

Prepared Statement of
Pharmaceutical Research and Manufacturers of America

Hearing on Medical Research and Education

Before the U.S. Senate Special Committee on Aging

July 27, 2009

Chairman Kohl, Ranking Member Martinez, and Members of the Committee:

Thank you for the opportunity to submit this statement on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA's member companies are leading research-based pharmaceutical and biotechnology companies that are devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. In 2008, PhRMA's member companies invested an estimated \$50.3 billion in research and development – an increase of over \$2 billion from 2007 – and were developing or seeking regulatory approval for 2,900 molecules that might eventually be used to treat U.S. patients. PhRMA companies are leading the way in the search for new and better treatments for patients.

PhRMA appreciates the invitation to submit its views relating to subjects discussed in today's hearing on the important role that biopharmaceutical companies and others in the health care industry can play in supporting balanced, accurate, and beneficial medical education. Biopharmaceutical companies provide support for physician education about new medicines through a number of mechanisms, including direct interactions between company representatives and physicians, company sponsorship of healthcare professional peer education sessions (sometimes referred to as "speaker programs"), and company funding for independent continuing medical education programs sponsored by accredited CME providers. With regard to each of these mechanisms, companies strive to follow all applicable laws and regulations and to maintain the highest standards of ethics and professionalism. Pharmaceutical companies must comply with applicable Food and Drug Administration (FDA) regulations, as well as fraud, abuse and anti-kickback laws enforced by the U.S. Department of Justice, in all communications about medicines. In addition, biopharmaceutical companies have adopted self-imposed guidelines on marketing activities, embodied in the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code"), other industry codes, and individual company policies.

A. Purpose of Continuing Medical Education (CME) and Importance of Independence

Continuing Medical Education (CME), also known as Independent Medical Education (IME), is a critically important mechanism for physicians and other health care providers to obtain information and insights that enhance their knowledge and skills and improve patient care and clinical outcomes. It is vital that such education be current, address knowledge, competence, and performance gaps of learners, and be free of commercial bias.¹

¹ We note that there are many factors that can influence physician prescribing and patient use of medicines, such as peer reviewed research and payor coverage, formulary, and utilization management decisions. See, e.g., D.P. Goldman, et al., "Prescription Drug Cost Sharing:

B. Industry funding of CME

Pharmaceutical manufacturers may support CME for a wide range of reasons. Central to their support is a belief that they are participants in the healthcare system, and therefore should participate in the educational process by which physicians and other health care professionals remain current. The pharmaceutical industry is an evidence-based industry, and thus it supports inclusion of all evidence-based scientific exchange to promote optimal patient care. Such support of activities is critical to the industry's mission and should not be construed as an intention to create bias or control the content of educational activities.

There is also a great deal of literature on the underutilization of medicines, and barriers to adherence and noncompliance with treatment regimens. To the extent that Providers independently identify specific performance gaps or barriers, and educational activities can address some of these issues directly or indirectly, patient outcomes are improved and there is evidence that overall health care spending could be reduced.²

Providers have an obligation under accreditation standards set forth by the Accreditation Council for Continuing Medical Education (ACCME), the leading accrediting body for CME providers, to assess the outcome of their activities on learners and understand the educational value of the activities and whether they meet their objectives. Outcomes measurements may also provide information on new or remaining educational needs among activity participants. These

Associations with Medication and Medical Utilization and Spending and Health," *Journal of the American Medical Association*, July 4, 2007; S. Soumerai et al., "Use of Atypical Antipsychotic Drugs for Schizophrenia in Maine Medicaid Following a Policy Change," *Health Affairs*, April 1, 2008; and H. Huskamp, "The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending." *New England Journal of Medicine*, December 4, 2003. In fact, IMS Health reports that in 2007, 67 percent of all prescriptions filled were generic (IMS Press Release, "IMS Reports U.S. Prescription Sales Grew 3.8 Percent in 2007, to \$286.5 Billion," March 12, 2008).

