mean, under the supervision, direction, or whatever, of medical colleges, place where people normally go to learn medicine? Or, do you think it has to be integrally connected to the industry, whether it be devices or pharmaceuticals?

That’s really—I mean, you know, isn’t there another way of doing this that would not necessarily just go feed at the trough of those that are trying to promote a product?

I understand, doctors are smart enough to see the difference. It’s perfectly good in America; we still believe in free enterprise, I think—at times I wonder, but I do think— [Laughter.]

Profit is a good motive, and marketing is a good thing. These are all good things. The question really is—is that interplay, and maybe the lack of transparency. Maybe the alternatives might also be equally good, and reach a good outcome, as well.

Dr. STOSSEL. Well, you covered a lot of ground there, Senator.

Senator MARTINEZ. Yeah.

Dr. STOSSEL. Anything's possible. But, in my view, I think the real question is, Is the system really broke? Do we need to fix it? It's—if "broke" means "not perfect," it's broke. But, I don't see it that way. I see CME as pretty darn effective, as it's currently constituted.

Medicine obeys the laws of physics, chemistry, biology, but it also obeys the laws of economics. When I hear from a patient or a family member that they get the best information from a commercial source, I want that best information. I don't care who pays for it.

Now, there's—there is this bit of asceticism that creeps in—

Senator MARTINEZ. Well, you're talking there—you're talking there about advertising on TV.

Dr. STOSSEL. No, I'm talking about—

Senator MARTINEZ. The "purple pill," or whatever.

Dr. STOSSEL [continuing]. That the setting and the mechanism by which—that in order to promote the product, the new product, that the physician can't possibly learn about, because they have so many things to keep track of, that the companies make an effort to get those parties together. So, the physicians, the patients, now hear about these products—

Senator MARTINEZ. That's not CME, though. I mean, if I'm going to the doctor and say, "Hey, I just heard about this, and it may help my problem"—

Dr. STOSSEL. I think any education about—

Senator MARTINEZ. But, I think that's fine. I mean, that's patient education, that may be public information, marketing, advertising. I separate that from what is educational opportunities.

See, I'm wondering about you, a well-intended physician who signs up to go to a class, to get some credits and learn something, and sits in the room and says, "I didn't know this is what I was going to get. I didn't come here to get a pitch. I came here to learn."

Dr. STOSSEL. But, I don't think that happens, Senator. I think—

Senator MARTINEZ. You just don't like—

Dr. STOSSEL [continuing]. That the—if it's happening regularly, I'd like to see the evidence for it. Now, you mention transparency, that's—I'm all for transparency, although I think that, as an abstraction, it's a lot easier to deal with than what—the way it works on the ground.

Senator MARTINEZ. OK. Well, thank you.

The CHAIRMAN. I just want to—before I comment on— Martinez, before we turn it over to Senator Franken—I don't believe you're saying that we can't do what we're doing, but do it better. I think you're saying we should recognize the value of what we're doing and not throw it out. But, you're not suggesting we couldn't do it better.

Dr. STOSSEL. Can always do it better, sir.

The CHAIRMAN. All right. Thank you.

Senator Franken.

Senator FRANKEN. I just wanted to make a comment, Dr. Stossel, on a couple of things you said.

First of all, you seem to try to draw conclusions from stories. Medicine is a lot better now than it was when we were kids. That doesn't mean that industry should fund CME. It doesn't follow. You said that accumulation of anecdotes doesn't equal data, but you used anecdotes. I don't see the connection between your testimony and any kind of proof about the issues that were raised.

Now, Mr. Kopelow, I hear that you're doing some things now, and I'm wondering, is this in response to the criticism that you've been hearing from our first panel, or is it just a natural outgrowth of what you do?

Dr. KOPELOW. The input to the ACCME began with Senator Kennedy in the 1990's, and our standards of commercial support, and our system has been responsive to what's been going on in the profession and in Senate over the last few years.

Senator FRANKEN. OK. I just wanted to ask one thing. You talked about—companies being on probation.

Dr. KOPELOW. Yes.

Senator FRANKEN. How long are they on probation? How long are they allowed to be on probation before they have to stop doing what they're doing?

Dr. KOPELOW. Well, they have to stop what they're doing immediately, and they have to demonstrate—

Senator FRANKEN. What if they don't? How long is probation?

Dr. KOPELOW. They can be on probation up to two years.

Senator FRANKEN. Two years?

Dr. KOPELOW. Yes.

Senator FRANKEN. So, they could continue doing what they've been doing for two years, without being tossed?

Dr. KOPELOW. The issues that we've been hearing about today, no. The issues that we've been hearing about today, about the independence, the resolution of conflict of interest—our board, at its last meeting, talked about asking for demonstrations of compliance within 4 months, 8 months, and 10 months, and getting them off the rosters.

Senator FRANKEN. OK.

One last thing, Dr. Scully. Are you making these changes because of the perception of conflict of interest? I mean, you said something about—everything is—the money you're losing is worth regaining the trust of the patients. Is it about the perception, or is it about the reality, in your view?

Dr. SCULLY. Both.

Senator FRANKEN. OK. Thank you.

Thank you, all.

Dr. KOPELOW. Senator Kohl, could I respond to—

The CHAIRMAN. Yes, go ahead—

Dr. KOPELOW [continuing]. A question of Dr. Martinez?

The CHAIRMAN.—Dr. Kopelow.

Dr. KOPELOW. Most of the continuing medical education in this country is not commercially supported. If you take all the money that comes into the system, it's half. Most of the money is in a

small group of providers, and most of the continuing medical education is occurring in the hospitals, in the small county and State medical societies around the country, in our 1600 State-accredited organizations. It's not commercially supported, it's independent, and is occurring in the medical societies and in the hospitals and in the healthcare settings.

The CHAIRMAN. Thank you.

Senator MARTINEZ. But now, for that other half, you wouldn't object to the transparency that would make it clear when the line is blurred between marketing and science.

Dr. KOPELOW. Marketing—that line is not blurred in our continuing medical education enterprise. What we've heard about is in another time, in another place. But it—our accredited providers clearly draw the distinction and separation between promotion and education.

Senator MARTINEZ. Thank you.

Dr. KOPELOW. Thank you, sir.

The CHAIRMAN. Yes—

Dr. STOSSEL. Can I respond—

The CHAIRMAN [continuing]. Sir, Dr. Stossel.

Dr. STOSSEL [continuing]. To Senator Franken's comment?

A 50-percent drop in cardiovascular mortality is not anecdote. I personalized it. I think that this happened in the context of unregulated CME, excesses that existed in the past. Things have changed considerably in the last 10 years. The Joslin Clinic in Boston, has a very active education program. They've been trying to change physician behavior. That's the gold standard in continuing education. There are people in the companies that are passionate about that. Sure, they'll sell more product. But, it ultimately is what benefits the patient.

Senator FRANKEN. Thank you.

The CHAIRMAN. All right, thank you very much, gentlemen. You, also, have contributed a great deal to the subject, and we appreciate your taking the time and bringing us all the experience and knowledge that you have.

Thank you so much.

This hearing is adjourned.

[Whereupon, at 3:27 p.m., the hearing was adjourned.]

APPENDIX

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**UNITED STATES SENATE SPECIAL COMMITTEE ON AGING
HEARING ON MEDICAL RESEARCH AND EDUCATION
JULY 29, 2009**

**STATEMENT FOR THE RECORD:
The ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)
701 PENNSYLVANIA AVENUE NW, Suite 800
WASHINGTON, DC 20004**

Bringing innovation to patient care worldwide

The Advanced Medical Technology Association (AdvaMed)

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide written testimony for today's hearing on medical education and research. AdvaMed is a trade association representing more than 1,600 of the world's leading medical technology innovators and manufacturers of devices, diagnostic products and medical information systems. Our members are committed to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of the health care technology purchased globally. AdvaMed members range from the smallest to the largest medical technology innovators and companies. Nearly 70 percent of our members have fewer than \$30 million in sales annually and nearly 90 percent of our members have fewer than 100 employees. AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and in particular to the contribution that high quality health care technology can make toward achieving those goals.

Ethical, constructive interactions between innovators and health care clinicians are uniquely necessary in the field of medical devices. Many who are not involved in medical device development are surprised to learn that the average life-cycle for many devices is only 18 months because improvements – frequently based on input from practicing clinicians – are often incorporated into the next generation of the device shortly after the first device is launched. Given the pace of innovation and the sophistication of many medical technologies, it is essential that clinicians receive timely education and training on the variety of treatment options that may exist for a given disease and how to utilize medical technologies safely and effectively. Our industry is committed to helping advance medical education for clinicians so that patients have access to the highest quality care.

Preserving Public Trust in Continuing Medical Education (CME)

As important as this collaboration is to saving, extending and improving lives, maintaining public trust in the integrity of medical education is an equally high priority for AdvaMed and its members. We support efforts to ensure that medical education is funded and conducted in a manner that preserves the independence of medical education programs as separate from promotional efforts, and we support efforts to address concerns that threaten the integrity of medicine and public confidence. That is why our revised Code of Ethics, which became effective July 1 of this year, includes important guidance to medical technology manufacturers on how to responsibly and ethically support third-party educational conferences. As with all the principles included in our revised Code, the guidance related to support of education is intended to serve the best interests of patients.

AdvaMed recognizes that *bona fide* independent, scientific, educational, and policymaking conferences promote scientific knowledge, medical advancement, and the delivery of effective health care. For those reasons, under AdvaMed's Code, companies may provide grants to conference sponsors to reduce conference costs. They may also provide grants to an academic institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training. Our Code states that while a company may provide an educational grant to support the attendance of a Health Care Professional at a third-party educational conference, the conference sponsor or accrediting institution will select the attendees. Companies may provide grants when the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse, and the training institution or the conference sponsor selects the attending Health Care Professionals who are in training. Such grants also should be consistent with

applicable standards established by the conference sponsor and, importantly, with the standards of any body accrediting the educational activity.

AdvaMed's Code also states that the conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials. A company may not designate attendees or faculty who will speak at a third-party educational conference, as the Code contemplates that these decisions be made only by an independent third party. However, medical technology companies with new, highly advanced products are often in the best position to identify the small number of clinicians who are skilled users of those products and would be best suited to teach others. For that reason, the Code does not preclude a company from recommending a knowledgeable faculty member where the recommendation is permitted by the conference sponsor's guidelines. As always, though, the ultimate selection should be made by the conference sponsor.

Ultimately, the Code's guidance on support of third-party educational conferences is designed to ensure that industry funding of medical education is appropriate, preserves the independence of the medical education program, and is not promotional in nature.

The Role of Clinicians in Providing Peer to Peer Education and Training

In addition to the medical technology industry's commitment to support CME, companies take very seriously their responsibilities to ensure that clinicians are trained to use technologies safely and effectively. It is important to note that how well a medical device works depends, in large part, on the skill and training of the physician utilizing the technology. For many medical devices, physicians need hands-on education and training in order to perform medical procedures that utilize a device. In some cases, such training by manufacturers is even required by the Food and Drug Administration. The technique-specific nature of devices also makes physician involvement crucial to the training and education required after market approval, as specific techniques often need to be taught, and physician operators are best suited to provide this training to their fellow physicians. Moreover, because medical technologies undergo rapid, next generation improvements, some technologies require re-trainings with each advance. It is important to the safe and effective utilization of new medical devices and techniques that physicians have the opportunity to participate in such training. AdvaMed's Code of Ethics provides specific guidance on such company-sponsored education and training programs.

