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DRUG ADDICT TREATMENT AND REHABILITATION ACT OF 1972

HEARINGS
BEFORE THE
SUBCOMMITTEE ON
ALCOHOLISM AND NARCOTICS
OF THE
COMMITTEE ON
LABOR AND PUBLIC WELFARE
UNITED STATES SENATE

NINETY-SECOND CONGRESS

SECOND SESSION

ON

S. 2840

A BILL TO AMEND THE PUBLIC HEALTH SERVICE ACT SO AS
TO AUTHORIZE EMERGENCY ASSISTANCE FOR STATES AND
NONPROFIT PRIVATE AGENCIES IN THE ESTABLISHMENT
OF CENTERS FOR MAINTENANCE, TREATMENT, AND REHA-
BILITATION OF DRUG ADDICTS

MAY 23 AND 24, 1972



Printed for the use of the Committee on Labor and Public Welfare

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DRUG ADDICT TREATMENT AND REHABILITATION ACT OF 1972

TUESDAY, MAY 23, 1972

U.S. SENATE,
SUBCOMMITTEE ON ALCOHOLISM AND NARCOTICS OF THE
COMMITTEE ON LABOR AND PUBLIC WELFARE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:10 a.m. in room 6226, New Senate Office Building, Senator Harold E. Hughes (chairman) presiding.

Present: Senators Hughes, Randolph, Javits, and Schweiker.

Staff members present: Mary Ellen Miller, counsel; Julian Granger, professional staff member; and Jay Cutler, minority counsel.

Senator HUGHES. The Subcommittee on Alcoholism and Narcotics will come to order.

STATEMENT OF SENATOR HAROLD E. HUGHES, A U.S. SENATOR FROM THE STATE OF IOWA

Our subcommittee hearing today is on the subject of methadone, and it is intended to help bring us up to date on the subject of methadone as a maintenance drug for heroin addicts. We have before us S. 2840, the bill which Senator Javits introduced last November. I cosponsored that bill along with Senators Buckley, Cranston, Packwood, and Schweiker. It is designed to provide substantial assistance to drug rehabilitation and treatment centers which use methadone or any other approved drug in the maintenance of those who have been the victims of heroin addiction.

We will also have testimony on the methadone initiatives announced early in April by Dr. Jaffe and his colleagues from the Department of Health, Education, and Welfare. They will be our witnesses today, along with Dr. Vincent Dole, who is the noted pioneer in the use of methadone as a maintenance drug.

These hearings will be directed toward the broad questions of how widely and how wisely methadone is being used now, and what policies the Federal Government should adopt as to its use in the immediate and perhaps longer term future. To answer the questions, we will have testimony on the state of scientific progress in this field as well as on the administrative, treatment, and community problems which may be created by the wide-scale use of methadone.

We are very much interested to know whether there is any prospect for an alternative to methadone that will not have methadone's great disadvantage, its addictive character. We are interested in the research now underway on LAAM, which I understand is a variant of methadone that is longer lasting, and we would like to know about any im-

provements that are being developed in methods of testing patients to determine whether they are still taking heroin.

Since public funds in very substantial amounts are involved, it is the subcommittee's duty to inquire into the administrative procedures that must be followed in order to insure that the funds are used properly and effectively. The problem of drug addiction is so acute in so many communities that I am sure there will be temptations to cut corners in order to allow the prompt creation of treatment programs wherever they are needed. This could happen at the expense of necessary precautions against waste and mismanagement.

A sizable portion of the funds will be spent for the products and services of commercial enterprises beyond those in the communities where treatment programs are located. For example, methadone is produced by a major pharmaceutical company, and I assume that several other major companies are conducting research into various aspects of the problem of addictive narcotics and other dangerous drugs. In addition, each treatment program must enter into contracts for laboratory services. Presumably, this will cause some increase in the size and numbers of commercial laboratories throughout the country.

Inevitably, there are problems in delivering effective treatment services. The illegal diversion of methadone from treatment programs has been a problem. Moreover, we are aware that from both ethical and practical points of view, there are differences of opinion on maintenance of addicts with an addictive drug. Some people strongly prefer drug-free programs, while others consider maintenance to be the better form of treatment. The members of this subcommittee have not taken a position on either side, but we do want to make certain that appropriate help is available to each victim of addiction who seeks it. I would also like to be sure that each patient is encouraged to work toward the time when he will be free of any addiction, either to heroin or to methadone.

And finally, as a subcommittee of the Senate, we have a duty to consider seriously the views of those who believe that it is not only unethical for our Government to encourage the use of methadone, but that there are political or racial motives underlying that policy. Whether it is justified or not, this view does exist, and as we all know, it is being expressed in vocal and perhaps even inflammatory language. As chairman of this subcommittee, I have every confidence that political or racial considerations do not motivate any one here. Yet, I do feel that we must guard against allowing Federal funds for drug treatment programs to be used in any way that might intensify political or racial tensions. That kind of manipulation, if it happens, can only endanger the cause to which we are all committed, the prevention of addiction and the rehabilitation of its victims.

At this point I order printed a copy of S. 2840 in the record.

(A copy of S. 2840 follows:)

92D CONGRESS
1ST SESSION

S. 2840

IN THE SENATE OF THE UNITED STATES

NOVEMBER 11, 1971

Mr. JAVITS (for himself, Mr. HUGHES, Mr. BUCKLEY, Mr. CRANSTON, Mr. PACKWOOD, and Mr. SCHWEIKER) introduced the following bill; which was read twice and referred to the Committee on Labor and Public Welfare

A BILL

To amend the Public Health Service Act so as to authorize emergency assistance for States and nonprofit private agencies in the establishment of centers for maintenance, treatment, and rehabilitation of drug addicts.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 That the Public Health Service Act is amended by adding
4 at the end thereof the following new title:

5 "TITLE XI—DRUG ADDICT TREATMENT

6 "SHORT TITLE

7 "SEC. 1101. This title may be cited as the 'Drug Addict
8 Treatment and Rehabilitation Act of 1971'.

II

1 "FINDINGS; DECLARATIONS OF POLICY

2 "SEC. 1102. The Congress hereby finds and declares the
3 following:

4 "(1) Heroin addiction is a major aspect of an acute
5 national drug abuse and drug dependent problem and
6 heroin addiction itself is a national problem of un-
7 paralleled gravity and growing proportions which af-
8 flicts not only inner city residents but all urban, sub-
9 urban, and rural areas of this Nation;

10 "(2) Heroin addiction significantly contributes to
11 an increase in crime against persons and property;

12 "(3) Methadone maintenance with appropriate re-
13 habilitative services is a recognized effective interim
14 means for treating substantial numbers of heroin addicts
15 who voluntarily submit to such treatment for their
16 addiction;

17 "(4) Heroin addiction can seriously impair health
18 and can inflict pain and suffering on individuals, fami-
19 lies, and communities; and

20 "(5) The increasing rate of heroin addiction and
21 abuse constitutes a threat to national health and welfare
22 and an emergency requiring an immediate and effective
23 national commitment to increased health, education, and
24 rehabilitation efforts for narcotic addicts, including but
25 not limited to, the establishment of substantial numbers

1 of community-based programs of methadone mainte-
2 nance.

3 "DEFINITIONS

4 "SEC. 1103. As used in this title, the term—

5 " (1) 'heroin addict' means any individual who
6 habitually uses heroin (as that specific chemical desig-
7 nation is applied by title II of the Comprehensive Drug
8 Abuse Prevention and Control Act of 1970) and who
9 is in a state of psychic or physical dependence, or both,
10 arising from administration of that substance on a con-
11 tinuing basis. The heroin addict is characterized by be-
12 havioral and other responses which include a strong
13 compulsion to take the substance on a continuous basis
14 in order to experience its psychic effects, or to avoid the
15 discomfort caused by its absence; except that the Sec-
16 retary may modify this definition by regulations; and

17 " (2) 'rehabilitation' or 'rehabilitative services' in-
18 cludes such services as professional counseling, educa-
19 tional and vocational guidance, education, training and
20 job referral and placement and such other intensive,
21 skilled services applied on an in-patient or out-patient
22 basis, over such protracted period of time as may be
23 necessary to assist the individual to achieve maximum
24 utilization of his potential and to return, as soon as
25 practicable, to his or her family and community as a

1 productive, self-respecting, and self-sustaining member
2 of society; and

3 “(3) ‘State’ means each of the several States of
4 the United States, the District of Columbia, the Virgin
5 Islands, Guam, American Samoa, Trust Territory of the
6 Pacific Islands, and the Commonwealth of Puerto Rico.

7 “ESTABLISHMENT OF PROGRAM

8 “SEC. 1104. (a) For the purpose of enabling the Sec-
9 retary of Health, Education, and Welfare (referred to in
10 this title as the ‘Secretary’) to make grants to States to
11 enable any such State to establish and carry out a program
12 to provide medical and other assistance to heroin addicts
13 and pursuant to which methadone (or any other drug
14 designated by the Secretary by regulation to be an effective
15 heroin antagonist) may be administered to any individual
16 determined to be a heroin addict, there are authorized to
17 be appropriated for the fiscal year ending June 30, 1972,
18 the sum of \$; for the fiscal year ending June
19 30, 1973, the sum of \$; and for the fiscal year
20 ending June 30, 1974, the sum of \$.

21 “(b) Within sixty days following the date of the enact-
22 ment of this title, the Secretary shall promulgate such
23 regulations as he determines necessary, to enable him to
24 carry out the provisions of this title. Such regulations shall
25 include—

1 “(1) the method or methods to be employed and
2 the manner and conditions under which the physician
3 in charge of any treatment facility established under
4 any program pursuant to this title shall determine an
5 individual to be a heroin addict;

6 “(2) the method or methods and the manner and
7 conditions under which methadone may be adminis-
8 tered in any treatment facility established under any
9 such program and for what period of time, but in no
10 event shall any methadone be administered under any
11 program pursuant to this title in any manner other than
12 orally;

13 “(3) the criteria for administering heroin antagonist
14 drugs other than methadone in such treatment facilities
15 and the conditions under which such drugs may be ad-
16 ministered to heroin addicts.

17 “ALLOCATION OF FUNDS

18 “SEC. 1105. (a) For each fiscal year referred to in sec-
19 tion 1104, the Secretary shall, in accordance with regula-
20 tions, allot the sums appropriated for such year pursuant to
21 such section among the States on the basis of the relative
22 population, financial need, and need for more effective pre-
23 vention, treatment, and rehabilitation programs for heroin
24 addicts; except that no such allotment to any State (other
25 than the Virgin Islands, American Samoa, Guam, and

1 the Trust Territory of the Pacific Islands, for any fiscal
2 year shall be less than \$200,000.

3 “(b) Any amount so allotted to a State during any such
4 fiscal year (other than the Virgin Islands, American Samoa,
5 Guam, the Trust Territory of the Pacific Islands, and the
6 Commonwealth of Puerto Rico) and remaining unobligated
7 at the end of such year shall remain available to such State,
8 for the purposes for which made, for the next fiscal year
9 (and for such year only) and any such amount shall be in
10 addition to the amounts allotted to such State for such pur-
11 pose for such next fiscal year; except that any such amount
12 remaining unobligated at the end of the sixth month follow-
13 ing the end of such year for which it was allotted which
14 the Secretary determines will remain unobligated by the
15 close of such next fiscal year may be reallocated by the Secre-
16 tary, to be available for the purposes for which made until
17 the close of such next fiscal year, to other States which have
18 need therefor, on such basis as the Secretary deems equitable
19 and consistent with the purposes of this title, and any amount
20 so reallocated to a State shall be in addition to the amounts
21 allotted and available to the States for the same period. Any
22 amount allotted under subsection (a) of this section to the
23 Virgin Islands, American Samoa, Guam, the Trust Terri-
24 tory of the Pacific Islands, or the Commonwealth of Puerto
25 Rico for a fiscal year and remaining unobligated at the end

1 of such year shall remain available to it for the purposes
2 for which made, for the next two fiscal years (and for such
3 years only), and any such amount shall be in addition to
4 the amounts allotted to it for such purpose for each of such
5 next two fiscal years; except that any such amount, re-
6 maining unobligated at the end of the first of such next two
7 years, which the Secretary determines will remain unobli-
8 gated at the close of the second of such next two years,
9 may be reallocated by the Secretary, to be available for the
10 purposes for which made until the close of the second of
11 such next two years, to any other of such named States which
12 have need therefor, on such basis as the Secretary deems
13 equitable and consistent with the purposes of this part, and
14 any amount so reallocated to any such named State shall be
15 in addition to any other amounts allotted and available to it
16 for the same period.

17 “(c) At the request of any State, a portion of any allot-
18 ment or allotments under this title shall be available to
19 pay that portion of the expenditures found necessary by
20 the Secretary for the proper and efficient administration
21 during such year of the State plan approved under this
22 title, except that not more than 10 per centum of the total
23 of the allotments of such State for a year, or \$50,000,
24 whichever is the lesser, shall be available for such purpose
25 for such year.

1 “(d) Funds authorized under section 1104 of this Act
2 which are not expended in developing or modifying the State
3 plan shall be available only to provide maintenance, treat-
4 ment, and rehabilitation in accordance with the requirements
5 of this Act, on a priority basis in areas within the State hav-
6 ing the highest percentages of population who are heroin
7 addicts and where practicable, to community-based drug
8 treatment programs which have been in successful operation
9 prior to the enactment of this Act.

10 “STATE PLANS

11 “SEC. 1106. (a) Any State desiring to participate in
12 the program established by the Secretary pursuant to this
13 title shall submit to the Secretary a State plan for car-
14 rying out its purposes. Such plan must—

15 “(1) designate a single State agency as the sole
16 agency for the preparation and administration of the
17 plan, or designate such agency for supervising the prepa-
18 ration and administration of the plan;

19 “(2) contain satisfactory evidence that the State
20 agency designated in accordance with paragraph (1)
21 (hereafter in this section referred to as the ‘State
22 agency’) will have authority to implement such plan
23 in conformity with this title and with Federal policy
24 established pursuant thereto;

25 “(3) authorize the administration of methadone and

1 any other drug designated by the Secretary, to indi-
2 viduals who voluntarily submit to treatment and are
3 determined under regulations to be heroin drug addicts,
4 only in public or nonprofit private centers or in facilities
5 established or operated under the Community Mental
6 Health Centers Act, as amended or in facilities operated
7 or controlled in accordance with standards or criteria
8 established by State, city, or local authority in substan-
9 tial compliance with the provisions of this Act;

10 " (4) require that each drug program in each center
11 or facility be: (A) under the supervision of a licensed
12 physician qualified to treat narcotic addiction; (B) pro-
13 vide directly or through contractual arrangements for
14 the benefit of addicts in such program, vocational coun-
15 seling, education and services, psychological and psy-
16 chiatric therapeutic programs and services, appropriate
17 educational programs, legal assistance, and other neces-
18 sary rehabilitative services; (C) directly or through con-
19 tractual arrangements encourage efforts by the private
20 and public sectors of the economy to recruit, train, and
21 employ participants in methadone maintenance pro-
22 gram; (D) provide assistance directly or through con-
23 tractual arrangements to addicts in such treatment pro-
24 grams in obtaining employment; and (E) by appropri-

1 ate procedures and programs, encourage participants in
2 methadone maintenance programs, if possible, to become
3 drug free;

4 “(5) require that methadone and other heroin an-
5 tagonist drugs designated by the Secretary be admin-
6 istered in such centers or facilities only to individuals
7 who are determined under regulations as provided in
8 section 1104 (b) (1) to be heroin drug addicts and who
9 are required by the center or facility to participate regu-
10 larly in appropriate rehabilitation programs;

11 “(6) require that before methadone is administered
12 to an individual, a licensed physician qualified to treat
13 narcotic addiction shall determine that the individual's
14 addiction is such that other treatment is not likely to be
15 successful;

16 “(7) require that each center or facility be open at
17 reasonable times and hours for the administration of
18 methadone or other heroin antagonist drugs designated
19 by the Secretary;

20 “(8) require that each center or facility keep appro-
21 priate records concerning persons receiving methadone
22 or other drugs at such center or facility in accordance
23 with subsection (b) (1) of this section;

24 “(9) set forth, in accordance with criteria estab-
25 lished by the Secretary, a survey of the local and State

1 needs for the prevention and treatment of heroin abuse,
2 including a survey of the health facilities needed to pro-
3 vide services for heroin abuse and heroin dependence,
4 and a plan for the development and distribution of such
5 facilities and programs throughout the State;

6 “(10) provide such methods of administration of the
7 State plan, including methods relating to the main-
8 tenance of records and to the establishment and main-
9 tenance of personnel standards on a merit basis (except
10 that the Secretary shall exercise no authority with re-
11 spect to the selection, tenure of office, or compensation
12 of any individual employed in accordance with such
13 methods), as are found by the Secretary to be necessary
14 for the proper and efficient operation of the plan;

15 “(11) provide that the State agency will make such
16 reports, in such form and containing such information,
17 as the Secretary may from time to time reasonably re-
18 quire, and will keep such records and afford such access
19 thereto as the Secretary may find necessary to assure
20 the correctness and verification of such reports;

21 “(12) provide that the Comptroller General of the
22 United States or his duly authorized representatives
23 shall have access for the purpose of audit and examina-
24 tion to the records required pursuant to paragraph (11) ;

25 “(13) provide that the State agency will from time

1 to time, but not less often than annually, review its
2 State plan and submit to the Secretary an analysis
3 and evaluation of the effectiveness of the treatment pro-
4 grams and activities carried out under the plan and any
5 modifications in the plan which it considers necessary;

6 “(14) provide reasonable assurance that Federal
7 funds made available under this title for any period will
8 be so used as to supplement and increase, to the extent
9 feasible and practical, the level of State, local, and other
10 non-Federal funds that would in the absence of such
11 Federal funds, be made available for the programs de-
12 scribed in this title, and will in no event supplant such
13 State, local, and other non-Federal funds;

14 “(15) provide for the designation of a State ad-
15 visory council on heroin addiction which shall include
16 individuals and representatives of nongovernmental or-
17 ganizations or groups and of public agencies concerned
18 with the prevention and treatment of heroin abuse, and
19 heroin dependence, from different geographical areas of
20 the State, to consult with the State agency in carrying
21 out its plan; and

22 “(16) contain such additional information and as-
23 surance as the Secretary may find necessary to carry out
24 the provisions and purpose of this title.

25 “(b) (1) A complete medical, social, occupational, and

1 family history shall be obtained as part of the diagnosis,
2 classification, and treatment of each patient in a drug
3 program established pursuant to this title, the purpose of
4 which shall be to develop a complete and permanent con-
5 fidential personal history for purposes of the patients treat-
6 ment. All patient records (including all records relating
7 to any commitment proceeding) prepared or obtained under
8 this section or in connection with any treatment authorized
9 pursuant to this title and all information contained therein,
10 shall remain confidential and may be disclosed, with the
11 patients consent only, to medical personnel and then only
12 for the purpose of diagnosis and treatment of the patient,
13 or to Government or other officials for the purpose of ob-
14 taining benefits due the patient as a result of his drug abuse
15 or drug dependence. Disclosure may be made for purposes
16 unrelated to such treatment or benefits upon an order of a
17 court after application showing good cause therefor. In
18 determining whether there is good cause for disclosure,
19 the court shall weigh the need for the information sought
20 to be disclosed against possible harm of disclosure to the
21 person to whom such information pertains, the physician-
22 patient relationship, and to the treatment services, and
23 may condition disclosure of the information upon any ap-
24 propriate safeguards. No such records or information may
25 be used to initiate or substantiate any action or charges

1 against a patient or a former patient under any program
2 pursuant to this title under any circumstances.

3 “(2) Nothing in this section shall be construed to limit
4 the use of information by persons engaged in research pro-
5 vided that the confidentiality of patient records is preserved
6 by withholding names or other identifying characteristics
7 thereof.

8 “(c) The Secretary shall approve any State plan and
9 any modifications thereof which complies with the provi-
10 sions of this title and regulations issued pursuant thereto.

11 “SEC. 1107. (a) In any case in which a State has not
12 submitted a State plan within one hundred and twenty days
13 following the date of the enactment of this title, or in any
14 case in which a State plan or modification thereof has been
15 finally disapproved by the Secretary, funds allocated to such
16 State under section 1105 (a) of this title may be made avail-
17 able to qualified public or nonprofit private agencies within
18 that State directly by the Secretary in accordance with sub-
19 section (b) of this section.

20 “(b) The Secretary, within the limits of any such State’s
21 allotment referred to in subsection (a), is authorized to re-
22 ceive, consider, and act upon any application from any such
23 public or nonprofit private agency referred to in subsection
24 (a) which contains such information and assurances as the
25 Secretary shall by regulation prescribe. Grants made to any

1 such approved applicant pursuant to this section shall be
2 made for purposes of carrying out programs comparable to
3 those provided for in section 1106 of this title and subject to
4 such conditions as the Secretary shall by regulation prescribe.

5 “(c) In making grants under this section the Secretary
6 shall provide priority for grant applications in States and in
7 areas within the States having the highest percentages of
8 population who are heroin addicts and where practicable,
9 to community-based drug treatment programs which have
10 been in successful operation prior to the enactment of this
11 Act.

12 “REPORTS

13 “SEC. 1108. The Secretary shall conduct periodic surveys
14 to evaluate the effectiveness of the program established under
15 this title and he shall make comprehensive reports to
16 Congress of his findings and recommendations resulting from
17 such surveys. Such reports shall be made not less often
18 than twice each fiscal year beginning with the fiscal year
19 ending June 30, 1972.

20 “EFFECT OF OTHER FEDERAL LAWS

21 “SEC. 1109. On and after the effective date of this title,
22 no provision of Federal law shall be construed to prohibit
23 the administration of methadone or any other heroin antag-
24 onist drug designated by the Secretary, under any program
25 established pursuant to this title.

1 "VOLUNTARY SERVICE

2 "SEC. 1110. Notwithstanding the provisions of section
3 3679 (b) of the Revised Statutes (31 U.S.C. 665 (b)), the
4 Secretary is authorized to accept and employ in further-
5 ance of the purpose of this title, and in connection with any
6 drug abuse training, education, rehabilitation, research pre-
7 vention, or treatment program thereunder, voluntary and
8 uncompensated services.

9 "SHORT TERM GRANTS TO ASSURE AVAILABILITY OF

10 PERSONNEL

11 "SEC. 1111. To assure the availability of trained medical
12 and other health profession personnel for facilities participat-
13 ing in programs established under this title, the Secretary
14 may, under such regulations as he may prescribe, make
15 grants to medical schools and other appropriate public or
16 nonprofit private educational institutions to establish and
17 operate short-term educational programs including programs
18 of continuing education to train such personnel. There are
19 authorized to be appropriated \$----- for the fiscal
20 year ending June 30, 1972, and such sums as may be
21 necessary and for the next two succeeding years thereafter
22 such sums as may be necessary to make grants under this
23 section."

Senator HUGHES. Senator Javits, please proceed with your statement.

Senator JAVITS. I express satisfaction that the hearings are beginning on this bill. What I am seeking to do in cooperation with the chairman, who has been absolutely brilliant in this whole field of drug addiction and alcoholism, is to try to promote the establishment of comprehensive State and local methadone maintenance programs.

We all realize, and Dr. Jaffe primarily realizes, that this is not a cure for all addicts but it is, rather, a proven treatment modality for certain addicts in order to combat the scourge of heroin abuse which causes so much crime.

We must make a better showing, by proving that other means are more effective or develop an antagonist, which would be the best of all. No claim whatever, Mr. Chairman, is made here that this is the optimum way to proceed, but with tens of thousands of human beings on the streets who in their conduct are mad dogs, methadone maintenance seems to offer us the only immediate relief. The lives they take in muggings, et cetera, and the lives they destroy, can never be reclaimed. We must try to dam the flow to some extent of their unbelievable sickness which takes itself out on society now.

So I offer this bill only as an interim solution and nothing else. That is the way the distinguished doctor who first introduced me into this field, Dr. Marie Nyswander back in 1955, when I was attorney general of New York, sees it, and the way Dr. Dole, the leading expert in the field sees it. He says we can show rehabilitation of thousands of people who otherwise would have been hopeless heroin addicts, and that is about all that can be said for it.

Apparently the Food and Drug Administration has adopted the same attitude in changing its regulations so that there would be a chance to more flexibly use this drug. They say, "Methadone presently represents the only drug for which there is substantial evidence of effectiveness in the treatment of heroin addiction."

Now the thing that troubles me very deeply in my own home State and especially the city of New York is the waiting list for treatment in methadone maintenance which is now estimated at 18,000 certified addicts in New York City alone.

Mr. Chairman, black markets in methadone can exist, but isn't the waiting list itself a major factor in respect of black markets. And isn't it a fact that no matter what you are going to do by way of further treatment, therapeutic or otherwise, it is much easier to detoxify a heroin addict in the long run through methadone than to let him become a hepatitis infected heroin addict?

I support the FDA's proposed new regulations and I hope these hearings will focus public attention on the hopelessness of the problem, which has already suffered from too much delay, until, through the genius of Dr. Jaffe and his staff we can get a much more solid approach. In the meantime society cries for some answer and the chair has done me the enormous compliment of trying, as I say, to put our finger in the dike until the dike can be fortified through the scientific means for which I know Dr. Jaffe will give his every skill and time.

While I have the floor may I say, too, that we look forward with enormous expectation to the findings of the National Commission on Marihuana and Drug Abuse of which the chair and I are both members, and hopefully our report will come along contemporaneous-

ly with some new scientific breakthrough which we can then support and validate, which will be a lot better than the methadone. I thank you and ask that my prepared statement in its entirety be made a part of the hearing record.

Senator HUGHES. Thank you, Senator Javits, and it is so ordered.

PREPARED STATEMENT OF HON. JACOB K. JAVITS, A U.S. SENATOR
FROM THE STATE OF NEW YORK

Mr. Chairman, I am most pleased that hearings have begun on S. 2840, "The Drug Addict Treatment and Rehabilitation Act of 1971," introduced by myself and the chairman.

This bill is designed to promote the establishment of comprehensive State and local methadone maintenance programs. Methadone maintenance offers one solution—not a cure-all for all addicts—but rather a proven treatment modality for certain heroin addicts in order to combat the scourge of heroin abuse which is a plague on our society.

Grim testimony to the inadequate response to this epidemic of narcotics addiction are the recent Bureau of Narcotics and Dangerous Drug statistics which estimate national heroin addict population at 650,000 (and, unfortunately, 50 percent of these people live in New York.)

An interim measure—clearly proven effective for certain addicts—is needed now while the search for antagonists and other effective long-term solutions goes on.

Methadone maintenance offers us such an interim solution. Methadone is not a cure for heroin addiction, for, like heroin, it is addictive. However, it has the capacity for restoring to an addict the freedom to determine how he wishes to lead his life in society, other than as a slave to his heroin habit. Insulin is not a cure for diabetes, but it permits the sick person to function in society.

The leading experts in the field have been Dr. Vincent Dole and his wife, Dr. Marie Nyswander. In previous testimony before this subcommittee, Dr. Dole made it clear that methadone is "no panacea whatsoever," and stated:

We can show rehabilitation of thousands of people who otherwise would have been hopeless heroin addicts.

I am anxious to hear his comments on my bill and the recently proposed FDA regulations for the use of methadone.

Methadone programs previously were subject to controls exercised jointly by the Bureau of Narcotics and Dangerous Drugs and the Food and Drug Administration, based upon the proposition that the treatment was still experimental and that an IND permit was necessary to prevent abuse. The FDA has now concluded that:

Methadone presently represents the only drug for which there is substantial evidence of effectiveness in the treatment of heroin addiction.

I have long favored a liberalization of the regulations under which methadone may be made available to qualified personnel for use in approved programs to combat heroin addiction. I am pleased that the FDA's recently proposed regulations have removed metadone from the status of an "investigational" drug, permitting its marketing, yet at the same time imposed controls to prevent its abuse. This essentially is the course favored in the bill before us today.

There is at present a waiting list for treatment in methadone maintenance programs of a claimed 18,000 certified addicts in New York City alone. While I recognize the legitimate concerns of those who fear its abuse or the creation of a "black market" in methadone, I believe that the waiting list itself is a major factor which contributes to the black market in methadone. Frankly, I submit that an individual on methadone maintenance will be easier to detoxify in the long run than a hepatitis infected, functionless, and sometimes lifeless heroin addict.

I support the FDA's proposed new regulations, and I hope that these hearings will focus public attention on a problem which has already suffered from too much delay.

Senator HUGHES. On behalf of the subcommittee, Dr. Jaffe, I wish to welcome you and your colleague here to testify before the committee. If you would introduce your colleague for purposes of the record and proceed with your testimony.

STATEMENT OF DR. JEROME JAFFE, DIRECTOR, SPECIAL ACTION OFFICE FOR DRUG ABUSE PREVENTION, EXECUTIVE OFFICE OF THE PRESIDENT, ACCOMPANIED BY PAUL L. PERITO, DEPUTY DIRECTOR

Dr. JAFFE. I have on my left Mr. Paul Perito.

Mr. Chairman and Senator Javits, it is a pleasure to be here today to discuss with you the use of methadone in drug abuse treatment programs and S. 2840, to amend the Public Health Service Act to authorize emergency assistance for States and nonprofit private agencies in the establishment of centers for maintenance, treatment, and rehabilitation of drug addicts.

Senator HUGHES. I can't hear you, Dr. Jaffe. Would you pull the microphone closer?

Dr. JAFFE. Yes.

The use of methadone as one tool available in the treatment of heroin addiction has caused controversy while at the same time it has helped many people return to the mainstream of society. In admitting the validity of both those statements at the outset, it is important that a number of conceptual distinctions be made. First, the problem of narcotics addiction is only one of a number of forms of drug abuse with which this country must deal; second, the maintenance approach to managing narcotics addiction is only one of a number of treatment approaches; and, third, methadone is only one of several substances that may prove to be safe and effective in maintenance programs.

With these distinctions in mind, we can proceed to ask about maintenance concepts in the treatment of narcotics addiction and, more specifically, about methadone as a maintenance drug. I believe that there is a growing consensus about certain aspects of the maintenance concept. There are now few responsible observers who would contest the following basic proposition: That there exists a group of compulsive narcotics users who, provided with appropriately supervised supplies of opiod drugs, can remain socially productive, but deprived of such supplies through legitimate channels eventually seek out illicit

supplies to the detriment of themselves and the society in which they live.

The issues on which consensus has not yet been reached include the following:

1. What are the fundamental goals of the maintenance approaches?
2. What are the criteria for determining whether a given individual should be maintained on an opiod or offered (or compelled to accept) some form of treatment that does not involve maintenance?
3. What opiods and what routes of administration are best suited for use in maintenance programs—and what are the relative advantages and disadvantages of each?
4. For any given drug, what are optimum dosages for achieving various goals for different individuals?
5. How can a health care delivery system best balance the need to make treatment readily available against the problems that might arise from illicit diversion of opiods?
6. What services (if any) other than the availability of opiods, should be considered essential—and what contribution do they make to the overall treatment?
7. What social objectives can a society reasonably expect to reach by utilizing the maintenance approach?

There are, of course, some groups who object to the very concept of a maintenance program. The reasons for this opposition are sufficiently varied that it is not possible to respond to each specific objection in this presentation.

However, it must be clear that the Federal Government does not intend to pursue policies based on oversimplified answers to complex problems, and that compulsive narcotics use is a problem of exceeding complexity.

Most narcotics addicts have many social and psychological problems; in some instances these problems have preceded their addiction, but in almost every case such problems develop after they become drug addicts. Some of those who object to the concept of maintenance do so out of concern that these social and psychological problems will be ignored in favor of inexpensive programs restricted to dispensing methadone.

These groups can rest assured that the development of programs that merely dispense medication is not Federal policy. The Federal programs now under development envision the use of maintenance techniques within the context of broad efforts at overall rehabilitation. The resources devoted to treating individuals on maintenance programs need be no less than those directed at patients in nonmaintenance programs.

Yet, we must recognize that it may require more skill and more trained personnel to develop the rehabilitative efforts than to initiate the medical and pharmacological aspects of the treatment programs.

We must deal with the problem of whether to insist on the provision of rehabilitative services even when so doing will markedly delay the provision of any treatment at all.

There are some who object to the concept of maintenance because in practice it involves some risks—risks that some of the medication will be diverted and cause harm to the community, and risks that some patients will be started on a maintenance program who might have fared equally well on a nonmaintenance program.

There are no easy answers to these objections. Efforts to minimize these risks may give rise to still other risks—those of severely reducing the availability of useful treatment procedures by over elaborate or unnecessarily restrictive regulations.

There are a few who are wary of maintenance programs because they are suspicious of the motives of those who are engaged in the treatment process. They suspect that the treatment programs are more interested in social control than in rehabilitation. While there may be a certain inevitability to this kind of attitude, the real issue is whether those who are concerned have any meaningful alternatives to suggest.

In short, there seem to be people who want methadone freely available to all with little or no controls. There are also people who feel that no one should ever be treated with methadone lest controls on the drug become controls on people, and those who feel that the risks of diversion are so great that methadone, if used at all, should be rigidly controlled, regardless of the impact of such control in treatment availability.

The policies that evolve at the Federal level must be primarily responsive to the need to provide treatment to those who can benefit from it, but must be continually responsive to the concerns of those who present legitimate objections to the expansion of maintenance programs.

We believe that the measures we have instituted, which I will describe subsequently, deal effectively and practically with both concerns. There are still a few who would take the position that even the basic proposition that methadone helps some compulsive heroin users has not been proven; and that to proceed to other issues is premature. We feel that the mounting evidence will ultimately convince even the most skeptical that while the methadone maintenance approach often falls far short of the hopes of its most ardent supporters and proponents, it is certainly of greater value than its most severe critics have proclaimed.

This is not the proper context in which to review the data on water safety and efficacy, but it does seem appropriate to remind ourselves that safety with respect to any drug is never absolute.

Methadone has been shown to be safe when properly administered, and has no more inherent danger than other drugs when they are abused or improperly administered.

For example, there are many drugs that are presently in general medical use that are extremely dangerous, even lethal, if used incorrectly.

Medical practitioners are aware that in using any drug to treat a patient, there is usually a calculated risk. This risk must be balanced against the need and, as in this case, the possible benefits. On balance, methadone for maintenance use, just as methotrexate, penicillin, aspirin, tranquilizers, sleeping medicines for their specific uses, must be considered safe.

Methadone is neither inherently safe, nor inherently dangerous. But as with most drugs, it must be evaluated in context, it can be dangerous if improperly used, but it is sufficiently safe when administered properly to individuals who otherwise would be likely to continue to use intravenous heroin.

One could argue that to induce a significant degree of methadone dependence is in itself a major hazard. Yet even here we must weigh the seriousness of the syndrome being treated and in addition, we should note that in some programs there has been experimentation with eventual withdrawal of selected patients who have been maintained on methadone for periods in excess of 1 year.

So far the experience with this time-limited methadone maintenance program is not sufficient to determine its value. At present we can say that some individuals may require long terms or even lifetime maintenance on methadone, while other individuals will be able to undergo eventual withdrawal after they have gone through successful rehabilitation.

Methadone is not "the answer" to drug abuse. Indeed as we all know, there is no one answer. We do feel, however, that the use of methadone as one therapeutic tool in the armamentarium should be utilized to its fullest practical extent until such time as alternative methods of satisfactory treatment are developed.

At the present time, methadone maintenance is one of the most efficacious treatment modalities available, and, notwithstanding the risks associated with methadone, to do other than encourage the use of this modality would constitute a dereliction of duty on our part.

By encouraging the use of methadone maintenance we are not thereby discouraging the use of other treatment modalities. Methadone maintenance is effective only in certain classes of opiate dependent persons. In other classes, other modalities are more effective, and we must be aware that for those persons who are not amenable to successful methadone maintenance treatment or who are susceptible to other successful treatment, those other modalities must be utilized to the fullest practical extent.

Nor are we hindering or in any way restricting or discouraging research and other efforts designed to develop alternative means of treatment. To the contrary, we are exploring the antagonists and blockage drugs and encouraging research with a view toward developing nonaddictive, long lasting alternatives to methadone.

Since we are encouraging and anticipating the expansion of quality methadone maintenance programs, we obviously must take into consideration the question of illicit diversion, risks to the community and the patient, and the other factors which render methadone at best only a stop gap measure.

As this subcommittee knows, the Special Action Office, since its inception by Executive Order (11599) last year, has worked with the Food and Drug Administration, the Bureau of Narcotics and Dangerous Drugs, and other regulatory and health organizations both public and private to develop new regulations, which were published in the Federal Register on April 6, 1972.

These new regulations were designed to assure quality treatment in the form of methadone maintenance and to protect against the risks associated with such treatment. The Special Action Office, in attempting to facilitate the use of methadone as a therapeutic tool in the treatment of opiate dependent persons, is at the same time attempting to insure that the expansion resulting from such encouragement will not work to the detriment of the individual patient being treated nor to the community involved in such treatment.

The initiatives announced on April 3 are designed to deal effectively with both problems. On that day, the Special Action Office in conjunction with the Department of Health, Education, and Welfare, its Food and Drug Administration, and the Bureau of Narcotics and Dangerous Drugs of the Department of Justice, announced a major new program to assure the availability of valid data from methadone clinics and to eliminate diversion of methadone from these clinics.

This program began with the training of 100 FDA inspectors and Public Health Service medical professionals. Following the training sessions the group was organized into two-man teams which are presently conducting a nationwide program review of the more than 450 methadone maintenance programs in the United States.

The teams are each examining procedures intended to safeguard against the diversion of methadone and to prevent nonaddicts from entering methadone treatment. They will make recommendations to improve the quality of medical aid to patients in these programs, survey national treatment needs by measuring the number of patients on waiting lists, and determine the capacity of clinics to expand in order to treat additional patients if given additional resources.

At the same time, the Food and Drug Administration proposed new guidelines for methadone maintenance programs. These new regulations propose that methadone maintenance be removed from the class of experimental procedures, and be recognized as a legitimate medical treatment, to be used under strict governmental supervision.

They also recommend the removal of methadone from retail pharmacies while continuing to permit distribution through authorized methadone programs or through hospital pharmacies, or indeed to permit pharmacies affiliated with authorized programs to serve as dispensing points for medication.

Heretofore, methadone has been classified by the FDA as an investigational new drug (IND) under a procedure worked out jointly by officials of the FDA and BNDD.

The original purpose of the IND was to permit experimentation and research in order to accumulate sufficient data to make a determination as to the efficacy and safety, or lack thereof, of methadone as a maintenance drug in the treatment of heroin addicts.

For the most part, the original goals for which the IND was established have been met. As a result, we have concluded that methadone should be made available for all addicts who consent to use it under approved treatment programs. Retention of the drug solely on an investigational status no longer appears to be warranted.

At the same time, we have been concerned that the usual form of NDA (new drug application) approval could lead to greater diversion or misuse of the drug, since it permits unrestricted distribution and allows physicians to use wide discretion in prescribing the drug.

In order to provide the strongest possible control over the distribution and use of methadone, the new regulations utilize both the IND and NDA control mechanisms. Like an NDA, the drug will be available for treatment in all cases where there is medical justification.

Like an IND controlled drug, there will be a permanent record showing pattern of distribution of the drug because the institutions using the drug and the physicians and pharmacists operating in cooperation with the institution will be required to register all use of the drug.

Thus, a new closed system of distribution will be established under which any diversion or misuse can immediately be recognized and stopped at the source of supply. At the same time, the drug will be available for use without all the IND restrictions for all addicts for whom it is medically justified.

The new inspection program and the new guidelines represent major elements in the joint effort by the Special Action Office, the Food and Drug Administration, the Public Health Service, the National Institute of Mental Health, and the Bureau of Narcotics and Dangerous Drugs to expand the availability of treatment for heroin addicts across the country, while, at the same time, protecting the public against the illegal diversion of the drug or related problems.

In the context of our discussion of methadone let me address myself to S. 2840.

S. 2840, which was introduced on November 11, 1971, has many worthy goals. The idea of providing funds for expanded treatment programs throughout the country is consistent with what we are attempting to do.

