Panelists:
Dean, USA Medical School
IRB Chairperson, USA Medical School
Legal Counsel, USA Medical School
Dr. A
Dr. B
Editor, Journal of Clinical Trials
Investigative Reporter, The New York Post
President, National MRSA Patient Advocacy Group
CEO of Big Pharma

Case Study – What is your Point of View (POV)?

Dr. A, a faculty member in the Division of Infectious Diseases of the Department of Medicine of USA Medical School, has devoted her career to developing new therapies for methicillin-resistant Staphylococcus aureus (MRSA), a serious bacterial infection. In the course of her studies she identified a new antibiotic that is effective in killing the bacteria in vitro. She disclosed her discovery to her University and to the NIH, which supported her research. Her University licensed the antibiotic to a pharmaceutical company (BigPharma) in exchange for an upfront payment and potential future royalty payments if the drug is approved for human use. In accord with the Bayh-Dole Act and her University's policies, Dr. A will receive 25% of the upfront payment and any future royalty payments. Dr. A is very knowledgeable about the new antibiotic, including its likely pharmacokinetics and potential toxicity. The company performs animal toxicology studies, which are reassuring, and then asks Dr. A to lead the first clinical studies of the drug. Dr. A expresses concerns about her potential conflict of interest and so asks the newly recruited junior faculty member, Dr. B, if he would like to conduct the study.

Questions to be answered?

1. Does Dr. A actually have a conflict of interest in conducting the trial as judged by the current guidelines of the NIH, the FDA, the AAMC, and/or those of Weill-Cornell School of Medicine, Memorial Sloan-Kettering Cancer Center, or Rockefeller University?
2. Does Dr. A have a conflict of interest as judged by the IRB of USA Medical School?
3. Does Dr. B have a conflict of interest as judged by any of the above organizations?
4. Does USA Medical School have an institutional conflict of interest?
5. If Dr. A is judged to have a conflict of interest in conducting the study, should she still be allowed to help design the trial, analyze the data obtained during the trial, and/or recommend modifications to the manuscript?
6. Should the trial be registered, and if so, with whom?
7. Should the trial be conducted at USA Medical School's University Hospital?
8. Should the first study be conducted on normal volunteers or on patients with MRSA infection?
9. What, if any, disclosure should be made to the journal when the manuscript is submitted for publication?

Barry S. Coller, M.D.
Vice President for Medical Affairs & Physician-in-Chief
at The Rockefeller University

10. What should Dr. A disclose when she presents the results of the trial as part of her Grand Rounds presentations if she participated in the trial? If she acted as a consultant to the trial? If she did not participate in the trial?

Resources

a. GAO "Biomedical Research: HHS Direction Needed to Address Financial Conflicts of Interest" (November 2001) http://www.aau.edu/research/gao.pdf
- NIH Office of Extramural Research http://grants.nih.gov/grants/policy/coi/resources.htm
- NIH Guide - Financial Conflicts of Interest and Research Objectivity: Issues for Investigators and Institutional Review Boards, June 5, 2000 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-040.html
- AAMC Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research (Adopted by the Executive Council of the AAMC February 22, 1990) http://www.aamc.org/research/dbr/coi.htm
- AAMC Task Force on Financial Conflicts of Interest in Clinical Research http://www.aamc.org/members/coitf/
- AAMC Task Force on Financial Conflicts of Interest in Clinical Research - Charter and Charge http://www.aamc.org/members/coitf/chartercharge.htm
- AAMC Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research http://www.aamc.org/research/dbr/coi.htm
- AAU Report on Individual and Institutional Conflict of Interest
- http://www.aau.edu/research/conflict.htmlFDA guidelines
- FDA "Guidance: Financial Disclosure by Clinical Investigators" (March 20, 2001) http://www.fda.gov/oc/guidance/financialdis.html
- Conflict of interest regulations of each institution
- Review of Bayh-Dole Act (http://www.cctec.cornell.edu/cctec/about/history/bayhdole/index.cfm)
- IRB directives on conflict of interest