Further, under AdvaMed's Code of Ethics, engaging a clinician to provide such education and training would be considered a consulting arrangement, which is defined as any relationship between a health care professional and a company where services provided to the company by the health care professional are exchanged for remuneration. Consultants to medical technology companies serve a number of vital roles from beginning to end of a product's life cycle, beginning with product development and continuing through the conduct of clinical trials and hands-on training and education on the products. As noted above, this life cycle is often ongoing as technologies are constantly improved upon.

Under AdvaMed's Code, companies must pay consultants fair market value compensation for serving in this capacity and compensation should not be based on the volume or value of the consultant's past, present or anticipated business. Consulting arrangements for a clinician to serve as a speaker should include a written agreement that specifies the services to be provided, fulfill a legitimate business need, and the selection of the consultant speaker should be made on the basis of his or her qualifications and expertise to meet the defined need. Given the need to provide education and training to clinicians on the safe and effective use of medical technologies, it is possible that

these qualifications could include experience with, usage of, or familiarity with a specific medical technology; however, neither selection of, nor compensation paid to, consultants should be to reward past usage or constitute unlawful inducement. In addition, while a company's sales personnel may provide input about the suitability of a proposed consultant speaker, sales personnel should not control or unduly influence the decision to engage a particular health care professional as a consultant.

AdvaMed's Code also addresses the venues and circumstances where meetings with consultants – in this case, consultants serving as speakers – should occur. The venue and circumstances should be appropriate to the subject matter, and should be conducted in clinical, educational, conference or other settings, including hotel or other commercial available meeting facilities, conducive to the effective exchange of information. Company-sponsored meals and refreshments provided in conjunction with such events should be modest in value and should be subordinate in time and focus to the primary purpose of the educational program. As is the case with their interactions with all health care professionals, companies should not provide recreation or entertainment to consultants in conjunction with these meetings.

Conclusions and Recommendations

Again, AdvaMed and our member companies strongly believe in the importance of medical education for health care professionals and those in training so that clinicians have essential information on available treatment options and how to utilize them safely and effectively. While the medical device companies developing and improving advanced medical treatments often have the best available data, and other information relative to the use of medical technologies, we also recognize the need to ensure that industry involvement in funding medical education is appropriate and preserves the independence of medical education programs as separate from promotional efforts.

As Congress, accrediting bodies, medical institutions, specialty societies, and other organizations contemplate how to best achieve these goals, AdvaMed urges a deliberative approach to ensure that current pathways to continuing medical education are not disrupted and does not impose barriers and challenges that would jeopardize clinicians' access to the training they need to best serve their patients. This is particularly critical in the medical device sector where rapidly evolving and breakthrough medical technologies expand the frontiers of medical science, and quality continuing medical education is necessary to ensure patient access to the safe and effective use of these technologies.

In closing, we would like to reiterate to Chairman Kohl and the Special Committee on Aging, AdvaMed's support for appropriate disclosure of relationships between medical technology companies and physicians. We believe a uniform, comprehensive federal disclosure system can provide important information to patients in a manner that preserves important collaborations between industry and physicians that lead to advances in patient care. We were pleased to support legislation introduced last year by Chairman Kohl and Senator Grassley, the Physician Payments Sunshine Act, and we appreciate the sponsors' continued leadership and willingness to work with our industry this year as the bill is revised and moves through the legislative process.



Testimony of
Dr. Richard Murray
Vice President of External Medical & Scientific Affairs
Merck & Co., Inc.

“Medical Research and Education: Higher Learning or Higher Earning?”
Special Committee on Aging
United States Senate

July 29, 2009

Chairman Kohl, Ranking Member Martinez, and Members of the Committee, on behalf of Merck & Co., Inc., I am pleased to provide this statement on Merck’s commitment to transparency, our approach to support for Continuing Medical Education (CME), and the appropriate role that we believe our support plays in medical education and patient care.

To respond to public interest and strengthen trust in our company, Merck is undertaking a number of steps to increase transparency in many aspects of its operations, from research to sales and marketing practices. A major part of Merck’s effort is to publicly disclose its financial support to outside groups and individuals who work with the company on initiatives to educate audiences about key health care issues aligned with Merck’s mission. Merck believes that increasing the visibility of its activities ultimately will enhance the public’s trust in the company and increase the level of knowledge and understanding of how Merck helps advance medical and scientific education and health care overall.

We believe greater public attention to how we conduct our support for CME will enhance confidence in the medical profession and its use of CME to advance patient care. Our approach to CME support, and that of our industry colleagues, has evolved over time and will continue to evolve based on developing technologies and changing patient and provider needs. We believe CME is about helping physicians take better care of their patients and achieve improved health outcomes – whether using our therapies, other companies’ therapies, or no therapies at all.

The purpose of Merck’s support for continuing education is to improve the quality of health care through the support of accredited educational programs for health care professionals. High quality, accredited health care education serves to improve the rate of appropriate disease diagnosis and treatment. In addition, industry-supported CME has evolved to better ensure that we do not influence the choice of speakers or content of CME programs. Merck strives to meet this goal by separating grant funding decisions from marketing and sales operations.

The Accreditation Council for Continuing Medical Education (ACCME) determines the proper role for industry support for CME by establishing the criteria for accrediting CME programs and

promulgating the ACCME Standards for Commercial Support. Merck was an early adopter and strong supporter of the ACCME guidelines and standards, and we believe that the current standards provide a workable and appropriate way for Merck to support quality CME programs.

In alignment with the ACCME standards and Merck's own high ethical standards, Merck has established grant guidance documents with internal controls to ensure that the decisions around financial support for accredited educational programs are not influenced by sales and marketing. We strive to support only those programs that are high quality and independent from commercial bias. The policies and procedures we have adopted restrict the company's involvement in areas such as the identification of a program's educational objectives and methods, the selection of speakers, and the selection of content or persons and organizations that control the content. We generally support applications for funding in areas of particular interest to Merck and in which we have current or possible future medications to offer. Merck's areas of interest are broad and include a large number of different disease states, as well as more general topics, such as health care quality, that cut across multiple disease states.

The only ways to gain Merck consideration of applications are through direct interaction with a member of our Academic and Professional Affairs staff or through our online grant intake website. Sales and marketing personnel have no role with respect to CME funding support other than to refer unsolicited requests to our toll-free information line or to our online web site. We also restrict access to these applications to only our grants professionals who make selections in their sole discretion. We reinforce these procedures through regular, mandated training of our sales and marketing staff to ensure they understand the role Merck can play in CME support and the prohibitions on their involvement in grant application and selection.

Merck policy provides that CME grants can only be provided to an accredited Continuing Education (CE) provider to support either a CME program and/or enduring materials. A company headquarters-based Academic & Professional Affairs staff, with no involvement from sales and marketing personnel, reviews applications to ensure compliance with internal and external policies and procedures prior to approval of any grant funding. For example, Merck policy provides that a grant will not be supported if the staff cannot verify accreditation, the letter of agreement is received after the start of the program activity, or a speaker and/or product is identified in the grant application.

In addition, Merck's internal grant tracking systems are among the best in the industry. In 2006, as part of the Society for Continuing Academic Medical Education's (SACME) survey on CME trends and arrangements, Merck received the top ranking from medical schools surveyed for its knowledge of CME requirements and processes, adherence to national guidelines, and system ease of use, as well as strong feedback on the technical knowledge of our staff on the CME "rules of the road." These systems provide internal checks and balances and support compliance initiatives. Through our toll-free information number, live operators help explain the rules and procedures to all applicants and assist with any process difficulties. Furthermore, Merck has the longest experience in electronic application processing, which has enabled us to use the most innovative technology and web-based system architecture.

Merck fully supports appropriate limits on our role in CME because we believe CME is critical to advancing scientific and medical knowledge and ensuring good patient outcomes. We support CME with the knowledge and hope that our support will further the education of health care providers, enable them to be more likely to use Merck medicines and vaccines appropriately, and support their judgment not to use our medicines when other treatment choices are more appropriate.

Merck strongly supports transparency of our interactions with medical, scientific, and patient organizations, including financial support that we provide them. We believe this is an important step in building public trust with both Merck and those with whom we provide support. In October of 2008, Merck began reporting grants of more than \$500 provided by Merck's Global Human Health division to U.S. patient organizations, medical professional societies, and other organizations. You can find our reports at: <http://www.merck.com/corporate-responsibility/>. We update these reports on a quarterly basis.

In addition to the grant payments discussed above, in the fourth quarter of 2009 Merck expects to begin publicly disclosing certain payments to U.S. medical and scientific professionals who speak on behalf of the company concerning our products and/or health care issues. While we are pleased to have acted on a voluntary basis, we believe it would be valuable to extend these reporting requirements to other companies as well. That is why we have also been working with Chairman Kohl and Senator Grassley on their "Physician Payments Sunshine Act." This legislation, if passed, would standardize the reporting of company payments to physicians, and make such information publicly available. We believe making public our support enhances the visibility of Merck's commitment to help advance health and science.

We appreciate the opportunity to provide this testimony and we remain open to further discussion on transparency, including suggestions for improving the substance of CME and the understanding of our role in supporting it. We look forward to reviewing the testimony at this hearing and to continuing a dialogue with you and others on these important issues.

**STATEMENT OF DR. ROBERT GOLDEN
DEAN, UNIVERSITY OF WISCONSIN SCHOOL OF MEDICINE
AND PUBLIC HEALTH**

**BEFORE THE
SENATE SPECIAL COMMITTEE ON AGING**

July 28, 2009

Background

In keeping with the Wisconsin Idea, the University of Wisconsin School of Medicine and Public Health in Madison seeks to serve all of the people of our state...and beyond. The University of Wisconsin School of Medicine and Public Health in Madison is recognized as an international, national and statewide leader in educating physicians and other health care clinicians, investigating the causes and potential new treatments of disease, translating research into compassionate patient care and improving the health of communities we serve.

The University of Wisconsin Medical School became the UW School of Medicine and Public Health in 2005, thus embarking on a plan to develop an innovative model of research, education and service which bridges the heretofore separate worlds of public health and medicine. This novel approach is intended to help us better address the important environmental determinants of population health while meeting the individual health care needs of Wisconsin citizens. In so doing so, we hope to serve as a national model for our peers across the country.

We commend the Chairman and the Committee for your work to better understand the influence of industry on medical education and research, and for its efforts to urge clinicians and academic institutions nationwide to ensure adherence to the highest ethical standards in all relationships with industry.

The School of Medicine and Public Health and its leadership remain steadfast in support of efforts to ensure transparency and accountability in the delivery of health care in academic health centers and indeed, across the entire spectrum of health care. We are eager to work closely and openly with Congress to promote these standards and their effective implementation throughout our nation's health care systems.

The Value of Uniform National Conflict-of-Interest Standards

As attention to conflict of interest in health care has evolved, the complexity of relationships with industry, the understanding of institutional and corporate agendas, and the psychology of individual motivations, have all been increasingly identified as areas that require thoughtful exploration, judgment and oversight. The "true north" in

STATEMENT OF DR. ROBERT GOLDEN

conflict of interest is our recognition of the primacy of our individual and institutional commitment to the well being of our patients and our communities, a commitment not to be deterred by other interests. In our current system, dedication to this goal may be subtly or grossly undermined. Undermining that occurs as a result of personal or institutional avarice is indefensible. But more subtle influences may be operative and more balanced solutions must be sought when relationships between industry and academia can at once create positive and negative influences on our relations with those who imbue us with their trust.

Most academic health centers, ours among them, have been carefully examining our role in understanding and acting upon conflicts of interest. Along with our professional organization, the Association of American Medical Colleges, we have worked to be clear and declarative regarding some of the obvious conflicts created by relationships with industry (e.g., using academic influence to achieve personal gain while promoting commercial interest). At the same we are trying to be thoughtful in approaching some of the more nuanced questions that are generated at the interface of corporate and academic institutions, driven by different reward systems, but both seeking to enhance the public good.