The need to provide comprehensive services including rehabilitation and vocational training is clear. The requirement that patient records be kept confidential goes to the very core of what must be done in order to get drug users to volunteer for treatment.

Finally, we recognize the absolute necessity to provide trained personnel—both medical and paramedical—for programs which treat drug users. S. 2840 includes provisions to deal with all these areas.

It is important to note, however, that the bill was introduced prior to final congressional action on "The Drug Abuse Office and Treatment Act of 1972" (Public Law 92-255) and before promulgation by the Food and Drug Administration of the methadone regulations discussed previously.

We believe that the provisions in the legislation and those in the proposed regulations give us sufficient authority to accomplish the objectives in S. 2840 without additional legislation.

For example, S. 2840 authorizes the Secretary of Health, Education, and Welfare to make formula grants to States to enable them to carry out programs for medical assistance to heroin addicts by the use of methadone and other drugs designated by the Secretary. As this subcommittee is aware, last summer we made a commitment to provide treatment to all addicts in the United States that desire it, so that no one can use as an excuse for committing crimes in order to feed a habit the fact that treatment was not available.

That commitment remains, and we have already begun efforts to fulfill it. In coordination with the Office of Economic Opportunity, we are using the contract mechanism to expand and enlarge upon existing treatment facilities.

In each of these instances, we know there are persons waiting for treatment. Our intent is to use a contract mechanism on a fee-for-service basis so that we can offer treatment to people who have indicated they want it but have not been able to obtain it.

On May 11, 1972, OEO Director Philip Sanchez and I jointly announced awarding of \$2 million in such contracts for eight cities to do this. We feel this mechanism, unlike that of the formula grant approach, allows us to target the money to those areas where the need

is the greatest. In the future, we shall be making additional announcements of new efforts to end waiting lists for treatment.

The requirements in S. 2840 which relate to the submission of State plans as a condition of receiving grants are in many instances contemplated by Public Law 92-255 and the FDA's methadone regulations.

Section 1106(a)(1) requires that each State designate a single State agency as the sole agency for the preparation and administration of a plan. Section 409(e)(1) of Public Law 92-255 requires essentially the same thing as do the new methadone regulations.

On the issue of confidentiality, S. 2840 sets forth the requirement of a complete medical, social, occupational, and family history for each addict and requires that all such patient records be kept confidential. It requires that this information can be disclosed only upon a patient's consent and only to limited individuals. It further provides that disclosures for other purpose may only be made upon application to a court showing good cause.

However, the section would not infringe upon the use of medical records for legitimate medical research.

We believe the confidentiality provision in section 408 of Public Law 92-255 deals with this problem rationally and effectively. As a result, we see no reason for new provisions like those in S. 2840.

Finally, S. 2840 allows the Secretary to fund programs directly where no State plan exists, and directs that a priority be given to areas within States with the highest percentage of addicts and those community-based programs which have been most successful.

I am sympathetic with this provision because it would, if enacted, force responsive State activity in this area. However, Public Law 92-255 provides the Secretary with authority to fund directly special projects of a wide variety, including methadone maintenance projects. Under this authority, successes could be rewarded in much the same way as is contemplated under S. 2840.

For these reasons, we recommend against the enactment of S. 2840.

I will be happy to answer any questions you may have.

Senator HUGHES: Thank you very much, Dr. Jaffe.

To go back to some things that were not in your statement, if I may. Can you give us any estimates of the size of the problem now that are different from anything you have given us in the past?

What I am asking first is how many heroin addicts you estimate are in this country.

Dr. JAFFE: If you are focusing on heroin addiction, we have been acutely aware of the inadequacy of the data base almost from the day that the Special Action Office was established. Some months ago, Myles Ambrose and I impaneled a group under the auspices of the Office of Management and Budget to look into all of the indicators of the size of the problem that the Federal Government is now examining and developing. In addition, there is a committee which is composed of people from the Department of HEW, the Bureau of Narcotics and Dangerous Drugs, the Treasury Department, and outside consultants who have been working on this now for several months. We can only conclude that the data base is not the ideal, and in fact falls far short of even being adequate.

Most of our estimates are very crude and are largely "guesstimates." I think those communities that have large-scale programs with no waiting list come closer to being able to give us a reasonable measure or index of the size of the problem.

New York has such a registry; very few other places have one. Most of the data that we have, from which our estimates have been derived, are based on arrest figures. However, not everyone is arrested, and we know that many people who are arrested are not identified as addicts. We also know that in some instances people are identified as addicts who are not addicts. Reporting methods are also irregular.

We have engaged in a major effort to try to improve this. As you know, we are engaged in a massive survey of all of the methadone programs. That survey will give us indications as to how many patients have ever been treated by such a program, and how many people are currently waiting for treatment. In a sense, that is data which is equally vital, because regardless of the total number of people who are addicts, what really counts is the number of those who currently want treatment.

Senator HUGHES. If I can interrupt you, Dr. Jaffe, I realize the importance of everything you say, but I want to get back to the question. How many heroin addicts do you now estimate there are in this country, by whatever method you have?

Dr. JAFFE. The more I look at the data base, the less able I am to give you an estimate.

Senator HUGHES. What are you operating on when you ask for money, then?

Dr. JAFFE. We are operating on a number of indexes.

Senator HUGHES. I would like then for you to give me the number you think there are. Using the best thing you have to base it on, whatever it is, tell me.

Dr. JAFFE. Among users and addicts together, and that is the best we can do, we are probably looking at between a quarter of a million and half a million.

Senator HUGHES. I understand the problems and the fallacies in arriving at a final figure. Do you know how many are being maintained on methadone yet?

All these methadone programs should have been under control. How many are being maintained on methadone?

Dr. JAFFE. We will know with some precision in a matter of weeks. Right now it is estimated as somewhere between 50,000 and 60,000.

Senator HUGHES. About a quarter of a million to 500,000 users and addicts?

Dr. JAFFE. Yes.

Senator HUGHES. Do you have any idea how many are in drug-free treatment programs yet?

Dr. JAFFE. We have initiated a survey of treatment programs in the country as a whole. That data should be under analysis at this very moment, and sometime in June we should have a good idea.

We have known that there are approximately 6,000 treatment programs in this country, of which approximately 239 are federally sponsored, but, unfortunately, not one of them has had data on what their capacity was, and by capacity we mean the outpatients, inpatients, residential patients, and group therapy patients.

We modified a contract to get that kind of data. I think it would be very hard to give you an estimate of that, and I am not sure that even a crude estimate would be useful.

We suspect that it may be as high as another 50,000 people, but I doubt it.

I can try to get that for the record for you, and as I said, some of this will be available in a matter of weeks, and we can try to supply that for you.

Senator HUGHES. What was the figure you said you would have in a couple of weeks?

Dr. JAFFE. We will have two kinds of figures. There will be an analysis of the treatment capacity based on a survey of the treatment programs that were listed in the National Clearinghouse for Drug Abuse Information. There will also be the information coming back from the survey of methadone maintenance programs from the Food and Drug Administration, which will give us a more precise figure on the number of patients in methadone treatment programs and the number of people waiting to get into methadone treatment programs.

Senator HUGHES. Will you supply those figures for the record?

Dr. JAFFE. I will be delighted to.

(The document subsequently supplied follows:)

EXECUTIVE OFFICE OF THE PRESIDENT
SPECIAL ACTION OFFICE FOR DRUG ABUSE PREVENTION
WASHINGTON, DC 20506

June 8, 1972

FEDERALLY SPONSORED DRUG ABUSE TREATMENT PROGRAMS

1. Number of Treatment Programs

3/31/72 239

This figure includes NIMH, LEAA, VA, OEO, BOP, HUD and DOD.

2. Number of Clients in Treatment

3/31/72 29,835

This figure excludes DOD, LEAA and HUD.

a. Of the 29,835 Clients in Treatment:

- 1,426 were in detoxification
- 10,568 were on Methadone Maintenance
- 27 were receiving other chemotherapy
- 12,200 were receiving drug free treatment

(These breakdowns exclude VA, HUD, LEAA and DOD)

3. Data is not available from which to determine clients waiting for treatment.

All of the above figures, as you can see, reflect data compiled through March 31, 1972. In the record Dr. Jaffe refers to an ongoing survey, the results of which should be submitted by the end of this month. Once this more current data has been compiled, we will be happy to submit them to you.

Senator HUGHES. In other words, right now you don't have any idea how many people will need to be treated by methadone maintenance? Is that an accurate statement, or not?

Dr. JAFFE. I think that is a fair statement. But to give you an idea, it is certainly going to be more than 10,000 based on our estimates, and it is probably less than another 50,000.

But much of the issue depends on the availability of other forms of treatment and the acceptability of other forms of treatment, and it depends equally on the availability of heroin here. I think that people have observed that when, in fact, heroin is readily available, the motivation for the addict to seek other forms of treatment is less than when the supply goes down or the price goes up.

We suspect, therefore, that activity on the part of Myles Ambrose's group may reduce the availability of heroin and motivate more people to treatment. Whether these people who enter treatment will seek out methadone or drug-free therapy is not entirely clear.

I suspect the ratio will remain about the same, and the majority of people will be seeking methadone-type programs, at least initially.

Senator HUGHES. If I understand you correctly Dr. Jaffe, what you are saying is that as a maximum you would expect around 100,000 patients in methadone maintenance programs.

Dr. JAFFE. That is a crude, year-term estimate.

Senator HUGHES. Based on all the crude estimates we have.

Dr. JAFFE. If the data were better, I would try to make better estimates. I don't think we serve the country well by pretending we have a better idea of what is going on than we really do.

Senator HUGHES. Then as a maximum you would estimate if there are 500,000 users or addicts, 20 percent of those would be on maintenance programs?

Dr. JAFFE. The real issue is how many of those are abusers and how many of those are addicts to the point where they would require that kind of treatment.

There is a general belief that the early experimenter is not a candidate for this kind of treatment. I think the critical distinction, therefore, is between user and addict; and I wish we could say more about some of this. You know, we discussed the Vietnam issue before—

Senator HUGHES. We will again, too.

Dr. JAFFE. The early estimates lumped all those people together, addicts and users, and it was clear that when the good data began to come in that the addicts represented a small fraction of the total number of people involved.

Perhaps when we begin to get more information on this, we will have a better idea.

We have also taken other steps to identify people who are not coming into treatment programs. The treatment alternative to street crime program is one which attempts to provide a priority track for people who are arrested and turn out to be heroin users.

We hope the lockup facility will identify a group of people who are not presently being routinely identified, and will increase our information.

Senator HUGHES. On the lack of information, you have, and I am not trying to imply that there is any fault in anyone. You took over a position where there was no information or basis for gathering information, and programs were proliferated all over the government-

tal structure, Federal, State, and local. On what did you base your budget request for this program?

Dr. JAFFE. Well, when we submitted our original budget request, we were basing it on certain assumptions about the accuracy of projections from arrest data, frankly. We also based it on known estimates at that time of people waiting for treatment; and they were based primarily on the idea that treatment has a finite period of time; that is, that any given number of people, in need of treatment, will not be in need of treatment continuously, indefinitely.

There is a turnover rate in various kinds of treatment. Some people who elect the drug-free program may participate in the program for 3 months, may leave it, and may not really require treatment again until sometime in the future, if ever.

We would hope there will be, in fact, total recovery on the part of a number of people. So that people will be leaving the treatment system, while at the same time others will be entering.

The budget estimates were based on a formula, which I could show you, which put into the system some estimated turnover rates which we have known from previous experience, both for maintenance programs, for drug-free programs, hospital programs, and residence programs.

Given that turnover rate, we were looking at a budget which would say "What can we deploy, given the trained people, over the next year, and how fast can it be expanded in terms of drug-free maintenance?" I can actually get for the record the number of slots that we thought we could develop with the resources.

Senator HUGHES. We have already placed those in the record, I believe, Dr. Jaffe, at previous hearings.

Mr. PERITO. Yes, Senator, those are in the record.

Senator HUGHES. I think we have the complete record of it. I was not trying to get you to go over it completely again, but what I was really asking on behalf of Senator Javits is how much money will the administration request, and I am speaking to you as the administration, solely for methadone maintenance programs relying on the authority, which you say is adequate, of Public Law 92-255 and the proposed FDA regulations?

Dr. JAFFE. Let me be as direct as I can. Assuming 20,000 people were waiting for treatment, we have already demonstrated that initial hospitalization is required for only a small fraction of users, conversion to methadone maintenance, on an ambulatory basis, is possible.

We have done a survey of those costs. They range, per outpatient year, from approximately \$900 to \$1,800 per patient per year.

We estimated that even if there were 20,000 people waiting for treatment in those programs, the end to the waiting lists could be accomplished within a year with \$30 million.

Now, the amount of money appropriated in the fiscal year 1972 budget amendment in NIMH alone for treatment specifically is \$46 million, and in addition, the total fiscal year 1972 budget for the VA approximates \$18 million, and they, too, can participate in that kind of a program.

There are additional millions in the Office of Economic Opportunity. This is ample money to follow through on our priorities and the first priority, which I stated at the press conference when I was introduced by the President, is that nobody should have to wait for treatment.

I was addressing myself specifically to the waiting lists, which I think are unconscionable, and which our country should not have to accept.

If you ask how much is specifically earmarked for methadone, the answer is that we did not think it necessary to be that specific in outlining policies. The intent was clear, that there is more than ample money to treat all these people, and in addition——

Senator HUGHES. Are you saying to me, Dr. Jaffe, that you have an adequate amount of money in the budget now to treat all of heroin addiction in America today?

Dr. JAFFE. I did not say that, sir.

Senator HUGHES. What on earth did you say, then?

Dr. JAFFE. I said assuming there were 20,000 people waiting to enter methadone treatment programs, that there was ample money, even in 1972's budget, to eliminate the waiting lists.

Senator HUGHES. What programs would you take that money away from? It was appropriated for multidisciplinary programs, as you well know. Certainly when we fought for that budget for OEO, HEW, or other agencies, we didn't intend all of it to go for methadone maintenance.

Dr. JAFFE. When you were talking about what you fought for I believe you are addressing yourself to Public Law 92-255.

Senator HUGHES. I am talking about all the rest of the programs, too. We don't limit ourselves to your bill.

Dr. JAFFE. I am addressing myself to moneys that have been available this year, and theoretically they could have eliminated that waiting list, and still made adequate provision for additional expansion for the other kinds of drug abuse programs and other forms of treatment.

Senator HUGHES. Could we have done it without robbing any other programs.

Dr. JAFFE. I don't know what you mean by "robbed" and "other programs."

Senator HUGHES. I am talking about programs needed all over the country and in every major city, to the extent they are needed, and you are one of the greatest spokesmen for them. I don't think you're consistent. You are saying you have plenty of money. I am saying I don't believe you. That is what it boils down to.

Dr. JAFFE. I was addressing the question of how much was specifically earmarked for methadone.

Senator HUGHES. Right. That is what Senator Javits wanted to know. How much money will the administration request?

Dr. JAFFE. Are you stating that we should specifically earmark money for methadone at this point?

Senator HUGHES. You in the administration have a job to do, and we in the legislature have a job to do. You say you can do it without new law and without specific earmarking and we may decide differently, regardless of what you think. We would like to know how much you think you will request. You put a budget together, estimating what is to be spent for methadone, and so much of it for everything else.

How much is that? That is what we are asking.

Dr. JAFFE. Well, I think to give you a precise answer we will have to see how much is already allocated specifically for methadone. The

moneys that are now being deployed sir, are what I am referring to. To get that information has taken some months, due to existing inconsistencies in the reporting system.

Now, the needed consistency of reporting is, I believe, just beginning to come in, and we can't at this time tell you how much is now being allocated to methadone. We can make some reasonable estimates as to how much additional money is being allocated.

We can give you precise estimates for the future only when we know where we are. We have been struggling with that for months. Accurate data is just now beginning to come in. We would be happy to show you the matrix that we are attempting to get now which shows how many people are treated on methadone, nonmethadone, hospital care, and so on.

I think the answer has to be that we want to put as much money into methadone as is required to make sure that no one is waiting for that form of treatment. We intend to keep that commitment, and whatever it takes, we will make it.

We will expand it to that point.

Senator HUGHES. I understand that, Dr. Jaffe. You are dealing with philosophy, however. There has been conflict on our side for a long time. You are saying whatever money methadone programs need, you will see that they get it no matter where it comes from.

You have the power to transfer, or of putting enough pressure on agencies to get them to make that transfer. I am concerned not only that we treat with methadone but that we don't drain other programs in the process of doing it.

Dr. JAFFE. To the best of my knowledge no money has been taken from the other forms of treatment.

Senator HUGHES. You didn't have enough money in the beginning to really treat all the methadone patients. You say you did, I say you didn't in relationship to what we expected to do under existing laws.

Dr. JAFFE. There was a supplemental request in June of fiscal year 1972.

Senator HUGHES. Right.

Dr. JAFFE. Of \$67 million for NIMH. Additional money was made available to the Department of Defense and to the VA. With the passage of 92-255, there are additional authorizations that we have under consideration now for both fiscal year 1972 and fiscal year 1973.

Senator HUGHES. I am well aware of that; that is why I am asking the question.

Dr. JAFFE. Yes.

Senator HUGHES. That is why we want to know how much you want.

Dr. JAFFE. As soon as we can get the figures I will put them in the record.

Senator HUGHES. By July 1st, you are in a new fiscal year.

Dr. JAFFE. As you know, there were some slight changes in the Office of Management and Budget in the last few days, and it has delayed the process somewhat.

Senator HUGHES. Do you make the budget or do they?

Dr. JAFFE. We propose it, and we work with them on it.

Senator HUGHES. What percentage of it do you get back?

Dr. JAFFE. Well, thus far, I have gotten about 100 cents on the dollar.

Senator HUGHES. Have you, really?

Dr. JAFFE. Yes.

Senator HUGHES. I am sure other agencies would be glad to hear that. I am going to defer to my distinguished colleague from West Virginia. He has two other hearings, and was so interested in this that he came by.

Senator Randolph?

Senator RANDOLPH. Thank you. I know the Environmental Protection Agency, through Mr. Ruckelshaus, told us yesterday in the subcommittee hearing on air and water pollution that apparently the Office of Management and Budget is not always, let's say, receptive, and it is rather unique and comforting to know you have no problem, because so many other agencies do.

I do want to be helpful, although I am not informed to the degree of Harold Hughes and others who have been able to address themselves to these hearings and produce with witnesses the productive material which is necessary if we are to, rather than have timid steps, continue and step up all fronts the attack on drug abuse in this country.

I am not certain of just what the figures are, if they are available, but Dr. Jaffe, if the drug user, on heroin, we will say, moves from the use of heroin at least in part and is on a treatment program using methadone, does that addict remove himself from that group of which he is a member who are committing crime in this country?

It is very important, I think, for me at least, to know to just what extent you have figures or a background to answer this question.

Dr. JAFFE. We have data from a number of programs and the most candid answer is that if you pick a typical addict he meets to a certain degree some of the attribution of the goal you set up. The average addict uses less heroin, commits less crime, and works more. There is however, an average addict like there is half a child in a family.

What you actually find in a program is that a very few patients get jobs and stop all illicit drug use. Some other patients will in fact stop most of their drug use, perhaps stop most of the crime, work some of the time. If you look at it realistically you realize that in effect we are asking somebody who has been in a deviant subculture, engaging in drug use, crime, and probably not working to become ideal citizens, to become drug free, crime free, and productive.

In all candor, most patients make it some of the way, and as a matter of fact, the majority of the patients make it some of the way. Only a small percentage of the patients go all of the way to that ideal in these programs. I don't think it would be appropriate or honest to say that of every patient treated on methadone, none of them ever commit crimes again.

That is not the case. Crime is substantially reduced, but not eliminated. It is not fair to say that those people treated with methadone all get jobs. Depending on the economic situation, and the effectiveness of the counseling in motivating them to try to get jobs, employment generally goes up, and drug use does, in fact, go down fairly dramatically, but in any given program at a given time 20 percent of the patients may still use heroin from time to time as measured by urine tests.

One can look at such a vessel as being half full or half empty, depending whether you want to be a pessimist or an optimist.

Clearly there is an improvement and a beneficial effect for the community, but it falls far short of perfection. I think as long as we are

realistic about what we can achieve, we won't be disappointed when the final results come in.

Senator RANDOLPH. Speaking about the glass being half filled or half empty, I don't want to get into this type of discussion except to say it would be so much better, I think, if the radio and television weather commentators would speak about a day that is partly sunny—they invariably say the day will be partly cloudy. I have watched them, I have listened to them.

It is always "partly cloudy," never "partly sunny." I think here today, although we are caught in a web of crucial problems that there is hope, and I know that Harold Hughes believes in that, and that is why he is questioning you so much about these dollars—not just to add dollars, but that dollars be used effectively to reduce the addition and reduce the crime so that this will not be a matter of so much concern throughout this country.

I am sure that even though you may disagree here, there is a feeling that if we move too quickly, you might say, Dr. Jaffe, we oversaturate and we are not able to produce. As you have indicated here, you must deal with problems, and provide rehabilitative services, even when so doing may not result in satisfactory treatment at all.

Dr. JAFFE. That is a key issue. People will accuse us of taking the cheap way out if we don't fund it. If we wait until we get the staff, we can't fund it at all.

I do want to address myself to one point. When I was speaking about OBM, I was speaking historically, and one can't predict the future. I was in the cabinet room and the President looked around with respect to this particular program and simply made a comment, "I don't want any budget cutting on this," and he looked at the relative people.

Some of the relative people have left Government recently. The point is that I think the Presidential commitment will hold. I think it is incumbent upon us, however, to make those dollars productive, because I don't think you can expect a commitment to be independent.

If we turn money into treatment programs that are effective, we can expand as fast as our capacity to expand develops; and if in fact the money simply evaporates, then in fact I can't in good conscience go up and demand more.

I think my capacity to insist we need more is in part dependent on how well we are going to use it.

Senator RANDOLPH. I don't again, attempt to speak for the chairman, but certainly I have a sense of feel in reference to this matter that Harold Hughes does not want to continue a hybrid effort. He wants to move it down a road where he sees what is happening.

He wants a concentration of effort, and that is what you are talking about here, as well as dollars. Now, this final expression, Mr. Chairman, which is apart from your methadone subject matter today. I have been reading several news articles. These articles concern themselves with aliens, principally, smuggling into this country large amounts of heroin.

In one instance, in Miami, there came a smuggler of heroin. According to the story in the Miami Herald, the market value of that heroin when the man was apprehended and the heroin was confiscated, was said to be \$74 million. Do you know about this case?

Dr. JAFFE. Not this specific case.

Senator RANDOLPH. It, again, was a few weeks ago. I am not attempting to say what the value is, but that is what the story indicated, and I assume there was documentation and accuracy involved.

What concerns me, Dr. Jaffe, and I am sure it concerns many people who certainly are not experts in this field, but just seeing what takes place, in this instance, and this is all a matter of record, if the heroin was worth \$74 million in its sales value throughout the United States, what would happen, Dr. Jaffe, when the judge in this instance would have a bail bond in the insufficient amount of \$100,000?

Now, what happens? That is just a cost of doing business, isn't that right?

Dr. JAFFE. My own feeling is that you are absolutely correct. The people involved in the drug traffic control literally tear their hair out about this. Mr. Perito has extensive experience in this area, and I think he can respond to this in greater detail.

Mr. PERITO. Senator, at the present time there is consideration within the Department of Justice about an exploration of what, if any, changes should be suggested to the Congress insofar as the Bill Reform Act is concerned. I think you are particularly referring to the Federal bill, title 18, section 1346, which was enacted in 1966, and whether changes are needed in that or not is still a question that is being explored.

There is a high incidence of bail jumping in places like the southern and eastern district of New York. We have been able to have an input into some of the thinking, but the office as established by the Congress precludes us from making policy determinations insofar as law enforcement.

However, under title 3 of our bill, we are participating with law-enforcement authorities in the articulation of a national strategy which we must promulgate 9 months after the enactment of the bill; namely, on December 21 of this year.

So I think that insofar as your thinking is concerned, it certainly is relevant and poignant, and it is one of the areas that we will be exploring in the total context of articulating a national strategy, which we must do, as I say, in the next 9 months.

Senator RANDOLPH. I realize we are talking about rehabilitation here and treatment and all these matters, but hand-in-hand must be this effort to not only apprehend the smuggler and confiscate the heroin or other drugs, but see to it that this person does not go free, and does not have the opportunity to do the same thing again and that is exactly what we have given to him.

You know, we have given him an opportunity. We have said in effect well, we are not charging you very much money here. You go out and do the job over again. So if he is caught again, it is a repeat.

He may not be caught. So he continues to smuggle, and I ask that the record reflect, Mr. Chairman, once again, a \$74 million market value of this heroin, and a bail bond of \$100,000.

Mr. PERITO. Senator, I am particularly sympathetic with your views, having been a prosecutor in the southern district of New York for 4 years, and again having had defendants, especially foreign defendants, flee, and not being able to extradite them.

I am exceedingly sympathetic with that, and it is clear, as you have stated before, that the question of availability is inextricably tied to

our entire program. We meet on a weekly basis with Myles Ambrose, Director of the Office of Drug Abuse Law Enforcement. We are in constant contact with BNDD. We are trying, I think for the first time, to tie these two efforts, together. There is no question but that, as the study done in the southern district of New York between 1960 and 1970 showed, a very high percentage of defendants in narcotics conspiracy cases—over 50 percent—flee the jurisdiction and are not apprehended.

It also shows the confiscation of money as a result of failure to appear in excess of \$680,000. We met approximately 4 weeks ago with the U.S. attorney for the southern and eastern districts of New York, the Honorable Whitney North Seymour and Robert Morse.

We discussed the treatment alternatives to street crime, but I know their personal views in the jurisdiction where there is a high incidence of bail jumping, as well as the U.S. attorney in Miami, and you can be sure that will be taken into consideration when the national strategy is articulated.

Senator RANDOLPH. Thank you very much. Thank you, Mr. Chairman, for allowing me to go aside, really, but yet zero in on what I know is a very crucial problem in all this attempt being made to reduce the crime, reduce the addiction.

Thank you very much.

Senator HUGHES. Thank you, Senator Randolph.

Dr. Jaffe, the HEW fiscal year 1973 budget is now being considered by the Labor and HEW Appropriations Subcommittee, as you well know.

How much is requested in that budget for all these drug programs, can you tell me?

Dr. JAFFE. How do you want it broken down, sir?

By treatment, rehabilitation?

Senator HUGHES. I want the total.

Dr. JAFFE. We will get you that in a second. I believe it is \$167.9 million for HEW.

Senator HUGHES. How much of that is earmarked in your budget for methadone maintenance, can you tell?

Dr. JAFFE. There is no specific earmarking at all for methadone maintenance.

Senator HUGHES. Do you know what the original NIMH request was for drug programs?

Dr. JAFFE. Yes; I believe it was \$148.7 million, in NIMH.

Senator HUGHES. Yes.

Dr. JAFFE. What we reviewed and what was eventually passed was precisely what they asked for. Now, I won't go back to that, because I really think there were no substantial changes made in the area except for some shifting of requested amounts to other budget categories.

Senator HUGHES. All right. They are here anyway.

Because of the time and the witnesses, Dr. Jaffe—

Dr. JAFFE. You asked me the HEW budget. What I gave you was the HEW, and then you asked me how much did NIMH ask for.

Senator HUGHES. Yes.

Dr. JAFFE. They asked for around \$148 million, which is in the fiscal year 1973 budget.

Senator HUGHES. \$148 million?

Mr. PERITO. \$148.7, Senator. That is without the supplemental moneys that have not been sent up yet.

Senator HUGHES. Was that the original request, or after OMB reviewed it?

Dr. JAFFE. I don't recall precisely what the original request was. My recollection is that there were no substantial changes except for some shifting of requested amounts to other budget categories.

Senator HUGHES. It is late, and we have a number of witnesses left, and at the rate we have been going, I have 7 hours questioning left for you. I think the best thing I can do is submit some questions to you which I hope we can get written responses to a little better than we have on some other things we have asked your office for.

Dr. JAFFE. If you find that they are not coming through, Senator, I would appreciate your letting me know.

Senator HUGHES. All right, I will let you know right now on one, then. At your confirmation hearing, you promised the committee a letter on the need for the drug abuse education legislation.

Dr. JAFFE. That response was sent out, sir. This was on review of the Drug Abuse Education Act.

Senator HUGHES. None of us have seen it on either side of the aisle here. If it was sent out, who did you mail it to?

Dr. JAFFE. I saw the letter go to Senator Javits.

Senator HUGHES. His legislative assistant, Jay Cutler, has not received it.

Dr. JAFFE. I sent it, I signed it. I will get you a copy of it.

Senator HUGHES. Would you mind getting me one, too, and copies for the rest of the committee?

Dr. JAFFE. We will be happy to.

(The information subsequently supplied follows:)

EXECUTIVE OFFICE OF THE PRESIDENT,
SPECIAL ACTION OFFICE FOR DRUG ABUSE PREVENTION,
Washington, D.C., May 23, 1972.

Hon. JACOB K. JAVITS,
U.S. Senate, Washington, D.C.

DEAR SENATOR JAVITS: This is in response to your request at the Senate Labor and Public Welfare hearings on April 11, 1972, for a letter presenting my views on the Drug Abuse Education Act and my recommendations for its future role in the federal effort to combat drug abuse. Drug abuse education has always been an important segment of the overall efforts to prevent the abuse of drugs. The federal government in the past year alone has substantially increased the amount of funds available for education and training, and I am certain that, as time goes on, larger commitments to this aspect of our overall program will be made.

The Drug Abuse Education Act is due to expire in Fiscal Year 1973. The programs under it have been in operation for only 2 years, and I have just learned that little evaluation of the kind I believe is necessary rational judgment has been undertaken. Accordingly, I have instructed my staff to accelerate our plans for meaningful evaluation of those programs so that I will be in a position to provide you and the Congress with a realistic appraisal of what has been accomplished. Since we have over a year until the present Act expires, I feel there is sufficient time for this to be done. I am hopeful that we will have some answers in the not too distant future at which time, I will be glad to again discuss the matter with you.

Sincerely,

JEROME W. JAFFE, M.D., *Director.*

Senator HUGHES. It will eliminate some of the doubt we have about getting responses to other questions. Could I ask you just a couple of questions, and I will be brief, if you will. Don't give me a speech with each response. If you don't know this answer, tell me, or if it is in doubt, just tell me that.

First, I want to go back to one subject. Is there just one company manufacturing methadone?

Dr. JAFFE. No, there is one other.

Senator HUGHES. I have been told the Lilly Co. does not make a profit on the sale of methadone. Do you know whether that is true?

Dr. JAFFE. It is very hard to tell.

Mr. PERITO. Senator, just for clarification, on that, dolophine hydrochloride which they marketed for other indications, we assume that they must have made a profit on that. Whether they made a profit on the medication they have marketed for detoxification and maintenance is another question, but it is used as an analgesic in hospitals, and I assume they make a profit on that.

Senator HUGHES. I would like to clarify something on page 10 of your statement which worried me when you gave it. The first paragraph says "as a result, we have concluded that methadone maintenance should be made available for all addicts who consent to use it under approved treatment programs."

What do you mean by that word "consent"?

Dr. JAFFE. As you know there is great concern that the Government will force people to take methadone.

Senator HUGHES. That is the reason I am asking the question.

Dr. JAFFE. We feel that it would be inappropriate to require that people take medication, even though it is no longer considered investigational in that sense. Some people will raise the issue they don't have very much alternative if the court says, "Get into treatment," and methadone is the only treatment they want.

I am not sure that is coercion. People do have alternatives. I don't think it appropriate that the court order someone to take methadone, or that people be involuntarily committed to a methadone program.

I think that is what the intent of that statement is; it is a philosophical view.

Senator HUGHES. Let me get an example. Do you think men ought to be offered parole, for example, subject to the use of methadone?

Dr. JAFFE. Subject to treatment. Treatment can take a variety of forms. If someone relapses to heroin use, then the treating agency might say that he is not successful in an abstinence program, offer him methadone, and if he refuses it and says he elects to continue using heroin, he is obviously failing in the treatment, and one can say he has the option of having his parole removed, or moving into a methadone program.

Senator HUGHES. That is not what I am saying. Should a parole board say to the prisoner who is being reviewed for parole, "Will you go on a methadone maintenance program if we grant you a parole?"

Dr. JAFFE. I think that is much too specific, and I would be unhappy with that kind of alternative offered a man who is in prison who is not currently using a narcotic, and to say that he leaves prison and that they start to give him methadone. I think this vitiates the very possibility of recovery here.

Some data was presented yesterday to indicate that people who have, in fact, served a prison term have the best possibility of achieving long-term abstinence. I am not advocating prison terms. I am saying there is a possibility that if this one has been off narcotics long enough I am not sure it is appropriate to require that he take methadone to get a parole.

Senator HUGHES. Would you recommend against that?

Dr. JAFFE. I think I would; yes.

A lot of these will be under State jurisdictions, and the issue is whether or not we can, in fact, prohibit it. But I would recommend against this position.

Senator HUGHES. I understand, but your voice does have influence in State programs.

Dr. JAFFE. Yes.

Senator HUGHES. On programs that have Federal grants you can certainly set up guidelines, or at least I am under the impression you can.

Dr. JAFFE. We are working on those guidelines.

Senator HUGHES. I have one question that I don't want to pass up, because of its importance in the overall consideration of methadone. You mentioned it somewhat in your opening statement, and you have been aware of it all the years you have been working in the drug programs, and I have been, too.

There were stories in the press about 10 days ago about a conference in Baltimore, in which there were heated accusations that methadone was a tool of racial and political repression. When I have held hearings in black sections of cities in America, the statement has been made, that it was a vehicle of people to keep black males repressed.

I would like you to speak to that for a moment.

Dr. JAFFE. I find the statement somewhat mysterious. The people I have seen treated with methadone are not suppressed. They are liberated. They don't have to buy heroin at high prices from pushers. They are able to work, they are able to participate in the mainstream of society, some of them for the first time in their lives.

Now I have never viewed it as anything but something which frees somebody from pressure that otherwise seems inescapable, and I am referring primarily to people from minority groups. It is very hard for me to respond to something which seems illogical.

I have not seen the basis, or really perceived the basis then for the accusations, and if someone will enlighten me further on the logic of it, I will try to respond to it in whatever way seems appropriate.

I have heard the same things that you have. I have also seen thousands of patients treated.

Senator HUGHES. How many years did you work in the clinic in Chicago?

Dr. JAFFE. It began in 1966. We were using methadone in New York prior to that time.

Senator HUGHES. You found no evidence of this at all?

Dr. JAFFE. I think that to a certain extent if one feels that it is one's legitimate right to rob and steal from other people of the community, regardless of what ethnic groups they belong to, then you could raise an objection to methadone in some programs.

The programs operated in some areas do expect that the patients participating will, in fact, begin to be law abiding. To the extent that that is repressive and controlling, then one begins to have some basis for that kind of an accusation.

I don't happen to feel that expecting them not to commit major felonies is in any way repressive. So from my point of view it is not a legitimate objection, and we have taken the position that we will continue to offer this treatment to those who want to participate in it.

I have already taken the position we should not want to coerce people into it. We are really addressing the issue of whether the people should be volunteers for this kind of treatment.

Senator HUGHES. Thank you very much, Dr. Jaffe. I won't pursue the questions any further, because the hour is growing late. We will submit to you a written series of questions which we will get responses to as soon as you are able to give them to us.

(The information, subsequently supplied, appears on p. 187.)

The Chair calls Dr. DuVal.

STATEMENT OF DR. MERVIN K. DuVAL, ASSISTANT SECRETARY, HEALTH AND SCIENTIFIC AFFAIRS, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY DR. CHARLES C. EDWARDS, COMMISSIONER OF FOOD AND DRUGS; DR. BERTRAM S. BROWN, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH; AND DR. JOHN S. ZAPP, DDS, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION, HEW

Senator HUGHES. You may proceed, Dr. DuVal.

Dr. DuVAL. It is a pleasure to appear before you again, Mr. Chairman, to discuss new Federal initiatives on the use of methadone in narcotic addiction treatment, and also S. 2840, a bill to authorize emergency assistance in the establishment of narcotic addict maintenance, treatment, and rehabilitation programs.

The chairman and members of this subcommittee are already well informed on the problems of drug abuse and there is no need for a general discussion of the nature and the extent of this situation. More pertinent, I think, is a discussion of the steps now being taken to combat this serious problem which has generated widespread public concern.

HEW DRUG ABUSE ACTIVITIES

As you know, several agencies within the Department of Health, Education, and Welfare have programs concerned with drug abuse.

The National Institute of Mental Health supports treatment and rehabilitation programs, primarily through grants to public and private nonprofit organizations.

NIMH also supports research to provide knowledge as to the causes, prevention, and treatment of narcotic addiction and other forms of drug abuse. NIMH funds a wide range of drug abuse information and education activities, and coordinates the health education aspects of all Federal drug abuse education projects.

The Office of Education is active in the development of new drug abuse curriculum material and makes grants for the training of school personnel in the fundamentals of drug abuse education.

The Social and Rehabilitation Service supports vocational rehabilitation services, often an essential part of treatment programs for drug abusers.

The Food and Drug Administration has the important responsibility for a continuing evaluation of the safety and efficacy of methadone and other drugs used in drug abuse treatment programs. FDA is also responsible for assuring that the labeling of all drugs and the advertising of prescription drugs accurately reflect their drug dependence potential. In addition, FDA has authority to reclassify drugs from nonprescription status to prescription status because of drug abuse potential. Paregoric has recently been reclassified for this reason.

Mr. Chairman, in view of the fact that this remainder of the testimony is a recitation of the testimony Dr. Jaffe has given you, and in view of the fact that you have a large number of such witnesses, I would suggest that you authorize me to submit this for the record instead of taking your time to read it this morning.

Senator HUGHES. Thank you very much, Dr. DuVal, we will incorporate the statement in the record as though delivered.

(The prepared statement of Dr. DuVal follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT

BY

MERLIN K. DUVAL, M.D.

ASSISTANT SECRETARY FOR HEALTH AND SCIENTIFIC AFFAIRS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE

THE

SUBCOMMITTEE ON ALCOHOLISM AND NARCOTICS

SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

MAY 23, 1972

Mr. Chairman and Members of the Subcommittee:

It is a pleasure to appear before you again, this time to discuss new Federal initiatives on the use of methadone in narcotic addiction treatment, and also S. 2840, a bill to authorize emergency assistance in the establishment of narcotic addict maintenance, treatment, and rehabilitation programs.

The Chairman and Members of this Subcommittee are already well informed on the problems of drug abuse and there is no need for a general discussion of the nature and the extent of this situation. More pertinent, I think, is a discussion of the steps now being taken to combat this serious problem which has generated widespread public concern.

HEW DRUG ABUSE ACTIVITIES

As you know, several agencies within the Department of Health, Education, and Welfare have programs concerned with drug abuse. The National Institute of Mental Health (NIMH) supports treatment and rehabilitation programs, primarily through grants to public and private non-profit organizations. NIMH also supports research to provide knowledge as to the causes, prevention and treatment of narcotic addiction and other forms of drug abuse. NIMH funds a wide range of drug abuse information and education activities, and coordinates the health education aspects of all Federal drug abuse education projects.

The Office of Education is active in the development of new drug abuse curriculum material and makes grants for the training of school personnel in the fundamentals of drug abuse education.

The Social and Rehabilitation Service supports vocational rehabilitation services, often an essential aspect of treatment programs for drug abusers.

The Food and Drug Administration (FDA) has the important responsibility for a continuing evaluation of the safety and efficacy of methadone and other drugs used in drug abuse treatment programs. FDA is also responsible for assuring that the labeling of all drugs and the advertising of prescription drugs accurately reflect their drug dependence potential. In addition, FDA has authority to reclassify drugs from nonprescription status to prescription status because of drug abuse potential. Paregoric has recently been reclassified for this reason.

The Department's drug abuse activities have been increased almost 300 percent since 1971 to a total of \$168 million for FY 1973.

