

STANFORD  
UNIVERSITY

OFFICE OF THE GENERAL COUNSEL  
Debra L. Zumwalt  
Vice President and General Counsel



Telephone (650) 723-6397  
Facsimile (650) 723-4323  
zumwalt@stanford.edu

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Via Email and US Mail

Dr. Jane Steinberg  
Director, Division of Extramural Activities  
National Institute of Mental Health  
6001 Executive Blvd., Rm 6146, MSC 9609  
Bethesda, MD 20892

Re: NIMH Grant No. MH50604

Dear Dr. Steinberg:

As you know, Stanford University has been responding to questions raised by Senator Grassley concerning the above grant and Dr. Schatzberg's financial interests in Corcept Therapeutics, which has licensed a patent for certain uses of mifepristone. Separately, I am sending you a copy of the most recent letter (July 31, 2008) from Stanford to Senator Grassley responding to his questions.


As you will see from the letter, Stanford concluded that Dr. Schatzberg appropriately disclosed any potential financial conflict because of his relationship with Corcept Therapeutics both to Stanford and to NIH and that appropriate steps were taken to prevent bias or actual conflict of interest, including having someone else be the Protocol Director for the portion of the NIMH grant that involves mifepristone (Protocol 80148) so that he was not involved in the conduct of that research. NIMH was advised of the steps being taken to manage this conflict of interest and reviewed the actions taken. NIMH exercised oversight of this work to assure its integrity, scientific merit and safe treatment of patients, including intensive peer review and establishment of a Data Safety Monitoring Board to review reports on the research. We believe that the conflict was appropriately managed because after Dr. Schatzberg acquired the financial interest giving rise to the conflict, other faculty who had no conflicting financial interest assumed responsibility for the research involving mifepristone.

Nonetheless, questions continue to be raised because, due to the way this grant was initially structured as a single grant covering several very different areas of inquiry, Dr. Schatzberg remained listed as the Principal Investigator on the entire grant. Despite our belief that Stanford, NIMH, and Dr. Schatzberg have handled this grant in accordance with the regulations and applicable policies and with due regard for the integrity of the research, we can see how having Dr. Schatzberg continue to be named as the Principal Investigator on the grant may create an

appearance of conflict of interest and we want to eliminate that concern. Earlier, Dr. Schatzberg requested that NIHM permanently restructure this grant so that he would no longer be the Principal Investigator for the protocol in the grant involving mifepristone. Stanford University, with the concurrence of Dr. Schatzberg, will temporarily appoint another faculty member as the interim Principal Investigator on this grant. We hope this action and your review will eliminate any misunderstanding of Dr. Schatzberg's role with respect to the mifepristone research by those who may not be as familiar with the grant and oversight process. We want to work with you in this interim period to restructure the research on this grant to serve three important purposes, which are in the best interests of the NIH, the oversight process, and mental health research. First, we want to put to rest any confusion about the integrity of any the research involving mifepristone; second, the important research regarding mifespristone should continue; and third, the vital research on other issues regarding psychotic depression—research that has nothing to do with mifespristone—should continue as well.

Stanford looks forward to working with NIMH in the coming days to accomplish these goals. Dr. Ann Arvin, Stanford's Vice Provost and Dean of Research, returns tomorrow and will contact you to follow up immediately on these matters.

Very truly yours,



Debra L. Zumwalt

cc: Joe Ellis, Director, OPERA, NIMH  
Ann Arvin