It is our view that there is much to be gained if all of America's health care teaching institutions are required to abide by clear, thoughtful, and consistent standards in identifying, eliminating whenever possible, and managing conflicts of interest. Straightforward and efficient conflict-of-interest policies, consistently applied, will guarantee the same standards regardless of where a patient is seen. This approach will also avoid duplication of effort and the unnecessary costs and delays incurred if each health center seeks to "reinvent" their own conflict of interest policy "wheel".

For this reason, we wholeheartedly endorse legislative initiatives, including the Physician Payment Sunshine Act, which will create a uniform national code of conduct. As Congress moves toward the passage of health care reform, we hope to see the Sunshine Act language included in any final legislation adopted by Congress this year. Public reporting of physician remuneration by industry is by no means a panacea for all potential conflict of interest issues. Transparency, however, must be a basic element of any approach to conflict of interest.

University of Wisconsin School of Medicine and Public Health's Work on Conflict-of-Interest

The University of Wisconsin School of Medicine and Public Health sought to re-examine and revise its Conflict of Interest Policy to fully reflect the special covenant that exists between clinicians and patients, and based upon a commitment to transparency, accountability, and ethical conduct. More than a year ago, we decided to launch a major effort to review and update the various conflict of interest policies that existed for our school, our academic group practice, our university teaching hospital, and the other health affairs school and colleges on our campus, in order to create a consistent

STATEMENT OF DR. ROBERT GOLDEN

approach to this vital issue. Over the course of many hours of discussion and debate, we centered on four goals:

- *promote the highest standards of professionalism;*
- *vigorously manage conflicts-of-interest with industry;*
- *insure the absolute integrity of our evidence-based health care delivery programs; and*
- *maintain the trust and confidence of patients and the community at large.*

In November of 2008, the leaders of the University of Wisconsin's academic health center formed a Task Force on Industry Conflict-of-Interest in the Clinical Setting. The Task Force's mandate was to:

- *recommend ways to update and integrate the distinct conflict-of-interest policies and programs among various UW institutions with respect to education, research, marketing and receipt of gifts;*
- *recommend ways to improve and enforce the UW Health conflict-of-interest principles;*
- *develop actionable policies and procedures to guide the professional behavior of faculty, staff and students;*
- *craft a proposed governance structure and system to ensure adherence to the new, expanded conflict-of-interest regime; and*
- *focus on relationships and situations that may lend themselves to potential conflicts-of-interest, such as speakers bureaus, gifts to individuals and institutions, and patent disclosures.*

We have made substantial progress in rolling out the first phases of our new COI policy. We anticipate that we will complete the formal approval processes and the implementation of the entire set of policies during the 2009-2010 academic year. To date, we have done the following:

- In early 2009, we posted signs in all of our clinical care sites notifying patients that some of our faculty have consulting relationships with industry, and inviting them to let us know if they would like to receive a detailed accounting of their clinician's relationships. Such requests are handled in a way that protects the anonymity of the patient
- This year, all of our faculty physicians were required to submit detailed information on their outside activity report, including the exact amount of compensation for outside activities, including teaching, royalties, and consulting, rounded up to the nearest \$1000
- We anticipate that the policy, once approved by our governing bodies, will include the following features:
 - a ban on promotional talks for drug companies and membership on pharmaceutical company "speakers bureaus"
 - a ban on all gifts, with no minimum value

STATEMENT OF DR. ROBERT GOLDEN

- a ban on medical ghostwriting
- the elimination of drug samples in clinics
- strict limitations on the presence of pharmaceutical and device representatives in the clinical setting
- the formation of an internal oversight committee that will review each potential conflict of interest in the clinical setting and have jurisdiction for elimination or management of such conflicts
- The policy will be applied to every level of care in the UW Health system, including students, resident trainees, pharmacists, nurses, physician assistants, laboratory technicians, nurse practitioners, as well as physicians.

The University of Wisconsin School of Medicine and Public Health and CME

CME is one of those areas in which there has been an important interface between academic health centers and industry. This is a set of relationships that have come under increasing scrutiny, resulting in substantial debate about the institutional and individual conflicts they may engender. What is not debatable is that CME activities have historically been widely underwritten by industry and that CME, in its current incarnation, is quite dependent of industry funding. The question at hand is what financial relationships, if any, may continue to exist without undermining our patient covenant? Should all financial ties in CME between academia and industry be completely cut, or are alliances with the common aim of improving human health possible? As the Committee is aware, the recent Institute of Medicine report on Conflict of Interest offers strong recommendations that would minimize the influence of industry of CME.

The University of Wisconsin School of Medicine and Public Health recently convened a Task Force to review the activities of our CME program, known as the Office for Continuing Professional Development (OCPD). The Task Force concluded that the OCPD had a clear and comprehensive conflict of interest policy and conducted its work in strict adherence to current Accreditation Council for Continuing Medical Education standards. The Task Force noted the rapidly evolving thinking on the conduct of CME, and provided advice to carefully monitor and adapt to national norms and standards.

Mr. Chairman, we look forward to sharing updates on our continuing work in this area, and to sustaining our open collaboration with you, the Committee and your colleagues on Capitol Hill as we all seek to ensure that the practice and study of medicine reflect the highest standards of integrity, and that decisions relating to healthcare are made exclusively based on what is in the best interest of the patient.

We commend the Chairman and the Committee for their valuable work in this most important area and thank you for this opportunity to share our perspective.



COUNCIL OF MEDICAL SPECIALTY SOCIETIES

COMMITTED TO EXCELLENCE IN PROFESSIONALISM, EDUCATION AND QUALITY OF CARE

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Herb Kohl, Chairman
 Mel Martinez, Ranking Member
 Special Committee on Aging
 United States Senate

July 23, 2009

Dear Senators Kohl and Martinez,

The Council of Medical Specialty Societies (CMSS), representing 32 medical and surgical specialty societies with an aggregate membership of over 530,000 physicians in the US, appreciates the opportunity to contribute to deliberations of the Senate Special Committee on Aging, as it examines the impact of relationships between physicians and the pharmaceutical and medical device industries with respect to medical education and research.

We would like to provide information for your committee on:

- 1) the role of CMSS as a member of the Accreditation Council for Continuing Medical Education (ACCME);
- 2) the recently adopted recommendations of CMSS to specialty societies for creating conflict of interest policies;
- 3) the current charge to the CMSS Task Force on Professionalism and Conflict of Interest, and its relationship to the recent report of the Institute of Medicine (IOM) on Conflict of Interest in Medical Research, Education, and Practice; and
- 4) the role of CMSS as the convener of the sixteen national organizational members of the Conjoint Committee on Continuing Medical Education (CCCME) as it addresses the future of commercial support of continuing medical education (CME).

CMSS as a member of ACCME:

The Council of Medical Specialty Societies (CMSS) is one of the seven Member Organizations of the Accreditation Council for Continuing Medical Education (ACCME). CMSS fully supports the ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME Activities, and enthusiastically champions the 2004 revision. These Standards require that CME providers clearly and completely separate educational content from commercial influence, which may be perceived as resulting from commercial support.

The ACCME has current and relevant criteria requiring all CME providers to focus the goals of CME toward improvement of physician practice, thus improving the quality of patient care. These criteria include stronger guidance on complete independence from influence associated with commercial support, as well as stronger procedures for the identification and resolution of conflicts of interest. ACCME is assuming a position to strictly enforce its criteria, ensuring that the system of professional voluntary self-regulation works well.

CMSS recognizes that the perception of the incorporation of commercial influence into CME is real. We applaud ACCME for requiring accredited providers to identify and resolve all conflicts of interest prior to the education activity being delivered to learners. We believe that the creative experience of accredited providers can be generalized to prevent the incorporation of commercial influence into CME, and thereby protect not only the education of the learner, but the integrity of the CME enterprise.

CMSS recommendations to specialty societies regarding conflict of interest policies:

In 2008, CMSS convened a Task Force on Professionalism and Conflict of Interest, to address how specialty societies should manage and resolve their conflicts of interest and those disclosed among their members. In November, 2008, CMSS adopted the following recommendations to specialty societies for core principles to be included when creating organizational conflict of interest policies:

- a. Definitions of conflict of interest, including financial and fiduciary, whether considered “real” or “perceived”;
- b. Clarification of who is addressed in the society’s policy, including elected leaders, volunteers, representatives, members, staff, and the society itself;
- c. Delineation of activities addressed in the policy, including governance; undergraduate, graduate and continuing medical education; research; and clinical practice guideline development;
- d. Examples of conflicts of interest addressed in the policy;
- e. Disclosures of relationships addressed in the policy, including criteria for disclosure, and manner of disclosure (written, verbal, web, other);
- f. Consequences for failure to disclose relationships with a “real” or “perceived” conflict of interest;
- g. Management and resolution strategies for disclosed conflicts of interest;
- h. Clarification of circumstances requiring recusal, removal from participation or from the disclosed relationship; and
- i. Adherence to external standards and guidelines, such as the ACCME Standards for Commercial Support of CME, the AMA Ethical Opinion on Gifts to Physicians from Industry, and potentially others.

Charge to the re-constituted 2009 CMSS Task Force on Professionalism and Conflict of Interest:

Since adoption of the CMSS recommendations in late 2008, the environment has moved steadily toward further addressing the impact of relationships between physicians, their societies and industry. Interest of the Senate Committees on Finance and Aging, media accounts of outlier relationships between physicians and industry, the April 1 JAMA article by Rothman et al challenging specialty societies on their relationships with industry, the April 28 publication of the Institute of Medicine (IOM) report on Conflict of Interest in Medical Research, Education and Practice, and more have created a timely opportunity to take the critical next steps.

In 2009, CMSS has reconstituted its Task Force on Professionalism and Conflict of Interest with the following charge:

Develop and recommend a Code of Conduct for specialty societies, to enhance professionalism and to disclose, manage and resolve conflicts of interest in relationships with industry.

The task force has had its first meeting, and is addressing many areas of conflicts of interest challenged by the IOM report, including:

- guiding principles for society-company interactions
- charitable gifts
- dues, subscriptions, publications, and registrations
- educational grants and continuing medical education
- exhibit hall, sponsorships, and advertising
- satellite symposia

- individual relationships, including governance, and institutional relationships
- clinical practice guidelines
- research grants
- awards

Interim recommendations of this task force will be presented at the annual meeting of CMSS in November, 2009, with final approval at the April, 2010 CMSS meeting.

Conjoint Committee on CME (CCCME):

Since 2002, CMSS has served as convener of the Conjoint Committee on CME (CCCME), the members of which include:

Accreditation Council for Continuing Medical Education (ACCME)

Accreditation Council for Graduate Medical Education (ACGME)

Alliance for Continuing Medical Education (ACME)

American Academy of Family Physicians (AAFP)

American Board of Medical Specialties (ABMS)

American Hospital Association (AHA)

American Medical Association (AMA)

American Osteopathic Association (AOA)

Association for Hospital Medical Education (AHME)

Association of American Medical Colleges (AAMC)

Council of Medical Specialty Societies (CMSS)

Federation of State Medical Boards (FSMB)

Joint Commission (JC)

Journal of Continuing Education in the Health Professions (JCEHP)

National Board of Medical Examiners (NBME)

Society for Academic Continuing Medical Education (SACME)

In 2008-9, the organizations represented in CCCME went through a strategic planning process, resulting in a bold goal and three strategies:

Goal:

To utilize the CME system to contribute to improvements in US health system performance, as measured by international benchmarks (such as World Health Organization statistics, etc.);

Strategy 1:

To facilitate the integration of performance and quality improvement into continuing medical education;

Strategy 2:

To explore the development of curricula for CME at the system, specialty and practice levels;

Strategy 3:

To convene the national organizations to focus on assuring a system of financing CME that is free from the influence of commercial support, and which therefore responds to recommendation 5.3 of the Institute of Medicine (IOM) Report on Conflict of Interest in Medical Research, Education and Practice. It is anticipated that this process, begun in 2009, will take approximately two years, as predicted by the IOM.