METHADONE MAINTENANCE

Among the many approaches concerned with the treatment and rehabilitation of drug addicts is the use of a drug known as methadone. As you may know, methadone is an approved drug for marketing as an analgesic, an antitussive, and for the detoxification of narcotic addicts. Methadone has been under investigation for nine years for use as an oral substitute

for heroin in the maintenance treatment of narcotic addicts. It is the only heroin substitute tried to date for which there is evidence of effectiveness in the treatment of heroin addiction.

Consideration of methadone as a therapeutic tool must include a complete and realistic assessment of its assets and liabilities.

Methadone is an addicting, synthetic narcotic which, when taken by mouth, may produce a minimum euphoria, but obscures most of the pleasurable effects of narcotics during the duration of its effects and satisfies the physiological craving for other narcotics.

Experienced clinicians in the field agree that by itself methadone is not a miracle drug and does not cure the economic, psychological, social and anti-social problems of the addict. In fact, we believe methadone maintenance programs are most effective when combined with additional services which enable the patient to develop the inter-personal, social and vocational coping skills that are needed for a productive and satisfying life style. Methadone does, however, in many instances, relieve the crisis pressure of heroin use and enables an addict to enter a treatment system.

When used in the maintenance treatment of narcotic addiction, methadone has been subject to the investigational new drug (IND) requirements under the Federal Food, Drug, and Cosmetic Act.

In April of 1971, FDA published guidelines for investigating the use of methadone in narcotic addict maintenance treatment. These guidelines were intended to insure the availability of valid data on such use, to protect the community from the hazards of diversion and abuse of methadone, and also to insure satisfactory medical care in the treatment of narcotic addiction. The guidelines were developed in cooperation with NIMH and the Bureau of Narcotics and Dangerous Drugs (BNDD), Department of Justice. To date, under these guidelines FDA and BNDD have approved some 310 methadone maintenance programs; satellites of such programs bring the total of actual treatment programs to about 450. It should be noted, however, that the number of patients who can benefit from methadone maintenance under these guidelines, while significant, is not all inclusive. In other words, methadone is a very useful adjunct, but by no means a universal panacea for the total heroin problem in this country. Therefore, the Department must continue to pursue research questions about the drug as well as take effective action to control its distribution and use.

CONTINUED RESEARCH IS IMPORTANT

Studies are currently underway at the National Institute of Mental Health (NIMH) on the effects of long-term methadone use on human physiology and psychological functioning. These studies include the effects of methadone on the functions of the liver, hormones, brain as well as sleep. Studies are also needed on the interaction of methadone with other drugs which may have to be given to treat illnesses unrelated to the patient's

addiction. The effects of methadone on the developing human fetus and the health of young adults should be further studied. Lately, more information is needed on the effects of methadone maintenance on addicts with other diseases such as diabetes and heart disease.

A potentially important development in methadone maintenance therapy is the introduction of L-alpha-acetyl methadol (LAAM), a long acting methadone which will last 48 or even 72 hours instead of the present 24 hours that methadone administered orally is presumed to act. This may provide a much more convenient, and in many cases, more desirable substitute for the present drug which requires daily clinic visits and a take-home supply over weekends. The Institute has obtained a limited supply of LAAM and is encouraging its research evaluation. A recently approved grant will study the chronic psychosocial, physiological and cognitive effects of methadone and LAAM in the treatment of heroin addicts.

We should also mention that FDA is monitoring the testing of other drugs that may be useful as narcotic antagonists. The search continues for a medication that will block the euphoric effects of heroin for addicts, prevent withdrawal symptoms, be nonaddictive, effective orally, long acting, free from toxic effects, and compatible with normal performance and reasonable behavior.

It is our firm intent, although methadone is being more widely used and accepted, that we continue in a responsible medical and scientific tradition to ask the critical and difficult questions. In part, this is necessary to answer concerns about the use of methadone that have been raised by potential consumers of drug treatment services, particularly among certain groups who represent themselves as spokesmen for minority populations. We need to allay this kind of concern regardless of whether it is medically justified.

These foregoing areas of investigation do not negate the fact that methadone has served as an extremely effective tool in bringing many heroin addicts into treatment who had previously avoided any therapeutic efforts. We only suggest that no particular course of treatment is necessarily the appropriate choice for every patient population.

NEW STATUS FOR USE OF METHADONE

We do know that methadone maintenance treatment may continue for long periods of time. Because the short-term use of the drug has been shown to be relatively safe from a toxicity standpoint, and substantial evidence exists as to its effectiveness in the treatment of heroin addiction, we have, therefore, concluded that retention of the drug solely on investigational status appears to be no longer warranted. However, more information is necessary on the toxicity of long-term use. It has been suggested that the investigational status of the drug

should be retained both to obtain additional toxicity data and as a control mechanism, at least until greater experience is obtained in reducing the potential dangers of diversion and medical misuse.

Balancing the benefits against the risks, however, the Food and Drug Administration and numerous professional groups, advisory committees, and experts with whom it has consulted have concluded that the drug should be made available for all addicts who consent to use it in approved treatment programs. At the same time, concern has been expressed that the usual form of new drug application (NDA) approval could lead to greater diversion or misuse of the drug, since it permits unrestricted distribution and allows physicians to use wide discretion in prescribing the drug. Also, some have pointed out that it is premature to move completely from IND to NDA status because more information has yet to be obtained.

We concur that unlimited approval of an NDA for methadone would not be appropriate at this time. Therefore, to provide the strongest possible control over the distribution and use of methadone, the Commissioner of FDA published in the April 6 Federal Register new proposed Federal guidelines providing for methadone maintenance treatment under both the IND and NDA mechanisms, together with the authority granted under the Comprehensive Drug Abuse Control Act of 1970.

Like an NDA, the drug will be available for treatment in all cases where there is medical justification. Like an IND controlled drug, there will be a permanent record showing the pattern of distribution of the drug because the institutions using the drug and the physicians and pharmacists operating in cooperation with the institution will be required to register all use of the drug.

This approach will permit FDA to withdraw methadone from pharmacies where it is now available for the presently approved uses. Distribution of methadone will be restricted to direct shipments to approved investigational programs and hospital pharmacies. Thus, a new closed system of distribution will be established, under which any diversion or misuse can immediately be stopped at the source of supply. At the same time the drug will be available for use for all addicts for whom it is medically justified.

These new controls should not interfere with the availability of methadone in the treatment of severe pain or for detoxification of hospitalized addicts. Methadone for the treatment of severe pain on either an inpatient or outpatient basis will be available from hospital pharmacies. Methadone will no longer be permitted for antitussive use as the benefits of methadone for this use do not outweigh the risk involved from unsafe and ineffective use.

The proposed regulations would not admit patients under 18 to a methadone treatment program until additional studies are completed to determine whether this drug may be safely and effectively used in their treatment. Comments are also being solicited on this aspect of our proposed regulation.

STATE PARTICIPATION

We believe that State health or mental health authorities are essential to adequately controlling methadone, to assuring that the need for a methadone program exists, and to establishing criteria and guidance for rehabilitation efforts. Approval of a methadone program by the appropriate State health or mental health authority will be a part of approval of the programs by FDA.

In order to establish the necessary channels of communication, on April 21, FDA met with representatives of 48 of the 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands. (The other two States did not attend stating they had no significant drug problem.) Procedures for the implementation of methadone programs were discussed and the States were asked to provide FDA with the name of a designated authority or individual within the State to coordinate its drug abuse efforts with FDA in the regulation of its methadone program.

METHADONE PROGRAM INSPECTIONS

In another recent effort, FDA, in cooperation with Health Services and Mental Health Administration and the White House Special Action Office

for Drug Abuse Prevention, has launched an intensive inspection program to insure that existing programs are operating in accordance with the guidelines published last year.

Orientation sessions for 100 FDA inspectors and Public Health Service medical professionals were held by the Food and Drug Administration on April 3 and 4 of this year. Following these training sessions the group was organized into two-man teams to conduct a nationwide review of all the methadone programs. Recently, 30 teams have been added to insure that the inspection of all programs would be completed by May 31, 1972.

The teams will examine procedures intended to safeguard against the diversion of methadone from the maintenance clinics and to prevent non-addicts from entering methadone treatment. The teams will also make recommendations to improve the quality of medical and counseling aid to patients in these programs; survey national treatment needs by measuring the numbers of patients on treatment waiting lists; and determine the capacity of clinics to expand in order to treat additional patients if given additional resources.

The new inspection program and the new guidelines represent major elements in efforts to expand the availability of treatment for heroin addicts while protecting against illicit diversion and other related problems.

Clearly, we have a therapeutic tool which has significant benefits for part of the addict population, but if poorly managed, could have potentially harmful effects on the very population we are striving to help. We intend to ensure that methadone maintenance treatment is available to all those individuals and communities who can and wish to benefit from it. At the same time, we recognize our responsibility to apply the highest standards of public health administration to this program to prevent diversion and inappropriate use of the drug.

S. 2840

This brings us to the consideration of S. 2840, now before this Committee for review.

The bill would amend the Public Health Service Act by adding a new title, "Drug Addict Treatment," establishing a program of formula grants to the States to develop these programs with specific emphasis upon the administration of the heroin antagonist drug, methadone. State shares would be determined by a formula, taking account of population, financial need, and need for more effective drug prevention, treatment, and rehabilitation programs for heroin addicts. The authorizations are left open but no State would receive less than \$200,000 per fiscal year, as a minimum allowance.

As a condition of receiving grants under this program, the bill requires a State plan. The plan must, among other requirements, mandate the administration of methadone to medically determined heroin addicts who volunteer for treatment in public or nonprofit private centers, in facilities operated in accordance with State or local standards. In States in which there is no plan, public and nonprofit private agencies may apply to the Secretary for funds allocated to the State.

The bill also authorizes a separate program of short-term training grants to medical and paramedical institutions to assure the availability of trained medical and allied health personnel.

We believe that the provisions of S. 2840 are unnecessary. More than sufficient authority already exists to implement a broad spectrum of drug treatment and rehabilitation programs. The Community Mental Health Centers Amendment of 1970 (P.L. 91-211), for example, amended section 261 of the Community Mental Health Centers Act (P.L. 88-164, as amended). This now authorizes the Secretary of Health, Education, and Welfare to make grants to local public and nonprofit private organizations for projects to assess local needs and design service programs for narcotic addicts. An amendment to section 252 of the Centers Act permits the Secretary to make grants to any public or nonprofit private agency or organization for treatment and rehabilitation of narcotic addicts which the Secretary determines are of special significance because they demonstrate new or relatively effective or efficient methods of delivery of services. Additional grant programs for a variety of treatment modalities for drug abusers, were added to the Centers Act by the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91-513).

The Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), signed into law on March 21, 1972, also authorizes Federal aid programs to assist in coping with problems of narcotic and other drug abuse. These authorities, we believe, are more than sufficient to encompass support for maintenance programs.

We also wish to comment specifically on particular provisions of the bill.

Section 1106 requires each State in its State plan to mandate methadone maintenance as an essential service in all community mental health centers and certain other approved facilities. We do not believe this kind of provision is appropriate or desirable.

Methadone maintenance is one of a number of available treatments. While it is helpful to many addicts, it is certainly not applicable in every situation. The personal and therapeutic needs of addicts are varied and no one substance or therapeutic approach can effectively serve all patients. Other treatment approaches include detoxification and abstinence, therapeutic communities, and other counseling model treatments. Narcotic antagonists such as naloxane and cyclazocine are also being actively studied to determine their safety and utility. Legislating the compulsory use of any particular approach seems unwise. In addition, community mental health centers might not be considered the best delivery system for methadone maintenance programs in certain areas because of catchment population limitations.

We also believe the formula grant program proposed in the bill is an unresponsive approach to the formidable task of alleviating the multiplicity of problems attendant to heroin abuse and dependence. The Administration and this Department have repeatedly voiced its concern at the continued development of categorical formula grant programs which in effect further fragment our activities concerned with Federal health assistance. Formula grant programs bring with them the inability

to target available funds to specific areas of need. As a result, some areas are inadequately funded and others receive funds beyond their needs. Although drug abuse is a national problem, it is not equally distributed throughout the Nation. No formula is likely to match resources with need and the categorical aspect of the program would prevent the funds from being used for any other purpose, even if the State preferred. The separate application/award procedures that would be required would be only another block in the already confusing structure of Federal programs that serve to frustrate rather than facilitate the allocation of public resources. At a time when these resources are relatively limited in comparison with problems of national need, another categorical formula grant program is the most expensive possible approach to any problem.

Additionally, the great majority of States lack the personnel and resources to mount the comprehensive drug programs required by the bill and to administer a State plan. An example is the requirement that drug programs in every center or facility provide comprehensive rehabilitation services such as legal assistance. These kinds of conditions are unrealistic in terms of available public funds and premature in terms of State capabilities.

Finally, there are serious technical problems. The proposed Sec. 1109 would provide that no Federal law shall be construed to prohibit the use of methadone. Thus, the Food and Drug Administration would be

unable to withdraw approval of this drug if the circumstances warranted--such as the development of a safer antagonist or new information showing serious adverse affects. The provisions of the Federal Food, Drug, and Cosmetic Act are designed to protect the public from unsafe and ineffective drugs and they should not be abrogated.

The language of S. 2840 also leaves unclear whether the Secretary could impose all the present controls now applicable to methadone. It is also unclear whether all the controls applicable to investigational drugs under the Federal Food, Drug, and Cosmetic Act and the Controlled Substances Act could be applied if an investigational drug were designated as a heroin antagonist.

For these reasons we therefore recommend against enactment of the bill. We certainly share the concern of your Committee at the problems of drug abuse. However, we believe that existing legislation, including the recently enacted Drug Abuse Office and Treatment Act--P.L. 92-255--represent a fully sufficient legislative frame of reference to implement a national attack on this problem.

Dr. DuVAL. Our attitude is that the bill under consideration today is a duplication of authorities that exist. Our position is that the bill is unnecessary.

Beyond that, I don't think any of us has come prepared for a formal statement. We will be delighted to answer such questions as you may have.

Senator HUGHES. Dr. DuVal, both you and Dr. Jaffe referred in your statements to some 450 programs that were approved by the Federal Government to investigate the use of methadone in narcotics maintenance treatment. These were approved under guidelines published by FDA in April 1971, just about a year ago.

As I recall, these guidelines require periodic reports from each program. Could you tell me how many of these programs file such reports and what their findings were?

Dr. DuVAL. We have reports on a large number of them, but as I am sure you also detected from Dr. Jaffe's statement, and from mine, that part which was filed, we have put under a relatively crash-type program 100 inspectors into the field that are bringing all of the programs up to date from the viewpoint of contemporary useful information.

Between January 1 and April 4, 1972, for example, we have completed 80 of those inspections; and we are working between April 4, 1972, for completion by May 31, on a total of 329 additional.

The entire review will be complete by mid-June. That is the source of the figures that Dr. Jaffe had reference to earlier when he said we would know a lot more in a couple or 3 weeks.

Senator HUGHES. Could you supply us with a copy of that when it is completed, Dr. DuVal?

Dr. DuVAL. Yes.

(The information referred to follows:)

A REPORT ON THE ONGOING
METHADONE PROGRAMS

The following is an interim status report on the methadone inspection program, as of 6/23/72.

This inspection program was initiated to determine the status of methadone maintenance programs under part 130.44 of the methadone regulations published in the Federal Register on April 2, 1971.

An estimated 77,500 patients are under treatment in methadone maintenance programs. Additionally, approximately 33,000 addicts are on the waiting lists. These figures are based on data obtained from the Special Action Office Drug Abuse Prevention (SAODAP) Inventory List, data for which was collected during the April-May Inspectional Program.

At the present time, there are some 460 methadone programs in operation which include primary IND's and their satellites.

All approved IND methadone programs and satellites were visited during the period of January 1, 1972 and May 31, 1972.

- a. Treatment centers inspected *422
- b. SAODAP questionnaires prepared
(including 100 abbreviated) 460

*The 38 satellite programs of the New York City and Beth Israel IND's were specifically exempted from inspection.

Review of Inspectional Reports. As of June 23, 1972.

- a. Reports expected 422
- b. Reports received 358
- c. Reports reviewed 175

Review Results:

- a. Number of programs in substantial compliance 53
- b. Number of programs issued deficiency letters and scheduled for reinspection 113
- c. Number of programs with gross deficiencies, possible termination action 9

Senator HUGHES. In your statement, you say basically that the regulation on methadone would not admit patients under 18 unless additional studies are made to determine whether the methadone is safe and effective for this group.

You are also well aware that I think a tremendous number of teenagers are heroin addicts. There are addicts who have not even reached their teens yet. In some of the cites I have held hearings in, I had telephone calls from these kids. What do you propose for them?

Dr. DuVAL. We are not suggesting they would not be eligible. We are suggesting the juveniles would be handled under the IND form rather than under the new regulations.

I might add that I think the point you have made with which we are in complete concurrence shows more than ever the importance of doing research in order to find materials more effective than methadone, and certainly for which we can get evidence that the safety factor is such that we can use it more widely among the juveniles.

Senator HUGHES. In your statement you mention a recent meeting of the FDA and representatives of 48 of the 50 States. You note that two States did not attend, because they apparently have no significant drug problem. Can you tell me what those States are?

Dr. DuVAL. Montana and Wyoming.

Senator HUGHES. They don't want any money, then, for drug programs?

Dr. DuVAL. We can only take the evidence that they submit to us, Mr. Chairman.

Senator HUGHES. Is this what they are saying?

Dr. DuVAL. They have said that as far as they have been able to detect and measure, they do not feel they have a sufficient drug problem to have invested at this time in the concern that the other States have been investing.

Senator HUGHES. Do you believe that?

Dr. DuVAL. I would have then no way of knowing either way, Mr. Chairman. Of course, Montana and Wyoming, as you know, lack density of population, not only in totality, but in clustering. Under these circumstances, some of the situations that one sees as indigenous to the drug scene are not present in Wyoming and Montana.

Senator HUGHES. I hope you are not including alcohol in that.

Dr. DuVAL. You didn't ask about alcohol, Mr. Chairman.

Senator HUGHES. It is a drug.

They have a tremendous problem of alcoholism in some areas. I am amazed they would make a statement like that, particularly with the existence of military bases of some size in both States and also large ethnic populations. I am not thinking of black and Puerto Rican people, but American Indians, who can contribute to some of the problems because of the very nature of the social conditions they live in, usually; and that concerns me.

I will have to talk to Mike Mansfield about that and see if he feels that way.

I would like to ask Bert Brown if these States have no problem. Maybe we ought to conduct a study out there to see why they don't. What do you think?

Dr. BROWN. I think it is interesting that Montana has no problem considering the fact that there are two grant applications for drug

treatment programs for that State. I think we have the difference between the statewide definition of the problem by the State agency versus some concerned communities. So I think we have hard evidence that at least some people in the State of Montana are concerned that they have a drug problem.

Senator HUGHES. After talking with the majority leader in the Senate in the last 2 years—I am amazed at this. I am sure there must be lack of communication inside those States. I won't concentrate on this. It is really just suprising.

You heard me talking to Dr. Jaffe about budget requests, Dr. DuVal. Perhaps you could address yourselves to that for a minute. Could you tell us the total requests for grants received in 1971 and 1972 for NIMH drug treatment and rehabilitation programs?

Dr. DuVAL. I think we can do that. Let me be specific. You said grant requests received?

Senator HUGHES. The requests for grants received in your office. I am talking about people who applied for grants from NIMH.

Dr. BROWN. The total funds for all our programs at NIMH in fiscal 1972 were \$128 million. For treatment and rehabilitation, they were \$67 million. The question is how many people have applied for how many dollars that might be approved and funded.

We don't have a hard figure, but it looks like it will be somewhat more than that amount of money we have available.

Senator HUGHES. As I remember about a year ago, Bert, you had about five times as much money requested as you had funds available.

Are you cutting that down some, or do you still have a pile there?

Dr. BROWN. The available funds are getting much closer to the actual demand in the way of community applications.

Senator HUGHES. We still get a lot of mail from people who have sent in applications and are wondering why they are not being considered and what the delay is, and we are told to wait, sometimes, because of the unavailability of funds.

This stimulates our interest, naturally. We have had excellent cooperation from your department in trying to run these down, and I bring it up for that reason, but the indication is very strong to us that the funding has not been available in the first year to try to gear up to this to meet the needs.

Dr. BROWN. We are within shooting distance of having enough funds to make all the applications approvable and approved applications in fiscal year 1972. If we fall short, we are hopeful a supplemental will make all approvable or approved grants funded.

Senator HUGHES. On an estimate from the city of New York, what do you think it would take to take care of the narcotics program in the city of New York?

Dr. BROWN. Mr. Besteman whispered to me "a miracle."

Senator HUGHES. There is about \$67 million in the Nation, and I want to know how much would be needed to take care of that one city?

Dr. BROWN. If we could instantly launch all the treatment programs, staff facilities, organization and administration, I am sure that it would be somewhat more than the roughly \$100 million that were there, perhaps 300 or 400 million.

It is in the order of magnitude of hundreds of millions, to answer your question.

Senator HUGHES. That is the point I want to bring out. You are not saying that \$67 million is almost enough to solve the problem. You would agree with that; would you not?

Dr. BROWN. Yes, I would. It is proving to be enough, almost to put something in the outreached hand to help the communities.

Senator HUGHES. Could you tell me, Dr. Edwards, about cooperation now on the programs in methadone? Are you totally satisfied with the way the operational procedures are set up between FDA and NIMH?

Dr. EDWARDS. You are referring to the cooperative efforts between NIMH and ourselves? Yes, I think we have a very close working relationship with NIMH, with Dr. Jaffe's office.

Certainly the last 6 months it is far better than it has been since I have been here.

Senator HUGHES. What about research on other antagonists? What are you looking at now?

Dr. EDWARDS. I would ask Dr. Gardner who heads our Division of Neuropharmacological Drug Products to respond to that.

Dr. GARDNER. There are six actively being studied now, and there are a number of others probably coming up very soon.

Senator HUGHES. Do you have any reports you would give us that would be enlightening on any of these?

Dr. GARDNER. Yes, I do.

(The information referred to follows:)

A SUMMARY OF NARCOTIC ANTAGONISTS
NOW UNDER STUDY

There are at present six narcotic-antagonists which are undergoing clinical trials for the treatment of opiate dependence. In addition there is one methadone-like drug LAAM which is being studied as an alternative to methadone in maintenance therapy.

Briefly, a summary of the evaluational status of these agents follows:

(1) Naloxone (oral) - An injectable form of this compound has already been approved as a narcotic antagonist for treating acute opiate overdosage. However, oral naloxone as a narcotic blocking agent for the treatment of opiate dependence is still in an investigational stage.

At the present time it appears that the short duration of action of naloxone and the necessity of giving large oral dosages in man due to poor absorption will prevent this drug from being utilized on a large scale in the treatment of opiate dependence. However, some investigators have been able to extend the duration of heroin blocking action by up to 24 hours by giving very large oral doses.

The limited utility of naloxone thus far is unfortunate since the toxicity of naloxone is low and the side effects are minimal when compared to the other opiate antagonists under investigation. An additional advantage of this drug is that it has no agonistic (morphine like) activity, causes no physical dependence, and has no abuse liability.

(2) Naloxone Pamoate (injection). This formulation of naloxone was prepared to avoid the oral route of administration (since large doses are necessary) and to prolong the duration of narcotic blocking action of naloxone. Initially, animal studies were very promising in that the preparation appeared to block the effects of morphine for one to two days in rodents and for 7 to 14 days in dogs.

The results of the preliminary human studies have not yet been officially reported to the FDA. However, information presented informally and at scientific meetings indicates that the prospects for clinical utility of this preparation are not promising. Naloxone pamoate can last up to 48 hours in man. However, its duration of action is variable among subjects and there is some pain at injection sites. It would seem that a much longer duration of action would be necessary before the drug would be clinically useful.

(3) d,l, cyclazocine. This substance is a potent, orally active, and long lasting opiate antagonist which unlike naloxone has significant agonistic activity. This agonistic activity is manifest by its ability to relieve pain (as does morphine) and in a high incidence of central nervous system effects which may include hallucinations. These side effects are sometimes (though not always) dysphoric or unpleasant to those taking the drug.

The d,l, cyclazocine has been used in clinical trials to test its ability to block the effects of heroin and for potential practical utility in the rehabilitation of former opiate dependent persons. The theory of treatment being that if cyclazocine could provide continuous, or near continuous, blockade against heroin, then the addict would eventually cease or reduce the self-administration of heroin. In addition cyclazocine should prevent the development of physical dependence even if former addicts continued to inject heroin intermittently.

There are at present eleven studies in progress which are evaluating the usefulness of cyclazocine treatment in former opiate addicts. Although not enough data have been accumulated and evaluated to provide definitive statements regarding the effectiveness of cyclazocine treatment, most investigators agree that: (a) cyclazocine treatment alone, without additional psychiatric and counseling help is of little value in treating opiate addicts. (b) cyclazocine treatment when combined with other therapeutic modalities, does provide a useful tool for treating a certain segment of the addict population (c) that cyclazocine therapy is not applicable to all opiate addicts - at least by using the adjunctive methodologies currently at hand.

(4) l cyclazocine - This compound has been recently prepared and is being tested for the same purposes as d,l, cyclazocine. The hoped-for advantage of l cyclazocine (compared to the d,l form) is that it may have less or no CNS side effects such as dysphoria, dizziness, lethargy, etc. At the present time no formal reports of the clinical trials have been received at FDA. However, informal reports indicate that l, cyclazocine offers no distinct advantage over d,l, cyclazocine in incidence or severity of side effects.

(5) BC 2605 - This is an orally active potent narcotic antagonist. Studies are still in the initial phase of exploring possible dose ranges and side effects. Although reports are not yet formalized, preliminary studies indicate that this drug does have agonistic activity which is manifest by CNS effects similar to those of cyclazocine. (Dysphoria, hallucination, dizziness, etc.)

Studies are now underway to determine if one can initiate drug administration at low dosages and gradually increase drug administration as tolerance develops to the unpleasant side effects. Past experience has shown that this procedure does work for cyclazocine, thereby increasing patient acceptability of drug treatment. The results of these studies have not yet been communicated to the FDA.

(6) EN 16 39A - This is a narcotic antagonist with some degree of cyclazocine nalorphine-like agonistic activity (pupillary constriction and some psychotomimetic effects). However, these effects are less than with cyclazocine. It is orally active but less so than cyclazocine. This drug has not been extensively studied primarily because of its relatively less oral potency than other agents and because it offers no real advantage in terms of duration of action.

Summary:

The "ideal" narcotic antagonist for use in treating opiate dependence has not yet been developed. However, enough evidence has been gathered to indicate that this approach to treatment is feasible and useful for some, but not all, opiate dependent persons. Newer approaches such as the development of long acting (one week or more) depot preparations of antagonists appear to be promising. However, other than naloxone pamoate (which did not give the hoped-for duration of action) none of these preparations has yet been tested in man.

Addendum:

In addition to the antagonists there is also under investigation the heroin substitute which is a longer acting derivative of methadone. This substance is L-alpha-acetylmethadol (or LAAM). There are nine investigators presently studying the use of LAAM in maintenance therapy.

The feasibility of using LAAM appears promising. Its longer duration of action, compared to methadone, is a significant advantage of the drug.

LAAM is currently being tested for chronic toxicity in animals. The results of these studies will be evaluated in relation to the results of the present limited clinical trials before the feasibility of large scale use of LAAM is determined.

There is an additional study investigating the feasibility of combining the pure narcotic antagonist, naloxone, with the narcotic, methadone, for the purpose of preventing the abuse of methadone by the intravenous route. The theory for this combination is that naloxone is poorly

absorbed orally yet is a highly potent antagonist when injected. Therefore oral naloxone-methadone combinations could be used as normal in methadone maintenance programs; naloxone would be essentially a "placebo" by the oral route while methadone would have its usual effect. However, if injected, the naloxone would immediately precipitate abstinence symptoms or would block the euphorogenic effects of methadone.

Preliminary studies indicate that naloxone does not interfere with methadone when taken orally. Therefore this aspect of the proposed combination appears feasible.

However, because the duration of naloxone is less than that of methadone, the euphorogenic effect of methadone is postponed, not blocked, after intravenous injection. That is, the effects of methadone appear after the blocking effect of naloxone has worn off. In addition, the severity of withdrawal symptomatology which might be induced in opiate dependent persons who injected the combination have not yet been fully evaluated.

It would appear that this combination looks promising but is not ideal.

Dr. BROWN. Senator Hughes, we have a rather helpful report from the PMA special task force on drug abuse, which talks to some of the antagonists. It is dated April 21, 1972. It is brief and very helpful, covering some of the antagonists and other hopeful drugs. I was particularly pleased at this, because it shows we are finally getting private industry in on the act, somewhat more than lipservice.

Senator HUGHES. Will you explain that to the members of the committee?

Dr. BROWN. Yes.

Senator HUGHES. Will you give one for the record. I would like to incorporate it in the record, also.

(The information referred to follows:)

COOPERATIVE DRUG STUDY MAKING PROGRESS IN FINDING NARCOTICS
ANTAGONIST, HEROIN SUBSTITUTES, NEW APPROACHES TO THERAPY

(The Pharmaceutical Mfrs. Assn. Special Task Force on Drug Abuse made its second report to Rep. Rogers' (D-Fla.) House Health Subcommittee. April 21. The report was released at a press conference in Rogers' office)

Report No. 2, PMA Special Task Force On Drug Abuse

April 21, 1972

Our continuing assessment of the efforts of the pharmaceutical industry in combatting narcotic abuse permits us to report progress from a number of companies on several fronts. Many other firms have reported ongoing research programs in the drug abuse area but do not have specific advances to report at this time.

Narcotic Antagonists: Levo-cyclazocine, a potent narcotic antagonist reported by Winthrop to produce no psychotomimetic effects in limited human study, had been offered to the Addiction Research Center at Lexington, Ky., for further evaluation. An IND has been filed by Lexington, supplies of the drug were sent by Winthrop and studies in addicts have now begun. It is the object of the research at Lexington to determine whether levo-cyclazocine represents a true advance over previously used racemic cyclazocine.

Endo had reported its animal results with naloxone pamoate which indicated that a single injection of a suspension of the compound provided protection from narcotic challenge for two to three weeks. In the past few months clinical studies were carried out at Lexington and at NY Medical College under the supervision of Dr. Alfred Freedman. Endo reported that "preliminary verbal reports from both groups indicate that the duration of action of naloxone pamoate (in man) is not as long as anticipated, extending only for some 2-3 days after a single injection. Serious consideration of its potential, however, cannot be assessed until final reports are received."

Longer-acting narcotic antagonists are actually needed and Endo has initiated a pharmaceutical development program with the pamoate salt of EN-1639 which is both more potent and longer-acting than naloxone. This injectable preparation will be available for intensive preclinical evaluation within the next few weeks. In addition, the oral form of EN-1639 is undergoing toxicity studies in preparation for clinical trials scheduled later this year.

Bristol reported its animal studies with levo-BC 2605, a fully synthetic narcotic antagonist which was longer-acting and more potent than both naloxone and cyclazocine. Bristol filed an IND and initiated human studies. Sixteen subjects were given intramuscular doses ranging from 0.1 to 6.0 mg. At the 6.0 mg. level, one subject experienced hallucinations which were abolished within 2 minutes by an injection of 0.4 mg. of naloxone hydrochloride.

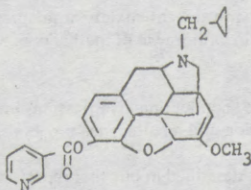
Cyclazocine, by comparison with levo-BC 2605, will produce hallucinations on injection of doses of 0.25 to 1.0 mg. per subject. Since levo-BC 2605 appears to be between 3 and 15 times as potent as cyclazocine in animals, it may offer a substantial therapeutic advantage. Further assessment of levo-BC-2605 for potency and duration of action in man will next be undertaken by doctors Martin and Jasinski at Lexington and by doctors Freedman, Fink and Resnick at NY Medical College.

"Ciba-Geigy furnished all available animal toxicity and pharmacology data on its new 'pure' antagonist GPA-2163, described in our first report, to Lexington for review and consideration of the compound

for possible evaluation in addicts. However, following review of these data the Addiction Research Center has informed Ciba-Geigy that it does not feel that GPA-2163 warrants such investigation at present, primarily in view of the compound's low order of potency relative to cyclazocine and some of the more recently available antagonists. In addition, Lexington felt that GPA-2163 did not offer sufficient promise of a prolonged duration of action, based upon the animal studies, to be of potential value."

SK&F reported preliminary findings on several interesting narcotic antagonists. The most potent of these, SKF-90667, was found to be of greater activity than naloxone or cyclazocine. The company prepared the compounds several years ago in a program which is now inactive. Information was offered "in the hope of possible utility in narcotic addicts should the agents now being tried clinically fail to make the grade."

SKF-90667



Lederle reported discussion with the White House Special Action Office for Drug Abuse Prevention (SAODAP) regarding research with the potent narcotic antagonist diprenorphine (M-5050). The compound was originally prepared and studied in animals by Reckitt and Colman, Ltd., a British firm.

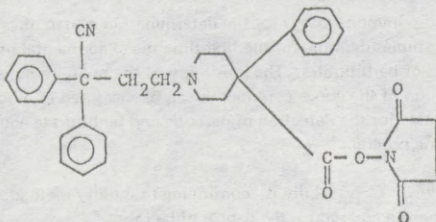
Roche, Abbott, Merck and Bristol have each reported that they are studying new narcotic antagonists in earlier stages of animal investigation. Some of these agents are of a new type. Others promise to be more potent than any antagonists yet developed. It will be some months, however, before preclinical studies will justify their trial in humans.

There are a number of other potentially useful known narcotic antagonists and heroin blocking agents which have not been developed because they were synthesized at academic institutions or at firms in other countries where narcotic addiction is not a major problem. These compounds should be made available for investigation in combatting narcotic abuse.

Proposals have been submitted by industrial firms to SAODAP suggesting specific narcotic antagonists worthy of being imported into the United States and developed once funds are appropriated by Congress to sponsor their development.

Heroin Substitutes: Searle reported its work with a series of isonipecotic acid derivatives. "SC-26100 and structurally related compounds have been investigated for their ability to block the withdrawal symptoms of morphine addiction. Thus far SC-26100 has been shown to be the most potent and longest acting compound of the series for blocking the withdrawal syndrome. Testing is presently under way to determine if SC-26100 can also be used prophylactically to prevent narcotic addiction."

SC-26100



HCl

(PMA report -- cont'd)

Mallinckrodt and S.B. Penick and Co. reported discussions with the SAODAP on the mfr. of levo-acetylmethadol (LAM) which has been found to be a useful longer-acting alternative to methadone. Both firms have expressed interest in the mfr. of the drug.

Counteracting Withdrawal Symptoms: Schering is currently sponsoring a research project in which the combination of perphenazine and amitriptyline "is being compared with placebo and methadone in patients who have been withdrawn from narcotic drugs. Perphenazine and amitriptyline, which are not addicting drugs, are being studied by Dr. Nathan Kline who states that 'there appears to be a substantial number of patients who turn to narcotics as a relief from depression; and if the underlying depression is removed the need for narcotics disappears'."

Pfizer is supporting related studies "with the antianxiety-antidepressant drug doxepin as an adjunct to methadone in heroin withdrawal, or in withdrawal of methadone, where dependence to that drug has developed."

Sandoz reported that the company is "conducting investigations into a possible role for thioridazine in assisting in methadone detoxification and maintenance programs."

McNeil is continuing with its studies, described in our first report, on the use of haloperidol in treatment of addicts.

Merck reported "we are investigating the utility of self-injecting rat, using morphine as the dependence producing drug. Using this model, we have confirmed the potential usefulness of haloperidol in the treatment of heroin withdrawal. . . We intend to enlarge on this study to determine whether major tranquilizers in general and other types of drug classes behave similarly to haloperidol. Such information may lead to improved treatment in the withdrawal process."

Merck also has under way "a formal clinical trial of mecamlamine in the treatment of heroin withdrawal in addicts. This study arose from a clinical observation that this drug prevented many of the symptoms encountered during withdrawal."

New Approaches to Drug Abuse Therapy: Our first report described a compound which, when given to monkeys for a period of time and then discontinued, caused the animals to show a revulsion to morphine when it was provided several weeks later. This finding, which suggested a wholly new approach to the problem of narcotic addiction, needed confirmation. Additional studies were started and will show whether the initial observation can be reproduced.

Roche is investigating an immunological approach to the treatment of narcotic addiction. "By coupling a narcotic to protein, an antigen capable of causing the formation of antibodies to narcotics has been developed. The potential activity of these antibodies as narcotic antagonists is presently under test in animals.

"Extremely sensitive radio-immune assays for the determination of narcotics and barbiturates have been developed. These studies describe for the first time the experimental production of antibodies that react with narcotics or barbiturates. The sensitivity of the radio-immune assay is such that as little as one part per billion of the above compounds can be measured in blood or urine. These methods should be valuable for the detection of narcotic and barbiturate abusers and for use as an adjunct to the methadone program."

Curbing Abuse of Legitimate Drugs: Lilly is "continuing to modify methadone to make it more acceptable as a substitute for heroin and reduce the danger of its misuse."

Mallinckrodt noted its continuing development of naloxone manufacturing procedures and its work "on the development of dosage forms less likely to be used illicitly, e.g., a liquid methadone concentrate made available in Nov. 1971."

Bristol reported on its extensive work with naloxone in combination with other drugs to prevent their abuse: "In the Oct. 20, 1971 *Federal Register*, it is stated that 'abuse of paregoric by addicts who process it into a form for intravenous administration is well known and well documented in medical literature. . . it is in the public interest for paregoric to be restricted to prescription sale.' Paregoric is a camphorated tincture of opium. Over 13 mil. ounces are sold in the U.S. each year for the control of diarrhea.

"Animal experiments at Bristol suggest that abuse of paregoric can be eliminated entirely by adding a mere 0.3 mg. of naloxone to each fluid ounce of the drug. The resulting preparation is still fully effective for the control of diarrhea. When boiled down, filtered and injected into rats, however, naloxone-treated paregoric is dramatically different from untreated paregoric. Rats receiving the former showed no change in their behavior while those receiving the latter rapidly became prostrate in a deeply narcotized state. Bristol will submit its data to FDA during March.

"In similar fashion, studies in animals and man using naloxone in combination with other legitimate drugs of commerce are in progress at Bristol, Lexington and at various hospitals and methadone maintenance centers. Methadone combined with naloxone at a ratio of 20 parts of the former to one part of the latter is fully effective orally but cannot be abused by addicts by injection.

"Animal studies indicate that naloxone in combination with legitimate drugs may also serve to prevent oral abuse by addicts. Addicted animals exhibit withdrawal symptoms when taking large doses of naloxone combination drugs orally while non-addicted animals experience full analgesia when the same naloxone combination drugs are administered in smaller quantity. The medical literature reports both oral and parenteral abuse of useful analgetic agents. Addicts are known to ingest such drugs in large multiples of usually prescribed dosage.

"If each oral analgetic dose were to contain 1.0 mg. of naloxone, the total quantity of antagonist ingested should be sufficient to produce feelings of withdrawal in addicted individuals, while non-addicted individuals taking the same naloxone combination drug in normal dosage would benefit from its full analgetic effects. Studies to test this approach to the curbing of oral abuse of legitimate drugs in man are scheduled."

Education and Information: Several companies have expressed their willingness to participate in the attack on drug abuse but have confessed a lack of knowledge as to how to proceed. A one day seminar on Combat of Narcotic Addiction and Drug Abuse has been arranged at the 13th Natl. Medicinal Chemistry Symposium of the American Chemical Society at Iowa City on June 19.

Representatives of SAODAP, the Addiction Research Center at Lexington, industrial firms, research institutes and university laboratories will discuss their latest findings before a group of 500 medicinal chemists. The American Pharmaceutical Assn. Academy of Pharmaceutical Sciences has also scheduled a one day symposium on Opiate Addiction for April 25 in Houston. It is hoped that these meetings will serve to stimulate ideas on new therapeutic approaches to the fight on drug abuse.

