AACAP GUIDELINES ON CONFLICT OF INTEREST FOR
CHILD AND ADOLESCENT PSYCHIATRISTS

Prepared by the AACAP Consensus Building Panel on Conflict of Interest
Washington, DC, February 14, 2008


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

Background: Physicians and Conflicts of Interest

- Conflicts of interest arise from a culture of entitlement among physicians, limiting ability to honestly acknowledge and manage potentially negative effects of these relationships (Campbell, 2007);
- Link found between number of second-generation antipsychotic prescriptions written and industry payments to a Minnesota child and adolescent psychiatrist (Harris, 2007);
- FDA Committee members financial rewards from industry relationships may reinforce with higher measures of expertise were more often granted waivers for financial conflicts of interest (Ackerly, 2007); and
- “Researchers Fail to Reveal Full Drug Pay,” front page, NY Times, Sunday, June 8, 2008 (Harris, 2008).

AACAP Decision to Develop a Consensus Building Panel on Conflicts of Interest

- Task Force on AACAP Policy and Procedures recommended a one day consensus building panel focused on conflict of interest issues for clinicians.
- Executive Committee approved the recommendation with the following requests:
  - The product of this conference be a bulleted set of guidelines addressing conflict of interest;
  - The panel be diverse, include clinicians, women, include those with previous interest or publications in ethics, and include those who represent consumer issues;
  - The panel distinguish between avoidable conflicts of interest, and those that can’t be avoided but managed; and
  - The guidelines should be based on the position that conflicts of interest can be managed.

Goal of the Consensus Building Panel is to develop draft ethical guidelines for child and adolescent psychiatrists. These ethical guidelines should:

- Include a description of the consensus building panel members, to indicate their expertise, their roles in the field of child and adolescent psychiatry, especially their clinical interests. (See Appendix for list of Panel Members and their disclosures)
• Arrive at a bulleted list for managing real conflicts of interest for child and adolescent psychiatrists in their role as clinicians.
• Be organized around the 4 A’s of conflict of interest: Awareness, Assessment, Acknowledgment, and Action.
• Include a plan for dissemination of the guidelines and input from possible components within AACAP to assist AACAP members with their ongoing or future conflicts of interest.

Preamble
Child and adolescent psychiatrists encounter conflicts of interest every day. As a necessary part of professional growth, the AACAP encourages each child and adolescent psychiatrist to:

• Understand that their first priority and responsibility is to their patients, and to maintain the trust between practitioner and patient.

• Know the definition of a conflict of interest. A conflict of interest occurs when there is a risk that patient care or patient welfare will be compromised by a secondary interest.

• Child and adolescent psychiatrists should serve as role models, educating medical students, residents and colleagues by their own example on how to manage conflicts of interest.

• These recommendations for managing conflicts of interest are not a static checklist but a process that should be handled in the future by a component of AACAP.

• Manage their conflicts of interest. These guidelines provide the individual child & adolescent psychiatrists with a list of suggestions to help manage conflicts of interest.

• These guidelines are meant to be recommendations, not absolute rules.

• Individual child and adolescent psychiatrists who have trouble with the guidelines in their practice may receive help in managing conflicts of interest by contacting the AACAP.

The Guideline’s Self-Assessment Questions

Does a conflict of interest exist in your professional life (these questions are not inclusive and are not arranged in order or priority)?

  o Are you aware that even small gifts induce an unconscious sense of obligation that can affect behavior?
  o Do you keep in your office items with industry logos on them?
  o Do you have meals paid for by private industry representatives?
  o Do you accept speaker fees, serve as a paid consultant, or paid advisor to a private company marketing health care products?
o Do you accept fees to answer telephone surveys about drug treatments or to speak to investment advisors about marketed medications?
o Do you accept items from exhibit displays at professional meetings and know their commensurate value?
o Are you being pressured by a hospital administrator to change your treatment plan to increase the income from the care for a patient?
o Do you disclose modifications to your treatment plans demanded by managed care companies to your patients?
o Is your managed care organization limiting treatment sessions or certain prescription drugs when treating a new child or adolescent patient?
o Are you pressured to make appointments for “Very Important Person” cases before families without such connections?

THE 4 A’s OF CONFLICTS OF INTEREST

AWARENESS OF CONFLICTS OF INTEREST
A physician’s first obligation in clinical care is to act in the best interest of their individual patients. Because of this, child & adolescent psychiatrists should be aware of:

1. Their responsibility to uphold the standards of the profession of child and adolescent psychiatry and the Code of Ethics of the American Academy of Child and Adolescent Psychiatry (AACAP).