The mission of the Council of Medical Specialty societies focuses on promoting adoption of policies that will improve the United States' healthcare system and health of the public. A core strategic priority of CMSS in 2009 is that CMSS and its member specialty societies are seen as role models of Professionalism, as measured by Altruism (putting patients' interests first), Voluntary Self-regulation, and Transparency. It is in the spirit of this priority of Professionalism that we submit the information herein to you.

We would be happy to testify at your hearing, should you be interested. Thank you for your consideration.

Sincerely,



Norman Kahn MD
Executive Vice-president and CEO

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Federation Of State Medical Boards • National Board Of Medical Examiners*

**Testimony before the Senate Special Committee on Aging
July 29, 2009**

**Daniel J. Carlat, M.D., Associate Clinical Professor, Tufts University School of
Medicine**

Thank you for the opportunity to address the Committee on Aging on the issue of the increasing involvement of the pharmaceutical industry in the education of American physicians.

I speak from the dual perspective of a practicing physician and the owner of a publishing business specializing in continuing medical education articles for physicians and nurses throughout the United States.

I am ashamed to admit that in 2002, I gave dozens of talks for Wyeth Pharmaceuticals on behalf of their blockbuster antidepressant Effexor, mostly to primary care physicians. Under the watchful gazes of Wyeth drug reps, I artfully emphasized the positive data about Effexor, and glossed over data regarding potentially dangerous side effects, such as high blood pressure.

Eventually, unwilling to tolerate the ethical compromises inherent in posing as an unbiased educator while at the same time accepting large payments from a drug company, I resigned from the Wyeth Speaker's Bureau. In all, I was paid over \$30,000 by Wyeth in 2002. In November of 2007, I published the details of my involvement with Wyeth in a memoir. The article, entitled "Dr. Drug Rep," was published in November of 2007 in the *New York Times Magazine*, and became the most e-mailed article in the *New York Times* for three days in a row (1). Clearly, Americans were astonished that doctors routinely enter into lucrative financial arrangements with pharmaceutical companies, and they were dismayed to learn that physicians' opinions can be bought for cash.

Since that article, several states, including Vermont, Massachusetts, and New Hampshire, have enacted legislation limiting the marketing influence of drug companies on physicians. My own state, Massachusetts, now bans most drug company gifts to doctors and requires public disclosure of payments for marketing services, such as promotional speaking and marketing consultation.

The Physician Payments Sunshine Act would institute national reporting requirements so that patients will be able to learn whether their doctors are receiving payments from drug companies. Clearly, such payments are not inherently unethical. Certain interactions between doctors and industry are not only appropriate, but are crucially important in the development of new treatments; generally, these payments are for bona fide services for designing and conducting industry-supported research. However, when companies pay physicians for purely marketing activities, a dangerous conflict of interest is inevitable. Monetary payments provide an incentive for the doctor to exaggerate the benefits of a product when they discuss it with other doctors or with their patients.

While the Physician Payments Sunshine Act would force disclosure of *direct* marketing payments from drug companies to doctors, there is another kind of marketing payment that would potentially be missed by the act. These are indirect payments in which companies provide educational grants to third parties, such as medical education communication companies (generally known as “MECCs”), medical schools, and medical societies. These organizations use the grants to organize courses for doctors, and pay key opinion leaders substantial fees to teach the courses.

This industry-funded continuing medical education enterprise (CME) has grown almost exponentially over the past several years. In 1998, the pharmaceutical industry contributed \$302 million (34% of the total) toward CME in the U.S.; by 2007, this figure had quadrupled, to \$1.2 billion (48% of CME funding). Last year, as a result of pressure from physician’s groups and Congress, commercial support of CME decreased somewhat to \$1 billion (44% of total funding). (See Appendix 1).

Where does all this money go? Most of it goes to MECCs, private companies that are often affiliated with marketing and advertising firms. These MECCs actively solicit drug company funds to create accredited education programs. Physicians are a captive audience, since most states require a minimum number of CME credits to maintain medical licenses. While ACCME (the national body that oversees such programs) explicitly forbids any direct communication between the funding drug companies and the employees writing the curriculum, this supposed firewall is rather porous. For example, a series of investigative reports in the *Milwaukee Journal Sentinel* revealed that drug companies have paid millions of dollars for CME courses accredited by the University of Wisconsin, courses which were skewed in favor of the products marketed by the funding companies. For example, Pfizer gave over \$12 million for a series of CME courses about smoking cessation. One of the course’s major recommendations was the use of Pfizer’s anti-smoking drug Chantix. Inexplicably, the drug’s dangerous side effects, such as hallucinations and suicidal ideation, were omitted from the course material (2).

Similar cases of marketing activities disguised as medical education abound. For example, in September of 2008 McMahon Publishing and Johns Hopkins University collaborated to present a conference entitled the American Conference on Psychiatric Disorders. It took place at the Marriot Marquis Times Square Hotel in New York City, and consisted of four lectures or workshops funded by different drug companies. While the conference was billed as an accredited educational event for psychiatrists, its true purpose was laid bare in its prospectus, which I located online, but which has since been removed by the company (for a more complete discussion of this conference, see The Carlat Psychiatry Blog, In Industry CME, \$85,000 buys you 90 minutes, \$103,000 buys one article, July 18, 2008, <http://carlatpsychiatry.blogspot.com/2008/07/in-industry-cme-85000-buys-you-90.html>).

This prospectus was essentially a marketing brochure directed at drug companies interested in using CME courses to market their products to doctors. McMahon’s fee for a 90 minute “Independently Supported Symposia” (a euphemism for “*Industry-Funded Symposia*”) was \$85,000 (which works out to \$944/minute). In return for this extravagant

sum, the publisher promised each drug company:

1. "Exclusive support of a symposium slot" (meaning that there would be no competition from any other drug companies during that time.)
2. "Audience recruitment and session promotion" (Special placards and signage throughout the hotel designed to encourage psychiatrists to show up to their course.)
3. "Certification through Johns Hopkins University School of Medicine" (Johns Hopkins received a substantial cut of the money in order to lend their name and prestige to the event.)
4. "Registration report/summary of participant evaluations" (I.e. the names and addresses of physicians for future promotional mailings.)

Furthermore, for \$103,000, McMahon offered to transcribe the course and convert it into a "Special Report," an 8-page, journal-sized monograph of approximately 4500 words with a 10-question multiple-choice post-test. This would extend the company's marketing message to a much larger audience, because the "Reports" were sent free to thousands of psychiatrists, as well as posted online.

The one day conference included four drug company supported symposia, meaning that the total income earned by the McMahon (a portion of which was presumably distributed to Johns Hopkins) was approximately \$752,000 (assuming \$188,000 per symposium). If this seems like an excessive amount of money to pay for a day of lectures, it is. Clearly, the drug companies were not simply paying for medical education; they were paying for advertising.

Because these payments were not direct payments from drug companies to physicians, they would have remained hidden if McMahon had not mistakenly posted their prospectus online.

I would like to conclude with recommendations based on my experiences with industry-supported medical education. The overarching theme is that full and detailed disclosure of drug company payments for CME is now required, because the medical education enterprise had been partially corrupted into a commercial activity. Unfortunately, the main incentive is for many stakeholders in this thriving business is to make a profit rather than to produce valuable and unbiased medical education.

Recommendations:

1. Drug companies should be required to disclose all funding for accredited continuing medical education programs. Such disclosure should include the following elements:

--The total amount of the grant.

- The name of the CME program.
- The nature of the program (ie., live courses, published articles, online courses, etc....)
- The names of all organizations involved in producing the program, including medical education communication companies, universities, medical societies, and hospitals.
- The specific amounts of money paid to each entity involved in the program (including any university which accredited the program, and any physician involved in giving talks or writing articles).

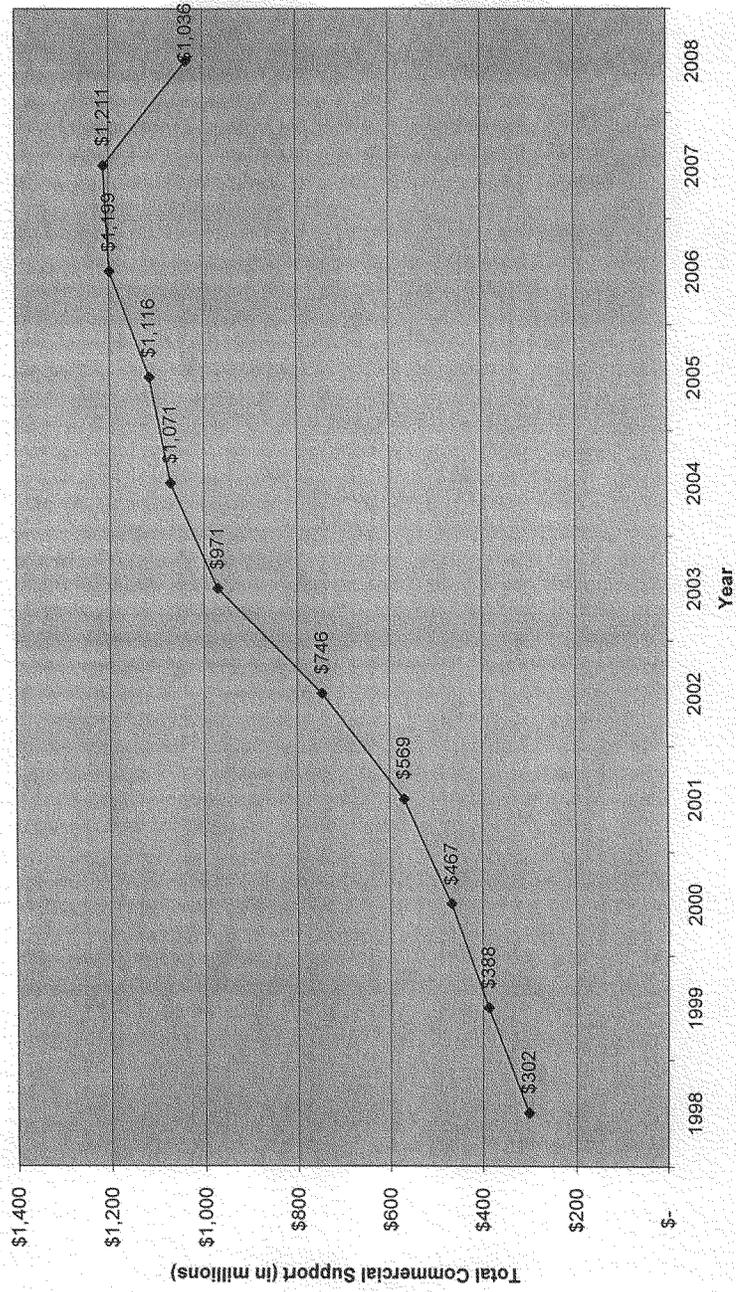
2. The Institute of Medicine should report to Congress on the progress made on their recent report on medical education, in which they recommended that:

“A new system of funding accredited continuing medical education should be developed that is free of industry influence, enhances public trust in the integrity of the system, and provides high-quality education.”