(PMA report -- cont'd)

Addiction Research Facilities: From the foregoing discussion, it is apparent that govt. and industry have worked well together in the past few months to maximize progress. When facilities were heavily taxed at Lexington, doctors Martin and Jasinski were most helpful in advising Bristol as to the best methods for carrying out its own early assessment of levo-BC 2605 in private facilities. SOADAP has served as a catalyst for keeping things moving along as fast as possible. Progress will undoubtedly be further enhanced once federal funds are appropriated for research in the combat of narcotic abuse.

Exec Cmte.
PMA Special Task Force on Drug Abuse

Irwin Pachter, PhD, Chairman
Sydney Archer, PhD
Robert Herting, MD
Kenneth Kohlstaedt, MD
Alan Rubin, PhD
Clyde Strickland, MD
Murray Weiner, MD

John Adams, PhD (Ex officio)
Chester Cavallito, PhD (Ex officio)

Senator HUGHES. I would like to know, Dr. Brown and Dr. Gardner, whoever can answer this the best, what you are doing in the way of research in the field of testing for heroin addiction or other drug or narcotic abuse?

What I am talking about is an alternative to urine analysis. Is there a saliva test, or other type of test?

Dr. BROWN. We have a small number of basic studies which are giving us leads to small amounts of compounds in urine that we can test in some way. I would be glad to supply that for the record. I don't have with me the specific research programs that are going at, say, small amounts of heroin in blood or saliva or urine at this time. I could supply it for the record. Perhaps Dr. Gardner is aware of that.

Dr. GARDNER. No; I am not.

(The information subsequently supplied follows:)

Current Studies on the Detection of
Opiates in Body Fluids Being Supported by NIMH

R01-20695 (9/71-8/73)

Foltz, Rodger L.

Battelle Memorial Institute, Columbus, Ohio

Rapid Identification of Drugs from Mass Spectra

This is a proposal to develop a technique for the rapid identification and quantification of drugs in biological samples (blood, urine) using chemical ionization mass spectrometry combined with gas chromatography. A computerized library of spectra, developed for the rapid identification of unknown samples, will have application in the treatment of drug overdoses from drug abuse or attempted suicide. Drugs studies will include barbiturates, tranquilizers, antidepressants, doriden, amphetamines, cocaine, narcotics, Darvon.

R01-17748 (9/69-3/73)

Wikler, Abraham

University of Kentucky, Lexington, Kentucky

Methods of Detection of Drugs of Abuse

This research is concerned with the examination and evaluation of the most commonly used methods for the detection of drugs of abuse in the urine. A large number of opiates, sedatives, hypnotics, stimulants, and hallucinogens will be studied over the three-year period of the grant.

R01-18960 (9/70-8/72)

Goldstein, Avram

Stanford University, Stanford, California

Methadone Plasma Levels in Narcotic Addicts

The aim of the proposed research is to learn what plasma levels of methadone are effective in satisfying narcotic drug hunger in addicts, thereby preventing illicit narcotic use; to ascertain the relationship of plasma level to dosage in the population of addicts under treatment; and to establish the extent of diurnal and other variations in plasma level in the individual patients. The goal is to improve the pharmacologic effectiveness of methadone maintenance treatment of narcotic addiction. Subjects are addict patients at the Drug Abuse Clinic, Mental Health Center, Santa Clara County Health Department.

Senator HUGHES. Are you doing research in other areas of testing?

Dr. BROWN. I don't have the answer.

Senator HUGHES. Specifically, I noticed a statement from the Department of Defense that a general had discussed the matter with Dr. Jaffe. I thought you probably had information on it. It was on the fact that they were working on the possibility of testing military dependents for drug use or narcotics addiction as well as the military people themselves.

Now, are you doing any research, or are you thinking about testing any civilian population by some method or means?

Dr. BROWN. I think I know the background to that, and that is the extensive experience the Armed Forces have had with the help of Dr. Jaffe in doing frontline testing in urine and blood screening et cetera. I think what is being talked about here is not so much new scientific techniques as perhaps doing spot testing or screening of civilian populations, dependents, and others, for those who are addicts.

When individuals come in for their routine medical examination at the hospital as dependents do, one might well test blood and urine for drugs and use the results in a very appropriate medical way, so the physician sitting down could say to the young boy of 16, "We notice that you have some signs of heroin." That would be within the medical confidential relationship, and I think it would enhance the physician's ability to help.

I can appreciate your feeling that this kind of screening has some ethical issues.

Senator HUGHES. I am sure you can. I am wondering how far you intend to carry that.

Dr. BROWN. We have no direct relationship to that.

Senator HUGHES. Would that involve school examinations, for children entering school, college, or high school? It is not only an ethical issue, but there is a constitutional question involved.

Dr. DuVAL. We agree.

Causing someone to testify against himself, especially without his knowledge, would have to be examined again, but this is not a departmental proposal.

Senator HUGHES. It is not, but my concern is that it might be. I want to know whether you are considering it, whether it is a proposal or not.

Dr. DuVAL. We are not considering it.

Senator HUGHES. You are not considering it, all right. I would like to request you to respond to written statements. We still have a witness to go. Excuse me. I am sorry, Senator Schweiker.

I didn't realize you had come in, and I have been sitting here looking at you for 5 minutes. I certainly don't want to pass you up.

Senator SCHWEIKER. I apologize. I was in the Appropriations Committee. I just have a couple of questions, and maybe you did touch on this in one of the answers.

I would like to ask Dr. Brown about roughly what the total budget request dollarwise for research was in all narcotics antagonists, and also what, then, the requests are for grant and contract support of the same program.

Just roughly. It does not have to be exact.

Dr. BROWN. The total research budget for all aspects of narcotics and drug abuse in 1972 broadly conceived, not just the narcotics and antagonists or alternatives, was \$29 million from grants and another \$3 million in contracts. This will go up in 1973 to perhaps \$30 million in grants, and \$4 million in contracts. Now the proportion for narcotic antagonists is a small proportion, in the 3 or 4 million range. We have even more focus in terms of methadone itself.

Methadone research itself is half a million. Methadone and narcotic antagonists, \$400,000; and grants on methadone and other narcotic drugs are perhaps \$121,000 to a total of \$1 million.

So in answer to the question, "What are you doing on methadone, narcotic antagonists?" it is approximately a million dollars' worth of effort.

Senator SCHWEIKER. The bulk of the rest of the money you talk about, what kind of work or projects is that going into?

Dr. BROWN. A very broad range, from the basic epidemiology and sociology, for example, looking at communities where abuses are located, through clinical treatment programs, the physiological studies, to animal testing.

The full range of research you are familiar with from the NIH ethos.

Senator SCHWEIKER. Going back to the other figure, you gave me a \$1 million figure roughly, for that same category grouping, what would be the request for grants and contracts that you might have?

Dr. BROWN. We do not have any grants or contracts in this area that we have not been able to honor. We have not had any difficulty in finding funds, nor would we in finding good programs in this area.

Senator SCHWEIKER. You are saying that what you feel are scientifically clinically valid or medically sound programs you have funded in this area?

Dr. BROWN. Yes, that is correct, Senator.

Senator SCHWEIKER. Once again, you might have commented on this earlier, so if you did, you don't have to give me a lengthy answer. I saw recently in the press the possibility and knowing it was a press story, I know it was a possibility of using one of the drugs as a non-addictive treatment.

Dr. BROWN. It might have been Dr. Al Freedman's testimony talking about a longer acting form of Naloxone.

Senator SCHWEIKER. I would like to get your professional advice as to where this is taking us and what you see down the road, realizing, I am sure, that it is that kind of a "guesstimate" situation.

Dr. BROWN. There are two basic approaches to the chemical treatment of heroin addiction. One is methadone, which replaces the drug and permits a person to function et cetera. The other is to have an actual blockage so that even if he took a heroin shot or methadone, nothing would happen.

The antagonist drug would block the effects. That is what Naloxone does. The problem is that you have to take it every 3 or 4 hours. This is some pharmacological technology—

Senator SCHWEIKER. Then it wears off at that point?

Dr. BROWN. Yes. We would have to work out a scientific way of taking it once a day, or, even better, implant it so that it lasts for a month. This is what Dr. Freedman and his colleagues are working on, to try to find a long acting form of this blockade agent, and there are

hopeful signs that compounds related to the original may permit us to do this.

They do have patients who do take the Naloxone three times a day, and it is a voluntary thing, and they do it because they leave the hospital inpatient department. They take a heroin shot to prove that nothing happens, before they go out. As long as they are taking this substance, the temptation is not there.

So you have a choice of not taking your pill and taking heroin. If you take your pill, you know you have protected yourself. Once that gets to be a habit, it seems to be working well in the handful of patients who have been researched.

Senator SCHWEIKER. In the broader sense, do you see any activity, line of endeavor, or research area more properly promising than this at the present time, or not? In a general way, how do you answer the question?

Dr. BROWN. Speaking from the chemical or pharmaceutical pharmacological point of view, for the past year or two I have been enthusiastic about at least exploring the possibilities of an immunological approach where you might actually receive an injection and develop antibodies in your bloodstream that are there all the time. Research has begun on this particular subject when again, the issues are more ethical, moral, almost constitutional types of issues.

Would the person have to decide to get it? There is research now going on in the immunological area, which I think is very helpful.

Senator SCHWEIKER. What is the theory in layman's terms then?

Dr. BROWN. The theory is basically this. If you have a germ and then you get sick and develop antibodies, you may never have that disease again, because whenever the germ comes into your system, you have the antibodies that take care of it.

Right now, we have the technology to link the active ingredient of a drug to protein and to create the antibody. You can take the active ingredient of marihuana, link it to a protein and get antibodies. So that just as you might have antibodies to stem streptococcus, you would have antibodies to heroin. The technology is there in the theoretical sense much as it was at the beginning of the Manhattan project.

It is an achievable thing, but it will run into great difficulties.

Senator SCHWEIKER. Do you have any specific studies directed to this right now?

Dr. BROWN. Yes. The PMA report I submitted for the record has some information on that.

Senator SCHWEIKER. How much crime do you feel is due to heroin addiction? I wondered, based upon your position, your overview of the problem, how do you relate in your own mind the relationship between crime and heroin addiction on a "guestimate" personal basis?

Dr. BROWN. For the whole country?

Senator SCHWEIKER. Yes.

Dr. BROWN. Excluding white-collar crime and looked at only in terms of street crime, my guess is about 27.2 percent. I don't want to be accused of not giving specific testimony.

Senator SCHWEIKER. That is pretty good guessing.

What about methadone waiting lists contributing to crime? Do you have any strong feeling about this in terms of methadone treatment that also perhaps the distortion of that program by not supervising

it properly, do you see any present indications that this is a serious problem?

Dr. BROWN. Yes. I have little doubt in my mind that the perhaps 20,000 or 25,000 people that Dr. Jaffe estimated are on waiting lists right now for methadone, most are engaged in active criminal activities, most of them being heroin addicts.

I have no doubt that reaching that group would be very useful in reducing crime.

Senator SCHWEIKER. That is all I have, Mr. Chairman. Thank you.

Senator HUGHES. Thank you very much, gentlemen, for your cooperation.

The Chair calls Dr. Vincent P. Dole of the Rockefeller University of New York.

**STATEMENT OF DR. VINCENT P. DOLE, ON BEHALF OF THE
ROCKEFELLER UNIVERSITY, NEW YORK, N.Y.**

Senator HUGHES. Dr. Dole, I understand your statement is extemporaneous, so you may go ahead. We welcome you again to this subcommittee.

Dr. DOLE. Thank you, Senator.

I am again happy to be asked. I can't speak to the question of how much money is needed for treatment of all the addicts in this country, but I do have feelings about the channels by which money is supposed to reach the poor devils confined in the cellblocks in the Tombs of New York City.

You and Senator Javits have been with me to the Tombs and have seen the situation. I can report to you that nothing much has happened since you were there. The distance between the high level planning in Washington and the cellblocks of the Tombs is very great. Getting money to actual treatment is like trying to run an irrigation ditch in the desert. By the time you come to the end of the ditch, there is no water.

I speak to you out of discouragement. It may be a special case, but my experience in New York City reflects a large, unmet need for treatment. I would like to see all of the waiting lists eliminated, and all the people needing treatment actually in good programs—but this is a very remote prospect in my opinion, and by remote I mean many years.

I would like to see any reasons for optimism. What I see mainly are unmet needs. Let me cite three examples from my own experience. The bureaucratic impediments to treatment of addicts are so substantial that I have been tempted to leave the field, but of course my wife and I are too committed to do that.

The first example relates to the prison detoxification program that you visited. We were able to get this program going, not with any help from any agencies, but simply because we had a concerned commissioner, and he gave us administrative support while we started the program with volunteers. That is the only way we could have done it. Later in the year, some months later, it was possible to get a trickle of Federal money from LEAA, and this still represents the only support the program has from any outside sources in addition to the routine budget of the Corrections Department.

The Federal supplement amounts to \$12 per man for the detoxification treatment. We keep this program in operation because we continue to reinforce it with volunteers.

In consulting Dr. Jaffe I learned that it would be necessary to channel any additional Federal money through the city's Addiction Service Agency—a notoriously inefficient bureaucracy. Moreover, our efforts to fund a placement program to bring addicts from prison to community-based treatment programs have been stifled by this bureaucracy.

Addicts in jail must be given an opportunity to talk to representatives of different programs. They must not be told, "You must take methadone," or any other specific treatment program. They must be approached as human beings, saying, "Let us see what plan we can find that would have a future for you. If you are interested, we can put you directly in touch with people who have services to offer." After we have a treatment plan, let us go with you to court and see if they can be persuaded to let you out into the treatment program. This we are trying to do, without any Federal support.

I spoke to the judges of the criminal courts, to the district attorney, and the Legal Aid Society. Everyone seems to feel that a release program was worth a try. Once again we began the work with volunteers. To my surprise the city agency picked up the idea as theirs, wrote it up into a large grant request and got a million dollars of Federal money.

In the meantime, we were trying to get people out of the Tombs with no funding. Lacking any other support, I persuaded Beth Israel Medical Center, which had some funding from the New York State Narcotics Addiction Control Commission, to assign one clinic so we could study what would happen when we brought a test group of hard core addicts, with records of 5 to 20 jail terms into a methadone treatment clinic. We obtained release of 340 patients over a 7-month period, and have retained approximately 55 percent. This was not as high a success rate as we would like to have achieved—but it was encouraging as a first attempt since none of these persons would have had much chance of surviving even a week in the community without return to heroin and crime. So here was a promising beginning, and once again, I sought Federal support and was told this would have to be a matter for the city's addiction service agency.

The State meanwhile, being short of funds, notified Beth Israel that it could not support any expansion of this clinic. As of today, this release program is closed. We are unable now to take anybody out of the Tombs. Meanwhile we are flooded with requests for methadone treatment. It is heartbreaking to go through the cellblocks and hear hundreds of inmates pleading for admission to a treatment program.

I also tried to set up a data system so that we could begin to know more about these addicts. I developed a questionnaire adapted for card punching and computer tabulations. We were interested in the social backgrounds and the ethnic distribution of the addicts, how they got addicted and how long they had been addicted, what treatment they had, whether their addiction was service connected, and so on. We have 20,000 of these questionnaires filled out but funds for computer analysis could not be obtained. The questionnaires are now sitting on shelves. I do not want to take your time for any more de-

tail, but something is wrong in the system of funding when hundreds of millions of dollars are appropriated in Washington and hardly any of it benefits the desperate addicts in the Tombs jail of New York City.

To show that the funding deficiencies are not limited to the Tombs let me cite the experience of the adolescent clinic that Dr. Nyswander and I started 4 years ago.

We wanted to reach the adolescent addicts that we could see in our local high school (Julia Richmond). The playground was notorious for the number of addicts using drugs and dozing on benches. We developed a low dose methadone treatment, with a view to first stabilizing the lives of these adolescent addicts, and then trying to detoxify them.

This experiment proved so successful that we expanded it into a joint project with the New York Hospital Medical Center. In order to get funds for this research we had to go to the Rockefeller Foundation since State and Federal funds were unavailable. The Rockefeller Foundation came in with money for 2 years. Now after these 2 years, the principal of this high school tells us that we have apparently cleaned up the problem of narcotics use in the high school because we have taken the pushers into treatment and thus broken the chain of supply. We did not eliminate all the drug problems in the school, but obviously this treatment program has been beneficial and should be replicated in other high schools.

At the present time, however, our grant with the Rockefeller Foundation is expiring, and we are pleading with them to renew it for at least one more year, because we still don't see any other source of funding. We have been trying to persuade other medical centers to set up adolescent clinics on this model, but they, too, are worried about funding. This demonstration shows what could be done if good medical centers provide treatment services for local high schools. I believe that we could go some distance toward preventing addiction—we could interrupt the early stages of drug use—if we had this type of center available for every major high school in the city.

What response do we get from Federal bureaucracy? Beth Israel Medical Center applied to NIMH for support of such a clinic and was told that their plan was disapproved because it was "not multimodal-ity." If we had applied for a more elaborate and expensive complex of facilities, I presume it might have been funded. I don't want to have one treatment procedure supported to the exclusion of all others, but I think it is a doctrinaire position to insist that every clinic follow a pattern set by administrators sitting behind desks in Washington. So we find ourselves struggling with the question of how can we fund more clinics in a pattern that has proven successful, although not accepted by the administrators at NIMH.

Well, in the Tombs and in Brooklyn, in the Bronx, in Queens, and in the jail for adolescents on Riker's Island—in all these jails—there is an enormous unmet need for treatment. We have detoxified over 30,000 cases in the past 13 months.

This is clearly a key target area for treatment. At least four out of five of these inmates are asking for a chance to enter a treatment program. There is great motivation but no response from society.

What we need to think of, if we want to make an impact on addiction-related crime, is treatment for every one of these criminal addicts in jail who gives evidence of really wanting help. That means

we must develop facilities in the jails for interviews with social agencies. We need treatment for at least 10,000 per year. This is a minimum figure, and just a beginning.

Coming to your proposed legislation, I see and welcome your intent to provide support for treatment services. Whether or not this funding would be redundant, and whether or not it would ever reach the sick addict in the cell block, I don't know but you are certainly right in recognizing the need for more treatment than is available at present.

Senator HUGHES. Thank you very much, Dr. Dole. I regret having to see you so discouraged by what is happening here. You have done such fine work and given so much of yourself trying to salvage the totally abandoned, whom nobody gives a damn about. You have been working in places like the Tombs and other prisons and institutions where children are incarcerated.

You tried, by giving your life, as your wife has, in trying to reach this center of hope. You have heard the testimony here all morning. You tell quite a different story.

How much are you getting in funds from the Federal Government for any of the programs you are working on?

Dr. DOLE. None, essentially. The Department of Corrections gets via the LEAA funds, which I gather are derived only from Federal sources, approximately \$12 per man for medical and nursing supplements that are needed for the detoxification programs in other jails.

All of my own research work, my own laboratory is supported from the State narcotics commission in New York State, and the adolescent program is supported by the Rockefeller Foundation.

Senator HUGHES. If I understood you correctly, in the last year and 1 month you treated 30,000 patients in the prison system of New York City, is that right?

Dr. DOLE. That is right.

Senator HUGHES. You say you have made cards on all these patients, and yet you don't have the money to put this information into a computer or do any followthrough for recordkeeping at all because there is no money available.

Is that correct?

Dr. DOLE. Yes.

Senator HUGHES. There is no way you can follow through on any of these patients, direct them to other programs or trace them down or do anything else for them without the money to do it. Is that correct?

Dr. DOLE. That is right. We have only a limited sampling of the data, some tabulations done by hand.

Senator HUGHES. You heard concern of both Senator Randolph and Senator Schweiker with regard to crime, and yet in the Tombs you are dealing with people having the highest incidence of crime in the United States are you not?

Dr. DOLE. That is true.

Senator HUGHES. Yet there is no money for this.

Dr. DOLE. It seems to be rather remote.

Senator HUGHES. The statements you have heard about funding must seem rather ridiculous to you, don't they?

Dr. DOLE. As far as my personal experience is concerned, they sound rather remote. I accept the intent to provide service.

Senator HUGHES. You use a better choice of words than I do, Doctor. It seemed rather ridiculous to me. It can seem remote to you. Professional respect, I guess, and all that.

Well, Senator SCHWEIKER?

Senator SCHWEIKER. Thank you, Mr. Chairman. You used, Doctor, the figure based on your experience in the Tombs there are 4 out of 5 people that you treated are people that came into the Tombs and were drug related in terms of their crime. Is that right?

Dr. DOLE. No, Senator. The figure of 4 out of 5 refers to the proportion of addicts that wanted treatment after release. If you consider all admissions to the Tombs for all causes, you find that about half of them are addicts. When I said 4 out of 5, I meant 4 out of 5 of these inmates were addicts seeking treatment.

Senator SCHWEIKER. I am sorry. I misunderstood it. But to get back to the figure, you are talking about 50 percent?

Dr. DOLE. Yes.

Senator SCHWEIKER. This is of the whole New York City average, about 50 percent of the criminals going into the jail system there are related to drug addiction in some form, is that accurate?

Dr. DOLE. Yes. In fact, the percentage of addicts in the Adolescent Remand Shelter, which takes boys between the ages of 16 and 20, is even higher. And also in the women's prison, the percentage of addicts is higher.

Senator SCHWEIKER. Following up Senator Hughes' line of questioning, in terms of your work and the need that you see from the viewpoint of your operations, what use would you put of the money, if Federal money were to be made available to you, what would be your priorities of use in terms of what purpose and what accomplishments?

Dr. DOLE. First, what is needed in the corrections system is a clearinghouse facility, which they do not now have. With the present system a man is thrown into a crowded, noisy jail. He stays there until he is picked out for trial. Some sort of plea-bargaining is done; he may be given a reduced sentence, put in prison for a time, and thrown again back to the streets. Nothing has happened.

What is needed in this system is a clearinghouse providing space for medical services, opportunities for interviews with representatives of various agencies, and social evaluation.

If you could have an efficient process for placement in suitable treatment programs, the corrections system could begin to put together a plan for aftercare. The courts would be given alternatives to prison.

This would be my first priority. I met yesterday with Governor Rockefeller, asking him to transfer to the New York City Department of Corrections a facility which had been fitted up by the State narcotics commission, but is now abandoned by them. If this facility were made available, it would be possible within a matter of a few weeks to set up a first rate classification and placement center. We could evaluate the addict's potential and needs. He would have a chance to find an alternative to prison.

I would want to associate this facility with a first rate medical center. I would also attempt to interest the courts in installation of a courtroom in the facility to reduce delay times, and I would provide interview space for all reputable treatment programs interested in helping the accused addicts.

A similar clearinghouse and placement facility is urgently needed for the adolescents in detention.

Senator SCHWEIKER. Following up what you just described as a rough estimate, how much money could you effectively and properly use, say, of course, in the next year to do this without, in other words, the way that you are set up to operate now and the time and resources, et cetera? How much Federal money could you properly spend for the program to spend what you describe?

Dr. DOLE. I cannot give you a reliable estimate of the expense of setting up and operating a new institution in the department of corrections. This would involve maintenance and custodial expenses that would have to be calculated by experts in the department. However, limiting my own concern to the provision of aftercare services for addicts released from jails, and adding to this budget the funds that could be effectively used to expand adolescent services, I would say \$2 million. This amount, if used effectively, would yield a lot of results.

Senator SCHWEIKER. Wouldn't it be true that with all this difference of opinion about what way do we go in treatment of drug addiction and what is the problem in terms of the questions raised this morning, wouldn't we be able to learn an awful lot of the answers under the kind of a program you have described?

Dr. DOLE. We obviously would. Indeed much important data is buried in the unanalyzed questionnaires. For example, the question came up a couple of weeks ago as to how many of the Vietnam veterans are getting into crime in New York City. The answer is sitting on shelves. One of the questions we asked was, "What was the source of your addiction, where, and how long?" It is just a question of tabulating the answers.

To get preliminary information, we asked a group of people to tabulate a couple of thousand questionnaires to get a sample. That was not really a proper statistical analysis, but the best we could do. Almost any question you might have that relates to crime and addiction has an answer buried in the questionnaires.

Senator SCHWEIKER. Doctor, you heard previous testimony indicating—well, I specifically asked about the funding on some of these projects, and yet as you know, there are waiting lists for people who want to get methadone maintenance and can't.

How do you account for this discrepancy? This is a matter of local organization and resources, at the local level, or just how do you explain it?

Why the gap here that we have just heard?

Dr. DOLE. It is partly an impediment to the flow of funds from Federal sources to treatment programs, and partly the tremendous demand. The other consideration is the efficiency with which programs can convert money into effective treatment. When this is done properly, the results are impressive. In New York City the health department has a dynamic methadone program run by Dr. Robert Newman. He has expanded his services with extraordinary rapidity, and yet has maintained control over quality of medical care. He told me the other day that his limiting factor in rate of expansion is the inability to find acceptable space and to recruit trained staff. He has approximately 10,000 addicts waiting for admission, and he said to me with amazement "No matter how many we admit, the waiting list is even getting bigger."

As you bring treatment facilities into view, more and more addicts come forward wanting treatment.

The target that we must take as a minimum in New York City is 50,000. Even with maximum financial support it will take 2 years to reach this figure, and it is very likely that after this we will find another 50,000 that want to be treated.

Senator SCHWEIKER. What is your specific reaction to some of the new FDA proposed regulations on methadone?

Dr. DOLE. I think the intent is very good. Clearly we need quality controls. To throw methadone maintenance treatment open for uncontrolled use would lead to chaos.

However, there are some points in the proposed guidelines that are ill advised. The stipulation that everyone come to a clinic twice a week forever is a mistake. The diversion of methadone which concerns all of us, is largely going to untreated addicts. Impediments on the delivery of service will increase the black market by widening the gap between demand and legitimate treatment.

Frequent, even daily, clinic visits are needed for the first few weeks or months of treatment, but a man who is rehabilitated must be able to live a more normal life. The proposed guidelines seemed to be directed only to the control of new patients.

There are other details of a technical sort such as frequency of laboratory tests that I have discussed with FDA. Thus, although I do not accept all the details of the proposed guidelines, I do endorse the general principles.

Senator SCHWEIKER. All right, Dr. Dole. The chairman had to go to another meeting, and he asked me to thank you very much for appearing. We certainly appreciate it. I am sure the committee will weigh very carefully some of your advice as well as your past working efforts.

Thank you very much for being with us.

Dr. DOLE. Thank you, Senator Schweiker.

(Whereupon, at 12:40 p.m. the subcommittee recessed, to reconvene at 9 a.m., Wednesday, May 24, 1972.)

DRUG ADDICT TREATMENT AND REHABILITATION ACT OF 1972

WEDNESDAY, MAY 24, 1972

U.S. SENATE,
SUBCOMMITTEE ON ALCOHOLISM AND NARCOTICS,
OF THE COMMITTEE ON LABOR AND PUBLIC WELFARE,
Washington, D.C.

The subcommittee met at 9 a.m., pursuant to recess, in room 6226, New Senate Office Building, Senator Harold E. Hughes (chairman of the subcommittee) presiding.

Present: Senators Hughes (presiding) and Javits.

Subcommittee staff members present: Mary Ellen Miller, staff director; Jay Cutler, minority counsel.

Senator HUGHES. The Senate Subcommittee on Alcoholism and Narcotics will come to order.

The Chair calls Dr. Robert Newman, director, methadone maintenance treatment program, City Health Services Administration, New York, N.Y.

Thank you for your willingness to come here and testify on this very important subject matter, Doctor.

STATEMENT OF DR. ROBERT NEWMAN, DIRECTOR, METHADONE MAINTENANCE TREATMENT PROGRAM, CITY HEALTH SERVICES ADMINISTRATION, NEW YORK, N.Y.

Dr. NEWMAN. I am very pleased to be here at this particular time because, as you know, there are a number of decisions being made here in Washington, and also at the State and local level, which will have a very profound effect on methadone maintenance programs throughout the country and the increasing number of patients who are dependent upon this treatment for their medical and social well-being. So I am especially appreciative of being here today.

I would like to first of all explain what my program is. This is the New York City Health Services Administration methadone maintenance treatment program. We have been in existence for just under 18 months, and in these 18 months we have developed an active patient census of over 5,500.

Senator HUGHES. How many was that?

Dr. NEWMAN. Over 5,500 in 18 months.

I think the independent evaluation that is now going on will show that this is not only a numbers game but also that we are providing very effective treatment to these patients.

This is very encouraging, especially being able to do this within the governmental structure. On the other hand, there certainly is no reason for complacency. In these same 18 months we have received over 23,000 applications for treatment. We have right now on our active waiting list (and this is a real number of people who have not been admitted, who are not being treated elsewhere, who are not in jail) over 8,200 persons.

These are people who are eligible, who have applied, who want treatment and who essentially have to wait on the streets because we don't have the capacity to accept them.

There is also no reason to think that we are even close to the end of this demand. We have been consistently getting between 300 and 500 new applications every single week, and there has been absolutely no change in this volume over the last 6 months.

Rather than dwell on the success, or the effectiveness, of the program at this stage, what I would rather do is discuss some of the main problems with the methadone maintenance program.

This is in keeping with the current trend—which is regrettable—of focusing only on the alleged problems and not paying any attention at all to the very definite benefits to patients and society.

I think it might be helpful, however, to discuss these problems from the perspective of somebody running one of the largest methadone programs in the country.

Senator HUGHES. Is it the largest?

Dr. NEWMAN. It depends on whom you ask. It is either the largest or second largest. Beth Israel may have a couple more hundred patients.

One of the most serious problems that has gotten a tremendous amount of publicity recently is the problem of illicit diversion of methadone. This seems to be the focus from beginning to end of the newly proposed Federal regulations governing the use of methadone. It is also very much in the news and very much the concern of lay and professional people alike.

I think the perspective from which the problem of diversion has been viewed has been very one-sided, and this is very inappropriate. Any illicit market, any market at all, whether it be legal or illegal, has to be viewed not only from the supply end but also from the demand end; we must decide not only how we can deal with limiting supply, but also why there is the demand.

In the case of methadone, there is no secret why people can be induced to sell methadone. It is simply the incentive to earn money.

The critical factor is why people want to buy methadone on the street. It is my very, very firm conviction that people want to buy methadone on the street, the overwhelming percentage, because this is known to be an effective alternative to continued heroin use and all that goes with such use.

Recognizing that we have 8,000 people on our waiting list, and that in New York City there are probably 20,000 people on various waiting lists for public programs, it would be naive to be surprised that some of these people buy methadone illegally when they are forced to wait as long as a year to get into a legitimate program.

Furthermore, the efforts to control the supply end, as far as I am concerned, have always failed with any kind of illicit market. This is true of, for instance, alcohol during prohibition. It has been true of the

approach to any drug abuse problem. So I think that just approaching it from the supply end simply isn't effective.

It is also self-defeating when the regulations, when the attempt to deal with illicit supply, at the same time limit the legal availability. I feel that the result is going to be self-defeating because the demand is just going to increase even more rapidly.

Some of the proposed new Federal guidelines which are presently under discussion, I am afraid, will have this self-defeating effect. For instance, it is proposed that initially, for the first several months, every patient has to come in at least 6 days a week, and that indefinitely thereafter, virtually without any limit at all, all patients have to come in two times a week. It is just irrational to mandate this irrespective of the clinical judgment of program staff. I think it is crazy.

Obviously, the capacity of a program is not only the total number of patients but also the number of visits that can be accommodated. By making these kinds of arbitrary requirements, what we are really doing is forcing more people to wait a longer period of time on the streets. I think this is counterproductive in terms of the goals, the stated goals, of the regulations.

Let me also say that the problem of deaths from the illicit use of methadone, which have also been reported very widely, are obviously of tremendous concern to me and to anybody involved with methadone maintenance. I think what we see here is the result of a very effective medication which is very dangerous when it is taken by self-administration on the street by people who can't get this treatment legally. Obviously, methadone is a potentially lethal medication. When it is used in inappropriate ways by people who are, in essence, treating themselves, there are bound to be deaths.

I think, again to respond to that problem, by making it even more difficult for people to enter legitimate programs we will see the deaths increase even further.

Obviously, the problem of children, accidental poisoning, is also of tremendous concern. I think this is a responsibility that patients and the programs have to accept, to minimize the likelihood of accidental ingestion. There is no question that with any medication, if it is in wide enough use, there will be a problem with accidental ingestion. I would point out that the No. 1 cause of accidental poisoning in America is aspirin.

In summary, if the response to these problems is to just totally eliminate the take-home privileges, I think there is going to be a disaster because there will be less people able to be treated well in the programs.

Let me leave the problem of diversion and go on to two other major categories of problems. The first set of problems is the result of the previous failure to deal effectively with the problem of addiction.

There is a very understandable skepticism and cynicism on the part of professional people, community people, employers, everybody, regarding the ability to treat a person's addiction.

When people talk about ex-addicts, just as when they talk about ex-offenders, I believe that they are really just using this as an indulgent euphemism. Very few people really feel that an ex-addict is distinguishable from an addict.

This orientation is reflected in the new Federal guidelines which also take the attitude that these people are basically manipulative, untrustworthy, and no matter how long they are in treatment, no matter how well they are doing, they are never to be considered normal human beings.

One of the results of this skepticism is the community opposition that we face in opening clinics. We simply haven't been able to get the point across in many areas that we are not just collecting a bunch of dope fiends and bringing them together for a legal fix. Our patients are very well motivated. They are receiving medication, and the overwhelming majority of them do very well and are in every way indistinguishable from any other normal person. To make this understood is a constant battle.

I would say that our major problem in expanding the program has been getting space, acceptable space, to open up new facilities. This for our own program has been an even greater problem than the problem of money. It is getting community acceptance to a clinic in a particular neighborhood.

Obviously, the same cynical and skeptical attitude on the part of employers is a very, very damaging one in treating our patients. Patients who enter methadone maintenance don't do so because they suddenly lose their taste for heroin. Overwhelmingly, people enter the program because they are sick of everything that goes with heroin addiction, and they want to leave the illegal life, the hustling, the constant battle with the police.

They want to leave that behind, and they want to lead a socially acceptable, working, productive life.

When this desire, when this motivation, is constantly thwarted by discrimination in employment, when they can't get jobs, when they can't get housing, when they are constantly harassed by welfare workers, when they are just generally harassed by the community at large that still views them as addicts, my own feeling is that a number of patients are going to just throw in the towel and say, "I can deal with my own problems, but I just can't deal with these external forces which prevent me from resuming a normal, productive life."

I am sure that this leads a lot of people to just drop out of the program and just go back to where they were before.

We are hopeful that with the continued success and expansion of the program, these attitudes will die away. But it is going to be a long, uphill fight.

There have been consistently very dramatic independent evaluation reports concerning greatly decreased arrest records and criminal activity of patients who enter the program. For the first time, cities around the country are seeing a dramatic decline in typically addict-related crime. While this certainly can't be attributed solely to methadone maintenance or to treatment programs in general, there is no question that currently treating in New York City alone roughly 20,000 previously hard-core heroin addicts—and treating them successfully—has to have an impact on the community.

We hope that this sort of recognition will lead to increasing acceptance of the program, and even more importantly, increasing acceptance of the patients as normal human beings.

I have talked about the problems that result from previous failures. Let me now talk about the problems that result from our present successes with methadone maintenance.

There exists a growing frustration with the overwhelming nature of the addiction problem, with the increasing prevalence of the problem, plus the attitude in America that anything is solvable by some kind of a drug. In this setting, I don't think it is surprising that methadone has been grasped by a lot of people as the panacea, as the single answer to the addiction problem. I think this is a totally inappropriate way to view methadone.

There is no question that methadone program proponents have, with their overzealous selling of the modality, contributed greatly to this feeling that methadone is the only answer. It is an inaccurate and very harmful conclusion. Methadone is definitely not a panacea; it is not the cure-all for addiction in America.

In communities that see methadone maintenance as a competitor for funding, who have the feeling that it is trying to replace all other approaches, we are bound to have very major problems. I emphasize again that community opposition is perhaps the greatest obstacle to further expanding the program.

There is another problem. If the legislatures and other agencies that decide how funding is to be distributed fund methadone under the conviction that methadone is going to solve the addiction problem, then it is just a matter of time before they are thoroughly disillusioned. I am concerned that when that happens, the continuation of this very essential and effective component of the addiction approach may be in real jeopardy. In other words, while we need funding, it is wrong to fund methadone maintenance in the belief or the hope that this is going to eliminate addiction in the community. It is not going to do that. I think this has to be understood by everybody concerned.

We are also under a lot of pressure right now, again based on this omnipotence that people attribute to methadone, to accept individuals for whom maintenance is not going to be effective; notably, involuntary referrals. My own very, very strong feeling is that "involuntary treatment" is a paradoxical term. I don't think that you can successfully "treat" people who do not want to be treated. I just don't feel it is possible.

I feel the results with commitment programs have generally been extremely poor, and I definitely urge people not to feel that this approach can be infused with new life by suddenly adding methadone to the regimen forced on people against their will. I don't believe methadone maintenance can be effective in those conditions.

Some would like us to make methadone maintenance the only alternative to incarceration. I think that is also wrong. That also is coercion. Even regardless of the constitutionality and desirability, I think it will be futile. I don't think you can treat people with methadone or anything else if they don't want to be treated. In other words, it is not a magic potion that is automatically going to solve somebody's problems if you suddenly force them to drink it.

The reason methadone is effective, and I think uniquely effective, is in large part due to the phenomenal motivation of the patients. It is incredible that people would even apply for a program for which they know they have to wait maybe 6 months, maybe 9 months, maybe 12 months. The majority are still there, and they are still willing to enter the program, when their name finally comes up 9 months later. That, also, is incredible.

With this kind of motivation, it is very difficult to do a bad job. On top of that is the inherent pharmacological validity of methadone as a treatment approach. It does produce a tolerance and this tolerance, or resistance, is not magical. It is exactly the same as the phenomenon with nosedrops which is common to almost everybody. The first few times one uses nosedrops the nasal passages open up and one feels great. The third day and the fourth day—essentially one could lie there all day with nosedrops dripping in with absolutely no effect. This is a question of tolerance and it is exactly the same thing with methadone. When people become tolerant to the effects of methadone, because it is a narcotic, they automatically have cross-tolerance, equal resistance, to all the other similar drugs, in other words, all the other narcotics. This pharmacologically is why methadone maintenance is effective.

I have talked about the external obstacles, discrimination, difficulties in employment and housing, and what a disastrous effect those problems can have.

I feel it is essential that the program provide supportive services, provide competent counseling to help patients deal with these external problems. Patients by and large can't deal with them alone and they do need assistance. This sort of assistance should be provided by a methadone maintenance program.

To summarize my comments, I would like to emphasize that for individual patients who seek this form of treatment, it has been demonstrated repeatedly over the years that methadone maintenance is uniquely effective. To these individual patients it really represents a difference between life and death. Our own program in 18 months, having gone from zero to over 5,500 patients, shows that it is possible to very rapidly expand this treatment service without sacrificing quality care.

We do have the means, we do have the ability, to continue very rapid further expansion.

There is nevertheless a continued gap which is unconscionable between the voluntary, spontaneous demand for treatment and the availability of treatment in established programs. One of the highest priorities of all levels of government has to be to eliminate this gap between demand and the legal availability in treatment programs. The discrimination against methadone patients has to end. This is going to be a slow, uphill battle, but it has to be won.

Finally, I would urge again that we keep in mind the limits of methadone. It is not a panacea, it is not the answer to the broad addiction problem in America. I definitely think it should not be funded at the expense of, or to the exclusion of, other forms of treatment and other prevention measures which are also very, very important.

If there are any questions, I would be happy to respond.

Senator Hughes. How many patients are you treating now?

Dr. NEWMAN. It is over 5,500.

Senator HUGHES. How many do you have in holding units?

Dr. NEWMAN. We are including in this 5,500 figure roughly 1,200 who are in what we call holding units. I would emphasize that the distinction between holding units and treatment units is really a very minimal one. There are counselors, supportive services, backup medical services for all the patients whether they are in so-called holding

units or treatment units. The holding units are not as heavily staffed as are the treatment units, but that is the only distinction.

