

AACAP GUIDELINES ON CONFLICT OF INTEREST FOR CHILD AND ADOLESCENT PSYCHIATRY RESEARCHERS

Prepared by the AACAP Consensus Building Panel on Conflict of Interest
for Researchers
Arlington, VA - August 19, 2008

Last Reviewed and Approved by Council on January 30, 2009.

*Because this is a living document, ongoing revision will occur.
Please forward recommended edits to research@aacap.org.*

Introduction

AACAP recognizes that research is funded by a range of sponsors and encourages the interactions of child and adolescent psychiatry investigators and sponsors, including government, private, and commercial organizations that serve the best interests of children and adolescents while maintaining scientific integrity. The AACAP has prepared these guidelines for researchers to uphold the trust in scientific findings among patients and their families as well as the public. The AACAP knows it is in the interest of our profession and our patients that members who engage in research disclose all relevant benefits, especially material financial interests. The AACAP supports principles of transparency and disclosure which are necessary but not sufficient in managing conflicts of interest. It is the basic principle of these guidelines that the first priority and responsibility of child and adolescent psychiatrists engaging in research is to maintain the integrity of scientific investigations they conduct in order to serve the best interests of patients.

AACAP has developed these guidelines as a supplement to existing guidelines on ethics and conflict of interest. Child and adolescent psychiatrists are expected to uphold the endorsed guidelines (see below), the guidelines developed by their institution, and these guidelines which were prepared with the special populations served by child and adolescent psychiatrists in mind.

Guidelines endorsed by AACAP include:

- Public Health Service (PHS) regulation 42 CFR Part 50, Subpart F - Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought, revised October 2000 - http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm
- Public Health Service (PHS) regulation 42 CFR Part, 93 – PHS Policies on Research Misconduct, revised October 2006 - http://www.access.gpo.gov/nara/cfr/waisidx_06/42cfr93_06.html

- International Committee on Medical Journal Editors (ICMJE) – Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, updated October 2007 - <http://www.icmje.org/>
- Accreditation Council for Continuing Medical Education (ACCME) – ACCME Standards for Commercial Support, updated 2007 - http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf
- AACAP Guidelines on Conflict of Interest for Child and Adolescent Psychiatrists, June 2008 - http://www.aacap.org/cs/root/physicians_and_allied_professionals/guidelines_on_conflict_of_interest_for_child_and_adolescent_psychiatrists
- AACAP Code of Ethics, June 1980 - <http://www.aacap.org/galleries/AboutUs/CodeOfEthics.PDF>
- American Academy of Child and Adolescent Psychiatry, Operating Principles for Extramural Support of AACAP Meetings and Related Activities, aacap.org.
- American Academy of Child and Adolescent Psychiatry, Guidelines for Commercial Contribution to the AACAP, aacap.org.
- PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Research, October 2002 - <http://www.phrma.org/files/Clinical%20Trials.pdf>

The goal of this Consensus Building Panel was to develop draft ethical guidelines for child and adolescent psychiatry researchers. These ethical guidelines were designed to:

- Include a description of the consensus building panel members, indicating their expertise, their roles in the field of child and adolescent psychiatry, and especially their experience in dealing with research conflicts of interest. (See Appendix for list of Panel Members and their disclosures);
- Arrive at a bulleted list for managing conflicts of interest for child and adolescent psychiatrists in their role as researchers;
- Be organized around the 4 A's of managing conflict of interest: Awareness, Assessment, Acknowledgment, and Action;
- Include a plan for dissemination of the guidelines and input from components within AACAP to assist members with future conflicts of interest;
- Define key terms involved in considering conflicts of interest.

Definitions

A Covered Individual: These guidelines will be consistent with the NIH's determination that role, not title, should identify the child and adolescent psychiatrist (CAP) affected by these principles. A covered individual is any CAP who shares the responsibility for the design,

conduct, day-to-day management of research subjects, or reporting of funded research, their spouse, domestic partner, and dependent children (consider addition of business partner and employer to this list).