1. Carlat D. Dr. Drug Rep. New York Times Magazine, November 25, 2007.
(<http://www.nytimes.com/2007/11/25/magazine/25memoir-t.html>)

2. Rust S and Fauber J. Drug firms' cash skews doctor classes. Milwaukee Journal Sentinel, March 29, 2009.
(<http://www.jsonline.com/news/42064977.html>)

Trends in Commercial Support of CME, 1998-2008
(total dollars in millions)



CME: Continuing Medical Education or Commercial Marketing Efforts?

Testimony submitted to the Senate Committee on Aging hearing on
Medical Research and Education: Higher Learning or Higher Earning?

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Disclosure: Dr. Fugh-Berman has been a paid expert witness on behalf of plaintiffs in litigation regarding pharmaceutical marketing practices.

Continuing medical education (CME) is the pharmaceutical industry's most important marketing tool. The development of marketing messages for a drug starts seven to ten years before a drug is submitted for FDA approval. Many of the marketing messages that are developed for each product do not mention the drug at all. A 'pre-launch' marketing message might emphasize the importance of a specific physiologic process in order to set the stage for acceptance of a drug that affects that mechanism, or might create an unnecessary diagnostic distinction in order to establish a niche for a drug entering a crowded market.

Selling disease

CME can be used to sell drugs by selling diseases. As a marketing article called "Proving the case for investing in CME" states: "The most significant benefits for industry may include creating disease-state awareness and disease state significance."¹ Another marketing article notes that: "CME activities are most valuable in introducing products early in their life cycles or for promoting mature brands with new indications and new clinical data."²

Industry-funded CME often emphasizes the severity or prevalence of specific conditions in order to prepare, or expand, a market.³ Manipulating physicians' understanding of the prevalence or severity of medical conditions can lead to overtreatment and expose patients to the adverse effects of drugs without significant benefit.

The marketing messages embedded in CME lectures, articles, on-line modules, and tests are never advertisements for a specific therapy because physicians will reject speakers or articles that obviously favor a specific drug. One marketing message might emphasize the risks of competing therapies; another the lack of evidence regarding an over-the-counter remedy.

CME is often used to promote unproven uses of a drug. While it is illegal for a drug company to promote off-label use of a drug, CME is not considered promotion and is not regulated by the FDA. Physicians can say whatever they want, so are used as mouthpieces for marketing messages that would be illegal coming from a company rep.

The academic physicians involved in industry-funded CME may protest, quite honestly, that they are expressing their independent opinions. However, these physicians are chosen because what they are saying aligns with a product's marketing messages, and they are supported only as long as their opinions do so.⁴ A physician who expresses doubts about a product's efficacy, concerns about its risks, or

¹ Raichle L. Proving the case for investing in CME. *Medical Marketing & Media*. Jun 1998; 33(6): 84.

² Bottiglieri D. Crowd Pleaser. *Pharmaceutical Executive*. Sep 2001; 21(9): 122.

³ Fugh-Berman A, Melnick D. Off-Label Promotion, On-Target Sales. *PLoS Medicine* 2008;5 (10): e210 <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050210>

⁴ Fugh-Berman A. Key opinion leaders: Thus are our medical meetings monitored. *BMJ* 2008;337:a789 http://www.bmj.com/cgi/content/full/337/jul15_1/a789

enthusiasm for a competing therapy will be unceremoniously dropped from a company's speaker's bureau.

Vetting bias in CME modules

There is little incentive for medical education and communication (MEC) companies or academic medical centers to attempt to ferret out bias in CME modules, because both depend on industry for survival. In 2008, 44% of the \$2.4 billion spent on CME came from pharmaceutical manufacturers. Sixty-nine percent of the income from events sponsored by medical education companies is from firms that manufacture FDA-regulated products. Academic medical centers are only a little better; 54% of CME income to medical schools comes from industry.⁵

Although academic CME providers do their best to vet industry-funded modules for bias, such review focuses on the detection of obvious advertising, the use of brand rather than generic names of drugs, and adequate disclosure of conflict of interest. No matter how vigilant they are, CME providers are not trained in recognizing marketing messages and cannot adequately assess industry-funded materials for bias.

As previously noted, marketing begins years before a drug reaches the market. Adequate vetting of CME modules would require knowledge of every drug, biologic, device, and diagnostic test that every company is marketing, developing, or considering. The task becomes even more daunting when mergers, acquisitions, co-marketing agreements and collaborative marketing arrangements (for example, among companies selling drugs in the same class) are taken into account. Similarly, disclosures of financial conflicts of interest are impossible to interpret without knowing every company's marketing plan for every drug on the market or in the pipeline.

'Unrestricted' grants

Unrestricted educational grants to academic medical centers and MECs are no solution. Although the new PhRMA Code of Ethics does not allow sponsors (companies that fund the event) to suggest speakers, sponsors may indicate which topics they are interested in funding. "Unrestricted" grants provided for grand rounds and lunch conferences depend on a sense of obligation rather than a quid pro quo. When lists of recommended speakers are supplied to organizers, it is unstated, but nonetheless understood, that company-paid speakers will be included in the lecture series.

The organizing board of the CME program may include speakers selected and paid by the sponsor. The desired messages about particular products or diseases may be made clear. Organizers understand that sponsors or exhibitors may withdraw if they don't like the content. Not every speaker in a lecture series or conference is chosen by industry. Pharmaceutical companies refer to presentations with marketing messages as "message talks," and sponsored CME programs usually include talks that are not connected with the sponsor's product. Although these camouflage talks may involve independent speakers, organizers know that they must avoid inviting speakers who might criticize a sponsor's products or oppose a sponsor's marketing messages.³

⁵ ACCME Annual Report Data 2008. Table 7. ACCME 2009 Jul 16. Available via the Internet: http://www.accme.org/dir_docs/doc_upload/1f8dc476-246a-4e8e-91d3-d24ff2f5bfec_uploaddocument.pdf. Accessed July 27, 2009.

Physicians will never hear about how a targeted disease is overdiagnosed or overtreated at a sponsored event. And rarely will they hear positive recommendations for a competitor's product, a generic product, or a non-pharmacologic therapy at a sponsored program.

ACCME

The ACCME Standards for Commercial Support⁶ to discourage potential conflicts of interest are both weak and ignored. A 2007 annual report by the ACCME, however, showed that 29% of providers failed to comply with Standard 2, which requires that any individuals that control content of a CME activity disclose and resolve conflicts of interest.⁷ Twenty-seven percent of the providers did not comply with Standard 3, which includes guidelines to prevent those with commercial interests from dictating the content of a CME activity. And 36% of providers were noncompliant with Standard 6, which requires that all commercial support and financial relationships of authors be disclosed to CME participants before the activity.⁶

The ACCME does not screen CME activities, and does not encourage audience members to report commercial bias. Although written complaints are accepted, the process is burdensome. Losing accreditation for any reason is rare; according to the annual reports published by the ACCME only one provider lost accreditation in 2005.

Conclusion

If sponsoring CME events did not increase product sales, drug companies would not do it. The large amount of commercial support poured into CME is in itself testimony that industry believes supporting CME is cost-effective. Industry influence on medical discourse limits the discussion to the most profitable therapies, which may not be best for patients. Industry-funded medical education is a contradiction in terms.

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Acknowledgments: Alicia Bell MS, Margaret Infeld, Clare Murphy, Stephanie Waterhouse, and Nicole Woodard provided background research.

About PharmedOut

PharmedOut, a project based at Georgetown University Medical Center, uses academic research and drug industry insider perspectives to educate prescribers about how covert marketing techniques affect prescribing behavior. PharmedOut was launched through a grant from the Attorney General Consumer and Prescriber Grant Program.

Our latest free, web-based, 3-CME credit educational module is called The Pharmalyzer: Are you prescribing under the influence? Our unique approach draws on academic and marketing materials

⁶ ACCME. Essential Areas and Elements, 2008. Available via the Internet: http://www.accme.org/dir_docs/doc_upload/t4ee5075-9574-4231-8876-5e21723c0c82_uploaddocument.pdf. Accessed June 30, 2009.

⁷ ACCME. Standards for Commercial Support, 2008. Available via the Internet: http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf. Accessed June 30, 2009.

combined with original interviews with industry insiders to create novel articles, videos, and educational materials. Our goal is to foster evidence-based, cost-effective prescribing and to decrease the adverse public health effects of inappropriate pharmaceutical promotion.

We provide original web-based CME modules and links to more than 150 free, non-industry-funded, web-based continuing medical education (CME) courses – enough for any physician, nurse, or pharmacist to complete annual continuing education requirements. Educational resources include our slideshows, Drug Ad Bingo (a teaching exercise), Fast Facts on Generic Drugs (a factsheet for patients), and seven original videos, featuring industry insiders. Our publications include Off-Label Promotion, On-Target Sales, Following the Script: How Drug Reps Make Friends and Influence Doctors, Do New Drugs Increase Life Expectancy?, Ethical Considerations of Publication Planning in the Pharmaceutical Industry, Prescription Tracking and Public Health, Key Opinion Leaders: Thus Are Our Medical Meetings Managed, and Smoke and Mirrors.



NAAMECC

North American Association of Medical Education and Communication Companies, Inc.

3416 Primm Lane Birmingham, AL 35216 205-824-7612 www.naamecc.org

NAAMECC Comments on Certified CME**Presented to the U.S. Senate Special Committee on Aging****July 27, 2009**

The North American Association of Medical Education and Communication Companies, Inc. (NAAMECC) is the trade organization representing U.S. medical education companies, as well as the clinical faculty and participants of member-developed Certified continuing medical education (CME) initiatives. We offer a special thanks to the Honorable U.S. Senator Kohl and his staff for inviting a statement regarding Certified CME and clarifying important issues in the CME enterprise in order to develop leadership positions that will guide the healthy future of independent, Certified CME.

NAAMECC's mission is to promote best practices in CME that meet the many and detailed requirements set forth for the conduct of continuing education activities for physicians, with the goal of providing education that improves patient care. NAAMECC functions as a resource for, representative of, and advocate for more than 70 medical education companies that help employ thousands of workers. NAAMECC member organizations design and develop Certified CME activities that annually reach more than 150,000 physicians and other learners in the healthcare professions.

NAAMECC supports measures promoting practices that are scientifically and ethically acceptable and preferable, including those set forth in the *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. While Certified CME should not be confused with medical practices and research involving human subjects, CME stakeholders must continue to recognize and uphold their ethical responsibilities in the development of excellent continuing education.

Current Healthcare Environment and CME

In order to fully address critical issues involving Certified CME today, we begin by taking note of the current U.S. healthcare environment. In short, the U.S. healthcare system faces several complex and intersecting challenges: along with an aging population and increased needs for advanced medical treatment, we are facing significant physician shortages at both the primary care and specialty levels. In the past five years, more than 15 studies have cited the effects of

physician shortages. As noted in the 2007 report of the Association of American Medical Colleges (AAMC), *Recent Studies and Reports on Physician Shortages in the U.S.*, most of these studies show that the care of underserved and elderly populations is likely to be affected by the shortages. In addition, rising costs combined with flat reimbursement from government and private insurers place additional financial pressure on both primary care physicians and specialists. While improved methods and new pharmacologic and non-pharmacologic treatment options are detailed in more than 150,000 medical journal articles published each month, physicians request and need Certified CME to help them make sense of the evidence and share best practices.

Consider what two physicians recently wrote in evaluations of Certified CME activities they attended in Fall 2008.

"I cannot stress enough how essential my CE courses, online and live, have been to me. It helps me to stay current with the latest advancements and developments in diagnosis, treatment and management to improve patient care. I need more CME courses, live and online, in the future."