Senator HUGHES. How long is a patient usually in a holding unit?

Dr. NEWMAN. It varies primarily with where the person lives. In some boroughs we have absolutely no facilities now. A person coming from one of those boroughs, for instance, Queens or Staten Island, may very well have to wait in a holding unit for 6 or 9 months.

I don't feel that there is really any major distinction between how patients do in one approach or the other because there isn't that much difference between the two clinics. It is just a matter of degree. It is a quantitative rather than qualitative difference.

Senator HUGHES. How is your program financed?

Dr. NEWMAN. We started off entirely financed by the State, through the narcotic addiction control commission. Since then we have also gotten a considerable city tax levy input and we have had a relatively small Federal grant of just over \$1 million in the past year. We will probably continue to have primarily State and city funding with perhaps some input from the Federal Government.

Senator HUGHES. Do you have any patient-cost figures worked out?

Dr. NEWMAN. Yes. Let me say that the per patient figure that we have is based on the total cost: the central office administration, data processing, urinalysis, and everything. It comes to roughly \$1,250 per patient per year.

Senator HUGHES. Per year?

Dr. NEWMAN. Per year, per patient.

Senator HUGHES. What kind of a recordkeeping system have you developed?

Dr. NEWMAN. I think an excellent one. We have a very, very tightly controlled data system. We have a network of 37 clinics now in the city. We know in the central office every single patient that is in every one of our clinics. No one can be admitted to any one of these facilities without having this admission reported in the central office. Nobody can be terminated without the termination being handled by the central office.

We know in the central office, therefore, every single patient in every single clinic. The medication records on a constant weekly basis are processed through the central office by computer. So we give to the clinics, and not the other way around, the analyses of what percent of their patients are on what dosages, what percent are coming in five times a week, three times, and so on, and how their schedule compares to the rest of the program.

We have an ongoing breakdown of all the terminations from the program by reason for discharge.

We have a monthly update of our waiting list broken down chronologically by borough.

It is really a very comprehensive and I think excellent data system. I would add that it was essential that we have this because we do have such a very wide network of diversified clinics in all of the boroughs.

The staff of the clinics is on the payroll of contract hospitals. As you can imagine, trying to supervise and very tightly control staff that is not on your own payroll can lead to major problems. But we have managed this by insisting upon the extremely tight data control system I have described.

Senator HUGHES. Would this be affected at all by the FDA record-keeping proposals?

Dr. NEWMAN. Absolutely not. We could deliver today every single one of the figures they ask for.

Senator HUGHES. The new regulations, as you know, prohibit private doctors from maintaining patients on methadone. What do you think of that?

Dr. NEWMAN. The only reason I didn't address myself to that is because I had hoped in my naivete that this was not implicit or explicit in the regulations. I feel the private physician has to be included in the delivery system of methadone maintenance and has to be included in a significant way, and not a token satellite handling five, 10 or 25 patients.

The problem is one of control. The problem is one of monitoring. I think it is almost a selfish attitude to say we would have trouble monitoring and enforcing our regulations by including private doctors, and therefore, we will make life easier for everybody and just write an edict and exclude them all.

In New York City the present private approved clinic population is between 3,000 and 5,000 people. I think anybody who wishes to propose limiting those who can provide this care must pay attention to what is going to happen to those already receiving care.

The alternative for these 3,000 to 5,000 patients in private programs, is going back to the streets and going back to heroin. They cannot be accommodated in the existing programs. The programs cannot be expanded artificially to accommodate them. I don't see how I could justify to the 8,200 people on my waiting list who have been waiting for the last 3 months, 6 months, 12 months, that they have to continue to wait while we take up these 3,000 to 5,000 people who are presently receiving care.

Whether they are receiving good care or bad care varies. The quality of any physician varies, unfortunately. The enforcement agencies and the county and the local medical societies have a responsibility to make sure that good quality care is given, that diversion is kept to an absolute minimum, that standards of admission and so on are adhered to. They have to accept that responsibility and they have to fulfill it.

I think it would be disastrous to exclude private clinics by fiat.

Senator HUGHES. You spoke very emphatically to the question of diversion for a reason that I have really never heard described before at hearings, and that is that you feel most of the illicit sales of methadone are to heroin addicts who are trying to get well or trying to stabilize themselves, rather than someone trying to get high. Is that correct?

Dr. NEWMAN. This is very definitely my conviction. I base this on talking to literally thousands of addicts over the past couple of years, both in the prison system and in our own program. Again, I am referring to New York City.

I would also add I am referring to the noninjectable types of methadone which are given in virtually every approved program. I am not talking about dolophine tablets which can be readily cooked up and injected. I am not talking about that.

When people take methadone on the street, my feeling is that almost without exception they take it in order to avoid withdrawal symptoms, either just today or just this afternoon or on an ongoing basis

while waiting to get into a maintenance program. They don't take oral methadone in order to get high. Obviously, there are going to be some exceptions, but I feel it is definitely the exception. When people want to get high, they are going to get high with the real thing and the real thing is not oral methadone.

Senator HUGHES. That is very interesting. Isn't that strange that we have never heard that before in all the hearings we held? It seems to make sense to me.

I am surprised we haven't heard about it before from the people working in the programs. How do you cope with the problem of illegal diversion in your own program?

You talked about the necessity of not having these patients come in every day after you get them stabilized, after you are relatively assured of their interest, and that they have started properly. How do you cope with the problem of diversion?

Dr. NEWMAN. I would first point out that decreasing clinic visits is not just for the convenience of the program. It isn't only that we can't accommodate all these patients every day. Even more important is the fact that it would be self-defeating in terms of the aims of the program to force people into this artificial regimen of every day reporting to the clinic. This is a clinical decision.

There has to be the facility to have people come in and pick up every day of the week, whether in the clinic, the hospital emergency room or whenever. But the staff has to decide clinically which patients are doing well and can be trusted and which ones can't. We would never lower the pickup schedule to twice a week simply because the person has been in treatment for 6 months. We would lower the pickup schedule to twice a week if the person is working, if we know he is working, if the person appears to be doing well.

Senator HUGHES. That is also a part of the therapy. When he reaches the point of deserving confidence, you feel it must be given.

Dr. NEWMAN. That is right. It has to be a clinical decision. As the new Federal regulations are written, after 3 months the number of visits could be reduced to twice per week. I am afraid that this regulation in practice is going to be interpreted so that after the first 3 months 95 percent of the patients in the programs will be dropped to twice a week pickup. That is crazy. I think this has to be a decision reached clinically.

No matter what we do in the programs to limit the supply, even if we force people to come in 7 days a week across the board as they do in some States, I think there would still be an illicit market because the demand, in fact, would increase. We would be driving out of the program a lot of patients who are doing very well in the program right now. They would feel with all the problems involved they would rather take their chances and buy it illegally.

If my wife had to go 7 days a week into a government-run clinic to pick up her birth control pills, I would be out on the street buying them for her.

Again, you have to consider not only the supply, which I don't minimize. Attention has to be paid to that. There have to be controls, and programs have to be held accountable for their practices in terms of limiting the number of days of pickup and so on. But to just focus on the supply without considering that very, very major demand factor will never lead to any kind of amelioration of the problem.

Senator HUGHES. You spoke of the problem of rising deaths from methadone overdose in children and so on. There has been a lot of publicity about this in both the New York and Washington areas.

Could you tell the committee what you think accounts for the increase? What is happening, Doctor?

Dr. NEWMAN. Yes. I am firmly convinced that people are taking methadone on the streets as a form of medication and not in order to get high. Again I refer to the oral type of methadone that is used by almost every program.

Senator HUGHES. Is it more dangerous than heroin, for example?

Dr. NEWMAN. I think it is pretty difficult to quantitate the two. I don't think it is more dangerous. But there are certain inherent problems in trying to consume on the streets, to treat yourself on the streets, with methadone, especially if methadone is given in a pre-mixed liquid form. Nobody has any idea what they are getting. God knows they have enough problems trying to guess what is in a bag of heroin.

When somebody drinks the Tang or whatever solution the methadone is mixed with, they don't know whether it is zero milligrams or 160 milligrams of methadone. I think when any medication, which potentially is lethal, is taken by self-administration, without any supervision, without a doctor's prescription, you are bound to have fatalities.

It is a tragedy that tremendous numbers of people, tens of thousands of people, are forced into this route because the public programs can't accept them. Really, it is almost an absurdity that given the extent of the problem over 8,000 people right now are told that we know they are going to stay on the streets and support an illegal habit and there isn't anything we can do about it except to continue to try to expand quickly.

I think as long as that situation exists you are going to have overdoses.

Senator HUGHES. One more question and I will turn to Senator Javits whose bill we are discussing.

You have pregnant women on methadone in your program?

Dr. NEWMAN. Yes, sir.

Senator HUGHES. Would you comment to the committee on the risks involved with pregnant women and also the risks involved to the babies of the women?

Dr. NEWMAN. Yes. I think the answer will be implicit in my telling you that the only group that we give top, immediate priority for admission to are pregnant applicants. We will accept a pregnant applicant immediately at the very top of the waiting list, no matter where she lives, no matter what the waiting list is in that particular area.

On the basis of what has been shown by experience, especially at Beth Israel where they have delivered several dozen methadone patients, we feel when there is a problem in the newborn infant these problems can be very readily dealt with medically.

They have followed up several dozen children over the course of several years and followed them up very intensively with complete laboratory tests, psychological tests and so on, and they have not found any problem with these children attributed to methadone taken by parents.

Even if people retain some doubt regarding risks to these children, if you consider the alternative right now to methadone maintenance for the pregnant women, I think there is no question that these applicants should be admitted immediately. We know what the alternative is. The alternative without question is continued heroin use on the street and everything that goes with it and everything that doesn't go with it. Prenatal care, by and large, is not something that the person who is hustling to maintain a habit on the street is going to seek. Adequate nutrition is usually something that the person is not going to receive. Usually the pregnant addict on the street is going to show up in the hospital for the very first time when the contractions are 5 minutes apart, when she is about to deliver, and she will usually have had her last shot of heroin 20 minutes before entering the emergency room. With that alternative, I think there is only one course to take and that is to give prompt admission to pregnant women who seek it.

Senator HUGHES. Then the baby would be addicted to heroin when it is born?

Dr. NEWMAN. Some are and some are not. The same is true of methadone patients who deliver babies. Some of the babies do show some withdrawal symptoms and some don't.

The withdrawal symptoms, per se, are generally very readily treated. But a baby who has gone through a gestation with no prenatal care, with totally inadequate nutrition on the part of the mother, who just shows up at the door before delivery, I think that baby is a very, very high risk.

Senator HUGHES. Senator Javits.

Senator JAVITS. Thank you very much.

Doctor, I apologize for not being here when you began your testimony but this is a morning when I have four executive sessions.

We are very proud of you in New York for what you have done and we are very pleased with your explanation of the situation in New York. The reason for this bill is the waiting list for methadone about which you have testified. There is no other reason.

I have no illusions about methadone's magical properties: I am thoroughly indoctrinated by you and other experts with the understanding that it can only be a part of the total treatment picture. This doesn't exclude any other agencies from searching for some other appropriate scientific solution.

But the waiting list is simply enormous. In fairness to you, because you are such a hard working doctor who has done so well, I believe that the new office with Dr. Jaffe will clean up the waiting list. I believe this is their first priority. I believe they have the resources and the organization to really do the job.

The only priority on which he is quite properly proceeding is the priority for veterans.

There is nothing I can add to the very thorough cross-examination by my colleague, Senator Hughes, who is so outstanding in this field, except to assure you that we are very conscious of the deficiency, and the deficiency is unforgivable. It has to be paid for.

You are so right about the fact that it is just beyond belief that there are 8,000 wild animals on the street instead of human beings who could be so inexpensively and easily brought into some kind of conformance with the society in which they live.

I would like for you to do this for us, if you would, if Senator Hughes would be kind enough to join me, to keep us informed. We don't know, often, living in these astral regions, what happens on the streets and in the clinics. I try and Senator Hughes tries. Keep us informed.

I ask unanimous consent that any reports you send us, whatever they may be, they be made part of the record.

Senator HUGHES. Without objection, it is so ordered.

Senator JAVITS. Keep us advised. This is the No. 1 case in New York City, with 8,000 on the waiting list. It is beyond understanding.

My understanding of the estimate is that there are several hundred thousand in the city alone. And when they say a town is going to pot, ridden with crime, how can you help it?

I think Senator Hughes has done a marvelous job in questioning you. Do keep us informed. We are not only legislators but we are ombudsmen. We can ride herd on agencies in an unparalleled way, if you have the initiative to give us the ammunition.

Dr. NEWMAN. Thank you.

Senator HUGHES. Thank you, Senator Javits. You did bring to mind a couple of things I would like to ask about, one being veterans.

You say you have an excellent recordkeeping system. What percentage of your patients and those on the waiting list are veterans?

Dr. NEWMAN. It is roughly 25 percent. Of those 25 percent who are veterans, that is of the men, roughly 45 percent state that the onset of addiction was in the military. We don't have it broken down by location of service. We feel that roughly 10 percent of all the men on our waiting list attribute their addiction to having started in the military.

Senator HUGHES. Do I understand that 45 percent of the 25 percent say that their addiction started in the military?

Dr. NEWMAN. That is right.

Senator HUGHES. And it continued even through their discharge or separation period?

Dr. NEWMAN. That is what they state; yes, sir.

Senator HUGHES. Are you getting any funding from the VA? Are you on a contract basis with the VA to help you treat these patients?

Dr. NEWMAN. It might sound peculiar but a year and a half ago I offered the funding if the Veterans' Administration would provide the backup hospital service, with whatever criteria of admission the Veterans' Administration system desired.

The response was that they really didn't have much of a problem, they really weren't interested. We have repeated this offer several times.

Let me just say that there seems to be some change in the wind. We have just received, in the last week, a tentative offer of funding to provide care for veterans. One of the stipulations is that every single one of the people admitted on this reimbursable fee-for-service basis would have to initially spend a certain period of time as an inpatient in a Veterans' Administration hospital.

Senator HUGHES. Are you aware of the reason for that?

Dr. NEWMAN. Sir, I believe it is that they don't otherwise qualify for benefits. In New York City, where we have 8,000 people waiting for admission, the Veterans' Administration methadone programs

claim to have absolutely no waiting list. That is a paradox. There has to be some explanation. If we have people who are willing to wait 12 months for admission, and who don't apply to a methadone maintenance program in the VA system, there has to be some reason. I suspect it is the mandatory 3-week or 6-week inpatient stay, which the addicts on the street as well as professionals know is simply no longer justifiable in medical terms.

Senator JAVITS. We know that. We are beating the doors of the VA in that connection.

Again, it is one of those ridiculous anomalies. They have a rule that you can't have clinical treatment unless you have a certain stay in a hospital first. So it applies to everything, the lame, the blind, and the addict. We are in the process now, with Dr. Jaffe, of beating that down.

Again, you have to keep us advised. As you say, they might tell us there are no people on the waiting list, but as you point out, if you have them on the waiting list and they are veterans, how can there be no people on the waiting list?

Dr. NEWMAN. Absolutely.

Let me expand on one other thing. As I said before, our No. 1 problem is space. If the Veterans' Administration provided space, within 3 or 4 weeks we could start admitting people to those facilities. We could expand far more rapidly and treat a lot more people, including a lot more veterans at once.

Senator JAVITS. What are the time parameters and the other facilities you need? Suppose you could get the money tomorrow for the 8,000. Obviously, you couldn't deal with them right way. What is the situation?

Dr. NEWMAN. The key factor is space. Our problem has not been money, because the city has given this top priority and has provided the money as we were able to spend it. If we had the space we could have expanded even more rapidly, twice as rapidly, as we have to date, without sacrificing quality care. We do operate in reasonably small units. If we had the space we could have done even better and we could do even better in the future.

Senator JAVITS. Is the space restriction financial, or the fact that you are unwelcome in the neighborhoods, or the fact that there is no rental space?

Dr. NEWMAN. The major problem is that we are unwelcome in neighborhoods. I would emphasize this is irrespective of what neighborhood it is. It is exactly the same in a Jewish neighborhood, an Italian neighborhood, or black neighborhood. People say, "We love addicts; give them methadone, all you want, but not on this block."

Obviously, if we had space within hospitals this would not be a problem. Even then the doctors would say, "Don't treat these people in the hospital. They are too sick." But that kind of opposition we can overcome.

Senator JAVITS. What about the many new office buildings that are empty in New York? That would take both finance and location.

Dr. NEWMAN. This is an avenue we have pursued. We have a number of clinics in office buildings. We have them in all different kinds of buildings. We have 300 patients being treated on the third floor of

a nurses' residence. Three hundred patients walk in, ride the elevator to the third floor, and that is the center. We have no problems.

We have other clinics in downtown Wall Street business offices. We haven't experienced any problems with our clinics once they are opened.

Senator JAVITS. What about the possibility of doing what they used to do in the old board of health days, which is to make a branch of the board of health a pharmacy, or a doctor's office, so you would have control and supervision. Is there anything you people have been doing in that regard?

Dr. NEWMAN. Yes. This is very feasible and desirable, but it has to be understood that this is sort of an outflow. This would free up some room at the top for new admissions but it probably wouldn't have any major impact. Perhaps I am saying that because our program is still so new.

Senator JAVITS. What can we do for you? If you don't need money—obviously, you do.

Dr. NEWMAN. I would qualify that, please.

Senator JAVITS. What can we do for you? What can Dr. Jaffe do?

Dr. NEWMAN. For instance, if the Veterans' Administration system were to tell me they would free up three rooms in one of their hospitals for use as a methadone facility, we could have a clinic operating there within 4 or 5 weeks.

Senator JAVITS. That is a big thing. We will get after the VA. I will take the liberty of committing my chairman and myself.

Senator HUGHES. I am on the Veterans Committee. I get an entirely different story from the VA than I am getting from Dr. Newman.

Dr. NEWMAN. I have in my files of 2 years ago, before we started the program, a written offer to the VA to provide all the funding if they would provide the space and backup facilities.

Senator HUGHES. Right now they say they don't have any problems.

Dr. NEWMAN. Because they have set up their approach in such a way as to discourage people from applying.

Senator HUGHES. But every program I visit, whether it is New York, Chicago, or Los Angeles, I find people telling me similar things to what you are telling me.

You are saying, according to rough figures, that at least 500 to 600 of the people you have on your program now, and another 1,800 of those waiting, are probably veterans, 45 percent of whom, or almost half, came out of the service addicted.

Dr. NEWMAN. That is true.

Senator HUGHES. I don't know if you know the nature of the discharges but I can tell you what I think they are, most of them. Yet, the President has committed himself to treatment regardless of type of discharge, even dishonorable.

To reconcile this difference is important. You say space in a veterans clinic in New York City is needed. If I understand it, they say they have no waiting list and they are taking care of the patients.

Dr. NEWMAN. The waiting list will depend on how unattractive or how impossible the admission criteria area. If you set up a 6-week mandatory inpatient stay, and this is unacceptable, you will not have a waiting list. You will not change your system, you are not going to expand your system, because you say you don't need it.

There has been little publicity, if any, by the Veterans' Administration system in New York publicizing the fact that they have addiction services available.

Senator HUGHES. Senator Javits, I have been told privately that the reason for this regulation is that the Veterans' Administration gets their funding on the basis of per-bed occupancy regardless of the nature of the problem. By doing this they can keep their per-bed occupancy at a very high level and thereby increase the funding in the Administration, even though the necessity of keeping the patient in the hospital may not be there at all.

Also, many of the patients who have been in the service will not go to VA for treatment under any circumstances. It was my understanding from Dr. Jaffe and representatives of the Administration that they were not prohibited from contracting space for caring for patients.

I would think with as many patients as Dr. Newman has, the Veterans' Administration could provide the space.

Senator JAVITS. I am told there is some bill which is pending, which is kind of impacted in the channels of getting something moving, and I think between Senator Hughes and myself now being alerted by you, Dr. Newman, and having a point of reference so that we can bring you down here to face the VA—I have done that before, just about a month ago—if you would be good enough to help us with that, we can move this along.

Do you need any authority from the mayor or the commissioner?

Dr. NEWMAN. I don't think we would have any problem. Let me say I could start off by sending Mr. Cutler a copy of all the correspondence that we have had. It is almost fantastic to read it.

Senator JAVITS. Send it to the chairman.

Dr. NEWMAN. Fine.

Senator JAVITS. Let the Chair have it. I know I am your Senator, but there is protocol. Let us have it. We promise we will dig into this very, very thoroughly.

Dr. NEWMAN. All right, sir.

Senator JAVITS. I would like one final question, if I may, in relation to a subject matter that came up yesterday that I think is important. New regulations apparently will limit methadone patients above the age of 18 years. In New York City, in the length of time I spent up there in two or three hearings, we ran into all kinds of juveniles who were addicted to heroin, many times not just months, but years.

What do you have to say about that?

Dr. NEWMAN. I feel this is an administrative policy which is totally unjustified on medical grounds. We have had to refuse people admission to the program who are 17½, who have been in and out of jail, who have been mainlining heroin for 5 years.

We have had to refuse them because there is some administrative edict that says if you are not 18 you can't be accepted. I think that is crazy. One case I remember because it was the 17-year-old son of a fairly high official in the Health Department. This person tried to gain admission for his son and we had to turn him down. This boy died. It is just a terrible bind to put the clinician in, that he can't use his clinical judgment, that by administrative fiat he can't admit anybody under 18, no matter how long they have been using heroin, no

matter how many times they have been in and out of jail. That is not the type of decision one can legislate.

Senator HUGHES. Do the new regulations give you sufficient flexibility for those under 18?

Dr. NEWMAN. Under the new regulations we would have to submit apparently an extremely tight protocol. This would be a research protocol. So it is feasible, but I think most programs in the country would be discouraged from going this fairly burdensome route.

Senator HUGHES. Dr. Newman, I think that pretty well covers the waterfront. I want to thank you again for coming down to testify. You have been very helpful to us.

Dr. NEWMAN. Thank you.

(The prepared statement of Dr. Robert Newman follows:)



METHADONE MAINTENANCE
TREATMENT PROGRAM
377 Broadway
New York, N. Y. 10013

THE CITY OF NEW YORK
HEALTH SERVICES ADMINISTRATION
DEPARTMENT OF HEALTH

TESTIMONY OF DR. ROBERT NEWMAN,
ASSISTANT COMMISSIONER, ADDICTION PROGRAMS
NEW YORK CITY HEALTH DEPARTMENT

TO BE DELIVERED BEFORE THE
SUBCOMMITTEE ON ALCOHOLISM AND NARCOTICS

MAY 24, 1972

At the present time there is a variety of legislative and administrative decisions being made which will have a profound effect on methadone maintenance treatment programs and the increasingly large numbers of patients throughout the nation whose medical and social well-being is at stake. Consequently, it is particularly gratifying to have the opportunity now to discuss with you some of the experiences of the New York City Health Services Administration Methadone Maintenance Treatment Program.

This Program accepted its first application and admitted its first patient almost exactly 18 months ago. In this past year and a half we have grown at an unprecedented rate and now have over 5,500 patients in active treatment. Such an expansion has been possible only through the extraordinary inter- and intra-agency cooperation within the New York City Administration, and the consistently high priority our Program has been given. Furthermore, we are confident that quality care has in no way been compromised in so rapidly achieving our present size, and that this will be confirmed by the independent evaluation now in progress.

While our ability to develop facilities to treat - and to treat successfully - this large number of patients strikes an optimistic note in a generally gloomy and overwhelmingly complex field, there is clearly no justification whatever for complacency. In these same 18 months we have received over 23,000 spontaneous and voluntary applications; our current active waiting list - unduplicated and eligible applicants only - numbers approximately 8,000. (The remaining applicants are accounted for in the following categories:

admitted and subsequently terminated; rejected; in treatment elsewhere; died; lost to follow-up prior to admission; duplicated applications). There is no indication that the demand is reaching a peak: we have continued to receive between 300 and 500 new applications every single week for well over six months.

Rather than dwell on our statistics of success, I shall address my comments instead to some of the major problems which we have experienced. I recognize that this is in keeping with the regrettable trend of the mass media in recent months to focus only on the alleged negative aspects of methadone maintenance treatment, and to virtually ignore the dramatic, proven benefits to patients as well as to society in general. I hope, however, that it will be useful to this Committee to discuss the problems from the perspective of a methadone program director.

ILLICIT DIVERSION OF METHADONE

There has been a great deal of attention directed recently to the illicit diversion of methadone. In fact, the new proposed regulations governing the use of methadone seem to have been designed almost exclusively with this problem in mind. It is my conviction that these F.D.A. regulations, and other suggested means of dealing with the situation, reflect a very inappropriate and one-sided analysis of the illegal use of methadone. (Note that my comments refer to the non-injectable methadone preparations used by virtually all approved programs; dolophine tablets, which can readily be mainlined, pose considerable potential problems and should not

be used in treating addiction).

Any market - whether legal or illegal - depends on two factors: supply and demand. When a commodity is known to be effective and/or desirable, and the legal availability is inadequate to meet the demand, then a black market becomes inevitable. This applies to such totally diverse items as nylons and penicillin in post-war Europe, babies in areas where bureaucratic red tape and/or limited supply pose major obstacles for prospective parents who wish to adopt, and abortions in those states where this operation is not available on request. It should be clear, therefore, that it is totally illogical to make a value judgement condemning a commodity simply because it is sold and purchased illegally.

The attempt to eliminate a black market by dealing only with the supply has almost without exception proven a failure. Certainly this is true of all the examples cited above; it also applies to previous attempts to deal with alcoholism (i.e. during prohibition), and all other drugs of abuse. In the case of the black market in methadone as well this approach is doomed to be self-defeating. Even if there is a modicum of success in lessening the illegal availability of this drug, consideration of the factors creating demand will lead to the inescapable conclusion that the consequences would be infinitely worse.

It is no secret why some persons can be induced to sell methadone; it is simply the incentive to make money. It is the reason why people seek to buy methadone that is critical. The answer, of

course, has already been stated: the demand for this effective commodity can not be met through existing legal channels. It is essential to understand that "effectiveness" in the case of methadone refers to its unquestionable therapeutic properties rather than to its ability to produce a certain degree of euphoria in non-tolerant individuals. There is absolutely no doubt that whatever "high" can be obtained by non-tolerant persons from the oral ingestion of methadone in no way compares with the effect of injectable heroin - even the markedly diluted heroin which is sold on the streets today. I, have personally spoken with thousands of addicts and ex-addicts over the past several years, and although illegal use of methadone is certainly not rare, the reason for use is virtually without exception therapeutic rather than euphorogenic: in other words, addicts take methadone in order to avoid withdrawal symptoms when heroin is for some reason not available to them, or when they wish to give up the use of heroin and all that goes with it; they do not buy methadone to get high.

Our own waiting list speaks for itself: there are over 8,000 hardcore heroin addicts who desperately want the help that methadone maintenance treatment offers, and who are forced to wait as long as a year or more for admission. In New York City there are estimated to be an additional 10,000 or more addicts awaiting admission to other publicly funded methadone programs. It is incredibly naive to react with surprise when it becomes known that some of these persons seek to buy illegally that which they are temporarily refused by approved programs. It is even more naive to anticipate

any salutary effect of proposed remedies which, even if they lead to a lessening of illicit supply, simultaneously curtail legitimate availability far more. Precisely this self-defeating result can be predicted if the proposed new Federal guidelines are implemented. Not only expansion capability, but even existing capacity of methadone maintenance programs will be severely reduced by requirements such as the following:

1. Mandating a minimum of six visits per week for at least three months after admission, and a minimum of two visits per week indefinitely thereafter, will obviously limit the number of patients that can be accommodated.

The number of patient visits as well as total number of patients are both critical factors in determining capacity of a Clinic. Furthermore, many addicts will be discouraged even from applying for treatment since this inflexible schedule will often prove incompatible with employment, education and family responsibilities (note that approximately 20% of all patients in our Program are employed at the time of admission). Finally, the schedule required will inevitably subvert the major thrust of the methadone maintenance treatment program: the return to a normal, productive role in society. There is an inherent contradiction in this therapeutic objective and the proposed attendance requirements.

2. Money is a limiting factor in the expansion of most methadone programs. The inflexible minimum of one urinalysis per patient per week will cost the publicly funded programs in New York City alone over \$3 million during fiscal year 1972-73. Requiring

this expenditure regardless of clinical judgement of the program staff is irrational and will further restrict the resources available for accommodating more patients.

3. The published regulations are unclear as to the effect on the private physician who has submitted an approved protocol but who does not have formal hospital affiliation. I am hopeful that such practitioners will not arbitrarily be excluded from employing methadone maintenance in the treatment of heroin addicts. Clearly there must be controls, and enforcement agencies as well as professional societies have a responsibility to monitor and impose sanctions against physicians who abuse their license to administer and dispense narcotics. On the other hand, it is estimated that between 3,000 and 5,000 persons are currently receiving maintenance treatment from approved private clinics in New York City alone, and the alternative for these persons is resumption of heroin use or the attempt to self-medicate with illicit methadone.

There have been numerous reports recently of deaths attributed to methadone. Certainly this problem is a major concern, but it must also be viewed in perspective. As already noted, a black market is inevitable as long as the demand for treatment is far greater than the legitimate availability of services. As is true of innumerable medical regimens, when methadone is self-administered the results can be lethal. Once again, the problem lies less with the inherent properties of this medication than with the unconscionable need which we impose on desperate addicts to seek methadone

in the only available market - the black market.

Additionally, medication which is consumed by persons for whom it is not intended can pose fatal dangers. Patients must be advised of the imperative need to keep methadone out of the reach of children, and it is the responsibility of programs to devise all means possible to lessen the danger of accidental ingestion. To respond to this problem, however, by greatly restricting the take-home privileges of patients is no more rational than if this approach were used for other medications such as aspirin, birth control pills, and the infinite variety of commonly used-and mis-used-drugs.

PROBLEMS EMANATING FROM PREVIOUS FAILURE TO SUCCESSFULLY TREAT NARCOTICS ADDICTS

The well-documented inability of the medical profession until very recently to deal effectively with heroin addiction has created a general attitude of skepticism and cynicism among all sectors of society regarding the concept of the "ex-addict." This term, like the term "ex-offender," is generally used as an indulgent euphemism. There remains the fear and the discrimination against the "dope fiend" which all too frequently becomes a self-fulfilling prophecy: when denied housing, employment, training and the general acceptance of society, ex-addicts, including methadone maintenance patients, may well conclude that their efforts at rehabilitation are futile and that while internal obstacles may be dealt with, those imposed by an outside world which at best is indifferent, at worst is openly hostile, are insurmountable.

We encounter these understandable but unfounded fears and antagonisms constantly. The unwillingness of many communities to tolerate a methadone maintenance clinic in their neighborhood is the single greatest limiting factor in the expansion of our program. We are only rarely attacked on conceptual issues related to the use of methadone; the common attitude is: "We love addicts; we love methadone; we are delighted that you are going to open a methadone clinic - but don't do it on this block!"

It is probably redundant to point out that an essentially similar attitude exists among employers (including governmental agencies), vocational training programs, housing authorities, Social Service Agencies, and others whose acceptance is critical if our patients are to be successful in their honest efforts to leave behind them their life of criminal addiction.

I am hopeful that the unparalleled success of methadone maintenance in the treatment of narcotics addicts will ultimately dispell the fears which exist. We are already seeing a marked decline in typically addict-related crimes in most cities which have large-scale methadone programs. Without question, these statistics can not be attributed solely to addiction programs, but it is highly likely that they do indeed account for a significant proportion of the decline. For patients in methadone programs, independent evaluation reports have already consistently demonstrated the dramatic reduction of arrests and the equally dramatic increase in socially acceptable and productive activities.

Nevertheless, old prejudices die hard, and even professionals in the addiction field seem unwilling to give up the notion of "once an addict, always an addict." The proposed new federal regulations reflect this bias from beginning to end. One widely publicized recent article in the prestigious Journal of the American Medical Association clearly impugned the reliability of urine specimens obtained under the direct supervision of "so-called ex-addicts." Small wonder then that the lay public is unwilling to accept the fact that methadone maintenance patients can and should be treated for what they are: normal human beings who, as a group, have the same spectrum of good and bad as any other group of individuals.

PROBLEMS EMANATING FROM OUR PRESENT SUCCESS

The frustration with the increasingly severe and widespread problem of addiction, and our almost total inability heretofore to deal with the situation, has existed side by side in this country with a feeling that there is an answer to everything, and that usually the answer is in the form of a drug. Given this combination of factors, it is not surprising that the unprecedented success of methadone maintenance is grasped by many as the long-awaited panacea to addiction in America. In truth, there are undoubtedly well-intentioned proponents of methadone maintenance treatment who have consciously or unconsciously helped promote this expectation, and whose over-zealous claims fell on most receptive ears. Ultimately such unwarranted expectations could be truly disastrous, and we are already experiencing many very serious problems as a result of these false hopes.

Those who control the distribution of scarce resources to combat addiction are naturally attracted to a treatment modality that has a well-documented and extremely impressive success record, that can serve large numbers of persons, and that is relatively inexpensive. The result is that there is an inclination to provide funds for methadone maintenance treatment facilities at the expense of other approaches - including preventive programs, drug-free modalities, therapeutic communities, and programs directed specifically at the adolescent and pre-adolescent drug abuser. The folly of such decisions is clear when the undisputed limitations of methadone maintenance are considered: this modality is clearly not preventive, it is not effective for those without a primary dependence on narcotics, and above all it is not effective in treating those who do not wish this form of therapy. Short-term hostility aimed at methadone programs considered to be competitors in the funding market is only one consequence - albeit a serious one when community opposition can block the opening of new clinics. Of even greater concern to me is the inevitable disillusionment which will ultimately be experienced by those who today support methadone maintenance in the belief that it is the cure-all, and the consequences of such disillusionment on subsequent continuation of this vital component of the approach to addiction.

Over-expectation also accounts for the increasing pressures on many programs - including our own - to "treat" addicts against their will. The concept seems to be that this magic potion, if forced down an addict's throat, will produce a prompt cure. There are those who would like to make methadone maintenance treatment the only alternative to incarceration for all addicts who are arrested. Others

would like to see this treatment made a condition for continued eligibility for Public Assistance. And there are those who sincerely believe that an involuntary commitment program - an approach which to my knowledge has never been successful and should be immediately abandoned - can be infused with new life by adding methadone to the regimen which is forced on the unlucky and unwilling recipient of services. These and other extensions of methadone maintenance treatment are, in my estimation, doomed to fail because they do not take into account the limits of this modality.

In fact, there is nothing magical about the effectiveness of methadone maintenance treatment. The unique results are a consequence of the following combination of factors:

1. Patients who are incredibly well motivated to leave a life of addiction and associated crime and to regain control of their own destiny.
2. The inherent pharmacological validity of methadone maintenance as a long-term treatment for narcotics addiction. In appropriate dosage, daily administration of methadone produces a tolerance - or body resistance - to the euphoria, the sleepiness and the respiratory depression of all narcotics, including methadone itself. This is no more mysterious than the experience common to most of us who have had occasion to use nose drops: while initially effective in clearing the nasal passages, repeated use leads to a total tolerance to the medication; this is not caused by the cold worsening, or the nose drops becoming weaker, but by the resistance to this drug which develops with repeated use.

Additionally, methadone maintenance eliminates the physical craving for narcotics in most former heroin addicts. The mechanism for this action is far less clearly understood, but it is confirmed by the overwhelming majority of patients in programs all over the country.

3. Addicts do not enter treatment because they suddenly lose their taste for heroin. Rather, it is generally a desire to escape from all that goes with the addiction, and to resume a productive role in society. As has been pointed out previously, there are major external obstacles which exist, and a competent supportive services staff in the clinic is often necessary to help the patient achieve "success."

In summary, I would like to emphasize the following points:

- a. Methadone maintenance has been well documented as a uniquely effective means of treating the overwhelming majority of heroin addicts who voluntarily seek this treatment modality.
- b. During the past 18 months the Methadone Maintenance Treatment Program of the New York City Health Services Administration has demonstrated that it is possible to expand at a very rapid pace without sacrificing quality care. In fact, we have grown from zero to over 5,500 patients in one and a half years.
- c. In New York City, as in virtually every other city in the nation, the spontaneous and voluntary demand for treatment remains far greater than the capacity of existing programs.
- d. This gap between demand for treatment and available capacity requires that the highest priority at every level of government be given to enable methadone program expansion so that

all eligible applicants can be promptly admitted.

e. Illicit diversion of methadone is indeed a problem, and will not be resolved until legal treatment is available promptly to all those who want and need it. Efforts at lessening the illicit supply will be self-defeating if they simultaneously diminish treatment capacity.

f. In the interests of the patients as well as society at large, the existing discrimination against ex-addicts in all fields - including attitudes - must be overcome; it is recognized that this will be a slow struggle.

g. The limitations of methadone must be recognized along with its effectiveness. Specifically, it must not be concluded that methadone maintenance is a panacea which will solve the enormous drug abuse problem which presently exists. Methadone maintenance can not and should not be forced on unwilling subjects. Other treatment and prevention approaches should be encouraged and supported.

Again, I wish to thank you for the opportunity to address this Committee. I shall be pleased to respond to any questions you may have.

Senator HUGHES. The Chair calls Dr. Carl Chambers, director, addiction sciences, Department of Psychiatry, University of Miami Medical School, Miami, Fla.

STATEMENT OF DR. CARL CHAMBERS, DIRECTOR OF ADDICTION SCIENCES, DEPARTMENT OF PSYCHIATRY, UNIVERSITY OF MIAMI MEDICAL SCHOOL, MIAMI, FLA., ACCOMPANIED BY CHARLES ELLIS, RESEARCH ASSOCIATE

Dr. CHAMBERS. Thank you, Mr. Chairman.

Senator HUGHES. We appreciate your taking the time to testify before the committee, Doctor.

Dr. CHAMBERS. Thank you. With your indulgence, I brought an individual with me, Mr. Charles Ellis. I would appreciate it if he could join me. He is a research associate in the division of addiction sciences. He is also the chief drug counselor in our Metropolitan Dade County drug program. He and his wife both have been methadone patients for some 7 years. He might be able to present you with a set of empirical data that those of us who just research the problem or treat it would not necessarily have.

We came here this morning to speak in favor of methadone, quite frankly, and to speak in favor of expansion of methadone maintenance in the Nation's attempt to address the problem of drug abuse.

In doing so, however, we would like to point out what we, as researchers, find as limitations and point out some areas where research and evaluation still needs to be conducted.

There would be no reason for me to talk to the committee about increased productivity among methadone maintenance patients, about decreases in criminality, about increases in emotional stability. You have had the best clinicians in the country before you to do that.

I think, however, as clinical researchers and as methadone clinicians from some time back, we would point out that productivity is not necessarily the automatic kind of phenomenon that some clinicians and some researchers would lead us to believe it is.

It is true that some 20 percent of all methadone maintenance patients when they come into a program are already productive, and that even after a year at that level of productivity they will not increase beyond 60 percent. Probably what we are getting is a group of clients who want to become productive and a group of clients who do not want to become productive. We will have to address them with that dichotomy.

It is our experience, and I think we can demonstrate it with hard research data, that if you do not make your client productive or do not assist him in becoming productive within the first 9 to 12 months, you might as well give up, that it doesn't make any sense economically from a cost-benefit standpoint to continue to try to make this individual productive. It might do us well to begin to talk about going on welfare as an alternative to the kind of productivity that most of us think about.

In programs where they draw from base populations where unemployment is probably already high it is unrealistic for us to demand that all of our patients go to work. I would choose that we not become too confused with the statistics on decreasing criminality as well. For

example, I have contributed some statistics to the literature on decreases in criminality that I am happy to live with. It was statistics that we generated from decreases in arrest rate. Anyone who has worked with arrest statistics and police figures and prison statistics and figures knows the limitations to those things.

Criminality does decrease but criminal involvement and criminality does not disappear in maintenance programs. You still have people who have spent large portions of their life stealing and in criminal involvement and this doesn't change with methadone.

If large numbers of people still need money, still can't qualify for training programs, educational programs, welfare programs, then the major source of income still is in criminal involvement.