Definition of Conflict of Interest: Webster's Dictionary defines a conflict of interest as a conflict between the private interests and the official responsibilities of a person in a position of trust. For these guidelines, a research conflict of interest is a conflict between a private interest and the duty to maintain the integrity of the science by the CAP researcher. Thus, a "conflict of interest" occurs when there is a risk that the CAP researcher will compromise the scientific integrity of the research because of a secondary or private interest. The main priorities of the CAP involved in research are to maintain the integrity of the science and protect the best interest of children.

Professional Role Model: Child and adolescent psychiatrists involved in research should serve as role models, educating medical students, residents and colleagues on how to manage conflicts of interest in their research.

Disclosure Threshold: AACAP supports the Association of American Medical College's recommendations that there be no minimum monetary threshold for reporting outside financial interests that are directly or indirectly related to the CAP's responsibilities to science, patients / research subjects, and to AACAP. All relevant financial or other relationships should be disclosed, with those most relevant to the researcher's work listed first. Relevant financial relationships include any honorarium, consultation fee, legal fee, dinner, gift, entertainment, travel, education, research, charitable contributions, royalty or license, ownership, or investment.

Interested Entity: Acknowledgment/disclosure must include all groups with which the CAP has a relationship that may have a commercial interest in the outcome of the research. CAPs should also disclose any commercial interest that could create an indirect conflict of interest, i.e. if a study fails, stockholders of competitive stock may benefit.

Material Financial Interest: Defined as a commercial interaction which contributes materially to the CAP researcher's income, or a position as proprietor, director, managing partner or key employee, or a position on another related organization's board, committee, etc. Examples of commercial interests leading to conflicts include: a speakers bureau, research contract payments (industry and non industry), consultantships, commercial managed care contracts, public agency service contracts, private law firm consultation, lobbying fees, professional organization governance positions, books, intellectual property, plane trips, other travel accommodations, etc.

THE 4 A's OF MANAGING CONFLICTS OF INTEREST IN RESEARCH

AWARENESS OF CONFLICTS OF INTEREST

A child and adolescent psychiatry researcher's first obligation is to protect and preserve the integrity of the science. Because of this, CAPS should be aware:

- a. That conflicts of interest are present for all CAPs who conduct or assist in research and/or hold positions for responsibility representing research to the public;
- b. Of the applicable laws, regulations and guidelines regarding all types of conflict of interest that apply to the CAP's work as a researcher
- c. Of the importance that the research subject really understands the research benefits and risk enough to give valid informed consent for participation in the CAP's research, including any financial benefits for the CAP from the sponsor;
- d. That there is an ever-present risk of being influenced by the sponsors of research and financial relationships outside of direct study support (such as speakers bureaus, consultancy and board appointments, or stock holdings) by those with a vested interest in the outcome of investigations. Influence may also come from entities antagonistic to research goals, such as competing service providers, cost control public agencies, benefits management businesses, and political factions;
- e. That all financial ties create the risk of conflict of interest which can undermine scientific credibility and authority;
- f. That any agreement with the sponsor of research should stipulate that the principal investigator doing research is eligible to participate in subsequent publications as an author, that negative results will be published, and that the author requirements for the study are compatible with uniform requirements for the International Committee of Medical Journal Editors (ICMJE). However, not every investigator at every site in a multi-site trial has the right to publish;
- g. That the principal investigator conducting an Investigator Initiated Trial (ITT) on a research topic of his/her own has the right to publish the results. The principal investigator may be required to provide the sponsor an opportunity to review the paper before journal submission to determine that the manuscripts stays within their intellectual property and patent rights;
- h. Of the ethical guidelines and financial support of the groups – private organizations and companies - with which the CAP affiliates;
- i. The conflict of interest that arises when a regional organization invites a speaker to present at a local meeting who has received funding support from a private industry in the form of research support, honorarium, and/or travel support;
- j. When considering various relationships, gifts, speaker's fees, consultation, free meals, travel, or offers from a pharmaceutical company or device manufacturer, managed care company, lobbyist, market researcher, investment advisor,

