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COLLEGE ON PROBLEMS OF DRUG DEPENDENCE, INC.

Executive Officer:

Martin W. Adler, PhD
Department of Pharmacology
Temple University School of Medicine
3420 North Broad Street
Philadelphia, PA 19140-5104
(215) 707-3242
Fax: (215) 707-1904
E-mail: baldeagl@vm.temple.edu
Website: <http://www.cpdd.org>

Testimony of the College on Problems of Drug Dependence

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before the
**Substance Abuse and Mental Health Services Administration
and
Food and Drug Administration**

Presented by
Maxine Stitzer, Ph.D.
Professor of Psychiatry
Johns Hopkins University

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The College on Problems of Drug Dependence (CPDD) is the nation's longest standing organization that addresses the problems of drug dependence and drug abuse and the leading scientific society in the field of drug dependence research. The CPDD is strongly in favor of the revision of the Methadone Regulations put forth in the *Federal Register* notice published July 22, 1999 (64 FR 39809). Specifically, the CPDD supports the proposal to repeal the existing narcotic treatment regulations enforced by the Food and Drug Administration (FDA). The CPDD supports the shift from the process evaluation of treatment programs currently carried out by the FDA to a system of accreditation based upon an outcome evaluation of treatment programs and the transfer of the responsibility for this accreditation program to the Substance Abuse and Mental Health Services Administration.

These changes reflect the fact that the system providing opiate maintenance treatment has developed to the point where the regulations currently imposed on the use of methadone and l-alpha acetyl methadol (LAAM) interfere with a clinicians ability to provide optimal individualized treatment to patients. Treatment experts agree that greater flexibility in the use of opiate maintenance procedures could greatly improve the attractiveness, retention and success rates of such treatment programs. Further, the process evaluation currently used by the FDA to approve opiate maintenance treatment programs does not evaluate whether such programs are providing maximally effective treatment services. An outcome evaluation for accreditation conducted by treatment experts could not only provide evaluation of the effectiveness of treatment programs but could also provide technical assistance and sound clinical advice to correct weaknesses where they are found. There are several areas which merit specific comment by the CPDD:

Criteria for Admission to Treatment

The Secretary has tentatively concluded that requiring a seven day waiting period between detoxification treatment episodes is too long and is asking for comment on shorter periods. The CPDD strongly supports the use of a two day waiting period between detoxification treatment episodes. To require longer periods means that addicts who relapse to heroin use will be exposed to unnecessary risk of over dosage, and HIV and other infectious diseases.

Office Based Treatment

The CPDD believes that strategies allowing the provision of treatment outside of the traditional program setting should be developed and implemented. The CPDD particularly favors the use of office based provision of long term treatment for patients who have successfully been treated in traditional programs. Graduation from a traditional program into treatment in a physician's office could provide for increased program treatment capacity and facilitate the patients transition from the drug using sub-culture to the general community. Further, there are many geographical areas in the United States where population density makes the establishment of traditional opiate maintenance treatment programs unfeasible. Under these circumstances it is essential that office based treatment be available.

Methadone Dosage Regulations

A large body of research has quite convincingly demonstrated that treatment outcomes in methadone maintenance are better when higher doses of methadone are prescribed. One study calculated that the odds of using heroin were reduced by 2% for every 1 mg increase in methadone dose. It is therefore surprising that the proposed regulations are silent on this

issue. While we are not suggesting that higher doses should be mandated, the regulations do provide an opportunity to guide clinicians toward the use of higher more effective doses. Specifically, across various studies, doses of 60-70 mg or higher are generally associated with better outcomes.

The proposed regulations would not permit the use of the medication as an incentive for therapeutically appropriate change. Although the CPDD recognizes that such incentive approaches may be controversial, there are numerous research reports that demonstrate the clinical efficacy of such approaches. The CPDD also recognizes that such incentive programs must be thoughtfully designed and implemented in order for appropriate therapeutic effects to be obtained. Thus, the CPDD strongly urges the inclusion of language that would allow waivers to be issued that would permit treatment programs with thoughtfully designed protocols to use medication as an incentive for therapeutically appropriate behavior change.

Medications Dispensed for Unsupervised Use

At the present time LAAM cannot be dispensed for patients to use at home. Although this long acting medication is taken only three times per week, it is problematic for patients to use this medication whose work requires them to travel for longer periods. Transferring them to methadone so that they can receive drug supplies for unsupervised use can present significant problems for some individuals. It is therefore the opinion of the CPDD that the restrictions on the unsupervised use of LAAM should be rescinded.

With regard to methadone, CPDD applauds the efforts demonstrated in the proposed regulations to make unsupervised use a more flexible aspect of treatment services delivery. The proposed regulations suggest four options for changing the current regulations governing unsupervised use. In general, the CPDD strongly favors Option 2 which follows the Institute of Medicine's recommendation. This option gives the Medical Director of programs greatest flexibility in the provision of medications for unsupervised use, a feature which is highly desirable from a clinical viewpoint.

The inclusion of guidelines for clinical judgements on allowing unsupervised use and the requirement for diversion control plans both are useful features that adequately address the basic issues involved in controlling unsupervised use. The CPDD would strongly suggest that in light of these safeguards and guidelines, it is unnecessary to impose further restrictions on the number of unsupervised doses per week that can be given after various months of treatment participation, and that these detailed regulations should be omitted. The CPDD also strongly favors a provision within Option 2 that 30 day medication supplies be available for unsupervised use by patients who have been in treatment for at least one year and demonstrated that they are capable of using their medication in an appropriate manner.

The CPDD is pleased to have contributed these comments on the proposed new Federal Regulations for substance abuse treatment programs that use methadone and LAAM. We believe that these changes will not only increase treatment capacity but will allow sound clinical judgment to be exercised in making treatment decisions for individual patients. This increased flexibility in clinical decision making should go far to increase the attractiveness and effectiveness of opiate maintenance treatment programs.