Again, don't get too excited about decreases in arrest figures until we analyze what it means. Clinicians have consistently reported getting along better with families and friends. As a scientist, I have been unable to count these things. I have been unable to establish the insight that some clinicians have.

I think there should be a national effort to look at how these things actually occur and what level we will be able to generate the methodological strategies necessary to look at them. At the present time, we don't have those methodologies.

Methadone, if it is used properly, can and does control the narcotic addict's physical addiction, but ancillary services are needed to affect the addict's reentry into the community. Methadone alone accomplishes little. Methadone plus a motivated patient, plus a competent staff, and plus an understanding community accomplishes a great deal. Unfortunately, these extra pluses don't exist in most programs.

I believe those of us who do the treating have a lot to learn about the modality, itself. We talk as if we know a great deal about the modality when in fact we do not. For example, we have never learned how to get the staff's perception of the addict and the addict's perception of treatment together. A very excellent study done last year would indicate that the addict comes into treatment and remains in treatment with the belief that his problem is primarily a physical addiction and if he transfers that addiction from his drug of choice to methadone his problem is essentially solved.

On the other end of the continuum, some 95 percent of all staff dealing with addicts believe the addicts to be emotionally ill, mentally ill, and incapable of coping in the current society. Staff tends, I think, sometimes to set up situations, set up clinic goals, to keep the patient passive and dependent and noncoping within the system. I think we really need to begin to look at these goals.

I think we must begin to look at the modality at a very realistic level. I still believe that we assume the modality does more than it really does. We have not learned, for example, with whom the modality works best. We have not learned how to screen patients into treatment, nor have we learned when to screen people out of treatment. I think these are areas that we have expertise in and we simply have not pursued them.

We have had the modality for some 8 years now and we have gained 8 years of experience. I say we have gained very little knowledge in those 8 years about the modality. One of the things we consistently do is to continue to expect more from our clients than we do from the base population from which they come. This is totally unrealistic and we

really need to begin to look at this problem. We have yet to determine or establish the determination of what role such things as urine surveillance, take-home medication, inpatient versus ambulatory stabilization, the role of various medication doses, the role of concurrent medications play in treatment. We haven't established what any of these mean in the modality.

We talk as if we have but we have not done so. It is our impression, and I have been associated now with three different methadone programs—Philadelphia, New York, and now in Miami—we believe that the more you structure a program, the more you control the program, the fewer problems you have with the program.

For example, if you are loose about how you interpret cheating behavior, if you are loose about how you take your urines and what you do with the results, then you get an extensive amount of cheating. If you, in effect, forbid cheating to occur, relatively low cheating does occur. If you tolerate such phenomena as lost medication and missed medication, both of which I personally see to be signs of diversion, then the medication is playing a role that you no longer have any control over. This needs to be looked at closely. If you forbid it, you get very little of it. If you tolerate it and every time an individual comes in with the hustle, "Somebody took my medication" or "I lost my medication", you are in essence feeding diversion.

What I am trying to say is that if society and the addict both are to profit from this modality, then I think we are going to have to insist upon very careful, highly structured, and highly controlled programs.

Let me share for you the results of three studies which I have been involved in in the area of diversion. I would not want to totally contradict what other speakers have said before you but I tend to think the problem is a little more complex than most people are willing to assume it is. I think a number of us have a role in it and we are not really ready to assume that we are playing those active roles.

One study, for example, in which I was involved was in the clinic of Philadelphia. It involved running short-term low dose ambulatory detoxification programs with no inpatient phase.

Senator HUGHES. Excuse me for a moment. Twice you have mentioned different dosage levels. I am not familiar enough with methadone maintenance to know the difference in dosage levels.

How do you calculate how much you give the man or woman? What is the difference and why the difference? Is it physical stature or is it the amount of heroin he used?

Dr. CHAMBERS. In all other medications I think it is, but in methadone programs it tends not to be that precise. We tend to look for a number of physical signs and a number of statements from the client himself. I think a general rule of thumb, not just for the layman because I think it is the same general rule that clinicians are currently using, is that if you present 40 milligrams a day to an individual and gradually take it away from him, then that is a "detoxification" procedure and he should suffer no physical discomfort with such a regimen.

On the other hand, if you begin with 40 milligrams and build the dose up, increase the dose above 40 milligrams, you are into "maintenance." The confusion in the field is how to determine what is "low dose maintenance" and what is "high dose detoxification." Most programs now accept the fact that to get the maximum benefit out of the medication you have to use at least 60 milligrams and probably don't

need more than 120 to stabilize an individual and maintain him with methadone.

Unfortunately, there are clinicians who do not read the literature, do not heed the suggestions, do not conduct the research themselves, and so forth and their doses are in excess of these limits—250 to 350 milligrams are not uncommon in at least one program.

Senator HUGHES. That will help me some. Thank you.

Dr. CHAMBERS. I was starting to discuss diversion.

We attempted to detoxify people on an ambulatory basis. It is cheaper and we thought we could do it. We knew the problems were considerably different than trying to detoxify inpatients but we attempted anyway.

It was done so for a number of years and it would not surprise me if the clinic is still attempting to do so. What was found in a very extensive follow-up study is that we were actually creating the demand for illicit methadone and at the same time producing a supply to satisfy the demand. Relatively naive addicts would come for detoxification and we would place them on a methadone reduction regimen. Too often they would get a taste of the methadone, leave the detoxification program and become primary methadone addicts.

Their major source of supply for the drug now that they chose to use it for its euphoric effect was methadone diverted from the maintenance patients being serviced out of the same clinic. The figures are in the literature. They are very high. Some 80 percent of our clients left prior to detoxification. In excess of 95 percent were using drugs at the time they left and some 25 percent became primary methadone addicts.

I think we, as clinicians, had a role in the production of these primary methadone addicts.

A second study was in New York.

Senator HUGHES. I have been under the impression that a heroin addict could not achieve euphoria on a maintenance dose of methadone.

Dr. CHAMBERS. If you will accept a rather smart mouth answer, I hope not very many people believe that. It could not be further from the truth.

Senator HUGHES. I am afraid too many of us do believe that.

Dr. CHAMBERS. That will make the addict very happy. His "euphoria" can be produced by any of the narcotics. It does not have to be heroin. He chooses heroin, I think, and there are undoubtedly people in the room who will differ, not because heroin is actually that much better but that he thinks it is that much better. It is part of the mythology about the drug, what it will do, what it won't do, what it will do for you, what it will do to you. So I think it is the "mythology" which brings heroin in.

If you are simply looking for the euphoria, if you are simply looking for a good high, then you should be shooting numorphan, not heroin. It is 20 times more potent than morphine. It is a beautiful drug. But they choose to use heroin instead.

Senator HUGHES. That teaches me a little bit.

Dr. CHAMBERS. The second diversion study was conducted in New York City. It really addressed the questions that the previous witness brought up, how available is methadone on the street, where does it come from and why do the addicts buy it.

In brief we simply went to the street and interviewed the first 100 active addicts we could find. We had no trouble finding addicts as we interviewed in Stuyvesant, a high-risk area in the city.

Of the 100 people we found, we found some 95 had purchased illicit methadone in the past. We found 53 buyers within the past 6 months out of the 100—50 of the 53 buyers reported purchasing the methadone for their own personal use. For example, they were not buying for resell. The majority of the buyers, some 79 percent, reported methadone was always available in their neighborhoods.

Not unexpectedly, the greatest source was patients enrolled in ambulatory programs who were on "take home" medication.

Of those 53 addicts who had illegally purchased in the last 6 months, 39 or 74 percent reportedly purchased the drug from active methadone patients. When we asked them why they bought the drug, how they used it, some 41 percent told us they used the drug to insure against withdrawal distress—simply buying insurance. It was always there. These individuals kept a "stash." If the addict could not buy drugs that day, he always had methadone to tide him over.

Some 40 percent bought the drugs solely to boost the weak heroin available on the streets. Only 17 percent, and I repeat because of the previous witness' testimony, only 17 percent said they bought the drug to clean up, to "self-medicate" because they couldn't get on a program. Some 2 percent had bought solely for resale.

Senator HUGHES. You said 40 percent bought the methadone to boost the weak heroin?

Dr. CHAMBERS. Yes, sir. It is not an antagonist. It does the same thing for the individual that heroin will do. An antagonist would neutralize what the heroin is doing. This simply replaces it or does the same thing. It is true of any of the narcotics. When people say there is nothing magic about methadone, they are right. You could "stabilize" an individual on codeine. You can "stabilize" him on morphine. The Clinical Research Center in Lexington has done all these things. It is just that methadone has certain properties that make it more advantageous than codeine, which makes people sick, and heroin, which is illegal in this country.

The third study, the most recent of the studies was done in Miami. I did the study primarily to address the issue of whether methadone maintenance is an appropriate modality for primary methadone addicts. If we are diverting large amounts of medication and people are choosing it as a primary drug, then we are going to have a large number of primary methadone addicts which will have to be serviced. I am not convinced that methadone maintenance is an appropriate modality for primary methadone addicts. For example, can you use methadone as a medicine when an individual has been using it to get high on?

In our clinic we do three intake urines on every person who comes in for treatment. These urines are taken prior to getting any methadone. We found that some 38 percent of all of our applicants for treatment had urines positive for methadone before we gave them any medicine. This indicated to us that there was a large diversion of methadone in our community. Approximately 10 percent of all of our intake patients were positive for methadone and were negative for heroin.

They were either self-medicating themselves with methadone before they came to us, or they were primary methadone addicts. We don't know which is true.

We now have the group under observation and we are treating them exactly as we do our normal methadone maintenance patient, to see if the maintenance modality works with these special clients.

There are a number of other people in the country attempting the same studies so the question of maintenance for methadone addicts might get resolved.

I think without question the major weakness of all methadone programs is that most of them don't provide for good researchers with the same care that they provide for clinicians. Our 8-year staffing grant, an NIMH staffing grant and we are in our second year, provides for only one program evaluator and one programmer. You cannot do research on a staffing grant. You can only do a limited program audit and generate population movement statistics.

Our proposed expansion grant under Dr. Jaffe doesn't even have those limited evaluating potentials. If researchers are not going to be intimately tied to methadone maintenance programming, then I don't really know who is going to answer some of the more basic, fundamental, and important questions about the modality.

These primary questions include such things as: Is maintenance an appropriate modality for persons addicted to methadone? We don't know.

Who doesn't come in for methadone treatment? One of the major reasons people are telling me that I should begin to consider heroin maintenance is that there is a large pool of people who won't come in for methadone. That has never been demonstrated. I don't know who doesn't come in for methadone and I don't know anyone who does know.

I don't know, what specific roles ex-addicts, paraprofessionals, should play in the treating process. I don't know whether they have unique skills that the clinician does not have or cannot develop. But we need to research this question.

We are unable at the present time to specify the times when an individual is ready to detoxify from maintenance. I am unwilling to accept the fact that most people must be long-term maintenance patients. Without question, some people will be on maintenance programs the rest of their lives but I think that these would be a minority, if we could better learn how to screen people for detoxification and learn how to proceed with the actual detoxification procedure.

We don't know what the long-term effects of methadone are going to be. We have some very gross kinds of measures, about weight gain, about loss of libido, et cetera, but no real clinical research trials on what happens to an individual that you have stabilized for 10 or 15 years on methadone.

I am sure you can think of other questions that you would like to have answered.

Unfortunately, researchers are not assigned routinely to methadone programs to pursue answers for these kinds of questions. They are put there to do program audits—how many people there are, what sex they are, what race they are. These are not research questions. These are program census statistics and don't even require researchers to generate them.

In addition to these comments on methadone and before I leave, I would like the committee to consider a couple of issues that have become basic concerns of mine in the drug field.

For example, I believe the narcotic addict is changing. I think he is essentially different from the patient we saw 5 years ago, and most assuredly is different from the patient we saw 10 years ago. The addict we see now is not a heroin street addict in the classical sense or as he is described in the literature. He is a polydrug user; he is a poly-criminal; he is much younger; he comes into treatment earlier, and he certainly has a different psychological makeup than the individual we were treating as late as 1965, 1966, and 1967.

For example, during those earlier treatment experiences, primarily in the Lexington-Fort Worth facilities, I couldn't find a narcotic addict who would consider using a psychedelic, who would think about using high doses of amphetamine. Now that is all I do find, people who don't have drugs of preference or choice. They leave the house in the morning and take whatever drug is available.

To illustrate the point, I had my analyst last week poll eight different people at random—four in each of the race/sex groups we are servicing. One was 16, a white female who was regularly using 16 different drugs; one a 19-year-old white female regularly using 24 different drugs; one a 17-year-old white male using 40 different drugs; one a 19-year-old white male using 34 different drugs; one a 17-year-old black female using 13 drugs; one an 18-year-old black female using 17 drugs; one a 19-year-old black male using 15 drugs, and one a 19-year-old black male using 22 drugs.

We defined "use" as once a week for its euphoric effect, using it to keep high.

As you can see from these kind of gross statistics, we aren't seeing heroin addicts any more. We see "polydrug users."

As a result of these "numbers" and we asked all the patients that we could contact on such short notice a series of specific questions such as how many used a psychedelic during the 30 days before entering treatment. In excess of 20 percent of our clients had used psychedelic drugs the month before they came in for treatment. Some 20 percent had been high dose amphetamine users in addition to the heroin or methadone, and some 60 percent—I repeat, 60 percent—had been users of one or more of the barbiturate sedatives or nonbarbiturate sedatives, sleeping pills or one of the sedative-hypnotics.

Continuing with the profile of the new client which I believe we have to face today, we have found criminal involvement has changed. I grew up in the late 1950's and early 1960's on the same texts that most everyone else in the field did which stated that addicts were passive dependent individuals who might break into your home, shop-lift from you, or steal from your car, but not people that you had to be afraid of. They did not commit crimes against persons.

As a matter of fact, this is false, and terribly misleading to the public. Some 60 percent of our male patients and some 30 percent of all of our female patients commit both crimes against persons and crimes against property. Some 55 percent and 25 percent admit to being armed robbers. We have a large number of addicts who are walking the streets armed. I believe this is a relatively new kind of thing for the addict and for us to deal with.

In addition, the arrest liability for these behaviors is very low. I don't want to antagonize the enforcement people of the country, but if you want to understand criminal involvement go to the addict himself and forget arrest statistics. We have gone to the addict and interviewed him while he is still active and our data would suggest that he is committing in excess of 120 crimes for each one that he is arrested. For each one that he is arrested, less than half of them are ever brought to the point where he is found guilty and either serves times or is put on probation for that offense. The arrest liability for committing crimes is relatively low.

Speaking to the issue of the new patient being a younger person, we know that he is. In 1965 the average age of patients seen at the Lexington facility was around 30. The average age of all people seen in the New York State narcotics program last year was only around 23, and it was a much larger population than the one we had in Lexington. The age of the addict has gone down considerably. We are not dealing with a 30-year-old adult. We are dealing with a 19-, 20-, 21-, and 22-year-old beginning adult.

During the same period of time when the ages were high, we did not see the individual in treatment until he had been addicted some 7 to 10 years. Now we get him into treatment during his first and second year. We are not only getting a younger addict but a novice addict.

I point these out not to give you numbers or facts because I am not sure what they mean. I rather ask you to ponder something. If we have generated all of our treatment modalities on the basis of the addict we were seeing in 1965 or so but the essential nature of the addict has changed, should we not consider what changes and new modalities ought to be pursued?

I would also hope that those who shape our national strategy would consider that probably more of our population have become dysfunctional from the abuse of nonnarcotic drugs, the so-called soft drugs, than from the abuse of narcotics.

Let me share the results of a study we recently did in Miami. It involved going to the emergency room and finding out what kind of OD's showed up.

Jackson Memorial Hospital is our county hospital and our teaching hospital. It has the fourth most active emergency room in the country. We get some five OD's a day in our emergency room. We followed those OD's for an 8-month period. Of those who survived, we found less than 30 percent—28.3 percent—had overdosed from using one of the illicit drugs. The remainder had overdosed from the legally prescribed and distributed drugs. We were very surprised to learn that because these OD's were overdoses from the legally prescribed and dispensed drugs were not from narcotics. Some 28 percent were for sedative overdose, and the sedative overwhelmingly was Doriden, at that time being marketed as a nonbarbiturate nonaddicting sedative-hypnotic. As a result of exposing the misuse of Doriden in our community we believe the incidence of its use has declined.

We found more of our people, for example, showing up in the emergency with OD's from Darvon than we did from heroin, and yet this is a drug which is essentially noncontrolled. I guess what we are saying is that we would hope that the national strategists would not overlook a couple of items we believe. One, there are people who have drug

problems which methadone will not address and there are people wanting in programs other than methadone. For example there are waiting lists for the Therapeutic Communities in my county. We would also choose that they not lose sight of the fact that in numbers we have a bigger problem with the nonnarcotic users.

Senator HUGHES. Thank you very much, Doctor. You have covered a lot of territory in your statement. You have raised a lot of questions.

How does it happen that addicts in maintenance programs have enough left over to sell?

Dr. CHAMBERS. Possibly Mr. Ellis has better insight into that issue than I do. It has been my experience that many addict-patients, once they get onto a take-home regimen often begin to manipulate their own medication. An individual cuts his own dose. If he is on 120 I believe he can cut that to 60 with no problem. Then he has 60 milligrams a day that he can sell. He then uses the money to buy stimulants or sedatives. He buys amphetamines, cocaine or some of the sedatives which he can inject to get high. In this way, he never has to worry about being sick but he can also have his high.

The question is how much diversion occurs from this process as compared to how much private physicians are prescribing and diverting, how much staff within methadone programs themselves are selling and diverting, et cetera.

Quite frankly, none of us know.

Senator HUGHES. Do you have any idea from your research, how many methadone addicts there are in the country?

Dr. CHAMBERS. No; we could hazard a computation. Primary methadone addicts are showing up in the Federal program. Roughly some 8 to 10 percent of all admissions may be methadone addicts. We are getting about the same figure in our community based programs. It is a difficult thing to assess. An individual might be a heroin addict the first 6 months of this year and his supply could dry up, his pusher might get busted, and he could switch to illicit methadone for 6 months and then move to get another drug.

One of the things I would reinforce with you, Senator, is that we don't have, at least in my data and surveys, the primary narcotic addict that we had in the past. We have a polydrug user. Methadone will address only the narcotic portion of this polydrug habit. If he is using eight different drugs from say, six different classes such as sleeping pills, minor tranquilizers, stimulants, psychedelics, and so forth, on top of his heroin, any programing we do with methadone addresses only the narcotic portion of his drug taking problem.

We have labored under a relatively naive assumption for a long time that if we addressed what drugs did to the individual we had a hedge on him. I think that is probably incorrect. If we don't begin to address what the drugs are doing for him, then we are going to continue to have, basically, the same kind of success we have had in the past 35 years which hasn't been all that great.

Senator HUGHES. Mr. Ellis, as I understand it, you are a counselor with Dr. Chambers.

Mr. ELLIS. Yes.

Senator HUGHES. If I heard correctly, you have been 8 years on methadone maintenance.

Mr. ELLIS. Not quite 7. I came to Florida several months ago and I was with the Beth Israel program for over 6 years.

Senator HUGHES. You and your wife are both on methadone maintenance?

Mr. ELLIS. Yes.

Senator HUGHES. How many years did you use heroin?

Mr. ELLIS. 19 years.

Senator HUGHES. Then you would be the typical heroin user Dr. Chambers was talking about?

Mr. ELLIS. Yes, sir.

Senator HUGHES. Why do you want to stay on maintenance?

Mr. ELLIS. I use the phrase that I was tired of being tired of that life.

Senator HUGHES. How old are you?

Mr. ELLIS. Forty-five.

Senator HUGHES. And you have been on methadone maintenance for 7 years. How many times were you in prison?

Mr. ELLIS. Four times.

Senator HUGHES. Each time you came out you went back on heroin?

Mr. ELLIS. Right away.

Senator HUGHES. During the first day or two?

Mr. ELLIS. Well, not quite.

Senator HUGHES. As soon as you could make enough money or steal enough?

Mr. ELLIS. Absolutely.

Senator HUGHES. Were you in Lexington?

Mr. ELLIS. Yes, sir.

Senator HUGHES. Did that give you enough contacts to take you all over the country?

Mr. ELLIS. Pretty near; yes.

Senator HUGHES. That is what I have heard. When you go to Lexington, you can make contacts to buy heroin all over the country. Then you don't have much trouble going to any city and finding out where to make a buy.

Mr. ELLIS. Yes.

Senator HUGHES. What do you, as a counselor, find with these young men and women coming in? Give me your concept of what is happening, if you can.

Mr. ELLIS. As Dr. Chambers mentioned, it is an absolutely new breed of drug user today. I don't consider them "junkies." I call them drug abusers. The oldtimers, if you will, either are on the methadone program or they have passed on. After being with this program all these years I found that being lax, as the doctor mentioned, does give you a chance to chippy with the medication.

I will give you an illustration. If you are getting 100 milligrams from the clinic you begin to feel that maybe 80 will hold you. Now you have an extra 20. Then you try 60, and so forth. Unless you have the proper facilities and laboratory workers and staff, methadone can't work properly. As they do down in Florida, they screen the urines out pretty near every day, which ultimately makes it impossible for one of these people that are abusing drugs to get away with it even if someone doesn't deserve the use personally. It shows up in the urine.

These junkies, so-called, today are altogether different than my era, for some reason. They think they are a lot smarter. It is just an absolute new breed. It is altogether different games.

Senator HUGHES. What success do you have in counseling them?

Mr. ELLIS. Fortunately, there are some that look to me as a former loser that came back, thanks to methadone, which only helped partly. I needed a lot of confidence that was placed in me by people. I went to school. I graduated from college since I have been on the program. I needed all types of work. It wasn't the methadone alone that did it. I needed a lot of insight into myself. My wife helped me quite a bit, strangely enough, and vice versa, I helped her.

The basic thing is, Senator, that if you are not honest with yourself, it is just a waste. You can get all the methadone in the world and that is only the surface of this cure.

As the doctor mentioned, you have to get jobs, schooling, and you have to be game for anything to want to help yourself. Of course, you have to do the work.

Senator HUGHES. There also has to be an opportunity for hope and dignity.

Mr. ELLIS. Absolutely. Trust—you have to place trust. There is a lot of success in these programs that I have seen. But by and large, unless you have a properly oriented staff, it seems that just "maintaining" isn't the answer, though I do approve of methadone.

Senator HUGHES. Tell me how methadone affects you.

Mr. ELLIS. How it affects me now?

Senator HUGHES. Did you feel any high from it?

Mr. ELLIS. Never. I can appreciate what euphoria is, Senator. I, for some reason, never got that so-called high. I wasn't looking for a high, as I did with heroin. I was just concerned about being normal, just going about my business day by day. One of the toughest jobs I had after I got on the program, and I told the doctor this many times, was that I stopped lying approximately 90-some-odd percent.

Senator HUGHES. That is a fair percentage.

Mr. ELLIS. Well, you have to sell some people.

Dr. CHAMBERS. It has to be normal.

Senator HUGHES. It is probably better than average.

Mr. ELLIS. That was the toughest job I had, Senator, to try to be truthful. The whole life was an out and out farce.

When I first got on the program, I knew I was going to succeed for one big reason, because I couldn't turn around in those years with heroin without getting busted, doing time for forging prescriptions, etc. I did 12 years out of my life in the penitentiary. It seemed that that wasn't the answer by any means. Sometimes they had no facilities, and they would send me to a State hospital even though I knew I wasn't insane. But when I heard about methadone, I latched onto it and I just, so to speak "went along" with the program. I was a little more fortunate than the average. I went to work for the program right away. I just figured I am going to make a success out of it and I have.

I have been helping many of my constituents. I try to show them the rights and wrongs of this game, and so forth.

Senator HUGHES. Do you want to get off of methadone?

Mr. ELLIS. Absolutely, yes, sir.

Senator HUGHES. After 7 years, when do you start?

Dr. CHAMBERS. I might interrupt here. Charles and his wife both want detoxification and have approached me both in New York and

in Miami. We have not detoxified them in Miami because we don't think it is a suitable time. A suitable time is a very nebulous kind of thing, but we want the best pluses going that we can have. They only recently relocated to Miami, they have bought a home for the first time, they are living in a nice suburban community for the first time, as opposed to New York City and I wanted them to get settled first. He will start his detoxification in another 30, 60 or 90 days in a very programed, clinical research manner. I have great faith it will hold.

Senator HUGHES. Clinically not only is this important but if I read Mr. Ellis properly, he is more interested in facing himself for what he is and gaining an identity. If he has a difficulty, I think he will be the first man to tell us so.

Dr. CHAMBERS. I am constantly amazed that we don't listen to our patients very well. I think they can come to us and tell us when they are ready for detoxification. If we tell them they are not ready, essentially what we are saying is that we are not ready yet.

Senator HUGHES. Mr. Ellis, I found, a lot of heroin addicts being maintained on methadone who are consuming alcohol by the gallon. I look at them as chronic alcoholics while being maintained on methadone. Do you find this in your constituency also?

Mr. ELLIS. I worked with the Beth Israel program for 6 years. Unfortunately, it was a problem there. The fellows who started drinking started for the same reason they started using junk. It is what they call today peer pressure and years ago it was that they didn't want to be chicken.

For the life of me, I could never get it across to quite a few of them that our livers are already damaged just from using narcotics, and yet they drink that good 45 cents a pint Gypsy Rose or Thunderbird, that has been chemically aged for 2 hours and it gets to them. It is really pathetic.

I understand they are starting an alcoholics program in New York. I hope they will be successful with it. The only way these fellows will stop drinking is for them to use the same reason they had wanted to get off of junk.

Senator HUGHES. Once they get off heroin, addicts need a job if they are going to stay off!

There are two or three things that can stop a person from getting a job. One is rape and another is a narcotics bust.

If you have one of those two things on your record, you have had it for the rest of your days. How do we begin? In addition, we need clinics in the neighborhoods throughout the Nation to maintain the addict.

Dr. CHAMBERS. Where we failed, Senator, is we have addressed only a very small piece of the problem. As a result addressing only that small piece, we have lost sight of what the problems are. It is true that all of us experience some difficulty in putting clinics in neighborhoods. It is no different than the trouble we have in placing low cost housing in neighborhoods as well. It is no different than if I went to build any kind of an institution or any kind of facility to address social casualties in a neighborhood. It is essentially the same problem, not unique to the addict. What we have forgotten is that these people are multiple casualties and we have addressed only one.

For example, in several thousand standardized tests we are able to show now that roughly a third of the addicts that we see, and we can't

believes ours are any different than anyone else's—we have tested in excess of 6,000—roughly one-third of them are really clinically depressed individuals. Roughly 10 percent are schizophrenic. An additional 20 percent are above the normal range on anxiety scores.

These are people who have a number of problems of which drug-taking, which we are addressing as the problem, really is probably only a symptom. I have no question in my mind but a large number of people in New York, in Harlem, and in the Bronx, use narcotic drugs as if they were major tranquilizers.

You and I know that if you build a cage for three rats and you put six in it what happens. You know that if you build a cell for three people and put six people in it what happens. We have built cells with literally thousands and thousands of people in them. We didn't really expect the kinds of reactions that we got. Drugtaking is normal behavior there. The sheer weight of density, the population problems, have brought a number of these things to us. We are not addressing that, we really are not. We are addressing only some of the symptoms.

Until we begin to address the other, until I can move some of my low cost housing into the suburban neighborhoods and split the density down where the "potentials for losing" interactions can be cooled off, I am going to have a drug problem, regardless of money, national priorities, or anything else. If not drugs they will cut one another's throats or something else. There will be some outlet.

We have viewed all drugtaking as if it were an individual pathological kind of a problem. Senator, it is a social problem. I really believe it is.

Senator HUGHES. I agree with you. We look at the individual and try to diagnose the illness without getting behind it to find out what is creating the climate that brings the illness. We can create a place of dignity after we find a man or woman who is willing to look at himself and try to get well. Then what does he find? The illness of the society he is coping with in which he is trying to help himself.

Dr. CHAMBERS. Exactly. I don't have any idea what will happen in my social system with one-third of the adult population regularly using tranquilizers, stimulants, and so on, daily.

Senator HUGHES. In relation to that, what do you think the responsibility of the medical profession is?

Dr. CHAMBERS. Some of us have fought for a long time for additional controls on not just the medical profession but the drug profession in toto. Part of the responsibility of profittaking should be returning some of it to the areas of education, to the areas of research, of "cleaning one's own house," and so forth. Our efforts had only a very minor impact. Regardless of how many scientific papers and how many addicts I troop into a drug company and say, "Look, you keep selling this drug as a nonaddictive, harmless compound and I have put it in the professional literature for 5 years that I treat people addicted to them—as long as it is a \$100 million a year drug item to that company, no one is going to listen to us.

Senator HUGHES. I want to thank both of you gentlemen, Dr. Chambers and Mr. Ellis, for your willingness to testify. You have been helpful to the subcommittee and me as we consider this legislation and this problem. The Committee on Labor and Public Welfare

also has the responsibility for generating legislation that helps to eliminate some of the social ills in our country that help to breed drug abuse. I appreciate this and I know the other members of the committee do though they are not here. We are extremely busy this morning, and the full committee is meeting in executive session in another room on another matter.

I am encouraged that we seem to be willing now to look at the problem at least. For years in the past we have been doing nothing but put people in prison and in jail as a solution to a problem.

Thank you very much.

Dr. CHAMBERS. Thank you.

Mr. ELLIS. Thank you, Senator.

Senator HUGHES. We will recess for about 30 minutes.

(Recess.)

Senator HUGHES. The subcommittee will come to order.

Dr. Mitchell Rosenthal, director, Phoenix House Foundation, New York, N.Y., will be our next witness.

STATEMENT OF DR. MITCHELL ROSENTHAL, PHOENIX HOUSE FOUNDATION DIRECTOR, NEW YORK, N.Y.

Dr. ROSENTHAL. Thank you, Mr. Chairman.

Senator HUGHES. Dr. Rosenthal, I apologize for the delay. Please proceed.

Dr. ROSENTHAL. I would like to say I am very pleased to have been invited, notwithstanding the delay.

New York City's health services administrator now estimates that more than 300,000 narcotic addicts live in New York City. I believe this is a reasonable, if modest, estimate.

However, there is no indication that the number of addicts has increased materially during the past few years. The number has always been high, while previous estimates have been unreasonably low.

Traditionally, New York has been assumed to contain about half of the Nation's addicts. This, I suspect, is no longer the case. The great increase in addiction has been most evident in cities that previously had few, if any, resident addicts. And our national addict count probably runs somewhere between three-quarters of a million to a million.

The number of serious drug abusers, who are not addicts, is most likely five times as great. As many as 5 million Americans are regular users of illegal psychoactive drugs, and a growing proportion of these drug abusers are young.

Present public policy, as it has developed and will continue to develop, virtually insures a total addict population of 2 to 2½ million and a drug-abusing population of 12 to 15 million in 10 years time.

If you gentlemen suspect that I am attempting to frighten this committee, that I am playing some grim kind of numbers game, you are absolutely right. The figures are only estimates, and as trustworthy as any estimates, but the reality they represent is irrefutable. Our present approach to addiction and drug abuse can only tragically compound the problem.

This policy, the present Federal encouragement of methadone maintenance treatment, and the provisions of the legislation now before this committee are not designed to solve the drug problem. They

are directed specifically toward the prevention of addict crime, the most politically pressing aspect of the drug dilemma. And I cannot argue with the political realities that give priority to the victims of addicts rather than the victims of drugs.

If the policies now strongly endorsed by the administration, and the programs that must inevitably follow from this philosophic base, could indeed eliminate or materially reduce the amount of addict crime, there might be some reason to discount or ignore their other, undesirable results.

But there is no evidence to support the notion that the Government's current approach will, in fact, have more than a minimal impact on the incidence of crime. What it is certain to do is to vitiate any real efforts to prevent the spread of drug abuse among the young.

At the heart of today's controversy, I believe, is a general failure to comprehend the relationship of addiction and crime and the nature of drug abuse.

Addicts commit crimes, and many criminals are addicts. This holds true throughout Western society. It is difficult to resist the notion that addiction then must cause crime—that the addict must resort to extralegal means to acquire the sizable amounts of money needed to procure illicit drugs. But addict crime is not so simple a cause-and-effect phenomenon.

The reality is that addiction and crime are parallel activities. The same people likely to become addicts are likely to become criminals. Both are classic ways of acting out, both fill the same emotional needs. They are dangerous, exciting, self-destructive and pleasurable experiences. Indeed, most addicts have already engaged in criminality before they become addicted.

Nor do we have any reason to believe that providing addicts with drugs will cause them to abandon their criminal ways. This has not been the experience of Britain's heroin clinics. Criminal addicts continue to support themselves by crime even when receiving free heroin.

I would speculate that some addicts receiving orally administered methadone might well turn to criminal activity or increase their criminal activity once they had been deprived of the emotional rewards of drug taking.

On the other hand, a certain number of addicts with heavy habits would probably restrict their criminality to meet their reduced economic needs. Putting it all together, we would most likely end up with roughly the same amount of addict crime we now have.

Some addicts would steal less, others would steal more, noncriminal addicts might well turn to crime and there would be, as a result of the dominant Federal policy, a larger national addict population and more candidates for criminality.

Using the iceberg cliché, addict crime is the merest tip of the drug problem. Just beneath it, still above the surface, is the general addict population that includes a good many habitual narcotic users who do not engage in crime (placed in a methadone program, these addicts would most likely continue their noncriminal ways and be counted as cured).

Beneath the surface are the great number of Americans dependent upon dangerous and illegally procured psychoactive drugs that are not narcotics and, save for barbiturates, not addicting.

And, at the base is the Nation's great drug-misusing majority: alcoholics and habitual alcohol users, the law-abiding prescription "freaks" (whose amphetamines, barbiturates and antidepressants are legally acquired and consumed) and the nonprescription "heads", who depend upon regular intakes of sleeping pills, relaxants, stomach remedies, and the like.

The abuse of illegally acquired dangerous drugs by young people, particularly adolescents, is a vital national concern. But our efforts to prevent the spread of drug abuse among the young have been woefully short of successful. And our current national posture, our emerging drug policies, will make us even less able to prevent widespread drug abuse. There is no difference between legally and illegally acquired psychoactives.

Alcoholism is, by far, the most destructive form of drug abuse. Young people know all this. They recognize our national acceptance of general drug misuse, even if we do not.

When the Government supplies drugs to some and condones its use by others, it cannot hope to discourage drug use by a third group. We then become the victims of our ambivalence, and our children become the victims of our folly.

Drug abuse is, in many ways, a contagious condition. Quite simply, the more drug abusers in a society, the greater the possibilities of infection. Open and socially sanctioned drug use is more contagious than secret and social condemned drug use. We can no more tolerate a certain amount of drug abuse than we can safely permit a limited amount of cholera.

Our very approach to drugs indicates our inability to perceive the true nature of the problem we are confronting. Young people most often choose drugs to help them deal or avoid dealing with difficult human problems.

Our current encouragement of methadone treatment and our hopes of an improved narcotic antagonist is evidence of a similar faith in chemical or mechanistic solutions to what are essentially complex human problems.

The legislators who now talk optimistically about eventually finding some means to inoculate children against addiction might just as reasonably hope for some way to vaccinate them against poverty, ignorance, or bigotry.

Chemical solutions are simple, quick, and uncomplicated. But the problems of addiction and drug abuse are not. I recognize that the partisans of methadone maintenance and the authors of this legislation have attempted to find a humane solution to a pressing political problem. But I submit that there is no simple solution and what appears to be humane is, in fact, dehumanizing.

For years, conventional wisdom and medical opinion both held that drug addiction was incurable. Yet, drug addicts were cured, almost invariably by their own efforts, and these remissions were written off.

Fourteen years ago, therapeutic communities began to cure addicts with drug-free residential treatment that succeeded where traditional general medicines and traditional psychiatry had failed.

Today, we know that only a small percentage of addicts will accept drug-free treatment, and a somewhat larger percentage will accept methadone maintenance. But the majority of addicts today will willingly choose no treatment now available.

Furthermore, a sizable number of those who choose either drug-free or methadone treatment will drop out of treatment after a short period of time. In addition, many methadone patients will continue to use drugs (mostly alcohol, and even heroin) while in treatment.

Faced with the dilemma posed by large numbers of addicts to whom no existing treatment program is acceptable, the inclination of many public officials is to devise more acceptable alternatives, specifically heroin maintenance or some form of heroin lure.

While there are differences between heroin and methadone (methadone can be administered orally, while heroin cannot; heroin effects last 4 hours, while methadone's last 24; orally administered methadone does not produce the high of intravenously administered heroin) the primary difference is in the minds of those officials who perceive methadone as a medicine and heroin as a drug.

Methadone is a potent, addictive drug. Given in what is called blockade dosage (in sufficient quantity to create a cross tolerance to as large an amount of street heroin as the addict can lay hands on) it is a massive daily dose of depressant, many times the size of the patient's previous habit. The advocates of heroin treatment can well argue, "If methadone, why not heroin?"

And, I, too, can ask, "Why not?"

Frankly, I believe some form of heroin treatment is inevitable as long as we approach the problem of drug treatment in the manner we now do—devising treatments acceptable to addicts.

We tend to ignore the basic reality of addiction and drug abuse. People who take drugs like to take drugs. They will persist in taking drugs in the face of argument, pleading, and their own best interests.

They will stop taking drugs only when they want to stop taking drugs, and that is when drug taking is sufficiently uncomfortable or unpleasant.

Today, the choice of what society can do about addiction is being made by addicts.

Addicts can now choose to live on the streets, to steal or deal drugs, to cop and shoot. They run the risk of being caught from time to time. But for many reasons, including the shortcomings of our criminal justice system, addicts are rarely sentenced, and then to only minimal prison terms. The criminal option is viable. Most addicts now choose it.

The option of being treated without having to give up drugs (through methadone maintenance) is available. And the option of being treated with their drug of choice (heroin) is a reasonable expectation.

Frankly, it is fairly absurd to consider a treatment for addiction that does out drugs as a cure. Drug taking is not an isolated activity. Addicts are not normal people who happen to take drugs. There is overwhelming documentation of the addict culture, with its criminality, amorality, and the dehumanization of its members.

While there are a number of addicts who control their own habits and their own behavior, they are not the population from which candidates for methadone maintenance will be selected.

Already the failure of existing methadone programs to control patient behavior, to stop their use of other drugs, to halt their criminality, has caused considerable anxiety among methadone advocates. Many

of whom now want to go the extra mile to heroin—a logical extension of their convictions.

What I am suggesting here today, gentlemen, is that we face squarely the dilemma of addiction and drug abuse; that the Government behave responsibly and not put the burden of choice on the addicts.

We can go on forever devising noncures and “treatment” programs that do no more than institutionalize addiction. Certainly, our society can afford to put a sizable part of its population on ice. Although, the fact that so many members of this group belong to racial or ethnic minorities should cause us some concern.

But, if we consider methadone maintenance, as its originators insist it is, a lifetime of treatment, our clinical bills will require a sizeable slice of the Federal budget in 20 or 30 years time, as the patient load continues to increase and no one is discharged before death.

Addiction can be cured, and it can only be cured by drug-free treatment. That does not mean that methadone could not be used in long-term detoxification programs that would be part of drug-free therapy programs.

We can overcome addict resistance to drug-free treatment, not by making the treatment more attractive—because a cure is never going to be that attractive—but by making the alternatives that less attractive.

I believe society has the right to demand that criminal addicts be cured. And if criminal addicts refuse to be cured then they must be dealt with by a criminal justice system that has the capacity to deal with them.

Gentlemen, you can accomplish all you will gain with methadone or heroin or any other program designed to appeal to addicts, simply by making drugs easily available in drugstores, at reasonable prices, and with suitable notice of their dangers and side effects.

The alternative is to treat criminal addicts as criminals, wholly responsible for their actions, unless they agree to be cured. And the only cure I know is drug-free. It is not an easy cure. There is no easy cure. But it does rehabilitate the addict, and return him to a life of full social responsibility and participation.