² M. Sokol et al., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," *Medical Care*, June 2005 (improved adherence to medicines for diabetes, hypertension and high cholesterol yields between \$4 and \$7 in savings for every additional dollar spent on medicines during the one year period studied by Medco); D. Cutler, et al., "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation," *Health Affairs*, January/ February 2007 (Harvard and MIT researchers estimated that if all patients with high blood pressure were treated to guidelines with antihypertensive medicines, an additional 89,000 premature deaths and 420,000 hospitalizations could be avoided annually); M. Cloutier, et al., "Asthma Guideline Use by Pediatricians in Private Practices and Asthma Morbidity," *Pediatrics*, November 2006 (a program designed to improve asthma care for children led to a 47% increase in the use of medicines that prevent asthma attacks, a 56% reduction in outpatient visits, and a 91% decrease in emergency room visits for treatment of asthma).

assessments are beneficial but add cost to the activity. Industry support can provide an additional source of funding to conduct these assessments.

We also note that manufacturers have medical education departments, staffed with professionals whose sole focus is to ensure that educational funding is provided to support the company's patient care-driven mission. To further strengthen and promote the independence of these departments, the revised PhRMA Code on Interactions with Healthcare Professionals, discussed below, calls for company grant-making functions to be separate from sales and marketing departments. Many companies may already have taken that action pursuant to the recommendation made in the OIG Compliance Program Guidance for Pharmaceutical Manufacturers in 2003 (the "OIG Compliance Program Guidance"). Companies have policies and procedures in place to assure grants are made in compliance with regulatory guidance and industry standards. Companies conduct internal training with respect to their grant-making functions. For these reasons, we hope the Committee understands that the grant-making function is carefully monitored to ensure that it remains consistent with industry's overall mission to help patients.

C. Company-Sponsored Speaker Programs

Healthcare professionals participate in company-sponsored speaker programs in order to help educate and inform other healthcare professionals about the benefits, risks and appropriate uses of company medicines. Company-sponsored speaker programs, while distinct from accredited CME, can serve an important role in informing healthcare professionals and promoting better healthcare. These speaker programs are regulated by the FDA, and companies maintain comprehensive programs to select, train, and monitor speakers to ensure compliance with FDA regulations and company policies on responsible interactions with healthcare professionals. As explained below, PhRMA has also responded to the medical community's request for greater transparency by requiring companies following the PhRMA Code to be clear about the differences between independent medical education and company-sponsored speaker programs.

D. PhRMA Code on Interactions with Healthcare Professionals

In 2002, PhRMA adopted its Code on Interactions with Healthcare Professionals (the "PhRMA Code"). The PhRMA Code covered a wide range of topics relating to interactions between pharmaceutical manufacturers and health care professionals, including support of CME. The PhRMA Code provided that CME funding should be given to the Provider and never to the physician, that the Provider should determine the content, faculty and educational methods, materials and venues of the activity and that payment should not be made for non-faculty healthcare professionals attending the CME or to compensate for the time spent by healthcare professionals attending the CME.

Nevertheless, in response to concerns by policymakers and others, PhRMA determined that it was time to review the PhRMA Code, and in July 2008, announced the adoption of an enhanced version of the Code (the “Revised PhRMA Code”). The Revised PhRMA Code went into effect in January 2009 and has been positively received by various stakeholders, including legislators and medical associations.

Among its provisions, the Revised PhRMA Code includes a number of new provisions specifically related to industry funding of CME. According to those provisions:

- Funding should be intended to support a full range of treatment options and not to promote a particular product.
- A company should separate its CME grant-making decisions from its sales and marketing departments.
- A company supporting CME should respect the independent judgment of the CME provider and should follow standards for commercial support established by ACCME or other entity that accredits the CME provider.
- Companies should not provide any advice or guidance to CME providers regarding content or speakers for a particular CME activity, even if asked by the CME provider.
- Companies should not provide meals or receptions directly at CME events. A CME provider, at its own discretion, may apply the financial support provided by a company’s grant to provide meals for all participants at a CME activity.

