



COLLEGE ON PROBLEMS OF DRUG DEPENDENCE, INC.

Executive Officer:

Martin W. Adler, PhD
Center for Substance Abuse Research
Temple University School of Medicine
3400 North Broad Street
Philadelphia, PA 19140-5104
(215) 707-3242
Fax: (215) 707-1904
E-mail: baldeagl@temple.edu
Website: <http://www.cpdd.org>

Board of Directors:

Kathryn A. Cunningham, PhD, President
Warren K. Bickel, PhD, Past-President
Thomas R. Kosten, MD, President-Elect
Dorothy K. Hatsukami, PhD, Treasurer
Leslie Amass, PhD
James C. Anthony, PhD
Nancy A. Ator, PhD
Anna Rose Childress, PhD
Thomas J. Crowley, MD
William L. Dewey, PhD
Toby K. Eisenstein, PhD
Sari Izenwasser, PhD
Herbert D. Kleber, MD
Horace H. Loh, PhD
A. Thomas McLellan, PhD
S. Stevens Negus, PhD
Alison Oliveto-Beaudoin, PhD
Linda J. Porrino, PhD
Sharon L. Walsh, PhD

June 23, 2005

Rear Admiral Steven Galson, M.D., M.P.H.
Acting Director, Center for Drug Evaluation Research
Food and Drug Administration
WOCII/Rm. 6027
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Galson,

We are writing to request clarification on how FDA solicits/incorporates expertise on drug abuse within the framework of CDER advisory committees. As you may be aware, several of our groups led by the College on Problems of Drug Dependence (CPDD) initiated a dialogue with your predecessor, Dr. Woodcock, on this subject in November 2000. The dialogue began because we learned that FDA was planning to discontinue the Drug Abuse Advisory Committee (DAAC) at the end of May 2002 when its charter was due to expire. Dr. Woodcock formally

notified the drug abuse research community of that decision in April 2001 indicating that "We foresee calling upon special consultants in Drug Abuse products with potential for dependence or abuse over a wide range of therapeutic classes to consult with Advisory Committees on matters of risk management, abuse liability and drug scheduling." Following a teleconference with CDER staff in July 2001, and at CDER's request, CPDD in collaboration with other groups, supplied a list of twenty-nine internationally recognized experts in drug abuse spanning all phases of drug development from preclinical evaluation to post-marketing surveillance and covering all therapeutic drug classifications.

When the DAAC charter was up for renewal in 2002, the committee was renamed the Drug Safety and Risk Management (DSaRM) Advisory Committee with an expanded scope that, importantly, retained a standing Drug Abuse Advisory Subcommittee. It is unclear whether that Subcommittee was ever populated or ever convened but we can find no record of such a meeting on the FDA website. However, when the DSaRM Advisory Committee charter was renewed in 2004 the standing subcommittee was no longer included in the description of the committee structure. Further, although the structure of the DSaRM Advisory Committee was to consist of a core membership "knowledgeable in risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management, and drug abuse"

Rear Admiral Steven Galson, M.D., M.P.H.
June 23, 2005

no one on the current roster is identified as having expertise in drug abuse. Finally, a formal poll of the twenty-nine experts identified to CDER by the College on Problems of Drug Dependence in September 2001 indicate that none have ever been contacted (as of April 2005) to serve in an advisory capacity to CDER.

We have appreciated FDA's willingness to participate in two recent CPDD-sponsored conferences directly relevant to the science of drug abuse liability assessment. The first on "Abuse Liability Assessment of CNS Drugs", reported in *Drug and Alcohol Dependence*, Volume 70, Issue 3 Supplement, 2003 and the second, on the "Impact of Drug Formulation on Abuse Liability, Safety and Regulatory Decisions" in April of 2005. However we are very concerned by the continuing diminution of drug abuse expertise within the CDER advisory committee structure particularly at a time when regulated industry is tailoring product development to lower abuse liability and prescription opiate misuse is rampant. Further, it appears that FDA is ignoring drug abuse expertise at a moment in the agencies history when attention to drug safety issues has never been greater. We note that FDA has recently issued a number of guidance documents concerning risk management, developed the Drug Watch program, created a Drug Safety Oversight Board and charged the Institute of Medicine with Assessing the U.S. Drug Safety System. These activities evince a much heightened awareness at the FDA about drug safety and within that context drug abuse issues should be of paramount concern.

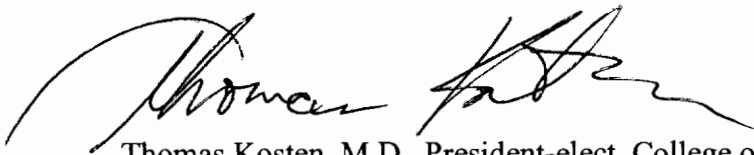
If there is a perception on the part of FDA that there is a diminished need for drug abuse expertise because of what is in the research and development pipeline, nothing could be further from the truth. Even a cursory review of the PhRMA website suggests that FDA will likely be reviewing dozens of products either for the treatment of drug abuse/dependence or with potential for abuse liability in the treatment of other diseases. Our members are involved in research on many new drugs that raise issues of potential abuse liability, and will require consideration of CSA Scheduling assignments and risk management strategies to ensure appropriate marketing and access. The novel pharmacologic profiles of many of these compounds are likely to produce mixed results on traditional assays of abuse liability that will no doubt effect important decisions the agency will need to make - decisions such as whether or not to recommend scheduling, if so, how to schedule, and the nature of risk management. These decisions will be as critical as whether or not to approve the drug and the conditions of approval and are the kinds of decisions that have historically benefited from outside guidance and expertise in order to gain a full range of perspectives.

Therefore, we strongly encourage FDA to reestablish a body of drug abuse expertise, like that embodied in the DAAC, which served the agency so well from 1978-2002. We believe this is crucial to enable the agency to appropriately regulate and manage new medications that include stimulants, sedatives, analgesics and novel compounds and formulations; compounds that have the potential to more effectively and safely address pain, cognitive and mood disorders, sleep problems, obesity and substance abuse. We look forward to continuing this dialogue and to

Rear Admiral Steven Galson, M.D., M.P.H.
June 23, 2005

developing a formal mechanism to ensure that FDA avails itself of the wide range of scientific expertise our organizations have to offer on drug abuse issues that come before the Center for Drug Evaluation and Research. We would be pleased to meet with you to brief you on the challenges, opportunities, and to help clear a path forward. Dr. Thomas Kosten, President-elect of the College on Problems of Drug Dependence and Past President of the American Academy of Addiction Psychiatry, has agreed to serve as a central point of contact for this initiative. Please feel free to contact him at thomas.kosten@yale.edu or 203.932-5711X7438.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas Kosten", with a large, sweeping flourish on the left side.

Thomas Kosten, M.D., President-elect, College on Problems of Drug Dependence

American Academy of Addiction Psychiatry
American College of Neuropsychopharmacology
American Psychiatric Association
American Psychological Association
American Society of Addiction Medicine
American Society of Pharmacology and Experimental Therapeutics
College on Problems of Drug Dependence
Research Society on Alcoholism
Society for Research in Nicotine and Tobacco