But more important than the means we chose to deal with today's addicts is the message we give to youth. If we, by our attitudes and our policies bar drug abuse as permissible behavior in our society, then we have a reasonable chance of arresting the spread of drug abuse among the young.

Thank you.

Senator HUGHES. Thank you, Dr. Rosenthal.

As you know, your viewpoint is different from that which we have had this morning from the other witnesses. What do you think would happen if we adopted your alternative of prison or treatment? How many addicts would apply for treatment?

Dr. ROSENTHAL. We had that experience in New York in 1966 and 1967, after the State legislature created the narcotic addiction control commission. There was, at least, temporary belief that there would be those choices, either to be in treatment “voluntarily” or to be picked up against your wishes by the State commission.

But what happened was we did not enforce the law. So it soon became apparent de facto that the addict really, in effect, still had the choice. There has been a consistent erosion of this position to a large

extent led by the American Civil Liberties Union and others, so that we have, in a sense, destroyed that law in New York and other places and addicts are making the choice themselves for the kind of treatment they want.

Senator HUGHES. Do you think that if we gave them the alternative they would seek treatment?

Dr. ROSENTHAL. Yes; I do. The other side of that is that during that period we had many, many more people coming for treatment. You see, acting out disorders in general, the motivation is not similar to other forms of medical illness or even psychiatric illness.

If the patient is anxious or depressed they go to the doctor and they say, "Doctor, I have a pain here. I hurt here."

The pain that is involved with addiction is usually the pain of an addict's family or community. It is usually the family or community that says to the addict, "I won't tolerate this any more. I won't bail you out any more. I won't clean up this mess for you. You have to go for treatment." When that happens in fact, people do come for treatment.

In Phoenix House in New York, where we are treating close to 1,200 people in 14 separate facilities, and one-third are teenagers, most of the teenagers are being brought by their parents who finally take the position of demanding that their youngsters go in for treatment.

I think we are caught up in the notion that it is either totally voluntary or totally nonvoluntary and we are forgetting that there is a very, very large middle ground that can be influenced by the position that we take as parents, as legislators, or as a community as a whole.

Senator HUGHES. Do you advocate treatment in prison?

Dr. ROSENTHAL. Absolutely. I am glad you asked that question because I think that treatment should begin in prison.

Really, prison ought to be an induction point, whether it is for addicts or really for anybody else who ends up in prison. That ought to be the place that we start treatment. Unfortunately, because so much of our correctional system has been run traditionally so badly, we have tended to discount that anything very viable can go on in a prison.

In 1967 and 1968, Phoenix was the subcontractor, along with the addiction services agency in New York, for the Narcotic Addiction Control Commission and treated some 600 addicts who were part of the general population on Rikers Island.

We were able to take over 1 month to a 10-month period of time 60 percent of those 600 people off Rikers Island and admit them to Phoenix houses and other places in New York. I think prisons really have to be the jumpoff point of beginning treatment.

I might say that even the residue that remained, of people we were not able to take off, it was largely affected because their hopes of not having to do anything but go back in the street were fanned by many very decent but misguided young attorneys who felt that if they just could get them out of prison and help them to get a decent job and to get started again, that it would be OK.

We have really misunderstood this thing because we have enough understanding to realize that practically any addict today is, in fact,

a victim. We have enough sociologic and psychologic understanding to realize we have laboratories in New York or Watts or in Washington that are guaranteed, practically, to produce addiction. Because of that we err on the side of being empathetic and giving license where we have this understanding, and saying, therefore, it is OK.

My point is that while we can understand the things that bring about a personality and a social disorder, we have to act responsibly and not go on and permit it to continue.

I think this choice is very clear for anybody on a very individual level. If you have a youngster who gets involved in drugs, I think it is very clear to a parent that he wants to do everything possible to get that youngster off drugs.

He is hopefully not going to give his youngster the option of deciding whether or not he wants to take methadone or to continue to use drugs in some illicit fashion.

Senator HUGHES. Doctor, you talked about a drug-oriented society. I agree with that judgment. Most are good if used for proper medical need, and all can be abused. How far would you go in overcoming this? Do you think, for example, that we ought to ban TV advertising on alcohol, aspirin, sleeping pills, and so on?

Dr. ROSENTHAL. Absolutely. I think the medical and pharmacological magic that is put out on television is a total sham, and it is very destructive. It feeds the whole notion that for every kind of human problem, from being involved in a traffic jam on freeways, to having a staff meeting that is going to be difficult, or to having your in-laws, that there is some pill if you only had the right one that is going to enable you to handle that problem.

You asked the question earlier this morning in regard to Dr. Chambers' testimony of why do we have all of these young polydrug abusers. One of the things we have found in looking at our Phoenix House population is that by and large the parents of these youngsters are themselves alcoholics, marijuana users, tranquilizer users, pep pill or sleeping pill abusers.

When children see their parents using drugs to solve these everyday problems they incorporate these values and then during that period of adolescence when children are moving away from the home and trying to be accepted by a peer group they have no internal values, no emotional antibodies that are going to help them to resist drug taking. That and parents abdicating their position of responsibility and feeling that the drug problem requires expertise and that unless they can discuss with their children the pharmacology of pot or the pharmacology of amphetamines that they can't take a position on this issue is part of the erosion that is leading to more and more drug taking.

Senator HUGHES. Do you see a direct relationship between the new electronic media of television and drug taking in our society?

Dr. ROSENTHAL. I do. I think the average 17-year-old in our society has watched some 17,000 hours of television. That time has been programmed in two ways: He has been programmed to believe that there is a chemical solution for everything, and it has done another curious thing to his parents. I think it has reduced the position of authority, the relative position of authority of the parent. Whether the father is a doctor, a teacher or any kind of person, next to the television set and the kind of universal authority the parent becomes far more dwarfed and feels far less able himself to make demands on his youngsters.

I think that is part of the increasing permissiveness which is so much a part of education and child rearing today, which I think is at the heart of not only the poly-drug-abuse problem with the young, but the poly-criminal profile that Dr. Chambers was describing earlier this morning.

Senator HUGHES. Doctor, in a paper which you coauthored in Science magazine, you indicated that some physicians hailed heroin as an answer to morphine addiction. Do you think we are facing a great academic reaction to the addiction in the country now?

Dr. ROSENTHAL. Yes. I think that if methadone programs now continue to be proliferated on an action program basis, and with little research and little restraint, and are seen as an immediate solution to this very pressing problem that we face, that we are likely to create many primary methadone addicts, and to take some polydrug abusers and turn them into methadone addicts—the term we use in medicine is iatrogenic—and we will iatrogenically be responsible for the creation of a large number of addicts.

I think the way to limit that is along two lines: One, by doing very careful research and screening as to who the people are that are coming in for treatment, and then in having a very clear route out of methadone so that it really is an intramove and not an end in itself.

Senator HUGHES. It should be in your opinion, used, as an interim detoxification process even though it may be a long detoxification process?

Dr. ROSENTHAL. Correct.

Senator HUGHES. Do you think methadone is helping to create an attitude among children that "We can go ahead with heroin because if we wind up hooked, methadone is all right"?

Dr. ROSENTHAL. Yes. I think particularly the black and Puerto Rican community is being hit the hardest when children see the people they look up to using methadone as a way of handling problems. We are severely weakening their values.

You see, if we were just concerned about the million addicts that we have today, if no new addicts were coming into the total addict population, in 10 years we would not have much of an addict problem. A significant number of people would die; a significant number would be treated by existing treatment programs, and a significant number of people would mature out and not be addicts.

The problem is the rate at which young people will come into the addict population. I think that we are going to adversely affect that rate with the thoughtless propagation of more methadone treatment programs.

Senator HUGHES. In a nutshell, if I understand your recommendations, the Federal Government should undertake no methadone programs on a general and wide scale basis unless those perhaps deal only with detoxification programs and are run in conjunction with other types of programs which attempt to rebuild total personality and character of the individual. Is that an analysis of it?

Dr. ROSENTHAL. I think that is fairly well stated. I think we have to be incorporated into the total spectrum of treatment that ends up with drug free as a goal, and that that isn't just a bit of rhetoric but it really has meaning so there are very defined goals of how long someone can be maintained in a methadone program.

And then very careful research and screening. We have gone from 1968 when we had 3,000 patients nationally on methadone to today where we have close to 70,000 patients nationally on methadone.

You may be misled because you have somebody who is as distinguished a researcher as Dr. Chambers today, to think that other people in other parts of the country are doing this kind of thoughtful research. It is not so. He is really an exception to what is happening. They are really doing largely action programs that tend to replicate and perpetuate our diagnostic misconceptions.

Senator HUGHES. Is there any effort that you know of to screen out so-called volunteers for methadone programs and those on the waiting list to try other types of drug-free programs?

Dr. ROSENTHAL. Not to my knowledge.

Senator HUGHES. Nothing is being done in that area, as such. There is no one trying to develop other methods.

Dr. ROSENTHAL. To my knowledge, the drug-free treatment programs have not been getting people referred to them or recommended by methadone programs who have large waiting lists.

Senator HUGHES. Dr. Rosenthal, I thank you. You have succeeded in making me rethink my own attitudes about this field. The possibilities that you raise are awesome indeed.

Regardless of what our motives, the possibility that we may be horribly wrong is rather frightening in itself.

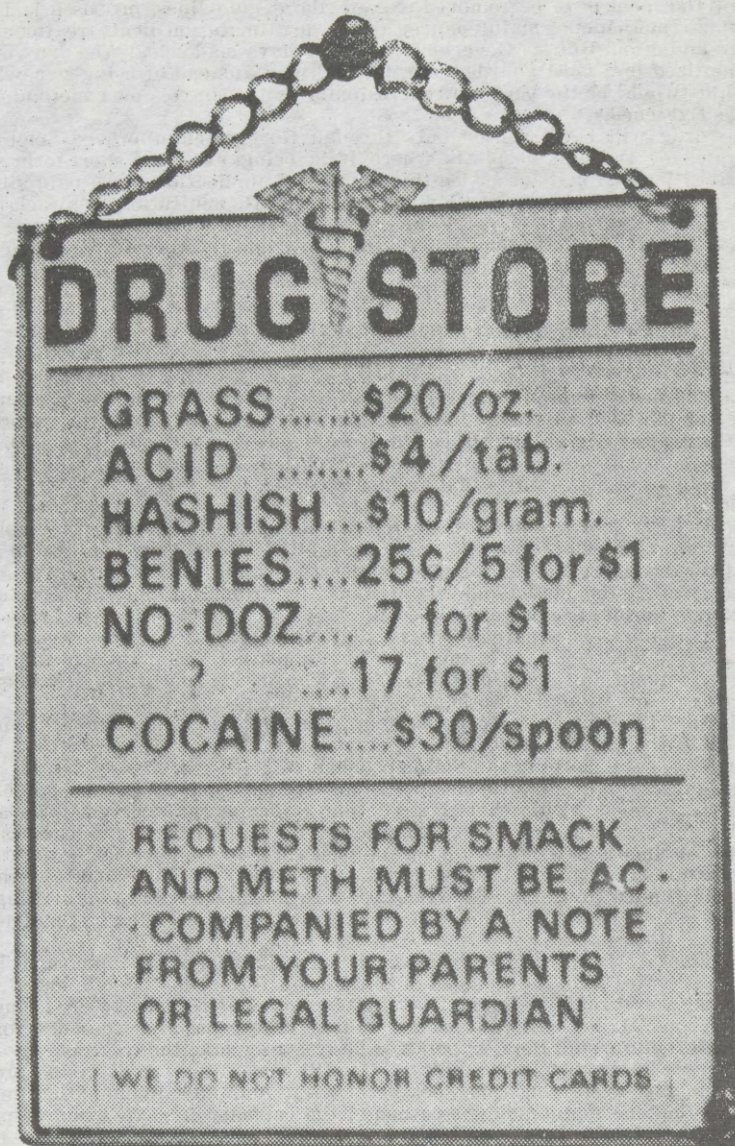
I thank you very much for coming to testify.

Dr. ROSENTHAL. You are very welcome, Senator.

Senator HUGHES. At this point I order printed all statements of those who could not attend and other pertinent material submitted for the record.

(The material referred to follows:)

Science/ Medicine



A whimsical sign at Manhattan's Bernstein Institute of Beth Israel Medical Center, sometimes called the "Mecca of methadone maintenance."

[From the New York Times, Sunday, Apr. 9, 1972]

METHADONE: A PLAN TO CONTROL ITS USE AND ABUSE

WASHINGTON—For nine years methadone has been studied, tested and used as a palliative for heroin addicts. Probably more than 100,000 patients have received it as a potentially rehabilitating substitute for the dangerous narcotic, but these treatments have always been under the official label "research."

Now the label is to be removed. New Federal guidelines, proposed last week, recognize methadone maintenance as a "legitimate medical treatment" for heroin addiction. But, as Government experts have made clear, the drug is being legitimized in a most guarded and unusual way. Instead of being somewhat relaxed, as would be the case with an ordinary drug, controls over methadone use will be tightened.

The drug will be dispensed only through Government-approved methadone programs or through hospitals where it is being used for short-term heroin detoxification or for its other legitimate medical application—as a pain killer for certain patients such as those dying of cancer. All institutions, physicians and pharmacists involved in the programs have to register all uses of the drug. It will be distributed directly to the participating programs and therefore need no longer be stocked in ordinary pharmacies. Each person in charge of a program must file an application for approval with the Food and Drug Administration. Adequate records must also be kept on the patients and on their visits although this may done in a way that preserves the individual's privacy.

As a key step in inaugurating methadone's new status, teams of Federal health officers will leave Washington this week to begin an intensive inspection of each of the 450 methadone programs in operation in the United States. Because the source of the drug will be under Government control, it follows that a program failing to meet the standards can be forced out of operation. The F.D.A. has invited comments on the proposed new regulations and has provided 90 days for such replies, but major objections are not expected.

Methadone is a synthetic chemical developed in Germany during World War II to cope with a shortage of the pain reliever morphine. When taken by mouth, in large quantities tailored to the particular addict's physiology, it prevents heroin withdrawal symptoms yet doesn't produce the "high" the addict craves. Those who stay with the methadone maintenance programs, in general, seem able to return to a normal life pattern.

Yet methadone is a narcotic. It is addictive and in injectable forms it does produce a "high." Thus, it is the focus of a black market of its own. Drug traffickers, patients and some of the doctors who use it for heroin treatment are diverting it, intentionally or otherwise, into the illicit traffic.

Critics of the drug also say its use simply substitutes one addiction for another. They note that heroin, itself, is a synthetic first developed in 1898 as a hoped-for answer to the morphine addiction problem.

On the other hand, its proponents say methadone is one of the few potent tools available to cope with a heroin addiction epidemic that currently devastates the lives of an estimated 300,000 Americans, most of them young. The best Government estimate, arrived at during the past three or four weeks, is that methadone maintenance programs now serve about 65,000 patients, 12,000 of them in federally funded programs. Between 20,000 to 25,000 others are on waiting lists. In addition, an unknown number of other patients are receiving methadone from individual doctors.

Dr. Elmer A. Gardner, director of the F.D.A.'s division of neuropharmacological drugs, estimates that the number of patients in formal methadone maintenance programs would roughly double if all those who want treatment were brought in.

Dr. Jerome H. Jaffe, director of the White House's special action office for drug abuse prevention, said the new policy is designed to make the treatment available to anyone who needs and wants it, while still controlling the diversion problem. From the survey starting this week he hopes to find out how many heroin users want methadone maintenance treatment; the capacity for expansion of present programs and how much the expansion would cost; and the extent of the diversion.

There has already been some criticism of the plan. For example, Representative Paul Rogers, Democrat of Florida, who intends to hold hearings on methadone, wants more attention paid to the possibilities of gradually withdrawing the patients from the drug after they have been maintained for a sufficient time.

There has also been both discussion and research on alternatives to methadone—non-narcotic chemical antagonists that would block heroin's effects. But specialists say they remain to be proved. Methadone, although it has its hazards and doesn't work for everyone, is here.

—HAROLD B. SCHMECK, Jr.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

[21 CFR PART 130]

NEW DRUGS

PROPOSED SPECIAL REQUIREMENTS FOR USE OF METHADONE

Methadone has been under investigation for use in the maintenance treatment of narcotic addicts for approximately 9 years. For the past 2 years, interest in this use has grown steadily and intensely. In the FEDERAL REGISTER of April 2, 1971 (36 F.R. 6075), the Food and Drug Administration published § 130.44 (21 CFR 130.44) which established guidelines for investigating the use of methadone in maintenance treatment, for assuring the availability of valid data on such use, and for protecting the community from the hazards of diversion and abuse of methadone. These guidelines were developed in cooperation with the National Institute of Mental Health (NIMH) and the Bureau of Narcotics and Dangerous Drugs (BNDD), Department of Justice. To date the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs have approved a substantial number of individual treatment units for use of methadone in treating addiction.

In addition to being used for investigational purposes, methadone has been prescribed by individual physicians and has been dispensed in medical institutions both for heroin detoxification and for maintenance therapy. It is not possible to determine how widespread the

use of methadone for maintenance therapy has been outside investigational new drug plans, but there is evidence that this use is substantial.

The Food and Drug Administration, in cooperation with the National Institute of Mental Health and the Special Action Office for Drug Abuse Prevention, is undertaking an intensive inspection program to ascertain that existing programs operating under investigational new drug status (IND) meet the requirements of § 130.44. Within the immediate future, each program will be visited by an inspection team. Programs will be allowed to continue to operate if they meet the existing requirements of § 130.44. However, in addition, the proposed special requirements contained in this notice are being encompassed by the inspection in anticipation of improved requirements to be in effect in the future. To reduce the potential for diversion and misuses methadone is also being withdrawn systematically from pharmacies that are not dispensing it solely as part of approved treatment programs using methadone.

The use of methadone presents difficult and unique questions of medical judgment, law enforcement, and public policy that have not previously been encountered with other new drugs. Methadone presently represents the only drug for which there is substantial evidence of effectiveness in the treatment of heroin addiction. Although the short-term use of the drug has been shown to be relatively safe from a toxicity standpoint, more information is necessary on the toxicity of long-term use. Balancing the benefits against the risks, the Food and Drug Administration and numerous professional groups, advisory committees,

and experts with whom it has consulted have concluded that the drug should be made available for all addicts who consent to use it in approved treatment programs. Retention of the drug solely on an investigational status appears to be no longer warranted.

At the same time, concern has been expressed that the usual form of NDA (new drug application) approval could lead to greater diversion or misuse of the drug, since it permits unrestricted distribution and allows physicians to use wide discretion in prescribing the drug. It has been suggested that the investigational status of the drug should be retained both to obtain additional toxicity data and as a control mechanism, at least until greater experience is obtained in reducing the potential dangers of diversion and medical misuse. The FDA recognizes these dangers and agrees that strong control must be maintained over the distribution and use of the drug. Since it is an opiod the potential for abuse is greater than for other drugs permitted for widespread medical use. The Food and Drug Administration could not conclude that it is safe if it cannot be properly controlled and would be required to disapprove its use. Some diversion and misuse will inevitably result from the availability of any drug, but it is particularly important that strong controls be available for methadone because of its known addicting potential. Finally, some have pointed out that it is premature to move completely from IND to NDA status because more information has yet to be obtained. The Commissioner concurs that unlimited approval of an NDA for methadone would not be appropriate at this time.

To provide the strongest possible control over the distribution and use of methadone, the Commissioner has concluded that both the IND and NDA control mechanisms should be utilized together with the authority granted under the Comprehensive Drug Abuse Control Act of 1970. Like an NDA, the drug will be available for treatment in all cases where there is medical justification. Like an IND controlled drug, there will be a permanent record showing the pattern of distribution of the drug because the institutions using the drug and the physicians and pharmacists operating in cooperation with the institution will be required to register all use of the drug. It will permit the Food and Drug Administration to withdraw methadone from its present unqualified approval status in pharmacies for detoxification, analgesic, and antitussive purposes. Thus, a new closed system of distribution will be established, under which any diversion or misuse can immediately be stopped at the source of supply. At the same time the drug will be available for use without all the IND restrictions for all addicts for whom it is medically justified.

The Commissioner recognizes that this is a novel form of control designed to reflect the unique problems posed by this drug. It has not previously been necessary to utilize IND and the NDA procedures concurrently in order to assure the safe and effective use of a new drug. Because of the seriousness of the medical and social problems associated with heroin addiction and because methadone is the only drug available for the treatment of heroin addiction, the Commissioner has concluded that it is no longer feasible to retain methadone solely

for investigational use. It is therefore appropriate to add the special requirements set forth in this proposal in order to permit the drug to be available wherever medical opinion concludes that it should be used in the treatment of heroin addiction.

The Commissioner feels that the mandate in section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 can be appropriately applied to determining the conditions under which methadone may be safely used in treating narcotic addicts. This requires the Secretary of Health, Education and Welfare section 1 after consultation with the Attorney General and with national organizations representative of persons with knowledge and experience in the treatment of narcotic addicts, to determine the appropriate methods of professional practice in the medical treatment of narcotic addiction The Secretary has delegated the authority to make this determination to the Commissioner of Food and Drugs.

In carrying out the requirements of the Comprehensive Drug Abuse Prevention and Control Act, the Commissioner has widely consulted and maintained close communications with the medical profession regarding use of methadone. Among those associations or groups consulted are the American Medical Association's Council on Mental Health, the National Research Council's Committee on Problems of Drug Dependence, the American Psychiatric Association's Commission on Drug Abuse, a task force of the American Society of Pharmacology and Experimental Therapeutics, the Joint Food and Drug Administration/National Institutes of Mental Health Psychotomimetic Advisory Committee, the FDA Drug Abuse Advisory Committee, the Special Action Office of the White House, and

the National Institute of Mental Health. The consensus is strong among medical experts and the Food and Drug Administration that currently available evidence on the safety and effectiveness of methadone is sufficient to permit its use for the maintenance treatment of narcotic addiction as proposed in this notice.

On the basis of the above considerations, the Commissioner of Food and Drugs, after consultation with the associations and groups listed above and the Bureau of Narcotics and Dangerous Drugs, and with the endorsement of the Special Action Office of the White House, proposes that the special requirements set out in this notice be imposed upon the use of methadone. These new controls should not interfere with the availability of methadone in the treatment of severe pain or for detoxification of hospitalized addicts. Methadone for the treatment of severe pain on either an inpatient or outpatient basis will be available from hospital pharmacies.

It is proposed that patients under 18 not be admitted to a treatment program using methadone until additional study is completed to determine whether methadone may be safely and effectively used in their treatment. Such additional study must be conducted pursuant to all the requirements of the usual investigational new drug plan. This will mean that juveniles will be excluded from virtually all ongoing treatment programs using methadone except investigational programs with an IND approval. Comment is solicited as to whether the benefits of completing additional studies outweigh the risks of excluding these patients from treatment programs at this time with the likely result that they will continue to use injected heroin.

Under this proposal, the distribution of the drug is limited to treatment programs using methadone and to hospital pharmacies approved by the Food and Drug Administration. Requests for approval of programs received by FDA will be sent to BNDD for any comment it may have prior to FDA approval. BNDD may inspect any such program or may furnish FDA any relevant information from its files. FDA will give great weight to any information, comments, or recommendation received from BNDD in determining whether approval should be granted or, once granted, should be revoked. Methadone will no longer be permitted for antitussive use as the benefits of methadone for this use do not outweigh the risk involved from unsafe and ineffective use.

The Food and Drug Administration believes that State health or mental health authorities are essential to adequately controlling methadone, to assuring that the need for a methadone program exists, and to establishing criteria and guidance for rehabilitation efforts. Approval of a program by the State health or mental health authority designated under the provisions of section 314(d) of the Public Health Service Act or by his designee will be a part of approval of the treatment programs using methadone by FDA. The Food and Drug Administration will contact each State to establish the necessary channels of communication and to establish procedure for the implementation of the program, and will provide information upon request.

Section 130.44 conditions for investigational use of methadone for maintenance programs for narcotic addicts (21 CFR 130.44) will continue in effect until a final order is issued after consideration

of the comments submitted on this proposal. To increase control over methadone and to improve patient care prior to the finalization of this proposal, however, the guidelines in § 130.44 will be enforced as a requirement for a methadone maintenance investigational program. Any IND that varies in any material respect from the protocol in § 130.44 will require justification.

The following additional provisions will be required of all methadone maintenance investigational programs during the time between the publication of this proposal and its final promulgation:

1. Only oral dosage forms of methadone formulated in such a way as to reduce its potential for parenteral abuse and accidental ingestion will be provided patients for unsupervised use under approved programs.
2. The selection of patients is to be carried out in accordance with the requirements of item V, B, of the form "Application for Approval of Treatment Program Using Methadone" which appears in proposed section 130.48 (b)(2)(i).
3. Dosage for detoxification and maintenance is to be in accordance with the requirements of item VIII, A, of the form "Application for Approval of Treatment Program Using Methadone" which appears in proposed section 130.48 (b)(2)(i).
4. The recordkeeping requirements are to be in accordance with the information requested in the form "Annual Report for Treatment Program Using Methadone" which appears in proposed section 130.48 (b)(2)(iii).

5. All patients in the methadone investigational program are to be given careful consideration for discontinuance of methadone in accordance with item VIII, D, of the form "Application for Approval of Treatment Program Using Methadone" which appears in proposed section 130.48 (b)(2)(1).

6. Distribution of methadone will be restricted to direct shipments to approved investigational programs and hospital pharmacies, unless an alternative method of distribution is approved by FDA after consultation with BNDD.

The above stated provisions will be required of all new and ongoing methadone investigational programs within 30 days of the date of publication of this notice. An amended "Notice of Claimed Investigational Exemption for Methadone for Use in the Maintenance Treatment of Narcotic Addicts" shall be submitted by all ongoing programs and by new programs. These amended forms may be obtained from the Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.

Accordingly, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 505, 701(a), 52 Stat. 1052-53 as amended, 1055; 21 U.S.C. 355, 371(a)) and the Comprehensive Drug Abuse Prevention and Control Act of 1970 (sec. 4, 84 Stat. 1241; 42 USC 257a) and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs proposes that § 130.48 be amended by adding a new paragraph (b), as follows:

§ 130.48 Drugs that are subjects of approved new drug applications and that require special studies, records, and reports.

5. All patients in the methadone investigational program are to be given careful consideration for discontinuance of methadone in accordance with item VIII, D, of the form "Application for Approval of Treatment Program Using Methadone" which appears in proposed section 130.48 (b)(2)(i).

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§ 130.48 Drugs that are subjects of approved new drug applications and that require special studies, records, and reports.

(a) * * *

(b) Methadone. Methadone is an approved drug for marketing as an analgesic and for the detoxification and treatment of narcotic addicts. Methadone has been under investigation for a number of years for use as an oral substitute for heroin in the maintenance treatment of narcotic addicts. The nature of the use of methadone in maintenance treatment is such that the drug may be used for long periods of time. Further chronic toxicity studies are needed to establish the safety of long-term use. In view of the usefulness of methadone and the tremendous social problems associated with the narcotics problem, the Commissioner of Food and Drugs finds that it is not in the public interest to withhold the drug from the market until further long-term studies have been completed. In view of problems of abuse and misuse associated with the widespread availability of methadone, adequate controls are essential for the safe use of the drug. The drug should nevertheless continue to be available for treatment of severe pain in patients where no substitute therapy is suitable.

In view of these considerations, the Commissioner of Food and Drugs has concluded that it is essential to the public interest to prescribe detailed conditions for safe and effective use of methadone. Methadone maintenance treatment will be permitted under both the IND and NDA control mechanisms established in the statute and regulations. These conditions of use are intended to assure that the required studies for assessing the safety of the long-term administration are performed, to monitor records and determine that required reports are maintained, to maintain close control over distribution and availability of the drug, and to detail responsibilities for such control:

(1) The following conditions must be met in order for methadone to be used for maintenance and detoxification in connection with a treatment program using methadone:

(i) The drug is limited to oral dosage forms formulated in such a way as to reduce its potential for parenteral abuse and accidental ingestion.

(ii) The manufacturers of methadone will develop additional data from chronic animal toxicity studies in which the drug is administered orally at high doses to dogs, or monkeys for 1 year and rats for 18 months or mice for 2 years. Observations will include effects on behavior, growth, food and water consumption, blood and urine chemistry, hematological systems, cardiovascular and respiratory systems. Post-mortem examinations will include complete gross and histopathological examinations. Reproduction studies following the FDA 1966 guidelines will be performed.

(iii) Further chronic clinical studies with particular attention to the toxicity of methadone in the hematopoietic, cardiovascular, endocrine, hepatic, and immunological systems will be performed under Federally sponsored programs.

(iv) Reports of studies will be submitted pursuant to § 130.13.

(v) At the end of each year after the date of approval, representatives of the Food and Drug Administration, the applicant, appropriate experts, and, if necessary, the investigator(s) will meet to determine whether or not clinical studies should be continued.

(vi) Shipments of the drug are restricted to direct shipments by the holders of approved or investigational new drug applications

for methadone to approved treatment programs using methadone. Alternative methods of distribution may be used if they are approved by FDA after consultation with the Bureau of Narcotics and Dangerous Drugs. These treatment programs using methadone must have been reviewed by the appropriate State health or mental health authority designated pursuant to section 314(d) of the Public Health Service Act, or his designee, and notification of the program's approval must have been received from the Food and Drug Administration. Prior to such notification, applications for treatment programs using methadone shall be reviewed by FDA and shall be sent by FDA to BNDD for any information, comments, or recommendations it may have.

(2) A treatment program using methadone shall be approved by FDA if all of the following conditions are met:

(i) The person assuming responsibility for the program must complete, sign, and file in triplicate with the Food and Drug Administration a Form FD _____, "Application for Approval of Treatment Program Using Methadone" as follows:

FORM FD _____

APPLICATION FOR APPROVAL OF TREATMENT PROGRAM USING METHADONE

Name of other identification of program _____

Address _____

Commissioner
Food and Drug Administration
Bureau of Drugs (BD-22)
Rockville, Maryland 20852

Dear Sir:

As the person (program director) responsible for this program, I submit this request for approval of a treatment program using methadone to provide maintenance treatment and detoxification for narcotic addicts. I understand that failure to abide by the requirements described below are a violation of the law and may result in revocation of approval of my application, seizure of my drug supply, an injunction, and criminal prosecution.

I. Attached is evidence to indicate approval of the program by the State authority designated pursuant to section 314(d) of the Public Health Service Act (or his designee).

II. Attached is the name, complete address, and a summary of the scientific training and experience of each physician and all other professional personnel having major responsibilities for the program and rehabilitative efforts and a signed Form FD _____, "Medical Responsibility Statement for Treatment Program Using Methadone"

for every licensed practitioner authorized to prescribe, dispense, or administer methadone under the program.

(Copies of the required form are obtainable from this agency at the same address to which this application is mailed).

III. Attached is the name, address, and description of each hospital, institution, clinical laboratory facility or other facility available to provide the necessary services. The program must have ready access to a comprehensive range of medical and rehabilitative services. These shall be described and shall comply with any guidelines established by Federal or State authorities.

IV. Attached is a statement of the approximate number of addicts to be included in the program.

V. The following minimal treatment standards will be used:

A. Attached is a statement which will be given to the addicts to inform them about the program. Participation in the program should be voluntary.

B. Care will be exercised in the selection of patients to prevent the possibility of admitting a person who has not been dependent upon heroin or other morphine-like drugs and thereby creating de novo a state of dependence upon methadone. The mere use of an opiate, even

if periodic or intermittent, cannot be equated with drug dependence. Admission to the program will be dependent upon a history of physiological dependence on one or more opiate drugs (which will be recorded in the applicant's medical record) and evidence of current physiological dependence on opiates as demonstrated by the results of urinalysis and signs of opiate withdrawal. It is highly unlikely that an individual would be currently dependent on opiates without a positive urinalysis for opiates and/or without demonstrating at least the early signs of withdrawal (lacrimation, rhinorrhea, pupillary dilatation, and piloerection) during the initial period of abstinence. Other positive evidence of use can be obtained by noting the presence of needle tracks and by obtaining additional history from relatives and friends. The withdrawal signs may be observed during an initial period of hospitalization or while the individual is an outpatient undergoing diagnostic evaluation (history, physical examination, and laboratory studies). Loss of appetite and increased body temperature, pulse rate, and respiratory rate blood pressure, are also signs of withdrawal, but their detection requires inpatient observations.

C. An exception to the requirement for evidence of current physiological dependence on opiates will be allowed under exceptional circumstances. For example,

methadone treatment may be initiated for an individual with a history of opiate addiction a short time prior to or upon release from a stay of 1 month or longer in a penal or chronic care institution. In these circumstances, the reasons for this exception, appropriate descriptions of the facilities, procedures, and qualifications of the personnel of the institution or other appropriate justification will be sent to the Food and Drug Administration at the time of filing this application or with the Annual Report.

D. Additional study is necessary to determine whether methadone may be safely and effectively used in the treatment of patients under 18. No such patients will be admitted to a treatment program using methadone unless prior approval of a Form FD 1571, "Notice of Claimed Investigational Exemption for a New Drug," has been obtained. Such approval will be granted only for a controlled clinical study and not for an ongoing treatment program.

VI. I agree that an admission evaluation and record will be made and maintained for each patient upon admission to the program and will consist of the following:

A. Personal history including age, sex, educational level, employment history, criminal history, and past history of drug abuse of all types;

B. Medical history and history of psychiatric illness and current legal problems, if any; and

C. Physical examination results.

VII. I understand that there is a danger of drug dependent persons attempting to enroll in more than one methadone maintenance program in order to obtain quantities of methadone either for the purpose of self-administration or illicit marketing. To prevent such multiple enrollments, I will participate in whatever local, regional, or national patient identification system exists or is developed. Except in an emergency situation, methadone shall not be provided to a patient who is known to be currently receiving the drug from any other treatment program using methadone. Except as provided in item XV of this form, information that would identify the patient will be kept confidential pursuant to section 303 of the Public Health Service Act and will not be divulged in any civil, criminal, administrative, legislative, or other proceedings conducted by Federal, State, or local authorities.

VIII. The following minimal procedures will be used for ongoing care:

A. Dosage and administration for detoxification and maintenance.

1. The methadone will be administered in oral form.

2. In detoxification, the patient may be placed on a substitutive methadone administration schedule when there are significant symptoms of withdrawal. The dosage schedule indicated below is recommended but should be varied depending upon clinical judgment. Initially, a single oral dose of 15-20 milligrams of methadone will often be sufficient. Additional methadone can be provided if withdrawal symptoms are not suppressed or whenever symptoms reappear. When patients are physically dependent on high doses of methadone, it may be necessary to exceed these levels. With the exception of such patients, 40 milligrams per day in single or divided doses will usually constitute an adequate stabilizing dose level. Stabilization can be continued for 2 to 3 days and then the amount of methadone can be gradually decreased. The rate at which methadone is decreased will be determined separately for each patient. The dose of methadone can be decreased on a daily basis or, at most, in 2-day intervals. However, the amount of intake must always be sufficient to keep withdrawal symptoms at a tolerable level. In hospitalized patients a daily reduction of 20 percent of the total daily dose usually will be tolerated and causes little discomfort. When the total dosage has decreased to 20 milligrams per day, the dose can be reduced by 50 percent per day without producing significant discomfort. If a patient complains

of undue distress, phenothiazine may be used in lieu of increasing ~~the~~ dose. In ambulatory patients, a somewhat slower schedule may be needed.

In any event, if methadone is administered for more than 3 weeks, the procedure will be considered to have progressed from detoxification or treatment of the acute withdrawal syndrome ^{to} that of methadone maintenance even though the goal and intent may be eventual total withdrawal.

3. In maintenance treatment the initial dosage of methadone should control the abstinence symptoms that follow withdrawal of heroin but should not be so great as to cause marked sedation or respiratory depression. It is important that the initial dosage be adjusted to the narcotic tolerance of the new patient. If such a patient has been a heavy user of heroin up to the day of admission, he may be given 20 milligrams orally for the first dose and another 20 milligrams 4 to 8 hours later or 40 milligrams in a single oral dose. If he enters treatment with little or no narcotic tolerance (e.g., if he has recently been released from jail or other confinement), the initial dosage can be one half these quantities. When there is any doubt, a smaller dose can be used initially. Then the patient should be kept under observation, and, if symptoms of abstinence are distressing, 10-milligram doses may be repeated as needed.

Subsequently the dosage can be adjusted individually as tolerated and required with a maintenance level of approximately 40 to 100 milligrams daily. Occasionally, higher dosage levels may be required but must be justified in the medical record.

4. The methadone will be dispensed by a practitioner licensed by law to administer drugs and administered by him or under close supervision. For maintenance, initially (the first several weeks), the subject will receive the medication under observation daily, or at least 6 days a week. For detoxification, the drug will be administered daily under close observation. It is recognized that diversion occurs primarily when patients take medication from the clinic for self-administration. It is also recognized, however, that daily attendance at a clinic may be incompatible with gainful employment, education, and responsible home-making. Therefore, in maintenance treatment, after demonstrating satisfactory adherence to the program regulations for at least 3 months and showing substantial progress in his rehabilitation, the patient may be permitted to reduce to twice weekly the times when he must receive the drug under observation. The rest of the time he may administer the drug himself, but no more than a 3-day supply will routinely be allowed in his possession. However, the requirement that the drug always be administered under supervision will

be relaxed only in the following instances: (a) If the patient is responsibly employed on a regular and full-time basis, or (b) if the patient is a full-time student in a recognized institution of learning and is regularly in attendance and performing satisfactorily, or (c) if the patient is a part-time employee and part-time student and otherwise meets the criteria set forth in (a) and (b) above, or (d) if the patient is directly responsible, as a parent or as one in loco parentis, for the day-to-day welfare of one or more children under the age of 10 and customary observed medication intake would cause such a child or children to be without adequate supervision. Additional medication may also be provided in exceptional circumstances such as illness, family crises, or necessary travel when hardship would result from requiring the customary observed medication intake for such specific period as may be in question. In such circumstances the reasons for providing additional medication will be recorded.

B. In maintenance treatment, a urinalysis will be performed at least once a week for morphine and any other drug clinically indicated. Patients with take-home privileges for methadone should also be tested weekly for methadone. Urine specimens will be collected under direct observation. It is recommended but not

required that patients be followed for other drug and alcohol abuse.

C. An adequate clinical record will be maintained for each patient. This record will contain the date of each visit, the results of each urinalysis, a detailed account of any adverse reactions, any significant physical or psychological disability, and other relevant aspects of the treatment program. If a patient misses appointments for 2 weeks or more without notifying the program, the episode of care will be considered terminated, and this will be noted on his clinical record. If he returns for care, he will be readmitted and his record will be reopened.

D. All patients in the maintenance program will be given careful consideration for discontinuance of methadone after social rehabilitation has been maintained for a reasonable period of time. The patient will be given sufficient information regarding the methadone maintenance technique, so that he can elect to pursue the goal of eventually withdrawing from methadone and becoming drug-free.

IX. A report on Form FD____, "Annual Report for Treatment Program Using Methadone" will be submitted to the Food and Drug Administration by January 30 of each year. (Copies of the form are available from this agency at the same address to which this application is mailed).

XIII. All representations in this application are currently accurate, and no changes will be made in the program until they have been approved by the Food and Drug Administration.

XIV. If the program or any individual under the program is disapproved, the program director will recall the methadone from the disapproved sources and return the drug to the manufacturer.

XV. Inspections of this program may be undertaken by the State authority and the Food and Drug Administration. The identity of the patient will be kept confidential except when the patient or his legal representative consents to the release of such information, when it is necessary to make followup investigations on adverse effect information related to the drug, when the medical welfare of the patient would be threatened by a failure to reveal such information, or when it is necessary to verify records pursuant to proceedings to revoke approval of the program.

Signature: _____
Program Director

(ii) The following completed and signed form referred to in items II and XII of Form FD _____ is submitted in duplicate to the Food and Drug Administration:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

FORM FD _____

MEDICAL RESPONSIBILITY STATEMENT FOR

TREATMENT PROGRAM USING METHADONE

(To be completed by the individual responsible for the dispensing of medication in each facility and every physician working in an approved program, whether ultimately responsible for dispensing medication or not.)