(media?), commercial vendor, law firm, or local / state / federal government agency, it is helpful for CAP researchers to ask themselves:

- Do I understand the intended purpose of this offer?
- Is there a likelihood that my acceptance of this offer will diminish the integrity of the research that I am doing?
- Am I aware of how accepting this offer can create a sense of obligation that might affect my later behavior?
- Do I have a commercial interest in or from any business which is supporting my research through another entity, such as the university's grants office, hospital, group practice, medical service organization, contract research organization, or site management organization?
- Do I have a leadership position in a for-profit business whose mission is involved with my own or my employees / affiliates research?
- Have I participated in the university's selection of a vendor in which I have a material financial interest?
- Have I assigned a student, employee, or practice affiliate to a project in which I have a commercial interest?
- Do I serve on the Scientific Advisory Board of any business? If so, do I receive research support from them at the same time?

ASSESSMENT OF CONFLICTS OF INTEREST

Child and adolescents psychiatry researchers should assess:

1. Whether the conduct of his/her research or interpretation of the results could be influenced by any financial incentives, such as stock options, excessive income awarded, an executive position at the company, future speaking engagements, and organizational or political advancement;
2. The CAP should assess the following features of a presentation or talk before agreeing to participate:
 - How is the talk categorized by the group providing the funds (i.e., promotional or Continuing Medical Education (CME))?
 - Does the CAP researcher approve of all parts of the presentation?
 - In the case of the pharmaceutical industry sponsored promotional talks where presentation of data and treatment is limited to within the FDA approved label, is the audience informed that the talk is promotional, that the topic may focus on data for only one drug, and is not a comprehensive review of all treatment options? Does the content provide fair balance of the drug's benefits and deficits?
 - When giving grand rounds, has host academic department publicly disclosed their major funding sources by category, dollar amount, and percent? Does the departmental disclosure include one of the presenter's own sources of funding and thus put him/her in conflict?

- Is it a CME presentation organized in compliance with ACCME guidelines, in which case the presenter should have complete control of the content of the presentation?
 - Is this a scientific presentation of data from a study the presenter was involved in, approved by a program committee for a recognized scientific meeting,
 - Does the host offer an appropriate speaker's honorarium that is not excessive?
3. When doing a consultation to a private company:
 - For whom is the consultation being given?
 - Why is the consultation being requested at this time?
 - What are the questions?
 - What they plan to do with the information?
 - What is the agenda?
 - Does the agenda allow adequate time for consultation and time to provide advice to the group receiving the consult?
 - Is the offer truly a request for a consultation or is it reimbursement for attending a promotional presentation?
 4. Whether the authors on publications have access to all raw data used for the publication's analyses and editorial contributions by authors are not censored by the sponsor.

ACKNOWLEDGEMENT OR DISCLOSURE OF CONFLICTS OF INTEREST

Not disclosing financial ties or other relationships with agencies and corporations that have vested interests in research outcomes creates the appearance of indifference at best and intentionally misleading others at worst. For that reason, the AACAP supports transparency as the main principle that guides disclosure and a crucial step in managing conflicts of interest. In an effort to highlight the most relevant conflicts of interest for the topic being discussed, the disclosure should begin with the substantive conflicts of interest relevant to the specific research from the CAP researcher's perspective. To this end, CAPs should:

1. Disclose at the beginning of every presentation at AACAP and other medical organization events all financial or other relationships with interested entities that have occurred the year prior to the talk being given. Relationships that might bias research outcome results include, but are not limited to, pharmaceutical, managed care, medical device, HMO, attorneys, CROs, public agency contracts, silent business partnerships or investment companies – or any honorarium, consultation fee, legal fee, dinner, gift, entertainment, travel, education, research, charitable contributions, royalty or license, ownership, or investment. The disclosure shall include a letter symbol in a chart, the letter designating the financial level of support (A=\$1-\$1000, B=\$1001 to \$5000, C=\$5001-\$20,000, D=20,001-\$50,000, E=\$50,000 up).
2. Researchers must comply with appropriate requests for disclosure of conflicts of interests made of them by academic institutions, government agencies, professional societies and publishers.

