

Statement by Eric C. Strain, M.D. on Behalf of the College on Problems of Drug Dependence

Food and Drug Administration

Peripheral and Central Nervous System Drug Advisory Committee

June 6, 2001

I would like to thank the FDA and the members of the Peripheral and Central Nervous System Drug Advisory Committee for providing me the opportunity to speak. My name is Eric Strain and I am a professor in the Department of Psychiatry and Behavioral Sciences at Johns Hopkins University School of Medicine. I am a Board Certified Psychiatrist with added Board Qualification in Addiction Psychiatry, and I am here today representing the College on Problems of Drug Dependence (CPDD). The College is the leading organization of drug abuse scientists in the United States. I am also the former chairman of the FDA's Drug Abuse Advisory Committee. I have sponsored my travel to today's meeting, and I have no relationship with Orphan or other pharmaceutical companies that make narcolepsy products.

There are two points that I would like to make during these brief comments. The first is that the College on Problems of Drug Dependence would like to emphasize the importance of science-based assessments of new medications, especially as they relate to issues such as abuse liability evaluation and safety of abused products. The College wishes to stress the long history that has led to the establishment of reliable and valid methods for determining abuse potential. This work includes both preclinical as well as clinical studies. Several academic medical centers contain rich experience in this area of research; methods have been well tested, and outcomes from previous studies have helped inform and guide agencies such as the FDA in making determinations regarding abuse potential, therapeutic efficacy, and safety of new medications. CPDD has played a key role in such matters, as its members are the primary group that have conducted such studies. The College wishes to strongly and forcefully advocate that decisions made by the FDA grow out of and be based upon well-conducted research, and whenever possible decisions should be derived from well-controlled studies and data driven. In order to achieve such goals, advice on substance abuse related matters should be solicited from experts in the field.

The second point I would like to make has to do with the Drug Abuse Advisory Committee. As the former, and the last chairman of this Advisory Committee of the FDA, I believe it is important for me to comment upon its termination. The Drug Abuse Advisory Committee has been dissolved by the FDA, and in the process the FDA has lost an important resource that can inform decisions regarding substance abuse. To my knowledge, today's meeting is the first FDA advisory committee meeting since this termination where issues of drug abuse are an important element in your discussions. I am pleased to see that there are several drug abuse experts represented here today, however I am concerned that the numbers do not allow the breadth of expertise that would have been found on the DAAC. Such breadth is essential to fully consider all of the issues involved in advising the FDA on the abuse potential of new medications, the extent of the public health consequences of such abuse, additional data that the FDA should require companies provide, and recommendations regarding post-marketing surveillance. The College is particularly concerned that comparable experience and knowledge brought to the Drug Abuse Advisory Committee by experts in the drug abuse field is no longer readily available to the FDA. In my experience as chairman of the committee, I was able to witness firsthand on repeated occasions the value of having a group of scientists and clinicians who could provide informed knowledge and experience to the FDA on matters such as those that appear to be on today's agenda. The loss of the Drug Abuse Advisory Committee to the FDA is significant and substantial, and adequate representation of drug abuse issues on other advisory committees needs to be clearly demonstrated by the FDA. I speak on behalf of the College in expressing the College's continued concern regarding the dissolving of this advisory committee. Given the tragic consequences of drug abuse to our society, its prevalence, and the growing body of medications for the treatment of substance abuse disorders, it is particularly concerning that the FDA has decided to terminate this particular advisory committee.

Again I wish to thank the FDA and the Peripheral and Central Nervous System Drug Advisory Committee for allowing me to make these comments today. The hope of the College is that these comments will spur tangible demonstration of the FDA's commitment to having adequate outside input by experts in the drug abuse field in the advisory committee process, either through the renewal of the Drug Abuse Advisory Committee or through adequate and substantial representation by drug abuse experts on other advisory committees where issues of drug abuse may be of substantial importance.