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STATEMENT

BY

H. WESTLEY CLARK, M.D, JD, MPH

CENTER FOR SUBSTANCE ABUSE TREATMENT

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH AND ENVIRONMENT

COMMITTEE ON COMMERCE

U.S. HOUSE OF REPRESENTATIVES

DRAFT

July 30, 1999

RELEASE ONLY UPON DELIVERY

Good morning Mr. Chairman and Subcommittee members. I would like to thank the Subcommittee for the opportunity to testify on the proposed Drug Addiction Treatment Act of 1999 and how that proposal relates to the role of the Center for Substance Abuse Treatment,

which is part of the Substance Abuse and Mental Health Services Administration. Although I will not address the specifics of the proposed legislation, I believe that, in general, CSAT shares the Subcommittee's concerns about making treatment medications available the correct way. Further, I would like to commend the Subcommittee and the Senate for their attention to this important public health issue.

CSAT shares the Subcommittee's's views on the importance of medications to treat substance abuse and drug addiction. Indeed, some of the most successful and cost-effective therapies available in the substance abuse treatment field today are those that use medication adjuncts. These therapies build on the large investment the public has already made in both the basic and clinical research on addiction funded by the Department.

CSAT's Role. CSAT serves a critically important role in the substance abuse treatment area as the primary Federal agency responsible for substance abuse treatment issues. Our role includes the development and dissemination of substance abuse treatment guidelines, many of which address the use of treatment medications that are of particular interest to this Subcommittee and clearly related to this hearing. Indeed, the Center has prepared and issued 33 Treatment Improvement Protocols and 22 Technical Assistance Publications, including treatment guidelines on the use of naltrexone, methadone and LAAM, medications used in the treatment of addiction. It is likely that future medications will also be the subject of treatment guidelines. But CSAT's role is not limited to developing and disseminating treatment guidelines. While treatment guidelines provide up-to-date, scientific information on the treatment parameters, CSAT will have an increasing role in determining appropriate treatment standards for medications that require such standards under existing and/or proposed Federal law. These new, direct oversight activities will complement the Center's longstanding commitment to provide technical assistance to the drug abuse treatment field. It is imperative to note that CSAT's treatment mission focuses on reducing treatment waiting time, reducing the "treatment gap" and

improving patient treatment outcomes.

Existing Federal Law. It important to realize that it is Federal law, the Narcotic Addict Treatment Act (NATA), that has established a unique special system for Federal oversight in this area. Briefly, this legislation enacted in 1974, requires a separate DEA registration under the Controlled Substances Act (CSA) for practitioners who use "narcotic" drugs in the maintenance or detoxification treatment of narcotic addiction. The special registration is based on a determination by the Secretary that the practitioner is qualified, under standards established by the Secretary, to provide this type of treatment. These standards are reflected in regulations developed and enforced currently by the Food and Drug Administration (FDA). This regulatory system has provided a "framework" for practioners to use narcotic drugs to treat narcotic addiction and has discouraged the inappropriate dispensing of narcotic treatment drugs. FDA has approved and DEA has registered over 900 "treatment programs" under this regulatory system. Both agencies monitor these programs under separate regulations. The Department's regulations under the NATA authority establish the conditions for using approved narcotic drugs in the treatment of addiction. Methadone and LAAM are the only two medications addressed in the current regulations. Finally, most States, and some counties and cities have narcotic treatment regulations in place.

The proposed Drug Addiction Treatment Act of 1999 sets forth a system that would allow physicians, under certain conditions and limitations, to prescribe certain approved scheduled narcotic treatment medications for the treatment of narcotic addiction. Hence, these medications, unlike methadone and LAAM, would not be subject to the requirements of NATA, nor to the protective regulatory framework established under that Act.