3. Disclose all financial ties or other relationships with agencies and corporations to those that must judge the scientific merit of the researchers work – including, but not limited to academic institutions or research employers, community or institutional review boards, potential research participants and their families, scientific publishers and editors, audiences of scientific presentations, and those boards, agencies or professional societies appointing the researcher to positions for their scientific expertise. Researchers should disclose in the following manner:
 - Provide a list of all conflicts, but list the most relevant conflicts to the presentation at the top of the list and highlight which conflicts are pertinent to the presentation or meeting topic;
 - Disclose conflicts of interest to:
 - parents, and as appropriate, to the subjects providing assent;
 - audiences attending clinical or scientific meetings
 - readers of scientific publications
 - medical students and residents during formal didactic lectures
 - Encourage research participants to ask questions about any situation where there is the risk of an investigator having a conflict of interest (e.g., “You will see on the consent form you are reading that the project is paid for by a pharmaceutical company; do you have any questions about my financial relationship with them?”);
 - Disclosure should be sufficiently specific to indicate whether the financial interest is a contractual arrangement including but not limited to:
 - Consulting fees;
 - Royalties;
 - Stock, equity, or stock options;
 - Institutionally defined inventor’s share; or
 - Board membership or other position with advisory or financial duties.

ACTIONS TO MANAGE OR ELIMINATE CONFLICTS OF INTEREST

It is best to manage or avoid conflicts of interest before being confronted by them. Child and adolescent psychiatrists doing research should:

1. Follow the applicable laws, regulations and guidelines regarding conflict of interest that apply to your work as a researcher. These may include state and Federal laws, NIH regulations, other granting agency regulations or guidelines, guidelines or requirements at your academic institution, etc;

2. Not participate in any speaker's bureaus or other speaking engagements that disallow proper content.
3. Recognize that accepting additional money from a for-profit company to do non-research related work (i.e., consulting or speaking) while working on a research contract with the same company may expose you to conflict of interest risks;
4. Exercise great care when involved with any entrepreneurial activities, including;
 - a. Not using federal funds to the benefit of a company, except when participating in a NIH Small Business Innovation Research (SBIR) grant;
 - b. Being aware of the problems that arise when taking equity in the company, as it has a larger potential for financial gain than other forms of compensation;
 - c. When holding a role in a start-up company, be guided by agreed-upon limits to the scope of the relationship;
 - d. Be aware of and adhere to federal requirements related to disclosure of inventions, adhering to patent law and institutional requirements;
 - e. Do not seek to influence your institutions technology transfer decisions for personal gain.
 - f. Avoid exploitation for personal gain when serving as a professional organization officer or representative at meetings with commercial entities.
5. Avoid doing research supported by companies in which you have outside financial interests ;
6. Negotiate for access to the raw data produced by the research (subject to local laws and government regulations) with the ability to participate in publication of the results if the CAP researcher is one of the principal investigators;
7. Ensure that those obtaining consent from research subjects have disclosed any conflicts of interest to their IRB, and the IRB has stated that it is appropriate for them to obtain consent;
8. Consider requesting external review of the statistical data prior to submitting an article where the statistical analysis and interpretation of results is done by an employee of the company that manufactures the treatment agent;
9. When giving presentations, explore the ability to discuss all alternative treatments.
10. Develop a plan to provide your patients with a description of your relationships with private companies to make patients aware of pertinent sources of income other than direct patient care. This can be in the form of a written statement, such as a handout, or accessible website posting.