In addition, the Revised Code includes updated and enhanced provisions regarding company-sponsored speaker programs. Those provisions state that:

- Companies should develop policies addressing the appropriate use of speakers, including appropriate utilization after training and appropriate number of engagements for any particular speaker over time.
- Speaker training sessions should be held in venues that are appropriate and conducive to informational communication and training about medical information; specifically, resorts are not appropriate venues, and entertainment or recreational events are not appropriate at speaker training meetings.

- Companies and the speakers they engage should be clear about the distinction between company speaker program and independent medical education. Speakers and their materials should clearly identify the company that is sponsoring their presentation and that the speaker is presenting information consistent with FDA guidelines.
- Companies should periodically monitor speaker programs for compliance with FDA regulatory requirements.

Finally, PhRMA listened to comments from policymakers and others asking for additional accountability to the Code. We strengthened the section on Adherence to the Code, which now urges all companies that engage in pharmaceutical marketing to follow the Code. In addition, companies that intend to follow the Code must:

(1) publicly state their commitment to abide by it;

(2) self-certify annually with signatures of the Chief Executive Officer and Chief Compliance Officer that they have policies and procedures to foster compliance with the Revised PhRMA Code; and

(3) authorize PhRMA to post names and contact information for company Chief Compliance Officers.

In addition, companies are encouraged to obtain a periodic external review to ensure that the company has policies and procedures in place to foster compliance with the Code. PhRMA will post on its website the names of companies that indicate a commitment to abide by the Revised PhRMA Code, the status of annual certification, and when a company has sought and obtained external review of compliance policies and procedures.

Thus, the Revised PhRMA Code is enhanced both with respect to its specific provisions on industry support of CME and speaker programs, as well as its provisions that ensure adherence to the Revised PhRMA Code and public accountability. *To date, 48 companies – including both PhRMA members and non-member companies – have committed to following the Code and been recognized as signatory companies on PhRMA’s website.*

E. Proposals for Limiting Industry’s Role in Funding CME

Over the past few years, numerous groups have examined the appropriate role of industry in funding CME. While we cannot anticipate every topic that might be of interest to the Committee, PhRMA offers the following perspective on several issues that have been addressed in the ongoing debate concerning medical education.

1. Imposing Limitations or Prohibitions on Company Funding of CME

Several groups and academic medical centers have proposed the idea of limiting or prohibiting companies from sponsoring CME, notwithstanding the strict parameters established by the ACCME, the PhRMA Code, and other mechanisms designed to ensure that company-sponsored CME remains free of bias. The option of eliminating commercial funding of CME would not benefit patients or physicians. There is no conclusive evidence that industry support of CME creates bias in CME.³ In the absence of such evidence and while waiting for the full implementation of recent changes to the Revised PhRMA Code and the updated ACCME Standards, PhRMA is concerned that elimination of funding may adversely impact physician education and patient care.

In fact, the ACCME-funded report raised the important point that changes in prescribing behavior following a company-sponsored CME course may in fact indicate that the CME course has served its intended purpose in educating physicians and stimulating improvements in patient care. As noted in the report, there may be multiple reasons prescribing may change after a CME activity, including new information about formulary placement⁴ and previous undertreatment for the condition.⁵ Changes in care resulting from a CME course therefore are not necessarily the result of commercial bias, and we should not discourage commercial support for CME that ultimately produces better outcomes for patients.

The multi-year examination of this issue by the Council on Ethical and Judicial Affairs (CEJA) for the American Medical Association is instructive. In

³ R. Cervero and J. He, "The Relationship between Commercial Support and Bias in CME Activities: A Review of the Literature" (commissioned by ACCME). ACCME acknowledged in its July 11, 2008 response to the Senate Committee on Aging Chairman Kohl's request that despite suspicions of bias resulting from industry support of CME that there is no evidence to support that conjecture. [CHECK]

⁴ Physician surveys consistently report that formularies have a major impact on prescribing decisions. A 2002 survey conducted by the Boston Consulting Group showed that 54% of physicians reported that formularies have a major impact on prescribing decisions. A Tufts Center for the Study of Drug Development also showed a strong impact. In fact, in 2007, 9 of the 10 most frequently prescribed drugs in the United States were generic. IMS National Prescription Audit Plus.