"There is tremendous value of CME in disseminating much needed clinical updates for learners, particularly community-based, primary care practitioners, who may not be in a position to fund their CME/CE efforts on their own."

As we debate key issues in the CME enterprise, we must remember our responsibility to consider the current healthcare environment, identify evidence-based problems, and develop solutions that increase the value and reach of CME activities that improve medical practices and patient care results.

Confusion Regarding Certified CME and Other Activities

Certified CME has often been confused with other forms of so-called "education," as well as marketing and sales activities supported by commercial interests. Make no mistake: any type of education that does not specifically meet the ACCME guidelines for independence, management of conflicts of interest and faculty disclosure cannot be presented as Certified CME and cannot be approved for AMA physician CME credit. Accredited providers are beholden to the ACCME rules and risk losing their accredited status and the authority to certify CME activities and issue credit.

Many stakeholders within and outside the CME enterprise have confused Certified CME with promotional activities branded under the name "professional education." In 2008, one report stated that "professional education" included:

- "CME"
- "industry marketing and promotional activities"
- "personal expenses associated with attendance at meetings"
- "educational travel grants for medical students"
- "free lunches"
- "residency positions"
- "company speakers' bureaus"
- "free or subsidized travel"

Unfortunately, the only thing on the list above that does qualify for physician credit and meet the definition for Certified CME is "CME." Everything else is not Certified CME. Certified CME is different. It can be funded through educational grants from pharmaceutical companies, the federal government, foundations, or registration payments from learner attendees. In those cases where a pharmaceutical manufacturer provides grant funding for a CME activity, the pharmaceutical manufacturer is not allowed to select faculty or take part in any decisions regarding the content or presentation of evidence-based material. Despite these facts, the public, news media, and some CME stakeholders still mistake Certified CME with unrelated activities.

Guidance for the CME Enterprise

Several opinions developed by the American Medical Association (AMA), as well as requirements for providers of Certified CME set forth by the Accreditation Council for CME (ACCME), are relevant to discussion of CME conflicts, challenges, and commercial funding. As noted in AMA Ethical Opinion 9.011 regarding Continuing Medical Education, "only by participating in continuing medical education (CME) can they (physicians) continue to serve patients to the best of their abilities and live up to professional standards of excellence." Further, this AMA opinion guides physicians to analyze CME options and choose "only those activities which are of high quality and appropriate for the physician's educational needs." AMA Opinion 9.011 also counsels physicians to participate only in CME activities that "are responsibly conducted by qualified faculty" and "conform to Opinion 8.061, 'Gifts to Physicians from

Industry.” The AMA opinion on CME also addresses appropriate practices for physicians serving as speakers, moderators, or other faculty at a Certified CME activity.

Responses to Past Mistakes in CME

Acting counter to the AMA opinions on CME, as well as ACCME standards and policies, a minority of bad actors broke existing rules and guidelines in the past. In response, the CME enterprise made significant improvements to its rules and structure between 2004 and 2008. The framework of Certified CME is now guided by more stringent standards, monitoring, and guidelines, including:

- Multiple requirements set forth by the board that accredits providers of CME, the Accreditation Council for Continuing Medical Education (ACCME), including:
 - ACCME Accreditation Criteria 1 through 15 (setting forth the minimum requirements to ensure educational rigor and independence)
 - ACCME Elements addressing appropriate educational Purpose/Mission, Planning, and Evaluation/Improvement
 - ACCME Standards for Commercial Support⁽¹⁾ requiring 1) Independence, 2) Resolution of Conflicts of Interest, 3) Appropriate Use of Commercial Support Grant Funding, 4) Appropriate Management, 5) Development of Content and Format without Commercial Bias, and 6) Disclosures to ensure transparency
 - ACCME Content Validation Value Statements requiring CME content to 1) include evidence-based clinical recommendations, 2) rely on research that conforms to generally accepted standards of experimental design, data collection and analysis, and 3) meet the definition of CME and not provide patient care recommendations in which risks outweigh the benefits
 - ACCME Audits of accredited education providers to ensure they fully comply with all criteria and policies
 - ACCME rapid response measures (announced in 2008) to identify compliance infractions, place accredited providers on probation, and work with these organizations to bring them back into compliance
 - ACCME on-site audits of educational activities (beginning in 2009)

⁽¹⁾ Available at http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf (“Standards for Commercial Support”).

- Enforcement action by the Office of Inspector General of the Department of Health and Human Services, which, according to the guidance, "has put teeth into compliance by industry, as the penalties for non-compliance include very large fines and potential incarceration."
- The U.S. Food and Drug Administration's (FDA's) standards for ensuring the independence of CME, which, while adopted by the agency primarily to address the use of CME as a subterfuge for "off-label" promotion, nevertheless establishes standards for ensuring the independence of CME from commercial influence.
- Several codes related to conduct and/or ethical interaction have recently been developed, including updates to the Pharmaceutical Research and Manufacturers of America (PhRMA) *Code on Interactions with Healthcare Professionals*, the Advanced Medical Technology Association (AdvaMed) *Code of Ethics on Interactions with Health Care Professionals*, and a newly developed *Code of Conduct for Commercially Supported CME*, which is a collaborative initiative involving NAAMECC and other leading CME organizations.

Accredited education providers, non-accredited education partners, and grant funders of Certified CME all must abide by updated rules that ensure the following:

- Grant funders, including pharmaceutical and medical device manufacturers, are not allowed any control over the specific content, speakers, or management of CME
- All education is independently reviewed and edited to address any possible bias
- Presentations must be evidence-based and meet updated criteria and guidelines set forth by the ACCME
- Compliance with ACCME Standards for Commercial Support
- Rapid response to any non-compliance findings of ACCME on-site audits of CME activities

Of great significance is the fact that no physician can be compensated simply to attend Certified CME activities. Learners at these activities have no incentive to participate or favorably evaluate presentations that do not comply with ACCME, FDA, and HHS OIG requirements for Certified CME. Perhaps this is why the 2008 Manhattan Research survey of 902 physicians showed that 92 percent of physicians who participated in CME believed it was not biased and a similar

percentage (91 percent) either supported or did not oppose commercial support of CME. This evidence, combined with the conclusion of the 2008 ACCME literature review that “there is no evidence to support or refute” speculation that commercial support produces bias in CME activities, forces stakeholders to consider the following:

1. Widespread education about ethical roles of physicians as CME participants and faculty,
2. Rigorous enforcement of updated CME compliance policies and measures, and
3. Cautious consideration of actions that limit freedoms of physician choice or harm development of quality education, especially in the absence of evidence to support additional changes

Response to 2009 Institute of Medicine Report on Conflicts

Despite all the best intentions, the federal Institute of Medicine is making proposals for CME's future based on facts from the distant past. In its 2009 report on *Conflict of Interest in Medical Research, Education, and Practice*, the IOM released a report (underwritten by the Josiah Macy, Jr. Foundation) calling for an end to educational grants from pharmaceutical and medical device manufacturers.

Some of the report's conclusions (Eliminate non-educational interventions from university campuses) make sense. But when you dig into the report's findings on CME, you find mostly outdated data and arguments that do not take into account the dramatic regulatory and accreditation board rules now required to ensure that CME excludes industry influence and addresses all conflicts of interest.

Most important, the report generally confuses Certified CME with other forms of so-called “education” and relationships that have nothing to do with CME. Again, Certified CME activities only are those developed by accredited providers of CME in compliance with all ACCME standards and guidelines, as well as FDA and Health and Human Services Office of Inspector General Compliance Guidance requirements that ensure CME is “independent from promotional influence.”

But by trying to address conflicts in research, education, and practice, the IOM mistakenly blends Certified CME with non-CME interactions. The result? Confusion and outdated data regarding CME, not clarity.

A few examples:

- In the report's table 5-1, the IOM mentions that drug companies provide lunches, pens, snacks, and dinners for medical students in the third year of schooling. The report complains of "non-educational" interventions in the learning environment. Worthy complaint, but the comments deal with grad school and do not apply in the least to Certified CME activities that occur after physicians are practicing.
- The IOM report cites studies about "influence" by manufacturers that date back to 1986. Oddly enough, the report does not mention at all the academic literature survey on bias produced by the ACCME in 2008 concluding that "no empirical evidence" exists to support a connection between industry grant funding for Certified CME and bias.
- In a flagrant violation of the principle of "evidence-based" reporting, the IOM report includes a "personal account" in which an unknown person states that CME speakers were hired on the basis of their support for a "sponsor's message." If this were the case, it would be a clear violation of ACCME standards and would cause the accredited provider to either be placed on probation or lose its accreditation. The report fails to mention that accredited providers must collect audience evaluations regarding any possible bias and have policies to address any such issues. In addition, the ACCME has a process for handling complaints and has implemented a monitoring system to detect and address any bias. Last, the report fails to mention that physicians are not compelled to attend any CME activity (they can get a year's worth of required credits over a few days at a single society annual meeting). Physicians attend CME because it's useful and needed, given the current explosion of healthcare information. Physician CME attendees also are required to evaluate activities for bias, and this information is easily obtained.
- The IOM report claims that bad CME activities were developed related to the federal Neurontin and Vioxx cases. The problem? The violations cited by the IOM report are specifically addressed and prohibited by current regulations (the CME enterprise has addressed past problems).
- The IOM report admonishes the ACCME by citing 2001 and 2003 articles stating that the ACCME Standards for Commercial Support of CME activities do not deter industry influence. Two problems: 1) the original articles did not include evidence to support the claim, and 2) the ACCME updated the Standards in 2004, as well as several new policies approved in subsequent years, to ensure that Certified CME is independent from promotional influence.

The CME enterprise has undergone many positive changes during the past five years. The media, public, and other stakeholders should acknowledge these improvements and support the development of independent, Certified CME.

Conclusion

In conclusion, NAAMECC would like to offer its thanks for your continued consideration and open dialogue regarding evidence and proposals that could improve patient care and public trust. We strongly support the efforts of U.S. Sen. Kohl and the Special Committee on Aging to foster this discussion and encourage you to consider the recommendations above, as well as the following:

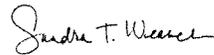
- support legislation and association efforts to educate physicians regarding all the current Certified CME criteria, policies, and need for ethical behavior, and
- monitor the current progress being made to ensure that regulations and standards are enforced and new avenues for support of Certified CME are opened.

Fruitful debate regarding ethical physician behavior can only be ensured when evidence-based ideas from all relevant stakeholders and education providers – academic institutions, medical education companies, professional societies, hospitals, and others – are included. By considering the suggested changes above, you will contribute to supporting a healthy future for Certified CME activities while helping improve evidence-based education and related patient care.