11. Only conduct research funded by a pharmaceutical company, managed care organization, institution, or foundation whose publications follow ICMJE guidelines for publication.
12. Do not accept additional payment made for participating in a clinical trial outside of salary payment for the work, as stipulated in the contract with the researcher's university, as is the case with NIH grants. Because academic researchers have institutional mission responsibilities, a researcher should not be accepting money earned from drug marketing of any kind, e.g., speaker's bureaus. The researcher should carefully consider the impact of accepting meals and other benefits from the company.
13. Expect to be paid appropriate fair market value compensation as defined by the HHS Office of the Inspector General if you participate in professional services such as consulting to business and industry clinical trials;
14. Not enter into consulting relationships with investment firms; and
15. Reveal any conflict of interest and provide objective evidence based support for recommended treatments when consulting or advising about drug formularies or treatment protocols or professional treatment guidelines.

Dissemination Plan for Guidelines

After the guidelines are approved by Council, they should be disseminated as follows:

1. Disseminate the final set of approved Guidelines for Managing Conflicts of Interest for Researchers by:
 - a. Sending out an AACAP Member Email;
 - b. Sending out a hard copy by mail;
 - c. Posting the guidelines on the AACAP web site;
 - d. Publishing an announcement in *AACAP News*;
 - e. Submitting formal articles on the AACAP COI Research Guidelines to the *JAACAP*;
 - f. Sending the guidelines to other professional associations involved in the medical care of families and children, encouraging publications in their newsletters;
 - g. Have a press release, with the option of a press conference, when the Guidelines are finished;
 - h. Encouraging member discussion opportunities in *AACAP News*;
 - i. Developing an eAACAP course for AACAP members on how to read published research articles; and how to understand the research funding process.
2. Present the COI Research guidelines to the AACAP Assembly.
3. Work with the Editor of the *Journal of the American Academy of Child & Adolescent Psychiatry* to harmonize the *JAACAP* and AACAP COI Research Guidelines;

4. Update the AACAP disclosure statement to ensure agreement with the Acknowledgement section of these COI Research guidelines;
5. Recommend that AACAP leadership address COIs at every level, both in policy and practice, such that those CAP researchers subject to the association's financial COI policies will be responsible for assessing, disclosing, and managing their financial interests to protect the integrity of the AACAP's values and decision-making, the integrity of human subjects research conducted by its members, and the integrity of scientific data presentations. These covered individuals and components include:
 - a. Officials of the institution (Executive Committee members, Chair of Program Committee, Journal Editor, Executive Director); and
 - b. The AACAP itself.
6. Publish a conflict-of-interest monthly column in the *AACAP News* written by a member of the consensus-building panel on conflict of interest.
7. Hold a Member Forum at the AACAP Annual Meeting.

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APPENDIX

Section 1

Acknowledgement and Disclosure of Conflicts of Interest by the Consensus Building Panel Members

Disclosures of Panel Members

The Chair asked panel participants to introduce themselves and to disclose his or her conflicts of interest that could bias or interfere with the drafting of these guidelines. Because of the importance of the panel, and the need for all members to be candid in their disclosures, each

participant was asked to relate their comments on the Disclosure of Affiliations forms approved by the AACAP Council in June 2008. Participants were asked to disclose at the meeting their professional affiliations and their roles in AACAP. They were asked to share any experiences managing or avoiding conflicts of interests, any participation in speaker's bureaus, and their financial relationships with private industry (direct income on which taxes are paid exceeding \$10,000, shareholdings of more than \$50,000, and indication of participation in industry-sponsored symposia or speaker's bureaus). Listed below are the panel members in alphabetical order.

A.J. Allen, M.D. – Dr. Allen is a child and adolescent psychiatrist, a member of AACAP, and a member of the AACAP Pediatric Psychopharmacology Initiative Subcommittee of the Work Group on Research. Dr. Allen is currently a full-time employee of Eli Lilly & Company serving as the Medical Director for Strattera. He is also a share holder in Eli Lilly & Company. He participated in the February, 2008 AACAP consensus-building conference to develop conflict of interest guidelines for practitioners.

Virginia Anthony – Ms. Anthony is the Executive Director of the AACAP and is married to a child and adolescent psychiatrist.

Paul Appelbaum, M.D. – Dr. Appelbaum is the Elizabeth K. Dollard Professor of Psychiatry, Medicine & Law and Director, Division of Psychiatry, Law, and Ethics, Department of Psychiatry at Columbia University. He is the author of many articles and books on law and ethics. He is currently chair of the American Psychiatric Association (APA) work group on conflicts of interest, co-chair of the ethics advisory board at Columbia University, and chair of the NIH Clinical and Translational Science Awards (CTSA) Clinical Research Ethics Workgroup.

Oscar Bukstein, M.D. - Dr. Bukstein is a professor of child and adolescent psychiatry at the University of Pittsburgh. He receives extramural funding support from the NIH. He is vice-chair of the Institutional Review Board at his institution. He is co-chair of the AACAP Work Group on Quality Issues which is responsible for the development of the practice parameters and a member of the Substance Abuse and Addiction Committee. He is the member of a CME speaker's bureau which allows him to control the content of his presentations. He also has edited a book that was published last year.

Catherine DeAngelis, M.D., M.P.H. – Dr. DeAngelis is the Editor-in-Chief of the *Journal of the American Medical Association (JAMA)* and in this capacity oversees the nine *Archives* journals as well. She is an accomplished author and presenter on conflicts of interest and ethics. She is also married to a child and adolescent psychiatrist.

Melissa DelBello, M.D. – Dr. DelBello is an academic child and adolescent psychiatrist whose research and academic careers have focused on neuroimaging techniques to study adolescents with bipolar disorder. She is a member of AACAP, and serves on the AACAP Program Committee as the Chair of the Annual Meeting Institutes and the AACAP Work Group on Research. A portion of her funded research is supported by pharmaceutical industry. She has also received more than \$10,000 for advisory and consultation with private industries, mostly for participation in research, consulting and speaker's bureaus. She is the Vice Chair of Clinical Research for the Department of Psychiatry at the University of Cincinnati. She is also the Director of Research, Training and Education for the Division of Child Psychiatry at the Cincinnati Children's Hospital Medical Center. She spends 15% of her time seeing patients in clinical practice at the Cincinnati Children's Hospital Medical Center.

Stacia Hall Fleisher, M.P.P. – Ms. Fleisher currently serves as the AACAP Director of Research, Training and Education. Prior to employment at AACAP, she worked for eight years at a non-profit preventive medicine/public health organization through a cooperative agreement with the Centers for Disease Control and Prevention. Prior to this employment, she worked for 3 months under an intern agreement with the Bryce Harlow Institute of Government and Business Affairs in the Eli Lilly and Company Government Affairs Division. Her father is on the board of the University Health Systems of Eastern Carolina. Her husband is responsible for financial and management operations for the Cystic Fibrosis Foundation and her father-in-law is a pediatric immunologist serving as Chief of the Department of Laboratory Medicine at the NIH Clinical Center.

Heidi Fordi – Ms. Fordi currently serves as the AACAP Deputy Executive Director and Senior Director of Meetings, CME, and Development. She has been employed with AACAP for 12 years and has collaborated with the AACAP Program Committee in the development of the AACAP Operating Principles for Extramural Support.

Pleas Geyer, M.D. – Dr. Geyer is an employee of the Division of Child and Adolescent Psychiatry at Carolinas Medical Center. He is a specialist in child and adolescent psychiatry and forensic psychiatry. He is on the Ethics Committee of his institution. Dr. Geyer also serves as a member of the North Carolina Chapter of the AACAP Assembly.

Laurence Greenhill, M.D. – Dr. Greenhill serves as president-elect of AACAP and works 50% in private practice with 20 hours dedicated to the private practice treatment of toddlers, adolescents and adults mostly with ADHD. He uses both therapy and psychopharmacology for treatment. He is the Ruane Professor of Clinical Psychiatry at Columbia University, serves as a Research Psychiatrist II at the New York State Psychiatric Institute (NYSPI), and is member of the NYSPI Institutional Review Board. Although he had participated – as recently as 2004 -- in speaker's bureaus, scientific advisory boards and marketing meetings with several pharmaceutical companies, increasingly strict rules for State of New York employees have prevented this involvement, particularly because the New York State Office of Mental Health states openly that conflict can't be managed, just avoided. Thus for the past three years, he has no income over \$10,000 from private industry, no shareholding activities, does not participate in speaker's

bureaus, and does not participate in industry-sponsored symposia. However, Dr. Greenhill is a principal investigator on one pharmaceutical industry supported research contract, has one investigator initiated study contracted with another pharmaceutical company, and has served as the chairman of the Pfizer Pediatric Ziprasidone Data and Safety Monitoring Board. Since becoming President-Elect of AACAP, he is not permitted to serve on any pharmaceutical-sponsored scientific advisory boards or speaker's bureaus.

James Harris, M.D. – Dr. Harris is a research and clinical psychiatrist and full professor at Johns Hopkins University. He was previously a division and training director there. He is past president of the society of professors of child and adolescent psychiatry. He serves on the ethics committee of the American College of Neuropsychopharmacology. He is married to Cathy DeAngelis, M.D., editor of *JAMA*, and a national spokesperson on conflict of interest between academia and the pharmaceutical industry. He was previously a division director and training director earlier in his career. He does not have any financial ties to industry but has received research grants through NIH and foundations.

David Herzog, M.D.- Dr. Herzog is the Director of the Harris Center for Education and Advocacy in Eating Disorders at the Massachusetts General Hospital and the Harvard Medical School Endowed Professor of Psychiatry in the field of eating disorders at Massachusetts General Hospital. He is the Secretary of AACAP and the Chair of the AACAP Development Committee. He currently receives research funding support from NIH and has a published book. He also participates in an eating disorders advocacy organization in Washington, DC.

Chris Kratochvil, M.D. – Dr. Kratochvil is a member of the AACAP Council, Development Committee, Work Group on Research, and Chair of the Pediatric Psychopharmacology Initiative. He is also affiliated with the REACH Institute, CME Outfitters, and American Professional Society for ADHD and Related Disorders. A portion of his research portfolio is supported by investigator-initiated projects sponsored by private pharmaceutical companies. He receives over \$10,000 overall from private industry but not more than \$10,000 from any one industry. He participates in NIH and industry sponsored research, and provides clinical care through his clinical research time. He has discontinued all promotional work with industry and has limited his relationships with industry to consultation work and clinical research.

Bennett Leventhal, M.D. – Dr. Leventhal is a professor of psychiatry and the Director of the Center for Child Mental Health and Developmental Neuroscience at the Institute for Juvenile Research at the University of Illinois at Chicago. He is a member of the AACAP Annual Meeting Program Committee and Work Group on Research. He receives research funding support from NIH and multiple pharmaceutical companies. He also serves as an advisor/consultant for two pharmaceutical companies and participates in three speaker's bureaus. Dr. Leventhal clarified that he indicated his participation in speaker's bureaus on his disclosure of affiliations form because he is aware that his participation in medical school grand rounds presentations is funded through pharmaceutical companies and he thought it was appropriate to list this participation as a speaker's bureau even though it differs in that he is able to develop his own presentation slides and materials.

Catherine Martin, M.D. – Dr. Martin is the Vice-Chair for Research at the University of Kentucky College of Medicine. She participates in several research grants funded by NIH, including a small business grant in which provides funding comes from the small business (Yaupon). She receives support from a NIDA funded study that itself receives free study drug and financial support for data management from Cephalon, a pharmaceutical company. Additionally, she participates as a faculty member on two career development awards, the AACAP K12 award and the BIRCWH award. She also received an honorarium from Shire US, Inc. through AACAP for her participation in the development of an online substance abuse curriculum.

Kristin Kroger Ptakowski – Ms. Kroeger currently serves as the AACAP Senior Deputy Executive Director and Director of Government Affairs and Clinical Practice. Prior to employment at AACAP, she worked at the National Alliance on Mental Illness.

Clarke Ross, D.P.A. – Dr. Ross is the CEO of Children and Adults with Attention Deficit/Hyperactivity Disorder (CHADD). CHADD policy prohibits staff from receiving direct honorarium or consultant fees. Approximately 26% of CHADD's overall revenue is from pharmaceutical companies.

David Shaffer, F.R.C.P., F.R.C.Psyc – Dr. Shaffer is a full-time faculty member and was director of the division of child and adolescent psychiatry at Columbia University and the New York State Psychiatric Institute for over thirty years. He is Chair of the AACAP Work Group on Research which receives funding support from multiple funding sources including pharmaceutical companies, NIH, and non-profit organizations. He is also President-elect of the International Society of Suicide Research. Dr. Shaffer has received numerous NIH grants throughout his career but has not participated in pharmaceutical company sponsored research, advisory boards, or speaker's bureaus.

Adrian Sondheimer, M.D. – Dr. Sondheimer is an associate professor of psychiatry at the University of Medicine and Dentistry of New Jersey, New Jersey Medical School. He is co-chair of the AACAP Ethics Committee and currently working to help revise the AACAP Code of Ethics. He does not receive any funding from pharmaceutical companies.

Chris Thomas, M.D. – Dr. Thomas is a professor at the University of Texas Medical Branch in Galveston, TX and a member of AACAP. He is a training director at 50% effort which includes clinical supervision of residents one day a week, 20% effort clinical care and research at Shriner's Hospital, and 15% research time supported by federal, state and private foundation grants. He also has one afternoon a week committed to a private clinic. Dr. Thomas developed the new Disclosure of Affiliations form approved by AACAP Council and serves as the Chair of the AACAP Rights and Legal Matters Committee. He does not receive funding from pharmaceutical companies.

Benedetto Vitiello, M.D. – Dr. Vitiello is an NIH employee at the National Institute of Mental Health. As an NIH employee he is not permitted to have stock related to health, not allowed to

receive sponsored travel by pharmaceutical companies, and can only participate in CME programs if they are not funded by pharmaceutical companies. For the purposes of awarding research grants, NIH may review major conflicts appearing within a grant application but the responsibility for monitoring and managing conflicts of interests rest with the applicant institution.

Harry Wright, M.D. – Dr. Wright is a professor of psychiatry at the University of South Carolina. He is chair of the AACAP Prevention Committee. Dr. Wright participates in several international research studies and commented that he must follow stringent ethic guidelines in his international collaborations. He does not receive funding from pharmaceutical companies.

Section 2

Example of a Journal's Conflict of Interest Guidelines:

Guidelines for Authors to Manage Conflicts of Interest in the Journal of the American Medical Association (DeAngelis & Fontanarosa, Impugning the integrity of medical science: the adverse effects of industry influence, *JAMA* 2008):

- All clinical trials be prospectively listed in registries prior to patient enrollment;
- All individuals named as authors on journal articles must fulfill authorship criteria;
- Journals must disclose all pertinent relationships of all authors with any for-profit companies and disclose funding sources for each article;
- For profit companies that sponsor biomedical research studies should not be solely or primarily involved in collecting and monitoring of data, in conducting the data analysis, and in preparing the manuscript that reports study results.
- All journals must require a statistical analysis of clinical trial data conducted by a statistician who is not an employee of a for-profit company;
- Authors who fails to disclose financial relationships or other COIs, or allows his name on work he did not perform, must be reported to the appropriate authority, such as medical school dean or department chair.
- Any peer reviewer who provides confidential information, such as a manuscript under review, to any third parties, such as for-profit companies, should be reported to the appropriate authority.
- Any editor who knowingly allows for-profit companies to manipulate his or her journal must be relieved of the editorship.
- Professional organizations and providers of CME courses should not condone or tolerate for-profit companies having any input into the content of educational materials or providing funding or sponsorship for medical education programs.
- Individual physicians must be free of financial influences of pharmaceutical and medical device companies including serving on speaker's bureaus or accepting gifts.
- When integrity in medical science or practice is impugned or threatened – such as by the influence of the pharmaceutical and medical device industry – patients, clinicians, and researchers are all at risk for harm, and public trust in research is jeopardized.