Appendix A: The Drug Evaluation Committee of the College on Problems of Drug Dependence

The Comprehensive Drug Abuse Prevention and Control Act (PL 91-513) and the Psychotropic Substances Act of 1978 (PL 95-633) gives exclusive authority to the Secretary of the Department of Health and Human Services to determine the abuse liability of substances and to make recommendations concerning their regulation and other drug policy decisions. Although the Secretary receives advice from the Drug Enforcement Agency (DEA), the Food and Drug Administration (FDA), and various other regulatory agencies, these laws explicitly state that the National Institute on Drug Abuse (MDA) must provide to the secretary information relevant to the abuse potential of suspected drugs of abuse and all information relevant to an assessment of their abuse potential. On the basis of this information from NIDA, and information from FDA and DEA, the secretary makes a judgment as to the dependence potential of new drugs.

NIDA's role in providing information relevant to the dependence liability of potential substances of abuse has placed enormous demands on the Institute. The agency supports a variety of activities in commercial and private laboratories around the country to provide this information. One of its principal sources of information comes from the College on Problems of Drug Dependence (CPDD) and, specifically, its Drug Evaluation Committee (DEC). The relationship between NIDA and CPDD is both formal and informal: NIDA provides over 98 percent of the funds required to assess the dependence liability of compounds in CPDD-sponsored testing facilities, NiDA is an official liaison member of CPDD, and CPDD provides direct input as requested in all NIDA decisions regarding the dependence potential of drugs.

Established in 1929, CPDD is the longest standing group in the country concerned with drug dependence and abuse. It is an independent body, affiliated with most scientific societies concerned with the dependence potential of abused substances and with regulatory and governmental agencies such as the World Health Organization (WHO), MDA, the National Institute on Alcoholism and Alcohol Abuse, DEA, and FDA. Each of these agencies has formal ties with CPDD via liaison membership. In turn, CPDD provides liaison representation to FDA and all other agencies on request.

CPDD has three major functions: to assess the abuse liability of psychoactive drugs; to hold an annual scientific meeting to review the status of the dependence liability of drugs; and, to seine as a consultant to the private sector and various governmental agencies on all drug-related matters and policies.

DEC oversees all aspects of CPDD'S dependence liability testing program. DEC is devoted to research on drugs of abuse and the determination of the dependence potential and abuse liability of specific classes of drugs: analgesics, stimulants, and depressants. Governmental and regulatory agencies, such as NIDA, DEA, and FDA have relied on DEC for information on the abuse liability of opiate-like compounds and stimulant and depressant drugs, In addition, CPDD is a collaborating center to WHO and provides information about the abuse potential of pharmaceuticals and scheduling worldwide. Producing this information is generally beyond the capabili-

ties of third world countries. Finally, CPDD provides the pharmaceutical industry and academic investigators information on new and novel compounds in the design and development phase. Thus, the information provided plays an important role in scheduling drugs, drug policy making decisions, and the facilitation of new drug development.

Approximately 50 to 60 drugs per year are submitted by industry, academic institutions, National Institutes of Health (NIH) laboratories, NIDA, WHO, and DEA (generally as a result of confiscation). A computerized list of submitted compounds is maintained at NIH; the code is broken only when testing is complete testing.

Appropriate quantities of the compounds are distributed for testing to the various laboratories that work under the auspices of CPDD. The test results are released as soon as practical, but at most within 3 years of receipt of the compound. Information about the drugs is confidential until one of three conditions is satisfied: the submittee grants explicit permission to release the data; 3 years have elapsed or, Federal and/or regulatory organizations request CPDD to provide information concerning the compound for the public welfare (e.g., a determination of whether the compound should be scheduled under the Controlled Substances Act prior to its marketing and distribution to humans).

Two university-based groups are involved with DEC'S evaluation of the analgesic types of drugs, and three with evaluation of the stimulants and depressants. The Medical College of Virginia, Virginia Commonwealth University, and the University of Michigan Medical School examine analgesics, using different methods to discern the physical dependence potential and abuse liability of presumed analgesics. Those two academic centers, along with the Mississippi Medical Center test stimulants and depressants.

'The programs' testing determines dependence liability of drugs and, on request, carries out more detailed studies to examine specific aspects of dependence liability, such as tolerance. For the last 30 years, this program has been largely responsible for obtaining basic scientific information on specific classes of compounds and the mechanisms involved in their acute and chronic pharmacological effects. DEC receives new compounds that are generally unavailable to other testing groups and provides scientific data on the pharmacology and abuse potential of new compounds. Thus the program contributes to the development of new drugs and the understanding of the mechanisms underlying the abuse liability of drugs.