2. Their roles and relationships with families and patients, private companies and professional organizations.

3. The definition of a conflict of interest, as stated in the preamble.

4. The many different roles and priorities of representatives from private pharmaceutical companies and other health care related companies as they relate to patient care.

5. The code of ethics of AACAP as it relates to roles and relationships with patients and families, and with private companies, professional organizations, and others.

6. The ethical guidelines and financial support of groups – both private organizations and companies - with which they affiliate.1

1 It is helpful to be aware of the pharmaceutical industry’s PHarMA guidelines which can be found at http://www.pharmacodes.com/index.html, while the PHarMA guidelines for interactions with healthcare professionals can be found at (www.phrma.org/code_on_interactions_with_healthcare_professionals/)
7. The availability of free medication samples have on treatment decisions that may generate a conflict of interest. Samples may bias provider and patient to select them over less expensive medications.²

8. Professional guidelines on conflict of interest, especially those of organizations to which they belong.

9. The HMO contract and the conflicts it may impose if it limits the number of sessions and/or the medications that can be prescribed.

10. Accreditation Council of Continuing Medical Education (ACCME) conflict of interest guidelines, International Committee of Medical Journal Editors (ICMJE) guidelines for manuscripts, and the pharmaceutical industry guidelines.³

**ASSESSMENT OF CONFLICTS OF INTEREST**

Child and adolescents psychiatrists should assess:

1. Treatment guidelines and practice parameters of health insurance panels that they participate in to determine if they are consistent with the practice parameters, such as those published by the American Academy of Pediatrics and AACAP.

2. Amount of payment for their interactions with private companies (e.g., publishers, pharmaceutical companies, patents, equity and options), caretaking agencies, organizations, or private individuals because the greater the amount, the greater the conflict.

3. Financial or other benefits to family members or partners that also are conflicts of interest to the child and adolescent psychiatrist.

4. Invitations to participate in manuscript authorship derived from clinical trials to determine if the defined authorship role on the project is consistent with the uniform requirements for authorship of the ICMJE (www.ICMJE.org), which means that ghost

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² The PHarMA Sponsored Partnership for Prescription Assistance (PPA), (https://www.pparx.org/Intro.php) that includes a means test for distributing vouchers and medications.

5. How the need to please parents or teachers may run counter to what the child and adolescent psychiatrist recommends for the patient.

ACKNOWLEDGEMENT OR DISCLOSURE OF CONFLICTS OF INTEREST
Transparency and disclosure are important to our patients and their families. For that reason, child & adolescent psychiatrists should:

1. Disclose, discuss, and answer questions from their patients and families about pertinent situations where there is a risk of conflicts of interest affecting their clinical care.

2. Disclose, at the beginning of every presentation, the income received from all sources other than direct patient care - including income from pharmaceutical, medical device, HMO, or investment companies – for any honorarium, consultation fee, legal fee, dinner, gift, entertainment, travel, education, research, charitable contributions, royalty or license, ownership, or investment.

3. Encourage their patients to ask questions about any situation where there is the risk of a provider having a conflict of interest.

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 should:

1. Consider not taking any gifts (pens, bags, flashlights all with company logos) from any entity marketing a product related to health care. Gifts affect treatment choices.

2. Consider not acting as a venue for advertising pharmaceutical products by carrying or displaying objects in their office with company logos on them.

3. Consider using only non-pharmaceutical sponsored patient information literature to educate parents in their practice.

4. Participate in at least one CME credit in ethics every two years.

5. Be in charge of the slides and materials when giving presentations; retain the right to discuss all treatment alternatives, including other possible medications.

6. Consider not participating on pharmaceutical industry sponsored speakers’ bureaus because speakers’ bureaus limit presentations, because of FDA’s regulations, to mandated slides and materials.
7. Examine the full range of alternatives for obtaining medications for all patients.  

8. Consider paying for meals or activities when attending promotional presentations.  

9. Consider using conflict of interest management strategies when dealing with parent or caretaker agency expectations that conflict with the best interest of the patient.  

10. Consider refusing payment or gifts to attend pharmaceutical talks.  

11. 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.  

Dissemination Plan for Guidelines
After the guidelines are approved by Council, they should be disseminated. The guidelines will be disseminated in the following manner.  

1. Placing the AACAP Conflict of Interest Guidelines on the AACAP website and broadcasting to members via member email.  

2. Publishing a conflict-of-interest article in the AACAP News written by a member of the consensus-building panel on conflict of interest.  