Treatment Standards for New Medications. CSAT, under the authority of the NATA, has also started to address the need for treatment standards for new treatment medications,

anticipating the approval of buprenorphine products in the near future. As part of this effort, we have initiated wide-ranging discussions with treatment providers, researchers, state officials and staff from NIDA, FDA, and ONDCP on how this new system might work most effectively and safely, to give the public the maximum benefit that may be available through new pharmacotherapeutic adjuncts to treatment. CSAT is beginning to identify issues and concerns from these discussions that relate to provisions in the draft legislation. I will briefly mention a few general concerns for the Subcommittee to consider as it deliberates in the future.

First and foremost is the need for a transition period following the approval and market availability of new medications like buprenorphine. This transition period would allow for the generation and analysis of treatment experience data and would help to ensure that public health risks associated with diversion and other factors are minimized. Moreover, this transition period would permit CSAT to continue to work with the medical community and other groups to develop physician training programs tailored for new medications like buprenorphine. A transition period would also allow CSAT to work with its partners to determine what services, including psychosocial services, will optimize the effectiveness of new medications and how such services should be provided to patients in different settings.

In carrying out its relatively new responsibilities under the NATA, CSAT will strive to fulfill the intent of the NATA, and shares the Subcommittee's goal to balance the need to assure that narcotic addiction treatment is provided in accordance with standards, and to assure that medication diversion concerns are fully addressed.

Other Factors - As we proceed, we must remember that, for many reasons, effective medical adjuncts already available for drug abuse treatment are underutilized, and new medications, to augment methadone and LAAM, have not been developed. A 1996 Institute of Medicine report identified Federal and State narcotic treatment regulations as an important factor that adversely

effect the development of new medications for addiction treatment. That same report discussed the need to increase the number of health professionals with addiction treatment training. In addition, many of the people who need and could benefit from pharmacotherapy are not likely to be insured, even for general medical coverage. It is clear that an effective strategy in this area is one which can address as many of these concerns as possible.

Changes in Regulatory Oversight. The Subcommittee should understand that this regulatory oversight system is in a period of transition. Last week, SAMHSA and FDA issued a proposed rule to substantially revise the longstanding Federal methadone regulation system. FDA, SAMHSA, DEA and the White House Office of National Drug Control Policy (ONDCP) developed this proposal to modernize and streamline the current regulatory system and to replace FDA's direct regulatory inspections with an accreditation-based approach, built on the same kind of peer-review that is standard in hospitals and other health care settings. The Department believes the proposed changes will enhance the quality of opioid treatment by allowing increased clinical judgement in treatment and through the accreditation process itself, with its emphasis on continuous quality assessment. CSAT will assume oversight responsibility upon finalization of these new rules.

Alternative Treatment Models. Historical and other factors have led to a unique system for the treatment of opiate addiction with opioid agonists such as methadone. The unintended result is that methadone treatment is almost completely separated from the rest of medical practice. CSAT is working to enhance the effectiveness of the treatment provided in the traditional narcotic treatment programs (or "methadone clinics"). In addition, the Center is working with various partners to investigate and evaluate alternatives to this system for future medications, like buprenorphine, which may have pharmacologic properties much different than methadone and LAAM.

The Subcommittee has identified a need to get more patients into effective treatment. Epidemiologic reports indicate that heroin abuse continues to rise in many regions, including parts of Florida and California. Surveillance also indicates increases for women and youth. And, public health agencies are struggling to address the problems of adolescent heroin addiction and HIV/AIDS, as well as hepatitis, tuberculosis and other infectious diseases associated with drug abuse. Part of our public health response has to be the availability of effective treatment earlier in the course of addiction than has previously been the practice and in channels where it has not been available before, such as the primary care setting. If effective intervention begins earlier in the course of an addiction, before too many of the psychosocial and developmental complications have occurred, it may even be possible in some patients to pre-empt the usual protracted and chronic course of heroin addiction. The availability of effective medications and the patients' need for these will give the physicians a reason to stay involved, while the newly diagnosed patient negotiates the unfamiliar world of counseling, treatment contracts and self-help groups.

