



American Psychiatric Association
1000 Wilson Boulevard
Arlington, VA 22209-3901
Ms. Michelle Dirst
Department of Government Relations
Telephone: 703.907.7800
Fax: 703.907.1083
E-mail: MDirst@psych.org
Internet: www.psych.org

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.