⁵ There is a great deal of research on underdiagnosis and undertreatment. A landmark 2003 study conducted by RAND Health found that US patients fail to receive about half of all recommended health care. The study found that medicines are underused in numerous situations for many conditions. Notably for quality standards related to medication, patients on average failed to receive recommended care 30% of the time. E.A. McGlynn et al, "The Quality of Health Care Delivered to Adults in the United States," *The New England Journal of Medicine* 348, no. 26 (26 June 2003); 2635-2645. Another RAND study assessed quality problems in the delivery of pharmacotherapy and identified 50% of all problems as underuse of needed medicines while overuse accounted for 3% of problems. T.P. Higashi, G. Shekelle et al, "The quality of pharmacologic care for vulnerable older patients," *Annals of Internal Medicine* 140, n. 9 (4 May 2004) 714-20.

2008, CEJA issued its initial Report on Industry Support of Professional Education in Medicine, recommending the elimination of commercial funding of medical education. The American Medical Association Reference Committee on Amendments to Constitution and Bylaws referred this recommendation back for further review after a significant amount of testimony by AMA Delegates that “stressed a need to consider more fully the role newly adopted accreditation standards play in addressing potential bias in educational content, particularly in continuing medical education,...that the report does not adequately address the potential differential impact and implication of restrictions on industry support across the range of stakeholders in medical education or other potential unintended consequences... [and] that supporting empirical references were problematic.” In 2009, CEJA issued a report, recommending a distinction between commercial-free CME, which would be ethically preferable and commercially supported CME that met certain conditions, as ethically permissible. Again, there was a significant amount of testimony by AMA delegates concerning the CEJA recommendations and they were referred back for further review.

Thus, any recommendations to eliminate funding of CME would appear to be unfounded and ill-advised based on the lack of evidence of bias and the unintended consequences for patient care that could result.

2. Imposing Limitations on Communications Between CME Providers and Company Sponsors on General Topics Sponsors Will Support

Some have suggested that accredited CME providers should not receive any communications from potential company sponsors that reference even the general topics for CME that the company may be interested in supporting. While PhRMA agrees that CME sponsors should conduct their own needs assessments to determine topics that might be appropriate for educational activities, manufacturers should be permitted, consistent with the Revised PhRMA Code, to publicize general topics in which they have funding available to support education.⁶ This information might be communicated in different ways

⁶ The Revised PhRMA Code’s Question and Answer section includes:

Q21 May a company publicize its interest in a general topic for a CME program for which a grant would be provided?

A. Yes, a company may communicate to multiple CME providers or the public a general topic for a CME program that might be of interest to physicians. For example, a company may publicize that it will consider funding the topics of new treatments or disease management techniques in a particular therapy area such as diabetes or hypertension. However, the company should follow CME accreditation standards considering the nature and specificity of the CME topics that the company may propose, keeping in mind the Code’s statement that financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine. In addition, the company may not suggest the speakers or review or make any suggestions concerning the specific content of a particular CME program, even if asked by the CME provider.

such as requests for educational grant applications⁷ or websites. There is a range of information that a manufacturer could convey as a general topic for which it has funding to support educational activities. For example, broad therapeutic areas such as asthma, breast cancer, epilepsy, oncology, Parkinsons or Type 2 diabetes are topic areas that a commercial interest might publicize that it is willing to consider funding. Similarly, general topics might include specific gaps in meeting clinical guidelines identified by government entities, or topics that cover broad gaps in management of disease or that cover multiple pharmacologic or non-pharmacologic approaches. As stated in the Revised PhRMA Code, “financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine.”

These communications should be permitted to continue. Without this information, Providers would be left to guess what areas of activities might be funded by various commercial supporters which would force them to do unnecessary research or submit unnecessary application requests, wasting valuable resources that could be better directed toward education.

3. Imposing Limitations or Prohibitions On Healthcare Professionals’ Ability to Serves As Faculty for Accredited CME and Educators in Company-Sponsored Speaker Bureaus

Some academic institutions or professional associations have proposed or adopted policies that dictate that healthcare professionals who serve on company-sponsored speaker bureaus cannot serve as faculty for accredited CME courses. PhRMA shares these groups’ interest in ensuring that speaker programs sponsored by pharmaceutical companies are separate and distinct from CME and that such distinction is clear to an audience, but respectfully suggests that transparency provides a better approach than limitations or prohibitions on healthcare providers’ ability to serve as peer educators in different contexts.

As stated in the Revised PhRMA Code, company speaker programs play an important and distinct role in pharmaceutical company efforts to communicate about their products and convey new information and developments; “Healthcare professionals participate in company-sponsored speaker programs in order to help educate and inform other healthcare professionals about the benefits, risks, and appropriate uses of company medicines.” These company-sponsored events are not CME, but these speaker programs are regulated by the FDA. By way of example, companies must submit all slide decks prepared for speaker programs to the FDA when they are used. The FDA frequently provides comments on such materials and may take enforcement action if necessary. Health care

⁷ These Requests could have different names such as funding announcements, requests for proposals, calls for grant applications or similar terms.

professional speakers are chosen because they meet criteria such as medical expertise, reputation, and knowledge in a particular therapeutic area. They are required by law to present information that is consistent with applicable FDA requirements. Internal legal and medical review is conducted of material before used by a speaker. Under the Revised PhRMA Code, speakers must “receive extensive training on the company’s drug products or other specific topics to be presented and on compliance with FDA requirements for communication.”

PhRMA understands that some healthcare stakeholders have expressed concern that audiences may be confused at times regarding whether a physician might be speaking on behalf of a company at a company sponsored speaker program or as the faculty for CME. Consequently, our Revised PhRMA Code addresses this concern by requiring increased transparency. Section 7 of the Revised PhRMA Code provides: “While speaker programs offer important educational opportunities to healthcare professionals, *they are distinct from CME programs, and companies and speakers should be clear about this distinction.* For example, speakers and their materials should clearly identify the company that is sponsoring the presentation, the fact that the speaker is presenting on behalf of the company, and that the speaker is presenting information that is consistent with FDA guidelines.” (emphasis added)

If executed in accordance with applicable FDA regulations and industry standards such as those set forth in the Revised PhRMA Code, company-sponsored speaker programs can provide worthwhile information about the benefits, risks and appropriate uses of medicines. Physicians generally find the information that they receive from pharmaceutical manufacturers to be very useful to them. Physicians may not always have the time to meet with manufacturer sales representatives during the course of their busy day. Moreover, many physicians would rather learn about a product from a peer physician. While the programs are not a substitute for and should not be confused with more broad-ranging CME activities, these speaker programs provide important information for physicians on specific products and their risks and benefits.

The quality of any informational program – be it a company speaker program or a CME activity – turns in large part on the expertise and skill of the presenter. It is natural that companies should seek out the most qualified physicians to address attendees at company speaker program events, and likewise, CME providers may independently turn to many of these same experts to serve as faculty in a CME activity. The consequence of imposing a restrictive policy on healthcare providers is either (1) physicians no longer serve as speakers for companies, which eliminates an important source of information about products for physicians or (2) physicians choose to continue to contract with companies to serve as speakers and no longer serve as faculty for CME activities. Either result is a loss for physician education and ultimately impacts the healthcare patients receive. PhRMA respectfully submits that physicians

should be free to help educate their peers in the context of company speaker programs or CME, as long as the message being delivered in each forum is accurate and not misleading and otherwise complies with the applicable laws or rules governing the event, and the audience is provided with clear disclosures about the speaker's relationship to the company funding the event.