In closing, I would like to emphasize that based on my personal experience as a treating clinician and researcher, it is essential, but sometimes complicated, to treat drug addicts effectively. Most heroin addicts require a combination of medical as well as psychosocial interventions. Treatment medications may themselves be somewhat abusable, in which case systems must be created to minimize their abuse and diversion. Since the group of patients to be treated with the new medications are the same patients at highest risk for abuse and diversion of all medications, the system to minimize and monitor for diversion must be especially robust.

We believe that we not only can, but must, strive to maximize the medical and public health benefits of new medications as well as existing medications, including methadone, LAAM, naltrexone and others. It is imperative as we proceed, however, that we take care to minimize any risks these treatment medication may present to the public.

H. Westley Clark, M.D., JD, MPH
Director, Center for Subtance Abuse Treatment
Substance Abuse and Mental Health Services Administration

Summary of Testimony
Subcommittee on Health and Environment
Committee on Commerce
July 30, 1999

The Center for Subtance Abuse Treatment (CSAT) serves a critically important role in the substance abuse treatment area. CSAT develops and publishes treatment guidelines that provide the substance abuse treatment field with up-to-date state-of-the-art information and guidance on substance abuse treatment. In addition, CSAT provides technical assistance to States and treatment providers as part of a "hands-on" treatment improvement program. CSAT has recently taken on additional responsibilities as the lead agency within HHS for overseeing opioid treatment programs ("methadone programs"), and as part of SAMHSA, jointly proposed new regulations intended to reform the oversight of methadone treatment. CSAT is also the lead agency for developing treatment standard regulations for new medications, including those that would be affected by the proposed Drug Addiction Treatment Act of 1999. CSAT's treatment mission focuses on reducing treatment waiting time, reducing the "treatment gap" and improving patient treatment outcomes.

The Drug Addiction Treatment Act of 1999, as proposed, sets forth a system that would allow physicians, under certain conditions and limitations, to prescribe certain approved narcotic treatment medications for the treatment of narcotic addiction. In essence, unlike methadone and LAAM, these new medications would not be subject to the requirements of the NATA.

In initiating the process to develop treatment standards under the NATA to address new medications like buprenorphine, CSAT has consulted with other Federal and State entities, as well as physicians and other practitioners. As a result of these discussions, CSAT has identified emerging issues that should be considered as standards, regulations, and proposals like the proposed Drug Addiction Treatment Act of 1999 are deliberated. These proposals need to consider a transitional period, so that the public health risks associated with the diversion of medications with abuse potential can be minimized; the type and level of training and experience for practitioners who treat patients with these new medications can be determined; and, the mix of psychosocial and other services that need to be provided with the new treatment medications can be ascertained.

CSAT shares the Subcommittee's goals and concerns in this area. And, as CSAT continues to execute its responsibilities in this area, the Center will strive to maximize the medical and public health benefits of the future medications while minimizing any risks they may present to the public.

Todd A. Summers
07/28/99 12:02:39 PM

Record Type: Record

To: Robert J. Pellicci/OMB/EOP@EOP

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Subject: Re: LRM RJP140 - - HEALTH & HUMAN SERVICES Testimony on H.R. ___ - Drug Addiction Treatment Act of 1999

Bob -

We have "no comment" on the above testimony, but appreciate the opportunity to review it.

Todd

From: Robert J. Pellicci on 07/28/99 10:12:15 AM

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Buprenorphine Testimony.

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LRM ID: RJP140

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

Wednesday, July 28, 1999

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
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PHONE: (202)395-4871 FAX: (202)395-6148
SUBJECT: **HEALTH & HUMAN SERVICES Testimony on H.R. ___ - Drug Addiction Treatment Act of 1999**

DEADLINE: **4:00 p.m. Wednesday, July 28, 1999**
In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: Hearing is before the House Commerce Subcommittee on Health and Environment on Friday July 30th. NOTE: This is the second HHS statement for the hearing - the previous one was circulated to you yesterday (see LRM #RJP138).

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