Name of practitioner licensed by law to administer

drugs _____.

Name of program or program director _____.

Program address _____.

Date _____.

The undersigned _____ agrees

to assume responsibility for the prescribing and administering of methadone under the above identified program and to abide by the standards for maintenance treatment and detoxification.

The name of each patient treated at a satellite facility and the frequency of visits will be registered with the program director. An annual report (Form FD _____)

"Annual Report for Methadone Maintenance Programs" will be submitted to the program director for submission to FDA. The patient must always report to the same satellite operation unless prior approval is obtained from the program director for treatment at another satellite operation.

I. The following minimal treatment standards will be used:

A. A program statement will be given to the addicts to inform them about the program. Participation in the program should be voluntary.

B. Care will be exercised in the selection of patients to prevent the possibility of admitting a person who has not been dependent upon heroin or other morphine-like drugs and thereby creating de novo a state of dependence upon methadone. The mere use of an opiate, even if it is periodic or intermittent, cannot be equated with drug dependence. Admission to the program will depend upon a history of physiological dependence on one or more opiate drugs (which will be recorded in the applicant's medical record) and evidence of current physiological dependence on opiates as demonstrated by the results of urinalysis and signs of opiate withdrawal. It is highly unlikely that an individual would be currently dependent on opiates without a positive urinalysis for

opiates and/or without demonstrating at least the early signs of withdrawal (lacrimation, rhinorrhea, pupillary dilatation, and piloerection) during the initial period of abstinence. Other positive evidence of use can be obtained by noting the presence of needle tracks and by obtaining additional history from relatives and friends. The withdrawal signs may be observed during an initial period of hospitalization or while the individual is an outpatient undergoing diagnostic evaluation (history, physical examination, and laboratory studies). Loss of appetite and increased body temperature, pulse rate, blood pressure, and respiratory rate are also signs of withdrawal, but their detection requires inpatient observation.

C. An exception to the requirement for evidence of current physiological dependence on opiates will be allowed under exceptional circumstances. For example, methadone treatment may be initiated for an individual with a history of opiate addiction a short time prior to or upon release from a stay of 1 month or longer in a penal or chronic care institution. In these circumstances, the reasons for this exception, appropriate descriptions of the facilities, procedures, and qualifications of the personnel of the institution ^{or} other appropriate justification will be sent to the Food and Drug Administration at the time of filing this form or with the Annual Report.

D. Additional study is necessary to determine whether methadone may be safely and effectively used in the treatment of patients under 18. No such patients will be admitted to a treatment program using methadone unless prior approval of Form FD 1571, "Notice of Claimed Investigational Exemption for a New Drug," has been obtained. Such approval will be granted only for a controlled clinical study and not for an ongoing treatment program.

II. I agree that an admission evaluation and record will be made and maintained for each patient upon admission to the program and will consist of the following:

A. Personal history including age, sex, educational level, employment history, criminal history, and past history of drug abuse of all types;

B. Medical history and history of psychiatric illness and current legal problems, if any; and

C. Physical examination results.

III. The following minimal procedures will be used for on-going care:

A. Dosage and administration for detoxification and maintenance

1. The methadone will be administered in oral form.

2. In detoxification, the patient may be placed on a substitutive methadone administration schedule when there are significant symptoms of withdrawal. The dosage

schedule indicated below is recommended but should be varied depending upon clinical judgment. Initially, a single oral dose of 15-20 milligrams of methadone will often be sufficient. Additional methadone can be provided if withdrawal symptoms are not suppressed or whenever symptoms reappear. When patients are physically dependent on high doses of methadone it may be necessary to exceed these levels. With the exception of such patients, 40 milligrams per day in single or divided doses will usually constitute an adequate stabilizing dose level. Stabilization can be continued for 2 to 3 days and then the amount of methadone can be gradually decreased. The rate at which methadone is decreased will be determined separately for each patient. The dose of methadone can be decreased on a daily basis or, at most, in 2-day intervals. However, the amount of intake must always be sufficient to keep withdrawal symptoms at a tolerable level. In hospitalized patients a daily reduction of 20 percent of the total daily dose usually will be tolerated and causes little discomfort. When the total dosage has decreased to 20 milligrams per day, the dose can be reduced by 50 percent per day without producing significant discomfort. If a patient complains of undue distress, phenothiazine may be used in lieu of increasing

the methadone dose. In ambulatory patients, a somewhat slower schedule may be needed.

In any event, if methadone is administered for more than 3 weeks, the procedure will be considered to have progressed from detoxification or treatment of the acute withdrawal syndrome to that of methadone maintenance even though the goal and intent may be eventual total withdrawal.

3. In maintenance treatment, the initial dosage of methadone should control the abstinence symptoms that follow withdrawal of heroin but should not be so great as to cause marked sedation or respiratory depression. It is important that the initial dosage be adjusted to the narcotic tolerance of the new patient. If such a patient has been a heavy user of heroin up to the day of admission, he may be given 20 milligrams orally for the first dose and another 20 milligrams 4 to 8 hours later or 40 milligrams in a single oral dose. If he enters treatment with little or no narcotic tolerance (e.g., if he has recently been released from jail or other confinement), the initial dosage can be one half these quantities. When there is any doubt, a smaller dose can be used initially. Then the patient should be kept under observation, and, if symptoms of abstinence are distressing, the administration of 10-milligram doses may be repeated as needed. Subsequently the dosage can be adjusted individually as tolerated and required

with a maintenance level of approximately 40 to 100 milligrams daily. Occasionally, higher dosage levels may be required but must be justified in the medical record.

4. The methadone will be dispensed by a practitioner licensed by law to administer drugs and administered by him or under close supervision. For maintenance, initially (the first several weeks) the subject will receive the medication under observation daily, or at least 6 days a week. For detoxification, the drug will be administered daily under close observation. It is recognized that diversion occurs primarily when patients take medication from the clinic for self-administration. It is also recognized, however, that daily attendance at a clinic may be incompatible with gainful employment, education, and responsible homemaking. Therefore, in maintenance treatment, after demonstrating satisfactory adherence to the program regulations for at least 3 months and showing substantial progress in his rehabilitation, the patient may be permitted to reduce to twice weekly the times when he must receive the drug under observation. The rest of the time he may administer the drug himself, but no more than a 3-day supply will routinely be allowed in his possession. However, the requirement that the drug

always be administered under supervision will be relaxed only in the following instances: (a) If the patient is responsibly employed on a regular and full-time basis, or (b) if the patient is a full-time student in a recognized institution of learning and is regularly in attendance and performing satisfactorily, or (c) if the patient is a part-time employee and/or part-time student and otherwise meets the criteria set forth in (a) and (b) above, or (d) if the patient is directly responsible, as a parent or as one in loco parentis, for the day-to-day welfare of one or more children under the age of 10 and customary observed medication intake would cause such a child or children to be without adequate supervision. Additional medication may also be provided in exceptional circumstances such as illness, family crisis, or necessary travel when hardship would result from requiring the customary observed medication intake for such specific period as may be in question. In such circumstances the reasons for providing additional medication will be recorded.

B. In maintenance treatment, a urinalysis will be performed at least once a week for morphine and any other drug clinically indicated. Patients with take-home privileges for methadone should also be tested weekly for methadone. Urine specimens will be collected under direct observation. It is recommended but not required

that patients be followed for other drug and alcohol abuse.

C. An adequate clinical record will be maintained for each patient. This record will contain the date of each visit, the results of each urinalysis, a detailed account of any adverse reactions, any significant physical or psychological disability, and other relevant aspects of the treatment program. If a patient misses appointments for 2 weeks or more without notifying the program, the episode of care will be considered terminated, and this will be noted on his clinical record. If he returns for care, he will be readmitted and his record will be reopened.

D. All patients in the maintenance program will be given careful consideration for discontinuance of methadone maintenance after social rehabilitation has been maintained for a reasonable period of time. The patient will be given sufficient information regarding the methadone maintenance technique, so that he can elect to pursue the goal of eventually withdrawing from methadone and becoming drug-free.

IV. To prevent diversion into illicit channels, adequate security will be maintained over stocks of methadone under my control and over the manner in which it is distributed, as required by the Bureau of Narcotics and Dangerous Drugs.

V. All representations in this application are currently accurate, and no changes will be made in the program until they have been approved by the program director and the Food and Drug Administration.

VI. If I am disqualified, I agree to return any remaining stock of methadone to the parent program.

VII. Inspections of this program may be undertaken by the State authority and the Food and Drug Administration. The identity of the patient will be kept confidential except when the patient or his legal representative consents to the release of such information, when it is necessary to make followup investigations on adverse effect information related to the drug, when the medical welfare of the patient would be threatened by a failure to reveal such information, or when it is necessary to verify records pursuant to proceedings to revoke approval of the program.

Signature: _____
Participating Physician

(iii) The following completed and signed form referred to in item IX of Form FD_____, "Application for Approval of Methadone Program," is submitted in duplicate in accordance with the instructions in item IX.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

FORM FD _____

ANNUAL REPORT FOR TREATMENT PROGRAM USING METHADONE

This form is to be completed in duplicate for each calendar year. One copy is to be sent to the Food and Drug Administration and one copy to the State authority on or before January 30.

1. Name of other identification of program _____

Address _____

Number of satellite units _____
(Attach a list showing address and person responsible for each unit)

2. Total Treatment Capacity _____

3. Drug Forms Dispensed:

Amount of each formulation dispensed (in grams)
during the year:

	Formulation	Amount
a.	_____	_____
b.	_____	_____
c.	_____	_____

4. Number of individuals who applied to the program but were not admitted or given admission evaluation _____.

5. Census of Patients Maintained on Methadone:

- a. Number under care at the beginning of the year being reported _____.

Of those in treatment at the beginning of the year:

- (1) Number continuously under care through the year being reported (still under care) _____.

- (2) Number discharged or transferred to other types of programs and not readmitted _____.
- (3) Number discharged or transferred to other types of programs and readmitted (still under care) _____.
- (4) Number discharged and readmitted (no longer under care) _____.

b. Number admitted to care during year--not previously treated in this program:

- (1) Number still under care at the end of the year _____.
- (2) Number discharged or transferred to other types of programs and not readmitted _____.
- (3) Number discharged or transferred to other types of programs and readmitted (still under care) _____.
- (4) Number discharged and readmitted (no longer under care) _____.

c. Number admitted to care during the year--previously treated in this program prior to the past year:

- (1) Number still under care at the end of the year _____.
- (2) Number discharged or transferred to other types of programs and not readmitted _____.
- (3) Number discharged and transferred to other types of programs and readmitted (still under care) _____.
- (4) Number discharged and readmitted (no longer under care) _____.

6. Demographic and treatment characteristics of patients under care at the end of the year being reported:

- a. Give the number of males and females in each age category:

Age	<u>Sex</u>	
	<u>Male</u>	<u>Female</u>
Under 18	_____	_____
18-20	_____	_____
21-25	_____	_____
26-35	_____	_____
36-45	_____	_____
46+	_____	_____

- b. For the year being reported, give the number of patients who have been under continuous care for the following periods of time:

Under three months _____

3 months to one year _____

One to two years _____

Two to five years _____

Over five years _____

- c. Total number of individuals treated to date _____.

- d. For the year being reported, give the number of patients stabilized at each dosage level:

<u>Daily Dosage</u>	<u>No. of Patients</u>
Under 40 mgm.	_____
40 - 59 mgm.	_____
60 - 79 mgm.	_____
80 - 99 mgm.	_____
100 - 119 mgm.	_____
120 - 160 mgm.	_____
Over 160 mgm.	_____

- e. For the year being reported, give the number of patients in the past 8 weeks who have fallen in the following categories:

	<u>No. of Patients</u>
No positive urinalysis for opiates for 2 months or more	_____
Occasional positive urinalysis for opiates (monthly or less)	_____

Frequent positive
urinalysis for opiates (more
than once per month; still
dependent) _____

In program for less than
2 months _____

7. Give the number of patients having significant adverse reactions, particularly reactions related to hematopoietic, cardiovascular, endocrine, and immunological functions (attach a completed copy of Form FD-1639 "Drug Experience Report" for each incident; forms obtainable from the Food and Drug Administration):

<u>Type of Reaction</u>	<u>No. of Patients</u>
_____	_____
_____	_____
_____	_____

8. Give the number of patients who have died while under methadone care (attach a completed copy of Form FD-1639 "Drug Experience Report" for each incident; forms obtainable from the Food and Drug Administration):

	<u>No. of Patients</u>
a. Definitely methadone-related	_____
b. Not methadone-related	_____

Signature: _____
Program Director

3. Within 60 days after receipt of an application for a treatment program using methadone, the applicant will receive notification of approval or refusal.

4. Refusal or revocation of a program approval.

(1) Refusal or revocation of approval of a program may be proposed to the Commissioner of Food and Drugs by the Director of the FDA Bureau of Drugs, on his own initiative or at the request of representatives of the Bureau of Narcotics and Dangerous Drugs or the

designated State authority.

(ii) Before presenting such a proposal to the Commissioner, the Director of the Bureau of Drugs or his representative will notify the program applicant of the proposed action and the reasons therefor and will offer him an opportunity to explain the matters in question in an informal conference and/or in writing. If an explanation is offered by the applicant but not accepted by the Bureau of Drugs and if the hearing is requested within 10 days after receipt of notification that the explanation is unacceptable, the Commissioner will provide the program applicant an opportunity for an informal hearing on the question of whether the applicant should be entitled to receive methadone for use in a treatment program. Representatives of the State authority and/or BNDD may participate in the conference with the Bureau official or with the Commissioner.

(iii) The Commissioner will evaluate all available information, including any explanation or assurance presented by the program applicant. If he finds that the program applicant has failed to submit adequate assurance that the conditions for receiving methadone for use in a program will be met or that the program applicant has repeatedly or deliberately failed to comply with the conditions for receiving methadone for treatment of addicts or that the applicant has deliberately submitted false information to the Food and Drug Administration, the Commissioner will notify the program applicant, the appropriate State officials, BNDD, and all other appropriate persons that the program applicant is not entitled to receive methadone for treatment of narcotic addicts.

(iv) If a program applicant has had a program application refused or revoked, such refusal or revocation may be reversed when the Commissioner determines that the applicant has presented adequate assurance that he will employ such drugs solely in compliance with the requirements for a methadone program.

5. Program directors will be allowed 3 months from the final promulgation of this paragraph in order to obtain the necessary approvals and establish procedures for adhering to these conditions. During this interim period the State authority may permit one or more hospitals in areas of the State without approved programs to dispense methadone for the detoxification and maintenance treatment of narcotic addicts. The holders of approved new drug applications will be notified by the Food and Drug Administration that methadone can be distributed to these hospital pharmacies after the State authority has so informed FDA.

6. Conditions for approving the use of methadone in analgesia and in hospitalized patients in detoxification.

(i) The drug is in oral or parenteral form.

(ii) Transportation is restricted to direct shipments to hospitals which have submitted a notification (FD _____ "Application for approval of Methadone Program,") to the Food and Drug Administration that they wish to receive the drug. The Food and Drug Administration will provide methadone manufacturers with the names of the hospitals that have submitted signed Forms FD _____, "Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification".

(iii) For a hospital to receive shipments of methadone for use as an analgesic and for detoxification, a responsible hospital ^{official} must complete, sign, and file in triplicate with the Food and Drug Administration a Form FD _____, "Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification," as follows:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

FORM FD _____

HOSPITAL REQUEST FOR METHADONE FOR ANALGESIA

IN SEVERE PAIN AND FOR DETOXIFICATION

Name of Hospital

Address

Commissioner

Food and Drug Administration

Bureau of Drugs (BD-22)

Rockville, Maryland 20852

Dear Sir:

I submit this notice of intent to receive supplies of methadone to be used for analgesia and detoxification.

I understand that the failure to abide by the requirements described below may result in discontinuance of shipments of methadone, seizure of the drug supply on hand, injunction, and criminal prosecution.

1. The name of the individual (pharmacist) responsible for receiving and securing supplies of methadone is _____.

2. There are _____ beds in the hospital. (Give the number).

3. A general description of the hospital and nature of patient care undertaken is attached.

4. The anticipated quantity of supply needed per year is _____.

5. Adequate security will be maintained over stocks of methadone to prevent diversion into illicit channels. All stocks will be secured in a locked cabinet or safe.

6. Methadone will be dispensed for detoxification of hospitalized patients only and for analgesia in severe pain for hospitalized and outpatients. If methadone is administered for treatment of heroin dependence for more than 3 weeks, the procedure passes from treatment of the acute withdrawal syndrome (detoxification) to methadone maintenance. Such treatment can be undertaken only by approved methadone maintenance programs. This does not preclude the maintenance of an addict who is hospitalized for treatment for medical conditions other than addiction and whose enrollment in a specific maintenance program has been verified by the hospital.

7. Prior to filling a physician's prescription for methadone for outpatients, I will obtain from the physician a statement indicating that all such prescriptions will be limited to use for analgesia in severe pain and his agreement to maintain records to substantiate such use.

These records will be available in the hospital or made available at the request of the hospital administrator. On January 30 of each year, the hospital will report to the Food and Drug Administration the names of all physicians who prescribed methadone for analgesia on an outpatient basis during the previous year.

8. Prescriptions will not be filled if they are written by a physician who has not submitted the required commitment to the hospital.

9. Accurate records are maintained showing dates, quantity, and batch or code marks of the drug used. The records are to be retained for a period of 3 years.

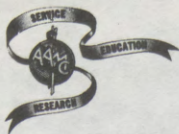
10. The Food and Drug Administration may inspect the supplies or use of the drug. The identity of the patient will be kept confidential except when the patient or his legal representative consents to the release of such information, when it is necessary to make followup investigations on adverse effect information related to the drug, when the medical welfare of the patient would be threatened by a failure to reveal such information, or when it is necessary to verify records pursuant to proceedings to revoke approval of the hospital.

Signature: _____
Hospital Official

Interested persons may, within 90 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: 2/14/72.

Charles C. Edwards



ASSOCIATION OF AMERICAN MEDICAL COLLEGES
SUITE 200, ONE DUPONT CIRCLE, N.W., WASHINGTON, D.C. 20036

JOHN A. D. COOPER, M.D., PH.D.
PRESIDENT

May 26, 1972

WASHINGTON: 202: 466-5175

Honorable Harold E. Hughes, Chairman
Subcommittee on Alcoholism and Narcotics
408 Senate Office Building Annex
Washington, DC 20510

Dear Mr. Chairman:

The Association notes with interest the planned consideration by the Subcommittee of the Drug Addict Treatment and Rehabilitation Act (S 2840), a bill to authorize emergency assistance to states and nonprofit private agencies in the establishment of centers for maintenance, treatment and rehabilitation of drug addicts.

The membership of the Association includes all of the 108 operational U.S. medical schools and their students, more than 400 of the major teaching hospitals, and 52 learned academic societies whose members are engaged in medical education and research. Through its members, the Association is deeply concerned with the problem of drug abuse and excessive use. A number of medical schools, for example, are currently involved with methadone maintenance programs in their areas.

The Association would like to comment on the Drug Addict Treatment and Rehabilitation Act, and respectfully requests that these comments be included in the permanent record of the Subcommittee hearings.

At the outset, the Association wishes to make clear its concern that methadone maintenance, although currently enjoying a growing popularity in the treatment of heroin addicts, not be regarded as the only treatment modality. It is an established treatment modality in urban areas, where the use of heroin is high. But it is not the only -- and, perhaps, not even the best -- method of treatment. The present excitement over its popularity should not be permitted to obscure this important, underlying issue.

The Association appreciates the importance of federal assistance in the establishment of centers for maintenance, treatment and rehabilitation of drug addicts through the administration of methadone or other efficacious treatment. It is not expert in this field, however, and therefore can

Honorable Harold E. Hughes
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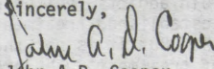
comment only generally. To the degree that methadone maintenance improves the health and well-being of the heroin addict the Association is generally supportive of such treatment.

The Association can speak with more authority on the program of short-term grants to assure availability of personnel as authorized in proposed new section 1111 of the Public Health Service Act on page 16 of S 2840. Such a program would provide useful additional federal assistance to the nation's financially hard-pressed medical schools in their efforts to provide an adequate supply of trained health personnel. As mentioned earlier, a number of schools, notably Yale, Columbia, Chicago and George Washington, already are involved in methadone maintenance programs in their areas. I am confident that other schools would be attracted to the field if sufficient financial assistance were available to help offset the additional cost of such programs.

In this connection, it might be useful to point out that last year's Comprehensive Health Manpower Training Act (PL 92-157) authorized grants to medical schools, as well as other health professions schools, for drug abuse control projects. Section 772(a)(7) of the Public Health Service Act, as amended by the 1971 health personnel legislation, authorizes grants for special projects to "establish and operate programs at schools of medicine or osteopathy (and where applicable at other health professions schools) (A) providing increased emphasis on, and training in, the science of clinical pharmacology, the prevention, diagnosis, treatment, and rehabilitation of alcoholism and drug dependence, and the assessment of the efficacy of various therapeutic regimens..." While the Association has no objection to the establishment of a separate program of assistance to medical schools for drug abuse control, it sees some value in coordinating the two assistance programs. This could be done, perhaps, through the addition of some appropriate language to proposed new section 1111 and an amendment adding complementary language to section 772, or through some other means more satisfactory to the Subcommittee.

The Association appreciates this opportunity to express its interest in the Drug Addict Treatment and Rehabilitation Act and hopes that its comments are helpful to the Subcommittee. I and the staff of the Association stand ready to provide any further assistance or information that you may desire.

Sincerely,


John A.D. Cooper

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United States Senate

COMMITTEE ON
 LABOR AND PUBLIC WELFARE
 WASHINGTON, D.C. 20510

July 23, 1972

Dr. Jerome H. Jaffe
 Director, Special Action Office
 for Drug Abuse Prevention
 New Executive Office Building
 Washington, D.C.

Dear Jerry:

At the close of your testimony before our Subcommittee on Alcoholism and Narcotics I indicated that I would submit additional questions to you on the use of methadone for the identification and treatment of persons addicted to heroin. Please accept my apologies for the delay in transmitting these questions and my thanks for the gracious cooperation your office has always given to the Subcommittee.

With regard to methods of testing for heroin and other drug usage, I understand that you believe that the military experience could have useful applications in civilian society, for example, in the screening of high risk groups.

1. How do you answer the objection that in encouraging programs that, unlike other public health screening programs, will require or at least induce people to reveal their commission of a criminal offense, the Federal Government may infringe upon constitutional rights?
2. What alternatives do you propose for those individuals identified as drug users through group screening?
3. In view of the difficulties the military services have encountered in achieving satisfactory levels of accuracy in the screening procedures, are you satisfied that the existing techniques are suitable for the initial screening of civilian groups?

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Dr. Jerome H. Jaffe

4. Would you comment on the relative merits of all the testing techniques now available for group screening?
 5. On the economic aspects of methadone maintenance programs, in working with grant applicants is your office able to provide guidelines designed to prevent excessive costs for such commercial services as the laboratory equipment and tests?
 6. Are federal grant funds being used to finance the purchase of FRAT or other such equipment?
 7. Have you found that inadequacy of supporting services is a widespread problem of the methadone maintenance programs?
 8. Can you estimate the number of additional trained manpower needed for the methadone programs recently surveyed?
 9. Will the training funds authorized in P. L. 92-255 be adequate if appropriated?
 10. What is the status of your budget requests for fiscal 1973 to be included in a supplemental appropriations bill?
 11. The newspapers continue to report deaths from drug overdoses involving methadone. For the record, would you comment on the dangers of other drugs, including alcohol, for persons being maintained on methadone?
 12. On the problem of illegal diversion, what is the status of your work on centralized registration systems?
- Your answers to these questions will be appreciated by the members of the Subcommittee in our continuing effort to understand the problems and requirements of drug abuse prevention and treatment programs.

With sincere best wishes,

Harold E. Hughes
Chairman, Subcommittee on
Alcoholism and Narcotics

EXECUTIVE OFFICE OF THE PRESIDENT
SPECIAL ACTION OFFICE FOR DRUG ABUSE PREVENTION

WASHINGTON, DC 20506

August 21, 1972

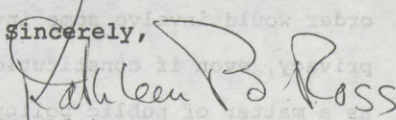
Honorable Harold Hughes, Chairman
Subcommittee on Alcoholism and Narcotics
Committee on Labor and Public Welfare
United States Senate
Washington, D. C. 20510

Dear Mr. Chairman:

Dr. Jaffe has asked that I forward to you in his absence the enclosed responses to those additional questions on the use of methadone for the identification and treatment of persons addicted to heroin which you submitted to him on July 23, 1972.

If you have any questions or feel that we might provide you with any additional information, please do not hesitate to let us know. We will continue to do all that we can to be of assistance to you.

Sincerely,


Kathleen B. Ross
Congressional Liaison Officer

Enclosure

QUESTION 1: How do you answer the objection that in encouraging programs that, unlike other public health screening programs, will require or at least induce people to reveal their commission of a criminal offense, the Federal Government may infringe upon constitutional rights?

RESPONSE: In a narrow sense, the objection may be answered by an analysis of the legal issues, that is, by addressing specific constitutional guarantees such as the Fifth Amendment in respect of self-incrimination and the Fourth Amendment in respect of searches and seizures, and by arguing that with appropriate limitations on the utilization of the information obtained, there would be no infringement of such guarantees.

In a larger sense, it must be admitted that any program that can detect the presence of any disorder would involve some invasion of individual privacy, even if constitutionally permissible, and as a matter of public policy can be justified only in terms of offsetting benefits. The benefits would have to be even greater if a positive diagnosis per se could cause an individual some harm. Such a potential does, of course, exist with many disorders which society views as related to deviant behavior. These same problems would arise in a program to diagnosis and control venereal disease,

QUESTION: What alternatives do you propose for those individuals identified as drug users through drug screening?

RESPONSE: At the present time we do not contemplate or provide prenatal care to unmarried pregnant women through public health procedures. The

formally sponsored Federally operated screening military experience suggests that in the case of heroin use these benefits can be substantial. In programs within the Continental United States should privately sponsored or locally sponsored groups indicate of us, we intend to recommend that arresting the downward spiral from experimentation to casual use to full-blown addiction, it appears that nothing succeeds like early intervention, and screening techniques seem to be one possible tool to bring such intervention to bear. We should keep in mind that we will soon have available medications such as the antagonists that when used early could be powerful tools in preventing addiction.

providing any financial support for the screening effort. Obviously, we could not prevent private groups from using private laboratories, but expenses. It is possible that in some instances, for example, a school or union group which could do such screening that the group will choose to pay their retention of an individual unless certain additional requirements are met, e.g., treatment. We have no way of knowing at this time what the value of identification and the offering of help alone will

QUESTION 2: What alternatives do you propose for those individuals identified as drug users through drug screening?

RESPONSE: At the present time we do not contemplate formally sponsoring Federally operated screening programs within the Continental United States. Should privately sponsored or locally sponsored groups inquire of us, we intend to recommend that individuals identified as drug users be offered appropriate counseling or treatment, or at least, a referral for appropriate counseling and treatment; that no criminal charges, civil commitment process, or any other judicial proceeding be instituted against individuals identified as users. We would also need assurances that such options are available before providing any financial support for the screening effort. Obviously, we could not prevent private groups from using private laboratories at their own expense. It is possible that in some instances, for example, a school or union group which opts to do such screening that the group will choose to prohibit retention of an individual unless certain additional requirements are met, e.g., treatment. We have no way of knowing at this time what the value of identification and the offering of help alone will

accomplish, versus identification and demand that treatment be sought to retain status as a participating member of the organization.

QUESTION 3: In view of the difficulties the military services have encountered in achieving satisfactory levels of accuracy in the screening procedures, are you satisfied that the existing techniques are suitable for the initial screening of civilian groups?

RESPONSE: Although existing techniques would be suitable for the initial screening of civilian groups, it is likely that if any group should elect to use the concept, newer screening procedures would be available that are far better than those in use by the military today. The military services, particularly the Department of Army because they used contract laboratories for part of their screening process, had initial difficulties standardizing criteria and procedures for screening and identification of drug abusers. However, that situation has corrected itself and screening now has a 90-96% reliability factor.

The important consideration in respect to "military service screening" is that we now have a valuable learning curve which has provided us with experience, identified subtle pitfalls to be avoided, and has tested, strengthened, and standardized a technique that could be transferred for application to civilian groups. The military has also developed a quality control monitoring system operated from Walter Reed Hospital. We hope to initiate a similar system for

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all civilian labs servicing treatment programs irrespective of efforts to use this technique for early identification. In addition, as a result of the stimulus provided by the expansion of treatment programs the technology in this area is changing rapidly with the advent of progressively more rapid, more accurate and less costly procedures.

QUESTION 4: Would you comment on the relative merits of all the testing techniques now available for group screening?

RESPONSE:

Group screening refers to the testing of large populations to determine the presence of various drugs of abuse. Such testing could be done by blood analysis but is, at the present time, most feasibly performed by urine testing.

When one discusses the relative merits of the various testing techniques available for the determination of drugs of abuse in the urine, one must first define the specific needs for that particular testing technique. For instance, when one refers to group screening, it might be assumed that the techniques should be sensitive, rapid, inexpensive, simple to operate in the field, and reliable.

At present, there are at least seven methods available or under development for detection of the drugs of abuse in the urine. The methods are listed in the chart below, which also indicates the relative merits of the various methods in a number of categories.

<u>Method</u>	<u>Drugs of Abuse</u>	<u>Speed (1-4)</u>	<u>Cost (1-4)</u>	<u>Sensitivity (1-4)</u>	<u>Technical Skill Required</u>
Thin-layer chromatography (TLC)	Morphine Methadone Barbiturate Amphetamine	1	2	2	3
Gas-liquid chromatography (GLC)	Morphine Methadone Barbiturate Amphetamine	1	3-4	3-4	4
Technicon ^a	Morphine	3	4	2-3	1-2
Free radical assay technique (FRAT) ^b	Morphine Methadone Barbiturate Amphetamine	4	4	2	1
Enzyme multiplier immunoassay technique (EMIT) ^c	Morphine Methadone Barbiturate Amphetamine	4	?	?	1
Radioimmunoassay ^d	Morphine	4	3-4	4	1
Hemagglutination inhibition (HI) ^d	Morphine	4	1-2	4	1

Legend:

Speed:
4 = fastest
Cost (equipment and reagents):
1 = least expensive.
Sensitivity (for morphine):
4 = most sensitive
Technical skill required:
4 = most skill required

Footnotes:

- a. Technicon is available in an automated or a non-automated system. Only detects free morphine.
- b. Tests for various drugs must be done sequentially. Company experimenting with a combination test.
- c. Experimental technique. Tests for various drugs must be done sequentially.
- d. No assays for other drugs of abuse at present. These are under development.

It should be remembered that this field is changing rapidly and that many of the methods listed (especially the last five) are being currently changed to make them more usable.

One more characteristic of each test (not mentioned in the chart) should be discussed -- false positives. Any method with a significant percentage of false positives must be backed up with another more accurate method. If the back-up method only confirms positives, the rapidity of analysis is not too important. With thin-layer chromatography and gas-liquid chromatography, it appears quite certain that, in the proper hands, the level of false positives is quite low. Some of the data available on the last five methods is conflicting. At present, all available information is being pooled and thoroughly analyzed to determine the percentages of false positives reported by various investigators with the different techniques.

QUESTION 5: On the economic aspects of methadone maintenance programs, in working with grant applicants, is your office able to provide guidelines designed to prevent excessive cost for such commercial services as the laboratory equipment and tests?

RESPONSE: We have detailed cost analyses and minimum service criteria for methadone maintenance programs, as well as therapeutic communities. In addition, we have a cost breakdown for all the laboratory urinalysis testing procedures available. As I am sure you know, there are many techniques available and all techniques have certain advantages and disadvantages. We do not recommend any one technique for analysis but recommend good quality control and cost effectiveness. In conjunction with other federal agencies, we are working on guidelines to establish better commercial services for drug screening.

Costs for outpatient chemotherapy vary as widely across the nation, as does the cost of living. A general estimate for outpatient methadone programs computes the annual per patient cost to range between \$1,000 and \$1,500. Table 1, below, a cost analysis model, is an average computation, based on costs around the country and delineates the costs for methadone to be \$1,300 per patient annually. The line items involved include Space, Utilities, Staff,

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Urinalysis, Medication, Intake, Equipment, Renovation and Overhead. While the costs involved vasculate widely, the line item computation should always remain within the realms of these nine items.

Table 2, is a similar cost model for a Therapeutic Community. Costs for such a modality range between \$3,600 and \$4,800 per patient annually.

The costs of urine tests are projected at \$2.00 each with slightly over 1 test per patient per week.

QUESTION 6: Are federal grant funds being used to finance the purchase of FRAT or other such equipment?

RESPONSE: Most community drug programs supported by federal grant funds are contracting to commercial laboratories for their urinalysis services. This is done mainly because of the efficiency of doing great numbers of analysis which individual programs do not handle. A good, efficient laboratory can usually do a thousand urinalyses per day. If the number is considerably less, the cost of each procedure increases markedly.

The Veterans Administration, Department of Defense, Bureau of Narcotics and Dangerous Drugs, and other such federal agencies are supporting some of their own centralized laboratory services to assay for drugs. The National Institute of Mental Health H80 Service Grants can be used to finance the purchase of laboratory equipment but most programs are not doing this for the reasons cited above. To the best of my knowledge, no recent grant has included funds for a FRAT system although in the past grants did provide funds for gas-liquid chromatography. New approaches using radioimmuno assay technics also require equipment but the cost is generally under \$6,500 per machine. We have strongly discouraged the Veterans

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Administration from investing in expensive equipment until the technology in the field is better clarified.

QUESTION 7: Have you found that inadequacy of supporting services is a wide spread problem of the methadone maintenance programs?

RESPONSE: It is difficult to assess the adequacy or inadequacy of supporting services in treatment programs since there has been little evaluation of programs. SAODAP has initiated a comprehensive evaluation system to assess treatment programs throughout the Nation. The initial results of this effort will be available late this fiscal year.

In addition, Health Services and Mental Health Administration and Food and Drug Administration conducted site visits to 450 methadone programs but their visits focused primarily on dispensing procedures. We believe that the recent expansion of training systems will eventually relieve the shortage of support service personnel.

QUESTION 8: Can you estimate the number of additional trained manpower needed for the methadone programs recently surveyed?

RESPONSE: Not as yet, since the evaluation effort is just getting underway. However, we can estimate manpower needs for expansion of programs. Since we intend to eliminate the 30,000 man waiting list by expanding by at least 30,000 slots and since counting turnovers we should probably assume a need for 1 staff person per 12 patients, we will need to train about 3,000 additional people of varying disciplines.

QUESTION 9: Will the training funds authorized in P.L. 92-255 be adequate if appropriated?

RESPONSE: All program areas, including training, were examined in detail during preparation of the justification for the recent request for a supplemental FY 1973 drug abuse appropriation. The funds requested for FY 1973 are considered adequate. Indeed, the problem may be to persuade some individuals now involved in treatment to utilize the training opportunities already in existence since at present there seems to be no requirement for training or credentials to participate in treatment programs

QUESTION 10: What is the status of your budget requests for fiscal 1973 to be included in a supplemental appropriations bill?

RESPONSE: On July 27, 1972, the President transmitted to Congress proposed supplemental appropriations, and these requests are now pending before the appropriations committees of the House and the Senate.

Twenty million dollars were requested to carry out section 224 of Public Law 92-255, authorizing pharmacological research.

Forty million dollars were requested to carry out the purposes of section 223, establishing a special fund for developing or demonstrating promising innovations and expanding programs which are exceptionally effective or exceptionally needed.

Sixty million dollars were requested for expenditure by the Secretary of Health, Education and Welfare to fund new activities authorized by Public Law 92-255.

QUESTION 11: The newspapers continue to report deaths from drug overdoses involving methadone. For the record, would you comment on the dangers of other drugs, including alcohol, for persons being maintained on methadone?

RESPONSE: There are reports of deaths of methadone patients from overdoses of drugs other than methadone. Though we can postulate a synergistic effect between methadone and other depressant drugs we know of no study which has shown that patients tolerant to methadone are more likely to succumb to the effects of other drugs. For the most part, individuals dying from overdoses of methadone have been those non-tolerant to it. This is an area where more research would be helpful and we are hopeful that some of the recently funded "centers" will see this as a priority.

QUESTION 12: On the problem of illegal diversion, what is the status of your work on centralized registration systems?

RESPONSE: As you know, we have been experimenting for some time with a Unique Identification Process that could prevent multiple clinic registration with total protection of patient confidentiality. The present system is based on the use of footprints. We are now satisfied that we could proceed with a nationwide application for narcotic addicts participating in methadone programs. We are therefore proceeding with the establishment of a Unique Identification Service which will function on a National scale to:

- a. Limit the diversion of methadone through the validation of all initial admissions to methadone treatment and detoxification programs.
- b. Provide a non-duplicate count of all narcotic abusers admitted to treatment.
- c. Provide reliable aggregate statistics on the incidence and prevalence of narcotic abuse, as well as related demographic and situational factors.

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The National Institute of Mental Health has initiated the procurement process and present plans are to have a fully operational system in November.

- A pilot test is being conducted by the Narcotics Treatment Agency in Washington, D. C. and seems to be acceptable to patients and staff.

TABLE 1.

M E T H A D O N EOUTPATIENT MODEL

150 Patients	
Space	11,000
2200 sq. ft. x \$5 per sq. ft.	
Utilities	3,000
STAFF	
1 Unit Director	12,500
% M.D.	12,000
% Psychiatrist	7,000
1 Therapist Supervisor	9,500
4 Ex-Addict Counselors or B.A. level	28,000
1 Registered Nurse	10,500
2 Licensed Practical Nurses	15,000
1 Voc. Rehab. Counselor	10,000
1 Clerk Typist	6,500
10% Fringe	112,000
	11,200
URINALYSIS	18,200
175 per week @ 2.00	
MEDICATION	5,460
10¢ a dose x 150 x 365	
INTAKE 200x\$30	6,000
(33% dropout rate)	
Equipment	4,000
Renovation Factor	11st year only
	10,460
Overhead 10%	11,200

150 ÷ 195,000 = 1300 per patient year during first year. This assumes that this unit is affiliated with a management structure to handle administration data analysis and to provide back-up for patients who cannot be handled on an outpatient basis.

TABLE 2.

THERAPEUTIC COMMUNITY
DRUG FREE RESIDENTIAL FACILITY

<u>ADMINISTRATION</u>		47,500
1 Director	16,000	
1 Administrative Asst.	8,500	
1 Chef	8,000	
1 Secretary	6,500	
1 Account/Bookkeeper	8,500	
<u>CLINICAL SERVICES</u>		54,000
1 Chief Counselor	10,000	
2 Counselors	14,000	
2 Therapists	20,000	
1 Vocational Rehabilitation Counselor	10,000	
<u>MEDICAL SERVICES</u>		
M.D. - 5 hrs. per week at \$15,000 per hour	3,900	18,900
2 Licensed Practical Nurses	15,000	
<u>FRIENGE BENEFITS 14%</u>		16,800
<u>FOOD - \$1.75 per day</u>		31,950
<u>EQUIPMENT</u>		20,000
<u>TRAVEL</u>		
3 cars at 2,000		6,000
<u>UTILITIES</u>		5,000
<u>URINALYSIS</u>		7,800
<u>BUILDING</u>		
Reht		15,000
Renovation		7,050
<u>TOTAL COST</u>		230,000

50 ÷ \$230,000 = 4,600 per client cost.

This assumes affiliation with an organizational structure for certain types of back-up services and administrative support.

Senator HUGHES. The hearing is concluded.

(Thereupon, at 12:40 p.m., Wednesday, May 24, 1972, the subcommittee recessed, subject to the call of the Chair.)



between the two. The person is considered
a person at 12:10 p.m. Wednesday, May 21, 1938, the same one
mentioned above, subject to the will of the Court.