Best Regards,



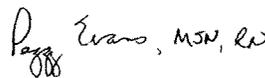
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**American Medical Student Association
Physician Payments Sunshine Act, S.301
Background**

1. On June 3, 2008, the American Medical Student Association (AMSA) released the AMSA PharmFree Scorecard grades that it gave to the 150 U.S. Medical Schools it surveyed on Conflict-of-Interest Policies. Only 7 schools had received an 'A' and 21 schools of the 150 surveyed had strong policies receiving a grade of either an A or a B.¹
2. The AMSA PharmFree Scorecard evaluated eleven areas of potential conflict of interest, including policies on restricting gifts and meals, industry-funded speaking for products, disclosure of financial ties with the pharmaceutical companies, acceptance of promotional drug samples, and interaction with sales representatives, among other criteria.¹ The AMSA PharmFree Scorecard is continuously updated and is available at www.pharmfreescorecard.org.
3. On July 10, 2008 the Pharmaceutical Research and Manufacturers of America (PhRMA) announced their revised marketing code that went into effect on January 1, 2009 as an effort of self-policing.² AMSA applauds the industry's recognition that gift giving creates biased prescribing habits, but is concerned that the revised code has many loopholes and exceptions.³
4. The revised PhRMA code prohibits the distribution of "reminder" items such as pens, mugs, and others displaying the company and product logo to health care professionals. In addition, sales representatives are not allowed to provide restaurant meals to health care professionals, but are allowed to bring in "occasional meals" while giving "informational presentations". The code also requires companies to ensure that their representatives are trained on applicable laws, regulations and industry codes of practice.⁴
5. **Most resident physicians believe that their behavior is not influenced by marketing messages.** Yet when a group of first and second year residents at university based internal medicine residency programs in a confidential survey were asked if they believed that industry promotions influenced their prescribing 61% said 'no.' Yet only 16% believed that the great majority of their colleagues are not influenced by marketing practices.⁵
 - a. Gifts, meals, marketing samples and personal relationships consistently play a role in shaping behavior (*such as prescribing practice*) on an unconscious level.⁶
 - b. A gift of *any size* creates a sense of indebtedness and obligation to repay the favor or gifts.⁷ Even the smallest gifts involuntarily influence an individual's processing and interpretation of information.⁸
6. **Congressional investigations revealed many conflict of interest cases between physicians and pharmaceutical companies.**
 - a. An investigation by the Senate Finance Committee uncovered that a prominent Harvard child psychiatrist, Dr. Joseph Biederman, whose work led to a 40-fold increase in the pediatric bipolar diagnoses from 1994 to 2003, did not disclose payments of \$1.6 Million from drug companies between 2000 and 2007.⁹
 - b. In 1993 the state of Minnesota passed the first law in the nation requiring disclosure of pharmaceutical industry gifting to prescribers and collection of data tracking such gifts. A 2007 analysis of 2000-2005 data by *The New York Times* found that as drug company gifting and payments to Minnesota psychiatrists rose six-fold between 2000-2005, state Medicaid pediatric antipsychotic prescriptions increased by nine-fold.¹⁰
 - c. Academic medical centers should not be asked to enforce or monitor conflict of interest among their own faculty and staff. *Despite Emory University's mandatory disclosure policy*, Congressional investigations found that the institution's chair of the Psychiatry Department and a

prominent researcher, Dr. Charles Nemeroff, underreported payments he received from drug companies from 2000 to 2007. The investigation documents showed that Emory had entirely relied on Nemeroff to make good on his promise to disclose all his income from the pharmaceutical industry.¹¹

7. **The Pharmaceutical Industry spends twice the amount on marketing that it spends on research and development.** In 2004, the total spent on domestic pharmaceutical marketing was \$57.5 Billion whereas \$31.5 Billion was spent on drug research and development in the U.S.^{12,13} Over the last 25 years, only 2% of the 3,122 drugs reviewed were truly therapeutically innovative while over 90% did not offer any real benefits over existing drugs.²⁹
8. **The Pharmaceutical Industry is increasing its direct-to-patient advertising.** Between 1996 and 2005, the industry increased its marketing expenditures by 300%, which was \$11.4 Billion with the greatest growth of 530% in advertising directly to consumers from \$985 Million in 1996 to \$4.24 Billion in 2005, making only 14% of 2005 total promotional expenditure.¹²
9. **The Pharmaceutical Industry is increasing its direct-to-physician marketing.** The pharmaceutical industry spends \$12 to \$18 Billion each year marketing to physicians including residents.^{27,28} In 2007, there were about 95,000 drug sales representatives; this is about 1 sales rep for every 7 physicians (based on 95,000/663,000).^{14,15} Pharmaceutical Executive magazine's approximation of about 250,000 doctors who are targeted by drug sales reps puts the ratio near 1 representative for every 2.5 physicians.^{16,17} In 2005 and 2006, primary care physicians who were seen as "heavy prescribers" were called on by an average 29 sales representatives in a week.¹⁸
10. **PhRMA, the trade group representing sixteen of the twenty largest pharmaceutical companies, led Washington's largest lobby, spending \$22.7 Million of the \$189 Million total in industry spending on lobbying the federal government in 2007.** The industry's top achievements were the blocking of inexpensive drugs importation from other countries, protection of pharmaceutical patents in the U.S and overseas, and greater market access in international free trade agreements for the pharmaceutical industry.^{19,20}
11. **While the Sunshine Act does not address promotional samples, they serve two roles in influencing prescribing behavior.** Physicians place a value on samples and are willing to spend time with industry sales representatives to obtain them.²¹ And a physician who hands out promotional "free" samples is more likely to continue prescribing that brand-name, more expensive medication once the samples are depleted. Additionally, the majority of samples are not given to low-income or uninsured patients.^{22,23} Individuals with incomes greater than 400% of federal poverty level are more likely to receive free samples than low-income patients. Similarly, a constantly-insured patient is more likely to receive these samples than an uninsured patient.²⁶
12. **Some more progressive pharmaceutical companies have support stricter disclosure policies that protect patients and public health.** In 2008, Eli Lilly moved ahead of the rest of the industry in announcing its plan to launch a public internet registry disclosing its payments to physicians.²⁴ In addition, Eli Lilly announced its support for the Physician Payments Sunshine Act when it was introduced last May as a part of its "transparency agenda."²⁵

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**American Medical Student Association
Physician Payments Sunshine Act, S.301
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The Prescription Project promotes evidence-based prescribing and works to eliminate conflicts of interest in medicine due to pharmaceutical marketing to physicians.

It is promoting policy change by working with

- *State and Federal Policymakers*
- *Academic Medical Centers*
- *Professional Medical Societies*
- *Private Payers*

Created with The Pew Charitable Trusts, the Project is led by Community Catalyst in partnership with the Institute on Medicine as a Profession.

April 2008

Continuing Medical Education

A Toolkit for Academic Medical Centers

I. Introduction

In 2005, commercial spending on continuing medical education (CME) totaled \$1.1 billion, accounting for 50 percent of all CME support (up from 34 percent in 1998).¹ Industry support of CME has grown in recent years as other avenues of pharmaceutical promotion have come under increased scrutiny and regulation.

However, industry influence on CME content has been extensively documented. Allowing the pharmaceutical industry to play such a role in physician education compromises clinical care and medical professionalism by, overtly or otherwise, "linking financial support of the programs to the marketing objectives of the companies that provide the funding."² Though it is not a new concern, leaders within the medical profession increasingly question the wisdom of allowing the large industry role in CME, which includes the development of curriculum, recruitment and payment of speakers, and furnishing of materials to doctors.

According to Relman, the pharmaceutical industry often plays an inappropriate role in CME events. "Pharmaceutical companies sometimes help organize and advertise the educational event; they may prepare teaching slides and curriculum materials, and they compile lists of possible speakers and indirectly pay them. They also may subsidize practitioners, medical students, residents, and fellows to attend."³

Pharmaceutical companies often control events indirectly through Medical Education Communication Companies (MECCs).⁴ The large MECCs industry organizes events for physicians, but serves the needs of its clients – the industry that pays the bills. MECCs receive 90 percent of their funding from commercial support.⁵

This toolkit is one in series prepared by the Prescription Project to assist medical schools and teaching hospitals developing new policies to address the conflicts of interest that arise from pharmaceutical and medical device industry marketing. For further assistance or more information, please email policy@prescriptionproject.org.

Pharmaceutical companies do not make investments for which a return is uncertain or unquantified. According to Brennan et al,⁶ companies acknowledge that they "carefully evaluate the market impact of expenditures and support only those demonstrating an increased use of their products." Pharmaceutical funding of CME has been shown to affect the information provided, and studies have shown that physician attendance at CME events resulted in more prescriptions for the sponsors' products.⁷

Interviews with professionals who organize CME at various medical centers clearly establish that pharmaceutical funding has a large influence on the topics that are discussed.⁸ Events covering diseases with pharmaceutical treatments will find funding, while other important topics with no pharmaceutical tie-in, such as domestic abuse or physician stress management, have a more difficult time finding support.

The Accreditation Council for Continuing Medical Education (ACCME) has established standards for commercial support (section III, below). However, ACCME does not audit individual programs and its standards have not been effective in ensuring the independence of CME events. Many programs continue to receive accreditation, despite serving primarily marketing purposes. According to Steinbrook, "given the underlying economics of CME and the small size of the ACCME, the goal of independence from commercial interests may be difficult to achieve."⁹

With this in mind, it is critical that policies to address conflicts of interest at academic medical centers (AMCs) include provisions to maintain the independence and rigor of CME. A model CME policy for an academic medical center should aim to eliminate both real and perceived conflicts of interest derived from the involvement of pharmaceutical and device companies playing such a central role in physician education.

II. Policy Considerations

- **Funding CME solely through academic medical center support and attendance fees:**

For most AMCs the complete elimination of industry-funded CME is not financially feasible. One large regional managed care organization has started completely self-funding their CME, admittedly with a substantial budget of close to \$5 million to provide the education for 6,000 physicians. According to interviews with organizers of this CME program, the policy has allowed them to make better use of several employees who formerly spent their time hunting for grants and ensuring unbiased CMS. CME costs are kept low by using in-house experts. Additionally, because they do not require outside funding, they are free to pursue non-pharmacological topics, including domestic violence awareness, leadership courses for their departmental chairs, and promotion of generic medications. This managed care organization monitors the behavior of physicians to be sure that the CME contributes directly to improved patient care. However, this organization provides little CME for outside physicians. For some institutions, especially AMCs that provide CME for its physicians and community physicians, such a policy may be unfeasible. In this case, there are other options for ensuring the integrity of CME.

Memorial Sloan-Kettering Cancer Center (MSKCC) in New York has attempted to cut back the cost of CME, without sacrificing quality. In January 2006, the cancer center's CME administrators banned all industry support for CME, which previously comprised 25 percent of the Center's CME budget. The steps they took may provide a template for academic medical centers looking to maintain a vital CME program without industry backing.

MSKCC:

- moved formerly off-site events to its on-site conference centers
- drew on in-house expertise for speakers when possible, rather than inviting outside speakers who must be fed and lodged
- stopped providing catered lunches at most CME events
- cut back on direct mail and journal advertisements for CME events
- charged 10 percent more to outside participants
- proposed establishing CME donor and start-up funds to raise additional revenue for future events.

After a six month trial, MSKCC opted to make the policies permanent. Attendance at CME events remained steady, and feedback from participants remained positive.

- **Establishing a central education fund:**

AMCs may establish a central repository to which industry can contribute funding for educational purposes. The AMC has sole discretion for distributing the funds toward unbiased educational programming and scholarship support. As recommended by Brennan et al., AMCs can establish a central fund for all industry contributions.¹⁰ Industry sponsors should be prohibited from designating individual physician or departmental recipients or topics to be covered. Monies for CME will be allocated based solely on need as determined by the AMC. UMass Memorial Medical Center has established a similar policy. Although sponsors can designate particular departments to receive their funds, donors cannot assign the money to specific physicians and cannot request particular topics.

- **Reviewing CME for bias:**

Whether or not funding for educational purposes is allowed, every institution should have an independent review system for CME attendees to monitor perceived commercial bias. In the absence of a central repository or complete elimination of commercial funding, a very rigorous evaluation system may help prevent bias from emerging in CME. The CME office of the University of Wisconsin-Madison, the largest CME office in the nation, has a multilayered system to check for bias. Presenters who are deemed "high risk" based on the monetary value of their industry connections must submit all their materials for prior review. The materials are reviewed by an unbiased peer of the physician (in the case of a cardiologist, the material will be reviewed by a cardiologist). Changes made by the peer must be adopted if the event is to receive CME credit. If an entire event is designated as "high risk" because of the amount of commercial support (or if only one or two companies are providing support), all materials to be presented at that conference must undergo peer review. The CME office maintains a large group of peer-reviewers, and the officials at the CME office are constantly recruiting and training new reviewers.

