#1453

August 25, 1998

Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville MD, 20857

Dear Dr. Woodcock:

I am writing concerning a courageous letter to the editor in yesterday's *Washington Post* from FDA medical officer, Dr. Robert Misbin criticizing some of FDA's policies regarding the testing and approval of new drugs. In addition to the substance of the letter, which I agree with and will discuss below, I am appalled by the information, provided to me by a *Newsday* reporter, that shortly after the article appeared yesterday morning, Dr. Misbin was asked to resign by one of his superiors because of this criticism of the agency. Whoever the official was who engaged in this harassment needs to be sanctioned/reprimanded by you and other FDA officials for stifling criticism in such an abusive way. Unless this official is reprimanded, the message to others is that the FDA will tolerate, and indeed condones, the silencing of constructive criticism by agency physicians and other scientists. This attitude can only lead to further deterioration of the already troublesome problems at the FDA which have led to a record number of drugs, mostly me-too drugs, being approved and a record number having to be taken off the market when they are found to be dangerous.

We have previously criticized the inappropriate and unethical use of placebos in HIV-positive pregnant women in Africa and Thailand on the grounds that known effective therapy, AZT, was being withheld. More recently, the FDA is aware that unethical placebo-controlled studies of a new high blood pressure drug were being done (SYST-EUR) on severely hypertensive people although effective treatment for this condition was already available.

The issue raised by Dr. Misbin concerning inappropriate use of placebos in diabetic patients speaks to the connection between inappropriate/unethical standards for studying drugs and the consequently lowered standards for approving drugs. If they can get away with it, a drug company will always prefer to compare their new drug to a placebo, a comparison which will almost always make their drug appear to have a bigger advantage in effectiveness than it would if compared to known existing therapy. By letting companies get away with this, the FDA is depriving itself of head-to-head

comparative information between known effective drugs and the experimental one. As indicated by Dr. Misbin, this kind of information would make it easier for the FDA to say no to a new drug which was either more dangerous or less effective than an existing one. We have long supported legislation which would require new drugs to be either safer or more effective than existing ones. Short of this, however, the FDA could do much more to discourage dangerous and unethical placebo-controlled trials and encourage more comparisons between known old drugs and experimental new ones.

I hope that the concerns raised by Dr. Misbin in his letter and discussed above are taken seriously by the FDA and that the destructive, unjustified and punitive response to his constructive criticism is the subject of a reprimand. I look forward to a prompt response to this letter.

Sincerely,

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group

cc: Representative Henry Waxman
Representative Christopher Shays