3. Holding a Member Forum at the 2008 AACAP Annual Meeting.  

REFERENCES


4 One company program is the PhRMA Sponsored Partnership for Prescription Assistance (PPA), (www.pparx.org/Intro.php
APPENDIX I

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

The Chair asked each panel participant 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, more stringent disclosure standards were used based on the American Psychiatric Association (APA) methods for screening advisors to participate in the development of DSM-V. Participants were asked to disclose their weekly time allotment for professional contact with patients and families, their professional affiliations, and their roles in AACAP. They were asked to share any experiences managing or avoiding conflicts of interests, 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. He currently does not see any patients. 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.

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

Scott Benson, M.D. – Dr. Benson is a full time private practitioner, and a member of AACAP and APA. He sees patients of all ages. He serves on the AACAP Work Group on Quality Issues and APA Committee on Public Affairs. His current private practice business partner is actively involved in industry speaker bureaus. His wife is a politician in the Florida legislature and his daughter is currently serving as Secretary for the Agency of Health Care Administration in Florida. He actively participates in lobbying efforts and is a trained pediatrician.

Melissa DelBello, M.D. – Dr. DelBello is an academic research child and adolescent psychiatrist whose career has focused on developing and using imaging techniques to study children and 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. 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, speaker’s bureaus and industry-sponsored symposia. She is the Vice Chair of Clinical Research at the University of Cincinnati. She spends 20% of her time seeing patients in clinical practice at the Cincinnati Children’s Hospital Medical Center.
Laurie Flynn – Ms. Flynn is the Director of External Relations for the Department of Psychiatry at Columbia University. She currently oversees the TeenScreen Program. Prior to her employment at Columbia University, she served as the National Director of the National Alliance on Mental Illness for 16 years, and is a national consumer advocate for children’s mental health. She is the mother of a daughter with mental illness and is a member of a family of three generations of completed suicide. She was appointed by President Clinton to serve on the National Bioethics Committee, subcommittee of the Secretary Advisory Council on Human Research Protection. She receives no funding from private industry.

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.

Stephen Grcevich, M.D. – Dr. Grcevich is a member of AACAP and child and adolescent psychiatrist in full time private practice overseeing a faith-based clinic exclusively for children and adolescents. He receives less than $10,000 from private industry for participation as an advisor/consultant. He is also an active participant in CAPTN, an NIH funded clinical trials network. Dr. Grcevich used to participate more frequently in partnerships with industry but terminated his relationship with one particular industry when he felt his ethics were in question with a change in the industry’s standards of operation for speaker’s bureaus and consultation.

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, has an endowed chair, 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 previously had participated in speaker’s bureaus, scientific advisory boards and marketing meetings with several pharmaceutical companies, increasingly strict rules for State of New York employees have run counter to 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 over $50,000, does not participate in speaker’s bureaus, and does not participate in industry-sponsored symposia.

Stacia Hall, M.P.P. – Ms. Hall 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 and her sister is a part-time public relations consultant for pharmaceutical marketing companies. Her fiancé is responsible for financial and management operations for the Cystic Fibrosis Foundation and her father-in-law to be is a
pediatric immunologist serving as Chief of the Department of Laboratory Medicine at the NIH Clinical Center.

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.

Chris Kratochvil, M.D. – Dr. Kratochvil is a member of the AACAP Council, 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. Like Dr. DelBello, 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 is currently pulling out of all promotional work with industry and limiting his relationships to consultation work although he is still participating in CME industry-sponsored symposia.

Earl Magee – Mr. Magee is currently the AACAP Executive Assembly Administrator and reports no conflicts or disclosures.

Jennifer Medicus – Ms. Medicus is currently the AACAP Assistant Director of Clinical Practice. Her father is a retired hospital executive administrator and her step-sister is a pharmaceutical representative for Novartis.

Susan Milam Miller, M.D. – Dr. Miller is an early career child and adolescent psychiatrist and member of AACAP. She is a community psychiatrist working part-time in a community clinic and part-time as a consultant for primary care. Dr. Miller is the previous past Jerry Weiner Resident Representative to Council and currently serves on the AACAP Committee on Medical Students, Residents and Early Career Psychiatrists and Work Group on Systems of Care.

Donna Norris, M.D. – Dr. Norris is a member of APA and AACAP. She has been involved in the Ethics Committee of her district branch for over 25 years, and has served on the board of registration in medicine for Massachusetts. She served as the APA Secretary/Treasurer for the DSM-V review process of conflicts of interest. Dr. Norris is a child and adolescent psychiatrist private practitioner who also specializes in forensic psychiatry. She also lobbies for child groups and medical organizations. She receives no funding support from private industry.
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.

Neal Ryan, M.D. – Dr. Ryan is the AACAP Program Committee Chair and participates in the AACAP Work Group on Research. He sees patients through private practice and does some research. He is a full professor of child psychiatry at the University of Pittsburgh Medical Center, has an endowed chair, and serves as an unpaid corporate board member for an informatics company which is a subsidiary of the University of Pittsburgh Medical Center. Dr. Ryan has participated in speaker’s bureaus many years ago but has declined to do so since. He currently is not serving on any advisory boards and currently does not receive any research support from private companies.

William Sexson, M.D. – Dr. Sexson is the husband of Sandra Sexson, M.D., child and adolescent psychiatrist and AACAP member. He is a neonatologist and Associate Dean at Emory University. His patient contact is approximately 25% per month. He is a Faculty Fellow at the Emory University Center for Ethics and completes over 200 consults a year. He is a national lecturer on ethics and provides ethics presentations frequently during grand rounds. He is also a registered lobbyist for child health issues.

Lynn Starr, M.D. – Dr. Starr is a behavioral pediatrician who has been invited to speak on issues of ethics involved in private pharmaceutical supported research at AACAP Annual Meeting Town Hall forums. She is a member of AACAP and currently serves on the AACAP Pediatric Psychopharmacology Initiative Subcommittee of the Work Group on Research. She currently does not see any patients. Dr. Starr is currently a full-time employee of Ortho-McNeil Janssen Scientific Affairs, LLC. She is also a stock owner in Johnson & Johnson.

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 Shriners 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. He also serves as the Chair of the AACAP Rights and Legal Matters Committee.

Ashley Wazana, M.D. – Dr. Wazana is a child and adolescent psychiatrist at Montreal Children’s Hospital and a member of AACAP. He serves as a full-time clinician. He has extensive research, writing and lecturing experience in psychiatry conflicts of interest. He has written numerous peer reviewed articles in *JAMA, Academic Medicine*, and others on this topic.
APPENDIX II

The following statement is one example of a "Statement for Parents" to be used to inform parents about the conflict of interest situation for any child and adolescent practitioner. It was developed by James C. MacIntyre, II, M.D., staff child psychiatrist at Carolinas Medical Center's Behavioral Health Center in Charlotte, NC. Dr. MacIntyre was Chairman of the AACAP Work Group on Consumer Issues from 1995-2006.

[Insert name/ office address of child psychiatrist]

STATEMENT FOR PARENTS

I have developed the following statement to inform parents and families and to help them better understand my practice and medical decision-making.

- I am a physician licensed to practice by the [ _______] Medical Board;
- I have completed specialty training in general psychiatry and sub-specialty training in child and adolescent psychiatry;
- I am certified by the American Board of Psychiatry and Neurology (ABPN) in both psychiatry and child psychiatry;
- I uphold the practice standards defined by the Code of Ethics of the American Academy of Child and Adolescent Psychiatry (AACAP) and the American Psychiatric Association (APA);
- I have /have not taken an ethics course as a condition of my membership in the American Academy of Child and Adolecent Psychiatry (circle one);
- I am a full-time salaried employee of [ ____________ ] (name of hospital or practice group).

DISCLOSURES

- In the past year, I have (please circle appropriate sub-heading):
  - Received financial support from any pharmaceutical or healthcare product company, including support for research;
    - None
    - Yes, received support (please list)
  - Financial interest (own stock, etc.) in any pharmaceutical or healthcare product company;
    - None
    - Yes, have an interest (please list)
  - Accepted speaker fees from any pharmaceutical or healthcare product company.
    - None
    - Yes, have received payments (please list)
o Received payments for consultation to pharmaceutical or healthcare product companies;
  ▪ None
  ▪ Yes (please list)

o Accepted free samples or gifts of value from any pharmaceutical or healthcare product company or its representatives;
  ▪ None
  ▪ Yes, accepted free samples

o A family member who is an employee of a pharmaceutical or healthcare product company.
  ▪ No family member
  ▪ Yes, I have a family member

My selection of any medication prescribed for a specific child and adolescent is based on a combination of the following factors:

- Careful clinical evaluation;
- My clinical experience, including experience gained participating in research;
- My analysis of published scientific/research studies (evidence-based);
- Current professional practice guidelines and practice parameters published by AACAP and APA;
- Current professional standards of care in this community;
- Consultation with colleagues (locally and nationally).