- **Incorporation of ACCME standards**

ACCME standards provide a baseline for the conduct of CME activities. While ACCME accreditation is not, of itself, sufficient to ensure that CME activities are unbiased, incorporation of these standards into institutional policies may be useful. Some institutions require that ACCME standards be met, whether or not an educational event is accredited.

- **Disclosure is not sufficient:**

It is important to note that disclosure of industry support for educational events is not sufficient in the absence of further limitations on that support. This is supported by the 2006 updated ACCME standards for commercial support.¹¹ Disclosure is an important intermediate step for institutions developing guidelines, but is not adequate protection against financial conflicts of interest, and should not be viewed as such. It is important that disclosures be public, and that efforts are made to resolve the conflicts that are disclosed. The University of Wisconsin (see above) provides a good example of how this might be done.

- **Prohibiting industry-sponsored events on campus:**

A thorough policy will also prohibit industry from hosting, or earmarking funds for, specific events on campus, through either direct funding or a corporate subsidiary (such as a Medical Education and Communication Company), whether CME credit is offered or not. Policy at Memorial Sloan Kettering Cancer Center distinguishes between industry support for "professional educational activities," which is prohibited, and support for CME, which is coordinated through a central office

Additionally, an institution should set conditions on events for which campus space may be rented, excluding wholly industry-sponsored 'educational' meetings and marketing events.

The intent of all such policies is to ensure appropriate distance between industry sponsors and end users.

- **Industry support for off-campus events:**

Because most faculty, residents, clinicians, or students are required to obtain CME credits and may select off-site programs whose commercial independence is not ensured by the institution, an AMC should prohibit industry from paying faculty or trainees to attend such events or providing other financial incentives to do so.

For an institution that adopts a model policy and rejects industry support for CME, the challenge becomes replacing the funding or scaling back program offerings.

III. Example Policies

Boston University School of Medicine/Boston Medical Center

2. Provision of Scholarships and other Funds to Trainees

Clinicians should ensure that support of educational programs for trainees by the pharmaceutical or device industries is free of any actual or perceived conflict of interest. These funding mechanisms may include grants for educational initiatives, scholarships, reimbursement of travel expenses, or other non-research funding in support of scholarship or training.

Specifically, the industry funding must comply with all of the following:

- a. The trainee is selected by the Department, Program, or Section.

- b. The funds are provided to the medical school or hospital development offices, or, in the case of CME-accredited activities, to the CME office.
- c. The Department, Program, or Section has determined that the conference or training has educational merit.
- d. The recipient of the funds is not subject to any implicit or explicit quid pro quo (i.e., "no strings are attached").

Industry Support for Educational Events

Clinicians should be aware of the Standards for Commercial Support established by the ACCME and the ADA CERP.... All continuing education events at the medical school or hospital must fully comply with ACCME guidelines (or where pertinent, to the ADA CERP) whether or not formal CME credit is awarded. In order to comply, clinicians will need to become familiar with the ACCME guidelines, and a clinician organizing a continuing education activity should consult with the BUSM Office of Continuing Medical Education for guidance.

In addition to complying with the ACCME Standards (or where pertinent, ADA CERP), educational events supported by industry at BMC or BUSM must also comply with the policies described under Sections 1 and 2.

University of Pittsburgh Medical Center and Schools of the Health Sciences

5. Support of Continuing Education in the Health Sciences

Industry support of continuing education ("CE") in the health sciences can provide benefit to patients by ensuring that the most current, evidence-based medical information is provided to healthcare practitioners. In order to ensure that potential for bias is minimized and that CE programs are not a guise for marketing, all CE events hosted or sponsored by the SOHS, UPMC, or University of Pittsburgh Physicians ("UPP") must comply with the ACCME Standards for Commercial Support of Educational Programs (or other similarly rigorous, applicable standards required by other health professions), whether or not CE credit is awarded for attendance at the event. All such agreements for Industry support must be negotiated through and executed by the Center for Continuing Education in the Health Sciences ("CCEHS"), and must comply with all policies for such agreements. Any such educational program must be open on equal terms to all interested practitioners, and may not be limited to attendees selected by the company sponsor(s).

Industry funding for such programming should be used to improve the quality of the education provided and should not be used to support hospitality, such as meals, social activities, etc., except at a modest level. Industry funding may not be accepted for social events that do not have an educational component. Industry funding may not be accepted to support the costs of internal department meetings or retreats (either on- or off-campus).

SOHS or UPMC facilities (clinical or non-clinical) may not be rented by or used for Industry funded and/or directed programs, unless there is a CE agreement for Industry support that complies with the policies of the CCEHS. Dedicated marketing and training programs designed solely for sales or marketing personnel supported by Industry are prohibited.

Industry Support for Scholarships, Fellowships or Other Support of Students, Residents, or Trainees

The SOHS and UPMC may accept Industry support for scholarships or discretionary funds to support trainee or resident travel or non-research funding support, provided that all of the following conditions are met:

- a. Industry support for scholarships and fellowships must comply with all University or UPMC requirements for such funds, including the execution of an approved budget and written gift agreement through the Medical and Health Sciences Foundation, and be maintained in an appropriate restricted account, managed at the school or department as determined by the senior vice chancellor for the health sciences. Selection of recipients of scholarships or fellowships will be completely within the sole discretion of the school in which the student or trainee is enrolled or, in the case of graduate medical education, the associate dean for graduate medical education. Written documentation of the selection process will be maintained.
- b. Industry support for other trainee activities, including travel expenses or attendance fees at conferences, must be accompanied by an appropriate written agreement and may be accepted only into a common pool of discretionary funds, which shall be maintained under the direction of the dean or department (as specified in the funding agreement) for the relevant school. Industry may not earmark contributions to fund specific recipients or to support specific expenses. Departments or divisions may apply to use monies from this pool to pay for reasonable travel and tuition expenses for residents, students, or other trainees to attend conferences or training that have legitimate educational merit.

Attendees must be selected by the department based upon merit and/or financial need, with documentation of the selection process provided with the request. Approval of particular requests shall be at the discretion of the dean.

Yale Medical Group

Industry Support for Educational Events on the School of Medicine Campus

[...]

In addition to the aforementioned ACCME Standards, educational events sponsored by industry on the Yale School of Medicine campus should comply with the following provisions:

- a. Gifts of any type are not distributed to attendees or participants before, during, or after the meeting or lecture;
- b. Funds to pay for the specific educational activity are provided to the Department, Program, or Section and not to an individual faculty member.

Stanford University School of Medicine

Provision of Scholarships and Other Educational Funds to Students and Trainees

Industry support of students and trainees should be free of any actual or perceived conflict of interest, must be specifically for the purpose of education and must comply with all of the following provisions:

1. The School of Medicine department, program or division selects the student or trainee.
2. The funds are provided to the department, program, or division and not directly to student or trainee.
3. The department, program or division has determined that the funded conference or program has educational merit.
4. The recipient is not subject to any implicit or explicit expectation of providing something in return for the support, i.e., a "quid pro quo."

This provision may not apply to national or regional merit-based awards, which are considered on a case-by-case basis.

Memorial Sloan Kettering Cancer Center

III. Support for Educational Events and Activities Sponsored by MSKCC

A. MSKCC does not accept educational grants or other forms of subsidy from industry for professional educational activities. All support and funding for Continuing Medical Education events sponsored by MSKCC will be coordinated through the Continuing Medical Education Office. See the MSKCC CME policies for guidance on how to set up a MSKCC CME activity. For information on setting up continuing education events for other disciplines (e.g., nursing, technologists), please contact your department administrator.

B. Industry support for fellowships is permitted. MSKCC (and not the industry sponsor) must have complete control over the use of the funds, including the selection of individuals to be supported and the course of training the individuals will undergo.

IV. Industry Sponsored Events outside of MSKCC

A. Meals or receptions hosted by industry at professional or educational meetings are acceptable as long as they are modest, conducted in a way that is conducive to exchange of information, and there is a bona fide scientific, educational, or business purpose for the meeting. MSKCC staff should avoid industry-sponsored events that are primarily social in nature.

B. MSKCC will not participate in the promotion of meetings that are not sponsored by MSKCC (i.e. distribution of flyers announcing an industry sponsored talk held off-site).

C. MSKCC staff members may not accept gifts or compensation for listening to a sales talk by an industry representative.

UMass Memorial Medical Center**3. Support for Continuing Medical Educational Programs**

i. **Recommended Policy:** all funding from vendors to support CME programs should be directed to the UMass Memorial Foundation where funding should be restricted consistent with the donor's request and supporting documentation. Funding may be restricted to a clinical department and overseen by the Department Chair. Funding may not be restricted to an individual physician or program. An oversight committee comprised of physician and other leaders will oversee Industry Sponsorship exceeding established thresholds (ie; \$10,000) for conflicts of interest.

b. Implications of Policy:

- i. Vendors wishing to support CME must direct contributions to the UMM Foundation. Vendors may not provide CME funding/support directly to clinical departments, divisions or individual physicians including chairs or chiefs. Vendor sponsorship contributed through the UMM Foundation may be restricted to the clinical department under the oversight of the Department Chair, but may not be restricted to any one physician, division or program.
 1. International/National/Regional Meetings Co-sponsored by UMass Memorial or UMass Medical School: these meetings are designed to benefit the broader community of physicians. Industry funding to support such meetings is acceptable provided such funding is exclusively for support of such meetings and, not to directly benefit UMass Memorial or UMass Medical School. Any funds provided to UMass Memorial or UMass Medical School or associated faculty associated with such meetings must fully comply with Section 4 – Consulting or Service Agreements below.
- ii. The above funds or, other departmental funds may be used to support CME programs, including speakers and, reasonable and appropriate provisions of food and facilities;
- iii. Vendors are not permitted to bring food into any UMM facility for any meetings and are prohibited from paying for such food.
- iv. An oversight committee of rotating physician leaders will review and oversee industry sponsorship exceeding established thresholds (ie; \$10,000) to assess potential conflicts of interest and, to propose approaches for management of conflicts of interest..
 1. Review any vendor contribution exceeding \$10,000 in support of CME, GME (fellow support), or general research support;
 2. Review uses of funds for consistency with restrictions and policy;
 3. Review aggregate vendor contributions semiannually;
 4. Advise Chairs, Executive Management and the Executive Management Compliance Committee regarding conflicts of interest and policy matters.

REFERENCES

- ¹ Accreditation Council for Continuing Medical Education 2005 Annual Report
- ² Reiman, A. Separating Continuing Medical Education from Pharmaceutical Marketing. JAMA. 2001; 185: 2009-2012.
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- ⁴ Editorial "Drug Company Influence of Medical Education in the USA." Lancet Vol. 356 Issue 9232. pg 781. 2001
- ⁵ Steinbrook, R. "Commercial support and continuing medical education." NEJM 352(3):534-535. 2005
- ⁶ Brennan, T. et al. Health Industry Practices that Create Conflicts of Interest. JAMA. 2006; 295: 429-433.
- ⁷ Huang, F. et al. Academic Psychiatry. 29:5, November-December 2005. pg 500.
- ⁸ Prescription Project interviews.
- ⁹ Steinbrook, Commercial support, 534-535
- ¹⁰ Brennan, Health Industry Practices, 429-433.
- ¹¹ http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf

